



European
Commission



Better Regulation
TOOLBOX

December 2025

‘Better regulation’ toolbox – December 2025 edition

'Better regulation' toolbox

This toolbox complements the better regulation guidelines presented in SWD(2021) 305 final

It is presented here in the form of a single document and structured around various chapters containing individual tools. It is also available and intended to be used as a series of web-based tools which are downloadable from the Commission's 'better regulation' website. https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

In general, the toolbox presents guidance, tips and best practice. Users are not expected to read and apply each individual tool but to use the toolbox selectively and with common sense. However, some aspects of the toolbox must be applied because they are linked to the requirements of the 'better regulation' guidelines, the Commission's working methods or political commitments given by the Commission. These are explained in the first Tool #1 on *principles, procedures and exceptions*. Questions about this toolbox can be sent to unit A2 of Directorate responsible for strategy, better regulation and corporate governance in the Secretariat-General (SG-BETTER-REGULATIONS@ec.europa.eu).

The 'better regulation' toolbox is used internally in the Commission and therefore contains references to internal procedures as well as intranet pages that are not publically available.

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TOOL #1. PRINCIPLES, PROCEDURES & EXCEPTIONS

1. COMMON 'BETTER REGULATION' PRINCIPLES AND PROCEDURES

Through its 'better regulation' policy, the Commission has committed to design, deliver and support the implementation of high quality policies. 'Better regulation' covers the whole EU policy cycle – planning, design, adoption, implementation, evaluation and revision. All EU interventions – legislative or non-legislative, policy initiatives or spending programmes – aim to achieve certain objectives through one or several means, in line with the goals and responsibilities set by the EU Treaty.

The European Parliament, Council and the Commission concluded an Interinstitutional Agreement on Better Law-Making in 2016. The three institutions recognised their joint responsibility to deliver high-quality legislation:

- In areas where it has the greatest added value for European citizens and strengthen the competitiveness and sustainability of the Union's economy;
- Which delivers the Union's policy objectives in the simplest, most efficient and effective way possible;
- Which avoids overregulation and unnecessary administrative burdens for citizens, administrations and businesses and particularly SMEs; and
- Which is designed to facilitate its transposition and practical application.

'Better regulation' is governed within the Commission by a set of common principles and follow established processes. These principles have developed over the years, based on progress in standards, methods and data sources and were also inspired by international work such as the 2012 OECD regulatory policy recommendations¹ and later work developed in the OECD. They apply to all DGs and services involved in the preparation, implementation or evaluation of EU interventions and associated stakeholder consultations. The application of these principles and procedures will help to provide a rigorous evidence base to inform decision-making and contribute to making Commission initiatives more effective, coherent, relevant and efficient. It should also enhance transparency, participation, learning and accountability.

Box 1. Key dimensions of 'better regulation'	
<i>Embedded in the planning and policy cycle</i>	Evidence from all preparatory and analytical work, including stakeholder consultations, should feed into the policy development process. Lessons from implementation and evaluations form part of the 'evaluate first' approach to policy development.
<i>Of high quality</i>	The Commission's impact assessments, stakeholder consultations, fitness checks and evaluations should conform to the requirements of the 'better regulation' guidelines; the Regulatory Scrutiny Board provides an independent check.
<i>Evidence-based</i>	'Better regulation' instruments should be based on the best available evidence. They should provide a transparent explanation of why some evidence may not be available and why it is appropriate to act in the absence of evidence. 'Evidence' refers to multiple sources of data, information and knowledge, including quantitative data such as statistics and measurements, qualitative data such as

¹ [Recommendation of the Council on Regulatory Policy and Governance - OECD](#)

	opinions, stakeholder input, conclusions of evaluations, as well as scientific and expert advice.
Strategic/forward looking	Integrating strategic foresight into policy-making to ensure that policymakers and institutions can anticipate changes and proactively shape the future developments.
Participatory/ open to stakeholders' views	Ensure wide participation throughout the policy cycle. The Commission should seek and consider a wide range of views and input and ensure that all relevant parties have had the opportunity to express their opinions. Web-based public consultations together with targeted consultations are key elements of a consultation strategy. Stakeholders should be given sufficient time to respond. In addition, stakeholders may provide feedback on legislative proposals adopted by the College and relevant draft implementing and delegated acts.
Respect for principles of subsidiarity and proportionality	'Better regulation' instruments should explain how respect for subsidiarity and proportionality is ensured. EU action should be relevant and necessary, offer value beyond what Member State action alone can deliver and not go further than what is necessary to resolve the problem or meet the policy objective.
Comprehensive	All relevant impacts of alternative policy solutions should be considered including economic, social, environmental impacts.
Coherent/ conducted collectively	Coherence across different policy domains and between related policy instruments is essential. New initiatives, impact assessments, consultations and evaluations should be prepared in cooperation with all relevant services in the framework of interservice coordination groups.
Proportionate	'Better regulation' instruments should be used in a way that is proportionate to the type of intervention or initiative, the importance of the problem or objective, and the magnitude of the expected or observed impacts.
Transparent	Being transparent to the outside world is important if initiatives are to be understood and credible. Results of evaluations, impact assessments and consultations should be publicly available. The reasons for disagreeing with alternative views should be explained.
Independent	Evidence should inform political decisions – not the other way around.
Appropriately resourced and organised	Sufficient time as well as appropriate human and financial resources should be available to enable each evaluation, impact assessment or consultation to deliver a timely and high-quality result. DGs should establish centres of expertise (or functions) to support 'better regulation' activities throughout the policy cycle.
Sustainable	The balanced integration of economic, social and environmental considerations and impacts, pursued through 'better regulation' contributes to the objective of sustainable development laid down in the Treaties ² and the EU commitment to implement the sustainable development goals (SDGs).

2. USE OF THE 'BETTER REGULATION' TOOLBOX

On the one hand, the 'better regulation' guidelines set out the mandatory requirements and obligations for 'better regulation' for each step of the policy cycle. The toolbox on the other hand provides more specific and operational guidance on the practical application of the guidelines and additional advice for applying 'better regulation' in practice.

Some elements of the toolbox are mandatory. Many of the tools are, on the other hand, advisory in nature.

² TEU, Articles 3 and 21, and TFEU Article 11.

Users of the toolbox are not expected to read and apply each individual tool but to use the toolbox selectively and with common sense when they need additional guidance.

3. EXCEPTIONS FROM THE PROCEDURAL REQUIREMENTS OF THE 'BETTER REGULATION' GUIDELINES

The 'better regulation' guidelines should be applied flexibly and in a proportionate manner that reflects the circumstances of each individual initiative. What matters is to conform to the spirit of the guidelines (and of relevant toolbox tools) and that as a result that DGs produce high quality impact assessments, evaluations etc. The Secretariat-General can be consulted about the practical application of the guidelines in individual cases.

There will, however, be occasions when certain procedural steps or processes cannot be done or need to be shortened or simplified for good reasons (e.g. political urgency, the need to respect confidentiality and security concerns etc.). Such exceptions from the requirements of the guidelines and toolbox are possible but prior approval is necessary. This should be done in the following ways:

- When a politically sensitive and important initiative³ is first presented for political validation, the need for flexibility or an exception should already be described (and justification provided) in the relevant fields of the Decide IT platform. The main exceptions concern: a deviation from the 'evaluate first' principle, not conducting an impact assessment, not conducting a public consultation (when procedurally required)⁴. The agreement of the Commissioner responsible for 'better regulation' will then explicitly cover the intended exception.
- If an exception is required after validation⁵, DGs must seek approval from the Director responsible for 'better regulation' in the Secretariat-General in consultation with the Cabinet of the Commissioner responsible for 'better regulation'.

DGs must request approval by sending a message to the following functional mailbox and should describe (1) what is being requested; (2) why it is needed:

SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu

All approved exceptions mentioned above should be documented in the relevant IA (*Annex I*), evaluation or fitness check (*Annex on procedural information*) staff working document as well as in the explanatory memorandum accompanying a Commission proposal.

³ See Tool #6 (*Planning and validation of initiatives*)

⁴ For other exceptions (for instance language regime, duration of public consultation, etc.) DGs must equally seek approval by sending a motivated request to the functional email address above.

⁵ After validations means concretely following the validation of a politically sensitive and important initiative (PSI), or if the initiative is not a PSI or it is validated within the lead DG (as for evaluations and fitness checks).

TOOL #2. THE REGULATORY FITNESS PROGRAMME (REFIT) AND THE FIT FOR FUTURE PLATFORM

1. REFIT

Simple and efficient legislation is a key objective for the Commission and an integral part of the 'better regulation' agenda.

In 2012, the Commission launched the Regulatory Fitness and Performance Programme (REFIT), to step up efforts⁶ on simplification and burden reduction.

The concept has evolved over time. REFIT now requires all evaluations⁷ and all revisions to systematically consider simplification and burden reduction. This should be done without undermining the achievement of the policy objectives.

REFIT is delivered through the 'better regulation' tools. Reviews of existing legislation (meaning both the evaluation and any subsequent revisions) should seek opportunities to simplify and reduce administrative burden for people, businesses and administrations, including through potential benefits offered by digital transformation and innovative practices⁸.

Concretely this means REFIT has to be considered:

- during planning⁹;
- by the interservice coordination groups that are set up to contribute to evaluations and impact assessments¹⁰;
- in the consultation of citizens and stakeholders;
- in evaluation reports¹¹;
- in impact assessments¹²;
- in the assessment by the Regulatory Scrutiny Board;
- in explanatory memoranda accompanying legislative proposals¹³.

Annex II of the Commission work programme includes the most relevant REFIT initiatives.

⁶ The Commission has long been making efforts to reduce regulatory burdens. In 2007, it launched the Administrative Burden Reduction Programme (ABR) to measure costs imposed by information obligations on business and to eliminate any unnecessary administrative burdens.

⁷ Evaluations covering legislation but also other instruments such as communications, strategies, frameworks, etc.

⁸ See Tool #28 for guidance on digital-ready policy making.

⁹ While REFIT aspects should be looked at in all revisions and all evaluations, when labelling them in *Decide*, the REFIT label should be applied to all revisions of existing legislation and evaluations with significant REFIT potential. A duly justified explanation should be included in case a revision or evaluation is not going to be 'labelled' REFIT in *Decide*.

¹⁰ Digital expertise will be useful for the design of simplification options; therefore Commission services can consider involving DIGIT in the interservice coordination groups.

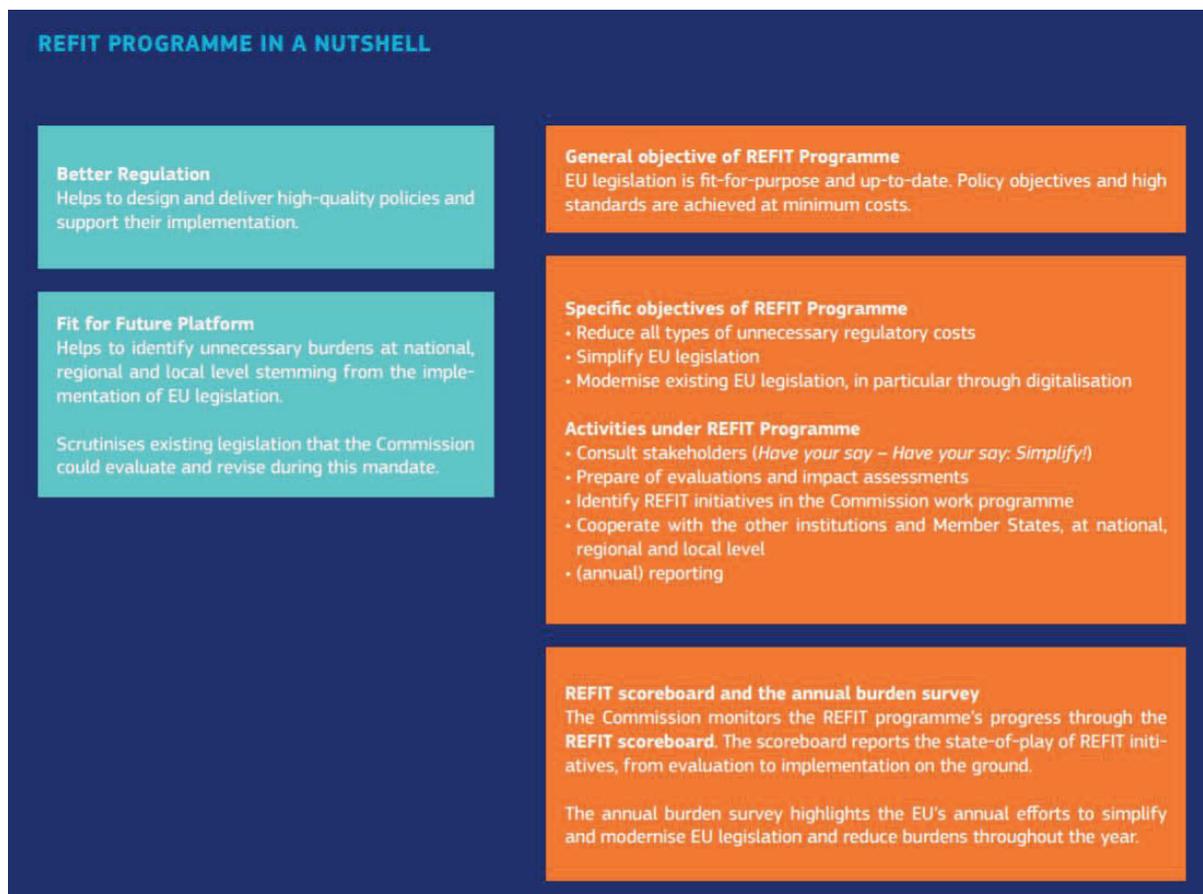
¹¹ See template for the evaluation report and in particular the section on efficiency and relevant REFIT information.

¹² See template for the impact assessment report and in particular the section on REFIT for the preferred option.

¹³ See Tool #40 (*Drafting the explanatory memorandum*)

There may be cases when simplification and burden reduction are not possible. This should be adequately justified in the explanatory memoranda accompanying legislative proposals and in the evaluation staff working documents. In cases where opportunities to simplify or reduce burdens are identified, the Commission services should try to quantify them to the extent possible.

Such quantification is crucial for applying the 'one-in, one-out' approach¹⁴.



The progress of initiatives since 2015 that include a simplification and burden reduction angle is monitored through the REFIT Scoreboard. Commission services provide information on REFIT for the files in their area of competence as part of the regular updating of the Scoreboard. The Scoreboard covers initiatives throughout their lifecycle: from evaluation to revision and implementation. Annually, the Commission also publishes an Annual Burden Survey. The survey provides illustrative REFIT examples.

2. THE FIT FOR FUTURE PLATFORM

The Fit for Future Platform (F4F)¹⁵ is a high-level expert group bringing together Member States, the Committee of the Regions, the European Economic and Social Committee and stakeholders. It also includes a collaboration with the SME Envoy Network represented by

¹⁴ See Tool #59 (*Cost estimates and the 'one in, one out' approach*).

¹⁵ Building on the experience with the predecessor REFIT Platform.

the EU SME Envoy. It was established through Decision (2020)2977¹⁶ that determines its mandate, role and the way it will work.

The Fit for Future Platform will contribute to REFIT by helping identify initiatives where there are opportunities to simplify and reduce burdens of EU laws, including through the use of digital tools.

The Fit for Future Platform will work on topics identified in its annual work programme. For each topic, it will adopt opinions with suggestions on simplifying and reducing potential unnecessary costs linked to EU laws, assessing whether identified Union legislation and its objectives remain appropriate, given the need to tackle new challenges and examining how digitalisation and increased use of electronic tools can support these objectives.

Commission services will be consulted on the topics for the annual work programme (both before it is finalised and during their assessment by the Platform). The opinions will serve as input to the evaluations and impact assessments and other evidence-based activities carried out by the Commission.

¹⁶ https://ec.europa.eu/info/sites/default/files/c2020_2977_en.pdf

TOOL #3. ROLE OF THE REGULATORY SCRUTINY BOARD

1. WHAT IS THE REGULATORY SCRUTINY BOARD?

The Regulatory Scrutiny Board (RSB or Board) is an independent body within the Commission that scrutinises the quality of impact assessments, fitness checks and selected evaluations. The Board provides quality assurance to the political level of the Commission enabling it to take decisions on the basis of the best available evidence.

The Board comprises a chairperson and eight members. All nine members are appointed by the Commission to serve full-time for a three-year non-renewable term, which can be extended by up to one year under exceptional circumstances¹⁷. The chairperson and four members come from within the Commission services. The four remaining members are recruited from outside the Commission. The Board acts independently and prepares its opinions autonomously. It does not seek or take instructions from within the Commission, nor from any other national or EU decentralised agency or other EU body. All Board members act in their personal capacity. They share collective responsibility for the decisions of the Board.

The Board's rules of procedure cover its mandate and proceedings. The Board publishes its opinions on impact assessments, fitness checks, and selected evaluations on the Commission's website together with the related reports. At the request of the Commission department concerned, the Board may, at its discretion, meet with services upstream on planned impact assessments, fitness checks or selected evaluations.

A Secretary, together with a team from the European Commission's Secretariat-General, supports the activities of the Board. This includes analytical and administrative support, such as planning and preparation of Board meetings, interactions with the services and associated follow-up.

2. SUBMISSION OF DOCUMENTS TO THE REGULATORY SCRUTINY BOARD

The Board scrutinises all impact assessments, all fitness checks and selected evaluations. The list of selected evaluations that the Board wishes to scrutinise is notified to DGs and services early in each calendar year¹⁸. The list is based on DGs' evaluation planning, management plans and information in *Decide* and the Commissions' work programme. The Board issues an opinion on each impact assessment report, fitness check and evaluation reports it scrutinises.

All the fitness checks and the evaluations selected for the Board's review shall be submitted for the Board's consideration well in advance of any related impact assessment report. In case a fitness check or an evaluation report is submitted to the Board in parallel with the corresponding impact assessment, the Board may scrutinise both reports at the same meeting, but shall examine them in two separate slots. In such cases, the Board shall in principle issue two separate opinions, but may decide to issue a single opinion. When an evaluation is not selected for scrutiny but it is annexed as a 'back-to-back' to an impact assessment report, the

¹⁷ Such as to ensure the continuity of the functioning of the Board, its balanced composition between internal and external members or its full capacity at times of exceptionally high workload.

¹⁸ The selection of evaluations for scrutiny is communicated to DGs in the second quarter of the year (T) and concern evaluations and fitness checks to be finalised in next year (T+1).

Board assesses its usefulness for the impact assessment, as part of its scrutiny of the latter, without having a separate meeting and without issuing two separate opinions¹⁹.

The tables below summarise which documents need to be transmitted to the RSB.

Impact Assessments	
What?	<ul style="list-style-type: none"> • Note signed by the Director General of the lead DG addressed to the chair of the RSB. • Draft impact assessment report (SWD). • Executive summary of the impact assessment report (SWD). • Minutes of the last meeting of the interservice coordination group set up to discuss the impact assessment report prior to submission of the impact assessment report to the RSB. • Where relevant, any underlying reports or studies prepared by consultants, or links to these. • Underlying evaluation report (SWD), as attachments or links to them.
When?	<ul style="list-style-type: none"> • The lead DG should reserve a slot²⁰ for a future Board meeting at which the IA report will be discussed. In general, the slot should be reserved at least 3 months before the Board meeting. However, it is recommended to reserve a slot as soon as an initiative is validated. • This slot should reflect the envisaged timing of the political initiative, the time needed to adapt or resubmit the impact assessment report in light of the Board's opinion(s), considering the impact of a potential resubmission, and the time needed to complete a formal interservice consultation and formal adoption by the College. • The documents shall be submitted to the RSB at least four weeks before the Board meeting where the draft IA report will be discussed. • In exceptional cases, the RSB may decide that the draft impact assessment report does not need to be discussed at a Board meeting, but can be dealt with in a written procedure. This can only be decided on a case-by-case basis once the draft impact assessment report has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.
How?	<ul style="list-style-type: none"> • All correspondence about the reservation of slots should be sent to the functional mailbox: REGULATORY-SCRUTINY-BOARD@ec.europa.eu • Transmission of the draft impact assessment report and associated documents should be via ARES. It is helpful if these documents are also sent to the RSB's functional mailbox. SECEM can also be used for confidential or sensitive files. • All other questions and enquiries should be sent to the RSB's functional

¹⁹ See Tool #50 ('Back-to-back' evaluations and impact assessments); where the evaluation SWD can also be integrated as an annex to the IA report (if the RSB has not selected the evaluation for scrutiny) and where the RSB will generally only issue a single opinion covering both the evaluation and IA elements in the report.

²⁰ A simple email request to REGULATORY-SCRUTINY-BOARD@ec.europa.eu

	mailbox.
<i>Resubmissions</i>	
	<ul style="list-style-type: none"> • Where the RSB issues a negative opinion, the lead DG will have to incorporate the Board's recommendations into a revised impact assessment report, to discuss those changes with the ISCG (a written consultation is also possible) and to submit a revised report to the RSB together with all the relevant other documents (see 'What?' section above). There is no time limit (neither minimum nor maximum) to resubmit the revised report. However, it is good practice to inform the Board in advance about the planned resubmission date. Still, the time before resubmission has to be sufficiently long to respond to the comments from the Board. • The RSB will aim to issue a revised opinion within four weeks following resubmission. In most cases, the opinion will be prepared following a written procedure. In some cases, the lead DG may be invited to a meeting with the RSB that will be organised by the Board's secretariat in consultation with the lead DG.
<i>Follow-up</i>	
	<ul style="list-style-type: none"> • The lead DG is expected to incorporate the Board's recommendations into a revised impact assessment report and to discuss the changes with the relevant interservice coordination group. • A second negative opinion does not allow the lead DG to start the interservice consultation without a derogation granted by the Commissioner responsible for 'better regulation'.

Fitness checks and evaluations selected for scrutiny by the RSB	
What?	<ul style="list-style-type: none"> • Note signed by the Director General of the lead DG addressed to the Chair of the RSB. • Draft evaluation report (SWD) / fitness check (SWD). • Executive summary of the evaluation report or fitness check, where applicable²¹. • Minutes of the last meeting of the interservice coordination group set up to discuss the evaluation report prior to submission of the draft evaluation report (SWD) or fitness check (SWD) to the RSB. • Where relevant, the underlying reports or studies prepared by consultants, or links to these.
When?	<ul style="list-style-type: none"> • The lead DG should reserve a slot for a future Board meeting at which the evaluation/fitness check report will be discussed. In general, the slot should be reserved at least 3 months before the Board meeting. However, it is recommended to reserve a slot as soon as the initiative is validated.

²¹ Executive summary is not needed in case the evaluation report accompanies a report to the other Institutions.

	<ul style="list-style-type: none"> • The documents shall be submitted to the RSB at least 4 weeks before the Board meeting that will discuss the draft evaluation report or fitness check. • In exceptional cases, the RSB may decide that the draft evaluation report does not need to be discussed at a Board meeting, but can be dealt with in a written procedure. This can only be decided on a case-by-case basis once the draft evaluation report or fitness check has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.
How?	<ul style="list-style-type: none"> • All correspondence about the reservation of slots should be sent to the functional mailbox: REGULATORY-SCRUTINY-BOARD@ec.europa.eu • Transmission of the draft evaluation report or fitness check and associated documents should be via ARES. It is helpful if these documents are also sent to the RSB's functional mailbox. SECEM can also be used for confidential or sensitive files. • All other questions and enquiries should be sent to the RSB's functional mailbox.
<i>Follow-up</i>	
	<ul style="list-style-type: none"> • The lead DG is expected to incorporate the Board's recommendations into a revised fitness check or evaluation report and to discuss the changes with the relevant interservice coordination group. • A negative opinion does not require a resubmission and does not prevent the launch of an interservice consultation on the fitness check or evaluation report. However, the decision to proceed with the interservice consultation without resubmission has to be taken carefully, considering also the importance stakeholders attach to the quality of evaluations. If the lead DG submits a revised report to the RSB, the Board will aim to issue an opinion within four weeks, in written procedure. There is no time limit (neither minimum nor maximum) to resubmit the revised report. However, it is good practice to inform the Board in advance about the intention to resubmit and planned resubmission date. The time before resubmission has to be sufficiently long to respond to the comments from the Board.

3. QUALITY CHECKLISTS AND MEETINGS OF THE REGULATORY SCRUTINY BOARD

The RSB will send out a quality checklist to the lead DG at least 3 working days ahead of the Board meeting scheduled to scrutinise the draft impact assessment report, or the draft evaluation report or the draft fitness check. In case of a written procedure, the DG will receive the quality checklist (to which the DG should respond in writing) within the same timing. This checklist will present an initial detailed assessment, together with the main questions that will guide the discussion during the Board meeting.

On a voluntary basis, the lead DG may respond in writing to the issues raised in the checklist at least one working day before the proposed Board meeting, indicating how they plan to revise the report. This written response should not exceed 10 standard pages.

The lead DG should communicate to the RSB (via the functional mailbox) who will represent the lead DG at the Board meeting. Except in cases of restricted Board meetings, and depending on the complexity of the file, attendance is generally limited to five-eight persons, and it is recommended that somebody from the DG's internal 'better regulation' support function also attends. The DG should be represented at the appropriate level (i.e. senior management).

4. OPINIONS OF THE REGULATORY SCRUTINY BOARD

In principle, the RSB issues its opinion within no later than three working days following the relevant meeting. This is delivered in ARES but may be sent via SECEM in some cases to ensure confidentiality.

The RSB's opinions can be positive or negative. The RSB will issue a maximum of two opinions, unless there are exceptional circumstances calling for a third opinion. For an impact assessment, a positive opinion is required before the interservice consultation (ISC) on the related proposal can be launched. While there is no formal need for a positive opinion to launch the ISC in the case of draft evaluation reports or fitness checks, these are expected to be improved in line with the Board's recommendations (see below). A comparison table should be added to Annex 1 of the evaluation report to explain the changes made to respond to the recommendations.

- **Positive opinion:**

In the case of evaluations and fitness checks, the author service must take the Board's recommendations for improvement into account and introduce any adjustments before seeking approval for launching the interservice consultation.

For impact assessments, the Board may issue two types of positive opinion:

- A *positive opinion* that sets out recommendations for improvement. The author service must take into account the Board's recommendations for improvement and introduce any adjustments before seeking approval for launching the ISC.
- A *positive opinion with reservations* is issued in cases that require adjustments to address important deficiencies. The author service must revise the report in accordance with the Board's findings before seeking approval for launching the ISC.

The interservice coordination group should have the opportunity to consider the revised version of the impact assessment report, the fitness check or evaluation report together with a draft of the underlying initiative/proposal (in the case of impact assessments) before the launch of the ISC. In any event, during the ISC the Secretariat-General pays special attention to the way impact assessment reports, fitness checks and evaluation reports have been revised to reflect the Board's opinion²² and the way in which an impact assessment report appropriately covers all relevant items of the draft initiative. The resulting considerations are reflected in the response of the Secretariat-General during the ISC.

²² A comparison table(s) should be added to annex 1 of the report to explain the changes made to respond to the recommendations in each opinion of the RSB (if relevant). The explanatory memorandum attached to the legal proposal should always report on the outcome of the RSB's scrutiny and its opinions (see Tool #40 (*Drafting the explanatory memorandum*) for further details).

- **Negative opinion**

Such an opinion is issued when the RSB concludes that the report contains serious shortcomings and substantial improvements are needed on a number of significant issues.

In the case of an impact assessment, the lead DG needs to improve the analysis significantly and submit a revised version of the report for a new assessment. If serious concerns persist, this second opinion may still be negative and will be final, unless exceptional circumstances require otherwise.

For fitness checks and selected evaluations, the lead DG may decide to submit a revised fitness check or evaluation report to the Board for its scrutiny before seeking approval for launching the ISC, but this is not mandatory.

The RSB opinion(s) are published in the Register of Commission Documents.

For **impact assessments**, the RSB's opinion(s) is/are published once the related initiative has been adopted by the College.

Where the Commission reports formally to the co-legislators on a **fitness check or an evaluation**, the RSB's opinion will be published following adoption by the College of the report (COM document). In other cases, the opinions of the RSB will be published once the evaluation report or the fitness check has been cleared for publication by the services following a formal interservice consultation.

5. UPSTREAM MEETINGS WITH THE REGULATORY SCRUTINY BOARD

At the request of the Commission department concerned, the Board may, at its discretion, meet with services upstream on planned impact assessments, fitness checks or selected evaluations. These meetings should be timed at a stage when DGs are in a sufficiently advanced stage of reflection of what they intend to do, while still being at a suitably early stage of the process to allow for the discussion with the Board to be considered.

At these sessions, Board members provide preliminary remarks in their personal capacities. The advice given shall not prejudice or bind the Board in its subsequent opinion on the concerned cases.

TOOL #4. EVIDENCE-INFORMED POLICYMAKING

1. PRINCIPLES OF EVIDENCE-INFORMED POLICYMAKING

Reliable evidence is a cornerstone of 'better regulation', vital to establishing an accurate description of the problem, a real understanding of causality and therefore intervention logic; to analyse or evaluate the ex-ante or ex-post impact; and to justify and develop new or update existing policy initiatives.

'Evidence' denotes in general anything presented in support of a claim, but in the context of this tool, it refers to **data, information, and knowledge from multiple sources, including quantitative data such as statistics and measurements, qualitative data such as opinions, stakeholder input, conclusions of evaluations, as well as scientific and expert advice.** Reliable evidence is based on the *appropriate method* to collect, interpret, process and transform data and information. The process is also based on transparent accounting of biases and uncertainties.

High quality research and analysis cannot be done overnight, so ensuring high-quality evidence is available when needed requires to anticipate and coordinate the needs for evidence and invest in sufficient capacity building. It also means mobilising and engaging the relevant experts, the research community, and stakeholders in the regulatory process from the start. This tool describes the good practices of preparing the evidence base that allows policymakers to take informed decisions. It also presents a practical method for the transparent use and validation of evidence within the policy cycle and provides guidance on policy questions in various situations, including the cases when the availability of evidence may be limited.

Each policy initiative relies on a **logic of intervention**²³, which plays a central role in guiding its development, implementation, monitoring, and evaluation. The intervention logic can also help in **identifying the supporting evidence needed in each phase of the policy cycle.** In particular, the monitoring and evaluation phases may benefit from a careful data and evidence planning²⁴ so that the effectiveness of EU legislation can be properly assessed.

The use of evidence should take into account the different framings, positions and perspectives on a given issue across all stakeholder groups, which are consulted with the 'call for evidence' or targeted consultations.

The evidence gathered should be proportionate and appropriate **for informing policy options or addressing the evaluation questions.** Evidence should be sufficiently described and be accompanied with factual judgements about its relevance, completeness and reliability. This includes:

- acknowledging the existence of various types and sources of data²⁵;
- clarifying the method used to collect, interpret, process data and transform it into information;

²³ See Tool #67 (*Data identification for evaluations & impact assessments*).

²⁴ More guidance on how to ensure data linkages between ex ante, the implementation and the ex post phases is provided in Tool #43 (*Monitoring arrangements and indicators*) and in Tool #67 (*Data identification for evaluations & impact assessments*).

²⁵ Tool #67 (*Data identification for evaluations & impact assessments*) explains different types of data to be used, how these can be integrated and what to consider when planning data collection.

- acknowledging possible cognitive biases; and
- acknowledging the degree of scientific uncertainty, and assessing in what way this may affect the policy decisions.

To ensure transparent policymaking and demonstrate that evidence is robust, all data and evidence steps – from gathering, use and communication – should be documented systematically. Transparency requires explaining and discussing internally and with stakeholders what the Commission does, why it does it and how it does it. However, deciding on an appropriate level of transparency also requires careful considerations of strategic objectives, feasibility concerns and legal and financial constraints.

2. SIX STEPS TO A TRANSPARENT USE OF EVIDENCE

Constructing the evidence base according to the principles spelled out in Section 2, can be achieved by respecting a six-step approach for generating and leveraging evidence. It consists of the following steps: understanding, mapping, collection, analysis, interpretation and presentation (Figure 1).

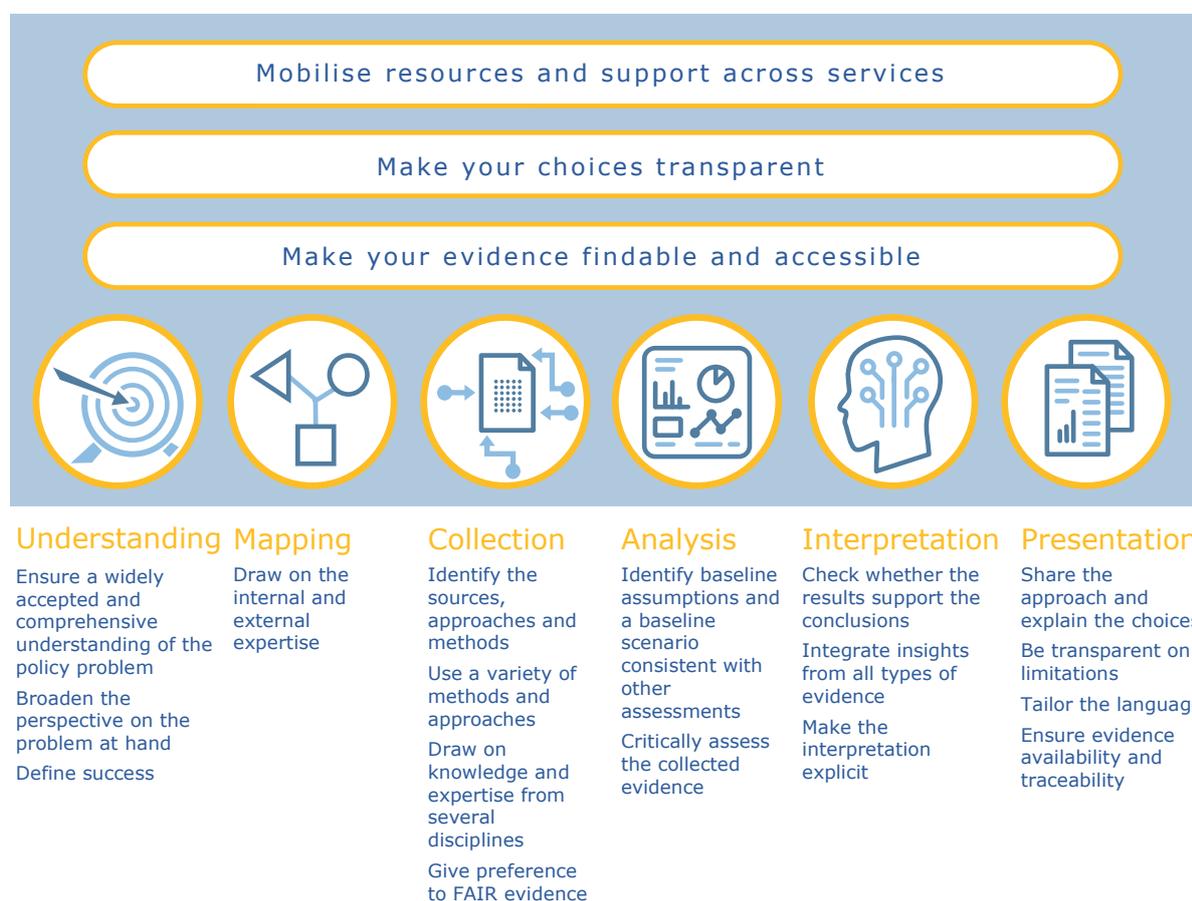


Figure 1. Gathering and communicating best available and transparent evidence for policy

The three horizontal considerations *throughout* the process of evidence gathering and communication are: **(i) mobilising resources and support across services; (ii) making the choices of evidence transparent by documenting them and (iii) making the evidence findable and accessible when possible.**

Mobilising an interservice coordination group at an early stage allows tapping into the richness and diversity of knowledge from across the Commission (see section 4). Engaging in collaboration and coordination across services enables broadening the perspective beyond a single policy area and enhances the coherence of Commission initiatives, avoiding as well the duplication of efforts and costs²⁶. Where practical, a dialogue with stakeholders and citizens from outside the Commission (e.g. through targeted stakeholder consultations), as early as possible in the process, may identify different framings of the problem and possible knowledge gaps.

Whenever possible, the evidence collected and used should be **FAIR**, meaning it is *findable, accessible, interoperable and reusable* (more on FAIR principles in section 4). **With all the steps documented** and the underpinning evidence made FAIR, **the policymaking process becomes more transparent and policymakers can take more informed decisions.**

1. Understanding

Ensuring a widely accepted and comprehensive understanding of the policy problem

It is recommended to have a complete and widely accepted understanding of the policy problem(s), as early as possible in the policy process (scoping phase, establishment and choice of the baseline). Any relevant existing evaluations and initial evidence about the nature and magnitude of the problem are important starting points. These are the bases for engaging at an early stage with colleagues within and outside the lead DG, as well as with stakeholders and citizens. Engaging others creates a much more reflective view of the complexity of real-life. It also helps in identifying cognitive and normative biases, resulting in a more robust collective understanding of the problem, and ultimately in more robust regulation. Lastly, engaging with colleagues, stakeholders and citizens may help generating shared ownership over the policy problems and the solutions, which will increase the likelihood of success. In an early stage of this phase, working on reaching a common agreement on concepts at stake and their definition will provide a sound basis for creating the needed collaboration.

Broadening the perspective on the problem at hand

When starting to work on a policy initiative, it is important to place the problem in a broad and forward-looking perspective, e.g., by taking into account the megatrends (see Tool #20 (*Strategic foresight for impact assessments and evaluations*)). This is likely to result in policy options that are fit for or adapt to evolving situations. Moreover, it helps to clarify how the strategic goals over the long term can be achieved, including taking into account sustainable development.

What does success look like? Using the intervention logic to link objectives to policy actions and to output/result/outcome/impact indicators

What the policy aims to achieve should eventually be measured: generally, what gets measured, gets done. Reflections on the policy problem will also need to cover policy objectives, actions, indicators of success and, where proportionate, quantifiable targets. When exploring the problem, one should consider not only the intended effects, but also possible undesired side effects and trade-offs.

²⁶ The [interinstitutional studies database](#) (not publicly accessible) is also instrumental in this respect.

The intervention logic provides the framing to do this (Tool #46 (*Designing the evaluation*)). In fact, an impact assessment, monitoring arrangements, and the evaluation should rely on the same intervention logic. For instance, to understand what the evaluation of a policy should assess, one should consider the results of a policy intervention against its objectives (as set out in the policy document or legislation) and the challenges it was meant to address.

In many areas, legislation and programmes are already in place, which means that new proposals should be conceived as part of that ongoing policy cycle. Previous Commission proposals were – in most cases – accompanied by an impact assessment, and interim and final evaluations are often available, too. This should all be taken into consideration to respect the policy cycle approach in which the Commission evaluates first, and then, knowing what works and what does not, designs new initiatives. *Information on approaches to evaluations can be found in Chapter 6.*

2. Mapping

Evidence mapping serves to draw a map of “what is already out there” on the topic and what further evidence needs to be collected.

Drawing on the internal and external expertise

An independent and transparent literature review of published knowledge may already provide some relevant answers of possible solutions to the problem and its impacts. For Commission in-house studies and data, good starting points are the lead DG and various sources of evidence listed in section 3. All the evidence generated by evaluations should be taken up during the process and be well reflected in the impact assessment. In case of an agreed ‘back-to-back’²⁷ approach, the evidence mapping should identify the evidence requirements for the evaluation and impact assessment work.

Also external experts, Member States representatives, EU decentralised agencies and other EU bodies, and stakeholders may be involved to provide inputs to the mapping exercise. They can contribute through the Commission’s consultation portal ‘*Have Your Say*’ in response to the ‘call for evidence’²⁸ published for every initiative. The input may also take the form of submitted studies, position papers, letters, or informal text contributions.

3. Collection

In this step, the sources and the methods to gather any missing evidence are chosen.

Identifying the sources, approaches and methods that can answer the main questions according to the intervention logic

The choice of methodological approach will determine largely the type of data that will be needed. Based on the intervention logic, one should critically examine if the selected sources, approaches and methods can answer the policy questions. While designing the policy initiative, the future collection of evidence for monitoring and evaluation should be taken into account (*see Tool #43 (Monitoring arrangements and indicators)*).

Using a variety of methods and approaches

The choice of the analytical methods and approaches depend largely on the questions to be answered as well as on the already available evidence, identified in the previous step. A

²⁷ See Tool #50 (*‘Back-to-back’ evaluations and impact assessments*)

²⁸ This approach will be applied flexibly reflecting the circumstances of each individual initiative.

combination of different quantitative and qualitative methods may be used. These can be brought together in various ways to get the most comprehensive picture and to increase robustness by cross-validating results gathered in various ways. For example, focus groups or individual semi-structured interviews can be used to explore little-known social phenomena by collecting pertinent experiences, views, beliefs and motivations, which can later guide quantitative data collection. On the other hand, these targeted consultation methods can also give a feedback at a later stage to refine the insights from quantitative methods.

Sometimes, it may seem there is no data available or it may be unclear what methodological approaches best suit evidence needs. It is important to carefully document what was possible, but also what was not possible during the collection phase. Both “quantification at all costs” and “giving up on data too easily” should be avoided.

When relevant, a practical solution to a lack of EU-wide data can be to conduct/contract out case studies (in-depth research on “typical” target groups). The selection of case studies is important to ensure that their results are representative. Again, integration of different methods for data collection and cross-verification of data enhances robustness of insights coming from case studies.

Drawing on knowledge and expertise from several disciplines

When choosing experts for gathering or interpreting evidence, wherever possible and relevant, representatives of various disciplines should be included to avoid “tunnel vision”. Commission staff must assess their interests, prior to the start of the work (avoidance of conflict of interest).

Giving preference to findable, accessible, interoperable and reusable (FAIR) evidence

Evidence FAIRness (see also *horizontal principles*) can be ensured only if this is taken into account already when the evidence is being selected or is starting to be generated. In particular, when negotiating licence agreements with external providers, any restrictions to sharing studies, data or code of models should be as limited as possible.

4. Analysis

The analysis processes the evidence collected from stakeholder consultations (see Tool #54), the application of causal evaluation methods on administrative micro-data (see Tool #68), or the running of models (see Tool #61), as well as other qualitative and quantitative methods.

Identifying baseline assumptions and a baseline scenario consistent with other assessments

It is important to be consistent with baseline scenarios used at least in closely related policy fields. *For more guidance on baselines, refer to the Tool #60.*

Critically assessing the collected evidence

Critical, independent and transparent assessment and validation of the collected evidence ensures that it is robust and reliable. Peer-review is a common method of quality assurance increasing credibility of the results and should be planned sufficiently in advance. It can help improve models and methods.

Different sources of uncertainty can affect the results. These sources of uncertainty should be accounted for and – where the type of evidence allows – quantified, and the most relevant ones should be identified and reported. (see Tool #65).

Cross-verification by using various sources (triangulation) is a good way to validate different types of evidence. Any limitations to the method(s) applied or the data collected should be clearly acknowledged, discussed during the assessment, addressed where possible and clearly documented.

5. Interpretation

In this step, the evidence collected and analysed in the previous steps is transformed into knowledge, which allows for drawing conclusions. The goal is to inform the decisions of the policymakers throughout the policy cycle or for the future design of policies.

Checking whether the results support the conclusions

When a first outline of conclusions has been established, it is a good moment to take a step back and think: are these conclusions supported by the aggregated evidence collected and analysed in the previous steps? In particular, it should be verified whether the evidence is strong enough to underpin the conclusions by comparing the results with the baseline. If some of the evidence does not align with expectations, or if different pieces cannot be reconciled, it is preferable to state all the evidence anyway, identifying the possible lack of uniformity or conclusiveness.

Integrating insights from all types of evidence

Different types and sources of evidence should be distinguished and treated according to their credibility, relevance and ability to provide useful insights. Gathered data may be incomplete and information may be biased, or suffer from other imperfections. Some evidence may lack scientific robustness but may still carry relevance because of the richness of the insights it offers (e.g. stakeholder experiences). Both “mainstream” and “divergent” views should be considered and reported.

Making the interpretation explicit

Interpretation of evidence should be as transparent as possible, so that all the choices, assumptions, weights, and value judgements are clearly explained and understandable. The interpretation of evidence should be related back to policy objectives and underlying choices, including the normative ones as established in step one.

6. Presentation

A good presentation of evidence and its conclusions facilitates good communication and allows policymakers to make well-informed decisions.

Being transparent on limitations

Transparency about the underlying judgements and the limits of the evidence used, including availability and robustness, is key. It is important to communicate what conclusions can and cannot be drawn at this stage. Transparency is also needed on the assumptions upon which the analysis is based: what is the level of aggregation of the variables, what are the inputs of the models, which estimates are used for the various parameters, etc. *Detailed requirements for evidence transparency in the impact assessment report are provided in Tool #11 (Format of the impact assessment report), while for the evaluation report – in Tool #49 (Format of the evaluation report).*

Thinking about the audience and tailoring the language accordingly

The evidence used should be clearly presented and cited by providing all relevant source details. To be transparent about the evidence underpinning the conclusions does not mean simply to include more quantitative and qualitative data in the report as this may be counterproductive. Technical details may be provided in annexes and supporting studies. Simple language for non-experts should be used whenever possible.

Ensuring that the key evidence is available in a timely manner and remains traceable

Especially when studies supporting the analysis provide technical details, these documents should be stored in stable and permanent databases or repositories, where they are equipped with persistent identifiers²⁹. The key evidence should be cited by providing all relevant details to allow its findability, including persistent identifiers and/or permalinks to ensure functioning hyperlinks³⁰.

Supporting evidence – including underlying data if it is open³¹ – should be made available to the co-legislators, and when possible to the public, no later than when the document in which they are cited is made public.

3. ADDITIONAL INFORMATION

FAIR principles help managing scientific evidence transparently³². Making evidence FAIR ensures that studies, data, but possibly also code of models, protocols applied and other research resources, are as far as possible “**findable** by anyone using common search tools; **accessible** so that the data and metadata can be examined; **interoperable** so that comparable data can be analysed and integrated through the use of common vocabulary and open formats; and **reusable** by other researchers or the public as a result of robust metadata, provenance information and clear usage licences.”³³

Sources of evidence

Chapter 8 provides guidance on various methodologies to collect and analyse data, ranging from models to behavioural insights. Tool #51 gives an overview of methods that can be used to consult stakeholders, both in open and targeted manner, such as interviews, focus groups, workshops, Eurobarometer Surveys and others. For guidance on questionnaire design and more generic consultation approaches see Tool #52; for the analysis and use of information received through the consultation of stakeholders, see Tool #54.

²⁹ The most commonly known persistent identifier is a DOI, a Digital Object Identifier, used for publications and data.

³⁰ Hyperlinks, in time, have the tendency to become permanently unavailable. The phenomenon itself varies over time, domain, and type of resource, and is a major concern in terms of traceability of evidence. A permalink, as the name implies, should be permanently available, and is usually a resolvable persistent identifier. If a persistent identifier or permalink cannot be obtained, a full citation for the source should be provided, so that it can be found through classical search mechanisms even if the related link is no longer available.

³¹ Restrictions to data access may apply due to information confidentiality constraints, data protection, intellectual property or other legal provisions.

³² A study on the cost and benefits of FAIR by DG RTD found that not applying FAIR principles to research data would in the long-term result in considerable costs. See also: “Turning FAIR into reality. [Final report and action plan](#) from the European Commission Expert Group on FAIR Data” 2018. More about FAIR Guiding Principles: <https://doi.org/10.1038/sdata.2016.18>, <https://www.go-fair.org/fair-principles/>

³³ <https://doi.org/10.1038/d41586-019-01720-7>

Data and statistics

- **Data.europa.eu** provides links to open access data produced by EU, national, regional and local public administration, as well as by some international organisations. The **JRC data catalogue** is integrated in the data portal.
- A **Commission data catalogue** provides the metadata on all key data assets held by the Commission that are relevant for the Commission's decision-making processes and functioning. The data sets may not be open.
- **Eurostat** provides free access to statistics at European level (from data collected by statistical authorities of Member States) using harmonised methodologies that enable comparisons between countries and regions.
- **Eurobarometer** monitors public opinion in Member States and provides results representative of the targeted populations on major topics (e.g. enlargement, social situation, health, culture, environment, information technology, the euro, defence, etc.). A Eurobarometer survey can be requested in the context of DG COMM's annual programming depending on the Commission's priorities.
- **OpenAIRE** - support open access and open data mandates in Europe by publishing EU-funded research results, including scientific publications and research data.
- **KnowSDGs** (Knowledge base for the Sustainable Development Goals) platform organises knowledge on policies, indicators, methods and data to support the evidence-based implementation of the SDGs.
- **UN SDG Indicators Database** - provides access to data compiled through the UN System in preparation for the Secretary-General's annual report on 'Progress towards the Sustainable Development Goals'.

Commission Services

- The Commission's **Central Intellectual Property Service** can help with tender specifications and license agreements³⁴.
- The Commission **Data Advisory Service**³⁵ is available to support with respect to data analytics and data management matters. For data publication contact the **Publications Office**.
- Consult the Commission harmonised procedures for the management of studies on a dedicated **SG page** and contact the material and **services** offered to ensure transparency, traceability and accessibility of all key evidence. Study reports and data should be properly stored, published and curated, as well as correctly referenced. For this, obtain early permanent identifiers (e.g., DOIs) and include them whenever these studies are cited. For referencing evidence sources, follow the **Interinstitutional Style Guide** and – for statistical data – [Eurostat guidelines](#).

³⁴ To make software or model code available to outside the Commission, consult the [guidelines](#) on the distribution of Commission software. For additional guidance on licence agreements with external providers, consult JRC work on [standard clauses](#) that could be used in negotiation with third parties.

³⁵ The Data Advisory Service is a single entry point for advisory services on data topics. Domain experts will be available to help with topics such as data management, data licensing and related legal aspects, data quality, data analytics, data architecture, data interoperability and data security.

- If models are used to support an impact assessment, contact **MIDAS (Modelling Inventory of the Commission)** team to insert the model description in the inventory.
- The **Publications Office** and the EU Community of Practice **on data visualisations (Connected)** may provide support on the subject.

Evaluations, impact assessments, and studies

- The Commission evaluations and impact assessments are published on the **register of Commission documents** and in **EUR-Lex**.
- Public studies prepared by or for EU institutions and bodies can be found in **EU Publications**.
- Also evaluations carried out by Member States and, where relevant, by third countries may be taken into account.
- All studies planned or already conducted on behalf of the EU institutions and bodies can be found in the **Interinstitutional Database of Studies**.
- Explore academic publications by searching **Commission library**.

Experts

- **Permanent bodies at EU level** are characterised by a high level and a broad range of expertise, prevention of conflicts of interest and transparency.
- The **Joint Research Centre (JRC)** provides science and knowledge for EU policies. It provides data and analysis to help design new policy initiatives and legislative proposals, to monitor existing ones, and to look beyond them, by anticipating challenges, needs, and transformations. It also hosts the Commission's **Knowledge4Policy platform (K4P)**, which makes available policy-relevant scientific knowledge to policymakers. K4P hosts the services offered by competence centres and knowledge centres and enables collaboration between scientists and policymakers (see also intro of Chapter 8).
- The scientific opinion "**Scientific Advice to European Policy in a Complex World**", developed by the Group of Chief Scientific Advisors with contribution from the JRC, provide guidance to the Commission for the provision and use of scientific advice to inform policymaking in the European context. It shows how to organise scientific advice for policymakers, how to address conflicts of interest, how to ensure that the policy advice is relevant and covers all relevant fields, and how to tackle uncertainties and disagreement among scholars.

These recommendations were further developed in the JRC **Science for Policy Handbook**, which brings science closer to a political process, where different values and perspectives, as well as different timeframes have to be considered and provides specific guidelines on the science advice process.

- The group of **Chief Scientific Advisors** provides independent, high-level scientific advice to the European Commission at the request of the College of Commissioners on any policy topic at any stage of the policy cycle. The Scientific Opinions draw on comprehensive evidence review reports that are produced by the network of European science academies (SAPEA consortium) and are initiated via Commissioners' cabinets contacting the Cabinet of the Commissioner responsible for Research and Innovation. The drafting of a scoping paper that sets out the context and the specific

policy question to be addressed then follows. Services can trigger the process by contacting the service in DG RTD responsible for the Secretariat of the Group of Chief Scientific Advisors.

- Decentralised/ Executive **EU Agencies** are characterised by a high level and a broad range of expertise.
- **Scientific committees** set up by the Commission, such as the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).
- **Expert groups are composed by outside experts that bring information regarding practical experience** in a given policy area. They can involve individuals and/or stakeholder representatives, organisations or Member States' authorities. A dedicated **public register** ensures transparency about group composition and interests.
- Commission online tools for the collection of expertise such as the web communication platform **SINAPSE** that enables the creation of **e-communities**.
- **Consultants** can provide input to the Commission's assessment. The lead DG and the interservice coordination group should work closely with the consultant to ensure that the results are of sufficient quality and that they can be used accordingly.

Stakeholders

- Besides collecting views, **stakeholder consultation** can also trigger submission of other types of information (e.g. data, lessons from implementation)³⁶. When using evidence gathered through consultation one should bear in mind the specific interest of stakeholders providing the information and try to validate the robustness of the results. Peer-reviewing or benchmarking with other surveys/studies or consultation activities can significantly enhance the quality of such information.

³⁶ See Tools #51, #52 and #53 on stakeholder consultation.

TOOL #5. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

1. INTRODUCTION & LEGAL BASIS

The principles of **subsidiarity and proportionality**³⁷ govern all EU actions. The Union can only act in areas where the Treaties confer competence to it. In areas not falling under its exclusive competence, the Union should only act where the principle of subsidiarity is respected. In all areas, in line with the principle of proportionality, Union actions should be restricted in their content and form to what is necessary to achieve the objectives defined in the Treaties³⁸. Non-compliance with the principles of subsidiarity and proportionality may be used as a reason to challenge the lawfulness of Union acts before the Union’s courts³⁹. In addition, national Parliaments have a specific role in scrutinising the Commission’s respect of the subsidiarity.

The **Task Force on Subsidiarity recommended the use of a grid**. It is a special template for assessing whether EU action is justified in light of the principles of subsidiarity and proportionality⁴⁰. The grid should be added as an annex to significant or politically sensitive legislative proposals accompanied by an impact assessment which do not fall under the exclusive competence⁴¹ of the Commission⁴².

Box 1. Example: choice of the internal market legal basis

- The internal market legal basis is commonly used as a legal basis for EU initiatives, but its choice has been contested and must be justified as appropriate compared to an alternative legal basis⁴³ (health, environment etc.).
- Measures adopted on the basis of Article 114 of the Treaty of the Functioning of the European Union (TFEU) should genuinely aim to improve the conditions for the establishment and functioning of the internal market. Mere disparities between national rules, an abstract risk of future obstacles to trade, or a distortion of competition, are not sufficient.
- However, action may be justified to prevent the likely emergence of such obstacles and the elimination of appreciable distortions of competition⁴⁴.

³⁷ Article 5(1) of the Treaty on European Union.

³⁸ Article 5(4) of the Treaty on European Union.

³⁹ Protocol No 2 of the TFEU on the application of the principles of subsidiarity and proportionality.

⁴⁰ COM (2018) 703 final, “The principles of subsidiarity and proportionality: Strengthening their role in the EU’s policymaking”.

⁴¹ The same applies to other areas in which it is exceptionally considered that the Union has an exclusive competence “by nature”. These are budgetary and institutional matters where it is clear that only the Union can, or even has to act, and where the action of the Member States is not possible (COM (2018) 703 final, “The principles of subsidiarity and proportionality: Strengthening their role in the EU’s policymaking”, p.26).

⁴² COM (2018) 703 final, “The principles of subsidiarity and proportionality: Strengthening their role in the EU’s policymaking”. p. 6 f. The grid should take the form of a staff working document and be added as an annex to the legislative proposal.

⁴³ EU Court of Justice; [case-law](#) on choosing the right legal basis – issues of single or multiple, etc.

⁴⁴ Case C-376/98 *Federal Republic of Germany v European Parliament and the Council of the European Union*, para 84.

The IA report should describe the appropriate **legal basis** for action derived from the Treaty. The choice of legal basis must be based upon the nature of the main/predominant objective and content, such as health, environment, security, internal market, etc. In cases of doubts, the Legal Service should be consulted at an early stage.

2. SUBSIDIARITY

The principle of subsidiarity is designed to ensure that decisions are taken as closely as possible to the citizen by the most appropriate level where the intended objective(s) can be most effectively achieved. The subsidiarity principle does not apply in areas where the Union has exclusive competence⁴⁵. In areas in which the European Union does not have exclusive competence, the principle of subsidiarity defines the circumstances in which it is preferable for an action to be taken by the Union. **Subsidiarity means that the Union should only act if, and in so far as, the objective of the action cannot be achieved sufficiently by the Member States (at national, regional and local levels)**. This principle aims to ensure that policy measures are decided at Union level only where necessary and as close as possible to the citizen.

A good analysis of subsidiarity is necessary⁴⁶ for all **impact assessments** accompanying legislative initiatives in areas which do not fall under the exclusive competence of the EU. In addition, every politically sensitive or important legislative proposal accompanied by an impact assessment will be accompanied by the assessment grid mentioned above as a staff-working document⁴⁷. Tool #11 (*Format of the impact assessment*) explains how it should be reflected in the IA report.

In practical terms, when preparing an impact assessment it is necessary to elaborate whether the EU has the right to act under the Treaty and what is the appropriate legal basis. Assessing subsidiarity requires explaining first why actions at the national level would not be sufficient to achieve the objective of the initiative. Secondly, subsidiarity requires assessing whether Union action would have an added value compared to action by the Member States. For example, it is useful to analyse whether the identified problems have the same underlying causes across the EU and to what extent Member States have the ability or possibility to enact appropriate measures. For evaluations and fitness checks, subsidiarity analysis should be part of the EU-added value assessment, which needs to be described and quantified as far as possible.

⁴⁵ The subsidiarity principle does not apply in areas where the Union has exclusive competence such as commercial policy or competition (see Article 3 TFEU). In other areas it is exceptionally considered that the Union has an exclusive competence “by nature”. These are budgetary and institutional matters, where it is clear that only the Union can – or even has to – act. Those are areas where the action of the Member States is not possible. For example, the draft budget, own resources, the multiannual financial framework regulation (the individual MFF programmes follow their particular legal bases), the citizens’ initiative, the comitology regulation, rules on access to documents of the EU institutions and bodies, data protection rules for the institutions, establishment of a European Voluntary Humanitarian Aid Corps, codifications of existing legislation.

⁴⁶ The Commission is bound by Protocol No. 2 of the TFEU to review (and subsequently to maintain, amend, or withdraw) any proposal it makes, where a sufficient number of reasoned opinions are received from national Parliaments regarding the non-respect of the principle of subsidiarity. The sufficient number means more than one third of the 56 votes allocated to national Parliaments or one quarter in the of field freedom, security and justice on the basis of Article 76 TFEU.

⁴⁷ COM (2018) 703 final, “The principles of subsidiarity and proportionality: Strengthening their role in the EU’s policymaking”. p. 6 f.

An analysis of **EU-added value** is also crucial for designing new policy measures and for evaluating existing initiatives. In practical terms, it means showing the benefits that the EU action brings, such as economies of scale or achieving political objectives more efficiently (less costly) at the EU level. In **evaluations**, the EU-added value questions are the flip side of the impact assessment subsidiarity check. This means that the subsidiarity analysis in the evaluations and fitness checks is done in the EU-added value part. The EU-added value analysis is part of the subsidiarity check.

It is very important to **gather stakeholders' views**. When presented in the impact assessment / evaluation, the analysis should be based on concrete arguments substantiated with qualitative and, as far as possible, quantitative evidence⁴⁸.

National Parliaments and the Committee of the Regions have rights and powers to monitor the application of the principle of subsidiarity and they will critically examine any related analysis provided by the Commission alongside its proposals.

The questions in the grid mentioned above can guide the analysis of subsidiarity in impact assessments. Below one can find steps to follow when answering, some practical tips and illustrative examples of qualitative subsidiarity analyses.

The following steps can help when assessing subsidiarity:

I. Question 1.2 of the Grid: Is the Union competence under the selected legal basis exclusive, shared or supporting in nature?	
Question	Does the legal basis (action under consideration) fall within one of the areas where the Treaty gives the Union exclusive competence (as defined by Article 3 of the TFEU) or is it an exclusive competence by its nature (i.e. where only the Union can/must act; see below in the section on relevant issues)?
If yes	State in the report that the subsidiarity principle is being respected (for example: "Trade policy and the negotiation of international trade agreements are areas of exclusive EU competence pursuant to Article 207 of the Treaty and therefore the subsidiarity principle does not apply").
If no	move to step II and III below
Relevant issues	The point of departure is shared competence. Exclusive competence applies in the areas defined in Article 3 of the TFEU. In addition, the Commission takes the view that in exceptional cases, certain legislative acts can be considered as falling under exclusive competence by their nature. These mainly concern budgetary and institutional matters where it is clear that only the Union can (or even must) act such as the draft budget, own resources, the multiannual financial framework regulation, the European Citizens' Initiative, the Comitology Regulation, rules on access to documents of the EU institutions, data protection rules, the establishment of a voluntary humanitarian aid corps. Codification of Union law is an exclusive competence whilst recast is not and it is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism.

⁴⁸ To be referred to rather than repeated if already presented in the problem analysis.

II. Question 2.3 of the Grid: Perform the necessity/relevance test	
Question	Can/have the objectives of the (proposed) action be(en) achieved sufficiently by Member States acting alone?
Relevant issues	<p>A key part of the analysis should be to qualify the “Union relevance” of the initiative being considered. The greater the relevance the more likely Member State action alone will/would be insufficient. Key issues/questions to consider are:</p> <ul style="list-style-type: none"> • How does the problem (e.g. negative externalities) vary across the national, regional and local levels of the EU? • Is the problem widespread across the EU or limited to a few Member States? • Does the problem have the same or different underlying cause across the EU? • How do the views/preferred courses of action of national, regional and local authorities differ across the EU? • To what extent do Member States have the ability or possibility to enact appropriate measures? • Would national action or the absence of EU level action conflict with the Treaty or significantly damage the interests of other Member States? • Are there transnational/cross-border aspects to the problem? Can these been quantified? • Will there be increased costs or problems if action is left to the Member States?
If yes	Union action in the area cannot be justified. In the context of IAs, the initiative under consideration should be abandoned or refocused as appropriate. In the context of evaluations, the recommendation should clearly stipulate that EU intervention can no longer be justified.
If no	<p>Illustrate the specific limits of Member States’ action, their underlying drivers, and why they would/have not be(en) “sufficient”.</p> <p>Move to next step.</p>
Examples	Relevant situations could involve cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital, or common challenges (such as migration) or joint commitments (such as the 2030 Agenda), or serious risks that could affect large parts of the Union (e.g. pan-epidemic health risks).

III. Question 2.4 of the Grid: Perform the EU added value test	
Question	Can the objectives of the proposed action be better achieved at Union level by reason of the scale or effects of that action?
Relevant	Key issues/questions to consider are:

issues	<ul style="list-style-type: none"> • Are there clear benefits from EU level action? • Are there economies of scale? Can the objectives be met more efficiently at EU level? • Are there benefits in replacing different national policies and rules with a more homogenous policy approach? • Will the functioning of the internal market be improved? If so, how will it be improved?⁴⁹
If yes	<p>Explain why for the case at hand, explicitly describing both the advantages and the disadvantages that Union action may have relative to Member States action.</p> <p>The principle of subsidiarity is complied with.</p>
If no	<p>Union action in the area would not be justified on the basis of subsidiarity. In the context of IA, the initiative under consideration should be abandoned or refocused as needed. In an evaluation this may lead to a recommendation to consider modifying the scope or stopping the intervention.</p>
Examples	<p>Situations where EU action produces clear benefits compared to action at Member State level by reason of its scale or its effectiveness or efficiency. Equivalent legal rights for individuals and business can ensure equity and remove distortions of competition.</p>

Box 2. Practical tips - be specific and avoid general statements	
Don't just say:	Explain that:
The subsidiarity principle is respected because the initiative's objectives cannot/could not be achieved sufficiently by Member States.	Action by Member States could not solve the problem for the following reasons (e.g. spill-over effects, insufficient scale of the project, need for cross-border data flows...)
EU action is/has been necessary to level the playing field	Only EU action could eliminate the costs (of up to €X on average) that EU enterprises incur to apply for additional authorisations in every EU host country they wish to operate in.
EU action is/has been needed to avoid the fragmentation of the internal market	EU action is needed to eliminate the following obstacles faced by producers to enter into other national markets... As shown in the problem section, this is estimated to...

⁴⁹ It is insufficient merely to find differences between national laws. There must be more than an abstract risk that such differences could present an impediment to the exercise of the fundamental freedoms.

<p>EU action is/has been needed due to the strong diversity of policies/practices across Member States.</p>	<p>The negative consequences resulting from diverse/non-harmonised policies/practices lead to significant market entry obstacles, such as higher establishment costs amounting up to.....</p>
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<p>Box 3. Illustrative examples of qualitative subsidiarity analyses</p>
<ul style="list-style-type: none"> • Initiative on Fair Minimum Wages in the EU: SWD/2020/245 final (section 3, p. 21); • Revision of Non-Financial Reporting Directive: SWD/2021/150 final (section 3, p. 14); • Protection of workers from the risk related to exposure to carcinogens or mutagens at work: SWD(2020) 183 final (section 3, p. 13).

3. PROPORTIONALITY

The principle of proportionality under the Treaty relates the policy initiative itself and needs to be distinguished from an IA which can be ‘proportionate’ in terms of the depth of the analysis provided. It means that **the action of the EU must be limited in its content and form to what is necessary to achieve the objectives of the Treaties that it intends to implement.** For any specific initiative, this also implies in terms of the content that “[d]raft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.”⁵⁰ Respecting the principle of proportionality is about ensuring that the policy approach and its intensity match the identified problem and objectives.

Proportionality should be considered in the impact assessment report⁵¹. The questions in the grid should help in assessing in the report whether an envisaged measure adheres to the principle of proportionality. Also in evaluations or fitness checks, proportionality should be considered. In particular, it should be checked whether the initiative has achieved its objectives at the lowest possible costs and with the lowest possible resources (mainly done under analysis of efficiency).

The following questions should help in assessing whether a measure adheres to the principle of proportionality⁵²:

Does the initiative go beyond what is necessary to achieve the problem/objective satisfactorily?

- Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)
- Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?

⁵⁰ Article 5(4) of the Treaty on European Union

⁵¹ In the context of IA for example, proportionality is a key criterion to consider in the comparison of the policy options.

⁵² These questions are drawn from the grid and slightly reformulated.

- Does the initiative create financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objectives of the initiative?
- Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?
- Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?
- While respecting Union law, are special circumstances applying in individual Member States taken into account?

Box 4. Case law examples of disproportionate/proportionate measures	
Fedesa	The prohibition on the use of hormones in livestock rearing was proportionate because other measures (such as consumer information) would have been less effective in relation to the objective of ensuring public health. This objective was also sufficiently important to outweigh the economic impacts on the livestock industry.
ABNA	Union legislation was adopted which concerned making information available about the content of animal feed so that contaminated ingredients could be identified more rapidly. However, the requirement that producers of animal feed provide the precise composition of feedstuffs to customers was disproportionate in relation to this objective as it needlessly infringed the economic interests of feed manufacturers (who wanted to safeguard secret feed formulations) who were already obliged to indicate the ranges of composition of each ingredient on labels attached to the animal feed they sold.
Affish	An EU Decision to ban the import of Japanese fish into the EU was challenged for being disproportionate in relation to public health objectives. Not all Japanese fish factories had hygiene problems but because it was not practical to check the hygiene standards of all Japanese fish factories and because a representative sample had been checked, it was deemed proportionate to ban all imports of Japanese fish.
Swedish Match	The prohibition of tobacco for oral use in Union legislation was proportionate notwithstanding intellectual property rights and the right to pursue a trade or profession in the EU. The objective of public health protection and the lack of alternative effective measures justified the ban's proportionate nature.
Cotton Support	The reform of the cotton support scheme under the Common Agriculture Policy reduced direct support by 65% (but complemented by an additional crop-independent single farm payment). This was deemed to be manifestly disproportionate in respect of the objective of maintaining cotton production because the Council had not considered employment costs of cotton production or the economic impacts on cotton "ginning" undertakings when exercising its discretion.
Kadi	Council Regulation (EC) No 881/2002 imposed certain anti-terrorism measures (assets freeze) against certain persons. These measures represented a disproportionate interference with the right to property because there were no procedural safeguards enabling the affected persons to have their case heard by national authorities.

TOOL #6. PLANNING AND VALIDATION OF INITIATIVES

Proper planning of initiatives is crucial to deliver on time and to provide the right level of quality. All acts⁵³ to be adopted by oral, written, empowerment or delegation procedure as well as 'stand-alone' staff working documents need an individual *Decide* Planning entry⁵⁴. Guidance on how to create and fill-in such an entry is available on [GoPro](#). No substantive work involving outside interlocutors or the Regulatory Scrutiny Board should start before the entry is validated⁵⁵. Equally, publication on the '[Have Your Say](#)' web portal requires prior validation.

The type of entry and thus the validation process depends on the importance and sensitivity of the act:

- **Politically sensitive and/or important** ('PSI') initiatives require validation by the responsible Director-General, Commissioner(s) and Executive Vice-President(s). The responsible service should introduce politically sensitive and/or important initiatives at least 12 months before their planned adoption date, as they are usually subject to 'better regulation' requirements⁵⁶. A step-by-step explication of the PSI workflow is available on [GoPro](#).
- **Non-politically sensitive and/or important** initiatives (i.e. acts that are not flagged as PSI) only require validation by the Director-General, in close coordination with the responsible Commissioner. It is, however, possible to add the Commissioner to the validation workflow. A step-by-step explication of the 'validated by DG' workflow is available on [GoPro](#)⁵⁷.

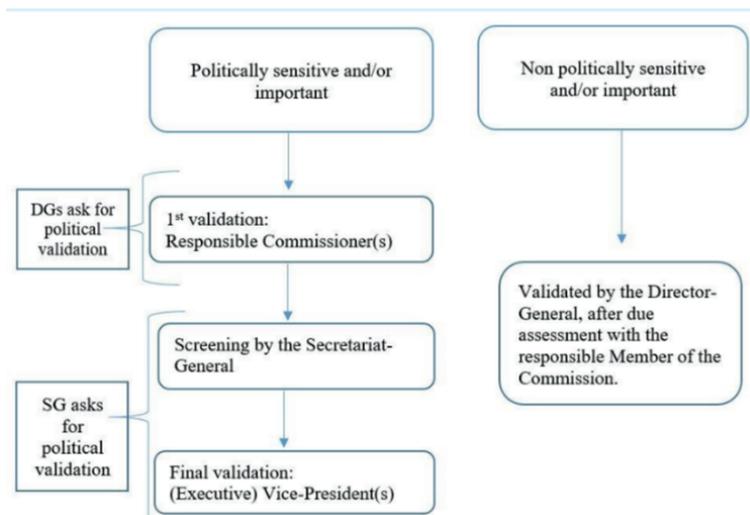
⁵³ This does not apply to acts concerning the management of litigation, corrigenda or in the exceptional cases where there would be no planning entry because of urgency reasons. In such cases, with the exception of decisions taken by empowerment or delegation, the Secretariat-General and/or the President's Cabinet will be involved in the validation of the first step of the process done in *Decide*, whether it is the launch of the interservice consultation or the launch of the oral or written adoption procedure.

⁵⁴ Some repetitive acts – provided they are neither politically sensitive nor important – can be handled in bundles which consists of one single *Decide* Planning entry for several interservice consultation or adoption processes. [Specific Planning entries for treatment in bundle - Guide to procedures - EC Extranet Wiki \(europa.eu\)](#)

⁵⁵ Only for urgent cases, encoding in *Decide* could be done at a later stage. Such exceptions require the agreement of the Secretariat-General.

⁵⁶ Any derogation requests with the corresponding justification should as a rule be included in the *Decide* Planning entry.

⁵⁷ It includes also details related to acts flagged as non-politically sensitive and/or important initiatives with additional Cabinet agreement, special cases.



Evaluations follow generally a workflow that is similar to the one called ‘validated by DG’⁵⁸. In case where an evaluation would be politically sensitive and/or important, the DG should use the ‘PSI’ workflow.

While several elements are to be considered when classifying an initiative, the table below provides a helpful overview. Please check [GoPro](#) for a more detailed and potentially updated overview. If in doubt, the SG Planning team can provide advice.

Initiatives considered as a general rule politically sensitive and/or important	Political sensitivity and/or importance to be assessed systematically on a case-by-case basis	Initiatives in principle not considered politically sensitive and/or important
<ul style="list-style-type: none"> • New legislative proposals • Communications, White Papers, consultation documents linked to the main political priorities • Proposals for the negotiation of international agreements • Acts adopted by oral procedure • Initiatives in the Commission work programme • Initiatives subject to a formal impact assessment, including delegated and implementing acts, for which an impact assessment is necessary • Initiatives in reply to a request from: <ul style="list-style-type: none"> ○ the European Parliament (Art 225 TFEU) ○ the Council (Art 241 TFEU) ○ an European Citizens’ initiative (Art 11 TEU; Art 24 TFEU) 	<ul style="list-style-type: none"> • Legislative proposals concerning exclusively technical amendments • Communications, White Papers, consultation documents not linked to the main political priorities • Delegated and implementing acts not requiring an impact assessment • Reports • Infringement decisions • State-aid, merger and anti-trust decisions • Evaluations and fitness checks • Proposals for the signature and conclusion of international agreements 	<ul style="list-style-type: none"> • Repetitive acts of a similar nature • Commission decisions adopted by delegation procedure or empowerment procedure • Internal financing implementing acts • Other acts not yet mentioned elsewhere (proposals according to Art 218(9) TFEU, opinions, recommendations, correcting acts, etc.) • Stand-alone staff working documents • Administrative acts

⁵⁸ <https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?pageId=456360710>, special cases, evaluations.

The Decide entry for PSI also includes important information that specifies the 'better regulation' requirements of this initiative. The lead DG needs to complete this information having in mind the need for a public consultation, the respect of the 'evaluate first' principle, the need to carry out an impact assessment and the REFIT dimension of the proposal. A sufficient and comprehensive explanation of these elements is critical for a smooth validation process. Also requests for exceptions to the 'better regulation' rules need to be clearly explained in the Decide entry⁵⁹.

Once initiatives are politically validated, they are listed as 'planned' in Decide. Services involved will receive an automatic notification. Some information, notably the short title, the summary and relevant dates, will be made available publically on the ['Have Your Say'](#) web portal shortly afterwards, unless the final validator in Decide Planning objects.

In case a proposed initiative is rejected, this decision is communicated to the responsible service via Decide. It will be specified whether the initiative can be resubmitted at a later stage / more appropriate moment or with a revised content.

Each service should regularly update/correct its Decide entries. This is essential, as Decide tracks the complete lifecycle of an initiative and is also used to report internally and externally on the status and the main elements of Commission initiatives under preparation.

In case of a change that fundamentally alters the type, nature or the scope of an initiative, a new validation might be required. This might imply reclassifying the initiative from 'validated by DG' to 'PSI' and resubmitting the initiative. However, if these changes have been decided just before or during the interservice consultation, they would have to be assessed and confirmed as part of this consultation and not via a new validation in Decide Planning.

⁵⁹ See also Tool #1 (*Principles, procedures and exceptions*)

Chapter 2 – How to carry out an impact assessment

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TOOL #7. WHAT IS AN IMPACT ASSESSMENT AND WHEN IT IS NECESSARY

1. WHAT IS AN IMPACT ASSESSMENT?

An impact assessment is a process comprising a structured analysis of policy problems and corresponding policy responses. It develops policy objectives and alternative policy options and assesses their impacts. It also considers subsidiarity, proportionality of options and how to monitor and evaluate the policy in the future. It helps to develop the Commission’s policy response to a certain policy problem by providing the evidence base for – and the impacts of – various options⁶⁰. If a preferred option is chosen, it presents the reasoning behind it. The process is presented in an impact assessment report.

The impact assessment report serves to support the policy-making decisions of the College of Commissioners. Externally, impact assessments help supporting and explaining the policy proposals and positions of the Commission vis-à-vis co-legislators, stakeholders and the public.

Though impact assessments are led by a DG, they are developed in collaborative efforts across Commission services. Services cooperate in an interservice coordination group⁶¹, which bring together relevant expertise and interests, including sectoral, legal, technical, digital and scientific expertise.

2. WHEN IS AN IMPACT ASSESSMENT REQUIRED?

An impact assessment is required when

- 1) a policy proposal is likely to lead to **significant⁶² economic, environmental, or social impacts⁶³ or entails significant spending**

and

- 2) the Commission has a **choice between alternative policy options** (‘room for manoeuvre’).

Consequently, in the following cases, an impact assessment is **not** required:

- when impacts are **small⁶⁴**;
- when **impacts cannot be clearly identified** ex ante;

⁶⁰ The report considers different alternative options addressing the policy problem. It assesses them and discusses pros and cons and policy trade-offs. There is no requirement to present a preferred option, although this is done in most impact assessments.

⁶¹ See Tool #8 (*What steps should be followed for an impact assessment*).

⁶² The ‘significance’ requirement also means that impacts will have to be reasonably identifiable. The policy proposal will have to be sufficiently specified so that an intervention logic can be established, along the lines of which reasonable assumptions about causality and impacts can be made.

⁶³ This is consistent with the objective in the Treaty to work for sustainable development (Article 3.3 TEU), described across its economic, social and environmental dimensions: based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment.

⁶⁴ It is the ultimate impact that counts. Thus, a small modest direct negative impact could still be large for certain stakeholders (SMEs etc.) and territories or have a significant effect because, if it cumulates with other pre-existing negative factors or generates important indirect/secondary effects.

- when there is **little or no choice available for the Commission**.

The benchmark criterion of 'significant impacts' applies to both the macro- and the micro-level. This implies that an impact assessment is not only required for proposals expected to have far-reaching impacts on the economy or society as a whole, but also for initiatives likely to have a significant impact on a particular economic sector or type of economic actor (e.g. SMEs)⁶⁵. The appreciation of what is considered 'significant' depends on expert judgment and should take into account the results of associated evaluations. The 'call for evidence'⁶⁶ should already set an initial appreciation of the expected significant impacts on which stakeholders can provide feedback and input for the impact assessment.

The 'room for manoeuvre' requirement means that an impact assessment is required, when there is a choice between policy options available for the Commission. The impact assessment is there to underpin this policy choice with a consistent evidence based analysis. Hence, if a choice is not available, an impact assessment is not required.

An impact assessment should be carried out only when this is useful. An assessment of whether an impact assessment is needed is therefore done on a case-by-case basis in context of the policy validation of an initiative. The result is reported in the 'call for evidence', so that the public is made aware of whether or not an impact assessment is under preparation. In this way, the Commission's decision to produce (or not) an impact assessment for a given case is published and subject to feedback from the public.

Similarly, in certain cases, where an impact assessment is not required, there may still be a need for providing evidence and analysis. This can be done in the form of a separate staff working document attached to the proposal or be reported in the explanatory memorandum. The decision whether an impact assessment is required or not should be clarified already in the Decide entry. This will be subject to a screening process prior to the political validation of a policy initiative. The screening process accounts for all 'better regulation' requirements pertaining to the case, including the 'call for evidence', public consultations, impact assessments and evaluations. In case of doubts, the Secretariat-General's unit in charge of 'better regulation' can help clarify the right approach.

In rare cases, there may be a need for modifying the decision on the need for an impact assessment after the political validation. This may be due to urgency, to a consecutive change in the scope or content of an initiative, or simply because a case turns out differently than originally envisaged. In such cases, unit in charge of 'better regulation' in the Secretariat-General will advise. In case of derogations to the requirements to carry out an impact assessment, the unit will seek agreement of the Commissioner in charge of 'better regulation'. The Commissioner will then decide whether an impact assessment or any other supporting document should be prepared.

3. THE NEED FOR AN IMPACT ASSESSMENT FOR SPECIFIC TYPES OF POLICY INITIATIVES

This section considers different types of policy initiatives and gives guidance on whether an impact assessment is necessary.

⁶⁵ To be significant, impacts need to affect external groups to the Commission, i.e. some groups of citizens or businesses. Hence, initiatives confined to EU Commission internal and/or governance related issues, which do not have clear identifiable impacts on citizens or businesses, are not considered to have significant impacts.

⁶⁶ See Tool #51 (*Consulting stakeholders*)

A. Initiatives for which the need for an impact assessment should be assessed⁶⁷
New legal acts
Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts ⁶⁸
Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law ⁶⁹
Recommendations for the negotiation of international agreements
Social partner agreements pursuant to Articles 154-155 TFEU ⁷⁰
Financial programmes (i.e. all basic acts for spending programmes and financial instruments) ⁷¹

B. Initiatives for which no impact assessment is required a priori:	
Type⁷²	Reason
Administrative decisions ⁷³	Lack of significant/identifiable impacts (or relevance for policymaking)
Enforcement of EU law (competition law enforcement cases, infringement decisions, etc.)	Lack of policy alternative as decision parameters are set by existing EU (case) law
Trade defence cases and enforcement action under international trade rules	Lack of policy alternatives
Budgetary procedures and measures, financing decisions and programme management decisions	Lack of policy alternatives/ex-ante evaluation not required
Policy communications	Lack of identifiable impacts

⁶⁷ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁶⁸ Repeals to remove legislation, which has been superseded by new legislative provisions are neither subject to an impact assessment nor require a 'call for evidence'. Repeals announced in the Commission work programme equally do not require a 'call for evidence' or an impact assessment as the Commission has already taken a decision informed by the available evidence (for instance the results of an evaluation).

⁶⁹ A key determining factor will be whether the Commission has any policy discretion over the content of its transposing measures.

⁷⁰ See Tool #10 (*Treaty-based social partner consultations and initiatives*)

⁷¹ See Tool #9 (*Spending programmes, financial instruments and budgetary guarantee*)

⁷² This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁷³ This may also cover governance/administrative processes for community policies and governance issues concerning EU agencies.

Action plans and strategies	Lack of identifiable impacts
Recommendations	Lack of identifiable impacts
Commission reports /scoreboards	No policy decision, lack of impacts
Communications to the Commission	No policy decision, lack of significant impacts
Economic governance: recommendations, opinions, adjustment programmes	Specific processes supported by country specific analyses
Green papers	No policy decision, lack of significant impacts
Legal guidance and alignments	Lack of policy alternatives / no significant direct impacts
Legal codifications	Lack of policy alternatives / no significant impacts
Conclusion, signature and provisional application of bi/multi-lateral agreements with third countries: conclusions signature, provisional application and/or prolongation of existing protocol.	Lack of policy alternatives given finalisation of negotiations
Policy initiatives that propose limited changes based on a thorough evaluation	Evidence base for a limited choice already provided.

In the specific case of **white papers, action plans**, normally an impact assessment is not required, unless these documents announce ambitious commitments which are significant and broadly identifiable already at this stage of the policymaking (for example a ten-year strategy to achieve certain environmental targets). Where action plans, strategies are setting out broad policy aims and processes, impact assessment may not be appropriate – given that impacts are not clearly identifiable. In such cases, impact assessments may be conducted at a later stage, when concrete follow-up actions to the strategy, action plan are being developed. **This should be clearly indicated in the Decide entry of such acts.**

Impact assessments are not required for **communications** clarifying the Commission’s approach to policy decisions already taken, reflecting case law, codifying existing case practice and providing legal guidance, or announcing more in-house type of work, such as the setting-up of expert groups, etc. In such cases, any relevant supporting analytical material could be presented in a staff working document accompanying the initiative, if necessary, in particular to reflect the outcome of stakeholders’ consultations. However, when

communications set out clearly defined measures with direct impacts on stakeholders the impact assessment requirement should be considered.

In the case of **policy recommendations**, an impact assessment is generally not necessary but this will depend on the level of detail (i.e. the degree of specificity/flexibility) set out in the provisions and the significance of the likely impacts that would stem from their implementation. A staff working document (i.e. not subject to the procedural requirements of an impact assessment) presenting potential impacts and policy approach is likely to be more proportionate in most cases. This may also be the case for strategies or action plans.

For **policy initiatives that propose limited changes based on a thorough evaluation**, which has clearly identified the necessary amendments to a policy or legislation, an impact assessment may not be necessary. This is the case, when adaptation derives directly from the findings of evaluations and fitness checks, if the scope and impacts of the proposed changes are already catered for in the evaluation (i.e. the proposed changes do not go beyond what was identified in the evaluation / fitness check). This is limited to situations, where such changes cannot be achieved in alternative ways.

Each year, the Commission adopts **hundreds of delegated acts and implementing acts**. Here, an assessment should be made as to whether an impact assessment is necessary. An impact assessment will be necessary where there are likely to be significant impacts and where the Commission has discretion. Many delegated and implementing acts are technical and have limited impacts⁷⁴. The empowerment to issue a delegated or implementing act may be defined narrowly, so that it leaves little discretion for the Commission and therefore excludes an impact assessment.

When it is considered to **set up a new EU function or a new EU decentralised agency or other EU body**, this normally requires an impact assessment, since there is likely to be significant impacts and a policy choice (which would include setting up or not an agency and/or to whom the new tasks should be assigned). The impact assessment should assess the need for such a new EU function and consider relevant alternatives. It should consider overall costs and benefits of the alternatives.

Box 1. Setting up a new EU task/function or a new EU decentralised agency or other EU body

When the Commission considers a new EU task or function, and in that context reflects on whether to set up a new EU decentralised agency or other EU body, the following guidance apply:

- Such an initiative would normally require an impact assessment. If in doubt, contact the 'better regulation' unit in the Secretariat-General.
- The impact assessment should assess the need for the new EU task or function, its relevance and coherence vis-à-vis existing functions/bodies.
- The impact assessment should consider relevant alternatives (i.e. assigning the task/function to the Commission, assigning it to one or more existing EU agencies or

⁷⁴ Technical content might have a strong impact on the digital implementation of a policy. For further details on the topic, check Tool #28 (*Digital-ready policymaking*).

other EU bodies, assigning it to a new decentralised agency or other EU body, etc.).

- If a new EU agency or body is considered, this option should be based on the requirements set out in the 2012 Joint Statement and Common Approach on EU decentralised agencies, including on governance⁷⁵
- The impact assessment should consider the overall costs and benefits of all options.
- The analysis should appear either in the impact assessment report itself or in an annex attached to it.
- Please contact the ‘institutional affairs’ unit in the Secretariat-General for more details on EU agencies or other EU bodies.

The Commission may base its policymaking on advice given to it by EU decentralised agencies. When doing so, the Commission does not need to conduct an impact assessment on the policy advice, which has already been properly analysed and consulted on by agencies.

Where the Commission is likely to deviate significantly from the advice of **an EU agency** then an impact assessment is necessary.

Box 2. Impact assessments and policy advice from EU decentralised agencies

- Whenever specific legislative procedures mandate an EU decentralised agency to carry out the main policy-design work and prepare an impact assessment-like document, no Commission impact assessment is necessary *a priori*.
- The Commission’s internal rules on ‘better regulation’ and impact assessment do not apply to EU agencies⁷⁶. However, the lead and partner DGs should ensure that the agency’s analysis broadly meets the Commission’s consultation and impact assessment standards. They should take responsibility/ownership for the quality of the assessment⁷⁷.
- The lead DG should (in consultation with the Secretariat-General) consider whether the Commission’s initiative would benefit from further analysis and complementary impact assessment. This could be the case due to its complexity, or the significance of the expected impacts or where the Commission is likely to deviate from the advice of the relevant agency or indeed where the agency’s analytical or procedural work does not meet the Commission’s usual standards.
- During policy preparations, the lead DG may decide itself or be asked by the Secretariat-General or other Commission services to supplement the agency analysis. In the latter case, the lead DG is responsible for submitting a draft impact assessment report to the RSB in accordance with the ‘better regulation’ guidelines and this toolbox.
- This procedure may also be used in situations when preparatory work has been assigned

⁷⁵ https://europa.eu/european-union/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

⁷⁶ Many EU agencies have established their own arrangements on ‘better regulation’ as part of the agency’s mandate (particularly in areas such as stakeholder consultation).

⁷⁷ In cases, where the EU agency’s analysis is complex, technical or scattered over several documents, the DG may summarise main elements from the agency in an analytical document supporting the initiative.

by the Commission to a dedicated expert or stakeholder group, which provides advice similarly to what an agency would do⁷⁸. This will require that the expert/stakeholder group conducts analytical and consultation work that broadly meets the Commission standards.

When the Commission is taking **decisions based on advice from a scientific body**, the impact assessment requirement should take account of a) whether the Commission deviates from the advice of the scientific body and/or b) if there are different choices to achieve the objectives. An impact assessment may be required, for example, if a scientific body may recommend a safe exposure level to a particular chemical, but the Commission has materially different policy choices for managing the exposure level of that chemical.

⁷⁸ An example may be the sustainable finance stakeholder group (Technical Expert Group), which carried out analysis and consulted stakeholders and on this basis issued a detailed recommendation for the taxonomy-delegated act to the Commission.

TOOL #8. WHAT STEPS SHOULD BE FOLLOWED FOR AN IMPACT ASSESSMENT?

1. INTRODUCTION

Preparing an impact assessment requires **careful planning and sufficient time**. Carrying out an IA takes on average around a year. It can take longer or shorter, depending on the data availability, the stakeholder consultation process, the need to rely on study contracts, the iterative nature of the impact assessment process itself, as well as the urgency of the associated initiative, etc. Moreover, prior to the impact assessment, the evaluation or fitness check has to be completed on time⁷⁹, unless a 'back-to-back' evaluation and impact assessment⁸⁰ are undertaken.

2. THE DETAILED STEPS IN PREPARING AN IMPACT ASSESSMENT

The preparation of an impact assessment will involve the following steps, as shown in Box 1:

(1) Planning

The lead DG introduces the planning entry in *Decide*. The lead DG should **assess whether an impact assessment is necessary** to support a policy proposal⁸¹ and may request a derogation from carrying out an impact assessment, providing a reasoned justification. Before the entry is politically validated, the Secretariat-General screens it and takes a position on the need for an impact assessment.

(2) Interservice coordination group (ISCG)

An ISCG steers the impact assessment process and **contributes to the preparation of the 'call for evidence' and the draft impact assessment report**. The ISCG should be set up immediately after the initiative is validated. Box 2 provides more details about the composition and role of the ISCG.

(3) 'Call for evidence'

After political validation of the initiative, the lead DG should prepare a 'call for evidence'⁸² together with the Secretariat-General. It is recommended to share the 'call for evidence' with and consult the ISCG members. The consultation of the ISCG may be conducted in written procedure.

A 'call for evidence' consists of a description of the initiative and, most often, a public consultation. It **sets out the key elements of the impact assessment**, including the problem definition, objectives, policy options and an initial appraisal of their expected impacts, data needs and consultation activities⁸³.

The Secretariat-General publishes the 'call for evidence' on '*Have Your Say*' (once the lead DG has uploaded it into *Decide*).

⁷⁹ An evaluation or fitness check will only be necessary where there is an existing policy or legislative framework in place. See Tool #45 (*What is an evaluation and when it is required*).

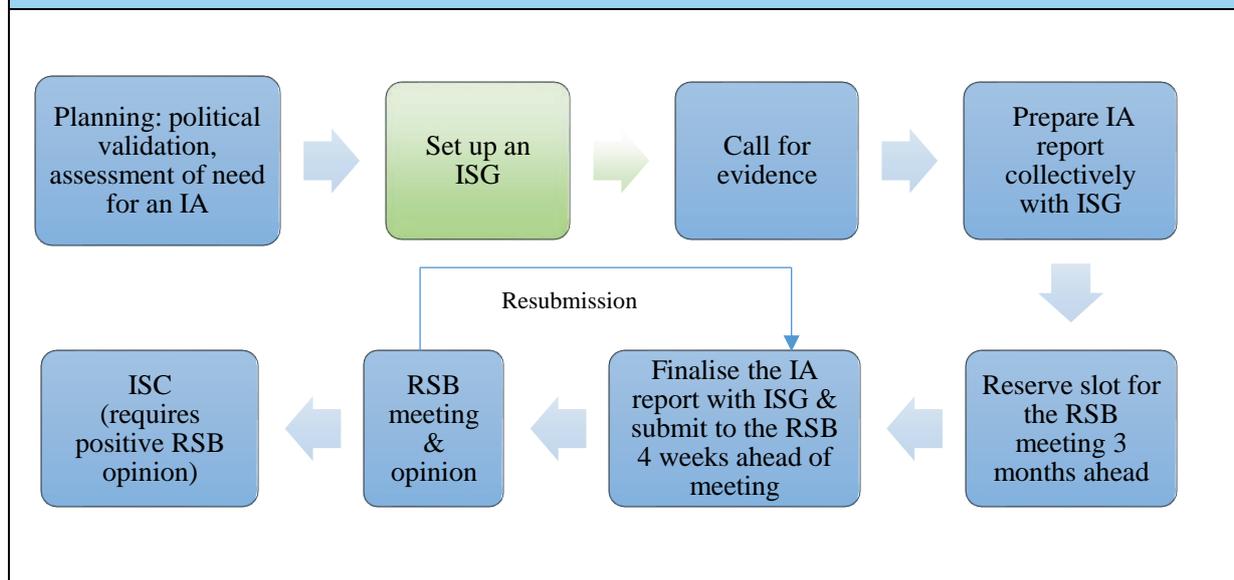
⁸⁰ See Tool #50 (*'Back-to-back' evaluation and impact assessment*)

⁸¹ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁸² See Tool #51 (*Consulting stakeholders*)

⁸³ The templates for the 'call for evidence' are available on [GoPro](#).

Box 1. Process to prepare a typical impact assessment



Preparation of the impact assessment report

The lead DG should prepare a draft impact assessment report with the help of the ISCG.

The toolbox includes specific tools to assist in the preparation of the impact assessment report, including tools on how to gather evidence, consult stakeholders or analyse impacts, and on the format of the impact assessment report. Working in multi-disciplinary teams can foster the quality of the impact assessment report.

The 'better regulation' unit (or impact assessment support function) from the lead DG should work together with those drafting the impact assessment report.

Regulatory Scrutiny Board (RSB)

The lead DG should reserve a slot for a RSB meeting at least three months ahead of the desired date⁸⁴. The lead DG should submit the final draft impact assessment report to the RSB four weeks ahead of the Board meeting, after having discussed it with the ISCG⁸⁵.

The Board reviews the **quality of the final draft report and issues an opinion**. If the Board's opinion is negative, the lead DG (in consultation with the ISCG) will have to submit a revised draft report to the Board, which will issue a second opinion, usually in written procedure.

⁸⁴ To book a slot, the lead DG should contact the RSB secretariat at REGULATORY-SCRUTINY-BOARD@ec.europa.eu

⁸⁵ See Tool #3 (*Role of the Regulatory Scrutiny Board*) for a list of documents that need to be submitted to the Board, together with the draft impact assessment report.

The lead DG should adapt the draft report in response to the opinion(s) of the RSB. The final version of the impact assessment report should explain how the Board's recommendations led to changes compared to the earlier draft(s).

(4) Interservice consultation (ISC)

A positive opinion from the Board is a precondition to launching the ISC on the associated initiative/proposal. In case of a double negative opinion from the RSB, it is only the Commissioner responsible for 'better regulation' who can authorise the launch of the ISC.

The lead DG will revise the draft impact assessment report to take into account comments made by other DGs during the ISC.

Box 2. Interservice coordination group contributing to an impact assessment (ISCG)

The ISCG should prepare and discuss all the key elements of the impact assessment and the policy initiative. The group should discuss the draft impact assessment report before it is submitted to the Board. The group should also be consulted (orally or in written) on the revised impact assessment report in case of resubmission.

Who?	<p>The Group is chaired by the Secretariat-General for all politically sensitive and/or important initiatives listed in the Commission work programme. For all other initiatives, it is chaired by the relevant DG or service.</p> <p>The lead DG (or SG, if it chairs the ISCG) should send an invitation to all DGs in charge of policies likely to be affected by the initiative or that will contribute to the objectives or the implementation of the initiative, along with the SG and the Legal Service ⁸⁶.</p> <p>In addition, DGs should actively screen initiatives at an early stage with a view to identify those that are relevant for their core policy areas. Where relevant, DGs should express their interest to participate in the ISCG to the lead DG, to ensure that the IAs provide a proper analysis of their core areas.</p> <p>The 'better regulation' unit (or IA support function) from the lead DG should also be part of the ISCG. It should support those in charge of the initiative to prepare the IA report, throughout the whole process.</p>
	<p>The Secretary-General (where the SG chairs the ISCG) or the Director-General of the lead DG should send an invitation (note) to the relevant DGs asking to nominate a representative.</p>
	<p>Where possible, existing ISGs should be used to steer the IA work, particularly where an ISCG has steered a related evaluation or fitness check. The Secretary-General or the Director General of the lead DG should send a note to the relevant DGs asking to confirm or nominate a representative.</p>

⁸⁶ For instance ECFIN (economic analysis), EMPL (social impacts), ENV (environment impacts), CLIMA (climate impacts), GROW (SMEs, competitiveness), JUST (fundamental rights), RTD (innovation), CNECT (digital policies), DIGIT (digital solutions and interoperability), COMP (competition), TAXUD (taxation), etc. It is recommended to invite always JRC, ESTAT and BUDG, for their specific knowledge on scientific research and analytical models, data and budgetary issues, respectively.

	<p>Consultants and agencies⁸⁷ are not regular members of the ISCG, but they may be invited to make presentations regarding supporting studies, expertise or contracts. Consultants and agencies should not be involved on substantive discussions taking place between ISCG members. The lead DG should make sure the confidential nature of internal ISCG discussion remains protected.</p>
<p>Why?</p>	<p>ISGs can help to enhance the quality of the IA report and the proposal:</p> <ul style="list-style-type: none"> • By mobilising the expertise available across the relevant DGs, ISCG discussions include internal and external dimensions and help to identify data, stakeholders, problems, policy alternatives, significant impacts and mitigating measures that might otherwise be missed. • By identifying potentially burdensome processes which could be simplified (including by using digital technologies). • Colleagues with specific expertise can provide methodological advice (for instance, ISCG members from the 'better regulation' unit or impact assessment support function, JRC, horizontal DGs, etc.). • Involving other services in the preparation of the impact assessment allows also to anticipate and solve problems that would otherwise emerge later in the process (e.g. during ISC). It helps to ensure early coherence and consistency with other initiatives in preparation and that the initiative contributes to broad policy objectives. • Colleagues from other areas are a good test of whether your arguments are clear and easy to follow.
<p>When?</p>	<p>An ISCG is established as soon as the initiative has been politically validated⁸⁸.</p> <p>The ISCG contributes to the preparation of a 'call for evidence' and agrees on the design of a stakeholder consultation strategy and any consultation documents (e.g. questionnaire for a public consultation). It should discuss any feedback received from stakeholders on the 'call for evidence' as part of the discussion on the draft impact assessment report.</p> <p>In the first meeting, the ISCG should help identify the most significant impacts. The ISCG should discuss intermediate results (e.g. modelling work or supporting studies) and impact assessment report drafts. Ideally, it should be involved in the preparation of terms of reference for external studies and the drawing up of the scope of possible modelling work.</p> <p>The ISCG should meet as many times as needed to cover the main elements of the impact assessment (problem definition, objectives, policy options, impacts, comparison of options).</p> <p>The ISCG should discuss the final draft of the impact assessment report before it is submitted to the Board. It should be consulted (orally or in written) on the revised impact assessment report in case of resubmission. At least at the last meeting of the ISCG <u>before the ISC</u>, the group will discuss the legislative proposal in parallel to the accompanying impact assessment.</p> <p>More meetings (and/or email consultations in between meetings) can also be</p>

⁸⁷ This applies to any EU agency.

⁸⁸ See Tool #6 (*Planning and validation of initiatives*)

	<p>envisaged, particularly in the case of complex initiatives developed over a long period. Meetings may also follow the timing of other milestones such as an external study or a stakeholder consultation. However, in light of constrained resources, it is advised not to multiply the number of meetings and also use written consultations.</p>
<p>How?</p>	<p>Meetings should be well prepared with invitations and documents being circulated at least one week in advance. Similarly, ISCG members should be given at least one week to provide written comments on drafts of the impact assessment report. The lead DG is advised to establish a collaborative workspace for sharing documents, which facilitates more flexible participation by DGs.</p> <p>Minutes of meetings should be prepared to record transparently and accurately the views of the ISCG members. The minutes of the last ISCG meeting should be attached to the cover note when the impact assessment report is submitted to the RSB.</p>

3. FORMAL STEPS FOR THE ADOPTION BY THE COLLEGE

Interservice consultation (ISC)

The ISC is used for requesting and obtaining the formal opinion of other services with a legitimate interest in a draft text. Generally, ISCs are mandatory for all documents requiring a decision by the College and for staff working documents⁸⁹.

The impact assessment report and the executive summary are presented as two separate staff working documents and are subject to ISC alongside the legislative proposal, Communication or Delegated / Implementing Act or other relevant instrument⁹⁰. All opinions of the RSB in relation to the impact assessment report must also be included in the ISC.

The lead DG may need to make final adjustments to the impact assessment report (and to the proposal accompanied by that report) to take on board comments made during the ISC.

Explanatory memorandum

In addition, the Commission's political appreciation of its final proposal should be set out in the explanatory memorandum⁹¹. The explanatory memorandum should recapitulate the proposal's compliance with the subsidiarity, proportionality and 'better regulation' principles, including the results of the evaluations, consultations and the impact assessment. It should also report on how the policy initiative contributes to achieving the UN sustainable development goals, the European way for a digital society and economy, the 'do no significant harm' principle and the compliance with the European Climate Law⁹². The explanatory memorandum of the initiative has to refer to main elements of the attached subsidiarity assessment grid⁹³.

⁸⁹ See [GoPro](#) for more details on interservice consultations.

⁹⁰ See Tool #11 (*Format of the impact assessment report*)

⁹¹ See Tool #40 (*Drafting the explanatory memorandum*)

⁹² See Tool #19 (*Sustainable development goals*) and #36 (*Environmental impacts*)

⁹³ Template for the subsidiarity assessment grid is available in [GoPro](#)

When the final proposal adopted by the Commission deviates significantly from the options assessed in the impact assessment, the explanatory memorandum should explain the reason why and clarify the likely impacts of this change. The changes in the proposal are not to be introduced ex post in the impact assessment.

College

The impact assessment report and executive summary are also presented to the College alongside the initiative intended for adoption. The Commission does not adopt these staff working documents but merely takes note of them. The staff working documents will also be transmitted to the other institutions with the instrument adopted by the College.

Press release

When the proposal is adopted by the Commission, the press release should mention that an impact assessment has been produced. The press release should provide the link to the impact assessment report.

Publication of the impact assessment report and the Board opinion(s)

Following adoption, the impact assessment report is published on the [Register of Commission Documents](#) and the '*Have Your Say*' web portal and transmitted to the legislator together with an executive summary, the subsidiarity grid, the adopted initiative; and the RSB opinion(s)⁹⁴. The final impact assessment report and the opinion(s) have to be uploaded in Decide as part of the adoption process. In certain cases, such as when information is confidential and sensitive, a decision to restrict or delay the publication may be considered. You should consult the unit responsible for 'better regulation' in the Secretariat-General (SG.A2) for further guidance on this. There are also corporate rules on how to manage and publish studies which are used to inform impact assessments.

Impact assessment report without a proposal

The Commission should produce an impact assessment report even when the conclusion of the analysis is that the Commission should not proceed with a proposal. These impact assessment reports should explain why it was decided not to take action. The RSB will examine them, and they will be published on the Europa website as staff working documents, subject to the approval of the Secretary-General.

In cases where the Commission has been specifically asked by the other institutions to consider a proposal but does not intend to put forward a proposal (on the basis of the impact assessment), then a short memorandum (accompanied by the impact assessment report) may need to be adopted by the Commission which delegates authority to the lead Commissioner or Director-General to communicate the findings of the impact assessment process to the other institutions. In such cases it is advisable to consult the SG-HELPDESK-PROCEDURES@ec.europa.eu.

⁹⁴ These also include the tables from Annex 3 of the impact assessment.

4. USE OF THE IMPACT ASSESSMENT REPORT BY THE EUROPEAN PARLIAMENT AND THE COUNCIL

The Commission should use the impact assessment actively when presenting the merits of the proposal and the underlying analysis during the legislative process. Based on the options analysis, it should also help explain why the Commission has chosen not to go for certain solutions, anticipating issues that may be raised by the European Parliament or the Council.

Relations with the European Parliament and Council on impact assessments are governed by the inter-institutional agreement. Within this framework, the other Institutions have made a commitment to assess the impact of substantial amendments they make to Commission proposals where they consider this to be appropriate and necessary in the particular legislative procedure. Like the Commission, the other EU institutions have committed to assess the economic, environmental and social impacts in an integrated and balanced way and to contribute to the implementation of the sustainable development goals.

The Commission may, on its own initiative or at the invitation of the European Parliament and/or the Council, also decide to complement its original impact assessment and the European Parliament and the Council are committed to take full account of this additional material. The European Parliament has developed internal capacity to review the quality of the Commission's impact assessments, to carry out complementary analyses and to assess substantive amendments introduced in the legislative process.

In any event, the European Parliament and the Council take an increasing interest in the Commission's impact assessments and you should insist on presenting your impact assessment work to them and to share information about data and methods used. You may also be invited to submit complementary analysis. Such requests need to be addressed on a case-by-case basis by the Commission. Any additional information would normally be provided in the form of non-papers validated through the Groupe de Relations Interinstitutionnelles (GRI).

In all cases where the Commission is asked to provide additional information, you should consult the Unit responsible for 'better regulation' in Secretariat-General as early as possible to get advice on how to proceed. The Commission is responsible for presenting its impact assessments to the Council and **under no circumstances should the Commission's contractors be involved** in such presentations.

TOOL #9. SPENDING PROGRAMMES, FINANCIAL INSTRUMENTS AND BUDGETARY GUARANTEE

1. INTRODUCTION

This tool explains the links between the requirements of the Financial Regulation and the requirements of the Commission's 'better regulation' policy in respect when preparing basic acts for spending programmes and financial instruments and budgetary guarantee⁹⁵.

The Financial Regulation requires that an ex ante evaluation is carried out to support the decision on new spending programmes. The remainder of this tool sets out when an ex-ante evaluation should be performed and when the ex-ante evaluation should take the form of an impact assessment. An ex-ante evaluation (or impact assessment) supports new spending programmes, financial instruments and budgetary guarantee while a retrospective (ex-post) evaluation assesses the functioning of existing programmes and instruments.

The special case of preparing a new multiannual financial framework is a unique process requiring a specific approach as regards scope and depth of analysis. For this process, practical guidance for the preparatory work is normally issued by Secretariat-General and DG BUDG.

2. WHEN IS EX-ANTE EVALUATION OR IMPACT ASSESSMENT REQUIRED?

According to the Financial Regulation, all programmes or activities involving significant expenditure (indicatively in excess of EUR 5 million) should be subject to both ex-ante and retrospective evaluations. This is to ensure conformity with the principle of sound financial management. In some cases, an impact assessment is required⁹⁶ rather than an ex-ante evaluation but an impact assessment still satisfies the requirements for ex-ante evaluation under the Financial Regulation.

Taking into account the general requirements to conduct an impact assessment and the requirements to perform ex-ante evaluations under the Financial Regulation, the following approach should be followed when preparing new spending programmes⁹⁷:

- An **impact assessment** should be prepared for the major programmes of the multi-annual financial framework according to the standard requirements for impact assessments set out in the 'better regulation' guidelines. Programmes that provide continuity as regards their broad content and structure and are of relatively small budget, do not require an impact assessment but rather an ex-ante evaluation in line with the requirements of the Financial Regulation.

⁹⁵ Financial instruments and budgetary guarantee provide support for investments by way of loans, guarantee, equity and other risk-bearing mechanisms and complement the traditional allocation of grants. Financial instruments and budgetary guarantee can also help to mobilise additional public or private investments and provide a variety of investments for better performance including greater financial discipline at the level of supported projects. Innovative financial instruments and budgetary guarantee play an increasingly important role in EU budget spending. They concern financial support other than pure grant funding and are meant to leverage public and private funding and consist, for example, of debt and equity instruments such as those under Horizon 2020.

⁹⁶ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁹⁷ In case of doubt, contact unit A2 in the Secretariat-General.

For all other financial programmes and instruments, an **ex-ante evaluation** should be prepared, where this is required by the Financial Regulation.

3. PROCEDURAL STEPS

An **ex-ante evaluation** is a staff working document of the Commission services that is linked to the Commission proposal. GoPro provides more detail on the rules to be followed when preparing SWDs. The usual steps include:

- Planning entry in Decide and political validation of the initiative;
- Setting up an interservice coordination group garnering knowledge inputs from relevant other DGs/services;
- Drafting a ‘call for evidence’ document to present the initiative (programme/instrument);
- Finalisation of the staff working document must be preceded by a formal interservice consultation together with the legislative proposal.

The ‘better regulation’ guidelines and toolbox set out the procedural requirements for preparing an **impact assessment**⁹⁸. These include a formal public consultation and scrutiny by the Regulatory Scrutiny Board.

4. THE CONTENT OF EX-ANTE EVALUATION

An ex-ante evaluation should include the following elements:

- (1) **Problem analysis and needs assessment:** The basic rationale of a financial programme is no different to that of a regulatory initiative; i.e. a problem is identified which requires public intervention. The problem analysis should provide the basis for formulating realistic and relevant objectives for the intervention and demonstrates the need for the intervention and its contribution to the implementation of the UN sustainable development goals (SDGs).

The specific tool related to the identification of problems in the context of an impact assessment is therefore relevant and should be used⁹⁹. The needs to be met should be outlined for the short or long term.

The lessons learned from evaluations of previous or similar programmes should be used to identify the problems that need to be addressed in the new programme.

A detailed analysis of the situation, motivations and interests of the key actors should provide an assessment of the needs of beneficiaries that should also shape the objectives of the programme. As for impact assessments, references to specific SDGs (or SDG targets) are recommended, where relevant.

- (2) **EU added value:** The financial programme should generate added value over and above what the Member States can achieve nationally. This added value might arise because of the increased scale of the intervention, efficiency savings from EU-level

⁹⁸ See Tool #8 (*What steps should be followed for an impact assessment*)

⁹⁹ See Tool #13 (*How to analyse problems*). The typical problems that a spending programme or a financial instrument would try to solve are the existence of a financing gap or failures in the financial markets.

action, supporting cross-border actions, etc. The financial programme should be complementary and coherent with other interventions in order to build synergies and may often complement or reinforce existing national actions and programmes. Relevant information can be found in the tool on subsidiarity and proportionality (in relation to the EU added value test)¹⁰⁰ and in the tool relating to the five criteria used for evaluation of EU interventions (which includes EU added value)¹⁰¹.

- (3) **Policy and management objectives:** Well-defined objectives should be developed that link logically with the identified problems. These objectives should clearly describe what the intervention is meant to achieve and how it contributes to wider Union policies and objectives, including to the Commission’s commitment to put the UN’s sustainable development goals at the centre of its policymaking. The objectives will provide the benchmark against which the success of the intervention will be assessed and provide the basic framework for a future ex-post evaluation (also see monitoring and evaluation). Again, the process of objective setting is no different to that in the context of an impact assessment and the relevant tool on setting objectives is highly relevant and should be used¹⁰².
- (4) **Policy options, including associated risks:** Alternative policy options and delivery mechanisms should be identified. In most cases, there are alternative ways to achieve an objective. For instance, alternative approaches may be identified at the level of:
- *Intervention strategies:* for example, financial assistance, regulation, information and networking activities;
 - *Instruments:* for example, grants, interest subsidies, guarantees, loans, financial instruments and budgetary guarantee. The reasons to allow the use of one or more instruments (or combinations) should be identified and explained;
 - *Channels of intervention:* direct support to the main beneficiaries, support to intermediate actors such as NGOs;
 - *Levels of intervention:* the level of intervention can be varied, for example, through the rate of assistance or through narrow/wide definitions of target groups.

This part of the ex-ante evaluation should also analyse what risks will be connected to the implementation of the intervention in order to identify appropriate mitigating measures. Different types and level of risks may influence one particular delivery mechanism over another, as could the findings of an earlier evaluation. Alternatively, the risk associated with a particular programme or option could lead to the decision not to proceed at all.

- (5) **Results and impacts:** The report should assess the expected results and impacts, in particular economic, social, and environmental impacts of the different options, in line with the general requirements for impact assessments. It should also evaluate the volume of appropriations, human resources and other administrative expenditure to be allocated with due regard to the cost-effectiveness principle. The options should be compared on the basis of their effectiveness and efficiency and other criteria such as risks and coherence (i.e. internal coherence of the proposed programme or activity and

¹⁰⁰ See Tool #5 (*Legal basis, subsidiarity and proportionality*)

¹⁰¹ See Tool #47 (*Evaluation criteria and questions*).

¹⁰² See Tool #15 (*How to set objectives*)

its relation with other relevant instruments). This should allow the most appropriate options and instruments to be identified.

- (6) **Monitoring and evaluation:** Appropriate indicators should be established which will be used to monitor the performance of the programme (in relation to the chosen objectives) and be used in its subsequent evaluation. This work on monitoring and evaluation will also form the basis of legal provisions, which should be considered for inclusion in the Commission's proposal for a basic legal act¹⁰³.

5. THE CONTENT OF AN IMPACT ASSESSMENT FOR FINANCIAL PROGRAMMES AND INSTRUMENTS INTRODUCTION

Whenever the ex-ante evaluation takes the form of an impact assessment (see section 2), you should clearly indicate in your impact assessment report that it also serves the purpose of ex-ante evaluation and fill in the obligatory Legislative Financial Statement¹⁰⁴.

As regards the content, it should cover all of the elements of an ex-ante evaluation. However, its format should be brought into line with the standard impact assessment report, adding subsections as relevant (e.g. relation to risk and cost-effectiveness assessments). The impact assessment report should also include an assessment of the results of stakeholder consultations, including the 12-weeks public consultation, and also refer to the opinion of the Regulatory Scrutiny Board. The standard 4-5 DGT-page executive summary should also be prepared and presented as a separate staff working document (translated into all languages).

6. GUIDANCE ON SPECIFIC ISSUES TO ADDRESS

While section 4 specifies the minimum content of an ex-ante evaluation, this section provides further guidance on the specific issues that should be addressed with regard to spending programmes, financial instruments and budgetary guarantee. The degree to which these issues will be assessed should remain proportionate to the amount of expenditure and resources involved, and will also depend on the political context and the time constraints.

It is important to carefully take into account the lessons learned from previous programmes, including (interim) evaluations, and the views of stakeholders when defining the problem. Within the context of the preparation of a new multiannual financial framework, it may well prove useful to cluster public consultations on several financial programmes to avoid overlaps in consultation. A specific complication arises when there is a lack of clarity on the available financial resources. Further, it is important to emphasise the importance of attaching sufficient attention to detailing the future monitoring and evaluation arrangements in the impact assessments, since these have in the past been underdeveloped in some cases leading to data availability issues in the further policy cycle.

6.1. Spending programmes

The ex-ante evaluation or impact assessment for a spending programme should:

¹⁰³ See Tool #43 (*Monitoring arrangements and indicators*) and Tool #44 (*Legal provisions on monitoring and evaluation*)

¹⁰⁴ Available at <https://myintracomm.ec.europa.eu/budgweb/en/Pages/index.aspx>. In filling in the Legislative Financial Statement you should coordinate with your financial unit.

- Use the financing available under the existing financial framework as the baseline scenario for programmes that already exist (including absorption levels, eligibility rules);
- This helps to explain what changes are being put forward for the next financial period compared to past spending levels. Such a baseline scenario should take into account lessons learned as well as the expected evolution of the 'exogenous' factors, such as GDP or employment levels. It should also reflect policy measures that have already been agreed, but which will come into force only in the future (including policies in other areas);
- However, it will often be useful to include a policy option to discontinue EU action. This will allow to assess the 'cost of non-Europe' and to provide clearer information to decision makers as their agreement is in any event needed to continue with any spending programme¹⁰⁵.
- In case the budgetary envelope is not yet known, the impact assessment should explore the consequences of various alternative scenarios with regard to the available budget allocation (and therefore varying levels of ambitions). These scenarios should correspond to, a reduction in the financing available under the existing financial framework by a certain percentage, a constant financial envelope or an increase of the financial allocation. Secretariat-General and DG BUDG will usually provide central guidance on the specific content of the required analytical documents according to the specific context in which the framework is developed.

Focus the options for implementation on issues such as:

- Programming (priority setting, allocation of resources, adjustments during the programme duration, rationale for grants versus financial instruments and budgetary guarantee);
- Management provisions and requirements regarding the prevention of errors, irregularities or fraud (audit, controls), conditionality, monitoring, evaluation requirements with due attention to administrative burden and proportionality;
- Simplification (online tools, selection procedures, outputs and results payments versus lump-sums, simplified cost options, ineligibility of certain costs, easy combination of different forms of support), options for management (full externalisation, externalisation plus technical assistance, direct management, shared management, decentralised management)¹⁰⁶.

Consider the different types of budgetary cost:

- Direct financial assistance or support (to beneficiaries or third parties) from the EU budget;
- Co-financing (or contribution) from Member State budgets which are directly tied to the EU expenditure or which are a direct consequence of the EU spending;
- Human resources needed to manage the intervention;

¹⁰⁵ See Tool #16 (*How to identify policy options*)

¹⁰⁶ See e.g. [Guidelines for the establishment and operation of executive agencies](#)

- Other administrative expenditure for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc.).

Assess (financial and operational) risks associated with the identified options, for which you may need to seek additional expertise (e.g. from your financial unit, internal audit service and OLAF).

Screen for compatibility with:

- The relevant state aid rules in case the proposal involves aid to undertakings which falls under the notion of state aid as defined by Article 107(1) TFEU¹⁰⁷; and
- International rules on subsidies to which the EU has committed itself in the context of the World Trade Organisation (WTO) or in Free Trade Agreements (FTAs) with third countries¹⁰⁸;
- International commitments, including the contribution to the implementation of sustainable development goals;
- Existing international or European standards.

When comparing the options, summarise all financial aspects as detailed in the Legislative Financial Statement. All figures in this statement have to be properly accounted in this section;

- Focus on improving evaluation arrangements and monitoring indicators¹⁰⁹, particularly in cases where deficiencies in the current arrangements have made it difficult to assess the performance of current programmes, while avoiding undue administrative burden.
- Specify how progress in disbursement, use and impacts of the allocated amounts will be followed up. This and the related legal provisions in the proposal¹¹⁰ will lay the ground for the elaboration of a comprehensive monitoring and evaluation framework – after adoption of the proposal – that includes all the necessary arrangements for carrying out monitoring and evaluation of the programme (indicators, access to data sources, frequency of data collection, data formats and processing, etc.).

¹⁰⁷ DG COMP can assist in this assessment

¹⁰⁸ DG TRADE can assist in this assessment

¹⁰⁹ See Tool #43 (*Monitoring arrangements and indicators*) and Tool #44 (*Legal provisions on monitoring and evaluation*)

¹¹⁰ In the programme proposals under the 2021-2027 Multiannual Financial Framework, standardised articles on monitoring and evaluation were included. The proposals also contained an annex with a list of indicators for annual corporate reporting. The legal provisions included an empowerment for a delegated act to amend the annex and to review or complement the indicators where considered necessary, and to establish a monitoring and evaluation framework. For certain programmes, given their specificities (such as the Common Agricultural Policy (CAP) and the European Regional Development Fund (ERDF)), this standard approach needed adjustments.

6.2. Financial instruments and budgetary guarantee

When preparing a proposal for financial instrument and budgetary guarantee, you will need to pay particular attention to:

Problem analysis:

- Identify market imperfections (like sub-optimal investment situations) or market failures and assess investment needs in view of the policy objectives¹¹¹;
- Demonstrate that identified market needs cannot be addressed appropriately and in a timely manner through either market-led activities or types of Union intervention other than funding by a financial instrument, such as regulation, liberalisation, reform or other policy action.

Subsidiarity analysis:

- Demonstrate that Union-level financial instruments and budgetary guarantee address identified market needs more appropriately than similar financial instruments at national or regional level, including those financed by European Structural and Investment Funds under shared management (ESIF);
- Take into account factors such as difficult access to funding at national level (in particular for cross-border projects), economies of scale or strong demonstration effects linked to the diffusion of best practices in the Member States.

Option identification:

- Determine the most efficient mode for delivering the financial instrument and budgetary guarantee and demonstrate that the planned financial instrument and budgetary guarantee is consistent with:
 - New and existing financial instruments, avoiding undesirable overlaps and achieving synergies and economies of scale while taking account of lessons learned from existing instruments;
 - Financial instruments and other forms of public intervention addressing the same market environment, avoiding inconsistencies and exploring potential synergies.

Analysis of impacts:

- Assess the proportionality of the envisaged intervention with regard to the size of the identified funding gap and the expected leverage effect of the planned financial instrument and budgetary guarantee.
- Assess the likelihood and possible costs of market distortions and crowding-out of private funding through the financial instruments and budgetary guarantee and identify means to minimise negative effects of such distortions.
- Examine additional qualitative effects, such as the diffusion of best practice, the effective promotion of Union policy objectives throughout the implementation chain or the access to specific expertise available from actors involved in the implementation chain.

¹¹¹ In the 2021-2027 CPR, the market failures and investments needs are assessed at the level of the programme, as per article 22 (3) a ii and iii.

TOOL #10. TREATY-BASED SOCIAL PARTNER CONSULTATIONS AND INITIATIVES

Before submitting proposals in certain social policy fields (see Box 1), the Commission must respect the two-stage consultation procedure of the European social partners¹¹², stipulated in Article 154 TFEU. In particular:

- Social partners must be consulted on the **possible direction of EU action**, in the first stage of consultation, and on the **content of the envisaged proposal**, in the second consultation¹¹³.
- During both stages, social partners may inform the Commission of their wish to initiate a negotiation process for a social partners' agreement in the policy area, as provided for in Article 155 TFEU. In such a case, the Commission suspends its initiative for the duration of the negotiations. If these are successfully concluded, social partners may request their agreement be implemented by the Commission presenting a proposal for a Council Decision.
- In addition, for agreements reached on their own initiative (i.e. not further to the Commission's first or second stage consultation procedure), in accordance with Article 155 TFEU, the social partners may also ask the Commission to present a proposal for a Council Decision.

Box 1. Article 153(1) TFEU

With a view to achieving the objectives of Article 151, the Union shall support and complement the activities of the Member States in the following fields:

1. improvement in particular of the working environment to protect workers' health and safety;
2. working conditions;
3. social security and social protection of workers;
4. protection of workers where their employment contract is terminated;
5. the information and consultation of workers;
6. representation and collective defence of the interests of workers and employers, including co-determination, subject to paragraph 5;
7. conditions of employment for third-country nationals legally residing in Union territory;
8. the integration of persons excluded from the labour market, without prejudice to Article 166;
9. equality between men and women with regard to labour market opportunities and treatment at work;
10. the combating of social exclusion;
11. the modernisation of social protection systems without prejudice to point (c).

¹¹² Social partners include employers' organisations and trade unions engaged in the European social dialogue. In order to be recognised, they should meet the representativeness criteria as set by the COM(93) 600 and Commission Decision of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level, COM(1998) 2334; OJ L 225, 12.08.1998, p.27.

¹¹³ To note that the Treaty-based two-stage consultation procedure with social partners does not fall under the regular minimum standards for consultation, but follows separate arrangements.

In the context of social partners' agreements for which the signatories request the Commission to present a proposal for implementation by a Council decision in accordance with Article 155 TFEU, better regulation principles apply.

Accordingly, the Commission invites the social partners to make publicly available the text of any agreement for which they may request the Commission to present a proposal for implementation by a Council decision in accordance with Article 155 TFEU.

Whenever the impacts of the agreement are likely to be significant, the Commission may carry out a proportionate impact assessment. Given the transparency of the process and the role entrusted to the social partners by Article 155 TFEU, no additional public consultation or 'call for evidence' will be necessary.

In its ruling of 2 September 2021 (Case C-928/19 P) the Court of Justice upholds the judgment of the General Court and points out that the Commission enjoys a discretion, when deciding whether it is appropriate to submit to the Council a proposal seeking such implementation pursuant to Article 155(2) TFEU. Further details regarding the implementation of this judgement have been set out in the Social Dialogue Communication¹¹⁴.

The table below details the policymaking process and the outlines the scope and/or depth of the required impact assessments.

I. For the social partners' consultations prescribed by Art. 154

The Commission's decision whether to launch the second stage of consultation on the content of the envisaged proposal should be informed by an **'analytical document'**.

In order to respect fully the autonomous decision-making of the social partners, such an analytical document should not identify a 'preferred policy solution'. Instead, it should focus on analysing the problem which EU action should address, present the objectives, analyse the impacts of the measures under consideration and explore the value added of EU action.

The analytical document shall be based on necessary analysis and information and shall take into account the results of the first stage social partners' consultation¹¹⁵.

A public consultation or a 'call for evidence' should not run in parallel to the two-stage social partners' consultation. The launch of a public consultation and/or of a 'call for evidence' can take place, if necessary, after the end of the second stage consultation with social partners and if no negotiation between the social partners is expected thereafter.

II. For social partners' agreements as provided for in Art. 155¹¹⁶

Following the ruling of the Court of Justice of 2 September 2021 (Case C-928/19 P), when it receives a request to implement at EU level an agreement concluded by the social partners, the Commission must take into account the general interest of the Union and determine whether that implementation is appropriate by also having regard to political, economic and

¹¹⁴ Communication from the Commission strengthening social dialogue in the European Union, [COM/2023/40 final](#)

¹¹⁵ Stakeholder consultation guidelines and the minimum consultation standards do not apply at this stage.

social considerations.

The Commission should subsequently inform social partners about the result of its assessment of the appropriateness of their request. In case the Commission considers that the request could lead to a proposal for a Council Decision, it may conduct an impact assessment, which, however, would not pre-empt the final decision of the Commission on this request.

The Commission may, after hearing the social partners, decide to specify its course of action.

III. For Commission initiatives in social policy fields under Art. 153

- When considering a proposal in the absence of a social partners' agreement

In the absence of a social partners' agreement after the second stage consultation, the Commission may still decide to put forward a proposal. In such cases, the decision should be informed by a standard impact assessment which would draw upon the analytical document prepared after the first stage of consultation – see (1) above.

TOOL #11. FORMAT OF THE IMPACT ASSESSMENT REPORT

1. INTRODUCTION

The impact assessment report should present the key information generated by the impact assessment process. The impact assessment report will take the form of a staff working document (SWD) which the College takes note of when it considers whether to adopt a new policy initiative. The report should therefore prioritise information, which is relevant to assist the College in reaching a decision on a specific initiative, i.e. to present pros and cons of different policy options. The impact assessment report will be transmitted to the other institutions and made public.

DGs should use the **standard format** described below. Certain information and specific annexes must be presented in the report. This is to ensure that politically important issues such as subsidiarity, proportionality, sustainability, environment, social impacts, economic impacts (including impacts on small and medium sized enterprises), digital impacts, and impacts on fundamental rights are systematically addressed. In line with the Commission's commitments, references to the contribution to relevant SDGs should be made explicit. It should also be clear who will be affected by the initiative and how.

The impact assessment report should be complemented by an **executive summary** not exceeding 4-5 standard DGT pages¹¹⁷. The executive summary serves as a communication tool to present the impact assessment reports in a quick and reader-friendly way. It should summarise the main elements of the analysis (problems, objectives, justification to act at EU level, policy options and the preferred option with its main envisaged impacts) in a visually attractive format and plain language¹¹⁸ that would help 'an uninformed reader' to familiarise oneself with the Commission proposal. This summary should be presented as a separate staff working document and be translated into all EU languages. Templates for the impact assessment report and for the executive summary can be downloaded from GoPro.

2. GENERAL REQUIREMENTS FOR THE IMPACT ASSESSMENT REPORT

The following general requirements should be respected:

- The impact assessment report should be drafted using non-technical language with non-expert readers in mind. The benchmark length of the main part of the report (i.e. without the annexes) should be **40 pages** (covering the substance, i.e. excluding the cover page, table of contents, glossary, and the list of abbreviations, but including tables, graphs and figures). Derogations to the maximum page limit should be agreed with the Secretariat of the RSB before the submission of the draft report for scrutiny;
- The impact assessment report should be a **self-standing document**, which follows the standard structure set out below. It should provide the reader with a picture of the main assessment results, while more detailed information or explanations should be provided in annexes¹¹⁹;

¹¹⁷ A standard DGT page is defined as 1500 characters excluding spaces.

¹¹⁸ [Get your document edited \(europa.eu\)](https://ec.europa.eu/euro-just/euro-just-portal/en/get-your-document-edited-europa.eu)

¹¹⁹ However, in line with the principle of proportionate analysis, the length of the different sections may for certain types of initiatives be adapted to reflect the focus of the analysis. For instance, for delegated or implementing acts, the impact assessment report would generally be more extensive on the sections describing the outstanding options for decision and their likely impacts, while the problem and subsidiarity

- The impact assessment report should use the template provided in GoPro, but must have a standard cover page created in Legiswrite¹²⁰;
- The impact assessment report should contain a table of contents, a list of abbreviations and a glossary explaining technical concepts;
- Underlying data, statistics, information, expert contributions, and stakeholder views should all be referenced, particularly where choices are made or conclusions reached based on them, as well as documented transparently following the recommendations given in Tool #4 (*Evidence-informed policymaking*).
- Tables, graphs, figures should be self-explanatory, meaning that they should be properly titled and sourced. Annotations should be added to tables, graphs and figures (where applicable) to explain methods, concepts, so that the messages can be understood without consulting the core text. Similarly, the core text should be comprehensible without having to consult the figure. Data visualisation principles¹²¹ should be applied.

Stakeholder views should be integrated, whenever relevant. Stakeholder views are particularly important for policy problems and options. The impact assessment report should include a description of the views of the different stakeholder groups and highlight whether the views differ across or within these groups. In particular, it should be clear which options are supported by the various stakeholder groups and about the reasons where stakeholder preferences or opinions have not been followed. Where social partners¹²² have been consulted, either under Article 154 TFEU or through a dedicated consultation process, a dedicated section should report on the positions taken by them.

3. DETAILED STRUCTURE AND CONTENT OF THE IMPACT ASSESSMENT REPORT

The impact assessment report should follow the structure below. Each section indicates the information or issues that should be covered. They do not replace the general guidance on impact assessments¹²³, which provides the complete picture of issues to address under each key question. Generally, there is flexibility in how to respond proportionately to the questions in the main 'better regulation' guidelines and how to structure the relevant sub-sections of the impact assessment report. However, the following issues should be described in all impact assessment reports¹²⁴:

sections would be relatively limited, mainly summarising/referring back to relevant analysis of the impact assessment of the basic act.

¹²⁰ [Legiswrite template CP-026 – SWD linked](#)

¹²¹ <https://data.europa.eu/apps/data-visualisation-guide/>

¹²² See Tool #10 (*Treaty-based social partner consultations and initiatives*)

¹²³ See '[Better regulation' guidelines](#)

¹²⁴ The proportionate impact assessment undertaken in support of social partners' agreements should moreover contain an assessment of the representativeness of the signatories and a legality check of the agreement in respect of Union law (see Tool #10 (*Treaty-based social partner consultations and initiatives*))

Section 1. Introduction: political and legal context

Issues to cover:

- What is the prevailing political and legal context as that justifies the need for the initiative and its timing?
- Are there relevant European Council conclusions, Council conclusions, EP resolutions or College decisions (such as strategies, actions plans, communications)?
- Have there been any previous policy initiatives in the same area for which the legislative process has not been finalised for any reason?
- How does it relate to the sustainable development goals? To which goals and where relevant target does the initiative contribute?
- Are related initiatives also under preparation? Which issues will each initiative tackle? How is coherence ensured?

Section 2. What is the problem and why is it a problem?

Helpful tools: #13 (How to analyse problems); #20 (Strategic foresight for impact assessments and evaluations); Chapter VI (Evaluations)

Issues to cover:

- What is the issue or problem that may require action? What is the size or scale of the problem? Is there a cross-border dimension? Why is it a problem?
- Consider using a visual aid to depict the problem tree, clearly separating drivers from problems, and problems from consequences, and identifying their links. The problem tree should also indicate external drivers/influencing factors or aspects which contribute to the (size of the) problem, but are outside the scope of the initiatives, i.e. which the initiative does not intend to address (e.g. global trends, digitalisation). Any representation should, however, be clear and correspond to the narrative.
- Who is affected by the problem? In what ways, and to what extent? Whose behaviour would have to change to improve the situation?
- 'Evaluate first' principle: Was a fitness check or an evaluation carried out of the existing policy framework? If not, why not? What did the evaluation or fitness check conclude? Is this reflected in the description of the problems?
- All initiatives to revise existing legislation are by default considered to be REFIT initiatives and must consider whether there is a problem in terms of the legislation being unnecessarily complex or imposing unnecessary costs.
- What are the main drivers? What are the market failures, regulatory failures, or behavioural biases, which are responsible for the observed problem? What evidence is there available?
- How likely is the problem to persist – how will the problem evolve (in general terms) in the absence of EU action?

- Are there links to any foresight activities undertaken in the problem area? If so, how does the persistence of the problem align with the foresight scenario(s)?

Section 3. Why should the EU act?

Helpful tools: #5 (*Legal basis, subsidiarity, proportionality*)

When developing this section it is worthwhile filling in at the same time the subsidiarity grid that needs to be attached to all politically sensitive and important proposals. A detailed set of questions in the grid helps assess the issues of subsidiarity, proportionality, and EU value added that need to be analysed and reported in the impact assessment.

Issues to cover:

- Does the EU have the right to act under the Treaty? What is the appropriate legal basis?
- Does the legal basis (action under consideration) fall within one of the areas where the Treaty gives the Union exclusive competence (as defined by Article 3 of the TFEU)? If so, the subsidiarity principle does not apply.
- If the initiative is subject to shared competence, how will the EU action ensure compliance with the subsidiarity principle?

Necessity for EU action:

- A key part of the analysis should be to qualify the “Union relevance” of the initiative being considered. The greater the relevance the more likely Member States’ action alone will/would have be(en) insufficient. Key issues and questions to consider are:
 - How does the problem vary across the national, regional, and local levels of the EU?
 - Is the problem widespread across the EU or does it only concern a few Member States or regions?
 - Does the problem have the same underlying cause across the EU?
 - How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
 - To what extent do Member States have the ability or possibility to enact appropriate measures?
 - Would national action or the absence of EU level action conflict with the Treaty or significantly damage the interests of other Member States?
 - Are there cross-border aspects to the problem? What is their extent and significance?
 - Will there be increased costs or problems if action is left only to the Member States?

Added value of EU action:

- Are there economies of scale? Can the objectives be met more efficiently (less costly) at EU level?
- Are there benefits in replacing different national policies and rules with a more homogenous policy approach?

- Will the functioning of the internal market be improved? If so, how will it be improved?

Section 4. What should be achieved?

Helpful tools: #15 (How to set objectives); #29 (Fundamental rights, including the promotion of equality); #43 (Monitoring arrangements and indicators)

Objectives link the analysis of the problem (and its drivers) to the options for the policy response. They set the level of policy ambition, fix the yardsticks for comparing policy options and determine the criteria for monitoring and evaluating the achievements of implemented policy.

Issues to cover:

- What are the general policy objectives? These are the Treaty-based goals, Commission priorities or strategic goals, to which the intended policy contributes. The general policy objectives should be in line with the overarching, long-term objectives (e.g. climate neutrality). If there is a potential conflict and some trade-offs¹²⁵ are inevitable, they have to be identified and analysed when choosing the preferred option.
- What are the more specific objectives to which the policy options should correspond? These set out concretely what the policy intervention is meant to achieve. They should be broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution. For each identified problem, there should be one or a set of specific objectives, which form part of the intervention logic: drivers – problems – general objective – specific objectives – policy options. Consider using visual aids to present this logical chain.
- What are the SDGs and relevant targets at stake for the initiative?
- How do the specific objectives link to the problem? How do they relate to each other, i.e. are there any synergies or trade-offs, including in relation to progress towards sustainable development (balance between economic, social and environmental dimensions)? Often it is helpful to specify objectives that require balancing. This way comparing the options will reveal trade-offs between options.
- For those legislative revisions for which problems of legislative complexity and/or unnecessary costs have been identified, there should be a specific objective relating to the desire to simplify and improve the efficiency of existing legislation.
- Are the specific objectives consistent with other EU policies and with the EU Charter of Fundamental Rights?
- Operational objectives are expressed in terms of the deliverables of individual policy actions. As such, they are typically option-specific. These should therefore, be reported for the preferred option (if it exists) in the section on monitoring and evaluation.

¹²⁵ The specification of objectives is determining for how options are assessed and therefore how policy trade-offs are presented. It is therefore important to choose (specific) objectives, which allow for a good presentation of trade-offs and political choices to be made.

Section 5. What are the various options to achieve the objectives?

Helpful tools: #16 (How to identify policy options); #60 (Baselines)

Issues to cover:

Baseline

- Each impact assessment should have a benchmark against which the policy options are compared. This benchmark is usually referred to as the baseline (scenario). It reflects what would happen under a 'no-policy-change' scenario without new policy intervention, and assuming realistic implementation of existing legislation (i.e. the dynamic nature of the baseline).
- Where two or more initiatives are prepared together as a package, each IA report should use the same baseline but should describe the likely consequences of the other initiative in terms of possible changes to the baseline. It may also be relevant to consider an alternative baseline/sensitivity case to demonstrate the impacts of the other initiative.

Options

- What are the regulatory and non-regulatory options for meeting the objectives and tackling the problems? All major options that are supported by stakeholders should a priori be included among the considered options.
- Policy options should be closely linked to the drivers of the problems and the identified specific objectives: a clear logic should underpin the intervention under consideration. The options should present alternative ways of meeting the specific objectives to differing degrees.
- It is highly recommended to include non-regulatory options, unless already ruled out or an obligation for legal action exists.
- Where relevant, the report should consider options, which imply not acting at EU level¹²⁶. This will increase awareness about the "the cost of non-Europe" as this is a commitment given by the Commission pursuant to the Interinstitutional Agreement on Better Law-Making.
- All initiatives to revise existing legislation are REFIT initiatives. For all such impact assessments, there is an obligation to have a separate subsection in section 8 on REFIT¹²⁷. For impact assessments where the problem description identifies burden reduction or simplification potential, this should as far as possible be reflected in the objectives and options. Options should reflect the objective to exploit the identified potential for simplification and improvement of regulatory efficiency without affecting the overall objectives of the legislation.
- Which options have been discarded at an early stage and why? Be particularly specific and precise for discarded options enjoying significant support among (certain groups of) stakeholders.

¹²⁶ Such an option is different from the baseline ('no-policy-change') option when the impact assessment is prepared for a revision of existing legislation. It is also valid in cases where the legislation includes a sunset clause and the baseline assumes the continuation of the current policy.

¹²⁷ See Tool #2 (*Regulatory fitness programme (REFIT) and the Fit for Future Platform*)

Section 6. What are the impacts of the different policy options and who will be affected?

Helpful tools: #18 (Identification of impacts); #19 (Sustainable development goals); #21 - #37 – on specific impacts; #56 (Typology of costs and benefits); #65 (Uncertainty and sensitivity analysis)

Issues to cover:

- What are the likely impacts of each of the short-listed options (i.e. all policy options having a potential to achieve the objectives and after having discarded those that do not for one reason or another)? All three broad categories of impacts (i.e. economic, social, and environmental) must be covered in a balanced and integrated manner as a contribution to sustainable development, unless one or other are clearly not relevant. Whenever this is the case, the impact assessment report must explicitly say so.
- List relevant positive and negative impacts, direct and indirect, intended and unintended, one-off and recurrent, including those outside the EU together with a quantitative assessment of those impacts where possible and proportionate.
- The costs and benefits of the initiative should be identified according to the standard typology of costs and benefits. Wherever possible they must be quantified (and if feasible monetised) in line with the ‘better regulation’ guidelines (i.e. taking account of the principle of proportionate analysis). Where assumptions are made, these should be listed, justified and referenced. Reasons should be given where quantification is not possible.
- Impact assessments should also identify any significant impacts in terms of contributions to the UN sustainable development goals. This can be done in context of the summary table in Annex 3. See Tool #18 (*Identification of impacts*), Tool #19 (*Sustainable development goals*) and the section on Annex 3 below.
- **Impact on SMEs:** The impact assessment report must include the assessment of SME impacts, with an explicit reference to the result of the ‘SME test’¹²⁸. The main part of the report should indicate whether the initiative is considered ‘not relevant’, ‘relevant’ or ‘highly relevant’ for SMEs on the basis of an agreement within the interservice coordination group, considering the suggestions from the ‘SME filter’, carried out with the support of the SME Envoy Network. Impact assessments for initiatives that are ‘relevant’ or ‘highly relevant’ for SMEs should include an ‘SME Check’. The check is a mandatory annex to the impact assessment report that provides an overview of the main results of the SME test to ensure transparency and clarity on the results of the test (see below). For those initiatives, the executive summary should refer to the ‘SME test’. The assessment of SME impacts should, as far as possible, include quantitative estimates.
- **Impacts on competitiveness:** The impacts on competitiveness must be analysed in the main part of the report and summarised in the compulsory Annex 5 (see section below on annexes)
- **Impact on fundamental rights:** When relevant, the impact assessment report must include the assessment of impacts on fundamental rights and on equality (including gender) in particular.

¹²⁸ See Tool #23 (*The ‘SME test’*)

- **Impact on the environment:** The Commission has in its Green Deal committed to 'a green oath'. This means that Commission proposals cannot lead to significant harm for the environment. Hence, in impact assessments, where significant negative impact on the environment is identified, this needs to be considered in view of the green oath.
- **Impacts on digitalisation:** The Commission has in its 2030 Digital Compass Communication set out a vision, targets and avenues for a successful digital transformation of Europe by 2030. To support this process, the Commission committed to assess how the options under consideration reflect the 'digital by default' principle and contribute to the digital transformation.
- **Describe who would be affected** (e.g. businesses, citizens, workers, consumers, public administrations, regions, third country actors, ...) and how. This includes taking into account the commitment in the 2030 Agenda of leaving no one behind, by identifying groups of persons in vulnerable situations that might be particularly affected by the policy and risks to aggravate inequalities. Annex 3 also requires a description of the actions and measures that need to be undertaken by those affected by the measure.
- Where relevant, specify uncertainties and how the estimated impact may be affected by changes in parameters and key assumptions.
- Outline potential obstacles that might be encountered for an effective implementation of the options and compliance by Member States and targeted entities.

Section 7. How do the options compare?

Helpful tools: #57 - #69 – methods

Issues to cover:

- In this section, all above elements are brought together to compare options transparently and to determine the policy choice, whether this identifies a preferred option or not.
- To introduce this, it is recommended to present the overall intervention logic (i.e. in a table or figure format), bringing together the various elements (drivers, problems, objectives, options). This could be standalone or complementary to the problem tree and any earlier presentation of the logic of the intervention (e.g. problems → objectives → options). In the latter case, it should focus on the links between options and impacts. A clear presentation of the intervention logic helps evaluating the legislation in the subsequent phases of the policy cycle.
- The comparison of options can be based on different methodologies according to the specific case (i.e. cost benefit framework; see Tools #57, #62, #63).
- Whichever method used, the comparison of options should always address the effectiveness, efficiency, and coherence of the options in relation to the specific objectives defined in Section 4.
 - The section should highlight key economic, social and environmental impacts, including when these are not part of the objectives.
 - Their costs and proportionality to the issue at hand.
 - The benefit/cost ratio, cost-effectiveness or net present value, if available;

- Their coherence with other EU policy objectives, including the Charter for fundamental rights, and with other policy initiatives and instruments (coherence) including the SDGs;

The comparison should clearly present trade-offs reflected in the choice of options. For instance, by highlighting more costly options, which may be more effective against less costly ones, which may be less effective. Here, the proportionality of measures may play an important role. Potential synergies between options can also be considered.

- The likely uncertainty in the key findings and conclusions and how these might affect the choice of preferred option should be analysed (potentially by sensitivity analysis).
- Multi-criteria analysis can be used to explicitly allocate weights to the different criteria in the comparison of options. When doing this, there should be a transparent justification for the weights, possibly complemented by a sensitivity analysis (see Tool #65).

Section 8. The preferred option

Helpful tools: #5 (Legal basis, subsidiarity and proportionality);

Issues to cover:

- Which policy option is preferred and why? Alternatively, explain why no preferred option is presented (e.g. inconclusive comparison of options). Where no overall preferred option is specified, consideration should be given to narrowing the range of possibilities and to providing clear evidence on the open policy choices.
- Where an impact assessment addresses many policy actions or problems, the accumulated proportionality can be difficult to assess without any indication of the preferred options for the component parts.
- An explanation as to how the preferred option conforms to the principles of subsidiarity and proportionality given the size and nature of the identified problem.
- This section should set out the main envisaged impacts of the preferred option, including costs and benefits. This can be more detailed in the summary table of Annex 3.
- This section explores the potential to simplify and improve the efficiency of that legislation (e.g. by reducing regulatory costs) in supporting impact assessments. Where no simplification or efficiency improvement is possible, the reasons should be explained. Similarly, reasons should be provided, if it has not been possible to quantify impacts.
- For proposals with significant costs implications a section presenting their expected contribution to the administrative burden reduction targets and on the application of the 'one in, one out' approach needs to be added¹²⁹.
- The overall impacts of the preferred option should be presented in chapter 8 and be reported in the summary table of annex 3. This table should be broken down by main elements but should always present the overall impacts of the preferred option.

¹²⁹ In accordance with Tool #59 (*Cost estimates and the 'one in, one out' approach*)

Section 9. How would impacts be monitored and evaluated?

Helpful tools: #43 (Monitoring arrangements and indicators); Chapter VI (Evaluations);

Issues to cover:

- Based on the intervention logic, this section should plan for future monitoring and evaluation – consider what should be monitored and evaluated and when. There is a commitment in the Interinstitutional Agreement on Better Law-making to consider systematically monitoring and evaluation provisions in new basic acts of Union law. In particular:
 - Identify core monitoring indicators for the main policy objectives against which progress will be evaluated;
 - Plan the monitoring arrangements to be in place from the outset and schedule¹³⁰ the evaluations in a way whereby the results can be used as input for future impact assessments.
 - The monitoring framework should as far as possible reflect both the size and development of the problem and its drivers, but also track direct and indirect impacts of the policy intervention.
 - For the preferred policy option:
 - Identify operational objectives and the corresponding monitoring indicators;
 - Further specify from when should monitoring start, by whom and how the results should be used, and when the future evaluation should be undertaken.

Annexes that **must** be included in the impact assessment report

Helpful tools: #3 (Role of the Regulatory Scrutiny Board); #51 (Stakeholder consultations); #40 (Drafting the explanatory memorandum); #56 (Typology of costs and benefits); #58 (EU standard cost model); #59 (Cost estimates and the 'one in, one out' approach)

Annex 1. Procedural information concerning the process to prepare the impact assessment report and the related initiative.

- Identify the lead DG; Decide or work programme references;
- Organisation and timing: provide the general chronology of the impact assessment and specify which DGs participated in the interservice coordination group and how many meetings of the group were held;
- RSB scrutiny. Explain how the Board's opinion(s) have led to changes compared to the earlier draft. This should be presented in tabular format – the first column identifying the Board's all recommendations (covering both the box B and C in the RSB opinion) and the second column how the impact assessment report has been modified in response;

¹³⁰ In both terms of having data already available and the right moment in the Strategic Planning and Programming cycle.

- Explain which evidence has been used in the impact assessment together with sources and any issues regarding its robustness (i.e. has the information been quality assured?)
- External expertise. Describe how expert advice has been used in the impact assessment process, including scientific expertise or use of Commission expert groups. Describe any studies or work carried out to feed into the impact assessment by external consultants, with references and internet links where available.

Annex 2. Stakeholder consultation – synopsis report

- This annex summarises all stakeholder consultation activities undertaken in the impact assessment it informs.
 - The aim of this annex is (i) to inform policymakers on the outcome of all consultation activities; and (ii) to inform stakeholders on how their input has been taken into account *and* to explain why certain suggestions could not be taken up.
- The content of the annex should include:
 - A key outline of the consultation strategy, referring to the consultation objectives as defined, identified stakeholders and selected consultation methods and tools. If no public consultation has been performed or if the usual duration of 12 weeks has been shortened an explanation should be given;
 - Indicate if the Commission's minimum standards have all been met, and, if not, why not;
 - Documentation of each formal consultation activity, including, if applicable, an explanation as to how and why the initial consultation strategy was modified;
 - Information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached;
 - Short description of the methodology and tools used to process the data.
 - Description of the results of each consultation activity, including qualitative and interpretative analysis; if different consultation activities have been undertaken in the context of the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions in relation to contributions and main stakeholder categories;
 - The description should include information about any diverging views between or within stakeholder groups;
 - Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses) and their treatment. The information should include the share of contributions and their viewpoint.
 - For ad hoc contributions received outside the formal consultation context, a separate discussion should be added, describing the origin of the contributions received including identification of the type of stakeholder and their represented interests,
 - Where applicable, a paragraph summarising the feedback received on the 'call for evidence'.

- Explanation on how the information gathered in the context of the consultation work as well as feedback received has been taken into account into the further work on the initiative, evaluation or fitness check. Where relevant, this should include explanation on why certain widely supported views were not, or not entirely, considered.
- If national Parliaments have contributed, it is recommended to inform in a separate discussion which national Parliaments contributed (Member State and chamber) and what issues they addressed.

Annex 3. Who is affected by the initiative and how?

This annex should clearly set out the **practical implications of the initiative for a representative enterprise and/or public administration** (or particular groups or individuals if directly regulated). It should always be prepared and be based on the preferred policy option (where this is specified). If no preferred option is indicated, the summary table should be filled in for the most pertinent policy options. Without reproducing the provisions of the legal text, it should indicate which key obligations will have to be fulfilled and over what timescale. It should describe in a proportionate manner the actions that the enterprise or public authority might need to take in order to comply with the obligations under the proposed intervention and indicate wherever possible the likely costs to be incurred in meeting those obligations. For example, the frequency and complexity of financial reporting for SMEs.

Please indicate any significant impacts on the environment – particular in case of negative impacts, which can be relevant in the context of the 'green oath'.

Significant impacts relating to the UN sustainable development goals should also be highlighted here and presented in Table III (see below)¹³¹.

Impacts of the preferred option on fundamental rights must be presented.

All these specific impacts – fundamental rights, SMEs, SDGs and 'green oath' related will have to be reported as well in the explanatory memorandum (see Tool #40).

Quantified estimates of costs and benefits of the initiative (wherever possible) including any reductions (or increases) in regulatory costs should be presented. Preferably, this should be done at the level of 'societal' costs and benefit, i.e. summing up the costs for affected businesses, public administrations, and affected citizens, respectively. So costs should not just be presented for a single representative company or a single regulatory process. Benefits should also be presented by groups affected (i.e. business, citizens, administrations).

In particular, when the initiative is likely to add or remove significant administrative burdens on businesses or citizens, this information should be singled out in Annex 3, based on the calculations conducted in the online administrative burden calculator¹³².

The entries should follow the assessment of impacts in section 6 and be presented in a tabular format (see below). If such quantification is not possible, the reasons why should be given and qualitative estimates should be considered as second best options. Where no preferred option is specified, the information should be presented for each of the retained options.

¹³¹ Except for very technical initiatives where the relation to SDGs would at best be indirect.

¹³² [Administrative Burden Calculator](#)

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	Amount	Comments
Direct benefits		
e.g. Compliance cost reductions		
e.g. Reduced air pollution emissions		
Indirect benefits		

(1) Estimates are gross values relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate in the comments column which stakeholder group is the main recipient of the benefit;(3) For reductions in regulatory costs, please describe in the comments column the details as to how the saving arises (e.g. reductions in adjustment costs, administrative costs, regulatory charges, enforcement costs, etc.);.

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs						
	Direct administrative costs						
	Direct regulatory fees and charges						
	Direct enforcement costs						
	Indirect costs						

(1) Estimates (gross values) to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (adjustment costs, administrative costs, regulatory charges, enforcement costs, indirect costs);.

III. Contribution to the administrative burden reduction targets – Preferred option(s)					
Administrative costs [M€]	New recurrent costs (INs) (nominal values per year)	Removed recurrent costs (OUTs) (nominal values per year)	Net cost (INs – OUTs) (nominal values per year)	New one-off costs (INs) (annualised total net present value over the relevant period)	Removed one-off costs (OUTs) (annualised total net present value over the relevant period)
All businesses					
- in which SMEs					
Public administrations					
Citizens			X		

IV. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	Expected progress towards the Goal	Comments
e.g. SDG no. 4 – quality education	Increase in the participation in early childhood education from 94.8% in 2018 to 98% in 2025	
e.g. SDG no. 7 - affordable and clean energy, 12 - responsible consumption and production, 13 - climate	Expected increased energy efficiency of microwave ovens will save 1.2 TWh of energy over the next 5 years contributing positively to SDG no. 7 (affordable and clean energy) and SDG no. 13 (climate) but due to increased turnover of devices may negatively affect SDG no. 12 (responsible consumption and production).	The trade-off will be mitigated by introducing requirements for recyclability of components and availability of spare parts for 7-years after the end of production.

Annex 4. Analytical methods used in preparing the impact assessment.

When impact assessment analysis relies on modelling or other analytical methods, a dedicated annex should be included that describes these models/methods and how they have been applied in the impact assessment in more detail.

- A general description of the model(s)/method(s) used which addresses:
 - The developer of any model and its nature (public/private/open source);
 - Model/analytical structure and modelling/analytical approach with any key assumptions, limitations and simplifications;
 - Intended field of application;
 - Model/method validation, transparency and quality assurance, including the extent to which the model/method has been discussed with external experts, including peer review (please provide relevant references); in case of simulation models, information

on accessibility of model documentation, accessibility and openness of code, inputs and outputs should also be included;

- Information on intellectual property rights.

NOTE: For models that make a substantial contribution to the assessment of policy options, this information can be generated using the Modelling Inventory and Knowledge Management System of the European Commission (MIDAS); see Tool #61 (Simulation models).

- How the model/method has been applied in the impact assessment, in terms of:
 - Appropriateness of the model(s)/method(s) for the specific impact assessment study presented;
 - A concise description of the baseline(s) scenario used in any modelling exercise in terms of the key assumptions, key sources of macroeconomic and socio-economic data, the policies and measures the baseline contains and any assumptions about these policies and measures (such as the extent to which they are deemed implemented by the Member States, or their estimated impact following implementation).
 - The extent to which assumptions and input data have been discussed with external experts or Member States;
 - Explanation of the likely uncertainty¹³³ in the analytical results and the likely robustness of the results to changes in underlying assumptions or data inputs;
 - Explanation as to how uncertainty has been addressed or minimised in the analytical work with respect to the policy conclusions;
 - The steps taken to assure the quality of the analytical results presented in the impact assessment; and
 - Any further details on the performed analytical work, e.g. details on the modelling exercise including model configuration for the specific problem, input data and sources, other models involved, as well as the institution who ran the model.

Annex 5. Competitiveness check

Based on the analysis in the main report (or relevant annexes), the Competitiveness check should summarize the main impacts of the preferred option on competitiveness. Annex V should include a standardised table with an overall assessment (score) of each of the four competitiveness dimensions, accompanied by a short narrative including key figures (synthetic assessment). Annex V should also inform about the competitiveness position of the sectors that are likely to be most affected by the proposal ('health' of the sectors). The annex should be short (2 to 4 pages).

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

¹³³ See Tool #65 (*Uncertainty and sensitivity analysis*)

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness		
International competitiveness		
Capacity to innovate		
SME competitiveness		

- Based on the analysis of competitiveness in the main report, the table should present the overall assessment of each of the four competitiveness dimensions, i.e. (i) cost and price competitiveness, (ii) international competitiveness, (iii) capacity to innovate and (iv) SME competitiveness.
- Each of the four competitiveness dimensions should be assessed according to the following scale: positive impact of high magnitude (++), positive impact of moderate magnitude (+), neutral impact (0), negative impact of moderate magnitude (-), negative impact of high magnitude (--), or not applicable (n.a.).
- To ensure coherence and avoid repetition, the table should include references to the section of the impact assessment report (or its annexes) where the detailed analysis behind the assessment can be found.

2. SYNTHETIC ASSESSMENT

- The table should be accompanied by a short narrative summarising the expected impacts of the initiative (preferred option) on competitiveness and the main factors that affect competitiveness. If no impacts on competitiveness are signalled, this should be duly justified.
- The synthetic assessment should draw on the analysis provided in the main report (or its annexes). It should provide key figures on costs and benefits and any information that is particularly relevant for the overall assessment (for instance, if impacts are expected to evolve over time).
- The synthetic assessment should follow the structure of the table. This means that the four dimensions of competitiveness should be covered while also explaining if any of them is not relevant for the initiative.

For each of the four dimensions, other tools providing specific guidance can be useful, in particular tools #21 (*Sectoral competitiveness*), #22 (*Research and innovation*), #23 (*The 'SME test'*), #24 (*Competition*), #25 (*Internal Market*), #27 (*External trade and investment*), #56 (*Typology of costs*), and #57 (*Methods to assess costs and benefits*).

3. COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

- If the policy proposal is expected to affect certain sectors in particular (either because of its sectoral nature or in case of horizontal proposals because some sectors would be more directly affected), the impact assessment should assess their current competitive position. The Competitiveness check should present the findings of such analysis.

- The sectoral analysis should use indicators and qualitative information to weigh up the competitive position of EU companies in a sector against non-EU companies in the same sector (international competitiveness) and against companies in other sectors that serve as a benchmark. This will show if the sectors most affected by the initiative are currently under particular 'stress' due to the cumulative impacts of regulation (at EU, national, regional or local level) or other factors (such as technological developments, limited availability of resources or limited demand).
- For horizontal proposals that affect large parts of the economy, a sectoral analysis may not be relevant, which should be properly explained in the Competitiveness check.
- The assessment of the sector's performance should consider a number of indicators covering different dimensions of competitiveness. An analysis of time series can help assessing how the sector's performance has evolved.

Annex 6: 'SME Check' (for SME 'relevant' and 'highly relevant' initiatives)

The annex is compulsory for initiatives that are classified as 'relevant' and 'highly relevant' for SMEs. It consists of a standardised table providing an overview of the results of the 'SME test' (Tool #23). Additional information can be provided if considered useful for the analysis of SME impacts, unless it is already presented in other parts of the impact assessment report and its annexes.

1. OVERVIEW OF IMPACTS ON SMEs

Relevance for SMEs¹³⁴

(1) IDENTIFICATION OF AFFECTED BUSINESSES AND ASSESSMENT OF RELEVANCE
Are SMEs directly affected? In which sectors?
Estimated number of directly affected SMEs
Estimated number of employees in directly affected SMEs
Are SMEs indirectly affected? In which sectors? What is the estimated number of indirectly affected SMEs and employees?

¹³⁴ <https://ec.europa.eu/docsroom/documents/63274>

(2) CONSULTATION OF SME STAKEHOLDERS
How has the input from the SME community been taken into consideration?
Are SMEs' views different from those of large businesses?

(3) ASSESSMENT OF IMPACTS ON SMEs¹³⁵
What are the estimated direct costs for SMEs of the preferred policy option?
Qualitative assessment
Quantitative assessment
What are the estimated direct benefits / cost savings for SMEs of the preferred policy option¹³⁶?
Qualitative assessment
Quantitative assessment
What are the indirect impacts of this initiative on SMEs?

(4) MINIMISING NEGATIVE IMPACTS ON SMEs
Are SMEs disproportionately affected compared to large companies?
If yes, are there any specific subgroups of SMEs more exposed than others?
Have mitigating measures been included in the preferred option?

¹³⁵ The costs and benefits data in this annex are consistent with the data in annex 3. The preferred option includes the mitigating measures listed in section 4.

¹³⁸ The direct benefits for SMEs can also be cost savings.

CONTRIBUTION TO THE 35% BURDEN REDUCTION TARGET FOR SMEs
Are there any administrative cost savings relevant for the 35% burden reduction target for SMEs?

2. ADDITIONAL INFORMATION

This section should include key elements of the analysis underpinning the assessment of impacts on SMEs (direct costs, direct benefits, and indirect impacts), mitigating measures, and additional elements that the lead service considers useful for the analysis, if these elements are not presented in other parts of the impact assessment report and its annexes. If already included in other parts, a reference list of where these elements can be found is sufficient.

Optional Annexes
<i>Helpful tools: #4 –evidence-informed policymaking; #49 – the evaluation report, #50 – ‘back-to-back’ evaluations and impact assessments</i>

Annexes can be used to present additional technical material particularly to support the information presented in the main body of the impact assessment report (e.g. a more detailed description of the concerned market or monitoring indicators). Annexes should not be excessively long, be restricted to information which is **relevant** and pertinent to the overall purpose of the impact assessment and contain references and permanent links to external information sources wherever possible (rather than reproducing the material in the impact assessment report), following the recommendations on the transparency of evidence given in Tool #4 (*Evidence-informed policymaking*).

In situations, where an impact assessment is accompanied by an evaluation (for example in a so-called ‘back-to-back’ situation – an impact assessment and an evaluation based on the same public consultation), the **evaluation should be annexed to the impact assessment** (see Tool #50 (*‘Back-to-back’ evaluations and impact assessments*)).

TOOL #12. HOW TO APPLY PROPORTIONALITY TO IMPACT ASSESSMENTS

The impact assessment (IA) should provide the Commission with evidence-based answers to key IA questions, including the key trade-offs involved. The scope and depth of **the analysis should always be proportionate**¹³⁷ and consistent with the importance and type of initiative and the nature and magnitude of the expected impacts. This relates not only to the IA report, but also to all stages of the IA process. **All impact assessments should be proportionate**, which means that a separate and lighter impact assessment category does not exist. The depth of the analysis always has to be commensurate to the context and impacts of the proposal.

1. THE APPROPRIATE SCOPE AND DEPTH OF ANALYSIS

Setting the appropriate depth and scope of the overall analysis implies deciding:

- The *resources and time allocated to the overall IA process*, including data collection, analysis, stakeholder consultation and conducting external studies;
- The *relative effort required to answer each of the IA key questions* (i.e. should more resources be invested in verifying the existence of a problem or in analysing alternative options?) If the report cannot proportionately analyse, estimate and quantify all relevant problems and impacts, the limitations should be explained in the report.
- The *specific focus of each step of the analysis* (i.e. should the comparison of policy choices focus on broad options or on alternative measures within a given policy approach? At which level of aggregation should impacts be assessed? On which specific issues is it worth drilling down?).

It is the **responsibility of the lead DG, in cooperation with the interservice coordination group (ISCG)**, to determine the level of analysis considering all relevant factors as well as any unsurmountable constraint in the availability of time, resources and data. Setting the level and scope of analysis is likely to be an **iterative process**. It should be done as **early** in the planning process as possible and be discussed with the DG’s management, the support function and the interservice coordination group. Indications should also be provided in the ‘call for evidence’. Proportionality might have to be **adjusted flexibly** as the analysis evolves and as the stakeholder consultation unfolds. The process should include deciding which specific tools in the ‘better regulation’ toolbox are relevant to apply in the specific case. DGs can also discuss proportionality of the IA with the RSB in upstream meetings¹³⁸.

2. FACTORS AFFECTING THE LEVEL OF ANALYSIS

The proportionate level of analysis varies from case to case but is influenced by some general factors and the nature of the particular policy instrument.

¹³⁷ The ‘principle of proportionate analysis’ as used in this tool is related to the depth and scope of analysis that is applied when conducting an impact assessment. It should not be confused with the ‘proportionality principle’ enshrined in Article 5 of the Treaty on European Union. (‘The content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties’).

¹³⁸ See Tool #3 (*Role of the Regulatory Scrutiny Board*)

2.1. General factors

<i>The political importance of the initiative under consideration</i>
Does it relate to a Commission priority? Does it cut across several policy fields? Does it address important threats or challenges in society? Does it contribute to the commitment to implement the SDGs? Is it particularly controversial? Could it raise concerns related to subsidiarity and proportionality? Are there polarised views on the best policy option? Is the initiative particularly important in the interinstitutional context or for certain Member States? etc.
The IA should provide sufficient evidence to respond to the concerns likely to arise during the internal decision-making process or after Commission adoption.
<i>The stage of policy development</i>
If an initiative breaks new ground , it is important to systematically analyse the problem to be addressed, carefully assess the necessity and added value of EU action and consider a wide range of options for action. Resource investment, data collection, analysis and stakeholder consultation efforts should be commensurate. In this case, an evaluation is normally not necessary.
When revising existing legislation , an evaluation should be the starting point. Its results should be used to verify whether the legislation is still necessary and in line with the subsidiarity principle, and which specific provisions should be modified having proven ineffective, excessively costly or outdated.
When preparing the IA for a delegated act or an implementing measure , the mandate given to the Commission will be the starting point. This may already restrict the discretion of the Commission and therefore determine the relevant analysis. The subsidiarity analysis carried out for the basic legislation may also be a starting point. The new IA should focus on the actual outstanding decision at stake, related options and their impacts. Similarly, an IA for transposing an international agreement into EU law should focus on whatever margin of discretion exists for the Commission.
<i>The magnitude and complexity of the problem being addressed</i>
The more complex the problem being addressed and the more pervasive its implications for society, the economy and the environment, the greater the need for an in-depth analysis. On the other hand, the smaller and more narrow the problem, the more the need to do a focused problem analysis and discuss - based on evidence - the opportunity of acting at the EU level.
<i>The significance of the expected impacts</i>
In terms of their absolute and relative size but also their relevance for specific stakeholders (e.g. SMEs, specific sectors, etc.). The analysis should focus on assessing those (intended and unintended) impacts that are expected to be more significant. The greater the likely impact, the more thorough the assessment should be and the greater the efforts to collect data and quantify impacts (keeping in mind that some impacts may not be quantifiable). Similarly for the impacts that are likely to be irreversible.

The risk of negative unexpected consequences

Could getting the policy wrong have significant negative unexpected consequences? The more likely this is, the greater the need to acknowledge and, to the extent possible, assess the risks and likely consequences.

2.2. Nature of the policy instrument

The appropriate level and focus of the analysis is also linked to the type of policy initiative, in particular by looking at how stringent requirements it would impose on Member States, citizens, businesses or any other economic or institutional actor¹³⁹.

In the end it is the content and likely significance of related impacts rather than any formal classification that determines the degree of analysis, **the following table illustrates how impact assessments may differ for different types of initiatives**. It will often be the case that the exact form of the initiative will only become clear in the course of the assessment of the different options. The indicative guidance below, together with the criteria established above, will help you to establish the right level of analysis for your IA.

Box 1. Legislative instruments

IA should focus on:

- Detailed description of problems/challenges, and how they are likely to evolve;
- Detailed subsidiarity analysis to explain the necessity and added value of EU action;
- Short and more detailed description of general and specific objectives respectively;
- Identification of options. If the range of feasible options is limited by obligations to respect fundamental rights, political constraints or previous policy, analyse different implementation options, levels of ambition, priority setting or choices of instruments;
- Thorough and clear assessment of the most significant economic, social and environmental impacts for all options, as far as possible in quantitative terms;
- Identification of operational objectives for the preferred option and the corresponding monitoring indicators;
- Clear, focused and consistent structure of problems, objectives, options and impacts.
- In the case of a revision (which is always classified as a REFIT initiative): clearly spell out the simplification benefits and quantify these as far as possible (including any reductions in regulatory costs);
- Clear identification of who will be affected and how; measurement of regulatory costs and benefits;
- In the case of preparing an initiative that is part of a package of policy proposals, the IA should clearly delineate its scope and discuss possible interactions with other, parallel initiatives forming the package.

IA should avoid:

- Disproportionate presentation of the policy context
- Unfocused and unstructured discussion of concerns

¹³⁹ See Tool #17 (The choice of policy instruments)

Separate guidance has been prepared in respect of expenditure programmes and financial instruments¹⁴⁰ and initiatives in the social policy field pursuant Articles 154-155 TFEU¹⁴¹.

For initiatives, which are constrained by their policy context, it may be necessary to deviate from the standard structure of an impact assessment. Such deviations to the format should be envisaged early and discussed in the inter-service group, with Secretariat-General and in an upstream meeting with the RSB.

This could, for instance, be the case for **delegated/implementing acts**, where an impact assessment has already been produced for the higher-level legislative act (a regulation or a directive). That legislative act and its impact assessment serve as a frame for the delegated/implementing act, which will allow for some 'shortcuts' in the IA of the delegated/implementing act. In this case, the problem definition is given by this framework and the impact assessment for the delegated or implemented act needs to clearly frame its scope, namely what remains to be decided and is subject to the current assessment.

Box 2. Implementing acts and delegated acts

IA should focus on:

- Main outstanding decisions and related options, namely, where the basic act leaves scope for Commission choice, where the Commission may consider deviating from advice given by specialised agencies, or where impacts are likely to be significant (and have not been covered in the basic act IA);
- Identification of specific objectives relating to the outstanding decisions, linked to the objectives/requirements of the basic legislation;
- Thorough and clear assessment of impacts in relation to the options, taking full account of relevance of technical detail and using quantification to the extent possible in particular of regulatory costs and benefits;
- Identification of operational objectives for the preferred option and the corresponding monitoring indicators.

IA should avoid

- Repetition of analysis covered by the IA of the basic act (e.g. in relation to the overall problem, subsidiarity principle, objectives, etc.)
- Redoing relevant analysis undertaken by specialised agencies, to the extent that the lead DG judges this analysis to be credible and carried out in line with Commission IA principles; such analysis should on the contrary feed into an IA as appropriate.

There may be constraints in the policy context, which justifies adapting the structure of impact assessment. This may be the case for example, **where important policy preparation work has already taken place in expert- or stakeholder groups** before the Commission's impact assessment work. This may compare to a situation, where the Commission receives advice from a EU decentralised agency (see Tool #7 (*What is an impact assessments and when it is necessary*)). In such cases, where the initiative deviates from the analysis of the expert group in a significant way, the impact assessment shall assess and justify such deviations.

¹⁴⁰ See Tool #9 (Spending programmes, financial instruments, and budgetary guarantee)

¹⁴¹ See Tool #10 (Treaty-based social partner consultations and initiatives)

Furthermore, the policy context may imply that it is not relevant or possible to develop alternative policy options, for instance where the option relies on intense technical preparatory work or dialogues with stakeholders. In such cases, relevant alternative options may be limited or not available. It will be important to discuss and agree on such adaptations early with SG A2 and/or in upstream meetings with the RSB.

The proportionate level of analysis varies from case to case. A few examples may illustrate how in practice impact assessments have taken account of constraints in the policy context or otherwise.

- [Impact assessment on ecodesign requirements for refrigerating appliances SWD\(2019\)341](#)
- [European Partnerships in Horizon Europe](#)
- [Impact assessment on a delegated act for taxonomy](#)

TOOL #13. HOW TO ANALYSE PROBLEMS

1. INTRODUCTION

The first step of an IA is to verify the existence of a problem or a need¹⁴². The problem analysis is a crucial step in the impact assessment as only a correct diagnosis of the problem and its causes can lead us to the appropriate policy response.

The problem analysis will (i) identify the problem; (ii) estimate the scale of the problem; (iii) analyse its causes/drivers; (iv) identify who is affected and involved; and (v) assess the likelihood that the problem will persist¹⁴³. The findings from evaluations, fitness checks, implementation reports and infringement-related information should form an integral part of the problem definition.

The answers to these questions should give decision makers the necessary information to decide whether a policy response is warranted. Care should be taken when identifying problems as **this aspect is most often criticised by the Regulatory Scrutiny Board**. Moreover, every impact assessment is underpinned by a certain intervention logic, which connects the problem to its drivers, the objectives and policy options. If the problem is ill-defined, it is unlikely that the impact assessment would identify relevant objectives or effective policy options.

Box 1. Tips and commonly encountered issues

- A commonly made mistake is to conclude that a problem exists because a policy framework, regulatory measure, database etc. does not yet exist at EU-level. These “*missing elements*” (often presented as the “lack of” a policy instrument) are not problems as such but may in fact be the possible policy solutions to appropriately defined problems. At the same time, it is a valid approach to identify a problem as a “lack of progress” towards meeting previously defined policy objectives (for example, the sustainable development goals; see Tool #19).
- “*Backward engineering*” refers to situations where the problem analysis is performed with a specific policy option in mind. This not only undermines the quality of the analysis, but it also hurts the credibility of the whole impact assessment process.
- The problems and their causes are often not supported by sufficient tangible evidence. Such evidence is in the first place statistics and other information collected on the basis of verifiable and reliable methods by trustworthy and neutral sources. Be aware that stakeholder views are a special type of evidence, often reflecting interests of certain groups of stakeholders that can complement data by giving an indication of the relative importance of the problems. However, in specific situations stakeholder views can be the only external source of evidence supporting the identification of a problem. (For more information on evidence, see Tool #4)
- A public consultation is not a survey. Its results are not meant to be based on representative samples; percentages of opinions expressed in a public consultation cannot be generalised and should be used carefully (see Tool #54). What matters most in the

¹⁴² It is sometimes useful to think not of a problem but of a “need” which should be addressed as is often the case in the context of preparing financial programmes and financial instruments.

¹⁴³ The problem analysis should also take account of megatrends. See Tool #20 (*Strategic foresight for impact assessments and evaluations*).

results of a public consultation is to gain insight into the views of different stakeholder groups and to collect arguments and problem perceptions that the impact assessment needs to analyse further. It does not matter whether these arguments are 'majority views' or 'minority views'; they both need to be reflected as all relevant arguments should be considered in the impact assessment.

- Where the problems and drivers are numerous, complex or interrelated, it is often a good idea to use visual aids to describe them and to link them through to the objectives and policy options (e.g. problem trees, tables linking drivers – problems – specific objectives – general objective – options).
- Wherever possible, the problem analysis should try to disentangle complex problems into several simpler problems that perhaps can be addressed separately. The analysis should however clearly map the interdependences between the problems, as this will be relevant for assessing the impact of the policy options.
- It is important that the problem analysis identifies the roles, issues and drawbacks for stakeholders so that the initiative can be designed in a way that tackles effectively the behaviour of the various actors that would need to change.
- If the initiative aims to revise an existing piece of legislation and an evaluation was carried out, the findings of the evaluation should be integrated into the problem analysis. In an ideal case, the evaluation will cover most of the issues of the problem analysis. The problem analysis will then only update these findings in function of the recent developments and new political priorities.

2. FIVE KEY ISSUES TO ASSESS

When analysing a problem, the following five issues should be covered:

A. Establish what the problem is and why it is problematic (i.e. its negative consequences).	
Why?	To identify the issues that might have to be addressed by an EU intervention.
How?	Take into account the context section of the impact assessment (see Tool #11 (<i>Format of the impact assessment report</i>)). This is relevant for the problem analysis as political decisions can also define the scope of the initiative.
	However, even if there is a political commitment to tackle a problem, the problem analysis should still establish thorough evidence that there is a problem. Briefly recall the relation between the problem and the challenges addressed in the SDGs.
	Clearly but succinctly, describe the current situation (the status quo). This should make clear and present what the problem is from the findings of relevant evaluations and fitness checks.
	Show what and whose behaviour would need to change and why. Elaborate on why the identified problem must be addressed.
	Consider whether there may be additional (or related) problems linked to the pursuit of general objectives and principles such as international issues

	<p>(international regulatory or market changes, international agreements or competitiveness disadvantages, dependencies) lack of coherence with EU development objectives, etc.</p> <p>Consider the economic, social and environmental consequences where relevant.</p>
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B. Assess the magnitude and EU dimension of the problem	
Why?	To show whether a problem is relevant or not.
How?	You should, make (and show) the effort to collect and use all evidence that can give an idea of the importance and scale of the problem. Mobilising methodological expertise on quantification is often helpful ¹⁴⁴ . The extent to which a problem can be quantified or even monetised varies from case to case.
	Provide contextual information on the scale of the problem by describing e.g. the size of the regulated market/sector, its structure, the number of affected businesses. Present this information in relative terms so that the importance of the problem can be established. For instance, 'there are 230 mn passenger cars on EU roads, of which about 16% that are older than 20 years and subject to emission standards defined by Euro 3 or earlier norm.'
	Explore the relevance of possible cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital. These aspects link clearly to the assessment of subsidiarity ¹⁴⁵ .

C. Establish the causes ('drivers') and assess their relative importance.	
Why?	To help identify policy options which address the problem.
How?	Map the main underlying causes (drivers) of the problem. Classify the main underlying causes by type, to determine whether they lie in people's behaviour or in some other source (see below). While an exhaustive list of all possible causes and sub-causes is not needed, you should approach this part of the analysis with an inquisitive mind, i.e. also consider causes outside of your usual action radius. In dynamically changing areas, megatrends help to identify drivers of the problem and its long-term development (see Tool #20 (<i>Strategic foresight for impact assessments and evaluations</i>)).
	Identify what drives the behaviour that would have to change to address the problem.
	Isolate those drivers that play a major role in determining a problem and differentiate those that could be targeted by the initiative from those falling outside of the scope because they are targeted by other initiatives or are outside the remit of EU competence. Relevant interactions among drivers should also be identified.

¹⁴⁴ See Chapter 8 on methods for details.

¹⁴⁵ See Tool #5 (*Legal basis, subsidiarity and proportionality*)

	Consider using a problem tree to depict graphically the relations between drivers, problems and their consequences. Avoid complexity as far as possible and keep this problem tree simple. This will help later to devise workable policy options.
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D. Identify the relevant stakeholders	
Why?	To help target your consultations and prepare the analysis of problem drivers and distribution of impacts.
How?	Identify those (EU and non-EU) stakeholders who are affected by the problem and those whose behaviour causes it. These could be subsets of the same group (e.g. a specific cohort in the general population).
	Relevant groups will depend on the nature of the problem. You should, however, think beyond the boundaries of the specific policy sector. Whenever relevant, you should distinguish within categories (i.e. micro, small, medium-sized and large enterprises), assess the way in which different types of agents (e.g., vulnerable vs. non-vulnerable individuals) react to the problem matter at hand, look at non-EU actors (i.e. developing countries, non-EU producers, etc.) and differentiate across Member States and/or EU regions. In line with the commitment of leaving no one behind, you should identify whether people in vulnerable situations may be affected (e.g. risk aggravating inequalities) but may not be organised as stakeholders.

E. Assess the likelihood that the problem will persist	
Why?	To verify if the need for a possible policy initiative is going to persist.
How?	The need for a possible policy intervention – or else the persistence of the problem – should be verified against the possible future developments as identified e.g. in a foresight exercise ¹⁴⁶ .
	To do this you should consider recent trends and implementation of existing policy at all relevant levels (Member States, EU, international).
	Policy changes that have already been adopted (that are yet to be implemented) should also be considered. The same applies to EU proposals put forward by the Commission but not yet approved by the Legislator.
	The hypotheses underlying the analysis should be explicit and well justified.
	Whenever future trends in some underlying drivers are particularly uncertain and/or highly significant for the expected development of the problem, this should be highlighted, and some form of sensitivity analysis considered (namely by presenting alternative scenarios).

¹⁴⁶ See Tool #20 (*Strategic foresight for impact assessments and evaluations*)

3. WHAT ARE THE UNDERLYING PROBLEM DRIVERS?

The first step of an impact assessment is to identify and characterise the problem to be addressed. To solve the problem, its underlying causes (or “**drivers**”) should also be identified. This is important for two reasons. First, it is impossible to design alternative policy interventions and study how these would tackle the problem without knowing how the underlying drivers are influenced (this link between problem drivers and policy options is part of the “**intervention logic**”). Second, the nature of the problem (in terms of size, geographic scale, the market actors) plays a key role in the justification of public policy action.

The analysis of the drivers and the links between them will determine whether the impact assessment can address the problem drivers one by one or needs to take a more complex approach because of the strong interdependencies between them (see Tool #16 (*How to identify policy options*)). Indeed, dividing complex problems into smaller and simpler ones can help identify more effective policy solutions.

The simplest situation is a two-level problem analysis: a problem can be explained by several problem drivers. To illustrate, if the problem is the number of deaths from road accidents, the problem drivers can be car design, car driver behaviour, inadequate infrastructure, etc. But there may be more levels when the analysis continues to pin down the factors underlying these problem drivers (for example, bad driving behaviour can be due to several underlying reasons such as mobile phone use, inadequate training, fatigue, etc.)¹⁴⁷. The challenge of the problem analysis is to structure the problems and the problem drivers in a way that is easy to understand and effective to address the various dimensions.

Once the problem drivers are identified, the analysis should focus on the most important ones, those the initiative can realistically address. The resources devoted to the analysis of the problem drivers should remain proportionate to their significance (see Tool #12 (*How to apply proportionality to impact assessments*)).

What types of problem drivers to consider?

A public policy intervention may be justified when:

- (1) **A market fails**, i.e. when market forces fail to deliver an efficient outcome (for example because market prices do not capture all costs to society, or because there is information lacking).
- (2) **Regulations fail**, i.e. when public policy action appeared justified and was implemented but failed to solve the problem satisfactorily or helped create new problems (e.g. two divergent regulations create an obstacle to the proper functioning of the internal market).
- (3) **Equity**/social considerations imply the efficient outcome may not be the most desirable one for the policy in question.

¹⁴⁷ Organisational science offers several methods to identify the underlying causes of a given problem. Of them, two are the most popular as they do not require sophisticated statistical analyses: ‘the root cause analysis’ and ‘the five whys method’. Both are iterative methods to determine the causality chain and discover the root cause of the problem in question.

- (4) **Precaution** prevails, i.e. when public health or environment can be harmed but there is no adequate scientific evidence to permit a complete assessment of the associated risks.
- (5) **Behavioural biases** influence our decision-making process in a non-rational way, e.g. consumers act on incomplete or incorrect information or on the basis of non-traditional economic considerations.

Each of these problem driver categories is described in greater detail below in general non-expert terms. General economics textbooks can provide more robust and technical analysis. For behavioural science, see also Tool #33 (*Consumers*) and Tool #69 (*Emerging methods and policy instruments*)¹⁴⁸.

3.1. Market failures

A. Externalities	
Issue?	Market prices do not reflect how one activity produces costs or benefits for other activities.
Relevance?	Market outcomes are based on prices. If these do not reflect the real costs and benefits to society, then market outcomes will not be optimal from the point of view of society. Decisions are taken without considering how they can affect others. We talk of positive or negative 'externalities' because the manner of one person's actions affecting another's well-being is 'external' to his or her decision-making.
Examples	Consumers do not take into account the cost of the pollution generated in the production of the goods they consume. More pollution than socially optimal is thus generated.
	When deciding to use a car, drivers do not take into account the costs that increased congestion would impose on others.
	When fishing, companies do not take into account the effect this may have on the rate of reproduction of the overall stock of fish in the area. Overfishing ensues.
	Vaccinating oneself reduces the chances of catching a disease for oneself but also for everybody else. If individuals only act based on self-protection, less vaccination than optimal may take place under voluntary programmes.
	In network industries, prices do not reflect the fact that the value of a product (say a social network) increases with each new customer. The same may hold in the case of certain technologies.
Possible policies ¹⁴⁹	Either aim to ensure prices better reflect ("internalise") the externality (for instance through a tax) and then let the market determine a new (improved) outcome or directly correct the market outcome (for instance, through regulation of the particular activity such as emissions controls on industrial

¹⁴⁸ See also https://knowledge4policy.ec.europa.eu/behavioural-insights_en

¹⁴⁹ This is a non-exhaustive list providing examples of policies that have been used to target specific drivers.

	installations).
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B. Public goods	
Issue?	Insufficient supply of public goods ¹⁵⁰ .
Relevance?	Private sector producers will not supply public goods to people because they cannot be sure of making an economic profit. This is because of the nature of public goods. One person's consumption of a public good does not reduce the amount available for consumption by others. And once supplied, a public good is available to be consumed by everybody in society. It is difficult, therefore, and/or undesirable from a societal perspective to charge individuals directly for consuming the good or service in question and consumers can take a "free ride" without having to pay for the good or service.
Examples	National defence is a public good as all people in a nation "consume" the same amount of national defence (provided by the government) and the benefits for each person do not depend on how much a person contributes towards providing it. Other examples are public health and welfare programmes, digital public services, or preparedness for natural disasters.
Possible policies	Public goods are provided collectively by the government, and then financed through taxation of individual households and businesses.

C. Non-existent or weak competition	
Issue?	Non-existent or weak competition between suppliers of goods and services.
Relevance?	Article 120 of the TFEU requires the Member States and the Union to conduct their economic policies in accordance with the principle of an open market economy with free competition that favours an efficient allocation of resources. If firms face no, or only weak competition, then the quantity and quality of goods and services they produce may fall short of the socially efficient level.
Examples	<p>Signs of insufficient competition are unusually high profits, or prices which are much higher than marginal cost, or signs of collusion between firms to fix prices as may be possible when there is only one enterprise (monopoly) or a limited number of firms supplying the market from either within the EU or globally.</p> <p>Where technology is such that it is efficient for a single firm to supply the entire market, we talk of economies of scale and a resulting "natural" monopoly. Network industries – transport, energy, and telecommunications – may exhibit some features of natural monopolies (e.g. retail energy suppliers, residential telephone cables).</p> <p>For public sector digital services, non-existent or weak competition can even question digital sovereignty, making core government services dependent on</p>

¹⁵⁰ A public good is a good that is both non-excludable (i.e. one user cannot exclude others from using it) and non-rivalrous (i.e. the use by one person does not reduce its availability to others). Examples are national defence, a radio signal, street lighting.

	specific technology solutions.
Possible policies	Regulation can prevent abuses of significant market power by ensuring third party access, tendering rules to ensure competitive bidding to prevent abuse or price regulation.

D. Markets are missing or incomplete	
Issue?	A market does not exist or is unable to develop completely.
Relevance?	Goods and services which are needed or wanted by society are not produced.
Examples	Private finance may not be available for all major new infrastructures such as bridges or roads because the revenue generated by imposing user charges would be insufficient. Potential students may be unable to pay for their education by borrowing against their expected future earnings. As a result, the workforce is less skilled than would be optimal.
Possible policies	Government subsidies or financial incentives may create the right conditions for the market to establish itself and develop. Governments or state-operated/guaranteed bodies may provide the necessary services.

E. Split markets – principal-agent problem	
Issue?	A misalignment of incentives exists.
Relevance?	Socially desirable (and economically rational) actions are not undertaken because market actors have different objectives that are not aligned.
Examples	Since tenants usually pay energy bills, landlords do not have the incentive to provide the most energy efficient appliances (such as a refrigerator or lighting systems) or improve a building's energy performance. A ship owner is not responsible for the fuel costs under a charter party and therefore has a reduced incentive to commission the building of a fuel-efficient ship or in making modifications to improve the fuel efficiency.
Possible policies	Financial incentives such as taxes can change/encourage different behaviour and/or the take-up of different products. Regulation can redefine the characteristics of products able to be placed on the market or overcome the landlord-tenant problem by, for example, increasing the prescribed renovation rate of buildings.

F. Imperfect information	
Issue?	Market players may have imperfect information leading to sub-optimal societal outcomes.
Relevance?	Information is needed for markets to operate efficiently. Buyers need to know about the quality of the good or service to assess its value. Sellers, lenders, and

	<p>investors need to know about the reliability of a buyer, borrower, or entrepreneur. Information also needs to be available equally to all market participants. Where it is not, the “asymmetry” can lead to sub-optimal decisions (e.g. a buyer may make the wrong choice because he is not in possession of the same information as the seller – or another buyer – is regarding product/service quality). There are two types of asymmetries: adverse selection (pre-contractual asymmetry) and moral hazard (post-contractual asymmetry).</p>
Examples	<p>As information on the energy consumption of different models of household appliances, or passenger cars, or the nutritional content of foodstuffs is costly to acquire, consumers may not take these factors into account when buying.</p> <p>Since lenders cannot easily/cheaply distinguish between good and bad borrowers, they have difficulties distinguishing between borrowers willing to pay a high interest rate because of the high return on the activities to be financed from those willing to commit to a high rate because they do not expect to pay back the funds (adverse selection). As a result, credit may simply be rationed. This is particularly relevant for the smallest enterprises. Since the costs to collect and process information on creditworthiness are largely fixed, they are more likely to be higher than the expected profits as the loan size decreases.</p> <p>Once the loan is granted or insurance contract (car, home, health) is signed, the customer may engage in activities that may lead to non-repayment of the loan or ignore basic precautions against risks because his actions (risky driving, having low-quality locks at home, smoking tobacco) are covered by the insurance contract (moral hazard).</p>
Possible policies	<p>Voluntary or mandatory labelling schemes with relevant information can inform consumer choice and enhance demand for better performing products. Markets can be regulated to ensure that all participants receive the same information at the same time.</p>

3.2. Regulatory failures

Intervention by public authorities to resolve market failures can fail to achieve a socially efficient allocation of resources. This can be the result of several factors.

First, public authorities may not arrive at the best solution for society in the first place. For example, public authorities may be influenced unduly by the (partial) information provided by one or more specific interest groups when designing new regulation (so-called “regulatory capture”).

Secondly, public intervention may be **poorly designed**, thus failing to achieve its objectives, achieving them with unnecessary high costs or wrongly targeted. Even when achieving its objectives, public intervention may still have **unintended negative consequences**, such as favouring incumbents, creating barriers to entry and innovation or leading to excessive cumulative regulatory costs for an industry (no matter how well justified each individual regulatory initiative affecting the industry may be).

Thirdly, public intervention may be **poorly implemented and/or enforced**.

Finally, public intervention may simply become **out of date** as the world evolves and problems and drivers change. This 'pacing problem' is especially true for innovative technologies, including those in the digital realm, and calls for new regulatory approaches.

As many Commission initiatives concern areas where EU legislation already exists, regulatory failures should always be considered as one possible source of the problem. To do this, you should first and foremost rely on an **evaluation** of the existing policy framework that should be carried out prior to the impact assessment according to the Commission's 'evaluate first' principle.

3.3. Equity

Achievement of equity/social objectives may also provide important reasons for policy intervention because even a perfectly competitive and efficient economy can produce outcomes that are unacceptable in terms of equity. Moreover, a growing body of research suggests that inequality can hurt economic growth¹⁵¹.

The definition of socially desirable outcomes depends on values and beliefs. While there is no single definition of the concept of equity, the three most common concepts of equity relate to **equity of endowments, processes, and outcomes**¹⁵².

Initial endowments of individuals differ and that can give some individuals an (unfair) (dis)advantage to compete in the market economy. E.g. being born into a well situated and educated family can better equip children with skills and abilities to function in the market economy. Public intervention can reduce those differences and improve the **equity of endowments** (e.g. improving the housing conditions of poor households can improve physical and mental health of children and consequently improve their skills levels.)

Consistent with commitments in the 2030 Agenda on Sustainable Development, **equity of process** suggests that people in similar circumstances should be treated equally, for example having equal access to services or employment. When this is not the case, there is then a need for public intervention, for example to tackle discrimination based on ethnic or racial origin, gender, sexual orientation, age, or disability.

The interventions to improve the **equity of outcomes** aim at correcting inequities that are based purely on individual circumstances, for example by supplementing market income with tax/benefits schemes. The interventions to improve the equity of endowments and of processes can greatly contribute to that.

Equity considerations should consider also **intergenerational equity** – needs and outcomes for future generations (e.g. those activities of the present generation do not worsen the situation of future generations).

Protection and fulfilment of fundamental rights afforded to citizens of the Union may also provide grounds for intervention.

¹⁵¹ Cingano, F. (2014), "[Trends in Income Inequality and its Impact on Economic Growth](#)", OECD Social, Employment and Migration Working Papers, No. 163, OECD Publishing, Paris.

¹⁵² Microeconomics for Public Decisions by Anne C. Steinemann, 2011, Askmar publishing

3.4. Precaution

A specific category of policy intervention is required in cases when public health or the environment can be harmed, and immediate action is needed based on the precautionary principle.

The principle aims at ensuring a higher level of environmental (or health) protection through preventative decision-taking in the case of risk. The precautionary principle may be invoked when there is the potential for serious harm, but scientific uncertainty persists about the form or magnitude of that harm. The principle has been integrated in EU legislation other than environmental protection (for example, general product safety, the use of additives for use in animal nutrition, the incineration of waste, the regulation of genetically modified organisms). The EU's regulatory framework for chemicals (REACH) is underpinned by the precautionary principle, while the EU food law sets out the precautionary principle as a general principle of (Union and national) food law. When there are indications that a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation and this evaluation does not allow the risk to be determined with sufficient certainty, the precautionary principle may be invoked, and the harmful product may be immediately withdrawn from a market. These risk management measures necessary to ensure the high level of health protection are provisional, pending further scientific information for a more comprehensive risk assessment.

As the application of the precautionary principle falls within the general framework of risk management, the responsible authorities (the Commission or one of its decentralised agencies) may decide, whether to act or not, based on the level of risk. If the risk is high, several categories of measures may be adopted. This may involve proportionate legal acts, financing of research programmes, public information measures, etc. and should normally be supported by an impact assessment or a staff working document.

3.5. Behavioural biases

Mainstream economic models assume that individuals always act in their best interest. Under this assumption, market forces will deliver an efficient outcome if there are no market failures. However, there is a growing body of evidence showing that this assumption does not correctly reflect behaviour of individuals since their **choices can vary systematically according to specific aspects of the decisions they face and/or the context in which their decisions are made**. In such cases, market forces cannot achieve an efficient outcome and a public intervention may be justified which better reflects individuals' actual behaviour.

Box 2. Illustrative examples

- The Consumer Rights Directive prohibits the use of pre-ticked boxes for online sales because evidence has shown that consumers are drawn towards default options regardless of their value.
- The Ecodesign framework removes the worst choices from the market (in terms of energy consumption / energy efficiency) helping the consumers process the information, and the energy labelling scheme communicates the key information in ways that consumers can easily understand.

Four key issues identified by behavioural analyses are particularly relevant for both the justification of a policy and its design. First, choices are influenced by the simplicity of information and the range of available options. Second, people are drawn towards more convenient options, especially default options. Third, the prominence of options or attributes can affect how they are weighed in decisions. Fourth, research has also identified clear decision-making errors such as the failure to take account of non-linear aspects such as the costs due to compound interest. Regulations can be designed in ways that recognise these behavioural traits and de-bias decision makers and promote better decisions (and using less intense measures such as “nudging” behaviour in the desired direction).

The non-exhaustive list presented below provides more examples of biases that have been tackled by *behaviourally-trialled or informed* policy initiatives¹⁵³.

A. Default bias	
Issue?	People are inclined to let the <i>default</i> rule dictate their decisions.
Relevance?	Neoclassical economic models assume that consumer preferences are revealed (i.e. that consumers know what they want). The evidence shows, however, that consumer preferences can be influenced by the way options are presented to them.
Examples	In online contracts, ancillary services (e.g. travel insurance when we want to buy an airline ticket, or a seat reservation when we want to buy a train ticket) used to be proposed with pre-checked boxes. The available evidence proved that consumers were much more likely to buy them than if they had been proposed with un-checked boxes.
	A cross-country investigation shows that the rate of organ donors is significantly higher (above 90%) in countries where organ donation is an <i>opt-out</i> choice, and much lower in countries where this is an <i>opt-in</i> choice.
Possible policies	The EU Consumer Rights Directive, which came into force in June 2014, clearly limits the use of pre-checked boxes (Art. 22). This ensures a more neutral <i>choice architecture</i> and makes sure that money stays by default in consumers' pockets.
B. Information overload	
Issue?	People have a limited ability to deal with voluminous and complex information.
Relevance?	Traditional economics assumes that information provision maximises consumers' ability to act in their own self-interest and make better choices as it reduces asymmetric information or uncertainty. Notwithstanding, evidence shows that information provision is often insufficient, namely when consumers are unable to process the information due to its sheer volume and/or level of complexity. Relatedly, too much information might also lead to procrastination or

¹⁵³ See *Behavioural Insights Applied to Policy: European Report 2016*, Sousa Lourenco J; Ciriolo E; Rafael Rodrigues Vieira De Almeida S; Dessart F. (2016), for a definition of such initiatives.

	inaction, as individuals might avoid making a decision due to fear that regret outweighs the gains from choosing.
Examples	In financial services, regulators have used behavioural insights to improve financial consumer protection by helping consumers to better compare and select products for their investment needs. Namely, available evidence from retail investment services showed that simplification and standardisation of product information reduces the negative impact of framing effects in investment decisions and helps consumers make more optimal choices.
Possible policies	The Regulation on Packaged Retail and Insurance-based Investment Products (PRIIPs) requires short, standardised documents with key information on investment products in a clear and understandable manner are made available to investors.
C. Social norms	
Issue?	People influence (and are influenced by) what others do.
Relevance?	Price-based approaches are commonly used to affect consumer behaviour. However, evidence shows that social factors, such as social norms, reciprocity, and fairness, can exert a powerful influence on behaviour. Social norms are rules of behaviour that affect the way we interact with others by signalling the appropriate behaviour. In other words, normative feedback (e.g. comparing the individual's behaviour to that of others) can significantly influence individual behaviour.
Examples	Available evidence shows that normative feedback on how one's electricity consumption compares to that of neighbours can encourage households to consume less electricity.
Possible policies	The US energy company OPower has introduced social norms to promote reductions in household energy consumption.

TOOL #14. RISK ASSESSMENT AND MANAGEMENT

1. INTRODUCTION

Assessing risks¹⁵⁴ is complex and often requires in-depth expertise and specialist knowledge spanning various policy fields. The purpose of this tool is, therefore, to introduce the key concepts rather than to explain how to assess risks and prepare risk management measures. The other purpose of the tool is to provide guidance on how risk assessment may contribute to the Commission’s impact assessment process.

Risk assessments (with slightly varying definitions) are carried out in a wide range of policy areas across the Commission and the EU decentralised agencies, including in relation to natural disasters, climate change, security, human/animal/plant health, environment, functioning of IT systems, financial markets, energy supply, air traffic.

Such risk assessments can support different types of policy decisions or actions taken by the Commission¹⁵⁵ including implementing risk management approaches determined in the basic legislation¹⁵⁶. Public health related risks are among the more well-known risk assessments as these relate to exposure to chemical substances (pharmaceuticals, chemicals, some foodstuffs, air pollutants, food contact materials, toys, cosmetics, food contaminants, etc.) and biological hazards (e.g. salmonella, campylobacter etc.).

When it comes to climate change¹⁵⁷, the list of legislation requiring risk assessment and risk management approaches include financial supervision, financial products, MFF infrastructure spending, Invest EU, Floods Directive, Union Civil Protection Mechanism. In cases where 1) the context allows sufficient room for manoeuvre for the Commission and different viable options are available to manage the identified risk(s), 2) those options are expected to have significant impacts that impact stakeholders to different extent and 3) there is absence of urgency, an impact assessment (IA) may be required¹⁵⁸. An IA may also be required for those decisions that invoke the precautionary principle, where these three conditions are met¹⁵⁹. In such cases, the results of the risk assessment feed into the IA process. In cases where no impact assessment is deemed necessary, but the precautionary principle is invoked, the

¹⁵⁴ Note that risk in the context of risk assessment explained here deals with a result of natural or manmade hazards and NOT uncertainty in a wider sense, as described in the Tool #61 (*Simulation models*).

¹⁵⁵ Note that the European Union Aviation Safety Agency, in short EASA, can also take risk management decisions.

¹⁵⁶ In areas such as food/feed safety, animal health, plant health, animal welfare, medicinal products, medical devices, cosmetics, biocides, chemicals.

¹⁵⁷ Climate change is a critical component of the European Green Deal and receives here particular attention.

¹⁵⁸ Emergency measures (to prevent contagion/spread of a disease etc.) would generally be exempt.

¹⁵⁹ The precautionary principle is detailed in Article 191 of the Treaty on the Functioning of the European Union. On 2 February 2000, the European Commission issued a Communication on the precautionary principle (COM(2000) 1 final) in which it adopted a procedure for the application of this concept. The principle aims at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk. The precautionary principle may be invoked when there is the potential for serious harm but scientific uncertainty persists about the form or magnitude of that harm. Following the Court ruling in Case T-74/00 *Artegodan* and through its application in case law after adoption of the before-mentioned Commission Communication, the principle has been integrated in EU legislation other than environmental protection (for example, general product safety, the use of additives for use in animal nutrition, the incineration of waste, the regulation of genetically modified organisms). The EU’s regulatory framework for chemicals (Regulation (EC) No 1907/2006 – known as REACH) is underpinned by the precautionary principle, while the EU’s general regulation on food law (Regulation (EC) No 178/2002) sets out the precautionary principle as a general principle of (Union and national) food law.

explanatory memorandum or an analytical document in the form of a SWD might set out the elements necessary for the exercise of the principle. In principle, all cases where the precautionary principle is invoked are subject to undertaking a risk assessment.

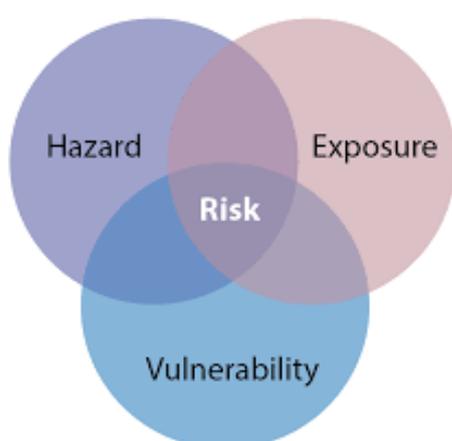
2. WHAT IS RISK ASSESSMENT?

To define risk assessment, the different elements need to be defined first, which are 'hazard', 'risk', 'exposure' and 'vulnerability'.

A *hazard* 'is something that can cause harm'. A hazard is any source of potential damage, harm or adverse effects on someone or something (e.g. the environment)¹⁶⁰. Hazard is a function of the inherent properties of the agent/event in question.

Box 1. Hazard and risk, exposure, and vulnerability

- While hazard represents a danger, risk expresses the combination of the level of hazard and the likelihood of its occurrence.



Risk = Hazard (expressed in terms of its negative impact) x Likelihood of its occurrence.

- Since the two variables are not independent of each other and while the impacts of the hazard depend on preparedness or preventive behaviour (as is the case of natural hazards), the risk should be expressed as a functional relationship rather than a simple multiplication of both variables.
- *Exposure* refers to the inventory of elements in an area in which hazardous events may occur. Exposure is a necessary, but not sufficient, determinant of risk. It is possible to be exposed but not vulnerable (for example by living in a floodplain but having sufficient means to modify building structure and behaviour to mitigate potential loss)¹⁶¹.
- *Vulnerability* is defined as the propensity or predisposition to be adversely affected. Vulnerability encompasses a variety of concepts and elements including sensitivity or susceptibility to harm and lack of capacity to cope and adapt.

Risk = Hazard (expressed in terms of its negative impact) x exposure x vulnerability.

A *risk* 'is the chance, whether high or low, that a hazard will actually cause somebody or something harm'. A risk is the probability that a person or something will be harmed or experience an adverse effect if exposed to a hazard¹⁶². Risk is a function of both the hazard and of the potential likelihood and extent of *being exposed* to the hazard. Although a risk is

¹⁶⁰ For example, in the area of food chain 'hazard' is defined "as a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect". See Article 3 point 14 of Regulation (EC) No 178/2002 on general food law.

¹⁶¹ https://www.ipcc.ch/site/assets/uploads/2018/03/SREX-Chap2_FINAL-1.pdf

¹⁶² For example, in the area of food chain 'risk' is defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. See Article 3 point 9 of Regulation (EC) No 178/2002 on general food law.

related to the hazard, it may also be related to the alternative measure(s) intended to reduce the initial risk.

Risk can be identified based on a wide range of evidence, including scientific studies, past experience, monitoring data, expert opinions, etc. For identifying and characterising chemical risks experimental data or models are being applied. When it comes to climate change, scientific models and climate scenarios customised to the sectoral and geographical context and relevant timeframe at stake allow for identifying risks.

Risk assessment is the process or method to identify hazard that has the potential to cause harm and to analyse risk associated with that hazard (assessing what is the likelihood of exposure to hazard and what are the likely impacts of exposure if hazard happens)¹⁶³. Risk assessment feeds into risk management, which is about designing and implementing measures that help reduce and – if possible – eliminate the likelihood of being exposed as well as help reduce and – if possible – eliminate the consequences of exposure. A *risk-based approach* in legislation aims at controlling or limiting the exposure to a hazard; it is managing the risk while accepting the existence of a hazard. A *hazard-based approach* in legislation aims at eliminating the hazard without an in-depth assessment of the risk (which is, however, assumed to exist based on general considerations), i.e. the likelihood of being exposed to that harm.

3. HOW TO GO ABOUT IDENTIFYING HAZARD AND ASSESSING RISK?

In conjunction with the in-house expertise, risk assessment requires mobilisation of **broad scientific expertise** – the more complex the situation, the broader the expertise needed (i.e. natural, physical, social, economic, etc.). Risk assessment may be carried out by **permanent bodies or services at EU level, such as:**

- EU decentralised agencies (such as EEA, EFSA, ECHA, EMA, ECDC, EASA¹⁶⁴);
- scientific committees set up by the Commission¹⁶⁵ (such as SCHEER);
- technical expert groups established by the Commission (such as the Platform on Sustainable Finance).

These bodies have been established, *inter alia*, for risk assessment purposes at EU level, and should be approached systematically when policy areas covered by their mandate and expertise are involved. Their participation in the risk assessment procedures is set by law and they may deliver scientific opinions in the context of authorisations or restriction settings, as well as scientific advice on those policy areas. They may also be approached in case of a need to complement and/or validate risk assessments or scientific input from **other bodies or sources such as:**

- permanent bodies at national or international level (such as WHO);

¹⁶³ For example, in the area of food chain, risk assessment is defined as the “scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation”. See Article 3 point 11 of Regulation (EC) No 178/2002 on general food law.

¹⁶⁴ European Environment Agency, European Food Safety Authority, European Chemicals Agency, European Medicines Agency, European Centre for Disease Prevention and Control, European Aviation Safety Agency.

¹⁶⁵ Scientific Committees are permanent expert groups governed by specific rules of procedure. https://ec.europa.eu/health/scientific_committees_en

- expert groups consisting of individuals appointed in their personal capacity and set up on an ad hoc basis;
- external consultants; or
- conferences, stakeholders' workshops, focus groups etc.

The Joint Research Centre (JRC) can support risk assessment by providing tools and models used in the assessment process as well as validating risk assessment methodologies. The JRC can also provide expert judgements where risk assessment bodies provide conflicting opinions or in cases where there is large scientific uncertainty.

Where the risk assessment feeds into the impact assessment process, the interservice coordination group should be consulted on the sources and the scope of the risk assessment and on the need to complement or validate the results. In cases where risk assessment is not carried out by one of the permanent EU bodies (as listed above), particular attention should be paid to ensuring wide coverage of scientific expertise and to the integrity of experts, as well as to the possible need for a combination of several sources of expertise.

Although the definition and stages of risk assessment may differ across policy areas and practitioners, its purpose remains the same – to assess the risks. The following **three steps** can be identified:

- (1) Identify and characterise the hazard and – identify and characterise the inherent properties of the agent or phenomenon in terms of potential negative effects (on population, environment etc.), establish the causal relationship between the hazard and its effect, describe the negative effect and determine its severity (e.g. occurrence of mutations, changes in the cell structure, etc.) and dose-effect relationships. Special attention should be paid to induced or secondary hazards (e.g. contaminated river flood).
- (2) Assess the likelihood of its occurrence – estimate the likelihood of the hazard (for the population, environment etc.) to occur^{166, 167}.
- (3) Characterise the risk – based on the results from the previous steps, determine quantitatively (e.g. death, injury, production loss, increase in poverty and inequality) and if not possible, qualitatively, the level of risk under given assumptions and uncertainties. Although the level of risk can be difficult to express in monetary terms (e.g. in the case of non-market impacts on environment and health), methods exist that can be used to attempt to monetise them¹⁶⁸.

Uncertainty is inherent in every stage of risk assessment. Irrespective of the different definitions and classifications of uncertainty¹⁶⁹, the key is to understand how important such uncertainty is and, on that basis, understand the reliability of the risk assessment. To do so,

¹⁶⁶ To be understood as the likelihood of the damage materialising – in chemical risk assessment for example, despite exposing the population to a chemical, the body may have the potential to eliminate it without causing damage.

¹⁶⁷ This component (at least in public health/food safety) is usually integrated in the risk characterisation step.

¹⁶⁸ See Tool #57 (*Methods to assess costs and benefits*) (including non-market impacts) and Tool #32 (*Health impacts*).

¹⁶⁹ Uncertainty is not to be confused with variability and should be considered as a separate element of the risk assessment process compared to uncertainty. Variability stems from the inherent diversity of the results shown by the data in a given context. While uncertainty can be reduced with further data/knowledge, variability cannot be reduced with further data/knowledge, but can only be further characterised.

uncertainty needs to be carefully evaluated and transparently reported on, even when it cannot be modelled or expressed in quantitative terms (e.g. because it is difficult to foresee the unknown unknowns, especially for new products or technologies)¹⁷⁰.

Considering risks associated with natural hazards

Through increasingly ambitious mitigation action globally, the Commission can act decisively to prevent the most dangerous adverse impacts of climate change. Furthermore, while hazards will increase, it does not automatically mean that they will also translate into disasters. It falls on the Commission to look for ways to manage risk and act 'climate-smart'.

4. HOW SIGNIFICANT IS THE RISK?

The significance of the risk is determined by the risk (or tolerability) criteria. These criteria may range from scientifically identified tolerable thresholds and controllability to risk-benefit trade-offs (including, inter alia, availability of substitutes), risk perceptions (for example in case of emerging risks) or societal values (for example related to equity or personal freedom considerations). The risk criteria may be defined in the existing legal basis (as it is the case for risk management action in food safety, cosmetics, pharmaceuticals) or, more generally, by an existing risk management approach and previous experience.

By comparing these risk criteria with the assessed risk, the risk manager can evaluate whether the risk is tolerable or not.

If a risk is intolerable, risk management measures should be taken to eliminate the hazard and/or the exposure or reduce the exposure to a tolerable level. It should be noted that the elimination of one risk, could result in its replacement by another, potentially with a more significant but uncertain risk (i.e. for example banning a particular hazardous chemical could result in substituting with a substance with unknown effects on human health) or could result in increasing the prevalence of other risks, resulting overall in a worse health situation (restricting the use of certain fungicides might increase the risk for mycotoxins, banning a sprout suppressing agent might result in an increase of acrylamide). Where it is not possible to eliminate an intolerable risk (e.g. in the case of natural hazards), it should at least be reduced by mitigation and preparedness measures.

A **tolerable risk** may be worth reducing through actions by private and/or public actors. Even where there is no or negligible risk, there could be reasons for public or private intervention (e.g. on a voluntary basis). Public perception of a risk may, for example, require an effective risk communication/awareness strategy.

The tolerability of risk needs to be evaluated even when it is not possible to (a) carry out a comprehensive risk assessment (because of the lack of knowledge), or to (b) determine the risk with sufficient certainty (as the sensitivity analysis may conclude¹⁷¹). Even in such cases, the guiding principles for assessing the tolerability of risk remain the risk criteria – which may already reflect the desired strength of evidence or level of protection¹⁷². Proportionate

¹⁷⁰ Guidance on Communication of Uncertainty in Scientific Assessments; <https://www.efsa.europa.eu/en/efsajournal/pub/5520>

¹⁷¹ See Tool #61 (*Simulation models*)

¹⁷² For example, tolerable but highly uncertain risks often become intolerable when the environment, human, animal or plant health is at stake. See e.g. [Article 191 TFEU](#) for the environmental policy.

risk management measures may then be based on the precautionary principle together with collection of additional evidence and review¹⁷³.

When it comes to assessing climate and natural disaster risks the screening of new Commission policy initiatives will be conducted following four Policy Coherence Principles which consist in: (i) considering risk before creating new exposure, (ii) reducing existing risk by building up resilience; (iii) managing residual financial risk and (iv) assigning risk ownership.

- **Considering risk before creating new exposure:** This principle follows from the fact that people, housing, infrastructure, and assets are most susceptible to be impacted when they have been physically placed in hazardous areas, and when the standard to which they have been built does not meet contemporary or anticipated resilient building standards and codes.
- **Reduce existing risk:** The Commission should also aim to reduce EU stock of climate vulnerability/exposure legacy from past investments decisions. The adaptation investment gap is vast and measuring it is still a matter for research, but it is commonly agreed that the ‘stock’ of existing assets at risk on the landscape is large. Risk-ownership for these stocks is diversified. Some are private assets, others are publicly held assets or infrastructure. EU action should promote increased adaptation action by all.
- **Manage residual financial risk:** The Commission should promote economically viable solutions for the transfer and/or mutualisation of financial risk related to climate change when it is not possible or feasible to eliminate or reduce it (e.g. private insurance, privately and/or publicly funded pools, other tools with potential public support).

These solutions can improve decision-making by helping speedy economic recovery after disasters, mutualise risks while promoting resilience, manage distributional aspects of climate-related impacts, and give risk-owners the time and financial space they need to adapt by remaining in the tolerable risk space through financial buffering as part of contingency approaches.

5. RISK MANAGEMENT

The purpose of risk assessment is to enable decision making either to eliminate risks or to mitigate risks. **Risk management measures** may include bans or limitations, as well as market-based instruments such as insurance or incentive schemes – which should be considered where possible as they are less restrictive and lead to an internalisation of negative effects (and thus an efficient outcome)¹⁷⁴.

In principle, risks can be transferred to a third party (e.g. by insurance) and/or mitigated by:

- eliminating the risk (e.g. by restricting the manufacture, the use or the placing on the market of a hazardous substance);

¹⁷³ The Communication on the application of the precautionary principles sets out the requirements for the application of the principle including assessments of costs and benefits, risk assessment etc. See [COM\(2000\) 1 final](#).

¹⁷⁴ See Tool #17 (*The choice of policy instruments*)

- reducing the hazard (e.g. through performance standards for products and processes, emissions, etc.);
- limiting the likelihood (e.g. through preventive, protective and control-related measures, information and education etc.);
- a combination of the two previous measures (in cases where both hazard and likelihood can be influenced and in multi-hazard situations more generally);
- reducing vulnerability;
- transferring the residual risk (financial risk transfer such as insurance, financial contingency planning);
- regularly reassessing climate risk and improving building standards for new constructions to heighten resilience;
- enhancing adaptive capacity, strengthening resilience, and reducing vulnerability (through design and early warning systems, emergency procedures, contingency arrangements, training, etc.).

In theory, the optimal level of risk reduction is found where the marginal costs of risk reduction equal the marginal reduction in risk. Where marginal values are unknown or too difficult to assess, total costs and total reduction of risk (i.e. benefit) can be used to determine whether such measures generate net benefit and are therefore socially desirable. It is important to consider the impact on innovative activities – and the possible foregone benefits in addressing emerging risks in the future.

When assessing the risk management options, it should be recalled that:

- the assessment of risk (reduction) resulting from alternative risk management measures may necessitate additional input from the risk assessment bodies unless already provided as part of the original risk assessment;
- achieving zero risk is unlikely or could come at prohibitive costs/effort;
- there might be benefits that could be foregone by banning a substance or a product – for example where a pharmaceutical product has serious side effects but represents the only way to cure a disease;
- there may be impacts and/or likelihoods that are not possible or appropriate to quantify but that should be considered nevertheless (e.g. where robust monetary values are not readily available as in the area of health, security, freedom and biodiversity or where the high level of uncertainty renders any quantification meaningless);
- when risks translate into possible harm to people or the environment and scientific uncertainty persists, risk management must consider the precautionary principle¹⁷⁵ as cost considerations are either not relevant (if there is only one option available to achieve the desired level of protection) or only relevant for the comparison of different options equally fit to achieve the same objective. If risks cannot be brought down to zero a very strict risk management plan needs to be deployed and should

¹⁷⁵ The precautionary principle may be invoked when there is the potential for serious harm but scientific uncertainty about the form or magnitude of that harm. In those cases, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

involve a political decision / public consultation and full communication and reinforced transparency rules.

One of the key preconditions for effective risk reduction measures is the feasibility of their implementation, monitoring, and enforcement – which need to be carefully assessed and which require making adequate arrangements.

6. WHEN AND HOW CAN RISK ASSESSMENT CONTRIBUTES TO THE IA PROCESS?

A risk assessment might be required by legislation; this is the case for instance in legislation applicable to the agri-food chain or pharmaceuticals which also tasks the Commission with risk management duties. In such cases, the applicable legislation frames the decision-making process, including the use of the risk assessment, and thus the Commission's discretionary margin in proposing the risk management measure. In these cases, when preparing implementing or delegated measures, an impact assessment is not required unless an assessment of different options with different impacts is called for (see Tool #32 (*Health impacts*)).

In other cases, a risk assessment might be needed because a new planned initiative takes a risk-based approach, or if it is based on the use of the precautionary principle, or if its intended objective is to eliminate or reduce a hazard-related risk when the subject matter is affected by climate change risk. When an impact assessment is required, this risk assessment outcome will feed into the preparation of it.

The green oath

With the introduction of the green oath to 'do no significant harm' (COM(2019) 640 final) as mainstreaming principle underpinning all new legislative proposals and delegated acts, each initiative should strive to explain how it upholds this principle. However, the application of 'do no significant harm' is different from risk assessment. The green oath applies by default and requires assessing how to best balance risk versus benefits. Each impact assessment will assess the policy options against this criterion when assessing the environmental impacts of the policy options.

When evaluating existing legislation, the evaluation should assess the extent to which the intervention is coherent with the climate-neutrality principle / greenhouse gas reduction under the 'coherence' criterion (see Tool #36 (*Environmental impacts*)).

How to plan and conduct the risk assessment¹⁷⁶

The table below gives an indication how risk assessment may contribute to the Commission's impact assessment process, where in the process, and by whom.

¹⁷⁶ In areas where the risk assessment process is not specifically described in legislation.

Risk assessment		IA process	Main actor(s)
1.	Identify potentially significant risk(s)	Identify problem	Lead DG together with ISCG (with input from risk assessors where relevant)
	Identify how and by whom the risk assessment will be carried out		
2.	Assess risk(s) and uncertainty	Assess problem and baseline	Risk assessors
	Complement and/or validate the risk assessment if needed		
3.	Identify risk criteria and evaluate risk	Define objectives	Lead DG together with ISCG (with input from risk assessors where needed)
4.	Develop risk management options to eliminate, transfer or reduce risk	Develop options	
5.	Use risk assessment to assess impacts, use sensitivity auditing to assess uncertainty	Assess options	
6.	Plan for communicating risk, reducing uncertainty, adapting the risk management approach if necessary, monitoring new/existing risks etc.	Outline monitoring and evaluation arrangements	

7. INFORMATION SOURCES AND BACKGROUND MATERIAL

- Commission communication on the precautionary principle (COM(2000) 1 final):
- Commission Staff Working Paper: Risk Assessment and Mapping Guidelines for Disaster Management, SEC(2010)1626 final
- Taxonomy Regulation (EU Regulation 2020/852)
- Climate-ADAPT
- EU Science Hub
- ECHA guidance on Chemical Safety Assessment

TOOL #15. HOW TO SET OBJECTIVES

1. INTRODUCTION

Objectives link the problems and their drivers to the policy options. Setting objectives helps to:

- set the level of policy ambition;
- fix the yardsticks for comparing policy options;
- determine the criteria for monitoring and evaluating the achievements of implemented policy¹⁷⁷.

2. HOW TO SET OBJECTIVES

Objectives can be set at different levels and at different times.

Box 1. General, specific, and operational objectives	
<i>After the analysis of the problem</i>	
General	These are the Treaty-based objectives that the policy aims to contribute to.
Specific	These set out concretely what the policy intervention is meant to achieve. They should be broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution i.e. the specific objectives are part of the intervention logic: problem-drivers-specific objectives-policy options.
<i>After identifying the preferred option (and when completing the monitoring and evaluation section)</i>	
Operational	These are defined in terms of the deliverables of specific policy actions. As such, they are typically option-specific . These should not, therefore, be reported in the same place in the IA report ¹⁷⁸ as the general and specific objectives, but reported in the section referring to monitoring and evaluation.

Not all impact assessments require objectives at the three levels. A legislative initiative generally requires setting general, specific, and operational objectives. A communication setting out broad policy objectives only requires general and specific objectives. For implementing legislation, there is no need to define general objectives that will have been discussed in the context of the basic act.

When setting objectives, notably specific and operational objectives, it can be useful to reflect on the S.M.A.R.T criteria. Objectives should be Specific, Measurable, Achievable, Relevant and Time-bound (i.e. 'S.M.A.R.T').

¹⁷⁷ See Tool #43 (*Monitoring arrangements and indicators*); and Tool #44 (*Legal provisions on monitoring and evaluation*).

¹⁷⁸ See Tool #11 (*Format of the impact assessment report*)

Box 2. What are S.M.A.R.T. objectives?	
Specific	Objectives should be precise and concrete enough not to be open to varying interpretations by different people.
Measurable	Objectives should define a desired future state in measurable terms, to allow verification of their achievement. Such objectives are either quantified or based on a combination of description and scoring scales.
Achievable	Policy aims should be set at a level that is realistically achievable and properly justified.
Relevant	The objectives should be directly linked to the problem and its root causes.
Time-Bound	Objectives should be related to a fixed date or precise time period to allow an evaluation of their achievement.

When objectives are multiple and interrelated, it is important to highlight the links between them, particularly any possible trade-offs. When problems are complex and have many underlying drivers, numerous objectives are often identified, be they general, specific, or operational. In these cases, an 'objectives tree' can be used to depict graphically the relations among different goals.

The objectives of the initiative must be in line with the **strategic objectives of the Commission**¹⁷⁹. For major policy initiatives, the objectives should also consider the challenges and opportunities identified through strategic foresight¹⁸⁰.

It may be possible to describe the aims of a given initiative in terms of delivering a qualitative or quantitative improvement in one or more of the indicators linked to one or more **sustainable development goals**¹⁸¹.

Moreover, under the **REFIT** programme all revisions of existing legislation should aim to **simplify and eliminate unnecessary regulatory burdens**, while achieving the underlying policy objectives. Impact assessments accompanying revisions should therefore include objectives related to simplification if the problem analysis identifies unnecessary regulatory burdens.

3. EXAMPLES

Example of a hierarchy of policy objectives

GENERAL	SPECIFIC	OPERATIONAL
Better protect the health and safety of users of Personal Protective Equipment (PPE)	Ensure high quality of products protecting against high risks including a high quality of their production process Ensure the reliability and high quality of conformity assessment activities carried out by notified bodies Ensure traceability of products	Remove inconsistencies in the list of products subject to the most stringent conformity assessment procedure Specify common criteria for the assessment, monitoring, and control of Notified Bodies to be applied equally throughout the EU.

¹⁷⁹ See in particular the [political guidelines of the Commission](#).

¹⁸⁰ See Tool #20 (*Strategic foresight for impact assessments and evaluations*).

¹⁸¹ See Tool #19 (*Sustainable development goals*)

<p>Create a level playing field for PPE economic operators</p>	<p>Ensure consistency of conformity assessment services carried out by notified bodies</p> <p>Improve market surveillance mechanisms and tools</p>	<p>Clarify the requirements for EC type-examination certificates</p> <p>Simplify and clarify the requirements for the technical file</p> <p>Require the EC Declaration of conformity to accompany every product</p>
<p>Simplify the European regulatory environment in the field of PPE</p>	<p>Ensure consistent application of the legislation</p> <p>Ensure the requirements are practicable</p>	<p>Clarify the scope of the Directive</p> <p>Simplify the applicable conformity assessment procedures</p> <p>Clarify the requirements set out in ANNEX II</p>

Source: SWD(2014) 118 final

TOOL #16. HOW TO IDENTIFY POLICY OPTIONS

Identifying alternative policy options is, in most cases, an iterative process. The aim is to consider as many realistic alternatives as possible and then narrow them down to the most relevant ones for further analysis.

1. FOUR STEPS TO FOLLOW

The following four steps are suggested to identify a realistic set of options:

- (1) Construct a baseline from which the impacts of the policy options will be assessed.
- (2) Start by compiling a wide range of alternative policy options.
- (3) Identify the most viable options; explain the discarded policy options.
- (4) Describe in reasonable detail the key aspects of the retained policy options to allow an in-depth analysis of the associated impacts.

I. The baseline

- The baseline is the benchmark against which the impact of the policy options is compared. In principle, the baseline is a **'no-policy-change'** scenario which includes all relevant EU-level and national policies which are assumed to remain in force. For uniformity across the impact assessments, the baseline should always be called 'baseline'. In addition, relevant Commission proposals (even if not yet adopted by co-legislators) should also be included.
- A particular situation is when the policy or legislation itself might envisage that it will come to an end on a given date (**'sunset clause'**) and that a positive decision of the Commission and Legislator will be necessary to continue the policy. Examples include targets to be attained by a given year in areas such as energy efficiency or spending programmes which are linked to a particular multi-annual financial programme. In such cases, two options are possible:
 - Explicitly include the 'sunset clause' in the baseline if, for example, a comprehensive evaluation concludes that the policy is ineffective. Policy options would then include establishing a new action and the impacts would be measured against a no-policy baseline. This approach should however be avoided if there are clear political commitments to continue the policy in some form for reasons other than its effectiveness.
 - Include a continuation of the current policy approach in the baseline even if it formally comes to an end; where, for example, a comprehensive evaluation concludes that the policy is effective. Given that the College or Legislator could (theoretically) decide not to propose or enact legislation, this approach should usually be accompanied by a policy option, which would explicitly repeal the current policy and would demonstrate the cost of the Union not acting ('the cost of non-Europe').

The most appropriate approach will have to be decided on a case-by-case basis and consider the degree of political commitment to a continuation of the current policy and the results of evaluations and fitness checks which may question the validity of the current approach.

- Where **two or more related initiatives** are prepared at the same time, each impact assessment report should use the same baseline, where possible, but should describe the

	<p>likely consequences of the other initiative in terms of possible changes to the baseline; it may also be relevant to consider an alternative baseline or sensitivity case to demonstrate the impacts of the other initiative.</p> <ul style="list-style-type: none"> • Where the impact assessment concerns regulatory initiatives based on a legal obligation for the Commission to act (e.g. through delegated or implementing acts), the baseline should be construed as a 'no-action' reference scenario which should not be considered as a valid policy option. • The baseline should include expected socio-economic developments (ageing, GDP growth, etc.) as well as important technological, market and societal developments, such as the pervasive nature of the internet, social media, and emerging technologies, which by themselves are bringing about large changes and challenges, for example for the Union's essential security interests. • The baseline should also be set for an appropriate time horizon. The length of the latter depends on the likely lifetime of any individual option and on the need to allow for impacts to be realised. It should include likely development and evolution of trends and longer-term challenges, using foresight elements (see Tool #20 (<i>Strategic foresight for impact assessments and evaluations</i>)). • After a rigorous qualitative description of the variables, the baseline should be quantified as much as possible. Significant variables that cannot be quantified should be developed rigorously in qualitative terms. This is important as it would avoid having an impact analysis (that compares the policy options with the baseline) that focuses on quantified variables only. • Where the current situation is one of incomplete implementation of policies, a realistic assumption should be made about how implementation will change in the future. • For more information on baselines, see Tool #60 (<i>Baselines</i>).
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II. Consider a wide variety of policy options in addition to the baseline (no policy change) to look at content, tools, and instruments.

	To think outside the box and avoid regulatory bias.
Why?	To show other parties that their preferred policy option has been considered (and explain why it might not be pursued).
How?	Ask what could influence the drivers of a problem? What could influence behaviours in a manner that would address the problem and help to achieve the policy objectives? Identify as many policy responses as possible within the political constraints and the possible scope of the initiative. The identification of the policy instruments to deliver these measures follows at a later stage of the impact assessment ¹⁸² . Consider the widest range of policy measures, from the less intrusive to the more interventionist and from the more classical tools to those suggested by the more

¹⁸² See Tool #17 (*The choice of policy instruments*)

	<p>recent developments in relevant academic fields, like behavioural economics and social psychology¹⁸³.</p> <p>Policy options should be closely linked to the drivers of the problems, the problems themselves and the identified objectives: a clear logic should underpin the intervention under consideration. Policy options should also be digital-ready and take fully into account digital solutions¹⁸⁴. Do not select options that are clearly not responding to the problems or objectives or only for the sake of having additional choices (if you have to discard policy options that were advanced by stakeholders, you need to clearly justify this).</p> <p>Ask stakeholders for ideas and opinions.</p> <p>Make sure to consider those options that can count on considerable support among stakeholders, experts, policymakers, Member States, and other EU institutions including options that can demonstrate the 'cost of non-Europe' as the Commission has committed to do (see below). In the impact assessment report, mention the origin of the policy options.</p> <p>Also, consider policy options that non-EU countries or individual Member States have successfully applied.</p> <p>Do not exclude a priori options with little support or facing strong opposition by some groups.</p>
<p>What?</p>	<p><i>Alternative policy responses</i></p> <p>Consider alternative types of policy responses to reach the objective as regards the content and design of the measure. For instance:</p> <ul style="list-style-type: none"> • Could the objectives be reached through alternative basic policy approaches? • If there are clear arguments in favour of a particular general policy approach, are there different options for the more detailed parameters of the initiative? <p>Consider soft-regulatory policy options (such as self- or co-regulation) and market-based solutions¹⁸⁵.</p> <p>Where they exist, international standards (or regulatory solutions of similar ambition implemented by third countries) should be considered to avoid unnecessary regulatory differences.</p> <p>When EU policy already exists:</p> <ul style="list-style-type: none"> • consider the option of 'doing less' – i.e. can it be streamlined, simplified or even repealed (where the Treaties do not lay down a specific obligation to act)? Could the objective be reached by improving implementation or enforcement of existing legislation? Would this go beyond the baseline? (see also cost of non-Europe below); • consider if there are ways to achieve existing objectives more simply and cheaply and to limit the administrative burdens of those affected by the policy¹⁸⁶. For example, consider whether the use of digital technologies could contribute to reducing administrative burdens (and where relevant

¹⁸³ https://knowledge4policy.ec.europa.eu/behavioural-insights_en

¹⁸⁴ See Chapter IV of the 'better regulation' guidelines and the Tool #28 (*Digital-ready policymaking*).

¹⁸⁵ See Tool #17 (*The choice of policy instruments*).

¹⁸⁶ This is required as part of the REFIT programme – see Tool #2 (*The Regulatory fitness programme (REFIT) and the Fit for Future Platform*).

	consider reusing existing solutions for electronic identification, signature, delivery, and invoicing, etc.).
	You will often have two sets of options, one for the policy content and one for the delivery instruments (regulation, directive, etc.; see also Tool #17 on policy instruments). You should look at the latter once you have a better view of the preferred policy option(s) for the content (so having identified the preferred policy option, then identify the appropriate legal instrument).
	If you are having difficulty identifying even two credible alternatives to the baseline, consider a different level of option aggregation (sub-options, alternative detailed parameters, implementation modes, etc. – see below). Alternatively, provide a strong justification for the fact that only the baseline and an alternative option are retained for in-depth analysis.
	The Commission has committed to explain the ' cost of non-Europe ' one of its initiatives as part of the Interinstitutional Agreement on Better Law-Making. There is no clear or agreed definition of this term, but it represents the opportunity cost of not acting at EU-level. More practically, there will be initiatives where it is appropriate to include an option to repeal a given policy (such as existing policies or programmes, which come to a clearly defined end and where the baseline assumes the continuation of the policy or programme). The impact of such an option gives a direct estimation of the costs associated with the Union not acting in a given area. In addition, where the Union acts for the first time in a given area, the benefits of EU action relative to the baseline also represent the cost of non-Europe.

III. Screen your options and separate discarded options	
Why?	To focus the analysis on the viable options. In choosing the options, it is important to focus on those elements that are most critical for the Commission to decide on (i.e. those with significant impacts). As with the problem analysis, you must ensure that the report remains focused and that it does not drown the major issues in a 'flood' of minor issues.
How?	<p>Excluding options at this stage should be clearly justified. Reasons should be as clear, self-evident and indisputable as possible. The report should explain when it had to discard policy options favoured by stakeholders. This should be done in a separate section on discarded options (if necessary, with further details in the annexes).</p> <p>The key criteria for screening the viability of your options are:</p> <div style="background-color: #ADD8E6; padding: 2px;"><i>Legal feasibility</i></div> <p>Options should respect the principle of conferral¹⁸⁷. They should also respect any obligation arising from the EU Treaties (and relevant international agreements) and ensure respect of fundamental rights. Legal obligations incorporated in existing primary or secondary EU legislation may also rule out certain options.</p>

¹⁸⁷ Under this fundamental principle of EU law, laid down in Article 5 of the Treaty on European Union, the EU acts only within the limits of the competences that EU countries have conferred upon it in the Treaties. These competences are defined in Articles 2–6 of the Treaty on the Functioning of the EU. Competences not conferred on the EU by the Treaties thus remain with EU countries.

	<i>Technical feasibility</i>
	Technological and technical constraints may not allow for the implementation, monitoring, or enforcement of theoretical options.
	<i>Previous policy choices</i>
	Certain options may be ruled out by previous policy choices or mandates by EU institutions. Unless there is compelling evidence that these choices should be revisited, there is no point in reinventing the wheel.
	<i>Coherence with other EU policy objectives</i>
	Certain options may be ruled out early due to poor coherence with other general EU policy objectives.
	<i>Effectiveness and efficiency</i>
	It may already be possible to show that some options would with certainty achieve a worse cost-benefit balance than some alternatives.
	<i>Proportionality</i>
	Some options may clearly restrict the scope for national decision-making over and above what is needed to achieve the objectives satisfactorily.
	<i>Political feasibility</i>
	Options that would clearly fail to garner the necessary political support for legislative adoption or implementation could also be discarded. This, however, does not mean that such options should not be mentioned or not be subject to at least a minimal assessment. Options superior to other options but lacking political feasibility may still be discussed at the legislative stage, which may increase their chances of being politically feasible.
	<i>Relevance</i>
	There is no point in retaining options that do not address the needs of the policy intervention as identified in the problem definition.
	<i>Identifiability</i>
	When it can be shown that two options are not likely to differ materially in terms of the proposed measures, their significant impacts, or their distribution, only one should be retained.
IV. Outline the retained options in greater depth	
Why?	To identify the impacts of alternative options.
	For transparency.
How?	Options should be sufficiently well developed to allow you to differentiate them based on their performance in achieving the identified objectives. The retained options should thus not be described vaguely. It should be clear how they would be implemented, monitored and enforced, by whom and over what

	<p>timeline and whether complementary actions might be necessary to ensure effective implementation (e.g. actions of a self or co-regulatory nature)¹⁸⁸. Enough detail on their actual content should be provided. Do express the options in terms of the specific actions that would need to be undertaken by various stakeholders. This facilitates the analysis (and quantification) of impacts and provides insights on the key elements for political choice (e.g. level of benefits and costs, distributional impacts, impact on SMEs, citizens, EU competitiveness, sustainability, etc.).</p> <p>Similarly, remember that you will have to finalise the analysis of compliance with the subsidiarity principle as well as show the proportionality of any preferred option.</p> <p>The description of the options should be sufficiently precise to be a comprehensive basis for developing the (legal) proposal.</p> <p>Be clear on how the policy options distinguish themselves from the baseline and from the other options. Do not leave it to the reader to identify these differences by himself in lengthy and lists-like descriptions. Always describe the underlying logic of the policy options.</p>
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2. BUILDING POLICY OPTIONS

In the 'better regulation' terminology, one needs to distinguish **policy measures** from **policy options**. While policy options address the problems in their entirety, policy measures address certain aspects of the problems or they are only effective when taken in combination with other measures. A policy option is a combination (or a package) of policy measures. A policy option can also be split up into **sub-options**; these are very similar packages of measures that only differ by one or a limited number of measures.

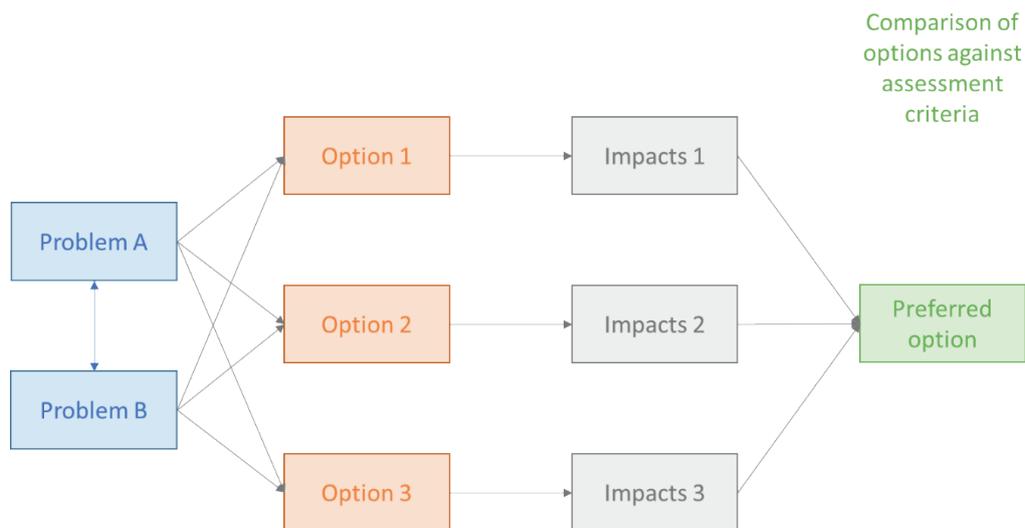
When selecting the policy options, it is necessary to choose the level of aggregation of the policy options: broad alternative options, alternative packages of measures, individual sets of measures targeting specific issues to be bundled together at the end of the analysis or a mix of high-level options and sub-options.

Different methodological choices are possible, each with its pros and cons. The best choice depends upon the specificities of the case at hand, notably the number of problems or specific objectives to address, the extent of spill-overs from one measure to another, the nature of the problem, the logic of the intervention, etc.

Figure 1a and 1b presents two possible approaches to building policy options taking some of these aspects into account. Other combinations are, of course, possible as well. The purpose of these two examples is to show that it is possible to consider separately the problems if the latter are not or only weakly inter-related. This can simplify the analysis (see also section 3 below).

¹⁸⁸ The early involvement of colleagues with policy implementation experience (like IT and data experts or counterparts in partner agencies) may greatly help in this exercise.

Figure 1a. How to build policy options?

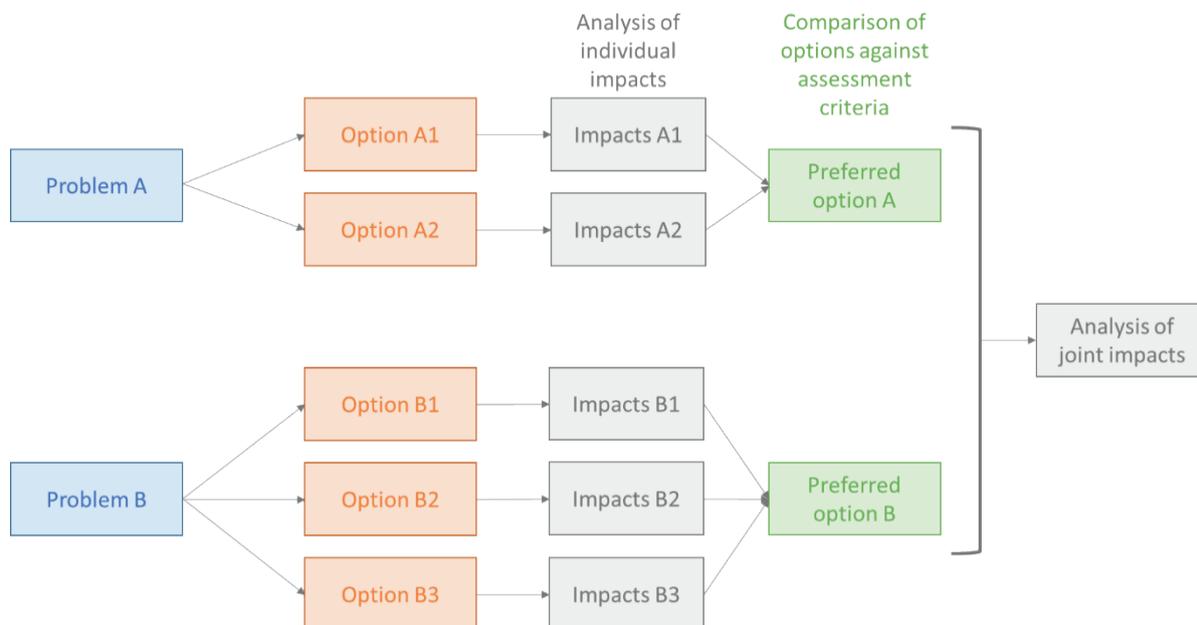


Source: RSB Annual Report 2020

In Figure 1a, problems A and B are interrelated. The three considered options can contribute to solving both problems. In this case, the impacts of all three options must be assessed individually and the preferred option is chosen after applying the comparison criteria (effectiveness, efficiency and coherence).

In Figure 1b, problems A and B are independent of each other and there are separate options for addressing them.

Figure 1b. How to build policy options?



Source: RSB Annual Report 2020

In this case, as the first step, the impacts of all sub-options considered to solve problems or specific objectives A and B must be assessed individually and the preferred options for A and

B chosen after applying the comparison criteria (effectiveness, efficiency, coherence). In the second step, because the problems were analysed separately, one needs to look as well at all the impacts of the set of preferred options together, to potentially identify synergies or trade-offs.

The screening process described under point III above may produce a list of **policy measures** that individually address one or several aspects of a problem, but not the entire problem. The policy measures are then the building blocks of the policy options, which will be a package of policy measures.

This packaging should be done very carefully¹⁸⁹:

- The impact assessment report should explain very clearly the underlying logic of the policy options. One should explain why each policy option combines the policy measures in a certain way and what the main differences between the policy options are. It is recommended to describe the policy options in a table that focusses on the most important policy measures and differences. The details on minor measures can be put in an annex.
- When packaging measures in different options, sufficient options should be created to allow the policy makers to choose between different relevant combinations of measures. For example, measures are often packaged in options by their degree of ambition. However, policy makers might want to be more ambitious in some areas than in others, which would not be reflected in the choice of options.

One should avoid that policy options are built around each other; if option 2 includes option 1 plus some additional measures, then option 3 includes option 2 plus some additional measures, etc., the policy measures of option 1 will end up to be included in all the policy options. This way of building policy options like Russian dolls that fit into each other, makes it very difficult if not impossible for the impact analysis to reject the policy measures that are included in option 1. This introduces a bias in favour of these policy measures. This does not exclude that some policy measures may be common to all policy options, because they are only minor measures and/or they appear obvious in view of the findings of an evaluation; but this should be explained clearly.

3. REDUCING COMPLEXITY

In the same way that the problem analysis should try to divide complex problems into smaller, less complex ones (see Tool #13 (*How to analyse problems*)), one should try to reduce the complexity of the policy options, without oversimplifying. This would largely facilitate the impact analysis. Various situations are possible:

- When the problems can be divided into several weakly related problems, it may be easier to devise the policy options for each of the problems (or problem areas) separately. The impact analysis can then be done problem by problem, and the preferred policy options can then be combined into one or several option packages at the end of the analysis. However, as the policy options will still aim for a common policy objective, the interrelations between the problems, even if weak, should not be left out of sight (see example);

¹⁸⁹ See [example](#).

- A particular case is when various problems remain related, but this relationship is unilateral, i.e. the solution found for problem 1 impacts on problem 2, but not the other way round. In this rare case, it can make sense to deal with the problems in a specific order to reduce the complexity of the overall problem (see example);

When the problems cannot be subdivided into smaller problems, you have no other choice than to build all-encompassing policy options following the above-described packaging method. You need to focus on the main issues in each package and perhaps devise sub-options where certain variations of the option package present a different take on specific sub-problems.

TOOL #17. THE CHOICE OF POLICY INSTRUMENTS

1. INTRODUCTION

A range of regulatory and non-regulatory instruments or combinations of instruments may be used to reach the objectives of the intervention. The merits of each alternative should be considered rigorously considering the following:

- Action at Union level is governed by the **proportionality principle**, which means that action should not go beyond what is necessary to achieve the objective. Proportionality is about matching the policy intervention to the size and nature of the identified problem and its EU (subsidiarity) dimension in particular¹⁹⁰. One of the key aspects of proportionality is the right choice of policy instruments to achieve the desired policy objective.
- The choice of instrument should consider the experience obtained from the **evaluation of the existing policy framework**, as an initiative is often not starting from scratch. For example, an evaluation may find that a voluntary approach has not been effective, so this choice is likely to be rejected or the scope of intervention expands. In addition, coherence with other related policy instruments will have to be considered for example to exploit synergies (e.g. compliance monitoring by competent authorities) and to avoid undermining the effectiveness of existing instruments or raising compliance costs.

Policy instruments at the EU level can be placed into the following broad categories although there may be overlaps or combinations (such as obligations to accept mutual recognition of alternative rules and standards):

- (1) ‘hard’, legally binding rules;
- (2) ‘soft’ regulation;
- (3) education and information;
- (4) economic instruments.

2. ‘HARD’, LEGALLY BINDING EU RULES

Binding legal rules are used to specify the behaviour required of organisations or individuals. It is appropriate to address activities with potentially serious risks of impacts for the economy, the environment or individuals and where legal certainty and enforcement backed by legal sanctions are necessary. It may also be the only available option if there is no scope for ‘softer’ self-regulatory actions by business organisations or when such approaches have failed (see Box 2). Alternatively, binding acts may be used to establish essential requirements (a framework), which are supported by ‘soft’ instruments such as technical standards.

When well designed, such hard rules provide clarity as to the expected behaviour, making it relatively straightforward to identify non-compliant behaviour. However, regulators will need to have the capacity, resources, and sector specific knowledge to make the legislation work effectively. In addition, the ‘one size fits all’ approach of uniform standards may not capture the variation in compliance costs across economic operators, which introduces inefficiencies and raises overall costs of the policy. Such command-and-control approaches may be

¹⁹⁰ See Tool #5 (*Legal basis, subsidiarity and proportionality*)

beneficial as a starting point, when regulators are faced with a significant problem yet have too little information to support a market-based instrument (or where the incentives for trading are limited) means the gains of a market-based instrument would be outweighed by the costs.

In the EU context, Article 288 TFEU establishes three types of binding acts:

Regulations are directly applicable in all Member States and binding in their entirety. Regulations are used most where it is important to achieve a uniform implementation of a policy intervention such as in the internal market or the governance of mergers.

Directives are binding on the Member States to which they are addressed in respect of the result to be achieved but the specific form and methods are left to national authorities to decide. Directives should, as far as possible, be general in nature and cover the objectives, periods of validity and essential requirements, while technicalities and details should be left to the Member States to decide. A proper balance should be struck between general principles and detailed provisions to avoid excessive delegated acts supplementing the legislative act. Framework directives set out general principles, procedures, and requirements for legislation in different sectors. Subsequent secondary-order directives and regulations are then adopted with specific rules for individual products, sectors etc.

Decisions are binding in their entirety on those to whom the Decision is addressed (e.g. individuals, companies or Member States).

Box 1. Examples

- The Biocides Regulation sets out the detailed rules concerning the making available on the market and the use of biocidal products;
- The National Emission reduction Commitments Directive (NEC Directive) sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.
- The Working Time Directive stipulates that too much overtime work is illegal. The directive sets out minimum rest periods and a maximum number of working hours, but it is up to each country to devise its own laws on how to implement this.
- The Machinery Directive sets detailed health and safety rules for placing on the market and/or putting it into service including market surveillance of machinery. The Directive sets out only the essential health and safety requirements while more detailed specifications are given in voluntary harmonised European standards (i.e. 'technical standards' see section 3.2) adopted on the basis of a request made by the Commission.
- The European Capitals of Culture Decision establishes a list of countries eligible for proposing cities to hold the status of European Capitals of Culture for the years 2020 to 2033.

3. 'SOFT' REGULATION

When the subsidiarity and proportionality analysis of possible ways to address a given problem demonstrate that traditional law instruments (regulations, directives, decisions) are not necessary, the Commission may resort to 'soft', more flexible approaches instead. A range of policy instruments is available, including Recommendations, technical standards, 'pure' voluntary bottom-up initiatives (self-regulation) to legislation-induced co-regulatory actions. In practice, it is often hard to define the exact nature of a given soft regulatory approach. Thus, the list of instruments below is only illustrative, with many hybrid solutions equally possible.

3.1. Self-regulation and co-regulation

Self-regulation is where business or industry sectors formulate codes of conduct or operating constraints on their own initiative for which they are responsible for enforcing. However, pure self-regulation is uncommon and at the EU level it generally involves the Commission in instigating or facilitating the drawing up of the voluntary agreement.

Self-regulation by the relevant industry can in suitable cases deliver the policy objectives faster or in a more cost-effective manner compared to mandatory requirements. They also allow greater flexibility to adapt to technological change (e.g. in the ICT-related areas of activity) and market sensitivities. Voluntary agreements work when the interests of society and the industry grouping coincide; otherwise it is unlikely that industry will voluntarily take the necessary steps without external influence such as the Commission, or other parts of civil society such as NGOs. Voluntary agreements may also appear when industry fears upcoming regulation and voluntarily restrict their room for manoeuvre. A challenge of such approaches is to ensure that the desired policy outcome is delivered in practice as the conventional enforcement mechanisms associated with regulation are not available.

Co-regulation is a mechanism whereby the Union Legislator entrusts the attainment of specific policy objectives set out in legislation or other policy documents to parties which are recognised in the field (such as economic operators, social partners, non-governmental organisations, standardisation bodies or associations). Recognition of such public-private arrangements may be done through cooperation agreements or in Union legislation. Under this 'light' regulatory approach, the relevant policy initiatives establish the key boundary conditions, objectives, deadlines, mechanisms for implementation (if relevant), the methods of monitoring the application of the legislation and any sanctions. Co-regulation can combine the advantages of the binding nature of legislation with a flexible self-regulatory approach to implementation that draws on the experience of the parties concerned and can foster innovation. Co-regulation can remove barriers to the single market, simplify rules and can be implemented flexibly and quickly. The New Legislative Framework type of legislation (see box 4) falls within this category.

Box 2. Examples of self- & co-regulation

Reduction of CO₂ emissions from cars: voluntary agreement replaced by legislation

The Commission previously recognised voluntary agreements with the European, Japanese, and Korean car manufacturers to reduce the CO₂ emissions of their new vehicles, but which were subsequently replaced by regulation. These commitments were recognised by the Commission in form of several Recommendations. On 7 February 2007, the Commission

adopted two parallel Communications: a Communication setting out the results of the review of the Community Strategy to reduce CO₂ emissions from passenger cars and light-commercial vehicles and a Communication on a Competitive Automotive Regulatory Framework for the 21st Century (CARS21). The Communications underlined that progress had been made towards the target of 140g CO₂/km by 2008/2009, but that the Community objective of 120 g CO₂/km would not be met by 2012 in the absence of additional measures. The Communications proposed an integrated approach with a view to reaching the Community target of 120g CO₂/km by 2012 and announced that the Commission would propose a legislative framework to achieve the Community objective by focusing on mandatory reductions of emissions of CO₂ to reach an objective of 130g CO₂/km for the average new car fleet by means of improvements in vehicle motor technology.

Better internet for kids: industry organising itself answering a call from the Commission

The CEO coalition to make a better internet for kids, launched in December 2011 in response to voiced requests from the Commission, is a cooperative voluntary intervention designed to respond to emerging challenges arising from the diverse ways in which young Europeans go online. Companies-signatories to the Coalition committed to take positive action to make the internet a safer place for kids by means of establishing a five-step action plan.

The civil society and researchers have also been involved in the negotiations of these agreements. They provided evidence of the (then) current state of play for child safety online, best practices, voiced opinions. The main civil society organisations involved were those active in the area of child safety. The Commission functioned as a 'broker' of trust, providing logistics and making sure all interested parties were invited in all negotiations, as well as providing publicity to the initiative.

One year after the launch of the Coalition, the signatories have made statements on how they implemented the action plan and proposed recommendations for improvement. At this stage the Commission has not appointed any independent expert to monitor the implementation although DG CNECT continues to follow the initiative but without concrete milestones/actions.

The success of self- and co-regulation depends in essence on several key factors which include representativeness, transparency, legal compliance, effective implementation, and monitoring¹⁹¹. The Commission services have prepared a set of best practice principles, which should be reflected in all self- and co-regulation initiatives (see attached appendix). These are divided into two phases: the inception phase and the implementation phase. In the inception phase, every self- and co-regulation initiative should be open to all interested parties sufficiently representing the sector/area at stake, that in good faith are willing to accomplish clearly defined objectives in compliance with the legal framework (EU and/or national). In the implementation phase, each self- and co-regulation initiative should be transparent as to the means of financing, be open to iterative improvements, and have built-in monitoring arrangements and evaluation mechanisms allowing for fair dispute resolution and sanctions.

The self- and co-regulation initiatives cannot a priori be excluded from any policy area. However, based on the information available in the monitoring database run by the EESC, they are present in areas covered by 15 DGs of the Commission. The bulk of them (80%)

¹⁹¹ Based on [EESC SMO report "European Self- and Co-Regulation"](#), July 2013 and re-affirmed in the [EESC own initiative opinion](#) adopted on April 22.

remains within the remit of six DGs, i.e. GROW, SANTE, EMPL, CNECT, FISMA and JUST.

Box 3. Experience of voluntary agreements under the Ecodesign Directive

- Directive 2009/125/EC establishes a framework for the setting of ecodesign requirements for energy-related products. Ecodesign aims at reducing the environmental impact of products, including the energy consumption throughout their entire life cycle. Mandatory and voluntary approaches are bundled within the same instrument.
- Implementing measures impose legally binding design criteria or recognise voluntary agreements. Three voluntary agreements have been implemented regarding the energy consumption of Game Consoles, Complex Set Top Boxes within the European Union; and the environmental performance of imaging equipment on the European Market.
- When recognising the voluntary agreements, the Commission issued guidelines on how the agreement should function, in line with the principles spelled out in the Annex to this tool.

3.2. Technical standards

Standards are private and voluntary documents developed by recognised standardisation bodies that set out specifications and other technical information regarding various kinds of products, materials, services and processes. They provide a common understanding among businesses, other stakeholders and public authorities on the commonly recognised state of the art, and they are frequently reviewed and revised. They are developed internationally by the international standardisation bodies and in Europe by the European standardisation organisations (ESOs, see Box 4). European standardisation is a key instrument for consolidating the Single Market, supporting the competitiveness of European industry in a global market, harmonising conflicting national standards and facilitating cross-border trade in a less intrusive manner than technical regulations. The Commission has an active standardisation policy and co-operation agreements with the ESOs.

Regulation (EU) No 1025/2012 sets the legal framework for the Union to use voluntary European standardisation as a recognised policy tool in support of Union legislation and policies for the products and for the services. It sets procedures for the Commission to request the ESOs to develop voluntary European standards or European standardisation deliverables which e.g. can be used to specify how to comply with generally worded legal requirements. Such standards can avoid regulation (like ‘harmonised standards’, see box 4) or they permit legislation which concentrates only on the essential requirements and where technical details can be left to voluntary standards.

The Regulation also sets requirements for ESOs about the transparency of their standardisation work programmes and standards, requirements on stakeholder participation and allows the Commission to finance the ESOs when they execute specific tasks on the basis of Commission requests. The Regulation aims to ensure that the European standardisation process is sufficiently inclusive allowing all stakeholders, including SMEs, consumers, workers, and environmental organisation to contribute (*see Box 4*).

Box 4. European standards

- A European standard is a standard that has been adopted by one of the three recognised¹⁹² European standardisation organisations (ESOs): the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) or the European Telecommunications Standards Institute (ETSI).
- The ESOs are private organisations, and they bring together industry, other stakeholders and the national standardisation bodies of EU/EEA and of some neighbouring countries. Once a European standard is developed and agreed, the national standardisation bodies, who are members of the ESOs, should transpose it as a national standard and they must withdraw all conflicting national standards. Moreover, more and more European standards are also adopted as identical national standards outside EU/EEA, around the world. The ESOs have also close co-operation with international standardisation bodies, and they transpose ISO¹⁹³/IEC¹⁹⁴ standards as equivalent European standards.
- The ESOs develop European standards and other deliverables mainly as a response to specific needs that have been identified by businesses and other users of standards. Since late 1980s the Commission has issued standardisation requests to the ESOs when specific voluntary standards are beneficial to support objectives of the Union.
- Around 20% of the European standards or other deliverables published by the ESOs have been developed in response to specific standardisation requests ('mandates') issued by the Commission. Most of these standards are known as 'harmonised standards', which support application of Union's harmonisation legislation for products (New Legislative Framework). In such cases, a standard may provide a 'presumption of conformity' with the essential requirements of the relevant legislation.
- DG GROW manages the Commission's relationship with the ESOs and provides tools, databases and guidance on how to use voluntary European standards to support Union legislation and policies. It also co-ordinates the preparation of standardisation requests to the ESOs.

Regulatory use of private technical standards, (i.e. a reference to technical standards in Union legislation) should be limited, as far as possible, to European standards adopted by the ESOs and requested by the Commission using its standardisation requests. This is because of the public-private partnership established between the Union and the ESOs and the recognition of ESOs by Regulation (EU) No 1025/2012. In addition, referenced European standards may be established on the basis of Commission requests to the ESOs; Regulation (EU) No 1025/2012 sets high inclusiveness and transparency requirements for the ESOs and all European standards are available as national standards in all Member States.

Box 5. Regulatory use of private technical standards in Union legislation

Issues to be considered when indirectly referencing voluntary harmonised European standards within the meaning of Article 2(1) c) and Article 10(6) of Regulation (EU) No 1025/2012:

¹⁹² Annex I of Regulation (EU) No 1025/2012 on European standardisation

¹⁹³ ISO - International Organization for Standardization; www.iso.org

¹⁹⁴ IEC - International Electrotechnical Commission; www.iec.ch

- Voluntary standards cannot override national legislation.
- Essential or other legal requirements given in the Union act itself should be suitable to be supported by technical specifications given in voluntary and consensus-based harmonised European standards elaborated by private European standardisation organisations.
- The domain where technical specifications for products or for services are needed should be mature enough to allow elaboration of technical specifications having a status of voluntary standards.
- Considering the voluntary nature of harmonised European standards, the essential or other legal requirements should be sufficiently comprehensive, self-standing and understandable to be applied directly by economic operators even without harmonised European standards. If this is not the case, and harmonised standards are still selected as a policy option, it should be considered whether alternative technical specifications should be available in the absence of any harmonised standards.
- Whether ESOs, in co-operation with relevant stakeholders, will have resources and/or willingness to accept the relevant future standardisation request (an implementing act) to elaborate the requested harmonised European standards.
- Overall time needed to draft and adopt the Commission's standardisation request and to elaborate a minimum set of harmonised European standards by the ESOs considering the date by which the proposed Union act should be fully enforceable.

3.3. Recommendations

Recommendation is a legal instrument that encourages those to whom it is addressed to act in a particular way without being binding on them. A Recommendation enables the Commission (or the Council) to establish non-binding rules for the Member States or, in certain cases, Union citizens¹⁹⁵. A Recommendation can be used when there is not sufficient evidence that would justify a need of a binding legislative instrument, or in policy areas where the EU has supporting competence, complementing the action of Member States, and cannot by definition be prescriptive. The need for a Recommendation should be critically considered in light of its expected added value. Given the non-binding character of a Recommendation, which per se cannot guarantee that action will be taken by all Member States, detailed monitoring and evaluation arrangements should be envisaged to measure its success.

Box 6. Examples of Recommendations

- **Commission Recommendation** on access to a basic payment account
- **Council Recommendation** on the validation of non-formal and informal learning

3.4. Open method of coordination

The open method of coordination (OMC), created as part of employment policy and the Luxembourg process, has been defined as an instrument of the Lisbon strategy (2000).

¹⁹⁵ E.g. Commission [Recommendation 2002/236/EC](#) of 11 March 2002 on a common European format for curricula vitae (CVs)

The OMC provides a framework for cooperation between the Member States, whose national policies can thus be directed towards certain common objectives. Under this intergovernmental method, the Member States are evaluated by one another (peer pressure), with the Commission's role being limited to surveillance. The European Parliament and the Court of Justice play virtually no part in the OMC process.

The open method of coordination takes place in areas where Union action cannot supersede Member State competence such as employment, social protection, social inclusion, education, youth, and training.

It is based principally on:

- jointly identifying and defining objectives to be achieved (adopted by the Council);
- jointly established measuring instruments (statistics, indicators, guidelines);
- benchmarking, i.e. comparison of the Member States' performance and exchange of best practices (monitored by the Commission).

Depending on the areas concerned, the OMC involves so-called 'soft law' measures which are legally binding on the Member States in varying degrees, but which never take the form of directives, regulations, or decisions. Thus, in the context of the Lisbon strategy, the OMC requires the Member States to draw up national reform plans and to forward them to the Commission.

4. EDUCATION & INFORMATION

EU objectives may be reached by ensuring that citizens, consumers, and producers are better informed. This type of policy instrument includes information and publicity campaigns, training, guidelines, disclosure requirements, and/or the introduction of standardised testing or rating systems.

The instrument can be cost-effective, and it is easily adaptable to changing situations. It is generally most useful in those areas where:

- the lack or costs of collecting information is shown to be a key driver of the problem;
- the limited effectiveness of an existing piece of legislation is due to lacking information/clarity on how to comply with it (or enforce it).

A good example of an effective consumer information scheme is the energy labelling of energy using products.

5. ECONOMIC INSTRUMENTS

The use of market-based instruments (MBIs) most likely involves legislation, in form of hard regulation (a directive or a regulation).

Market-based instruments include:

- taxes;
- charges;
- fees;

- fines;
- penalties;
- liability and compensation schemes;
- subsidies and incentives;
- deposit-refund systems;
- labelling schemes; and
- tradable permit schemes.

There are numerous definitions for market-based instruments based on different approaches and applications. The OECD defines economic instruments as tools that “*affect estimates of the costs and benefits of alternative actions open to economic agents*”¹⁹⁶. Or to put it more simply, if a tool affects the cost or price in the market, then it is a market-based economic instrument. This definition focuses on the economic signals and incentives. If it changes the cost or price of a good, service, activity, input, or output then it is a market-based instrument.

MBIs – due to their economic nature – are most used in the environmental policy area where they fit very well as a tool to cater for market failures/externalities. For an incentive effect, MBIs rely on individuals and/or firms having the ability to respond to the price signal. Market-based instruments can be applied to different components – e.g. on the inputs and hence change the production costs, or on the outputs and hence change the price. In some situations, a change in cost will result in a change of the price (if the cost changes can be passed on to the consumer) and in other cases there will be less pass-through. The change in behaviour may not be immediate after prices change as it depends on elasticity of demand, which in the short term is in fact usually inelastic as there might not be adequate alternatives or substitutes or the ability to change consumption patterns.

Tradable offsets and permits allow producers to negotiate with each other to ensure overall compliance, which does not necessarily have to be enforced on all producers at the same level. The main advantage of tradable offsets and permits is their flexibility and cost-effectiveness. They allow potentially major reductions in compliance costs, since these can be redistributed to firms facing the lowest adjustment costs. Moreover, they may be easier to police since they offer incentives to firms to comply. Their main disadvantage is their potential complexity related to issues such as the need to ensure a satisfactory initial distribution of permits. The most obvious example of such an instrument is the EU Emissions Trading System.

Taxes, charges, and fees are potentially useful policy instruments to influence **private** behaviour towards public objectives. They also raise revenues. As other market-based instruments, they provide flexibility and cost-effectiveness and can be used to ensure that users pay the social price of their consumption. At the EU level, the ability to co-ordinate taxes is limited due to the need for a unanimous decision by the Council. When tax instruments are used to attain specific policy objectives, it must be ensured that they comply with EC rules on state aid. An example of such an approach is the proposal to overhaul the

¹⁹⁶ Organisation for Economic Co-operation and Development (OECD). 1994. *Managing the environment: the role of economic instruments*. OECD, Paris.

outdated rules on the taxation of energy products in the European Union and consider both their CO₂ emissions and energy content¹⁹⁷.

6. BEHAVIOURAL INSIGHTS, REGULATORY SANDBOXES AND COMBINATIONS OF INSTRUMENTS

More effective policy instruments could emerge if insights provided by behavioural sciences and empirical studies are available. Assumptions about the behaviour of individuals and businesses based on classical rational choice theory are not necessarily corroborated by observed evidence. Behavioural sciences may help bridge the gap between conventional assumptions that are adopted in most models and the observed biases in such a way to obtain a realistic representation of the problem matter and of its determinants. Tool #13 (*How to analyse problems*) provides several examples where the design or the intensity of the instrument is affected by behavioural insights¹⁹⁸.

Technological transformation, the emergence of new products, services, and business models can be quite challenging from a regulatory perspective. To enable firms to test innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority, a relatively new policy instrument – a 'regulatory sandbox' – can be set up. A more detailed description of regulatory sandboxes can be found in Tool #69 (*Emerging methods and policy instruments*).

Some instruments are naturally complementary. New legislation or Recommendations can be informed by behavioural insights. Relevant examples are the ban of pre-checked boxes in the Consumer Rights Directive or the Recommendations on Online Gambling, which put forward behavioural solutions to tackle irresponsible gambling. The use of economic incentives (e.g., taxation, tax reductions) and information disclosure can also be informed by behavioural evidence, notably when issues related to social norms and information overload are shown to be relevant.

Information disclosure is unlikely to be wholly effective on its own, but it will nonetheless be important to complement other instruments. Monitoring is also likely to be needed to ensure the success and credibility of voluntary initiatives undertaken by industry. Economic instruments in the form of tax reductions coupled to binding rules can incentivise more effectively the desired behaviour (such as an investment in low-carbon technologies). Another example is the phase-out of leaded petrol in the European Union in 2000, which was accompanied in most Member States by a reduction in the duty level of unleaded petrol.

Some combinations can be counterproductive and should be avoided. More generally, where combinations of policy instruments are envisaged, they should aim to be mutually supportive and carefully calibrated to achieve policy goals in the most effective and efficient way.

¹⁹⁷ [Revision of the Energy Taxation Directive](#)

¹⁹⁸ See Tool #13 (*How to analyse problems*) and Tool #69 (*Emerging methods and policy instruments*)

7. APPENDIX: PRINCIPLES FOR BETTER SELF- AND CO-REGULATION

1. Conception

1.1. Participants

Except in cases where the competitive nature of an initiative makes this inappropriate, participants should represent as many as possible of potential useful actors in the field concerned, notably those having capacity to contribute to success. In case some organisations, notably SMEs, do not have the capacity to commit directly to the action, they may be represented by a relevant umbrella organisation.

Where, at launch, not all possible parties have come on board, later engagement should remain possible, and the conditions for it should be clearly stated. Participants are each fully accountable and respected for their specific contributions.

1.2. Openness

Envisaged actions should be prepared openly.

The preparatory phase should include the involvement of any interested parties: public authorities, enterprises, legislators, regulators, and civil society. Public authorities should be ready to convene, moderate or observe, as most helps the process and if deemed appropriate.

The initial blueprint, or 'concept agreement', for any action should be multi-stakeholder and developed in a concerted and collaborative way involving open exchange between interested parties. Where the field is too large to be effectively managed, the leaders of the action may select those mainly having capacity to contribute to success. Others wishing to support the initiative should be able to join deliberations with interested parties on terms that contribute to the process of decision-making.

The preservation of a similar degree of open governance in the operation of any resulting agreement is equally desirable. The initiative and its constitutive texts must therefore be widely publicised and easily accessible.

1.3. Good faith

Participants of different sizes and types have different contributing capacities. The different capabilities of participants, including the situation of SMEs, and smaller non-profit organisations, should be considered when designing the envisaged action.

Participants should bring to the preparatory process all information available to them that can contribute to a full analysis of the situation. Similarly, in launching an action, participants should ensure that their activities outside the action's scope are coherent with the aim of the action.

Both in developing and in executing self- and co-regulatory actions, participants are expected to commit real effort to success. They retain the possibility to withdraw, should the action fail to reach the agreed objectives.

1.4. Objectives

The objectives of the action should be set out clearly and unambiguously. They should start from well-defined baselines, both for the issue on which change is being pursued and for the commitments that participants have made. They should include targets and indicators allowing an evaluation of the impact of the action undertaken.

1.5. Legal Compliance

Initiatives should be designed in compliance with applicable law and fundamental rights as enshrined in EU and national law. Participants are encouraged to have recourse to existing guidance provided by public authorities. In case of doubts, an assessment clarifying, *inter alia*, impact and complementarity with the *acquis* and with the Charter of Fundamental Rights should be conducted.

2. Implementation

2.1. Iterative improvements

Successful actions will usually aim for a prompt start, with accountability and an iterative process of 'learning by doing'. A sustained interaction between all participants is required. Unless the action covers a short time span, annual progress checks should be made, against the chosen objectives and indicators, as well as any available broader background data.

2.2. Monitoring

Monitoring must be conducted in a way that is sufficiently open and autonomous to command respect from all interested parties. Each participant shall monitor its performance against the agreed targets and indicators. Monitoring results are shared by each actor for discussion with the participants as a whole and are made public. A monitoring framework or template will be commonly agreed. The results of the monitoring will be aggregated where possible. This should be done in a way that is transparent and objective.

2.3. Evaluation

Evaluation will allow participants to assess whether the action may be concluded, improved, or replaced. The participants regularly and collectively assess performance not only against output commitments, but also as to impact. This should identify any shortfall in expected collective impact, any scope to improve the efficiency or effectiveness of the action, and any other desirable improvements.

2.4. Resolving disagreements

Disagreements inevitably arise involving either participants or others. As part of the iterative process of improvement, such disputes should receive timely attention, with a view to resolving them. These procedures may be confidential.

In addition, complaints by non-participants should be submitted to a panel of independent assessors which consist of majority of non-participants. The outcome of their work is made public. Non-compliance should be subject to a graduated scale of sanctions, with exclusion included and without prejudice to any consequences of non-compliance under the terms of the Unfair Commercial Practices Directive.

2.5. Financing

Participants to the action will provide the means necessary to fulfil the commitments. Public funders or others may in addition support the participation of civil society organisations lacking fully adequate means themselves to play their appropriate role. Such financial support should be made publicly known.

Chapter 3 – Identifying impacts in evaluations, fitness checks and impact assessments

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TOOL #18. IDENTIFICATION OF IMPACTS

The identification and assessment of the most significant impacts is a core task of every impact assessment, evaluation, and fitness check. Given the need to consider impacts across the economic, environmental, and social pillars, this screening is important to ensure that the subsequent assessment focuses on the most important impacts for each specific case, in line with the principle of proportionate analysis. Once an initiative has been adopted and implemented, it is also important to monitor and ultimately evaluate to see whether the impacts originally expected in the impact assessment materialise and to what extent. This tool looks at the initial identification of impacts from the impact assessment perspective, but the typology of impacts will also be valid for evaluations and fitness checks.

1. DIRECT AND INDIRECT BEHAVIOURAL CHANGES AND POLICY GOALS

A policy option should aim to deal with the identified problem by inducing direct and indirect changes to the behaviour of those influencing it (i.e. addressing the problem drivers). These changes are also likely to have a bearing on the achievement of other policy goals. **The first step in impact analysis is the identification of this chain of impacts.**

A. Start by considering direct behavioural changes	
Why?	As a direct result of an option, someone somewhere will be incentivised to do something differently (or maintain a certain activity) than would have been the case without the policy intervention.
Who?	<p>Those directly affected by an initiative. In the case of a legislative proposal, these include the addressees of any regulatory obligation, the public authorities responsible for implementation and enforcement and those who are expected to be the final beneficiaries of the proposal.</p> <p>It is suggested to refer to the following categories of potentially affected groups for your analysis:</p> <p>Citizens – whenever changes are widespread and do not affect any particular subgroup.</p> <p>Consumers – whenever users of a particular product/service are affected.</p> <p>Workers – whenever employees in general or in a specific industry are affected.</p> <p>Enterprises – businesses in general or in a specific sector. It is necessary to distinguish enterprises according to their size (micro, small, medium and large) whenever they are to respond to different regulatory requirements (i.e. exemptions and special regimes) or are likely to be affected differently by the same policy measure.</p> <p>Public authorities – distinguish between EU, national and sub-national levels as appropriate.</p> <p>Member States, regions – whenever impacts are different across Member States or where the option addresses regions differently according to their industrial, environmental, geographic or social characteristics (e.g. urban, rural, cross-border, or as regards the EU outermost regions).</p> <p>Third countries – whenever they are directly affected. Relevant subgroups of countries (main trading partners, developing or neighbouring countries, etc.)</p>

	and, within countries, entities (businesses, citizens etc.) should be used.
	The above list is indicative and different groupings should be used whenever relevant given the specific nature of the initiative and its direct implications for specific groups (for instance, <i>innovators, researchers, students, youth, elderly, genders, immigrants, people suffering from discrimination or physical disadvantages</i> , etc.) or people living in urban, rural, island, mountain, cross-border areas or in the EU outermost regions.
What?	To identify direct impacts, ask whether the option under consideration would imply new regulatory obligations? If so, what actions would the targeted parties (businesses, citizens, public authorities etc.) must take to comply with such obligations? How would they need to change their behaviour?
	Would the option exempt certain actors from the regulatory obligations (e.g. micro enterprises) or cover specific regimes (e.g. for SMEs)? What impact would this have?
	What additional actions would need to be taken to implement, monitor, and enforce a new legislative requirement?
	Is any other action expected to be taken as a direct result of the option under consideration?
Examples	Removal of certain (dangerous) products from the market; requiring pollution abatement equipment to be fitted to industrial installations or vehicles; providing consumers with additional information to influence their purchasing behaviour; being able to pay less for EU-level patenting because of reduced translation requirements, lower or no EU taxation on imported products ¹⁹⁹ , etc.
B. Consider indirect behavioural changes	
Why?	Direct changes will often prompt indirect (or second-order) changes and so on. These can be as important as the primary effects and may provide an important link in the chain of actions leading to the solution of the problem.
Who?	Indirect behavioural changes may regard both those directly affected as well as others. The same groups or territories as listed above can be used for the analysis (but a different set of groups may be relevant for second-order impacts).
What?	Consider those second-round effects that are both a direct consequence of the primary changes or further removed (typically the result of changes in the price and/or quality/availability of the goods and services produced in the regulated sector) and territorial spill-overs to neighbouring regions.
Examples	Thanks to a new regulatory measure, EU companies can obtain EU patents at a reduced cost (first round). Thanks to this, the profitability of research and development in the EU is increased. All else equal, this increases incentives for R&D spending (second round).
	Thanks to a new labelling requirement, potential consumers of a given electric good can compare data on energy efficiency more easily (first round). As a result, they increase consumption of more energy efficient products (second round). At the same time, companies' costs increase due to the need to respect

¹⁹⁹ Concerns the outermost regions of the EU.

	the new labelling requirement (first round). Given the existing market structure, these increased compliance costs are transferred on the price of the good. Demand for the good decreases (second round). The net effect needs to be determined.
C. Consider ultimate impacts on relevant public policy goals	
Why?	All the changes identified will eventually affect the state of the world relative to the 'no-policy-change' or baseline scenario.
What?	The analysis should first identify what all these changes imply for the attainment of the specific and general objectives of the initiative in question.
	Secondly, the analysis should look at how other public policy objectives may be (positively or negatively) impacted by the option under consideration.
	The set of potentially relevant public policy objectives is defined by the existing EU/Commission policy commitments, the Commission's political priorities and, ultimately, the EU Treaty. They include goals related to the economic, social, and territorial cohesion and environmental sustainability, as well as respect for the fundamental rights, in line with the UN 2030 Agenda and its sustainable development goals. They can all be considered intermediate goals to the ultimate goal of maximising societal welfare.
	Specifically relevant objectives will vary from initiative to initiative and from option to option.
	An indicative list is provided in the tables below. Specific impact assessment tools or indicative lists of issues are provided for most of them and should be consulted whenever relevant.

At the end of this process, you should have mapped out all potentially relevant impacts according to affected parties and areas of relevance. The next step is to identify which of these impacts are likely to be significant and thus in need of a more focussed analysis.

2. DIRECT AND INDIRECT BEHAVIOURAL CHANGES AND POLICY GOALS

In the impact assessment process, a stepwise approach is followed:

- (1) identifying potential impacts of the selected policy options;
- (2) selecting those impacts which are likely to be significant; and
- (3) assessing the latter quantitatively wherever possible, otherwise qualitatively.

Step 1: Identification of potential impacts

The table below summarises the key impacts, which should be screened objectively to identify all potentially important impacts – considering both positive/negative, direct/indirect, intended/unintended as well as short/long-term effects. Some of the categories are cross-cutting and can be analysed from different angles (for example employment, income distribution, impacts on consumers or environmental impacts). A (well-justified) choice

should then be made on the most significant impacts to be retained for a more thorough analysis. More details about the individual impacts²⁰⁰ follow in section 4.

<i>Overview of key impacts to screen*</i>			
Impact on	Economic	Social	Environmental
Climate			✓
Quality of natural resources (water, soil, air etc.)			✓
Biodiversity, including flora, fauna, ecosystems, and landscapes			✓
Animal welfare			✓
Working conditions, job standards and quality		✓	
Public health & safety and health systems		✓	
Culture		✓	
Governance, participation, and good administration		✓	
Education and training, education, and training systems	✓	✓	
Conduct of business	✓		
Position of SMEs ²⁰¹	✓		
Administrative burdens on business	✓		
Sectoral competitiveness, trade, and investment flows	✓		
Functioning of the internal market and competition	✓		
Public authorities (and budgets)	✓		
Sustainable consumption and production	✓		✓
Efficient use of resources (renewable & non-renewable)	✓		✓
Land use	✓		✓
The likelihood or scale of environmental risks	✓		✓
Employment	✓	✓	
Income distribution, social protection, and social inclusion (of particular groups)	✓	✓	
Technological development / digital economy	✓	✓	
Consumers and households	✓	✓	
Capital movements; financial markets; stability of the euro	✓	✓	

²⁰⁰ The obligation to screen these impacts is the consequence of the Treaty on the Functioning of the European Union (Articles 8-14).

²⁰¹ To systematically screen the potential impact on SMEs, the SME-test needs to be performed in all impact assessment reports. See Tool #23 (*the 'SME test'*).

Property rights; intellectual property rights	✓	✓	
Territorial impacts (specific (types of) regions and sectors)	✓	✓	✓
Innovation (productivity and resource efficiency); research (academic and industrial)	✓	✓	✓
Fraud, crime, terrorism, and security, including hybrid threats	✓	✓	✓
Resilience, technological sovereignty, open strategic autonomy, security of supply	✓	✓	✓
Transport and the use of energy	✓	✓	✓
Food safety, food security and nutrition	✓	✓	✓
Waste production, generation, and recycling	✓	✓	✓
Third countries, developing countries, and international relations	✓	✓	✓
Sustainable development	✓	✓	✓
Fundamental rights	✓	✓	✓

* - The 'tick' denotes an indicative dominant category of impact

Step 2: Selection of the significant impacts

Not all impacts for all possible stakeholders need to be examined. The most relevant ones should be selected based on the principle of proportionate analysis (see Tool #12 (*How to apply proportionality to undertake a proportionate impact assessments*)) considering the following factors:

<i>The relevance of the impact within the intervention logic</i>
All key parameters of an option that will directly contribute to the achievement of the policy objectives should be retained for further analysis to assess the effectiveness and efficiency of this option.
In the case of legislative proposals, this implies <u>always</u> retaining for further analysis the changes required to comply with, and to implement and enforce, the proposed legal provisions.
<i>The absolute magnitude of the expected impacts</i>
The analysis should also focus on those impacts with the greatest magnitude.
<i>The relative size of expected impacts for specific stakeholders</i>
While some impacts may be small in absolute terms, they may be particularly significant for some specific party due to: <ul style="list-style-type: none"> • The relative size of the latter – for instance, micro and small enterprises. • The concentrated nature of the impacts – on specific regions and types of territories²⁰², industry, and stakeholder groups, etc.

²⁰² On the EU outermost regions and on urban, rural, , sparsely populated, mountainous, insular, cross-border territories

- The cumulative impact that new obligations may have on any actor, which is already subject to significant direct regulatory compliance and/or implementing and enforcement obligations.

The importance of impacts for Commission horizontal objectives and policies

When the analysis of impacts shows that there are potentially significant trade-offs between the objectives of the initiative (and its effects) and other politically important objectives (e.g. climate, territorial, or geopolitical), the relevant impacts should be analysed in depth.

When the initiative is part of a larger strategy (or action plan or similar), the impact assessment should also assess the contribution of the initiative to the strategy.

When it comes to delivering on the SDGs, one important aspect is to address explicitly the interlinkages between the different SDGs, assessing synergies and trade-offs, as a tangible manner to progress towards sustainable development in an integrated manner, balancing its three dimensions (economic, social, and environmental). This is a central requirement to fulfil the commitment to ensure policy coherence for sustainable development. (see Tool #19 and #35)

Sensitivities and diverging views

The impact assessment should help explain the reasoning behind the Commission's proposal. It should therefore also take account of potential sensitivities or diverging views. For instance, if there are specific aspects that are likely to come up in the legislative negotiation process or that stakeholders may be concerned with, these should be covered in the analysis.

The expected significance of impacts should be assessed in terms of changes relative to the baseline²⁰³. However, it is important not to leave out anything that is of relevance for political decision-making. The choice should take account of stakeholders' views and relevant expertise, including within the interservice coordination group.

At the end of this process, you should have selected those significant impacts that need to be further analysed and have a good idea of their sign (positive or negative), their intensity, and of whom they would benefit or burden. The choice of impacts to be retained for deeper assessment should be clearly justified.

However, regardless whether they are relevant for a given initiative, there is still a need to report on some specific impacts in all impact assessments and justify why you have not assessed them further, should this be the case. This concerns specifically impacts on SMEs, competitiveness, and fundamental rights.

Step 3: Assessment of significant impacts

The key principles to be followed in analysing the significant impacts are explained in the 'better regulation' guidelines covering impact assessment.

There is no single best method which would apply to all possible Commission initiatives. There is, however, an obligation to make the most sensible methodological choice given the specificities of the case at hand, the availability of data, and the requirement to carry out a proportionate analysis.

²⁰³ See Tool #60 (*Baselines*)

Significant impacts should be assessed qualitatively and, whenever possible, quantitatively.

However, the analysis should not be done in function of the available data. All significant impacts must be assessed even if they cannot be quantified. The analysis should indeed be quantified as far as possible (though in a proportionate manner), but when data are lacking for significant impacts, this should be complemented with or replaced by a qualitative analysis (see also Chapter 8 and Tool #4 (*Evidence-informed policymaking*)).

All legislative revisions require identification of the simplification potential and – whenever feasible – quantify the burden reduction (see Tool #2 (*The Regulatory fitness programme (REFIT) and the Fit for Future Platform*)). Quantification of administrative costs is also crucial for implementing the ‘one-in, one-out’ approach (see Tool #59 (*Cost estimates and the ‘one in, one out’ approach*)).

3. METHODOLOGICAL GUIDANCE

For methodological guidance, seek the advice of your DG (or the Secretariat-General) ‘better regulation’ support function as well as that of the specific help desks set up in various DGs for specific types of impacts.

Refer to the various tools on how to assess impacts²⁰⁴, costs and benefits²⁰⁵ and to the other tools of relevance for the initiative in question.

4. LIST OF POTENTIAL IMPACTS

The table below can be consulted for further details on each screened impact type and includes a reference to a relevant tool for further guidance²⁰⁶. The last column indicates the most relevant sustainable development goals (SDGs) identified for each listed impact (see also Tool #19 (*Sustainable development goals*)).

Impact on	Key questions	SDG
<p>Climate (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane, nitrous oxide, etc.) into the atmosphere? • Does the option affect economic incentives set up by market-based mechanisms (MBMs) created by Union law (e.g. first and second round incentives and price signals under the EU’s Emission Trading System)? • Does the option affect the emission of ozone depleting substances (CFCs, HCFCs etc.)? • Does the option affect our ability to adapt to climate change? 	
<p>Air quality (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc.)? 	

²⁰⁴ See Chapter 3 of the toolbox

²⁰⁵ See Chapter 8 of the toolbox.

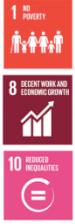
²⁰⁶ The order corresponds to the order presented in Section 2 above and does not imply a different degree of importance.

Impact on	Key questions	SDG
		
Water quality and resources (Tool #36)	<ul style="list-style-type: none"> • Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources? 	
Soil quality or resources (Tool #36)	<ul style="list-style-type: none"> • Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)? 	
Biodiversity, flora, fauna, and landscapes (Tool #36)	<ul style="list-style-type: none"> • Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? • Does it affect protected or endangered species or their habitats or ecologically sensitive areas? • Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors, or buffer zones? • Does the option affect the scenic value of protected landscape? 	
Animal welfare (Tool #32)	<ul style="list-style-type: none"> • Does the option have an impact on health of animals? • Does the option affect animal welfare (i.e. humane treatment of animals)? • Does the option affect the safety of feed? 	
Working conditions, job standards and quality (Tool #30)	<ul style="list-style-type: none"> • Does the option affect wages, labour costs or wage setting mechanisms? • Does the option affect employment protection (the quality of work contracts, risk of false self-employment)? • Does the option affect undeclared work? • Does the option affect work organisation? • Does the option affect occupational health and safety? • Does the option affect the exercise of labour standards? • Does the option affect social dialogue? • Does the option affect access to vocational training and career development advice? • Does the option affect participation, information, and consultation schemes for employees? 	
Public health and safety and health systems	<ul style="list-style-type: none"> • Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, 	

Impact on	Key questions	SDG
(Tool #31)	<p>occupation, nutrition)?</p> <ul style="list-style-type: none"> • Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise, air, water, or soil quality? • Will the option affect health due to changes waste disposal? • Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? • Are there specific effects on particular risk groups (determined by age, gender, disability, minority of ethnic or racial background, social group, mobility, region, etc.)? • Does the option affect the quality and/or access to health services and the financing and organisation of health systems in particular in urban, rural, mountainous, insular, sparsely populated areas and in the EU outermost regions? • Does the option affect the cross-border provision of health services, referrals across-borders and cooperation in border regions? 	
<p>Culture (Tool #31)</p>	<ul style="list-style-type: none"> • Does the proposal have an impact on the preservation of cultural heritage? • Does the proposal have an impact on cultural diversity? • Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources? 	
<p>Governance, participation, and good administration (Tools #10, #28, #30)</p>	<ul style="list-style-type: none"> • Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? • Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? • Does it affect the autonomy of the EU and national social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? • Does the implementation of the proposed measures affect public institutions and administrations, for example as regards their responsibilities? • Does the option make the public better informed about a particular issue? Does it affect the public's access to information? • Does the option affect political parties or civic organisations? • Does the option consider eGovernment principles? 	
<p>Education & training, and education & training systems (Tools #30, #31, #34)</p>	<ul style="list-style-type: none"> • Does the option affect the level of education and training outcomes? If yes, will it affect differently the level of education in urban, rural, cross-border, insular, or sparsely populated and mountainous areas or in the EU outermost regions? • Does the option affect the skills used by individuals? • Does it have an effect on the education and mobility of workers? • Does the option affect the access of individuals to education or and/or vocational and continuous training and quality? If so, how are different social groups (determined for example by age, gender, disability, minority 	

Impact on	Key questions	SDG
	<p>ethnic or racial background etc.) affected?</p> <ul style="list-style-type: none"> • Does it affect the cross-border provision of services, referrals across-borders and cooperation in border regions? • Does the option affect the financing and organisation of education and training systems? • Does it affect universities and academic freedom/self-governance? • Does the option change the productivity of the human capital? 	
<p>Conduct of business (Tools #21-25)</p>	<ul style="list-style-type: none"> • Will it impose additional costs on businesses? • How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? • Will it lead to creating new or closing down businesses? • Are some products or businesses treated differently from others in a comparable situation? How are individual Member States affected? 	
<p>SMEs (Tool #23)</p>	<ul style="list-style-type: none"> • What is the impact (positive or negative) of the option on the operation and competitiveness of SMEs and micro-SMEs in particular? 	
<p>Administrative costs on businesses (Tool #58)</p>	<ul style="list-style-type: none"> • Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)? 	
<p>Sectoral competitiveness, trade and investment flows (Tool #21, 27)</p>	<ul style="list-style-type: none"> • What impact does the option have on the cost of doing business which includes the costs of intermediate inputs (e.g. energy) and production related factors such as labour and capital? • What productivity effects does the option have? • What impact does the option have on a business' capacity to innovate i.e. its ability to produce more/higher quality products and services that meet customers' expectations? • What impact does the policy option have on a business' market share and comparative advantages in an international context (e.g. imports, exports, investment flows, trade barriers, regulatory convergence, etc.)? • How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? • How will investment flows be affected and the trade in services? • Will the option give rise to trade, customs, or other non-trade barriers? • Will the option affect regulatory convergence with third countries? • Have international standards and common regulatory approaches been considered? 	

Impact on	Key questions	SDG
<p>Functioning of the internal market and competition (Tools #24, #25)</p>	<ul style="list-style-type: none"> • What impact (positive or negative) does the option have on the free movement of goods, services, capital, and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc.? 	 
<p>Public authorities (Tool #58)</p>	<ul style="list-style-type: none"> • Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? • Does it bring additional administrative costs on public authorities? • Does the option require the creation of new or restructuring of existing public authorities? 	
<p>Sustainable consumption and production (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option lead to more sustainable production and consumption? • Does the option change the relative prices of environmentally friendly and unfriendly products? • Does the option promote or restrict environmentally un/friendly goods and services? • Will it lead to businesses becoming more, or less polluting through changes in the way in which they operate? 	 
<p>Efficient use of resources (renewable & non-renewable) (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option affect the use of renewable resources (fish, wood etc.) and lead to their use being faster than they can regenerate? • Does it reduce or increase use of non-renewable resources (groundwater, minerals etc.)? • Does the option lead to changes in business opportunities linked with more efficient use of resources? 	     
<p>Land use (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? • Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture, or land abandonment)? • Does the option affect the type of economic activity linked to the change in land use? 	   
<p>The likelihood or scale of environmental and climate risks (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms? • Does the option affect the developments in the insurance markets? 	 

Impact on	Key questions	SDG
		
<p>Employment (Tool #30)</p>	<ul style="list-style-type: none"> • To what extent are new jobs created or lost? • Are direct jobs created or lost in specific sectors, professions, regions or countries? Which specific social and or age groups are affected, including groups determined by gender, disability, migrant, or minority of ethnic or racial background? • Are there significant indirect effects which might change employment levels? • Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses? • To what extent does the option influence opportunities and incentives of workers/specific groups to work (i.e. supply of labour through labour market participation or mobility)? • Does the option have overall consequences for economic growth and employment? 	
<p>Income distribution, social protection and social inclusion (of particular groups) (Tools #30, #33)</p>	<ul style="list-style-type: none"> • Does the option affect peoples'/households' income and at risk of poverty rates? • Does the option affect inequalities and the distribution of incomes and wealth? • Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds? • Does the option affect the financing and organisation of social protection systems? • Does the option affect the access to and quality of basic goods and services particularly for those subject to social exclusion and from disadvantaged backgrounds? 	
<p>Technological development / Digital economy (Tool #28)</p>	<ul style="list-style-type: none"> • Does the option affect processes that could be simplified or even automated? • Does the option potentially create synergies with existing digital policies? • Does the option affect one or several existing digital eco-systems and actor and/or the exchange of data between different actors and systems (including across sectors and borders)? • Does the option consider the reduction of burden and costs for businesses and citizens through the use of digital technology? • Does the option affect the pace of the digital transformation of economic or social sectors, including public services and the take-up of innovative digital technologies? • Does the option affect the digital accessibility or the digital gap? 	
<p>Consumers and households</p>	<ul style="list-style-type: none"> • Does the option impact consumers' ability to benefit from the internal market or to access goods and services from outside the EU? 	

Impact on	Key questions	SDG
(Tool #33)	<ul style="list-style-type: none"> • Does the option affect the prices, quality, availability or choice of consumer goods and services? • Does the option affect consumer information, knowledge, trust, or protection? • Does the option impact the safety or sustainability of consumer goods and services? • Does the option impact vulnerable consumers? 	
Capital movements; financial markets; stability of the euro (Tools #21-25)	<ul style="list-style-type: none"> • How does the option contribute to improving the conditions for investment and the proper functioning of markets? • Does the option have direct impacts on macro-economic stability? 	 
Property rights, intellectual property rights (Tools #22, 29)	<ul style="list-style-type: none"> • Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? • Does it affect the protection and enforcement of intellectual property rights (patents, trademarks, copyright, other know-how rights)? 	 
Territorial impacts (specific (types of) regions and sectors) (Tool #34)	<ul style="list-style-type: none"> • Does the option affect economic activity, environment, or people living in cities, rural, cross-border, insular, mountainous, or sparsely populated areas and in the EU outermost regions to a significantly different extent than elsewhere in the EU? • Is the problem concentrated in certain areas (e.g. rural), regions, or Member States? • Does the initiative affect certain areas (e.g. rural), regions, or Member States in a disproportionate manner? • Does the initiative address regions differently according to their traits/endowments and thus lead to uneven territorial development? • Does one or the other option distort the principle of territorial cohesion as one of the founding principles of the EU? • Does the initiative have an effect on the EU outermost regions taking into account their constraints (as per art. 349 TFEU) and on other island, cross-border and mountain regions taking into account their characteristics (as per art. 174)? <p><i>If the answer to any of these question is positive, the Territorial Impact Necessity Check will help assess the need of a more in-depth analysis of territorial impacts</i></p>	   
Innovation (productivity and resource efficiency), research (academic and industrial), (Tool #22)	<ul style="list-style-type: none"> • Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production methods, technologies, and products? • Does it promote or limit academic or industrial research? • Does it promote greater productivity/resource efficiency? 	  
Fraud, crime, terrorism and security, including	<ul style="list-style-type: none"> • Does the option improve or hinder security, or affect crime or terrorism risks? • Does the option affect the criminal's chances of detection or his/her 	

Impact on	Key questions	SDG
<p>hybrid threats (Tool #26)</p>	<p>potential gain from the crime?</p> <ul style="list-style-type: none"> • Is the option likely to increase the number of criminal acts? Does it have an impact on a specific type of crime (money laundering, fraud, corruption, illicit production and trafficking, cybercrime, etc.)? Will it divert people away from or prevent crime? • Does it affect law enforcement capacity to address criminal activity? • Will it have an impact on security interests? • Does the option risk creating additional vulnerabilities and exposure to hybrid threats²⁰⁷? • Does the option address directly or indirectly a persistent hybrid threat challenge? • Is the option likely to reduce the exposure to hybrid attacks/incidents? • Does it affect the victims of crime and witnesses or their rights? • Does the option affect the risk of environmental fraud? 	
<p>Resilience, technological sovereignty, open strategic autonomy, security of supply</p>	<ul style="list-style-type: none"> • Does the option affect the EU's resilience in the relevant policy area? • Does the option improve or hinder the technological sovereignty of the EU as regards critical technologies? • Does the option reduce or exacerbate existing dependencies on third countries as regards critical technologies and value chains? • Does the option affect the Union's essential security interests, in particular as regards critical technologies, infrastructure and value chains? 	
<p>Transport and the use of energy (Tools #21, 22, 36)</p>	<ul style="list-style-type: none"> • Does the option affect the energy intensity of the economy? • Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc.) used in energy production? • Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? • Does it increase or decrease vehicle emissions? • Will the option increase/decrease energy and fuel needs/consumption? 	
<p>Food safety, food security and nutrition</p>	<ul style="list-style-type: none"> • Does the option affect the safety of food and feed? • Does the option affect food and nutrition security (both in EU and third countries): production (including agricultural products), distribution, trade, and consumption of food (including access, affordability and nutritional quality)? 	
<p>Waste production, generation and recycling (Tool #36)</p>	<ul style="list-style-type: none"> • Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of, or recycled? 	
<p>Third countries, developing countries,</p>	<ul style="list-style-type: none"> • Does the option alter the recognition of the International Labour Organisation's core labour standards and other ratified ILO Conventions 	

²⁰⁷ Hybrid activities by State and non-state actors aim to destabilise countries by undermining public trust in government institutions and by challenging the core values of societies and deepening social divisions. Hybrid threats range from cyber-attacks disrupting the economy and public critical services to targeted disinformation campaigns and hostile military actions.

Impact on	Key questions	SDG
<p>and international relations</p> <p>(Tools #27, 35)</p>	<p>(classified as up to date by the ILO) and the implementation of the ILO Decent Work Agenda in third countries?</p> <ul style="list-style-type: none"> • Are there employment, social protection, and poverty impacts in non-Member States (including developing countries)? • Are there the impacts on gender equality and on the most vulnerable groups of society, including persons with disabilities? • Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy? • Is the option compliant with legal commitments such as WTO Agreements and Free Trade Agreements, Economic Partnership Agreements, investment protection agreements and other preferential trade arrangements? • Does it affect EU foreign policy and EU/EC development policy? Does it comply with the obligation of Policy Coherence for Development? • What are the impacts on third countries with which the EU has preferential trade arrangements? Does it affect the interest of the ACP group of states party to the Cotonou Partnership Agreement? • Does it affect developing countries at different stages of development (least developed and other low-income and middle-income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries? 	
<p>Fundamental rights</p> <p>(Tool #29, #30)</p>	<ul style="list-style-type: none"> • Does the option impact on any of the fundamental rights endorsed by the EU Charter of Fundamental Rights: <ul style="list-style-type: none"> – Dignity (<i>right to life, personal integrity, prohibition of torture, slavery, forced labour, the death penalty</i>) – Freedoms (<i>liberty, privacy, protection of personal data, marriage, thought, conscience, religion, expression, assembly, arts and sciences, education, conduct business, work, property, and asylum</i>) <ul style="list-style-type: none"> ○ Does the option affect any of the individual's freedoms? ○ Does the option involve the processing of personal data and are the individual's right to access, rectification and objection guaranteed? ○ Does the option affect the freedom to conduct a business or impose additional requirements increasing the transaction costs for the economic operators concerned? ○ Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? – Equality (<i>equality before the law, non-discrimination on basis of sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation, cultural, religious and linguistic diversity, the rights of children and the elderly, integration of persons with disabilities</i>). <ul style="list-style-type: none"> ○ Does the option safeguard the principle of equality before the law and would it affect directly or indirectly the principle of non-discrimination, equal treatment, gender equality and equal opportunities for all? ○ Does the option have (directly or indirectly) a different impact on 	

Impact on	Key questions	SDG
	<p>women and men?</p> <ul style="list-style-type: none"> ○ Does the option ensure respect for the rights of people with disabilities in conformity with the UN Convention on the rights of persons with disabilities? ○ Does the option affect the rights of the child (or group) and respect of the UN Convention on the rights of the child? <p>– Solidarity (<i>right to fair working conditions, protection against unjustified dismissal, and access to health care, social and housing assistance</i>)</p> <p>– Citizens' Rights (<i>to vote in European Parliament and local elections, to move freely within the EU, to good administration, to access documents and to petition the European Parliament</i>)</p> <p>– Justice (<i>the right to an effective remedy, a fair trial, to the presumption of innocence, the principle of legality, non-retrospectivity and double jeopardy</i>)</p> <ul style="list-style-type: none"> ○ Does the option affect the individual's access to justice? <ul style="list-style-type: none"> ● Are the rights in question absolute rights, which may not be subject to limitations? ● Do the options have opposing impacts on different fundamental rights? 	

TOOL #19. SUSTAINABLE DEVELOPMENT GOALS

1. POLICY CONTEXT AND SDGs FRAMEWORK

The UN established its 2030 Agenda for Sustainable Development in 2015. It sets out a framework to steer sustainable development globally via a set of **17 sustainable development goals (SDGs)** and **169 targets**. The SDGs cover **environmental, economic, and social aspects**, and are relevant for the Commission's system of better regulation that aims to mainstream the sustainable developments goals into the policymaking process, so that every legislative proposal contributes to the 2030 sustainable development agenda of the UN²⁰⁸.



The EU is committed to implement the 2030 Agenda. The 2016 Communication 'Next steps for a sustainable European future' announced detailed monitoring of the SDGs in the EU from 2017 onwards. This commitment by the Commission was taken further in the 2019 Reflection Paper 'Towards a sustainable Europe by 2030'²⁰⁹, and the Commission work programme 2020 put the SDGs at the heart of its policymaking²¹⁰. The Commission has given a central role to SDGs across policies, as highlighted in the Commission staff working document 'Delivering on the UN's SDGs – A comprehensive approach'. The OECD is also active in promoting policy coherence for sustainable development. In December 2019, the OECD published a recommendation to help equip policymakers with the necessary institutional mechanisms and policy tools to support and promote coherent policies for sustainable development and the universal commitments made under the 2030 Agenda and the sustainable development goals²¹¹.

An **EU SDG indicator set** with 100 indicators to monitor the EU's progress towards the SDGs underpins the EU SDG monitoring report published annually by ESTAT. The EU SDG

²⁰⁸ For very technical initiatives, it might not be possible to make a link to SDGs. In this case, the report will indicate this transparently. In some cases, links to SDGs are only indirect, which should also be transparently reported.

²⁰⁹ COM(2019) 22 final

²¹⁰ Commission Work Programme 2020, « A Union that strives for more », COM(2020) 37 final of 29.1.2020.

²¹¹ OECD 2019, [Recommendation](#) of the Council on Policy Coherence for Sustainable Development, OECD/LEGAL/0381.

indicator set is open to regular reviews. It is closely related with and complements the UN’s indicator list from July 2017 that includes **231 individual indicators** to monitor the global progress towards the SDGs²¹². The Commission’s KnowSDGs (Box 1) presents a full description of all the 17 goals and 169 targets, including the list of UN and EU SDG indicators.

Every impact assessment or evaluation process will involve a pragmatic identification of the significant environmental, social, and economic impacts that will be assessed and reported²¹³. Tool#18 links the various impacts with the relevant SDGs. Each specific tool on impacts (tools #21 to #36) includes a table that helps to identify the relevant SDGs and includes a selection of the most relevant indicators. A number of tools also provide support to quantify the various impacts (and potentially changes in SDG-related indicators (see Chapter 8).

Since SDGs are universal, the EU commitment to support their implementation includes not only ensuring progress internally. For this reason, the assessment on progress towards the SDGs should keep into consideration the external effects, including in developing countries, which may call for applying in a complementary manner the tools relating to external impacts, in particular Tool #35 on impacts on developing countries and where relevant Tool #27 on external trade and investment.

2. SDGs IN IMPACT ASSESSMENTS, EVALUATIONS, AND FINAL PROPOSALS

The indicators and monitoring arrangements underpinning the SDGs can be used to describe the status quo, policy objectives, expected impacts of policy options and the observed changes resulting from new policies. As such, the SDG framework is highly relevant for impact assessments and evaluations. In addition, the expected benefits/impacts related to the SDGs should be reported transparently in the proposals that the Commission makes²¹⁴. Given that the 2030 Agenda is universal and applies to the EU (across institutions) and within Member States, this is useful information for the Legislator, consultative bodies, and national Parliaments in their respective treatment of the Commission’s proposal.

Impact assessments

The relevant SDGs should be identified²¹⁵ and the associated indicators should be used (if available) when preparing the following sections of the impact assessment report²¹⁶:

- **Problem definition**²¹⁷: It will often be possible to define the problem as a lack of progress in the area covered by one or more SDGs (and linked targets) as evidenced by the available SDG indicators and monitoring data presented at EU and national levels. Even where the SDGs (or linked targets) are not directly relevant to a given initiative it is still possible that some of the monitoring data collected to report on the SDGs in the EU is still useful to describe the consequences of a given problem.

²¹² Currently, 56% of those indicators are classified as tier 1 by the UNSC, meaning that data is regularly produced by countries for at least 50 per cent of countries and of the population in every region, while for the others, data is not regularly produced. (<https://unstats.un.org/sdgs/iaeg-sdgs/tier-classification/>)

²¹³ See Tool #18 (*Identification of impacts*)

²¹⁴ The principle of proportionate analysis applies; thus impacts will be quantified to the extent possible.

²¹⁵ See Tool#18 (*Identification of impacts*) and their link with SDGs.

²¹⁶ In addition, the same issues are relevant when preparing the ‘call for evidence’.

²¹⁷ See Tool #13 (*How to analyse problems*)

- **Objectives²¹⁸**: It may often be possible to describe the aims of a given initiative in terms of contributing to the implementation of one or more SDGs. At the initial stage, one should identify the relevant SDGs for the initiative at stake. In many cases, this can be further specified as delivering a qualitative or quantitative improvement in one or more of the indicators linked to one or more SDGs. The same indicators can be used to report on the performance of the initiative once implemented.
- **Policy options – baseline**: The baseline describes how the current situation is expected to evolve over time (without any policy intervention)²¹⁹. Again, the SDG-related indicators can be used to describe important aspects of the baseline.
- **Impact analysis**: The significant environmental, social, and economic impacts of each policy option are assessed in the impact assessment report. Where the SDG-related indicators have been used in the baseline, it is possible to present impacts of policy options in terms of the changes expected in those indicators from a given policy option, particularly for the preferred option. Ideally, such an assessment should be quantitative in nature.
- **Monitoring arrangements**: Every impact assessment should describe how the performance of the intervention will be monitored as part of a future evaluation. There may be a role for the SDG-related indicators²²⁰ particularly where these have been used to define the objectives to be achieved by the initiative.
- **Annex 3**: Every impact assessment must report in a dedicated table identifying the relevant SDGs for a given initiative. In addition, for the preferred option, the table needs to assess the progress towards the identified SDG targets. For the cases, where the SDG targets are quantifiable and so is the progress to reach them, the table should present these estimates. When the progress cannot be quantified, the table should give an indicative direction in relation to the relevant SDG targets (whether the preferred option is likely to get the EU closer to the target / improve, stay neutral or get away from the target / deteriorate). In view of interlinkages across the SDGs, the table should be accompanied by explanations describing possible synergies and trade-offs between specific SDGs and justifications for the proposed policy choices.

Include in the ‘call for evidence’ the above considerations on SDGs when preparing the documents to be published with the ‘call for evidence’ defining problems, objectives, policy options and a preliminary assessment of impacts.

For financial programmes and financial instruments²²¹, reference to the SDGs should also be considered for ex-ante evaluations in an analogous manner as for impact assessments.

Evaluations and fitness checks

The monitoring arrangements present the link between the evaluation, impact assessment and the relevant SDGs with their associated indicators and data collection activities.

When impact assessments pre-date the SDGs (and their associated indicators) or do not refer to the SDGs even though they may be relevant:

²¹⁸ See Tool #15 (*How to set objectives*)

²¹⁹ See Tool #16 (*How to identify policy options*) and Tool #60 (*Baselines*)

²²⁰ SDG indicators may be broader than operational objectives of an initiative. It may be difficult to disentangle the effect of a particular measure from other measures also acting on a specific SDG objective.

²²¹ See Tool #9 (*Spending programmes, financial instruments, and budgetary guarantee*)

- In the latter case, the evaluation could still refer to the contribution to the implementation of relevant SDGs.
- The evaluation can still make use of the SDG data sets and indicators when assessing the performance of the intervention so long as an appropriate baseline is used (complemented with the SDGs but consistent with the original impact assessment).
- The evaluation will then have to collect whatever relevant evidence exists to assess performance, linking it to the relevant SDG.

Commission proposals – explanatory memorandum

While it is important to mainstream the SDGs into policymaking processes, it is also important that the Commission reports transparently and effectively on its activities to make progress in the areas relevant to each SDG.

Therefore, when the Commission presents a new proposal (regulatory or financial) it will explain its objectives in terms of contribution to the implementation of the relevant SDGs at stake and expected impacts in terms of their associated indicators. This information will help inform the deliberations of the co-legislators. The explanatory memorandum²²² should summarise the key findings of the impact assessment (or ex-ante evaluation) relevant to the SDGs, based on the analysis presented in Annex 3 of the impact assessment (or the relevant analysis in ex-ante evaluation).

3. ADDITIONAL INFORMATION SOURCES AND AVAILABLE TOOLS

The Commission's website KnowSDGs (box 1) presents a full description of all the 17 goals and 169 targets, including the list of UN and EU SDG indicators. All the information is organised by goal, and for each EU indicator there is a direct link to the ESTAT data browser, where the user can visualise the full description of the indicator and access the corresponding data by country and year.

The platform offers interactive tools to explore: 1) how EU policies relate to the SDGs, 2) what SDG interlinkages are and how they can be identified, and 3) modelling tools that can be used to look at the SDGs through a quantitative lens

Box 1: Tools for the analysis of SDGs - the KnowSDGs Platform

The KnowSDGs (Knowledge base for the Sustainable Development Goals) platform provides interactive and easy-to-use tools and organises knowledge on policies, indicators, methods, and data to support the evidence-based implementation of the SDGs. The following tools are available on the platform to support policy makers in contextualising their policies within the SDG framework.

The **SDG policy-mapping tool** is designed to help policymakers identify the SDGs that may potentially be impacted or linked to their policy. Utilising automatic text classification, the tool provides a semantic analysis of any policy document to identify the relevant SDGs (at goals and targets level) that are addressed in the text, based on a database of relevant keywords. The tool is applicable at different stages of the policy cycle and is a useful guidance for policymakers in bringing the complete picture of SDGs to their attention, along with their extent and the complexity of their interactions.

²²² See Tool #40 (*Drafting the explanatory memorandum*)

In its interactive version – **the SDG Mapper** – the user can upload any policy-related text to a secure portal, and immediately receive a preliminary analysis of the relevant SDGs and targets. It also facilitates the production of infographics on the relevant SDGs, for instance in a draft proposal, thereby making it particularly useful in the ‘better regulation’ context. Since data interpretation is crucial to assure correct assessment of the relevant SDGs and targets, the JRC can provide additional support for deeper analysis and interpretation of results.

In addition, the **EnablingSDGs tool** facilitates policymakers in the identification of interlinkages – synergies and trade-offs – and interactions between different SDGs, assessing impacts of different policy choices, highlighting second-order effects and potential unintended consequences of the policy proposal. This specific toolkit facilitates engagement of policymakers (and eventually also stakeholders, scientists etc.) in a dialogue to identify and characterise the relevant SDGs interactions. This can contribute in a more tangible manner to ensure a balanced integration of the three dimensions of sustainable development.

Moreover, the **SDGs modelling tool** aims to facilitate the use of models for sustainability assessment in the SDGs framework, through the identification of appropriate model(s) for the assessment of specific policy options. The tool provides the list of all the models run or developed by the Commission and included in the Modelling Inventory and Knowledge Management System (**MIDAS**) and their contribution to the SDGs (at goal, target, and indicator level). This tool offers a transparent mapping of how model outputs can be directly or indirectly linked to EU/UN SDGs indicators, therefore screening which models could be suitable to quantitatively evaluate the impacts of policy options on SDGs, targets, and indicators.

TOOL #20. STRATEGIC FORESIGHT FOR IMPACT ASSESSMENTS AND EVALUATIONS

1. WHAT IS STRATEGIC FORESIGHT AND WHY IT IS IMPORTANT

Strategic foresight seeks to embed foresight, understood as the discipline of exploring, anticipating, and shaping the future, into EU policymaking. The EU must make sure that it develops policies that are robust and future proof, and that policymakers and institutions are prepared to anticipate changes to proactively shape the future according to the EU's political priorities. Strategic foresight can help anticipate trends, risks, emerging issues, and their potential implications and opportunities to draw useful insights for strategic planning, policymaking, and preparedness. It can also support policymaking in the initial stages of the policy cycle, from initial problem scoping to option design, but also in reviewing and futureproofing existing policies.

This tool focuses on the practical use of strategic foresight in impact assessments and evaluations. More systematic use of foresight analysis for preparing impact assessments, evaluations, and fitness checks, should help Commission services better deal with uncertainty and ensure that Commission initiatives benefit from:

- clearer understanding of megatrends and drivers of change, which may impact the policy problem and its future evolution;
- policy objectives that consider the key future challenges;
- future-proof policy options that are designed to address the key future challenges.

Public consultations could also include foresight-related questions, to capture the stakeholders' perspective in the given policy area.

2. STRATEGIC FORESIGHT METHODS

Various methodologies and approaches can support embedding the foresight into the 'better regulation' framework²²³:

Firstly, impact assessments should take account of **megatrends**. These are long-term global driving forces that are observable in the present and are likely to continue to have a significant influence for a few decades. They have the potential to lead to large- and broad-scale transformations (see Table 1).

Secondly, the analysis of megatrends can be complemented with **the use of future (long-term) scenarios** as the basis for the development of more resilient and future-proof policies. Scenarios are plausible consistent pictures of the future, describing the context of a policy area. They may consider one or more megatrends. They can be used to assess and stress-test how policies and policy objectives would perform in these future situations, leading to strategic reflections of alternative options for policy decisions today.

Using scenarios could allow:

²²³ The Competence Centre for Foresight (JRC-FORESIGHT@ec.europa.eu) can provide support with these methodologies. Other foresight approaches, beyond megatrends and scenarios, may also be used where relevant.

- considering key uncertainties by understanding viable alternative future developments and the role and interests of different stakeholders therein;
- anticipating changes in overarching EU policy objectives in the medium to long term;
- assessing the performance of existing legislation against alternative future situations/scenarios, to identify which policies and strategic objectives need to be revised to become more robust to future scenarios.

The design of scenarios is resource- and time-consuming and should be planned well ahead. If this is not possible, there is a sizeable number of existing scenarios (e.g. developed for climate policies²²⁴ or pension and inter-generational issues²²⁵) and foresight studies²²⁶ that may inform the futureproofing of other policy areas. Scenarios are also closely linked with other 'better regulation' tools such as baselines (Tool #60).

Table 1: Overview of megatrends in the Commission's Megatrends Hub²²⁷

<p>Continuing urbanisation By 2100, the urban population could reach 9 billion. Cities are increasingly functioning autonomously, setting new social and economic standards.</p>	<p>Growing consumption By 2030, the consumer class is expected to reach 5 billion people. This means 2 billion more people with increased purchasing power than today.</p>	<p>Diversifying inequalities Absolute number of people living in extreme poverty has been declining. The gaps between the wealthiest and poorest of the population are widening.</p>	<p>Increasing demographic imbalances World population may reach 8.5 billion by 2030, with rapid growth in many developing economies, while shrinking in many developed countries.</p>
<p>Diversification of education and learning New generations and hyperconnectivity are rapidly changing both educational needs and modes of delivery.</p>	<p>Shifting health challenges Science and better living standards reduced infectious diseases. Unhealthy lifestyles, pollution, other anthropogenic causes turn into health burdens.</p>	<p>Accelerating technological change and hyperconnectivity Technologies are changing the nature and speed of new scientific discoveries and are transforming systems of production, management, and governance.</p>	<p>Changing nature of work New generations entering the workforce and older generations working longer are changing employment, career models, and organisational structures.</p>
<p>Expanding influence of east and south The shift of economic power from the established Western economies and Japan towards the emerging economies in the East and South is set to continue.</p>	<p>Increasing significance of migration The social and political significance of migration has increased. Migration flows and dynamics have become more mixed in an interconnected world.</p>	<p>Increasing influence of new governing systems Non-state actors, global conscientiousness, social media and internationalisation of decision-making are forming new, multi-layered governing systems.</p>	<p>Changing security paradigm Diversification of threats and actors is generating new challenges to the defence and security communities, as well as to society as a whole.</p>
<p>Aggravating resource scarcity Demand for water, food, energy, land, and minerals are rising substantially, making natural resources increasingly scarce and more expensive.</p>	<p>Climate change and environmental degradation Continued unabated, anthropogenic pollution and greenhouse gas emissions will further increase changing climate patterns.</p>		

²²⁴ The [2020 Foresight study on Raw Materials](#) is based on the [2050 scenarios](#) to underpin the Climate Law.

²²⁵ E.g. [The 2021 Ageing report](#)

²²⁶ E.g. [Farmers of the future](#)

²²⁷ If time and other resources allow, a half-day [megatrends workshop](#) can help to understand how the future conditions may affect the policy objectives and policy problems. Ideally, this happens ahead of drawing terms of references for external studies and scoping possible baseline and modelling work (see Chapter 8). Involvement of a carefully selected group of 4-8 colleagues from related policy fields and possibly external experts with diverse and complementary perspectives can provide a multi-faceted assessment of long-term challenges and options.

Where relevant, based on the megatrends or scenarios, the following questions should be answered: (1) which megatrends apply to the policy problem? What do the scenarios talk about the policy problem? (2) which stakeholders are affected by the megatrends and scenarios?

These findings should be considered in a proportionate way in the relevant sections of the impact assessment (problem definition and baseline, policy objectives, policy options and their assessment) following the three steps below:

A. Identify the relevant megatrends/scenario that should be used	
Why?	Assure a systematic, future-oriented analysis of the problem drivers and their future evolution.
How?	Reflect on how relevant megatrends/scenario could affect the policy problem and its future evolution.

B. Analyse the impact of the relevant megatrends/scenario and define policy objectives	
Why?	Understand the effect of the relevant megatrends/scenarios on the policy problem and adapt policy objectives accordingly.
How?	Assess the long-term implications on the policy problem: which aspects of the problem would the relevant megatrends/scenarios affect/change? Which stakeholders would be more/less affected from this change?
	Integrate the findings into key challenges that need to be addressed by the policy options.

C. Design policy options to achieve future-proof policy objectives	
Why?	To future-proof the policy options to be resilient to changing boundary conditions.
How?	Develop policy options that address the key challenges identified in Step B to accommodate the evolution of the problem over time.
	Identify potentially weak aspects of other policy options and consider improvements to better address future needs.
	Consider in how far the policy options could themselves impact a megatrend/scenario, and whether this could have any effect on reaching policy objectives.

3. STRATEGIC FORESIGHT IN EVALUATIONS AND FITNESS CHECKS

Fitness checks and **evaluations** inform political priority setting, and contribute to strategic planning, as well as to the revision of existing legislation. While evaluations and fitness checks are ex-post assessment of existing policies, their goal is to provide input to future revisions of the policy instrument, asking: *is the intervention still relevant today and will it be relevant tomorrow?* Evaluations and fitness checks should look beyond the current relevance

and reflect on how the key evolutions, uncertainties and challenges of the future may affect the future relevance, coherence, and effectiveness of the policy area.

4. ADDITIONAL INFORMATION

- Stoermer, E. et al. (2020): Foresight – Using Science and Evidence to Anticipate and Shape the Future. In: Šucha, V and Sienkiewicz M. (ed.) JRC Handbook on Science and Evidence in the Policy Ecosystem. ISBN 978-0-12-822596-7, [DOI:10.1016/C2018-0-03963-8](https://doi.org/10.1016/C2018-0-03963-8)
- Wilkinson, A. (2017): Strategic Foresight Primer, EPSC. ISBN: 978-92-79-75373-2, DOI: 10.2872/71492
- ESPAS (2019): Global Trends to 2030. Challenges and choices for Europe. [ISBN: 978-92-76-04010-1, DOI:10.2872/074526](https://doi.org/10.2872/074526)
- European Parliamentary Research Service, Global Trends Team: Global Trendometer 2019. Essays on medium and long-term trends. [ISBN 978-92-846-6091-9, DOI:10.2861/051532](https://doi.org/10.2861/051532)
- ORBIS, the global foresight hub – online library of prospective studies
- Megatrends workshop tool to assess long-term implications of megatrends

TOOL #21. COMPETITIVENESS CHECK

1. INTRODUCTION

All impact assessments should assess how the proposed policy intervention is expected to affect competitiveness. The Competitiveness check (Annex 5 of the impact assessment) summarises the key impacts on competitiveness of the preferred policy option and the situation of the most affected sectors, when relevant (see step 2). The main report or dedicated annexes can present more detailed analysis.

EU initiatives are likely to affect competitiveness when they affect one or more of the following dimensions:

- **cost and price competitiveness** - the capacity to produce goods or services at a lower cost and/or offer them at a lower price;
- **capacity to innovate** - the quality or originality of goods or services, and technological development and innovation of products and/or processes;
- **international competitiveness** - the sectors' market shares on international markets, which reflect the comparative advantages of European companies;
- **SME competitiveness** – the ability of SMEs to compete with other market participants.

This tool is based on a more detailed operational guide on how to assess impacts on sectoral competitiveness²²⁸. The 2021 OECD report "*How do laws and regulations affect competitiveness: The role for regulatory impact assessment*" endorses and builds on the methodology presented below.

2. GETTING STARTED: ARE IMPACTS ON SECTORAL COMPETITIVENESS POTENTIALLY SIGNIFICANT?

The principle of proportionate analysis means that not all IAs need to assess sectoral competitiveness in depth. The first question to be answered is whether an initiative is likely to have a significant effect on sectoral competitiveness or not.

Step 1. Is the initiative likely to have significant impacts on competitiveness?

While the impacts on competitiveness need to be assessed for every policy intervention, you may use **the checklist** in Box 1 to get a first indication of the depth and scope of the analysis needed. Box 1 uses an example of a proposal to ban the use of hazardous materials in EU industrial products. This first assessment of the expected impacts on competitiveness does not require an in-depth study or quantitative techniques and you can use your expertise only. The replies may not be straightforward and may even change as you advance in your analysis.

²²⁸ [Operational guidance for assessing impacts on sectoral competitiveness within the Commission Impact Assessment system, SEC \(2012\) 91.](#)

Box 1 - CHECKLIST. Is the ban of use of hazardous material likely to have a significant impact on factors affecting the competitiveness of EU companies?

	Likely significant impact
Cost and price competitiveness	
Cost of inputs	Yes
Cost of capital	No
Cost of labour	Cannot say
Other compliance costs (e.g. reporting obligations)	No
Cost of production, distribution, after-sales services	Yes
Price of outputs (e.g. price controls)	Cannot say
Capacity to innovate	
Capacity to produce and bring R&D to the market	Yes
Capacity for product innovation	Yes
Capacity for process innovation (including distribution, marketing, and after-sales)	Cannot say
Access to risk capital	Cannot say
International competitiveness	
Market shares (EU single market)	Cannot say
Market shares (external markets) ²²⁹	No

If the impacts are expected to be significant or when there is considerable uncertainty (i.e. many unanswered questions in the checklist), a further analysis of the impacts on competitiveness would be warranted.

For proposals that are likely to have only a limited impact on competitiveness and for which a deeper analysis would be disproportionate, the assessment may remain mainly **qualitative**, but this should be justified in the Competitiveness check (Annex 5 to the impact assessment). Where impacts are expected to be **significant**, in addition to the qualitative assessment, you should strive to include **quantitative** elements and carry out a quantitative estimation of impacts. Whereas a simple analysis may be limited to direct effects, a deep analysis of competitiveness should consider direct and indirect impacts, both positive and negative, and account for short- and long-term effects.

Step 2. Which sectors are affected? What is the competitive position of the most affected sectors?

Before assessing the expected impacts of the initiative on competitiveness in depth, you should try to **identify the sector(s) most affected by the initiative and assess their current competitive position**.

²²⁹ The sector's market shares on the international markets.

For most **sectoral initiatives**, the identification of the most affected sectors will be straightforward, but some initiatives are **horizontal** and affect the whole economy (e.g. employment or energy policies). In such cases, you should look at the distribution of impacts across sectors. You may need to consider labour, energy, resource and capital intensities to better gauge the distribution of impacts and identify the most affected sectors if feasible.

When trying to identify the most affected sectors, it is important to consider direct impacts and indirect impacts. **Indirect impacts** are triggered by changes in relative prices and changes in supply and demand for inputs and outputs in the directly affected sector. They can affect downstream or upstream sectors as well as markets for complementary or substitute goods and may occur in parallel to the direct effects or with a delay (second round effects). They are important for two reasons. First, they may be greater than the direct effects if they affect many sectors. Second, they can alter the overall expected benefits/costs.

The interservice coordination group can help identify the sectors that are most affected by the initiative. In case it is impossible to identify a few most affected sectors due to the horizontal nature of an initiative, this should be explained and justified in the Competitiveness check (Annex 5 to the impact assessment).

If the policy proposal is expected to affect certain sectors in particular (either because of its sectoral nature or in case of horizontal proposals because some sectors would be more directly affected), **the impact assessment should assess their current competitive position**. The aim is to see if the sectors most affected by the initiative are currently under particular 'stress' due to the cumulative impacts of regulation or other factors. Such analysis should inform policymaking and provide useful context for the competitiveness analysis to see whether the additional regulatory costs seem bearable or whether this might 'push many EU businesses over the cliff'.

This analysis should also allow for a comparison of the competitive situation of EU companies in a given sector with (i) the situation of non-EU companies in the same sector (international competitiveness); (ii) the situation of companies in other sectors that serve as a benchmark, e.g. all manufacturing sectors, possibly differentiating companies by their size (SME competitiveness).

If data are available, the assessment of the current competitive position of the most affected sectors should be **quantitative, based on several indicators** covering different dimensions of competitiveness, and (where available) include a time series to assess the evolution.

The list of indicators in Box 2 below is indicative. It might be adjusted to consider the key impacts of the initiative. For example, initiatives with significant cost implications might require more in-depth analysis in relation to productivity and profitability of the sector, whereas those related to research might require analysing innovation related indicators. The availability of data for the sector concerned will also influence the type of indicators analysed.

Box 2. List of possible indicators

1) Key facts and trends concerning the sector:

- weight of the affected sector in the EU economy, as measured by its share

in value added, turnover and employment, and the evolution of key indicators over time (change in gross value added, turnover and employment in the last several years);

- number and distribution of firms, including the share of SMEs (possibly differentiating between different size classes)²³⁰;
- the “dynamism” of the sector captured by the number of high-growth enterprises (HGEs) and/or the number of employees working in HGEs²³¹.

2) Productivity and profitability of the sector

- labour productivity or total factor productivity of the sector;
- current costs and/or profitability, as measured by net profit margins, gross operating rates or return on equity²³², if possible differentiating between EU and non-EU companies and by size class of companies.

3) International position of the sector

- EU market share in global production or in global exports, and trade flows (EU exports and imports, EU trade balance);
- flow of Foreign Direct Investment (ratio of inward/outward FDI stock to value added). The ratio of inward FDI stock to value added indicates the contribution of FDI to capital formation and signals the attractiveness of the host country. The ratio of outward FDI stocks to value added is an indicator of corporate strength, where companies venture abroad to seize opportunities from foreign markets and resources;
- export market shares show how much of the total ‘world’ export is covered by the export of a particular country for each industry. They reflect the capacity to respond to external demand or to open up new markets in direct comparison to international competitors;
- revealed comparative advantage (RCA), which compares the share of a given industry’s exports in the EU’s total exports with the share of the same industry’s exports of a group of reference countries or the world as a whole;
- relative trade balance (RTB), which compares the trade balance of a particular commodity to the total volume of trade, exports plus imports;
- terms of trade, measured by, for example relative unit labour costs (RULC), to assess the cost of labour in a given industry relative to its productivity (unit labour costs) and relative to the corresponding index in another country;
- firms’ assessments of their competitive position in foreign markets, as inquired by the Joint Harmonised EU Programme of Business and Consumer Surveys.

4) Innovation in the sector

²³⁰ Concentration measures should be analysed in relevant markets. For example, in the context of a regulation about glyphosate, one would want to understand the level of concentration in the glyphosate market, not the entire chemicals sector.

²³¹ [High-growth enterprises - statistics - Statistics Explained - Eurostat](#)

²³² It could also be interesting to analyse distributions of profit margins or return on investment, across firms and across time, using firm-level databases, yet this requires having licenses to access such databases and the technical capacity to use them.

- numbers of innovation active or innovative firms, as a percentage of total firms in the sector;
- R&D expenditure in the sector.

Most of the above data can be found in the Eurostat database, in particular in the sections on Structural Business Statistics, production of manufactured products (PRODCOM) and international trade in goods (COMEXT) [and services](#) (EU trade in services). Furthermore, the OECD database is a valuable source. Section 5 furthermore lists several additional databases which could be consulted.

You should also take stock of existing sectoral and market studies and evaluations completed by the Commission and pay particular attention to the sectors already identified as being at competitive disadvantage, for example in the Draghi report²³³, as well as any other sector that may be identified as strategically relevant. You may also consult the websites and publications of the respective business associations or concerned social partner organisations.

The analysis of the competitive position of the most affected sectors should be summarised in Annex 5 of the impact assessment (Competitiveness check).

3. QUALITATIVE AND QUANTITATIVE ASSESSMENT OF IMPACTS ON COMPETITIVENESS

Annex 5 should present an overview of the **impacts of the preferred option on competitiveness**, along four dimensions of competitiveness, i.e. (i) cost and price competitiveness, (ii) international competitiveness, (iii) capacity to innovate and (iv) SME competitiveness.

Based on the analysis in the main report, Annex 5 should present an **overall assessment (score)** of each of the four competitiveness dimensions in a standardised table. The table should be accompanied by a **synthetic assessment (short narrative)** summarising the expected impacts of the preferred option on competitiveness and the main factors that affect competitiveness, including key figures on costs and benefits and any information that is particularly relevant for the overall assessment (for instance, if impacts are expected to evolve over time). If no impacts on competitiveness are signalled, this should be duly justified.

The assessment of the impacts on competitiveness should include quantitative analysis to the extent possible. Whereas qualitative assessment is mainly a narrative, quantification of impacts on competitiveness may require descriptive statistics, input-output analysis using national or sectoral accounts, applied general equilibrium modelling, or other econometric exercises. For policy proposals that affect a diverse set of sectors, models such as computable general equilibrium (CGE) and macro-econometric input-output models can be used to quantify overall impacts²³⁴. The impacts on competitiveness may vary over time, which should be reflected in the analysis.

The steps suggested below give an overview of possible outputs of the qualitative and quantitative analysis, rather than specific tools and methods to deliver them, as these would

²³³ The sectors identified by the Draghi report are energy, critical raw materials, digitalisation, broadband networks, computing, semiconductors, energy-intensive industries, clean technologies, automotive, defence, space, pharma and transport.

²³⁴ See Tool #61 (*Simulation models*)

depend on the issue at hand. The assessment of the competitive position of the most affected sectors (step 2) provides a valuable context and a starting point for the competitiveness analysis.

Step 3. What is the impact on cost and price competitiveness?

A policy proposal may have impacts on the cost of business operations and thus on returns on investment and investment flows. It may impose direct compliance costs on affected sectors, or it may affect costs indirectly, due to the change of behaviour of suppliers, consumers, employees and investors resulting from the intervention.

When assessing the impacts of the preferred option on cost and price competitiveness, you may consider the following questions:

- Is the initiative likely to affect the production costs for companies, by affecting the cost and availability of production factors such as labour (workers protection legislation, social security contributions, labour taxes, etc.), capital (access and costs of financing), natural resources, intermediate goods and services, energy, etc?
- Is the initiative likely to affect the compliance costs for companies (i.e. adjustment and administrative costs, other costs), such as time spent to comply with new policy requirements, adjustments to the production process, additional equipment, restructuring of the sector, etc?
- What is the likely impact on competition, market power in relevant markets and access to markets? Is the initiative likely to affect the number of suppliers or producers (licenses, permits, authorisation, barriers to entry and exit...), their ability and incentives to compete (price controls, bans or limits to marketing, standards favouring particular technologies...), the choices and information available to consumers (licenced shops, limits to mobility of customers between suppliers or producers, transparency and comparability of information ...), the free movement of goods, services, capital and people (self-employed and workers)?
- Considering the competitive position of the most affected sectors (step 2), what are the likely implications of changes in costs? Does any additional regulatory costs (the difference relative to the dynamic baseline) seem bearable for the most affected businesses?
 - Would the sector need a major restructuring such as closing of production lines, substitution of technologies, substitution of skills, etc.? Might it lead to closing down of enterprises?
 - Would companies, including SMEs or microbusinesses, be able to meet the cost of restructuring? Might the initiative lead to closing down of enterprises, job redundancies, etc.?
 - Will the impacts on costs and prices be different in the short and the long term?
 - Will the initiative help companies to improve their competitiveness in the long term (e.g. due to a first-mover advantage)?

It should be considered that additional regulatory costs may not affect companies uniformly, and in particular **SMEs' competitiveness** may be affected more profoundly by additional costs due to the more limited scope for economies of scale (see also Step 6).

For a more in-depth analysis, you may need to **quantify** the impacts in terms of changes in compliance and/or operational costs. It may be useful to complete the analysis with an overall cost breakdown (cost of labour, raw materials, energy etc.).

Step 4. What might be the impact on the sector's international competitiveness?

The assessment of impacts on competitiveness should consider the possible differential impact of the preferred option on domestic and foreign firms. For instance, if a policy proposal is likely to increase costs for EU producers (by e.g. introducing stricter product-safety requirements on the EU market), it may not affect EU manufacturers' relative prices and market shares if their non-EU competitors face the same requirements and there are no suitable cheaper substitutes. However, if the policy affects the production process (e.g. through stricter resource use or pollution standards), or raises labour costs (e.g. through new safety-at-work requirements), then EU manufacturers may be at a competitive disadvantage compared to firms located elsewhere.

When assessing the impacts on international competitiveness, the typical questions you may answer are:

- What is the likely impact of the initiative on the competitive position of EU firms with respect to non-EU competitors (i.e. level-playing field)?
- What is the likely impact of the policy option on trade and trade barriers (tariffs and non-tariff barriers)?
- Will the proposal impact an area where international standards, common regulatory approaches or international regulatory dialogues exist?
- Is it likely to affect cross-border investment flows, including the relocation of economic activity towards or away from the EU?
- What is the likely impact on resilience of EU companies?
- What is the likely impact on market shares in international markets?

You should consider the competitive position of the most affected sectors (step 2) in comparison with businesses outside the EU. In this context it is important to look at the current profitability of the EU companies as compared to international competitors to see if and to what extent additional costs of the initiative might put EU companies at a disadvantage compared to their international competitors.

See also the Tool #27 (*External trade and investment*).

Step 5. What is the impact on the enterprises' capacity and incentives to innovate?

When assessing the impacts on the capacity to innovate, the following questions should be considered:

- Does the initiative affect the capacity of companies or institutions to carry out R&D? Is it expected to have an impact on relevant skills, protection of intellectual property rights...?

- Is the initiative expected to impact on the capacity or incentives for product innovation (new products or features)? Is it expected to affect the availability of technical skills, new technologies, the respect of technology neutrality...?
- Is the initiative expected to impact on the capacity or incentives for process innovation (production and distribution, marketing, after-sales services)? Is it expected to impact on management and organisational skills? Does it ensure the 'digital by default' principle?
- Does the initiative affect the access of companies or institutions to risk capital and financing?

Within this step, for a more in-depth analysis, you may need to **quantify** the expected impacts on the capacity of affected enterprises to innovate. This analysis should preferably include several input and output indicators on sector innovations. The data from the EU Industrial R&D Investment Scoreboard²³⁵ and the Eurostat Community Innovation Survey²³⁶ constitute a good starting point. Data may also be obtained from the industrial chamber of the corresponding sector.

See also the Tool #22 (*Research & innovation*).

Step 6. What is the impact on SME competitiveness?

The impact of the initiative on the competitiveness of companies may differ depending on the companies' size. The analysis should be built on the findings of the SME test²³⁷, which is an integral part of the impact assessment process, and the analysis of the three dimensions of competitiveness analysed under steps 3-5. While the SME test assesses the impacts of the initiative on SMEs, this step helps to understand whether the impacts of the initiative on the competitiveness of SMEs differ substantially from those of large companies.

When assessing the impacts on SME competitiveness, the following questions should be considered:

- Does the direct impact of the initiative on the competitiveness of SMEs differ substantially from that of large companies?
- Is SMEs' competitiveness likely to be indirectly affected through their position in the value chain or through subcontracting? Are such indirect impacts particularly relevant for SMEs?
- Is the impact on competitiveness of micro-companies likely to differ from the impact on small- and medium-sized ones?
- To what extent is the initiative designed to minimise negative impacts on the competitiveness of SMEs?
- Does the initiative include mitigating measures such as simplified reporting, phasing -in obligations for SMEs...?

You may need first to look at the relevance of SMEs and micro-companies in the affected sector(s). Particular attention may be necessary for micro businesses (under 10 employees) as they may have fewer resources for taking on any possible adjustment costs or administrative

²³⁵ <https://ec.europa.eu/jrc/en/publications-list>

²³⁶ <https://ec.europa.eu/eurostat/web/microdata/community-innovation-survey>

²³⁷ See Tool #23 (*The 'SME test'*).

burdens. Within this step, for a more in-depth analysis, you may need to **quantify** the expected impacts on SMEs competitiveness.

See also the Tool #23 (*The 'SME Test'*).

4. HOW TO MINIMISE ANY NEGATIVE IMPACTS ON SECTORAL COMPETITIVENESS

If the analysis made under the previous section shows that certain sectors are disproportionately affected or disadvantaged, you should consider using possible mitigating measures. The aim is to achieve the policy objectives without compromising the competitiveness of EU companies. The list below sets out some of the approaches you might consider.

- Full or partial exemption of certain sectors or subsectors. This might include less onerous compliance requirements or deeming a certain subset of rules not applicable to certain sectors (e.g.: the Data Protection Regulation sets different requirements for e-mail vs. traditional mail marketing);
- Extended transition/compliance periods before the rules come into force where, for example, a service or product needs to be redesigned to be compliant (e.g. some ecodesign schemes are introduced by phases where lighter compliance requirements are set for the introductory phase);
- Varying requirements by type and/or size of business or type of product/service. For example, SMEs are only required to register but not to be fully licenced; or exempting smaller businesses from having to register or from paying fees.

When considering mitigating measures, it is always important to consider the relevant trade-offs. For instance, excessively extending transitional periods or varying requirements by type of business may entail a risk of reducing the effectiveness of the initiative and may privilege certain types of enterprises and, therefore, harm fair competition or create threshold effects.

The relevant sections of the tools on the 'SME test', impacts on trade and investment and impacts on innovation, can provide more details on how to minimize any negative impacts in these areas.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. EU databases

EUROSTAT: the main source for EU statistics, with data on industrial sectors' performance, structure, development, trade within the EU and outside the EU, employment, etc. Certain specific sections can be particularly useful:

- EU Structural Business Statistics ([SBS](#)): describe the detailed structure, economic activity, and performance of businesses over time, providing data on number of enterprises, persons employed, turnover, value-added, investment, productivity, SME share of added value and employment. It covers industry, construction, trade and services (data available for the EU-27 and for the Member States). The statistics can be broken down to a very detailed sectoral level (several hundred economic activities based on NACE classification).

- **PRODCOM:** Statistics on the production of manufactured goods in the Member States, measured by value (euros) and by volume (kg, m², number of items, etc.). Prodcum data cover the economic activities of mining and quarrying, manufacturing, and materials recovery, which refer to the sections B, C, and E of the 'Statistical classification of economic activities in the EU' (NACE).
- **EU Science and technology database:** R&D, innovation data, patent statistics, knowledge-intensive sectors, human resources in science and technology. It includes the Community Innovation Survey (CIS) - a survey of innovation activity in enterprises. The harmonised survey is designed to provide information on the innovativeness of sectors by type of enterprises, on the different types of innovation and on various aspects, such as the objectives, the sources of information, the public funding, the innovation expenditures etc. The CIS provides statistics broken down by countries, type of innovators, economic activities and size classes.
- **EU Digital economy and society:** statistics on digitalisation, which can be useful to analyse the uptake and usage of ICT, level of digitalisation of businesses, digital skills, etc.
- **EU trade in goods (COMEXT):** monthly data on imports and exports, providing values and quantities of the trade by product and partner country. In addition, data is available aggregated by product group, end use, mode of transport or tariff (if applicable), as well as some seasonally adjusted data and indices. Annual data on trading companies, including information about activity sector, enterprise size-class, ownership, type of trader, and indicators on trade concentration.
- **EU trade in services:** information on international trade in services, international supply of services by mode of supply, services trade by enterprise characteristics.
- **EU Short-term business statistics (STS):** the earliest statistics released by Eurostat to show emerging trends in the European economy, data for industry, construction, trade, services, excl. financial and public services. Include indices for production, turnover, producer and import prices as well as for some other indicators (construction costs, labour input), and quarterly indicators on business registrations and bankruptcies.

AMECO: annual macro-economic database with data for the EU, the euro area, EU Member States, candidate countries and other OECD countries, for a total of over 40 countries. Data is organised in eighteen chapters, from population and employment via main national accounts aggregates such as gross domestic product to sector accounts and the cyclical adjustment of public finance variables.

EU Industrial R&D Investment Scoreboard: The Scoreboard is a benchmarking tool which allows to, every year since 2004, monitor and analyse industrial R&D investment trends in the context of the EU's 3% of GDP R&D investment policy target, which is a key performance indicator of the EU's long-term competitiveness. Currently, it monitors the world's top 2,000 R&D investors. The data is published as a four-year time series to allow, for instance, to examine links between R&D and business performance.

ORBIS: Firm-level database by Moody's (subscription is required) containing comprehensive information on around 580 million companies across the globe. It can be used to research

individual companies, search for companies with specific profiles, and for general analysis, for issues such as turnover, employment, profits, investments, etc.

BACH - Bank for the Accounts of Companies Harmonised: Aggregated and harmonised information on the financial statements of non-financial companies, available for free, from 12 Member States (AT, BE, DE, ES, FR, HR, HU, IT, LU, PL, PT, SK,); 3 firms' size classes (small, medium-sized and large enterprises); 17 NACE sections and about 80 NACE divisions; time series of over 20 years; over 90 items, including assets, liabilities and the profit and loss account. It is used to analyse the assets, liabilities, financial position and profitability of enterprises, according to their sector and size class.

Joint Harmonised EU Programme of Business and Consumer Surveys: The programme interrogates every month some 120,000 company managers from across the EU about various aspects of their business (trend in production, employment, etc.). Once a quarter, manufacturing managers are explicitly asked whether the competitive position of their firm on foreign markets outside the EU improved, stayed the same or deteriorated.

EU KLEMS Growth and Productivity Accounts: For detailed sectoral productivity and total factor productivity for quantitative studies focusing on technical change in the industry (manufacturing).

data.europa.eu – the official portal for European data. A single point of access to data produced by EU, national, regional, and local public administration, as well as by some international organisations.

5.2. International databases

COMTRADE is a UN database that aggregates detailed global annual and monthly trade statistics by product and trading partner. It covers approximately 200 countries and represents more than 99% of the world's merchandise trade.

IEA Statistics & Balances (International Energy Agency). For energy prices, fossil fuel prices, etc.

IMF balance of payments (International Monetary Fund)

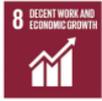
OECD.Stat: Contains statistics covering OECD members and the following areas:

- industry and Service Statistics;
- structural Analysis (STAN) Databases including Input-Output databases;
- structural and Demographic Business Statistics (SDBS) including Structural Business Statistics per economic sector;
- international Trade by Commodity Statistics (ITCS); and
- productivity Levels and GDP per capita.

UNCTAD: For data on foreign direct investment (FDI) to assess import and adoption of technical change through capital investment.

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

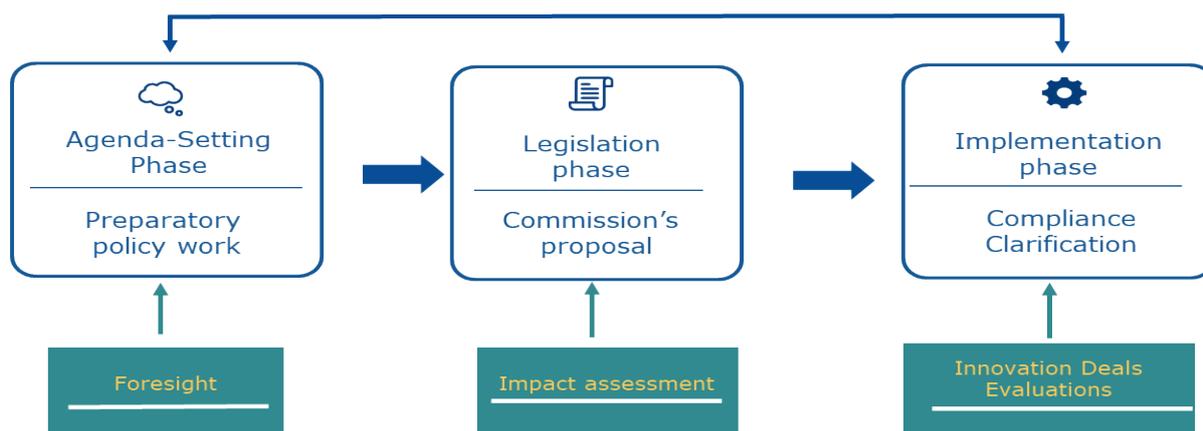
Relevant SDGs indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Real GDP per capita • Investment share of GDP • Purchasing power adjusted GDP per capita • Gross domestic expenditure on R&D • R&D personnel <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Annual growth rate of real GDP per capita • Annual growth rate of real GDP per employed person • Proportion of small-scale industries in total industry value added • Research and development expenditure as a proportion of GDP • Researchers (in full-time equivalent) per million inhabitants • Worldwide weighted tariff-average 	  

TOOL #22. RESEARCH AND INNOVATION

1. INTRODUCTION

This tool provides guidelines for analysing the interaction between EU initiatives and innovation in line with the innovation principle²³⁸. It ensures that the innovation dimension is considered when preparing and implementing EU legislation.

This approach also ensures that EU legislation considers emerging innovations that are in line with EU policy objectives, thus facilitating their development and adoption.



The innovation dimension may be considered at three key stages of the policy cycle:

- **agenda-setting:** foresight and horizon scanning;
- **preparation of EU legislation:** impact assessments;
- **implementation of EU legislation:** innovation deals and evaluations.

2. AGENDA SETTING: FORESIGHT AND HORIZON SCANNING

Foresight uses a range of methodologies, such as scanning the horizon for emerging changes, analysing megatrends, and developing multiple scenarios about the future. It is useful whenever there is a high degree of uncertainty surrounding changes to the relevant future context and to ensure that short-term actions are grounded in long-term objectives²³⁹. Horizon scanning is a methodology for detecting early signs of potentially important developments through examination of potential threats and opportunities, with emphasis on new technology²⁴⁰.

DG Research and Innovation can support an analysis of technological and business process innovation, drawing among others on the results of horizon scanning and foresight, e.g., should it be requested by the ISCG. This kind of analysis is particularly useful when the initiative:

²³⁸ See also Communication “A renewed European agenda for Research and Innovation – Europe’s chance to shape its future”, pp. 9-10: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018DC0306>

²³⁹ See European Commission (2020)493, 2020 Strategic Foresight Report, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0493&from=EN>; and Tool #4.

²⁴⁰ According to the OECD. Foresight: <https://www.oecd.org/strategic-foresight/whatisforesight/>

- (1) involves upstream policy formulation and generation of strategic options for an emerging policy area or a policy area that has not been regulated yet;
- (2) involves an assessment of existing legislation in light of technological changes and business process innovation, especially taking account of the relevance of existing rules;
- (3) touches upon an area or areas characterised by quick technological progress and intense innovation
- (4) affects specific research and innovation rules at EU level.

While having primarily an anticipatory function, horizon scanning can also relate to other stages of the policy-making cycle, including evaluation. For instance, its findings can be used in evaluations preceding legislative reviews, if horizon scanning results point to an important development that could affect the functioning of existing legislation.

DG Research and Innovation is putting in place a **Regulatory Advice Mechanism (RAM)** to provide upstream advice and improve the general understanding of the relation between innovation policy and regulatory policy, thus contributing to the overall resilience of the EU's regulatory framework. The mandate of this expert group is to identify anticipated impacts of beneficial innovations and provide recommendations on regulatory design to maximise their diffusion and use, while ensuring they can be deployed safely and sustainably. The group will:

- scan the horizon for promising discoveries and trends, also building on the work of the Framework Programme for Research and Innovation;
- explore and suggest novel regulatory approaches in the face of challenges cutting across various policy domains;
- deal with technologies, services and business models that have concrete applications and show the potential to bring significant benefits to the EU economy and society, especially to accelerate the green and digital transitions. As an illustration, possible topics could include: customer quality assurance and product guarantee in decentralised customised mass manufacturing (e.g. 3D-printing), recycling of urban biowaste, and innovative personal means of transport.

The **Regulatory Advice Mechanism** can be activated upon request from the concerned Commission services, by contacting DG Research and Innovation.²⁴¹

In cases where scientific advice or scientific evidence are needed to inform policy-making or underpin policy choices (for instance during the agenda-setting phase), the Group of Chief Scientific Advisors, at the heart of the Commission's Scientific Advice Mechanism (SAM)²⁴² can be requested to assist policy- and decision-making with targeted, up-to-date scientific evidence or science-informed recommendations.

This can be done where evidence is necessary to understand and assess the multiple dimensions of policy options and to interpret information and data critical to make informed policy choices. SAM complements and orients the routine assistance of the JRC in better

²⁴¹ Questions can be sent to the functional mailbox : RTD-INNOVATION-PRINCIPLE@ec.europa.eu

²⁴² https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en#about-the-advisors. See also Tool #4 (*Evidence-informed policymaking*).

regulation work. The request should be advanced by the College at the behest of services via the cabinet of the Commissioner(s) responsible for the policy issue at stake.

3. PREPARATION OF EU LEGISLATION: IMPACT ASSESSMENTS

The assessment of the potential impact of a policy initiative on research and innovation starts with the type of initiative and its overall objectives. Consider whether, and to what extent, the initiative may have positive or negative impacts on research and innovation capacity at the firm, sector, or EU level. For example by:

- (1) creating (or reducing) barriers to innovation or weakening (or strengthening) the incentives for investing in innovation²⁴³;
- (2) creating (or reducing) opportunities or incentives for innovation that could better support the achievement of policy objectives;
- (3) affecting specific research and innovation rules at EU level (e.g. patent law, technology transfer legislation) or spending programmes. These will have an effect on the incentives and rewards for innovation, as well as perhaps the location choice of research, development and market entry.

DG Research and Innovation is available to support with targeted analysis, guidance and help in the design of EU initiatives at the request of, and in cooperation with, the lead DG.

The stepwise approach:

Step (1) Include research and innovation angle in consultations

Depending on the extent to which a planned policy initiative is likely to have significant impacts on innovation and research, questions on these aspects should be a central element of the consultation strategy (for which separate guidance exists²⁴⁴). The public consultation should include questions on potential impacts on research and innovation, on emerging techniques and technologies and on impacts on companies scaling up in size²⁴⁵. The public consultation should reach out to relevant stakeholders, in particular start-ups, research institutes, innovation foundations, civil society organisations dealing with sectoral legislation, etc.

There is a risk that this sort of consultation exercise will predominantly identify the views of incumbent firms and therefore may not fully consider the impact on or possible creation of new business models, new firms or new technologies and services. This should be considered in the analysis of responses received²⁴⁶. This risk can also be mitigated by targeted consultation with research and innovation ecosystem actors, for instance through round tables, focus group meetings, hearings etc. DG Research and Innovation may help to identify key stakeholders and facilitate engagement.

Step (2) Assess potential impacts on research and innovation

²⁴³ See also Tool #21 (*Sectoral competitiveness*)

²⁴⁴ See Tools #50 to #54, on consulting stakeholders

²⁴⁵ See COM(2025) 270 final; [The EU Startup and Scaleup Strategy - Choose Europe to start and scale](#) which contains actions to help startups and scaleups that are also linked to SME and internal market impacts.

²⁴⁶ See Ashford/Renda, 2016. <https://www.ceps.eu/publications/aligning-policies-low-carbon-systemic-innovation-europe>

The checklist below provides an indicative set of questions to assess whether the proposed initiative affects research and innovation²⁴⁷.

Impact on research and innovation	Y/N
<i>Does the measure affect the research, testing or demonstration phase?</i>	
Does the intervention impact the generation of new ideas , their adaptation and application (e.g. from the knowledge base to industry)?	
Does it affect the cooperation (e.g. circulation of data, research results or researchers) between public and corporate R&D ?	
Does the proposed intervention potentially affect the establishment of, access to and functioning of R&D infrastructures ?	
Could the measure add or ease an administrative burden to testing, piloting, or demonstrating new goods, services, and products?	
Could compliance costs and time for the development of innovative technologies/solutions be affected?	
Does the intervention provide an equal playing field for public and private actors?	
<i>Does the measure affect application of innovative solutions or to bring them to market?</i>	
Is the intervention in an area with a relatively fast pace of innovation , and where legislation risk being outpaced by technological development?	
Can the initiative affect the introduction of future innovative solutions that may better achieve its policy objectives?	
Can the measure affect the innovation dynamics of specific markets ?	
Can the measure add or remove an administrative burden to bringing new goods, services, and products on the market?	
Will the initiative stimulate multi-disciplinary scientific research?	
<i>Does the measure affect incentives around investment or scaling up in Europe?</i>	
Can the intervention change the innovation incentives and choices for R&D investments?	
Can the intervention lead to a difference in innovation investment incentives in the EU compared to third countries?	
Can the intervention affect the incentives for companies to scale up in Europe?	
Will the proposed initiative lead to societal/organisational innovation?	

If the assessment leads to the conclusion that the proposed initiative has an impact (positive or negative) on research and innovation, further analysis on the specific impacts of policy options should be carried out. DG Research and Innovation will support an evidence base for policy options and the relation with innovation through the screening and feedback to policy of relevant projects funded by the Framework Programme.

Step (3) Address legislative design considerations

²⁴⁷ See Tool #21 (*Sectoral competitiveness*) for guidance on how to quantify the impact of legislation on the capacity of enterprises to innovate.

The interaction between a policy option and innovation depends on a range of factors, including regulation design, implementation, and enforcement. This section will help you to understand (i) the potential impact of the design of your proposal on research and innovation behaviours and outcomes, (ii) how to mitigate negative impacts on research and innovation and (iii) how innovation can be leveraged to better achieve policy objectives. Questions may not be relevant for all types of policies.

The table below describes several ways in which regulation and innovation interact. The description of each issue is followed by a series of questions designed to facilitate further reflection on whether and how it might be relevant to the options being considered in the impact assessment.

If you answer 'yes' to a question, please consider what steps you can take to maximise R&I capacities and the potential of innovation to achieve policy objectives. Where possible, the table points to specific instruments in Step 4 that can be applied to address the identified challenge. These are, however, by no means the only instruments that can be used.

Legislative design considerations	Y/N	Relevant instruments (Step 4)
<i>Flexibility and future-proofing²⁴⁸</i>		
Legislation should remain open to innovative solutions that will help achieve the policy objective of the measure under consideration. It should aim for technology neutrality and seek to avoid lock-in to one specific technology solution or technique. Generally, the less prescriptive and detailed a measure is, the more room it leaves for potential innovation. Excessively prescriptive and detailed regulation can create barriers to entry for innovative solutions, even if the innovation could contribute to achieving the policy goal of regulation. They can also limit the possibility to adapt rules in a timely manner, when circumstances change.		
Does the measure give operators as much flexibility as possible while ensuring that the policy objective will be met? Has the impact on innovation of the proposed measure been examined in the context of the proportionality test?		1,2
Does the proposed measure contain targets? Is it designed to allow for the possibility of emerging technologies or processes that could better meet or exceed these targets?		2, 4, 5
Are definitions used future-proof and unlikely to become outdated with the appearance of new innovations?		3
Are provisions allowing for regular updates of the measure in case of rapid technological developments?		3
Does the measure address a time-specific issue?		3
Is the proposed measure adaptable to scientific progress and new scientific discoveries?		1, 2, 3, 4, 5
Does the proposed legislation respect technology-neutrality?		2, 4, 5

²⁴⁸ According to the OECD, future-proofing means stress-testing existing or proposed strategies and policies. Source: <https://www.oecd.org/strategic-foresight/>

Compliance costs		
Compliance costs divert resources from other purposes, potentially including research and innovation. Compliance costs may at times discourage innovation if they fall disproportionately on innovators compared to incumbents, for example because of the costs of testing and obtaining authorisation ²⁴⁹ . Testing and authorisation processes for regulatory compliance may require spending on research – this is sometimes considered 'defensive' R&D as opposed to R&D that itself aims to develop new technologies, processes, or products.		
Have you taken steps to reduce the likelihood that the compliance costs of the policy option will divert resources from R&I activities?		2, 4, 5
Does the policy option seek to achieve a balance between requirements for 'defensive' R&D and incentives for R&D to create novel solutions?		4, 5
Have you taken steps to reduce unjustified variation in compliance costs between incumbents and potential innovators?		1, 2, 4, 5
Have you taken steps to ensure that compliance costs do not create a particular obstacle for innovative SMEs?		1
Regulatory certainty and clarity		
Regulatory uncertainty can hamper investment, including investment in R&I, because it increases risk and potentially also the cost of finance. Regulatory uncertainty can take different forms. It may be caused by real or perceived instability: is the regulator likely to change the regulatory framework in the foreseeable future? It may also be caused by a gap or lack of clarity in regulation when it is unclear whether an innovation would comply. There are trade-offs between the need to reduce regulatory uncertainty and the need to maintain flexibility.		
Will the proposed measure minimise regulatory uncertainty?		
Is it clear to which products/technologies this policy option applies?		1, 2
Will the proposed measure expire at a certain date or is there a date fixed for its review and possible modification? If so, does it strike the right balance between providing regulatory certainty on the one hand and the possibility for adaption to scientific and technological progress on the other?		3
Timing and stringency		
There is a balance to be struck about the stringency of regulations. On the one hand, a regulation that is overly stringent or imposes requirements within an unrealistic timeframe may encourage the market to use existing solutions. This can hamper investment and the deployment of solutions. On the other hand, the need to meet ambitious standards can stimulate radical innovation, provided regulation leaves sufficient time and is sufficiently stable to allow the market to develop new solutions.		
Does the initiative introduce new requirements within a timeframe that is in line with the market's investment and innovation cycle?		
The single market and harmonisation and interactions with other policies		
A lack of harmonisation between Member States, and even between EU Member States and other countries, can discourage investment in the development of innovative solutions and create barriers to market access. The creation of a well-functioning single market can encourage investment in the scaling up of innovations.		

²⁴⁹ Note that this is not always the case, as compliance costs can also have the opposite effect of encouraging innovation; this can only be established on a case-by-case basis when assessing the impacts of a specific policy or initiative.

Will the proposed measure help to ensure a consistent approach across the EU? Will it effectively address any identified problems created by differences in implementation in different Member States?		
Could the implementation of the legislation result in inconsistent requirements or regulatory practices between Member States in relation to innovative solutions?		
Is the proposed initiative aligned with requirements at the international level (e.g. international standards)?		
Does the proposal consider potential interactions with cross-sectoral legislation or requirements governing different sectors?		

Step (4) Apply tools to leverage the potential of innovation and reduce negative impacts

This section provides a non-exhaustive list of approaches to improve the design of your legislation for innovation-friendliness and to leverage innovation for better achieving your policy objectives. These concrete suggestions need to be considered on a case-by-case basis. Using them in legislative design helps formulate legislation with sustainable innovation in mind.

Please also refer to Tool #17 for support in assessing whether the choice of different policy instruments (e.g. directives versus regulations) could allow you to achieve better outcomes for innovation.

Instruments of adaptive regulation:

1. Experimentation clauses²⁵⁰

An experimentation clause enables the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to innovative technologies, products, or approaches, even if they do not conform to all existing legal requirements.

Experimentation clauses can be appropriate when detailed product or technological characteristics must be defined in legislation, but the policy goal could be met in the future by different, innovative solutions. They may also be proposed with the express intention of encouraging innovation and experimentation. A sophisticated experimentation framework is referred to as a regulatory sandbox – testing innovations in a real-world environment subject to regulatory safeguards and support.

The **Regulation on the Approval of Motor Vehicles** (2018/858) defines the process by which Member States certify that a vehicle model meets EU safety, environmental and production requirements. Article 39 (*Exemptions for new technologies or new concepts*) allows Member States, subject to authorisation from the Commission, to approve technologies or concepts even though they do not meet certain requirements. Pending the Commission decision on whether to authorise the exemption, the Member State may grant provisional approval that is valid only on its territory.

²⁵⁰ See also Tool #69 (*Emerging methods and policy instruments*)

2. Outcome-oriented legislation

Outcome-oriented legislation sets a measurable objective without prescribing the exact mechanisms by which the objective is to be achieved. It gives concerned organisations the flexibility to decide how to achieve the objective.

Outcome-oriented legislation should, in principle, be the preferred option unless there is a clear need to define the exact mechanisms by which the objective is to be achieved. It avoids creating a situation of lock-in to a particular technology or approach and creates a more level playing field for innovative technologies or approaches to compete against incumbents.

The **Regulation on personal protective equipment** (2016/425) lays down requirements for the design and manufacture of personal protective equipment to ensure the protection of the health and safety of users. The technical specifications listed in Annex II of the Regulation do not prescribe the specific technology or materials to be used provided they do not adversely affect the health or safety.

3. Sunset clauses

Sunset clauses terminate or repeal some or all provisions of a legal text after a specific date, unless further legislative action is taken to extend them. They can be used to ensure that legislation does not become an obstacle to innovation in rapidly changing market or technological environments. They can also serve as a tool for legislative experimentation, as they allow the lawmaker to test a new legal approach or regulatory framework for new technologies in a clearly delimited way. The risk of regulatory uncertainty must also be considered when considering their use.

The **European Union Agency for Network and Information Security** (ENISA) is an EU decentralised agency created in 2004 for an initial period of five years. Article 25 of Regulation (EC) No 460/2004 specified that its operations must be evaluated to determine whether its mandate should be extended. Under Regulation (EU) 526/2013, ENISA received a new seven-year mandate, with a possibility of extension following an evaluation (Article 32 on 'Evaluation and review' and 36 on 'Duration'). The temporary mandates reflect the rapid evolution of information and communication technologies, the changing threat landscape, and the evolution of Union policy in this field. Since June 2019, ENISA has a permanent mandate (Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 - Cybersecurity Act)

4. Test of alternatives

A test of alternatives requires applicants for regulatory approval to consider potential alternatives, and to justify why their chosen solution is the optimal way to meet the policy goals underlying regulation. Applied rigorously, the requirement to examine alternatives has the potential to encourage innovation and the search for new approaches to existing goals.

A test of alternatives may be relevant when projects, products or technologies have a negative impact on a core regulatory objective like consumer or environmental protection or even fail to meet standards, but a regulator nonetheless has reason to approve due to their wider benefits. In such cases, a test of alternatives can help to ensure that the desired wider benefit is achieved using the best available technology.

The **Environmental Impact Assessment Directive** (2014/52/EU) defines the environmental impact assessment to be applied by Member States when authorising projects likely to have significant effects on the environment. Article 31 specifies that developers must submit an outline of the main alternatives they have studied.

5. Top-runner approach

The top-runner approach refers to legislative provisions that envisage the updating of a requirement to reflect higher performance levels that have become possible because of scientific or technological progress. If an innovation achieves a higher performance level, then that performance level becomes the new requirement. The top-runner approach encourages innovation by rewarding first movers, since other market operators are obliged to adopt that innovation – or seek their own innovation that performs equally well or better.

The **Industrial Emissions Directive** (2010/75/EU) aims to protect human health and the environment by reducing harmful industrial emissions. Member State authorities may grant operating permits for industrial installations only if those installations do not exceed certain emission levels. The emission levels are set according to what can be achieved by Best Available Techniques, as defined in a Commission Implementing Decision. Article 74 provides for the periodic updating of the Best Available Techniques and the acceptable emissions level in accordance with scientific and technological progress.

Combining different approaches and instruments

In practice, legislation may combine different instruments and approaches.

For example, the Industrial Emissions Directive (2010/75/EU) includes provisions that correspond to the top-runner approach (Article 74), outcome-oriented legislation (Article 15, paragraph 2) and an exemption mechanism (Article 15, paragraph 5).

REACH (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) combines the test of alternatives with the top-runner approach (Articles 55, 60 and 61).

4. IMPLEMENTATION OF EU LEGISLATION: INNOVATION DEALS

Innovation deals contribute to future-proof EU legislation by addressing perceived regulatory obstacles to innovative solutions stemming from existing EU rules. They are voluntary agreements with stakeholders: innovators, civil society, national/regional or local authorities and the Commission services. Innovation deals feed in the evaluation and REFIT process of the Commission and may result in a revision of EU rules.

An innovation deal will consist of:

- definition of the perceived regulatory **problem** encountered by innovators and
- identification of a **solution** to this problem in cooperation with the innovation deal team.

Early indications of the innovation deal pilots point towards the need for clarification (instead of revision) of several of the so-called 'regulatory' barriers perceived by innovators. Other

barriers may need an intervention at national level or a revision of EU rules to benefit all innovators facing similar obstacles.

So far, two innovation deals were carried out in the area of circular economy: “Sustainable wastewater treatment combining anaerobic membrane technology and water reuse” and “From e-mobility to recycling: the virtuous loop of the electric vehicle”²⁵¹.

New innovation deals can be triggered via an open call, and guidance from DG Research and Innovation is available for all Commission services. Any innovator or group of innovators that encounter an EU regulatory obstacle impeding its close-to-market activities can apply for an innovation deal under conditions specified in an open call, to be prepared by the Commission.

If the existence of an obstacle to innovation arising from EU regulation is confirmed by providing clear evidence from the innovation deal, the Commission will take the results into account when evaluating the legislation in question. The result of an innovation deal can also be used to undertake further real-world testing through a regulatory sandbox, an innovation lab or other similar experimental approaches.

Pilot innovation deal example:

Anaerobic membrane technology for reuse of wastewater in agriculture: The aim of the deal was to investigate the (perceived) regulatory barriers that may prevent a broader application of Anaerobic Membrane Bioreactor (AnMBR) technology to allow reuse of the reclaimed water and nutrients in agriculture. The innovation deal indeed identifies an EU regulatory barrier, as wastewater treatment plants based on the AnMBR technology cannot receive a permit to operate in sensitive areas. Recommendations from the innovation deal include: (1) changing existing rules to enable fertigation in sensitive areas while ensuring that environmental objectives are achieved, (2) developing guidance for Member States to integrate environmental risks relating to nutrients, (3) reflecting on methods for water pricing and recovering costs from polluters when water is reused in agriculture.

5. FURTHER INFORMATION AND SUPPORT INNOVATION PROVIDED BY DG RTD

Catalogue of services on research and innovation:

- Provide Regulatory Advice Mechanism reports with upstream policy advice;
- Support evidence base for impact assessments; identify key R&I stakeholders and stimulate the participation of innovators in stakeholder consultation by enhancing their publicity in the communities of innovators;
- Support the evidence base for impact assessments;
- Develop innovation deals and support the evidence base for evaluations.

Information about the content or application of this tool: RTD-INNOVATION-PRINCIPLE@ec.europa.eu

²⁵¹ <https://op.europa.eu/en/publication-detail/-/publication/e361ec68-09b4-11ea-8c1f-01aa75ed71a1>

Complementary 'better regulation' tools:

Tool #4 (*Evidence-informed policymaking*) deals with evidence and scientific advice.

Tool #20 (*Strategic foresight for impact assessments and evaluations*)

Tool #69 (*Emerging methods and policy instruments*), deals with regulatory sandboxes.

Tool #21 (*Sectoral competitiveness*) deals with the capacity of enterprises to innovate as part of competitiveness-proofing.

Tool #23 (*The 'SME test'*) considers innovation in the context of small and middle-sized enterprises.

Tool #24 (*Competition*) on the link between market competition and innovation.

Tool #28 (*Digital-ready policymaking*) deals with impacts related to information and communication technologies as well as digital policy aspects.

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Gross domestic expenditure on R&D • R&D personnel <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Research and development expenditure as a proportion of GDP • Researchers (in full-time equivalent) per million inhabitants <p>All of the above indicators can be mapped against the individual SDGs²⁵² to show the transversal nature of R&D.</p>	

²⁵² An example of such analysis is provided in [Keeping our eyes on the Horizon](#), Monitoring flash series: a Horizon 2020 monitoring report

TOOL #23. THE ‘SME TEST’

1. INTRODUCTION

Small and medium-sized enterprises (SMEs) account in EU-27 for more than 99% of all enterprises in the non-financial business sector and more than 90% of them are microenterprises. The latter are companies with fewer than 10 employees²⁵³. The Commission aims to improve the business environment for SMEs by permanently anchoring the ‘think small first’ principle in policymaking²⁵⁴. This requires considering the specific characteristics of SMEs when designing legislation and simplifying the existing regulatory environment. The principle calls for new legislation, administrative rules, and procedures to be simple, easy to understand, and straightforward to apply.

The ‘SME test’ tool helps to assess the impacts on SMEs in impact assessment reports with the intention to ensure effective and efficient rules and minimise the burden imposed on SMEs²⁵⁵. Since 2022, the Network of SME Envoys identifies in the ‘SME filter’ initiatives that are likely to significantly affect SMEs and that therefore need to be carefully analysed. Since May 2025, impact assessments for initiatives that are considered ‘relevant’ or ‘highly relevant’ for SMEs should include an ‘SME Check’. The check is a mandatory annex to the impact assessment report to provide more transparency and clarity on the results of the ‘SME test’ (see box 1 below).

Minimising burdens on SMEs is particularly important, because the costs of regulation often affect SMEs disproportionately compared to large companies²⁵⁶, while the benefits of regulation tend to be more evenly distributed among companies of different sizes. SMEs benefit less from economies of scale than large companies do and have less capacity to absorb fixed costs of measures. They also find it more difficult to access capital, and their cost of capital is often higher than for larger businesses²⁵⁷. In addition, asymmetries in bargaining power towards larger companies expose SMEs to unfair business practices or conditions.

This is why legislation with simplified procedures benefits SMEs. In addition, regulatory simplification helps SMEs to comply with legislation and fosters the achievement of policy objectives at EU level. When transposing EU law, national, local, and regional authorities can add requirements to legislation that are burdensome to SMEs, it should be standard practice for Member States to make use of their own procedures to assess and measure impacts on SMEs (so called national ‘SME test’).

²⁵³ [SME definition](#)

²⁵⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:et0001>

²⁵⁵ In case an EU policy initiative was considered as “relevant” or “highly relevant” for SMEs at the impact assessment phase, the evaluation of this initiative should also cover the effectiveness and efficiency of the intervention for SMEs.

²⁵⁶ On average, a business with fewer than ten employees faces a regulatory burden (measured per employee) that is roughly twice as high as the burden of a business with more than ten but less than twenty employees and about three times as high as the burden of businesses with more than twenty but less than fifty employees. For bigger companies, the burden per employee is only one fifth or less of that of small enterprises. In other terms: where a big enterprise spends one euro per employee to comply with a regulatory duty, a medium-sized enterprise might have to spend around four euros and a small business up to ten euros. (Report from the Expert Group on “Models to Reduce the Disproportionate Regulatory burden on SMEs”, May 2007).

²⁵⁷ https://ec.europa.eu/growth/access-to-finance/data-surveys_en.

Box 1. Key elements of the 'SME test'

- **The 'SME test' must be always performed and all impact assessment reports must give an account on it a proportionate way²⁵⁸.**
- **This means concretely that the application of the 'SME test' varies with the 'relevance' of the initiative for SMEs.** 'The SME' test explains how the level of relevance ('not relevant', 'relevant', 'highly relevant') is established based on the 'SME-filter' and the discussions in the interservice coordination group. It also explains what is to be considered as a proportionate analysis of SME impacts (see section 2 step (1) and box 3).
- **All initiatives that are 'relevant' or 'highly relevant' for SMEs should include a compulsory annex on SMEs in the impact assessment report, the 'SME check'²⁵⁹. It provides an overview of the main results of the 'SME test' and can also include other elements that the lead service needs or wishes to provide²⁶⁰.**
- The impact assessment report itself (in the section on impacts of the policy options) must also include a reference to the results of the 'SME test' with a cross-reference to the 'SME check' annex for the main findings for 'relevant' and 'highly relevant' initiatives. If the initiative has not been identified as 'relevant', this should also be stated in this section of the report.
- As data about costs for SMEs are often not easily available, it is particularly important to properly plan the consultation process. **The input received from the SME community from consultations should be systematically reported on in the impact assessment.**
- If significant adverse impacts on SMEs are expected or if policy options impose a disproportionate burden on SMEs compared to large enterprises, it is strongly recommended to **consider different ways to minimise burdens** during the design of these policy options. This includes considering mitigating measures and incorporating mechanisms into the legislation to monitor the impact on SMEs (see below section on mitigating measures).
- **Exemptions** should be considered only as mitigating measure of last resort as they may create thresholds. Multiple exemptions across different policy areas taken together may create barriers that can become a disincentive to the further growth of the companies. When an exemption is applied, it is necessary to also consider possible indirect effects that might require additional measures to support SMEs.
- **SME-friendly provisions** are standard legal clauses that can be incorporated in legal proposals where appropriate to tailor rules to the specific needs of SMEs. These include provisions such as longer transition periods and specific guidance for SMEs, the need to pay particular attention to the impact of delegated acts and implementing acts on SMEs, as well as review clauses and sunset clauses. For this purpose, internal guidance is available²⁶¹.

²⁵⁸ See Tool #11 (*Format of the impact assessment report*).

²⁵⁹ Annex 6 in the template for impact assessment Staff Working Document

²⁶⁰ Annex 6 in the template for impact assessment Staff Working Document and related GoPro guidance.

²⁶¹ [SMEFriendlyProvisions_EN_2024Oct](#)

Small and medium-sized enterprises are defined at the EU level²⁶². There are three main categories – micro, small, and medium – based on the following criteria: staff headcount, financial parameters (annual turnover or balance sheet)²⁶³, and the ownership criterion²⁶⁴. According to the latter, a firm that is controlled or controls other companies (through ownership, control, or other relationships) needs to include part or all the staff headcount, turnover, or balance sheet data from those companies, too²⁶⁵.

To define SMEs for the purposes of (quantitatively) assessing impacts on them, it is recommended to use the headcount criterion. Financial parameters (turnover or balance sheet total) may also be used if relevant, knowing that the related data are scarcer and less readily available. Taking business ownership into account is generally burdensome and the available data are often incomplete and/or not sufficiently reliable.

2. THE APPLICATION OF THE ‘SME TEST’

In impact assessments, the analysis of SME impacts should first consider whether SMEs are disproportionately affected compared to large companies. If so, alternative mechanisms or flexibilities in the approach that might help SMEs comply should be considered. The ‘SME test’ consists of four steps that are applied in a modular way (see box 2).

Box 2. The four steps and key questions to apply the ‘SME test’

When applying the test, you are guided through the four different steps by a set of key questions. Answers to those questions will need to be reflected when reporting on the results of the ‘SME test’ in the ‘SME check’ annex.

Step (1): identification of affected businesses and assessment of relevance;

Step (2): consultation of SME stakeholders;

Step (3): assessment of the impact on SMEs;

Step (4): minimising negative impacts on SMEs.

²⁶² Defined in [Commission Recommendation 2003/361/EC](#) and its subsequent amendments.

²⁶³ The flexibility to choose either turnover or balance sheet intends to cater for the differences between sectors which have by their nature higher turnover figures (like trade and distribution) and those which tend to have higher asset level (like manufacturing).

²⁶⁴ To qualify as an SME, a company should employ less than 250 staff and have either a net turnover of less than €50 million or a balance sheet total of less than €43 million. Small companies have less than 50 employees and either a net turnover or balance sheet of €10 million, while micros have less than 10 employees and either a net turnover or balance sheet of €2 million. Meeting the staff headcount threshold is obligatory, therefore companies with more than 250 employees can never be considered SMEs, while for balance sheet total and turnover, companies may choose the one that is more favourable to them.

There is some flexibility with regards to the thresholds (staff headcount as well as the financial thresholds): a company can go beyond the thresholds during one year without losing the SME status. If this is also the case in the second consecutive year, the SME status is lost.

²⁶⁵ In 2015, almost all enterprises in the EU had fewer than 250 employees. However, applying the ownership criterion to Orbis data (i.e. including downstream and upstream partner companies and linked companies), would result in excluding approx. 10% of the abovementioned SME population (more than two million enterprises). Analysis of the 2018 SAFE survey micro database suggests that 87% of EU companies with less than 250 employees were autonomous in 2018, compared to 94% for some non-EU countries. Autonomous companies are not evenly distributed by size category: 95% among companies with 0-9 employees, 88% among those with 10-49 employees and 70% among those with 50-249 employees. (Evaluation of the SME Definition, 2021).

Step (1) – identification of affected businesses and assessment of relevance

The ‘relevance’ of an initiative for SMEs is important because it determines the level of assessment required for performing a proportionate ‘SME test’. An initiative can be classified as: ‘not relevant’, ‘relevant’ or ‘highly relevant’ for SMEs. If an initiative is considered ‘relevant’ or ‘highly relevant’ for SMEs, its impact assessment must include the ‘SME check’ (Annex 6). However, the extent to which SMEs are affected, and the relevance of an initiative should already be analysed and flagged when the ‘call for evidence’ is developed (see Tool #51 (*Consulting stakeholders*)).

The threshold question of step (1) is: **To what extent is the initiative relevant for SMEs (‘not relevant’, ‘relevant’, ‘highly relevant’)?**

Several additional guiding questions help reply to this key question:

- *Are SMEs within the scope of the initiative?*
- *Does the initiative specifically target SMEs?*
- *Will the SMEs be significantly impacted directly or indirectly by the initiative?*
- *Are SMEs impacts likely to be more substantial than on other companies, for example in terms of adverse effects?*

Since January 2022, the SME filter has helped to identify initiatives that are relevant for SMEs. The Network of SME Envoys²⁶⁶ filters EU initiatives to signal to the Commission those that merit close attention from an SME perspective²⁶⁷. The filter is applied to all the initiatives announced with a call for evidence and requiring an impact assessment. The results of the SME filter are public²⁶⁸. To timely feed into the policy preparation process, the Network of EU SME Envoys provides the results of the filtering process to the Commission services no later than 1 month after the publication of the ‘call for evidence’ on the ‘*Have Your Say*’ portal.

The questions listed in italics above and the SME filtering process help to distinguish between ‘not relevant’ and ‘relevant’ initiatives. To further identify highly relevant initiatives, the interservice coordination group can be guided by the following questions:

- *The horizontal (cross-sector) nature of the initiative: are SMEs of all sizes (micro, small, medium) across the EU concerned by the initiative?*
- *Is a very high impact of the initiative expected overall on affected SMEs, in particular in terms of compliance efforts?*
- *Has an evaluation identified important problem(s) for SMEs, such as high regulatory costs, supply chain disruptions, a widespread lack of compliance, critical feedback from SMEs and their representative organisations, etc.?*

If the initiative is assessed as ‘relevant’ or ‘highly relevant’ for SMEs, the characteristics of the affected businesses/sector(s) should be identified and included in the ‘SME check’ (Annex 6) of the impact assessment. Examples of elements to consider include:

- proportion of the employment concerned in the different categories of enterprises affected, average number of employees

²⁶⁶ [SME envoys network | Internal Market, Industry, Entrepreneurship and SMEs \(europa.eu\)](https://ec.europa.eu/internal_market/industry/entrepreneurship/sme_envoys/)

²⁶⁷ [Communication-sme-strategy-march-2020_en.pdf \(europa.eu\)](https://ec.europa.eu/internal_market/industry/entrepreneurship/sme_envoys/communication-sme-strategy-march-2020_en.pdf)

²⁶⁸ <https://ec.europa.eu/docsroom/documents/63274>

- weight of the different kinds of SMEs in the sector(s) (micro, small, and medium ones)
- links with other sectors and possible impacts on subcontracting or along the value chain; for instance, there may be an impact not only on the targeted sector but also on its suppliers or customers; such indirect impacts should also be considered.

Relevant sources of information should be explored²⁶⁹. These could also include information available from organisations representing SMEs' interests.

Even when exempted from the scope of a legislative initiative, SMEs can be affected through the supply chain or subcontracting, or through changes that affect their ability to access finance, the Single Market, non-EU markets, skills, raw materials, data, customers, etc. This indirect effect shall not be underestimated (see step (3) below). Experience has shown that SMEs rarely have enough leverage to counter trickle-down effects; therefore, indirect impacts are, to a certain extent, unavoidable and shall consequently be fully included in the assessment of impacts.

Box 3. Application of the SME-test according to the “relevance” of the initiative for SMEs

The purpose of step (1) of the ‘SME-test’ is to determine whether to move to the next steps based on the reply to the threshold question (see step 1 above). This question needs to be discussed in the **interservice coordination group**.

For initiatives that are likely to have little or no impact on SMEs (‘not relevant’), the impact assessment report can provide an ‘SME test’ which is limited to step 1. In this case, the impact assessment report should reflect this in the section on the impacts of the policy options. Any input received from the SME community, including from the public consultation, should be reported in Annex 2²⁷⁰.

For initiatives that are ‘relevant’ or ‘highly relevant’ for SMEs, the remaining three steps of the ‘SME test’ need to be adequately applied and the results reflected in the ‘SME check’ annex.

For initiatives considered to be ‘highly relevant’ for SMEs, it is necessary to undertake an in-depth analysis of the impacts on SMEs (by size-class)²⁷¹.

Step (2) – consultation of SME stakeholders

Several guiding key questions need to be addressed in step (2):

- *What are the main tools of the consultation strategy to reach out to the SME community?*
- *Is a targeted consultation of SMEs envisaged (e.g., SME panel, workshop, reality checks, etc.)?*

²⁶⁹ A useful starting point to find this information are the Structural Business Statistics produced by Eurostat. To the extent that a differentiation is made of companies by their size, Step 2 “What is the competitive position of the most affected sectors?” of the Competitiveness check tool can provide an analysis on the structure and performance of directly affected sectors (see Tool #21 (*Competitiveness Check*)).

²⁷⁰ Generally, this should be possible without execution of step 2 as public consultation always offers the possibility for SMEs to participate and as the questionnaires of such consultations always allow identifying SMEs (see Summary table in annex 2).

²⁷¹ In case the impact assessment report is supported by a study, this requirement could be included in the terms of reference.

- *What input has been received from different size classes of SMEs (i.e., micro, small, medium) and their representative organisations in the consultations? What are their key concerns and insights?*
- *Are SMEs' views different from those of large businesses?*

When SMEs are affected by the policy initiative, the SME dimension should be a clear part of the consultation strategy (for which separate guidance exists²⁷²). All public consultations of legislative initiatives must allow respondents to identify themselves as individual SMEs (by size, including self-employed) or as organisations representing SMEs. In addition to public consultations, consultation activities may involve targeted actions, consultations such as reality checks, round table discussions, focus group meetings, hearings targeting SME representatives, SME panel consultations carried out with the assistance of the Enterprise Europe Network or other specific consultations – aimed at providing inputs into the ‘SME test’²⁷³. Whenever it is deemed useful and relevant, the start-up community should also be targeted by the consultation activities.

Considering the consultation possibilities outlined here above, for initiatives that are ‘relevant’ for SMEs, consultations of SMEs and/or their representative organisations, such as targeted consultations, can be considered in addition to the public consultation. The public consultation questionnaire will include questions identifying SMEs and specifically targeting them. For initiatives that are considered ‘highly relevant’ for SMEs, the consultation strategy should envisage targeted consultations of SMEs and/or of their representative organisations.

The relevant annexes of the impact assessment report (i.e. Annex 2 on stakeholder consultation and the ‘SME check’ annex) need to reflect the analysis of the input received from the SME community as outlined here under step 2.

- If no SME-specific input has been received, this should be stated.
- For initiatives that are ‘relevant’ for SMEs: the report should describe the differences in stated positions between SMEs and large businesses or other stakeholders. If there are no differences between the position of SMEs and large companies, this should be stated.
- For initiatives that are ‘highly relevant’ for SMEs: in addition, the analysis of replies, position papers, etc. has also to investigate if there are significant differences within different size-classes of SMEs (i.e. micro, small, medium).
- It should be clarified how SME-specific input has been taken into consideration.

The SME dimension in public consultations is also explained in Tool #52 (Consultation strategy).

Step (3) – assessment of the impacts on SMEs

The following guiding questions need to be addressed in step (3):

- *What are the estimated direct costs for SMEs?*
- *What are the estimated direct benefits/cost savings for SMEs?*

²⁷² See Chapter 7 on stakeholder consultations.

²⁷³ DG GROW units A.2 and B.4 coordinate the preparation of these panels.

- *Have indirect effects on SMEs been considered, even if SMEs are exempt from direct obligations?*

Quantification of costs and benefits is often challenging, and evidence sources such as studies, stakeholder consultations, etc. should be used extensively. It is likely that an EU measure would have direct and indirect impacts on SMEs. The direct benefits, such as improved working conditions, increased competition, etc., should (at some stage) be reflected in reduced costs to SMEs. Yet, these benefits may be offset by various regulatory costs some of which may be disproportionately felt by SMEs.

For initiatives that are 'relevant' for SMEs, activities to collect information about the costs must be considered. When initiatives are 'highly relevant' for SMEs, the impact assessment must plan such activities (analysis of existing studies, targeted consultations, studies underpinning the IA, etc.).

Whenever an SME-related threshold is introduced to differentiate the application of a given policy measure on companies, the effects of the threshold on the potential scaling-up of companies should be assessed²⁷⁴. Specifically, policy measures that exempt SMEs have to always carry out an assessment if there can be an indirect impact on SMEs and on their ability and willingness to grow and if it is necessary to accompany that exemption with additional measures that support SMEs and create an environment that does not discourage their growth.

When an indirect impact on SMEs is likely to occur (for instance, through a trickle-down effect in the value chain), considering entire value chains would better highlight the consequences of the proposed legislation on specific companies within that chain. This approach would reveal obligations that could affect SMEs (e.g. through business-to-business contracts), even if they are excluded from the initial scope. In this case, the SME-check annex should include an estimation of how many SMEs could be affected (also expressed in terms of employees) and an estimation of the main indirect impact qualitatively and, where possible, quantitatively or explain why it is not possible.

For initiatives that are 'relevant' for SMEs, costs and benefits²⁷⁵ of the proposals for SMEs (and microenterprises in particular) compared to large companies must be analysed qualitatively for all policy options and – to the extent possible – quantitatively for the preferred option.

For this purpose, the overall costs identified may be compared to the number of persons employed to calculate the average cost per employee²⁷⁶. They may also be compared to the company's profit margin²⁷⁷.

In addition, the following elements should be considered:

²⁷⁴ For example, in the proposal amending Directive 2013/34/EU disclosure of income tax information by certain undertakings and branches, MNE Groups with a total consolidated group revenue exceeding €750 million will be required to prepare the country-by-country reporting. The threshold effect was expressly considered in the IA.

²⁷⁵ See Tool #56 (*Typology of costs and benefits*); and Tool #57 (*Methods to assess costs and benefits*)

²⁷⁶ It is recommended to use the ranges of the SME definition: 0-9, 10-49, 50-249 and 250+ employees.

²⁷⁷ Representative samples of different size of companies can also be used. The use of profit margin considers the cumulative cost of legislation, which is not reflected if turnover is used.

- possible impacts on barriers to entry, competition in the market and market structure, for example in terms of possibilities for SMEs to enter markets²⁷⁸;
- possible impact on innovation²⁷⁹.

For initiatives that are 'highly relevant' for SMEs, the distribution of the costs and benefits of the proposals should be analysed qualitatively and quantitatively²⁸⁰ for each policy option by business size (i.e. differentiating between micro, small, medium and large enterprises) to the extent possible. A one-size fits all approach for all SMEs might not be effective or efficient because the impact on micro-companies is likely to substantially differ from the impact on medium sized ones. Therefore, costs and benefits accruing to each size-class of SMEs should be presented and analysed separately.

When data is unavailable or it is not possible to estimate costs thoroughly, calculating costs could involve providing a concrete example of what one company must do to be fully compliant, or focusing on a limited set of companies to estimate the anticipated costs. Examples could be included in the 'SME test' for different types of companies, such as a micro-enterprise, a small company, and a medium-sized company. Creating focus groups based on company size and estimating or calculating costs in cooperation with the involved companies could be an effective approach.

If despite efforts to quantify costs, the data collection has not been successful to achieve this, the impact assessment report should state it, explain the reasons for it and focus on qualitative analysis.

The key results of the assessment of SME impacts on the preferred option as outlined here under step 3, need to be included in the 'SME check' annex²⁸¹.

Step (4) - minimising negative impacts on SMEs

The following guiding questions need to be addressed in step (4):

- *If SMEs are disproportionately affected by the preferred option compared to large companies, are there any specific subgroups of SMEs more exposed than others?*
- *Is it possible to identify an SME-friendly policy option in the impact assessment to minimise negative impacts and maximise positive impacts of SMEs?*
- *If no SME-friendly option can be identified, what specific mitigating measures can be included in the preferred option? What are their expected benefits?*
- *Have SME-friendly provisions been considered in the final proposal? Which provisions and why?*

A well-designed proposal should aim to be SME-friendly by default, eliminating the need for specific mitigating measures. This requires designing the various policy options with SMEs in mind from the outset. If this is not the case and the options are found to disproportionately

²⁷⁸ See Tool #25 (*Internal market*)

²⁷⁹ See Tool #22 (*Research and innovation*)

²⁸⁰ See Tool #56 (*Typology of costs and benefits*); and Tool #57 (*Methods to assess costs and benefits*)

²⁸¹ The results should also inform the analysis of SME competitiveness (See tool #21 and reported in the competitiveness check annex 5).

affect SMEs or some specific subgroup of SMEs, measures to mitigate such impact are necessary and need to be included in the preferred option.

Mitigating measures

The analysis may show that micro, small and/or medium-sized enterprises are facing a relatively higher burden than large companies and that specific measures, where they already exist, have not proven to address the SME needs sufficiently or adequately. In such case, one might consider the use of specific mitigating measures to ensure a level playing field and the respect of the proportionality principle. For example:

- simplified reporting, exploring possible synergies with already existing reporting obligations, lower frequency for certain obligations or the use of simplified templates;
- simplified obligations
- making available the necessary support measures (such as information and training campaigns, guidelines, IT tools, one-stop-shops/helpdesks/hubs);
- simplification initiatives which can particularly benefit SMEs (example: possibility to use on-line facilities such as digital compliance assistance tools, or lighter treatment for companies that are certified by a third party²⁸², common translated forms);
- reduced fees and additional financial support; proportionality of sanctions/administrative fines;
- self-certification procedures, and longer validity periods for administrative certificates;
- inclusion of SME expertise in expert groups that are relevant for the initiative;
- imposing obligations on SMEs counterparts rather than on SMEs themselves (example: in the case of third-party certification, the certifier could be required to submit the relevant information or certificate directly to the authorities, instead of placing the burden of notifying the relevant authorities on individual companies);
- using exemptions from certain regulatory requirements for SMEs (or specific size categories). However, exemptions can create thresholds and multiple exemptions across different policy areas taken together set up barriers to the further growth of the companies. Therefore, this approach is not always favourable to SMEs and should be used with caution.

If mitigating measures are deemed necessary, it is important that the costs and benefits they may incur are also fully considered and included in the final impact (cost-benefit) assessment. This includes the impacts of any SME specific measures or exemptions (i.e. no fees for micros can turn into higher fees for small companies) and also the effect on the potential scaling-up of companies.

If the SME definition is to be used for clarifying the scope of a mitigating measure, it is good practice to make a dynamic reference to it at least in the recitals²⁸³. In addition, for initiatives that are 'highly relevant' for SMEs, the impact assessment report should consider setting

²⁸² Reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, is one of the criteria to be taken into account in the general [rules on official controls](#).

²⁸³ By using the following reference: "as defined in Commission Recommendation 2003/361 and its subsequent amendments".

specific indicators to monitor the impact of the preferred option on SMEs and differentiate them in their sub-groups, or parts thereof, when relevant²⁸⁴.

Systematic consideration of SME-friendly provisions

SME-friendly provisions are a specific category of mitigating measures and refer to standard legal clauses that can be incorporated in draft proposals. They address aspects of legislation that impact the business environment. They are commonly applicable across multiple legislative acts (e.g. phased implementations) and are designed to ease the practical application of EU legislation by SMEs. The following SME-friendly provisions should be systematically considered where appropriate and justified:

- (1) the possibility of allowing longer transition periods for SMEs, to ensure predictability and facilitate compliance by SMEs;
- (2) requirements for specific guidance for SMEs to be provided by the Commission and/or Member States regarding the implementation of the proposed legislation (e.g. summary of the legislation, online training material) when necessary;
- (3) a requirement for the Commission to pay particular attention to the impact of delegated and implementing acts on SMEs, which often define the level of costs for SMEs;
- (4) a review clause or sunset clause in secondary legislation with the timing consistent with the ex-post evaluation process.

For this purpose, internal guidance is available²⁸⁵.

3. INFORMATION SOURCES AND SUPPORT

Support for the execution of the ‘SME test’ is provided by DG GROW. You can contact the ‘SME Test’ Helpdesk via email (see below).

- ‘SME test’ on Europa
- ‘SME test’ available support
- ‘SME test’ Helpdesk: GROW-SME-ENVOY@ec.europa.eu

Data sources

- Structural Business Statistics (Eurostat)
- SME performance review ([European Commission](#))
- ESTAT [business demography](#)
- Survey on access to finance of enterprises ([annual publication since 2013](#))

²⁸⁴ Examples can be found in COM/2020/682 (Art. 10.2 “*disaggregated ... by company size*”). Impact on SMEs can also be an element to be specifically considered in implementation reports/review (for example, Directive 2019/1152 Art. 23 “*the Commission shall, after consulting the Member States and the social partners at Union level and taking into account the impact on micro, small and medium-sized enterprises, review the implementation of this Directive and propose, where appropriate, legislative amendments*”).

²⁸⁵ [SMEFriendlyProvisions_EN_2024Oct](#)

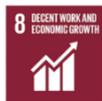
- [Digital intensity by size class of enterprises \(ICT usage in enterprises\)](#) (annual publication since 2002, excludes micro-enterprises)
- [Community Innovation Survey](#) (biannual publication since 2004, excludes micro-enterprises)
- [OECD Data explorer](#) (which includes a section on SMEs and entrepreneurship)
- [Regular Flash Eurobarometers](#) on “SMEs, resource efficiency and green markets” (2012 FL342, 2013 FL381, 2015 FL426, 2018 FL456, 2022 FL498, 2024 FL549) and on “SMEs, start-ups, scale-ups and entrepreneurship” (2020 FL486, 2025 FL559)
- Flash Eurobarometers on “SMEs and skills shortages” (2023 FL537) and on “European Year of Skills: Skills shortages, recruitment and retention strategies in small and medium-sized enterprises” (2023 FL529)

EU definition of SMEs:

- [Small Business Act - COM/2008/394](#)
- [Review of the “Small Business Act” for Europe - COM/2011/0078](#)
- [Definition of SMEs: Commission Recommendation 2003/361/EC](#) 
- [The revised User Guide to the SME definition](#) 
- [SME self-assessment tool](#)

4. RELEVANT SDG INDICATORS

To track progress, the SDG indicators below can also be considered, though the list should not be considered exhaustive.

Relevant SDGs indicators	SDGs
<p>No specific indicators on SME available in SDG-EU framework. However, information can be found at:</p> <ul style="list-style-type: none"> • Small and medium-sized enterprises: an overview • Structural Business Statistics Database <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Average income of small-scale food producers, by sex and indigenous status • Proportion of small-scale industries in total industry value added • Proportion of small-scale industries with a loan or line of credit • Volume of production per labor unit by classes of farming / pastoral / forestry enterprise size 	  

Annex 1: Summary table

DIFFERENT STEPS OF THE SME-TEST AND RELATED QUESTIONS	OVERVIEW OF ESSENTIAL ELEMENTS TO BE INCLUDED IN THE IMPACT ASSESSMENT REPORT (by 'relevance' of the legislative initiative for SMEs)		
Step (1) Are SMEs among the affected businesses?			
Are SMEs within the scope of the legislative initiative?	If yes, identify the characteristics of the affected businesses/sector(s).		
Will SMEs be likely impacted directly or indirectly by the legislative initiative?	If yes, identify the characteristics of the affected businesses/sector(s).		
Threshold question: To what extent is the legislative initiative relevant for SMEs? Reply to be agreed in the ISCG.			
	'not relevant'	'relevant'	'highly relevant'
Step (2) Are SMEs properly captured in your consultation activities?			
Are SMEs solicited to participate in the public consultations and can they be identified on the basis of the questionnaire?	Identification of SME respondents ²⁸⁶	Identification of SME respondents (enterprises by size and SME organisations)	Identification of SME respondents (enterprises by size and SME organisations)
Has the consultation strategy envisaged adequate tools to reach out to the SME community?		Consider consultations of SMEs and/or of their representative organisations	Plan targeted consultations of SMEs and/or of their representative organisations
Does the impact assessment report analyse the input received from the SME community?	Distinguish SMEs in the analysis of the consultation results ²⁸⁷	Distinguish SMEs in the analysis of the consultation results Report on differences between SMEs and large companies	Distinguish SMEs in the analysis of the consultation results Report on differences between SMEs and large companies Report on differences within SME size classes (where relevant)
Does the impact assessment report describe how the input from the SME community has been taken into consideration?	Description ²⁸⁸	Description	Description

²⁸⁶ This is also required for non-relevant SME initiatives and does not require the execution of step 2.

²⁸⁷ See previous footnote.

²⁸⁸ See previous footnote.

Step (3) Has the impact on SMEs been assessed?			
Have adequate activities been planned to assess the impact on SMEs?		<i>Consider</i> an ad-hoc activity to collect information on costs for SMEs	<i>Plan</i> ad-hoc activity to collect information on costs for SMEs
Does the impact assessment report provide for a proportionate assessment of impacts on SMEs and on their ability to grow?		Assess costs and benefits for SMEs, in particular micros, compared to large enterprises. Qualitative analysis for all policy options and – to the extent possible – quantitative analysis for the preferred option.	Assess costs and benefits differentiating between SMEs and large enterprises and – where relevant – within SMEs of different size-classes. Qualitative and – to the extent possible – quantitative analysis policy option.
Step (4) How has the impact assessment tried to minimise negative impacts on SMEs?			
Is the impact assessment considering options that minimise the negative and maximise the positive impact on SMEs?		Make sure there are options that are favourable for SMEs and their growth.	Make sure there are options that are favourable for SMEs and their growth.
When significant adverse impact on SMEs has been identified under steps 3, does the impact assessment consider measures to mitigate/redress the impact on SMEs?		If the preferred option has a significant adverse impact on SMEs, consider the use of mitigating measures or the design of the option in an alternative way.	If the preferred option has a significant adverse impact on SMEs, consider the use of mitigating measures or the design of the option in an alternative way.

TOOL #24. COMPETITION

1. INTRODUCTION

Competitive markets encourage enterprises to be efficient and innovative, thereby creating more choice for consumers, reducing prices, and improving the quality of goods and services. Increased competition typically improves a country's economic performance, opens business opportunities to its citizens and reduces the cost of goods and services throughout the economy. When governments intervene in markets to regulate the behaviour of businesses, this may in some cases restrict competition further than is necessary to achieve the desired policy objectives.

The first step in competition analysis is to define the relevant market in the internal market and to apply concepts such as market power. This is to be done in accordance with the 1997 Commission Notice on the definition of relevant market, currently in the course of being reviewed²⁸⁹.

The **relevant market** is the market affected by the proposed policy initiative. Broadly speaking, it combines the characteristics and use of as well as the demand for the products or services and their geographic availability,

More specifically, a relevant market comprises all products or services that consumers regard as interchangeable or substitutes by reason of their characteristics, their prices and their intended use (e.g. luxury sports cars are not considered by consumers to be close substitutes with small economy cars, so would not be in the same market).

A relevant geographic market comprises the area in which the firms concerned are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous (significant differences arguing in favour of separate geographic markets may include, for example, trade barriers, consumer preferences, language...).

Market power in the internal market is defined as the ability of a firm to raise prices above competitive levels in a profitable way. Market power can arise due to a variety of reasons and last for a shorter or longer period. A firm may be able to temporarily increase prices above competitive levels. However, in the absence of market power, such price increases are unsustainable because customers can then switch to other competitors.

Against this background, in assessing competition effects of policy options under an initiative, the key issue is to determine whether the proposed policy option may lead to an increase in market power, with implications for prices, efficiency and innovation. Any assessment of market power will have to be made in the relevant market.

Once the relevant market has been clearly defined, some characteristics that describe the **structure of the market** should be considered to allow for an assessment of whether there may be a negative impact on competition resulting from the policy option under the initiative. Those variables may include:

- the number of firms;
- the firms' market shares;

²⁸⁹ Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997.

- other competition parameters impacting the relative position of competitors (e.g. strong IPRs, financial resources, brand recognition and first mover advantage);
- existence of entry and exit barriers and
- market power of buyers and suppliers.

All these characteristics will impact the ability of consumers to switch to competitors in case of a price increase and so will be relevant in assessing market power.

An additional key component of a competition assessment is the evaluation of **barriers to entry and exit**, defined as factors that might hinder the entry and exit of firms into and from the relevant market. When important barriers to entry or exit exist in a market, any new regulation imposing additional constraints on competition can cause significant harm.

Different types of barriers to entry include:

- natural barriers, such as strong economies of scale, i.e. cost advantages enterprises obtain due to scale of operation, with cost per unit of output generally decreasing with increasing scale as fixed costs are spread out over more units of output;
- barriers created by the conduct of incumbent firms, for example high switching cost and limited access to networks; and
- regulation that can impose additional entry barriers (e.g. legal restrictions on new entry in certain sectors like licenses, patents, exclusive rights; costly and cumbersome bureaucratic and administrative procedures to start new businesses; local professional body certifications, e.g. medicine, law).

Types of barriers to exit include:

- sunk costs, i.e. costs that cannot be recovered when a firm chooses to exit a market (e.g. set-up costs that cannot be recouped, advertising expenditure);
- labour related exit costs such as staff redundancy costs;
- regulatory exit requirements;
- long-term contracts;
- first mover disadvantage;
- government intervention;
- managerial barriers.

2. CRITERIA FOR POTENTIALLY SIGNIFICANT IMPACTS ON COMPETITION

The checklist below has been developed by the OECD as part of its competitive framework to screen policies for potential detrimental effects on competition. **A more detailed analysis as introduced in sections 3, 4 and 5 should be performed in case of a positive reply to any of the questions in the checklist in Box 1 below, where there is also a first indication that the effect is significant.**

Box 1. The competition checklist

Further assessment and reflection about possibly better policy options should be performed if a proposed policy option may have any of the following effects:

(A) Limiting the number or range of suppliers and producers

This is likely to be the case if the policy option:

- grants exclusive rights for a supplier or producer to provide goods or services (e.g. many municipalities sign a long-term contract with a single supplier of products or services);
- establishes a license, permit or authorisation process as a requirement of operation (e.g. requirements that only companies which fulfil certain minimum requirements for formal education may perform a certain service);
- limits in other ways the ability of certain types of suppliers or producers to provide goods or services (e.g. public procurement requirements for tenderers to have many years of experience may keep out new businesses and start-ups);
- significantly raises the cost of entry or exit by a supplier or producer;
- creates a geographical barrier to the ability of companies to produce or supply goods or services or to invest capital (e.g. strict rules for regional development projects).

(B) Limiting the ability of suppliers and producers to compete

This is likely to be the case if the policy option:

- limits suppliers' or producers' ability to set the prices for their goods or services (e.g. minimum and maximum prices);
- limits freedom of suppliers or producers to advertise or market their goods or services (particularly for potential entrants);
- sets standards for product quality that provide an advantage to some suppliers or producers over others (e.g. by requiring a particular technology or by setting unduly strict standards that are difficult or impossible for the large majority of existing producers to meet) that are above the level that some well-informed customers would choose;
- significantly raises costs of production for some suppliers or producers relative to others (especially by treating incumbents more favourably than new entrants, for instance exempting incumbents from new rules for a certain period or under specific conditions).

(C) Reducing the incentive of suppliers or producers to compete

This may be the case if the policy option:

- creates a self-regulatory or co-regulatory regime which risks collusion or setting high entry barriers by sector associations;
- requires or encourages information on suppliers' or producers' production levels, prices, sales, or cost structures to be published (which could allow cartels to be better policed and the punishment of members if they offer consumers better conditions than those agreed);
- exempts the activity of a particular industrial sector or group of suppliers or producers from the operation of general competition law (e.g. the EU insurance sector and the motor vehicle retail sector benefit from block exemption regulations that other sectors do not benefit from).

(D) Limiting the choices and information available to customers

This may be the case if the policy option:

- limits the ability of customers or producers to decide from which supplier or producer they purchase (e.g. allowing sale of certain products, for instance e-cigarettes, only in certain type of licensed shops or pharmacies);
- reduces mobility of customers between suppliers and producers of goods or services by increasing the cost of changing suppliers (recognising this, some EU legislation prohibit charging consumers for switching cost, for instance of mobile phone services);
- allows suppliers and producers to confuse customers with misleading, unreliable or rapidly changing information that prevents them from shopping effectively (e.g. telecom liberalisation in some countries may temporarily have led to a multitude of ever changing tariffs that confused, rather than helped consumers to make good choices).

3. PRACTICAL ASSESSMENT OF IMPACTS OF OPTIONS ON COMPETITION

The following list of criteria may help in the analysis for impact assessments. The same criteria are also applicable to evaluations. The proportionality of analysis, as with any aspect in the impact assessment process, will depend on the significance of the competition effects. As a rule of thumb, the higher the market power of firms identified in the relevant market, the more careful the assessment should be (e.g. in a very atomised market structure with low entry barriers, market power is very limited). Not all the criteria may be relevant for a particular project or initiative.

Impacts	Key criteria
Impacts on existing firms	<p><u>Impact on the cost of meeting the regulation:</u></p> <ol style="list-style-type: none"> (1) the policy option creates additional costs for existing firms, to be quantified where possible (e.g. new requirements for licences or permits); (2) types of costs: fixed (non-recurring) or variable (recurring) costs; fixed costs may represent an additional entry barrier. (3) Analyse if the size of the costs relative to businesses' annual sales revenues: <ul style="list-style-type: none"> - vary by the size of the business (for example, where small businesses are more adversely affected); - are higher for new entrants or decrease over time; - depend on other characteristics of the firms or of the market(s) (for instance: vertically/horizontally integrated markets, location such as urban vs. rural, coastal vs. internal etc.) <p><u>Impact on the exit of firms:</u></p> <ol style="list-style-type: none"> (1) where new costs or requirements may lead some businesses to exit the market: <ul style="list-style-type: none"> - which businesses are more likely to exit (small or large firms; older incumbents etc.?) - in some cases, it could be relevant to make a distinction between a dominant supplier or producer and their competitors.

Impacts	Key criteria
	<p>(2) where the initiative limits growth opportunities of existing competitors;</p> <p>(3) where the initiative favours the incumbent over existing competitors;</p> <p>(4) where the initiative limits the possibility of inefficient firms to exit the market, raising barriers to exit that cause market inefficiency.</p> <p><u>Impact on the anti-competitive behaviour of firms:</u></p> <p>(1) impact on the incentive for anti-competitive practices of firms (collusion, etc.);</p> <p>(2) a history of collusion or other anti-competitive practices in the sector should be accounted for in the decision-making process (DG COMP can help to provide such information).</p> <p><u>Impact of state aid measures:</u></p> <p>(1) impact on competitors of the firm benefiting from State aid;</p> <p>(2) impact in the form of distortions of competition on the internal market;</p> <p>(3) past evidence of similar measures;</p> <p>(4) appropriateness of the measures and proportionality of the aid granted in relation to the needs.</p>
Impacts on entry of new firms	<p>(1) <u>Restriction of entry:</u></p> <ul style="list-style-type: none"> - for all entrants: for example, if a regulation limits the total number of pharmacies per 5,000 people, this applies to all types of pharmacies and will limit the extent of competition in the market in a very explicit manner; - for specific types of firms: new firms rather than incumbents, small and medium entrants rather than large undertakings, foreign firms rather than national firms. <p>(2) <u>Limitation of access to specific resources:</u> for instance input products, know-how, distribution channels.</p>
Impacts on consumer prices	<p>(1) Identify likely causes of price increase:</p> <ul style="list-style-type: none"> - increase of production costs; - increase in market power; - greater information sharing and cooperation among businesses leading to collusion
Non-price impacts on consumers²⁹⁰	<p>(1) <u>Impacts on the quality and variety of products and consumer choice</u> (for instance where the regulation sets a minimum of quality standard; or creates barriers to entry).</p> <p>(2) <u>Impacts on the incentive to innovate:</u> high barriers to entry or exit through long protection periods for incumbents; prohibition of advertising.</p>

²⁹⁰ See Tool #33 (Consumers)

Impacts	Key criteria
Impact on upstream and downstream markets²⁹¹	Analyse the policy options to determine: <ol style="list-style-type: none"> (1) different impacts on vertically-integrated firms (e.g. because of the difference in switching costs); (2) incentives to increase vertical integration in the market, thereby potentially increasing entry and exit barriers; (3) how the bargaining power of buyers will be affected; (4) how the bargaining power of suppliers will be affected.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON COMPETITION

Where the initial assessment concludes that a policy option entails significant risks to weaken competition, it is necessary to determine if there are other policy options less likely to distort competition while still achieving the policy objectives.

The question is whether the anti-competitive elements are *strictly necessary* to attain the policy objectives, or if they could be amended to reduce or eliminate their negative impact on competition. There may be cases where no valid alternative options can be found. Nonetheless, before reaching such a conclusion, a thorough analysis of all possible alternative options should be carried out.

Less restrictive measures that can be used in place of more restrictive ones include:

(1) *Tailored transition periods or provisions when adopting new legislation*

New rules and regulation may place a heavy burden on existing firms who made their investments in production facilities and started operations under the older rules. Since significant changes in the existing structure can be prohibitively costly, in specific cases, existing firms can either be exempt or given a specific timeframe to conform. The extent of the adjustment period may also be conditioned on firm-specific characteristics such as technology, the date at which the capital was required, and firm size.

In such cases, it may be useful to carefully consider the implication of transition clauses. It is important to bear in mind that provisions imposing asymmetric standards on existing firms versus newer ones may deter new entrants (entry barriers), dampen new investment by incumbent businesses, and allow continuation of inefficient production (exit barriers).

(2) *Using economic incentives rather than regulation to deal with externalities*

Externalities include environmental, economic, health, safety or other costs and benefits generated by a product or service and not reflected in its price or cost²⁹².

²⁹¹ For a given firm, upstream markets are all the markets of its suppliers. Downstream markets are the markets of the firm's clients (that can be both consumers and other firms along the value chain).

²⁹² If a product or activity generates external costs (e.g. negative environmental effects), it will tend to be oversupplied, as the full costs are not reflected in the product's / activity's price or marketplace return. Equally, if a product or activity generates external benefits (e.g. technology spillovers), it will tend to be undersupplied.

Regulation of the quantity supplied, price, or characteristics of externality-generating products or activities is one possible approach of attempting to correct for these externalities. An alternative approach is to use economic incentives, such as subsidies, taxes, or fees, to internalise these products' externalities, so they are reflected in their market price. When feasible, this approach uses competitive market forces to determine efficient prices, quantities, and product characteristics instead of attempting to estimate and regulate outcomes. Another alternative is to create market solutions where none existed before.

Example: The EU Emission Trading System (ETS), by creating emission rights and allowing to trade these rights, reduced the anticompetitive impacts of setting new emission standards.

(3) *Ensuring adequate consumer information rather than mandatory product characteristics*

Protecting consumers is often used as a reason to establish mandatory product characteristics. While health and safety protection should generally be achieved by means of product design and manufacture, in some cases adequate information disclosure may be sufficient, allowing consumers to make informed decisions.

Example: Setting labelling requirements to disclose the content of food products instead of banning those products.

(4) *Voluntary rather than mandatory product specifications*

Setting product specifications and quality norms is often necessary and may serve the public interest. At the same time, stringent rules and regulation on content and minimum quality can, in some cases, clash with consumer preferences and disadvantage those consumers (e.g. low income consumers) who may prefer to pay a lower price for lower quality.

Voluntary standards can permit suppliers to signal that their products meet certain standards, while allowing them to provide other products that do not meet the standards if some consumers prefer such products (provided that they do not entail additional significant risks).

Example: The EU Ecolabel is a voluntary label helping consumers to identify products and services that have a reduced environmental impact throughout their entire life cycle; it promotes environmental excellence without limiting consumers' choice.

(5) *Reliance on enforcement under competition rules in addition to sector-specific regulation to deal with inappropriate competitive behaviour*

As a complement to sector-specific regulation, general competition rules and their enforcement provide a framework for preventing business practices that are likely to harm competition and consumers, while allowing practices that promote competition, innovation, and consumer benefits.

Example: In the pharmaceutical sector, patent settlement agreements between originator and generic companies may result in anticompetitive practices, e.g. delaying generic market entry to the detriment of consumers. The EU approach has been targeted at monitoring the situation and assessing problematic cases individually. As a result, there are fewer and less important settlements that are likely to raise competition concerns, while at the same time the overall number of settlements has steadily increased.

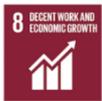
5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- The OECD Competition Assessment Toolkit²⁹³ contains the checklist mentioned above and many useful examples for assessment steps and better option development.
- *Volume 1 (“Principles”)* contains a checklist and basic explanations about the interaction between regulation and competition for readers who are not experts in competition policy.
- *Volume 2 (“Guidance”)* contains further explanations and examples for readers who want to perform an analysis of competition effects in ex-ante or ex-post assessments of policy instruments.
- *Volume 3 (“Operational Manual”)* contains further practical examples and recommendations how to conduct a competition assessment regarding a single policy instrument or regarding the situation in a whole sector.

More information about EU competition policy is available on DG Competition’s website. Its consumer webpage gives an easily understandable overview for non-experts: http://ec.europa.eu/competition/index_en.html

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Real GDP per capita <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Annual growth rate of real GDP per employed person 	

²⁹³ <http://www.oecd.org/competition/assessment-toolkit.htm>

TOOL #25. INTERNAL MARKET

1. INTRODUCTION

The Treaty on the Functioning of the European Union establishes an objective to create a common market with full respect for the four pillars of free movement covering goods, services, capital, and workers, while paying due attention to legitimate and proportionate public policy interests. In the internal market, all citizens²⁹⁴ and companies are treated equally and in a non-discriminatory manner and the cross-border provision of goods and services should be as easy as within each individual Member State.

The proper functioning of the internal market may constitute the objective of an initiative. It may also constitute an important interest to be borne in mind where the main aim of the initiative is different.

The application of legal bases geared towards the proper functioning of the internal market may raise questions and the Legal Service should be consulted in case of doubt. A few non-exhaustive remarks regarding Article 114 TFEU (by way of prominent example) are described in Box 1.

Box 1. Article 114 TFEU

Article 114 of the Treaty on the Functioning of the European Union provides the legal basis for actions in the area of single market:

“(...) The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.”

- Measures adopted on the basis of Article 114 TFEU should objectively and effectively aim to improve the conditions for the establishment and functioning of the internal market. The risk of impaired functioning of the internal market should be sufficiently concrete: mere disparities between national rules or an abstract risk of infringements of fundamental freedoms or of distortion of competition, are not sufficient. Action may also be justified to prevent the likely emergence of such obstacles.
- Article 114 should not be used as legal basis if the establishment and functioning of the internal market is secondary or incidental to another objective (e.g. health or environment protection).

All Commission policies²⁹⁵ should be assessed for their potential effect on the functioning and effectiveness of the internal market. This tool consists of a series of questions to help you identify different angles in which your proposal may influence the internal market.

In case it is intended to rely on Article 114, having regard to the criteria set out above, the problem definition should include an analysis of the situation of the internal market. The impact analysis section should also discuss the possible impacts of the different options on the functioning and effectiveness of the internal market.

²⁹⁴ The term ‘citizen’ as used in this tool comprises different relevant (sub-) groups, including consumers, workers, and professionals.

²⁹⁵ https://ec.europa.eu/info/policies_en

When evaluating existing legislation, consider assessing its impact on the internal market. Be aware that some impacts might be unintended or unanticipated at the time your legislation was proposed. Consider these also for legislations that did not have the Single Market as a core objective or were not based on article 114.

2. INTRODUCTION

A number of problems on the internal market have been identified in a [Communication on Identifying and addressing barriers to the Single Market](#) and in the accompanying [staff working document](#), which can be a source of information.

The questions below can be used at various stages of the impact assessment process. They are relevant for both problem definition and analysis of options:

(1) *Questions to describe market structure, identify internal market related problems, market failures, their size and drivers*²⁹⁶:

- What are the trade flows of goods/services inside the EU and/or between Member States? How many companies provide relevant goods/services in the EU? Do they operate cross-border? Do they perform intra-EU sale/purchase of goods/services? Are there specific Member States where they operate and others where they are absent – why? Do companies operate in foreign markets through establishment (e.g. by setting up a branch, subsidiary, joint venture, etc.), or through posting of workers or by cross-border provision of services? What are the revenue and market shares of companies from other EU Member States and from cross-border provision of goods/services?;
- What are the skill and qualification structures of employees/professionals affected by the proposal in the EU and in the Member States? How many do work in other Member States? Do they work as posted workers or are they employed on a temporary or permanent basis? Are there barriers imposed by authorities, professional bodies, labour unions, employers (e.g. in contracts, standards or certificates) or others? Are these barriers especially burdensome for foreigners / targeting foreigners / foreign qualifications or diplomas?;
- If there is no/little cross-border trade, is this because of the type of goods/services that foreign companies provide? Are these goods and services really not tradable? Are there other reasons (e.g. supply or demand specificities at national level like climate, consumer preferences, language, culture)? Can these goods/services become tradable in the future (e.g. due to innovations, IT advances,...)?;
- Are there barriers imposed by market participants (such as territorial constraints on retailers, exclusivity contracts or cooling-off periods preventing competition following the termination of a contract)?;
- Can customers buy cross-border (e.g. can they buy in internet stores of the same company located in another Member State)? Is there a discrimination based on origin/nationality/residence? Are foreign buyers treated differently than locals when buying in another Member State for example by receiving different prices, different

²⁹⁶ See Tool #13 (*How to analyse problems*) for instance for guidance on market and regulatory failure analysis

terms and conditions such as ways of payment, delivery options, possibility to return, guarantee, redress, insurance?²⁹⁷;

- Are there market-imposed obstacles to the free movement of capital? (e.g. Stock Exchange Rules on listings, additional requirements for reporting or requirements to use certain standards such as Accounting Standards, etc.)? Are any of these especially targeting foreign capital providers? Are there differences in treatment of financing provided by financial institutions (e.g. venture capitalists) to companies (especially SMEs) based on their country of establishment? Are there any differences in treatment by type of funding?
- Are there any barriers to cross-border mobility of citizens or businesses that are caused by poor administrative cooperation or information exchange between public authorities?
- For any of the questions above: if digital solutions are involved, is there sufficient consideration of interoperability for cross-border exchange²⁹⁸?

(2) *Questions to identify regulatory failures:*

- Is the matter under consideration regulated in some Member States? Are there Member States with no rules at all? What are the underlying reasons in both cases, and are they still valid? Is there a risk for regulatory arbitrage if some Member States have rules and others not? How were the rules implemented in practice (e.g. rules on protection of ‘whistleblowers’)?;
- Is the regulatory framework harmonised – do companies/citizens face different rules/requirements in each Member State?
- In case of different national rules, is there a mutual recognition principle²⁹⁹ in place? How does it work? If not, why not?
- Are there regulatory barriers to foreign companies accessing the market?
- Are they justified by overriding public policy interest? Are they proportionate? Are they cumbersome³⁰⁰? For example, is there a need for obtaining permits, certificates, licences, attestations, passing of exams, provision of certified/translated copies of documents; number of documents to be submitted, need for audit, length of procedures; legal form or shareholder requirements, different accounting, or reporting rules. Are the rules easy to comply with (e.g. electronically via points of single contact; e-procurement platforms) and are translations or rules readily available?
- Are certain rules more cumbersome for foreigners (e.g. need for translation, need to appoint a local representative, need for additional certificates)? Are certain rules easier for foreigners (e.g. mutual recognition means that companies can accept standards/certificates of other Member State)? Is there scope for simplification?

²⁹⁷ Please note that certain EU acts restrict the non-discrimination principle, e.g. the Rome I Regulation (EC 593/2008) grants the consumer protection of his own national law in case the trader directs its activities to the Member States where the consumer is domiciled. The principle is that consumers should not have lower level of protection than in their home Member States.

²⁹⁸ See Tool #28 (*Digital-ready policymaking*)

²⁹⁹ The existing mutual recognition principle covers trade in certain goods as well as recognition of professional qualifications.

³⁰⁰ See Tool #24 (*Competition*)

- Is there ‘gold plating’ – Member States adding national/local rules to the harmonised EU ones? If so, what are the reasons? Are there rules in other fields that affect the area under consideration? Could all these additional rules discourage cross-border activity?
- Are the procedures to be followed clear, transparent and publicly available? For example, selection mechanism for tender winner in public procurement, non-publication of tenders; lack of meaningful information about regulated professions;
- Can companies/citizens enforce their rights easily?
- Can different levels of law enforcement encourage/discourage cross-border activity (e.g. rules exist but are not used)?;
- What is the cost in terms of time and money to enforce one’s rights (e.g. length of court proceedings, etc.)?
- Does the regulated market structure create barriers? For example, very long contracts awarded by authorities that form a barrier to market entry (e.g. highway long term concessions). Is there centralisation of public procurement favouring large scale (national) suppliers (e.g. medicines)?;
- Does the country of origin/establishment influence the ability to access/transfer capital (e.g. obtaining a bank loan, venture capital, listing on stock market, acceptance of payment with a debit/credit card issued in other Member States)? Is the cost of access/move of capital higher for foreigners?

3. ASSESSING IMPACTS RELATED TO THE INTERNAL MARKET

Impact assessments might investigate problems directly related to obstacles/barriers to the freedom of movement of people, goods, services, and capital in the Single Market (a possible corresponding objective being to remove market distortions for companies, workers and consumers). An impact assessment might also look into other policy issues, but the options under analysis could impact the functioning and effectiveness of the Single Market. As a general rule, one should be careful not to concentrate only on long-term or short-term effects as costs are usually born in the short term while benefits generally materialise in the long term.

One should also consider the distribution of impacts. Some benefits and/or costs may concern or concentrate among selected groups only. Therefore, one needs to identify stakeholders, regions or Member States who will be most affected (e.g. in a given sector, benefits can be similar for all companies, but costs to SMEs can be bigger – as percentage of turnover or profit margin – than for large companies)³⁰¹.

Box 2. Key questions for assessing impacts

- What impact (positive or negative) does the option have on the free movement of goods, services, capital, and persons (self-employed and workers)?
- In case of evaluations: were there unintended impacts (positive or negative) of the

³⁰¹ See Tool #23 (*The ‘SME test’*)

evaluated legislation on the free movement of goods, services, capital, and workers?

- Will it lead to an increase/reduction in consumer choice³⁰², higher/lower prices due to less/more competition, the creation/elimination of barriers for new suppliers and service providers, the facilitation/prevention of anti-competitive behaviour or emergence of monopolies, market segmentation, more or less convergence of consumer and business conditions across the EU, etc.?

You could further consider using benchmarks to assess the level and effectiveness of market integration, such as goods market and services markets, trade between Canada and USA, trade between US states or trade between EU/EEA Member States³⁰³.

When evaluating existing legislation, consider assessing its impact on the Single Market. Be aware that some impacts might be unintended or unexpected at the time your legislation was proposed. Consider these also for legislations that did not have Single Market as a core objective or were not based on Article 114.

3.1. Identification and measurement of potential direct impacts of options

Based on the evidence gathered in the problem definition phase regarding the additional barriers/burdens borne by citizens and companies involved in cross-border activities, the most probable direct impacts on internal market of the policy options should be identified and measured, including their impact on the identified barriers/burdens.

This should be done by identifying the potential costs and benefits under the various policy options in relation to the baseline scenario of complying with all the national rules for a company that wants to do business in another Member State, or the extra burden a citizen would face when trying to work/shop in another Member State.

To estimate the costs and benefits of EU action, adequate data on the situation in the Member States are needed. These data should ideally describe the current situation in the Member States, as well as projected savings/costs due to EU action. A variety of data sources is available, including constant monitoring of the situation in the Member State, expert groups, representative surveys (e.g. Eurobarometer), dedicated enterprise surveys (Enterprise Europe Network, SME panels), external studies and public consultations³⁰⁴, as well as data produced by European public administrations (see data.europa.eu).

In many cases, the main benefit of internal market harmonisation/rules lies in cost savings following the replacement of 27 different national rules and procedures that companies and citizens face with one harmonised EU regime or by creating a 28th (EU) regime (e.g. costs of patenting fees for an EU unitary patent vs. 27 national patents).

To estimate the potential savings thanks to the internal market or the costs of ‘no internal market’ one could consider the following conceptual model:

(1) Calculation of individual company/citizen savings/costs following the replacement of national regimes by an EU-wide one

³⁰² See Tool #33 (*Consumers*)

³⁰³ See Tool #27 (*External trade and investment*)

³⁰⁴ See Tool #4 (*Evidence-informed policymaking*)

- ‘Baseline scenario’ (national rules/regimes): what is the cost per company of following the current regime(s) assuming that it wants to cover/serve all Member States (e.g. obtaining patent protection in each Member State? Under alternative scenarios e.g. only a subset of Member States and related costs can be considered such as following the actual behaviour of companies who choose to protect their patent only in a limited number of Member States).
 - ‘EU scenario’ (harmonised EU rules/regime): what is the cost of following just one EU regime (e.g. obtaining EU unitary patent)?
- (2) ***Extrapolating the above individual-level costs and benefits/cost savings (for companies or citizens) to the whole sector/market or population***
- When extrapolating, consider the number of citizens/consumers/companies that are likely to be affected by the EU rules. This can be all citizens/consumers/companies or just a subset whose activities are cross-border. You may also consider whether the EU rules might incentivise more citizens/consumers/companies to engage in cross border activities in a longer run.

To make this kind of calculation, detailed data per company and Member State on the costs related to the current regime(s) are necessary (e.g. one-off and recurring costs for each procedure, including required staff and working time, legal representation, translation costs, etc.). In addition, you need to estimate (ranges of) the costs that a future single EU regime would impose and changes in company/citizens behaviour regarding cross-border trade and investment that would follow³⁰⁵.

To extrapolate the above calculated costs and benefits to estimate the cumulative costs and benefits for the whole sector/market or population, and eventually the whole EU, a distinction must be made between static and dynamic scenarios:

- In a static scenario, one takes the number of companies that are active cross-border as given and uses it to multiply the cost estimates per company obtained under point (1) for both 27 regimes and the EU regime for all scenarios analysed under the baseline.
- In a dynamic scenario, estimate expected change in the number of companies’ active cross-border in the baseline case and following the EU regime. The cost estimates per company obtained under point (1) then must be multiplied by the number of companies active cross-border in a new dynamic baseline and the estimated number of companies active cross-border under the new harmonised EU regime, respectively.

For quantifying costs you may also consider following the **Single Market Gap** procedure suggested by CEPS in their [2014 study for the European Parliament](#) on “Indicators for Measuring the Performance of the Single Market – Building the Market Pillar of the European Semester”³⁰⁶.

3.2. Identification and measurement of the Single Market benefits

You should strive to assess the benefits of the internal market especially for consumers, companies, and employees. These could be direct (e.g. free movement of citizens) and indirect (e.g. more choice and lower prices due to increased trade and competition).

³⁰⁵ See Tool #57 (*Methods to assess costs and benefits*)

³⁰⁶ For more explanation and detailed examples, see page 70 of the full report.

The benefit analysis is usually qualitative due to inherent measurement difficulties. However, whenever possible, try to quantify. Some examples are presented below on how to measure market integration:

Benefit	Measurement
Trade creation: trade between Member States, improved value chains, outsourcing of goods and services, more trade in internal border regions (especially for services dependent on geographical proximity).	Export/Import to GDP, degree of price dispersion / convergence, wage dispersion / convergence
More competitive markets: leads to bigger choice, higher quality and lower prices for consumers, continuity of supply, lowering switching cost.	Foreign Direct Investments (outward and inward) to GDP, delivery of services through establishing affiliates; Hirschman-Herfindahl index (HHI); dispersion of consumer prices and their evolution over time; choice and switching in consumer markets; consumer and business confidence in cross-border (online) transactions.
Efficiency gains / productivity: economies of scale and scope.	These efficiency gains measured using unit labour costs — defined as the ratio of total labour costs (total hours worked multiplied by the hourly wage) to Gross Value Added, deflated by the Gross Value Added price index. Productivity increases due to backward- and forward-linkages in the value chain/across sectors.
Innovation: sufficient demand to recuperate development cost for product and process innovation.	Expenditure in Research, Development, and Innovation (RD&I), number of personnel employed in RD&I activities, number of patents and innovative activity. Expenditure for digital transformation of business models.
Free movement of people: job opportunities in other Member States, studying abroad, labour mobility, commuting, 'brain gain'	EU citizens working in another Member State as % of total labour force, number of exchange students, cost of qualification recognition procedures; international comparisons – cross-border mobility between EU Member States and in other regions (such as United States, Canada or Australia).
Free movement of capital: More investment opportunities, diversification	Interest rate convergence, foreign listing, share of foreign assets/liabilities in financial sector
Policy influence and synergies, cooperation and coordination	Synergies from having common approach, common institutions, elevating influence of individual MS. Coordination of policies (reduced likelihood of retaliatory actions, addresses coordination failures) Mainly qualitative description.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

3.3. Identification and measurement of the Single Market costs

The same holds for the analysis of costs. A list of potential sources is given below.

Cost	Explanations
Trade diversion	Preference to trade within EU rather than with outside world (share of trade with non-EU countries).
Adaptation cost	Cost for companies to face bigger competition. Possible unemployment in non-competitive sectors. Different market structure (players, supply chains).
Employment and companies	Potential for loss of employment in uncompetitive/unregulated sectors/companies (at least in short term), bankruptcy of underperforming companies; 'brain drain'; other possible social impacts and/or fundamental rights impacts ³⁰⁷ .
Impact on national budgets	Tax arbitrage, tax avoiding schemes; unemployment benefits for redundant workers.
Costs for EU/national budget	The functioning of the Single Market might require dedicated administrative bodies financed from the EU or national budgets.
Administrative costs ³⁰⁸	Costs for companies to comply with new administrative obligations.
Adjustment costs	Cost of applying EU rules.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

4. HOW TO MINIMISE NEGATIVE IMPACTS ON THE INTERNAL MARKET

According to the fundamental freedoms of the Treaties, certain negative impacts on the internal market are outright prohibited. This applies in particular to discriminations based on nationality or residence. Options that would lead to the illegality of the measure have to be excluded in all cases.

To minimise potential negative impacts on the functioning of the internal market beyond these legal requirements, and depending on the circumstances, you can consider including the following into your options:

In relation to the content of a policy option:

- promoting standardisation (e.g. IFRS accounting rules for listed companies; codes of conduct, European standards, model documents, eGovernment action plan principles, European catalogue of standards, DSI technical specifications and standards, etc.);
- promoting transparency and information (preferably in multiple languages) – e.g. setting information points/one stop shops for (e.g. points of single contact), digital by default and digital once-only principles;

³⁰⁷ See Tool #30 (*Employment, working conditions, income distribution social protection and inclusion*).

³⁰⁸ See Tool #56 (*Typology of costs and benefits*) for definitions

- limiting any unnecessary administrative and private obstacles to cross-border movement/trade;
- mutual recognition, harmonisation and best practice dissemination;
- exploiting synergies and/or implementing relevant mitigating measures in other related policy areas (competitiveness, social/employment, fundamental rights).

In relation to the policy instrument:

- regulations can limit the risk of 'gold-plating' associated with the transposition by Member States of Directives;
- consider an EU regime of common rules that could be applied in cross-border situations without changing national rules (e.g. the European Common Sales Law);
- limiting to a bare minimum the number of implementation options in directives;
- use of IT solutions to foster access to information (e.g. e-procurement; SOLVIT; points of single contact);
- exchange of information between authorities (e.g. internal market information system, RAPEX);

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

Contact point: GROW-IMPACT-ASSESSMENT@ec.europa.eu

Useful links:

- [Single market scoreboard](#)
- [Barriers to trade](#)
- [Single market for goods](#)
 - [International trade in goods](#) (look for intra EU trade)
- [Single market for services](#)
 - [International trade in services](#) (look for intra EU trade)
- [Other Databases](#)
- [2021 Annual Single Market report](#)

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Real GDP per capita • Gross domestic expenditure on R&D • R&D personnel <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Annual growth rate of real GDP per employed person • Research and development expenditure as a proportion of GDP • Researchers (in full-time equivalent) per million inhabitants 	 

TOOL #26. PREVENTION OF FRAUD

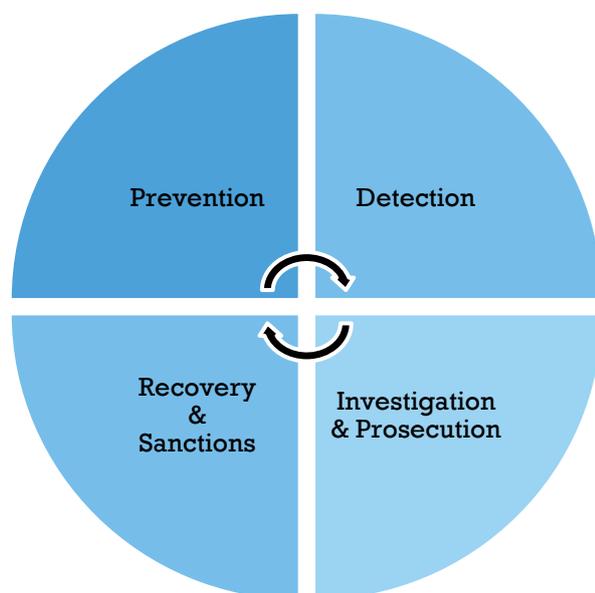
1. INTRODUCTION

The notion of fraud covers any intentional act or deliberate and wrongful omission, affecting the EU's financial interests and/or reputation. The key element which distinguishes fraud from (non-fraudulent) irregularity, error or non-conformity, is intention. Fraud can happen through various means, e.g. cost mischarging or double funding, false documents, plagiarism, non-disclosure of conflicts of interest, corruption and staff misconduct. Therefore, the definition of fraud cannot be limited down to the narrow understanding of fraud as a criminal offence³⁰⁹.

The risk of fraud, in its wider concept, should be examined in parallel with the risk of corruption. The abuse of a (public) position for private gain takes place when a receiver (passive corruption) accepts a bribe from a giver (active corruption) in exchange for a favour. Corrupt payments facilitate many other types of fraud, such as false invoicing, fictitious expenditure, or failure to meet contractual obligations/specifications.

Fraud can have a significant negative impact on EU policies, both financial and reputational. Financial fraud affects the objectives of EU action by reducing the amount of financial support available for achieving the desired positive impacts. Non-financial fraud may impair product safety, consumer protection and public health, e.g. where the certification of a product is obtained fraudulently. Both financial and non-financial fraud can undermine the trust that citizens and other stakeholders have in the Union's actions and institutions.

Under Article 325 TFEU and Article 36(2)(d) of the [Financial Regulation](#), the Commission is duty-bound to fight fraud. This fight is often illustrated in the anti-fraud cycle:



³⁰⁹ [Directive \(EU\) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law](#)

2. FRAUD-PROOFING OF THE POLICY CYCLE

The [Commission Anti-Fraud Strategy](#) (CAFS) includes the obligation to fraud-proof the legal framework for expenditure and revenue and explicitly refers to the consideration of fraud-related aspects in evaluations and impact assessments³¹⁰.

For most policy proposals, (the reduction of) fraud is not a primary impact to be assessed in the accompanying impact assessment (IA). It should however be screened as a potential indirect impact when assessing different options in the IA.

Box 1. Fraud proofing as part of the impact assessment

In the context of an impact assessment, fraud comes into play at two levels:

1) Fraud potentially obstructing the attainment of policy objectives

Fraud may undermine the effectiveness of a policy option in achieving one or more of the pursued policy objectives, notably because fraudulent activities take away funds from their intended purpose on a large scale or hinder the proper functioning of health and safety rules.

Example:

A regulation limiting the toxicity of exhaust fumes of cars that allows measuring toxicity levels only in a laboratory. The achievement of the regulation's policy objective of protecting public health may be undermined by fraudsters who may develop defeat devices that conceal high toxicity levels during laboratory tests.

2) Fraud as a policy option's potential side-effect

If a certain policy option is susceptible to increase fraud risks that do not directly affect the policy objective, the IA needs to flag such a potential effect as an unintended consequence of that policy option, most frequently in financial and reputational terms.

Example:

To speed up the award and payment of emergency aid, one option is to fully digitalise and automate the application and award procedure. The IA should assess any risk that fraudulent applications might be accepted as an unintended consequence of that option.

Depending on the scale of fraud, this example might as well fall in the first category – large-scale fraud might lead to a suspension of the programme upon detection or might use up the available funds prematurely if it goes undetected. In both cases, the primary objective of the policy will not be reached.

Considering the anti-fraud dimension in an IA will help both the Commission and the co-legislators to understand better the wider implications of the risks associated with various policy options and allow them to identify mitigating measures at an early stage. Assessing the underlying data flows of the policy (see Tool #28 (*Digital-ready policymaking*)) can help detect possibilities for fraud.

Therefore, one should equally consider fraud proofing in other stages of the policy cycle.

³¹⁰ Point 24 of the CAFS Action Plan, SWD(2019) 170.

Box 2. Fraud proofing beyond impact assessment

Apart from some specific cases³¹¹, the IA is usually the first stage in the lifecycle of a policy initiative at which fraud risks, their potential detrimental effects, and ways to mitigate them become relevant.

Fraud proofing continues, however, after the impact assessment with

- **fine-tuning** the chosen policy-option to minimise fraud risks; and
- **finalising** the Commission decision or proposal in the formal procedures of **inter-service consultation** and **adoption** and accompanying it through the **legislative process** where applicable;
- including, in this context, **standard anti-fraud clauses** in legislative acts, especially spending programmes, **for the Multiannual Financial Framework 2021 – 2027**.

Fraud proofing extends further to the implementation of the adopted policy, for example through a fraud-resilient design of:

- delegated and implementing acts where applicable;
- guidance and templates (for calls for tenders/proposals/expressions of interest, model contracts/agreements) with systemic importance;
- internal procedures;
- IT solutions;

and concludes with the **evaluation** of the policy in question, including its anti-fraud stance.

As stated in Points 23 and 24 of the CAFS Action Plan, fraud proofing comprises the whole policy cycle. It is primarily the responsibility of a policy-making DG, but **OLAF should be associated to that exercise from its early stages**. This is particularly relevant for complex and time-bound projects and for negotiations with implementing partners; in both cases the course of action may be steered into certain directions early on.

Apart from fraud and corruption in public procurement processes, other weaknesses in the enforcement of EU law, such as lack of effective enforcement of environmental rules, or breaches of safety in transportation, can cause serious harm to the public interest and create significant risks for the welfare of society. Any new proposal should include effective systems of compliance.

Whistleblowers play a key role in preventing and detecting breaches of EU law. They are often the first to know about threats or harm to the public interest inside their organisation. Their reports and public disclosures feed therefore national and EU enforcement systems with information leading to effective detection, investigation, and prosecution of breaches of Union law. Accordingly, policymakers should assess in the impact assessment whether enforcement of the proposed legislative act would benefit from introducing rules on reporting by and protection of whistleblowers exposing infringements of that legal act (see also section 3 below).

³¹¹ When it comes to policy projects that focus on the fight against fraud (such as the establishment of the European Public Prosecutor’s Office), fraud-related considerations will already determine the development of policy options, i.e. before the impact assessment sets in.

3. MANAGING AND COUNTERING FRAUD RISKS

OLAF's experience with preventing and investigating fraud shows that the design of (spending) programmes is the first step in effective fraud prevention. OLAF and other Commission services have encountered many types of fraud that had negative economic and social impacts and put the Union's reputation at risk. When screening policy options for fraud, it is important to keep in mind that preventing or detecting fraud is often not the direct target of a programme design, but still is to be considered as an additional component of the overall structure and process. Identifying fraud risk requires not only factual knowledge of the background situation (nature of the business, the environment in which it operates, the effectiveness of the existing internal controls), but it also involves some sort of creativity, assumptions, and acceptance of approximation.

Because managing fraud risk aims at proactively identifying, assessing, and addressing vulnerabilities, it requires *communication* and *knowledge*.

Communication is the first requirement of fraud risk management. It becomes effective by making the management process visible. Communication actions must be tailored to the peculiarities of the organisation in such a way to facilitate the participation and involvement of all relevant actors.

Knowledge is the second essential requirement of this process. The management of fraud risks should involve different layers of the organisation: management, authorising officers, finance cell teams, legal departments or legal advice units, geographical desks, auditors and, where appropriate, external consultants. The available tools for fraud risk identification and assessment include interviews, surveys, focus groups, and anonymous feedback mechanism.

"The ability to think the unthinkable" or "thinking like a fraudster" is useful in this exercise, while basing oneself on factual references in the real working environment. For example:

- considering previous fraud incidents and what could have been done to prevent them;
- evaluating the existing control systems in four steps: 1) *mapping* the existing controls; 2) *testing* them; 3) *validating* them; and 4) *integrating* (considering the results of the tests run to enhance further the efficiency and effectiveness of the control systems).

The assessment of the impact of the policy proposal on the exposure to fraud may be facilitated by asking the following questions:

- To what extent do the options identified rely on statements or documentation from parties involved in the implementation?
- How can deception adversely affect the objectives of this policy?
- Are there any significant differences in terms of negative impact of potential fraud between the identified options?

The fraud risk management process should also ask how the risks of exposure to fraud could be reduced. Beside measures of a general nature, such as including the anti-fraud dimension in the framework of checks and audits or tailor-made anti-fraud controls specific to the policy in question, the following approaches could be useful:

- **Procedures to detect potential fraud.** When transactions are processed, ex ante checks should increase the level of assurance to identify possible inconsistencies leading to

suspicion of frauds. Ex post controls on the other hand will allow a more in-depth scrutiny for the riskier projects thanks to on-the-spot audits.

- **Diversification of the sources of information.** Where funding relies on contractors' or beneficiaries' statements on their compliance with the financing conditions or certification criteria, the policymakers should think of ways of collecting information from other sources for verification purposes. In particular, one should consider a specific reference to the applicability of the [Directive on the protection of persons who report breaches of Union law](#). It allows whistleblowers to report breaches affecting the financial interests of the Union and ensures their protection in case they suffer retaliation (see section 3 below).
- **Increasing transparency.** Increase the transparency of the envisaged policy options, for example by requiring to make certain statements public or publish findings about the implementation of the policy, with due respect for the protection of personal data³¹².

The consideration of fraud-related aspects in evaluations, fitness checks and impact assessments will be facilitated through (and the quality of these instruments in this respect will benefit from) the implementation of the [Commission Anti-Fraud Strategy, which has two objectives](#):

- [to strengthen the Commission's](#) capabilities in the collection and strategic analysis of fraud-related data;
- to foster coordination and cooperation in the fight against fraud and tighten corporate oversight in this respect.

Box 3. Fraud-risk management

The management of fraud risk should provide information about its level in a given policy area and how the policy proposal is likely to increase or decrease fraud risks in that area. In summary, three components may be distinguished:

- **Identification of fraud risks related to each policy option**

This task may be inspired by the DG's own risk register and anti-fraud strategy, reports by European Court of Auditors and Internal Audit Service, OLAF's case compendia, specific final reports and other documents that **reflect past experience and allow drawing parallels to the policy in question**. More importantly, the task requires creative **thinking 'out of the box' and cooperation** among a variety of actors – at least the policy unit in charge, the OLAF correspondent and other services concerned (including OLAF and executive agencies if they need to implement the policy).

- **Assessing the fraud risks: rating the likelihood and impact of fraud risks materialising**

This exercise involves checking the **fraud vulnerabilities** in the policy area concerned and how these may be influenced by each policy option. Similarly, the fraud risk assessment needs to estimate the damage that various types of fraud could do under the different policy options, including **financial damage, reputational damage, and damage to the attainment of policy objectives** (if any – see Box 1). In general, assessing *likelihood* and *impact* of fraud risks mainly serves to rank fraud risks by significance and by priority of containment. In the framework of an impact assessment, such rating should ideally quantify the potential impact

³¹² See e.g. the Commission's [Financial Transparency System](#)

of fraud risks to facilitate their integration into the overall comparative analysis of the different policy options.

- **Conceiving mitigation measures**

Before drawing a conclusion on the impacts of a policy option, the impact assessment needs to review possible improvements and/or mitigating measures to reduce its negative impacts. As part of the impact assessment, the fraud risk assessment should focus on the **residual risk** after considering existing anti-fraud measures as well as additional ones, especially tailor-made measures that could be introduced to counter fraud risks induced or increased by the policy option in question. The impact assessment should also try to estimate the **cost of complementary measures**. **Red flags** should be developed to swiftly identify symptoms of potential frauds.

Methodological guidance

For guidance on risk management, see Tool #14 and the Commission’s [Risk Management Implementation Guide](#). Pragmatic guidance for the estimation of the cost-effectiveness of controls has been issued by DG BUDG³¹³.

The fraud risk assessment should respect the requirement of **proportionate analysis**, depending, for instance, on the magnitude and relevance of the impact analysed. When quantitative analysis is not possible or proportionate, impacts should be assessed qualitatively and the reasons for not having undertaken quantification explained in the IA report.

4. WHISTLEBLOWER PROTECTION

The EU protects persons who report breaches of Union law. With a view to strengthen the enforcement of EU rules, the relevant [Directive on whistleblower protection](#) obliges Member States:

- to **establish internal (within the organisation) and external (to the competent authorities) reporting channels** for potential whistleblowers to report on breaches of EU law under a strict confidentiality regime, and
- to **provide for measures of support and protection** in case the whistleblowers are retaliated against due to their internal or external report or public disclosure, provided they satisfy the conditions established by the Directive.

When drafting an impact assessment for new legal acts or for amending existing ones, policymakers should assess whether providing for reporting channels and for protection for whistleblowers would strengthen enforcement of these acts, by checking the following:

- Does the legal instrument **fall within one of the policy areas** of the material scope of the Directive³¹⁴?
- Could breaches of the rules of the legal instrument **cause harm to the public interest**?³¹⁵

³¹³ [Guidance on the estimation, assessment and reporting on the cost-effectiveness of controls, 2018](#).

³¹⁴ As spelled out in Article 1 of the Directive on whistleblower protection: (i) public procurement; (ii) financial services, products and markets, and prevention of money laundering and terrorist financing; (iii) product safety and compliance; (iv) transport safety; (v) protection of the environment; (vi) radiation protection and nuclear safety; (vii) food and feed safety, animal health and welfare; (viii) public health; (ix) consumer protection; (x) protection of privacy and personal data, and security of network and information systems.

- Is there a need to **strengthen the means of enforcement of the legal instrument** (i.e. would the instrument benefit from additional tools to ensure an effective enforcement beyond, for instance, complaints, audits etc.)?
- Would reports by **whistleblowers strengthen enforcement** of the EU legal instrument (i.e. namely because they can bring to light hidden unlawful practices that only 'insiders' can reveal), so that providing for clear and confidential reporting channels and for protection of whistleblowers would be **likely to increase detection** of breaches of those rules?

If the answer to the above questions is affirmative, it is recommended to include rules on whistleblower protection in the proposed or amended legislative acts by including a reference to Directive 2019/1937 and amending its annex to add the concerned legislative act in its scope.

For more details, please refer to the [Note on “Inclusion of rules on reporting on breaches of EU law and protection of the reporting persons \(i.e. rules on “whistleblower protection”\) in future EU legal acts: criteria and legislative technique”](#)³¹⁶.

5. SUPPORT

On prevention of fraud, OLAF Unit C.1 Anti-Corruption, Anti-Fraud Strategy and Analysis can provide further assistance: OLAF-FM-C1@ec.europa.eu

On the need to introduce whistleblower protection to a new legal act, DG JUST Unit C.2 (fundamental rights policies) can provide further assistance:

EU-WHISTLEBLOWER-DIRECTIVE@ec.europa.eu

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Perceived independence of the justice system • Corruption Perceptions Index • Population with confidence in EU institutions <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Financial Soundness Indicators • Proportion of businesses that had at least one contact with a public official and that paid a bribe to a public official, or were asked for a bribe by those public officials during the previous 12 months 	 

³¹⁵ Some examples of breaches of EU rules considered as harmful to the public interest: breaches of rules on Union harmonised and non-harmonised products; on safety transport; on environmental protection, on nuclear safety, breaches of the Union food and feed law; breaches affecting the internal market, such as of the rules on financial services, on anti-money laundering, on consumer protection or of procurement rules, etc.

³¹⁶ Ares (2020)1980728.

TOOL #27. EXTERNAL TRADE AND INVESTMENT

1. INTRODUCTION

External trade and investment are powerful engines for growth and job creation. As tariffs have largely been dismantled, disproportionate regulatory requirements or unnecessarily divergent regulations have become the main barrier to trade. It is more difficult to identify them and to quantify their impacts than it is for tariffs or measures applied at borders. This is particularly true for services which, given their intangible nature, are often hard to identify in statistics and other analyses.

Regulations and standards adopted in pursuit of various public policy objectives may constitute technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) or fall under the general WTO disciplines on goods or services and other non-tariff measures (NTM). These can have significant impacts on both exports and imports by requiring firms to spend resources to adapt their products, duplicate testing of safety requirements, undergo burdensome certification procedures, interpret, and comply with several sets of legislation, etc. This can be especially the case for developing countries, as well as for SMEs. Considering the obligation to consider Policy Coherence for Development, potential negative impacts from a measure on the EU's efforts to promote sustainable development in these countries need to be identified.

EU legislation and other types of policy measures must comply with the EU's existing international legal commitments. The EU is legally bound by many international trade agreements: first and foremost, the World Trade Organisation (WTO) Agreements; but also bilateral, multilateral and plurilateral agreements containing – for example – provisions on trade in goods, services, digital trade, intellectual property, or investment matters, many of which go considerably further than WTO Agreements. In terms of easing possible negative impacts on developing countries and leaving them more time to adapt, it should be noted that the principle of Special and Differential Treatment (SDT) for these countries is enshrined in the WTO as well as in the sustainable development goal (SDG) 10.a in the Agenda 2030 for Sustainable Development.

While an impact assessment certainly does not constitute a legal assessment of the compliance of proposed regulatory measures with WTO rules, it is important that services systematically consider the broad legal obligations as well as the broader policy objectives associated with the EU's trading regime when formulating (and assessing) their policy options. Any option that is clearly in breach of the EU's international legal obligations should be discarded at an early stage. Therefore, the assessment should begin as soon as possible after starting to prepare a legislative proposal, so that the scope can be adjusted and adapted while the legislative proposal develops.

While promoting the EU's role and leadership in international standard-setting, it is also important to avoid as far as possible unnecessary divergence, tensions, and sources of conflicts with EU's trading partners. The international dimension of the issue should therefore be carefully considered when the options are assessed, and engagement with the main trading partners should be sought from an early stage, including through outreach activities. In particular, the impact of a measure under the various policy options should be examined also in relation to third country producers or service providers. The impact assessment should also ascertain that the preferred option does not result in *de facto* discrimination of third country goods and companies in a manner that would go counter to

established trade rules. Due consideration should also be given to the impact on developing countries. Indeed, these requirements and regulations may prominently affect developing countries, and in particular least developed countries, as these may lack the awareness or the capacity to be able to identify and handle them. Consideration should also be given to the impact of the envisaged initiatives on EU neighbouring countries and those that are candidates to accession to the EU. The issue of potential external spillovers of EU initiatives, including trade initiatives, on developing countries may lead, where appropriate, to assessing to impacts by also having recourse to Tool #35 (*Developing countries*).

2. SCREENING OF OPTIONS AGAINST THE EU'S INTERNATIONAL LEGAL COMMITMENTS

When designing the options, the following issues should be considered³¹⁷:

2.1. Consistency with the WTO Agreements

The WTO Agreements cover a wide range of issues. A full-fledged analysis of WTO compatibility can and should be undertaken by specialist lawyers in the Legal Service and DG TRADE and should not be performed either by the Commission's services themselves or as part of an external consultant's report in support of an impact assessment.

However, at the stage of identifying options in the context of an impact assessment, it is important to rule out those that would obviously lead to an outcome incompatible with WTO or other international obligations. The impact assessment should focus only on options that are, in principle, legally viable. In this regard, certain basic questions should systematically be considered when designing the options:

- Does the option allow imported goods or foreign services or service suppliers to enter the EU market, when they are WTO-compliant? If not, see Box 1 for further details on whether exceptions to WTO rules are available.
- Does the option ensure *de iure* and *de facto* non-discrimination between imported goods or foreign services or foreign service suppliers, and goods produced in the EU or EU services or EU service suppliers (the 'national treatment' principle)? If not, see Box 1 for further details on whether the exceptions to WTO rules are available.
- Does the option ensure *de iure* and *de facto* non-discrimination between goods or services or service suppliers of different WTO member countries (the 'most-favoured nation' principle)? If not, see Box 1 for further details on whether the exceptions to WTO rules are available.
- If the option involves product requirements that would be covered by the Technical Barriers to Trade (TBT) Agreement³¹⁸ or the Sanitary and Phytosanitary (SPS) Agreement³¹⁹, can you demonstrate that the requirements are proportionate to the objectives pursued (see Box 1 below)?
- If the option regulates the movement of goods on sanitary or phytosanitary grounds, is it based on a risk assessment supported by sound scientific evidence (see Box 1 below)?
- Is the option compliant with WTO rules on subsidies, intellectual property, and procurement?

³¹⁷ Assistance from DG TRADE on these matters should be sought whenever appropriate.

³¹⁸ http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

³¹⁹ https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

Box 1. Trade agreements and the pursuit of legitimate public policy objectives

WTO exceptions

GATT Article XX of the General Agreement on Tariffs and Trade (GATT) allows governments to adopt trade-restrictive measures that would otherwise be inconsistent with GATT obligations (in respect of non-discrimination or import restrictions) in order to (among other things) protect public morals, human, animal or plant life or health, as well as exhaustible natural resources, provided that the measures adopted are necessary to achieve genuine public policy objectives, their design do not entail arbitrary or unjustifiable discrimination between countries where the same conditions prevail and they do not constitute disguised protectionism. In particular, it should be assessed whether less trade restrictive alternative measures are reasonably available and capable of achieving the objective equally effectively.

GATT art XXI provides exceptions for security reasons. Similar exceptions exist in WTO rules for trade in services, investment, procurement, etc.

The Sanitary and Phytosanitary Measures Agreement (SPS)

- SPS measures are measures that aim to protect human, animal or plant life or health from risks arising from pests or diseases of plants or animals or from food safety risks. The SPS Agreement seeks to balance the protection of health with the liberalisation of trade in primary and processed agricultural products. WTO Members can set their own standards to protect human, animal or plant life or health within their territory based on a risk assessment underpinned by science. Restrictive SPS measures should be applied only to the extent necessary to protect human, animal, or plant life or health. They should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.
- WTO Members must rely on international standards, guidelines, and recommendations where they exist. However, if those international standards do not achieve the required level of protection, WTO Members may use measures that result in higher standards if there is scientific justification. The SPS Agreement also allows for provisional SPS measures where there is some indication that a risk exists, but a risk assessment is not possible due to a lack of sufficient scientific evidence.
- The SPS Agreement includes provisions on control, inspection, and approval procedures. Governments must provide advance notice of new or changed sanitary and phytosanitary regulations, and establish a national enquiry point to provide information. Specific rules may apply to developing countries to facilitate their compliance with SPS standards.

The Technical Barriers to Trade Agreement (TBT)

- The TBT Agreement regulates technical regulations, standards, testing and certification procedures, and seeks to ensure that they do not create unnecessary obstacles to international trade. Domestic measures shall not be more trade-restrictive than is necessary to fulfil a legitimate objective, such as the prevention of deception practices, national security requirements, the protection of human health or safety, animal or plant life or health, or the environment.
- Procedures used to decide whether a product conforms with relevant technical regulations have to be fair. The TBT Agreement discourages methods that would give domestically produced goods an unfair advantage and encourages mutual recognition of standards and

procedures.

- WTO Members are required to establish national enquiry points and to keep each other informed through the WTO. Around 900 new or changed regulations are notified each year.

Finally, note also that under WTO law it is possible under certain circumstances to regulate the way certain products, including imports, are produced or to restrict imports because of concerns about their production methods. However, in light of the potential not only for trade disruptions and for trade tensions, any such action should focus on issues of overriding legitimate public policy interests, in particular those that have a global dimension and have an impact on the EU (such as climate change, cross-border pollution). It should be based wherever possible on internationally agreed standards or principles, and supported by solid evidence, and should not be used to protect EU producers from competition or to level the economic playing field. The measure(s) taken would need to be designed particularly carefully to fulfil the conditions for WTO compatibility. Any such measure should also be manageable from the point of view of monitoring compliance and should not create a disproportionate burden for economic operators or for third country exporters, in particular those in developing countries. Priority should be given to the less trade restrictive measures available and, where possible, solutions should be used that allow sufficient flexibility for third countries to adapt and for the EU to cooperate with third countries.

2.2. Consistency with the EU's Free Trade Agreements (FTAs) or the customs union with Turkey

The EU has free trade agreements (FTAs)³²⁰ or other trade agreements with many countries in the world (Japan, Canada, Singapore, Vietnam, South Korea, Colombia, Peru, Central America, Southern Mediterranean countries, Chile, Mexico, South Africa, etc.), and has recently concluded or is currently conducting negotiations with several others. These are coherent with and incorporate some of the WTO rules mentioned in the previous section (including the relevant exceptions), and on many accounts also go beyond what would follow from the WTO agreements. The more recent agreements build on the WTO rules and contain detailed provisions on regulatory matters³²¹, some dealing with specific sectors (cars, electronics, pharmaceuticals, digital trade, energy, and raw materials, etc.). They also regulate – in more detail than the WTO Agreements – trade in services, investment, or intellectual property; and often have more far-reaching provisions on procurement. They also contain commitments on Trade and Sustainable Development. In recent negotiations, the EU is introducing also new disciplines on sustainable food systems. The customs union with Turkey (concluded in 1995) is a deeper agreement that ensures the free movement of all industrial goods and requires Turkey's alignment to the EU's external customs tariffs as well as to broader commercial policy in areas such as intellectual property rights (IPR) and competition.

³²⁰ For further detail, please refer to <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/>

³²¹ Including provisions regarding the level playing field in the FTA with the United Kingdom. In future FTAs, a chapter on Sustainable Food Systems may also be included.

2.3. Consistency with investment protection provisions/agreements

Investment protection provisions can be found in Member State agreements (there are more than 1000 of them)³²², in the Energy Charter Treaty, and in FTAs or in specific investment EU investment agreements. Generally, they provide for the possibility of requesting compensation when measures discriminate against investors and their investments, unlawfully expropriate³²³, or amount to arbitrary treatment of the investment. These protections are comparable to protections found in the European Convention on Human Rights, the EU Charter on Fundamental Rights and in Member States constitutions. It is important to avoid measures that could be inconsistent with such provisions. Note however that the reform of investment protection provisions promoted by the EU through changes to substantive policy and in the Investment Court System has been confirmed by the Court of Justice as protecting the right to regulate to pursue legitimate policy objectives. Investment provisions should not be interpreted in a way that hinders this prerogative of the EU.

2.4. Other legal effects

Two additional elements should be considered when designing the options. Through Agreements on Conformity Assessment and Acceptance of Industrial Products³²⁴ (ACAAs) with some neighbouring countries, the EU has “expanded its regulatory space” in some sectors. In these sectors, ACAA-countries have aligned their law to the EU *acquis* and would therefore be affected by any legislative changes. When designing an option in a sector covered by an ACAA, attention should be paid to the administrative capacity of partner countries to implement this new EU legislation.

On the other hand, the EU has concluded Mutual Recognition Agreements (MRAs) with some trade partners (US, Japan, Canada, Australia, New Zealand, and Switzerland) which cover some specific sectors. In some situations, involving EU rules (for example on testing of products), the operation of these MRAs provides sufficient assurances that the imported products meet the relevant EU standards.

3. HOW TO ASSESS IMPACTS ON EXTERNAL TRADE AND INVESTMENT

A series of questions should be examined when analysing the potential economic impact of the options considered:

3.1. Which economic operators should be considered?

All economic agents, producers and consumers, firms and households, should be considered. Producing firms are also consumers of intermediate goods and services (such as raw materials, components or business services). EU firms increasingly rely on the global economy for both diversified supplies of goods and services and sustained demand for their output. The impact analysis should therefore not restrict itself to the direct effects of the

³²² For a list of investment agreements between Member States and third countries, see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:131:0002:0098:EN:PDF>

³²³ In order to be lawfully expropriated, property held by foreign investors must be: taken for a public purpose; on a non-discriminatory basis; in accordance with due process of law; and accompanied by compensation. Unlawful expropriation includes both direct and indirect expropriation.

³²⁴ For more on ACAA, see http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/aaaa-neighbouring-countries/index_en.htm.

options on the specific sector concerned but should also consider the sectors and firms along the value chain.

The analysis should also consider the impact on third countries. It is also important, for instance when consulting stakeholders in the impact assessment context³²⁵, to provide equal opportunities for third country operators and EU importers to express their views.

Measures may have differentiated impacts on companies of different sizes. The impact on SMEs should specifically be considered, as administrative compliance requirements tend to disproportionately burden these operators.

3.2. How will the options affect European exports?

Exporters will be directly affected by measures which increase the costs of production in the EU, and thus either reduce their profit margins or render their products more expensive (and thus possibly less competitive) in third markets. Exporters which are part of value chains and dependent on inputs from third countries will also be affected by barriers affecting their imports (see 3.3 below)³²⁶. EU exporters can also be indirectly impacted by potential reactions by third countries if they perceive that the EU measure does not respect international trade rules or would be driven by protectionist objectives.

3.3. How will the options affect European imports, and value chains in general?

The costs of compliance with a new regulation may in some cases make imported products or operators uncompetitive and may therefore have the effect of an indirect trade barrier, even if the legislation as such is not (formally) restrictive or discriminatory. Many EU firms are dependent on inputs from firms based in third countries. Therefore, measures that directly or indirectly risk having an adverse impact on global value chains may jeopardise economies and jobs (importers also contribute to jobs and growth in Europe).

Generally, the analysis should consider effects throughout the whole value chain, in respect of EU firms dependent on imports but also EU firms competing with imports. The relationship between sectors within the EU can be found in EUROSTAT's input-output table, while the relationship between sectors in the EU and sectors in third countries can be found in the UN Broad Economic Categories (BEC) classification (see also <http://www.wiod.org/home>).

3.4. How will the considered options affect investment flows?

Could the considered options affect costs to such a degree that it could have an impact on investors' foreign direct investment (FDI) decisions? For both EU and foreign firms, there is a risk of relocation if a regulation is thought to be too costly. Conversely, if a regulation is seen as comparatively inexpensive to comply with, it can provide incentives for further FDI in the EU³²⁷. Policy options may also affect decisions on investment location through other means than costs.

³²⁵ See Chapter VII on stakeholder consultations

³²⁶ See Tool # 21 (*Sectoral competitiveness*)

³²⁷ See Tool # 21 (*Sectoral competitiveness*)

3.5. Does the option affect the potential for trade in services?

Trade in services differs in character from trade in goods in that it may be ‘invisible’ and non-tangible. Virtually all commercial services are tradable, if not by traditional cross-border trade, then by accessing the foreign market as an investor and selling services through a local affiliate. Assessment of policy options affecting service providers from third countries should be undertaken. Special regard should be given also to digital trade and the disciplines on data localisation requirements as agreed for instance in the EU-UK Trade and Cooperation Agreement.

3.6. Could developing countries be affected?

Article 208(1) of the Treaty on the Functioning of the European Union (TFEU) sets a legal obligation to ensure policy coherence for development (PCD) by providing that the EU “*shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries*”.

Developing countries are very heterogeneous. The 2012 Communication on ‘Trade, Growth and Development’ sets new policy orientations for the EU’s policy on trade and development for the next decade. In particular, it prioritises Least-Developed Countries (LDCs) and other countries most in need³²⁸. The following questions should be examined in particular:

(1) *Are the products covered by the proposal to a large extent produced in developing countries, particularly LDCs and other countries most in need?*

Particular attention should be given to cases where a country is markedly dependent on a specific export.

The Partnership Agreement between the European Union and members of the Organisation of African, Caribbean and Pacific States³²⁹ obliges the EU to inform the OACP States in good time of any intention to take a measure which might affect their interests. The CARIFORUM-EU Economic Partnership Agreement contains a similar obligation regarding bananas, rice, rum and sugar. More generally, the EU should seek to engage with developing countries from the early stage and reflect on possible ways to address or mitigate the impact of measures on them.

(1) *Will the proposal have an impact on the competitiveness of exports from developing countries, particularly LDCs and other countries most in need?*

Developing countries should not face obstacles that make their preferential access to the EU market (through low or zero tariffs) impossible to enjoy in practice, i.e. situations where their cost competitiveness resulting from the tariff preferences is eroded by costs imposed on them by new regulations. Adjustment costs are normally much higher and may be prohibitive for firms in developing countries. This needs to be considered when enacting regulations for products that are significant exports for a developing country.

Such an analysis is particularly important for LDCs and other developing countries which are very dependent on a few export commodities and therefore liable to be affected

³²⁸ See Tool #35 (*Developing countries*)

³²⁹ Article 12 of the Cotonou Agreement, signed in Cotonou on 23 June 2000, revised in Luxembourg on 25 June 2005 and revised in Ouagadougou on 22 June 2010.

disproportionately by the proposal. Particular attention should be paid in cases where vulnerable groups in developing countries are affected negatively. Accompanying measures (technical assistance, capacity building) should also be considered.

Consideration should also be given to the cumulative impact of the measure at stake with other measures taken in parallel and having similar effects on the same developing countries.

(2) *What are the sustainability impacts of the measure relevant for developing countries?*

In addition to the issue of potential barriers to trade, another aspect to be considered in relation to trade and developing countries is the impacts on sustainable development more broadly, which implies looking beyond trade balances and trade flows quantitatively. For example, a particularly employment-intensive sector might be disproportionately affected by a measure. An EU measure can also have unintended negative environmental side effects in developing countries. Inspiration can be drawn from Sustainability Impact Assessments (SIAs), which precede trade agreements signed by the EU and which explore such channels. Sustainable development chapters in trade agreements can be leveraged to mitigate potential negative effects.

This may often imply considering an external dimension for a range of environmental and social impacts that are the subject of dedicated tools (e.g. on climate, biodiversity and other environmental concerns, and social aspects such as labour conditions). These measures aiming at promoting holistically sustainable development will also relate to the broader Tool #19 (*Sustainable development goals*), as these need to be pursued both within the EU and externally, including in our relations with partner countries in the context of the sustainable development chapters of trade agreements.

3.7. Will the proposal increase or decrease regulatory convergence with the main trading partners?

Unnecessary regulatory differences between the EU and its trading partners can reduce or even prevent trade and investment. Beyond the internationally applied regulations and international norms or agreements with which the EU is legally bound to comply (e.g. the WTO GATT, GATS, TBT, SPS Agreements), it is important to verify whether the proposal will be in line with any other non-binding international arrangements between the EU and third parties, or with initiatives which the Commission or Member States are pursuing at a global level (e.g. harmonisation of technical regulations or standards at the International Maritime Organisation, the World Forum for Harmonization of Vehicle Regulations at the UN Economic Commission for Europe, the International Civil Aviation Organisation, or the International Telecommunications Union).

It is also important to assess whether the options considered will contribute to greater regulatory convergence with the EU's main trade partners (such as US, Japan, China) and whether it allows possibilities for regulatory cooperation (see also section 4 below).

When developing a new regulation or standard, the analysis should include an assessment of the main regulations affecting the products/services covered by the proposal in major third countries' markets, and a comparison between these regulations and the options considered by the Commission.

The assessment of regulatory approaches (e.g. delegated and implementing acts) should also consider how to enable the EU to engage in and adapt to any further development of rules in an international context.

In areas where there is a proliferation of overlapping unilateral measures from different trading partners, this should also be considered as it is liable to create a trade barrier especially for SMEs and smaller trading partners.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON EXTERNAL TRADE AND INVESTMENT

Unnecessary trade distortions from the specific perspectives of TBT and SPS can be avoided or minimised by considering the following elements:

- The measure could be accompanied with an external outreach and communication plan especially towards countries identified most likely to be affected. This can be done in the WTO (see below), under dialogues of relevant FTAs, but also through EU delegations in the respective countries.
- When the European Commission gives a mandate to standardisation bodies to develop a new standard, those bodies should be instructed to consider, as a basis for European standards, international standards that are in use in the global marketplace. This is in line with the WTO TBT Agreement.
- The TBT and SPS agreements in the WTO require all WTO members to notify draft technical regulations and conformity assessment procedures or SPS measures that might have a significant impact on international trade to the WTO TBT and SPS committees for scrutiny. This forum provides a good opportunity to avoid unnecessary trade frictions with third countries before technical regulations or SPS measures are adopted and develop into trade barriers.
- The Commission has several regulatory dialogues or high-level platforms with third countries in areas such as product safety, information society, raw materials and energy, as well as financial services, in particular with major economies such as the US, China, Japan, Russia as well as FTA partners. Without prejudice of the EU right to regulate in the general interest, these dialogues provide useful tools to avoid unnecessary frictions and barriers.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- For information about [WTO rules](http://www.wto.org/english/docs_e/docs_e.htm), see http://www.wto.org/english/docs_e/docs_e.htm
- For a list of EU trade agreements see <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/> and for a list of investment agreements between Member States and third countries see <http://ec.europa.eu/trade/policy/accessing-markets/investment/>
- Information is available from the following freely available databases about:
 - which countries produce and export to the EU the goods or services covered by an initiative and what is the value of this trade (EU imports)
 - to whom the EU exports the goods or services covered and the value of the trade

- which countries invest in the sector/s in the EU affected by the legislation and what is the value of these flows and stocks of investments
- [EUROSTAT – COMEXT that include the EU28 imports and exports](#) of goods with all partners and all products disaggregation (see <http://ec.europa.eu/eurostat/data/database>).
- [WITS and UN COMTRADE that cover trade in goods](#) of all countries in the world with all the partner countries.
- [EUROSTAT – Balance of Payments statistics](#) that covers trade in services and FDI by partner country and product (see <http://ec.europa.eu/eurostat/data/database>).
- To [distinguish between final goods and input goods](#), please refer to the United Nations Broad Economic Categories (BEC).
- Operational Guidance for assessing impacts on sectoral competitiveness with the Commission Impact Assessment System SEC(2012) 91 <https://ec.europa.eu/transparency/regdoc/rep/2/2012/EN/2-2012-91-EN-F1-1.PDF>

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Real GDP per capita • Investment share of GDP • Employment rate • Purchasing power adjusted GDP per capita • Adjusted gross disposable income of households per capita • EU imports from developing countries <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Annual growth rate of real GDP per capita • Proportion of informal employment in non-agriculture employment, by sex • Proportion of tariff lines applied to imports from least developed countries and developing countries with zero-tariff • Worldwide weighted tariff-average • Developing countries' and least developed countries' share of global exports • Average tariffs faced by developing countries, least developed countries and small island developing States 	

TOOL #28. DIGITAL-READY POLICYMAKING

1. INTRODUCTION

In line with the 2030 Digital Compass Communication³³⁰, ‘better regulation’ will promote the ‘digital by default’ principle in forthcoming EU legislation as an important instrument to support digital transformation.

This tool aims to help policymakers make the best use of digital technology and data in their policies thus meet the call of Member States to propose digital-ready and interoperable policies by default³³¹. Best use of digital technology and data helps deliver on the needs of businesses and citizens with and without digital skills, benefiting from the opportunities and mitigating the risks of the digital age.

Policies (and legislative acts) are digital-ready if they enable smooth and digital by default³³² policy implementation and foster digital transformation through best use of digital technologies and data.

This implies that policymakers work in a multidisciplinary team and consider the following digital-ready components:

1. user-centric processes ready for automation,
2. alignment with digital policies (for example on accessibility, eID...),
3. the once-only principle and the reuse of data,
4. the evolving ICT landscape,
5. innovation and digital technologies, and
6. digital-ready drafting.

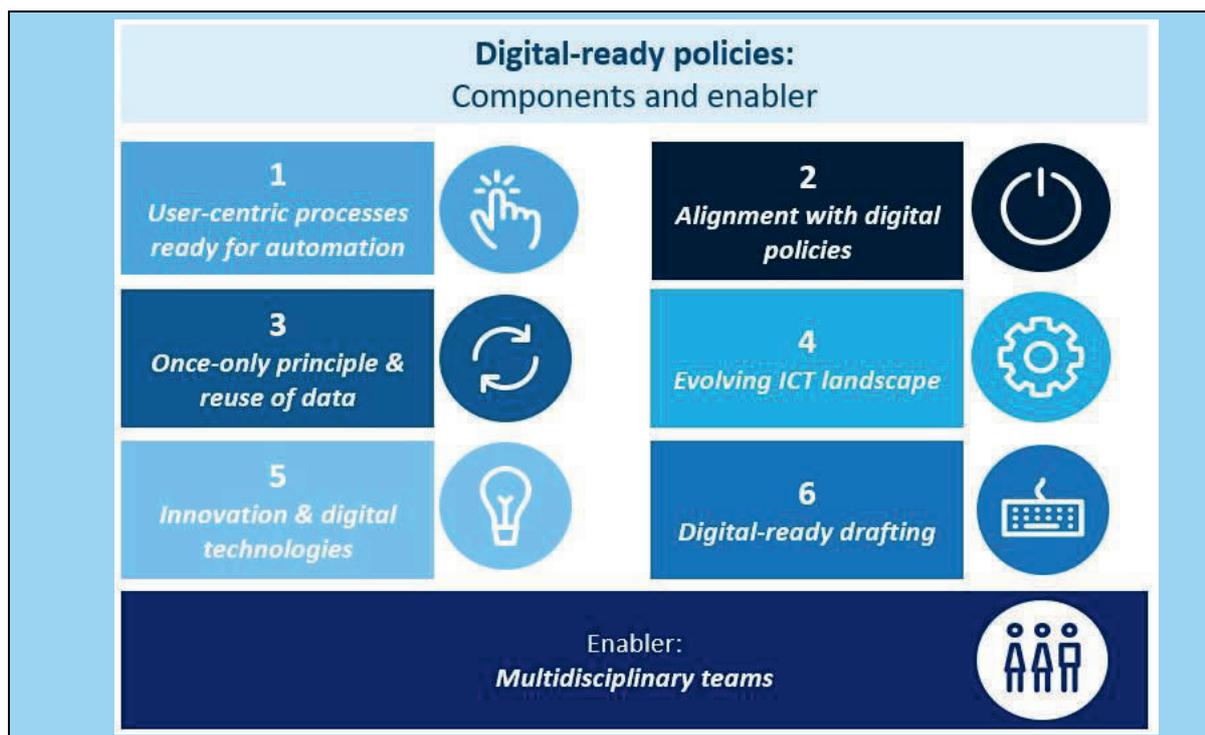
Digital-ready policies consider the fast-evolving world of digitalisation and technology; thus, they are digital, interoperable, future-proof and agile by default. By addressing the gap between policy formulation and its digital implementation, they deliver cost-efficient, user-centric, and interoperable digital services. The lack of interoperability³³³ between systems, organisations or countries can be especially costly. Achieving interoperability can mean cost reductions, enhanced user satisfaction and may hold significant potential in achieving policy objectives more effectively in the long term.

³³⁰ Commission Communication, [2030 Digital Compass: the European way for the Digital Decade](#), COM(2021) 118., COM(2021) 118.

³³¹ [Berlin declaration on digital society and value-based digital government](#), signed at the ministerial meeting of 8 December 2020: Call on the Commission to ensure through the ‘better regulation’ framework that policies and legislative acts proposed by the European Commission are digital-ready and interoperable by default.

³³² The [Commission’s ‘better regulation’ Communication](#) commits to promote the ‘digital by default’ principle in forthcoming EU legislation as an important tool to support digital transformation. According to the [Commission’s Digital Strategy](#), digital by default means that the default choice of Directorates-General (DGs) will be to deliver services digitally via multiple channels.

³³³ Interoperability is defined in the [European Interoperability Framework](#) (EIF) as the “*ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems*”



To reap these benefits, it is important that policymakers in all phases of the policy cycle:

- work in multidisciplinary teams (section 2);
- consider the components of digital-ready policies (section 3);
- assess digital-ready impacts (section 4);
- seek support on digital and data management matters (section 5).

2. MULTIDISCIPLINARY TEAM

Good practice example:

- ☺ When revising the Union legislation on blood, tissues and cells, DG SANTE identified opportunities to create a system of data platforms in this policy domain, by linking existing databases and prototyping an umbrella platform. For this reason, DG SANTE reached out to *data and ICT experts* in DG DIGIT already in the policy design phase, to run a feasibility study on various technical options and their impact on the policy options.

The EU Policymaking Hub calls for [collaboration across policy areas](#) to reconcile different views, priorities and perspectives during policymaking. The emphasis is on policy collaboration, ensured through the interservice work, including the interservice coordination group meetings and the interservice consultation. The multidisciplinary team complements and reinforces the effectiveness of this traditional policy collaboration, by inviting colleagues with diverse professional profiles in the core team of the lead service. Those colleagues can be part of the lead DG or come from other services. When designing digital-ready policies, the **multidisciplinary team** should ideally include:

- **Business analysts** to help analyse, simplify, and document the processes and data flows, and to ensure the smooth implementation of the policy (see sub-section 3.1).

- People with an overview of **the EU digital legislative landscape** able to identify cross-links, dependencies, possible conditionalities or synergies with other digital initiatives (see sub-section 3.2).
- **External experts** to provide their expertise in the policy area (see sub-section 3.2).
- **Data experts** to provide information on existing and reusable data, on their use and visualisation (see sub-section 3.3).
- Your **Data Protection Coordinator** to help detect questions of data protection early in the process (see sub-section 3.3),
- People with **digital / ICT knowledge – including knowledge about**
 - **security**,
 - **accessibility** for persons with disabilities and alternatives for people with fewer digital skills,
 - **the current ICT landscape** and future necessities and possibilities for the digital implementation of the policy (see sub-section 3.4).
- People with **policy implementation experience** to make the policy fit for purpose. Policymakers may contact colleagues in decentralised agencies or in Member States³³⁴ who could involve experts with first-hand experience of implementing the policy (see sub-section 3.4).
- People with **knowledge about innovative digital technologies** to give advice on their potential use (see sub-section 3.5).
- **Experts in legal drafting** to help with clear and simple wording, which is a must for smooth digital implementation (see section 3.6).

As first step in a multidisciplinary policy-design, the team needs to agree **on clear policy goals** that ensure a shared understanding.

Have I considered...

- early in the process to set up a multidisciplinary team to make sure that the needed resources are available.

3. COMPONENTS OF DIGITAL-READY POLICYMAKING

This section explains the main components of digital-ready policies. Each component is introduced by good practice examples and closed with a checklist for the policymaker. The components may depend on each other; for this reason, an iterative implementation approach is suggested.

3.1. User-centric processes ready for automation

Good practice example:

- ☺ Setting inland waterway transport rules for vessels must consider the cross-border

³³⁴ Policymakers can reach out to various policy implementation actors through the [Better Legislation for Smoother Implementation community](#).

nature of the policy as the inland waterways network do not stop at borders. Some ports are both in inland and maritime, which requires also cross-sector considerations. In the [Digital Synergy Study](#) the potential for streamlining the use of existing digital solutions has been thoroughly analysed from the users’ point of view, allowing for both cross-border and cross-sector interactions.

- ☺ When the [e-invoicing policy](#) was introduced, e-invoicing was not widespread among SMEs. Instead of introducing an obligation for companies to only use e-invoicing with public administrations, the legislation imposed on public administrations to accept (also) e-invoices according to the relevant EU standards and provided a reusable technical solution ([CEF building block](#)).

Policies aim to solve real-life problems by selecting the most appropriate course of actions to move away from the existing (as-is) situation towards the desired (to-be) situation **defined by the policy goals**. By doing so, policies affect various **business processes** (for example, how a public administration provides a service, how a business applies for funding or which entity has the mandate to act)³³⁵. By assessing the affected business processes with the help of the main stakeholders involved³³⁶, policymakers can identify opportunities for simplification and automation³³⁷, which should result in **user-centric processes** supported by digital technology – thus respecting the principle of ‘digital by default’. This can reduce administrative burden for businesses, citizens, and administrations, while increase users’ satisfaction at the same time.

Policies can sometimes unintentionally set barriers for Member States, businesses or even for the Commission itself in performing their business processes with the support of digital technologies. To avoid creating barriers and to facilitate automation, policymakers should **analyse the business processes of the different stakeholders** affected by the policy. This will help them make informed decisions on where streamlined processes are necessary³³⁸ and where variations should be allowed or even enabled. Policymakers can seek advice from a *business analyst* or from DG DIGIT’s UX Office at this stage³³⁹, who can ensure that the analysis of the business processes is **centred on users’ needs**³⁴⁰ and **pays attention on cross-sector or cross-border links between business processes**, as they can create interoperability barriers if not considered early on.

If the policy is affecting the treatment of personal data, a clear description of processes can also help perform the [data protection impact assessment](#)³⁴¹ (if necessary) – possibly as part of the general impact assessment³⁴².

³³⁵ The operation of organisations (public or private) is bound by legal acts and they need to ensure that their business process comply with the legislation in force and get adapted when the legislation changes.

³³⁶ A right approach to perform business process improvement is to involve stakeholders early on. Tool #1 provides the necessary guidance on the principles to follow when performing a stakeholder consultation. In addition, [Chapter 7](#) provides guidance on the operations to follow for conducting a stakeholder consultation. When digital technologies are used those stakeholders may become users.

³³⁷ Automation means that the business process can be partially or entirely executed through digital technology.

³³⁸ For example, the business process around regulatory reporting that will be steered by the European Commission or its Agencies.

³³⁹ For support, contact the Commission’s business process management community – [BPM@EC](#) or [User Experience Framework - EC Extranet Wiki \(europa.eu\)](#)

³⁴⁰ User-focus is one of the leading principles of the [European Commission Digital Strategy](#).

³⁴¹ The data protection impact assessment (DPIA) is regulated in Art. 39 Regulation (EU) 2018/1725 for data to be processed by Union institutions, bodies, offices and agencies and in Art. 35 GDPR for data to be processed by the Member States or others. For DPIAs to be carried out by the Commission as controller, the [Commission’s data protection officer](#) provides templates.

Have I considered...

- which business processes are being affected by my policy?
- getting advice on how to analyse business processes with the users’ needs in mind?
- giving special attention to cross-border and cross-sector aspects of the problems being tackled – for example a need for transnational data flows or ICT systems?

3.2. Alignment with digital policies**Good practice example:**

- ☺ DG HOME has realised that its policy proposal on *strengthening the automated data exchange under the Prüm framework* would benefit from interoperability considerations³⁴³. It has invited DG DIGIT in the interservice coordination group timely, so this policy can be designed with interoperability in mind.
- ☺ During the COVID-19 pandemic, DG SANTE worked with Member States, to develop digital contact tracing technologies. Involving DG CNECT and DG DIGIT enabled a secure, interoperable technical solution for digital contact tracing technologies in the EU to be developed, and to set up the necessary IT infrastructure, the European Federated Gateway Service for citizens to be able to use their national apps in other EU countries.

When designing the policy, it is imperative to assess the consistency and interaction with existing legislation and with on-going policy developments, to avoid incoherent regulatory requirements or conflicts with overarching policy objectives. This is highly relevant for digital policies because of their cross-cutting nature. Important digital policies regulate for example open data, personal data, e-Identity, security and privacy, data and internet governance, web and ICT accessibility, digital connectivity infrastructure and its take-up. As this is a fast-evolving regulatory environment, important legislation and policy initiatives are presented in [this repository](#) outside of the toolbox.

To ensure consistency and promote digital transformation, policymakers should also assess the links between their future policy and existing international or European standards in the field. For further guidance on standards please check Tool #17 (*The choice of policy instruments*).

Policymakers are invited to consider the spill-over effects that digital policies, infrastructure, services and technologies might have not only for the EU digital sector’s competitiveness (supply of ICT equipment, cloud technologies and solutions, data analytics, AI, high performance computing, connectivity infrastructure, etc.), but also as drivers for digital transformation across different policy domains (poverty, inequality, inclusion³⁴⁴, health,

³⁴² See Article 39 (10) of Regulation (EU) 2018/1725 (for data processed by EU bodies) or Article 35 (10) of Regulation (EU) 2016/679

³⁴³ Learn more about public sector interoperability policy, which enables digital transformation, on the [EU policymaking hub](#).

³⁴⁴ See also Tool #30 (*Employment, working conditions, income distribution, social protection & inclusion*).

transport, education, working conditions, agriculture, smart mobility, social security coordination) and public administration³⁴⁵.

A good way to get input on EU digital policies is to invite DG CNECT and DG DIGIT to the inter service group preparing the policy proposal.

Have I considered...

- the digital legislation and policies in place and how my initiative relates to them?
- the possibility to promote the objectives of digital policies³⁴⁶ through my initiative (for example increasing the speed and efficiency of digital network deployment)?
- inviting DG CNECT and DG DIGIT to the interservice coordination group to explore room for cooperation?

3.3. Once-only principle and reuse of data

Good practice example:

- ☺ Regulation (EU) 2018/1999 on the governance of the Energy Union and Climate Action sets out an approach around five dimensions (energy security; the internal energy market; energy efficiency; decarbonisation; and research, innovation, and competitiveness) on how the Commission and Member States should work together and how individual countries should cooperate to reach the 2030 targets of the Energy Union. In order to alleviate the administrative burden of reporting, it systematically reuses information, for example collected through [EU ETS](#) (greenhouse gas emissions), [Copernicus](#) (geo-spatial data) and [Eurostat](#) (statistical data).
- ☺ The [proposal for a Directive on pay transparency](#) allows Member States to entrust an existing body to compile the required reporting information based on (existing) administrative data, such as data provided by employers to the tax or social security authorities.

Today, citizens and businesses often must provide the same information multiple times when interacting with public administrations. The [Once-Only Principle](#)³⁴⁷ should allow public administrations in Europe to reuse or share data and documents that people have already supplied, in a transparent and secure way. The [Single Digital Gateway](#) is one important instrument to implement the once-only principle but every EU policy can contribute to it.

³⁴⁵ For example, smart villages and communities are promoted through the Common Agricultural Policy Rural Development, EU Cohesion Policy, EU Framework Programme for Research and Innovation, Connecting Europe Facility, Recovery and Resilience Facility, etc.

³⁴⁶ For example, on Gigabit connectivity the [Europe’s Digital Compass](#) expects that by 2030, all European households will be covered by a Gigabit network, with all populated areas covered by 5G. Read more on connectivity targets [here](#).

³⁴⁷ “The once-only principle means that citizens and businesses provide data only once to public administrations, while public administration bodies take actions to share and reuse these data at regional and national level, or across borders – always in respect of data protection regulations and other constraints.” ([ECDS Handbook](#))

Data is a relevant resource that EU policies should increasingly tap into. Policymakers should know what data assets³⁴⁸ are linked to their policies and aim to remove obstacles to acquiring, sharing, combining, and reusing these data assets, while ensuring coherent data governance and continuous data management. The *EC [data advisory service](#)* provides consultancy and support on data governance and data management matters to Commission staff, while the *[EC Data Catalogue](#)* allows Commission staff to look for data that the Commission already holds.

To enhance the potential of data reuse – also outside the Commission – and understanding of the context and how the data was used to inform EU policies, data should be used in the impact assessment and evaluation reports in the way that allows the traceability of the data and the analytical steps to draw conclusions in the medium to long term³⁴⁹. Using data standards is a key enabler for data re-use. Data used in impact assessment and evaluation reports should be made available for internal reuse on the *[EC Data Catalogue](#)*, as long as their licensing conditions allow for it.

Before starting a data collection, speak to your local data correspondent and IT contacts. Look for **reusable data assets**, for example

- [existing data managed by the Commission](#) (for example in the *[EC Data Catalogue](#)*³⁵⁰),
- public sector data made open by public sector bodies and research institutions in Member States (in line with the '[Open data Directive](#)') available on the *[European Data Portal](#)*,
- the forthcoming *[European Single Access Point \(ESAP\)](#)*, a repository of reporting from financial and non-financial businesses, that will contain a wide range of information disclosed from businesses,
- other reliable sources (for example UN, OECD).

When **personal data** is processed, speak to your Data Protection Coordinator (DPC). There may be domain-specific rules relating to personal data (e.g. for health). Your local data correspondent will know more about this and can advise you on such subjects. Keep in mind the requirements of GDPR/Regulation (EU) 2018/1725. This means that when preparing legislative texts, for example setting up interoperability gateways or mandating re-use of data, you should ensure that the text will provide a lawful basis for the processing of the data³⁵¹.

When personal data is aggregated for statistical purposes, such data may be further used for different purposes, including regulatory reporting or strategic foresight³⁵². If you own such reusable data sources, make them easily findable for your colleagues for example by including them in the *[EC Data Catalogue](#)*.

³⁴⁸ A data asset is any collection of data, any data set or any information that is somehow linked, e.g. by common codes or metadata, which has been created by the Commission, collected from Member States or other stakeholders, or acquired from third parties in the context of projects, policy or administrative processes. Data assets may be structured or unstructured, static or dynamic, raw or curated. Data assets are in digital formats. (*[Data governance and data policies at the European Commission](#)*)

³⁴⁹ See Tool #4 for guidance on transparent use and communication of evidence within the policy cycle.

³⁵⁰ Currently as interim version (until 2023). The interim EC data catalogue solution is to allow Local Data Correspondents and statistical correspondents to manage metadata of their data assets more autonomously.

³⁵¹ The conditions for reusing personal data for other purposes are further set out in Art. 6 (4) of Regulation (EU) 2016/679 or for data processed by Union institutions in Art. 6 of Regulation (EU) 2018/1725.

³⁵² An alternative for aggregating data is to transform it to synthetic data. The JRC.B.6 is piloting this approach.

Beyond data, it is also important to **reuse concepts**³⁵³, which should be well-defined to avoid overlaps. This applies particularly to regulatory reporting³⁵⁴, where the burden generated by regulatory reporting clauses should be minimized, making the most of reusing concepts and related datasets³⁵⁵.

Have I considered...

- assessing which data is needed to design, implement, and monitor my policy?
- exploring what data is already available for reuse across policy domains, within the Commission and beyond (from Member States or third parties) and contacting the EC data advisory service and my Local Data Correspondent?
- fostering the reusability of the data sets managed under my policy?

3.4. Evolving ICT landscape

Good practice example:

- ☺ [eDelivery](#) is a digital [building block](#) that supports the exchange of electronic data and documents in an interoperable and secure way. It was mandated in the Inland Waterway Transport policy to serve the exchange of navigation information between Member State systems and the central European system. Such approach reduces the implementation costs in Member States as it reuses existing infrastructures³⁵⁶. This was achieved thanks to a close collaboration between the ICT experts of DG DIGIT and the policymaker.

When designing the policy options, policymakers should involve *ICT experts* to analyse the capabilities provided by the existing ICT landscape, which may offer opportunities, but may create limitations at the same time, together with the potential future landscape that should anticipate the evolution of the context.

Reusing existing ICT solutions could reduce costs and accelerate implementation. Reuse can be understood as the case of one Commission DG benefitting from a solution developed by another DG³⁵⁷, but also existing solutions developed in Member States³⁵⁸. The reuse of the most prominent reusable [EC building blocks](#)³⁵⁹ should be assessed for any European initiative together with the IT components available in the [Reusable Solutions Platform portal](#). IT experts may consider the reuse of opensource interoperable solutions available on [Joinup](#), a

³⁵³ A concept is an abstract notion representing a class of things. Data are instantiations of concepts. E.g. Country is a concept. Belgium, Netherland are two instances of the concept Country.

³⁵⁴ Visit the [regulatory reporting community of practice](#) for more guidance on reporting and see Tool #43.

³⁵⁵ Examples for concepts and core vocabularies can be found on the EU Vocabularies tab on the Portal [of the Publication Office](#).

³⁵⁶ See Annex 1 of the Commission [Delegated Regulation \(EU\) 2020/473](#).

³⁵⁷ For example, the [IMI system](#) owned by DG GROW to provide Member States with the tools that they need to cooperate with each other in order to improve the implementation of Internal Market legislation reused by DG EMPL in the context of professional qualifications. Other examples are the [EU Single Window](#) and [Traces](#) solutions that can now be re-used by other DGs.

³⁵⁸ Some of the also available on [Joinup](#)

³⁵⁹ Available building blocks are: Big Data Test Infrastructure, European Blockchain Services Infrastructure, Context Broker, eArchiving, eDelivery, eID, eInvoicing, eSignature and eTranslation.

collaborative platform created by the European Commission. Using building blocks also helps ensure interoperability between different solutions e.g. e-Delivery.

To start with, policymakers should contact *their DG's IT unit* for advice. It could also be useful to get in touch with *the decentralised agencies managing ICT systems* for the policy and with *contacts in the Member States* using these ICT systems. In case a policy option may entail a solution to be supported by the EC, the [corporate IT Governance](#) should be involved promptly, in order to timely learn about the opportunities and limitations within the Commission's ICT ecosystem and to ensure good planning and efficient use of resources.

Have I considered...

- the opportunities for costs or administrative burden reduction by reusing an available ICT building block?
- contacting my DG's IT unit and/or the corporate IT Governance for advice?

3.5. Innovation and digital technologies³⁶⁰

Good practice examples:

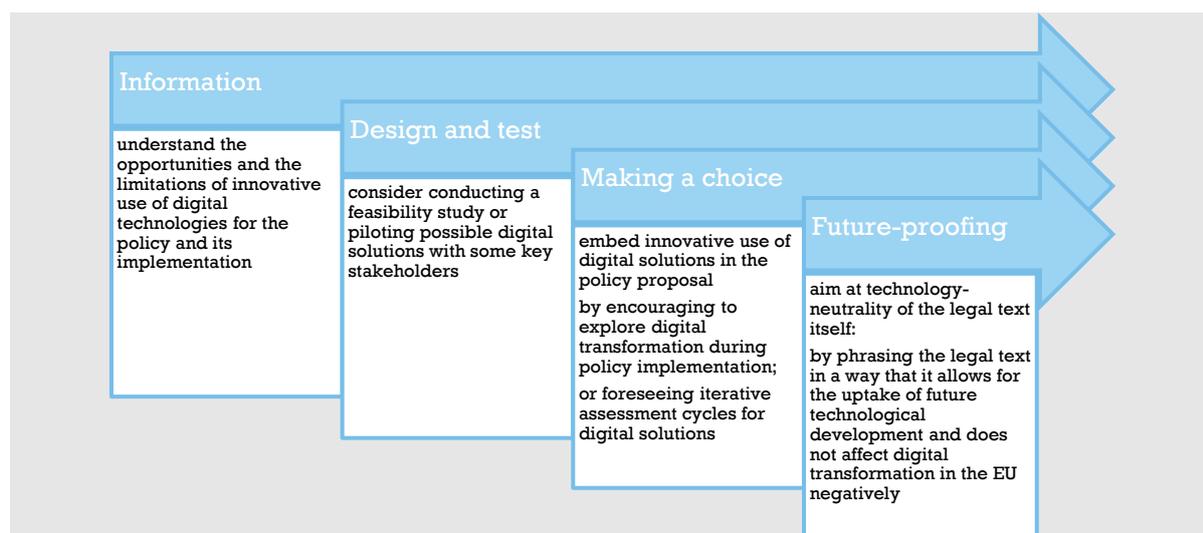
- ☺ Since 2018, DG AGRI has modified the Common Agricultural Policy legislation to allow an alternative operational control method, checks-by-monitoring, which uses free-of-charge Copernicus sentinel satellite imagery, automatically interpreted by deep learning algorithms to replace traditional on-the-spot checks of CAP beneficiaries. During the COVID-19 crisis this and other technologies (e.g. geotagged pictures) proved very useful to carry out checks without the need to visit the farms³⁶¹.
- ☺ DG JUST ordered a [study on the use of innovative technology in the justice field](#) that can help future digital-ready policymaking in the whole sector.
- ☺ DG EMPL, to address the identification and authentication of mobile citizens and the verification of their social security entitlements, has launched a pilot project, called European Social Security Pass (ESSPass) together with DG CNECT, DIGIT and the Italian social security institution, INPS, to assess the technical feasibility, the cost and the legal requirements for potential future large-scale deployments.

Digital technologies help respond to old problems in new ways thus fostering digital transformation. Given the increasingly complex or rapidly changing nature of the problems, innovative digital technologies may offer the only way to ensure the outcomes citizens and businesses are expecting. The [EU Policymaking Hub](#) gives an overview of the ongoing work on emerging digital technologies in the Commission and links to learning resources.

To embrace innovation through digital technologies in the policy, policymakers need to:

³⁶⁰ Please consult Tool #22 for guidance on innovation in general.

³⁶¹ Learn more about AGRI's use of innovative technologies to replace on-the-spot checks [here](#) and for the specific technological solution developed to better cope with Covid conditions [here](#).



Piloting the preferred digital solution to better assess the present regulatory constraints and the need for new regulation, or the revision of existing ones, is an important and useful step to consider. The implementation can be fostered through the roll-out of supplementary technical assistance programmes to enable the development of the technologies and build the capacities needed for their effective implementation at EU and national levels.

Strategic foresight³⁶² may bring valuable information on future digital trends, which may help policymakers to boost creativity/innovation and trigger further (indirect) socio-economic benefits while creating new opportunities for start-ups and SME.

When considering the take-up of digital solutions, policymakers should assess and address potential limitations, like the high costs of the phase-out of ICT legacy systems³⁶³ or the lack of agility, digital skills and ICT expertise, accessibility problems for people with disabilities or other barriers for vulnerable groups and people with fewer digital skills, and also the ethical legal barriers aiming at protecting fundamental rights³⁶⁴.

The [Innovative Public Service](#) – action of the European Commission and the [OECD Observatory of Public Sector Innovation](#) offer further resources on the topic.

Have I considered...

- whether innovative digital technologies could add value or reduce burden in the implementation of my policy?
- whether the proposed rules are technology-neutral?
- consulting with DG CNECT on innovative digital technologies?

3.6. Digital-ready drafting

Good practice example:

- © DG FISMA Knowledge Online on European Legislation (KOEL) provides a catalogue of concepts and terms for reuse – initially for the finance domain and more recently for other policy domains too. This helps policymakers to reuse existing

³⁶² Explained in Tool #20 (*Strategic foresight for impact assessments and evaluations*)

³⁶³ Legacy systems are ICT systems that have been since many years implemented in an organisation.

³⁶⁴ More about digital policies around AI are available [here](#).

terms and ensure clear and consistent drafting.

- ☺ DG EMPL ‘easy-to-read’ version of the [Strategy for the rights of persons with disabilities 2021-2030](#).

To draft the policy proposal in a digital-ready manner, the policymaker is advised to:

- set out clear rules in the legislative act while keeping those rules future-proof to technical development by including, where necessary, empowerments or delegations for the Commission to act and consider which technical aspects need to be set out in the legal act and which should be placed in the annexes³⁶⁵;
- where a policy requires the establishment of a system that is co-owned by European Commission and Member State³⁶⁶, define clear roles and mandates for the governance of the system in the legal act;
- use simple, precise, and concise wording – especially for the parts the implementation of which is likely to be automated (see also section 3.1)³⁶⁷;
- reuse existing concepts from the policy domain and ensure alignment with those in related policy sectors thus ensuring interoperability (see also section 3.3). This approach is particularly important when describing business-agnostic processes, like monitoring and reporting (see Tool #43);
- prepare an implementation strategy or other necessary compliance promotion tools (see Tool #38), highlighting opportunities for reuse as well as contact points for support;
- avoid setting the entry into force date right after bank holidays (e.g. 1 January) or setting ambitious deadlines not aligned with the complexity of the supporting information system. If not, there may be a lack of sufficient ICT support when the solution goes live;
- consider introducing experimentation clauses. These legal provisions enable the authorities tasked with implementing and enforcing the legislation to exercise – on a case-by-case basis – a degree of flexibility in relation to testing innovative technologies, products, services, or approaches. For example, they may serve as a legal basis for [regulatory sandboxes](#)³⁶⁸;
- explain in the explanatory memorandum of the legislative proposal how the initiative contributes to achieving the European way for a digital society and economy.

Have I considered...

- showing the draft proposal to my IT colleagues to see whether it facilitates digital implementation?
- facilitating the digital implementation of my proposal by accompanying it with an

³⁶⁵ Technical specifications for IT systems will normally not be fully replicated in legal text.

³⁶⁶ Examples for such systems are the [Coronavirus EU interoperability gateway](#) or the [European Union spatial data infrastructure](#) under the INSPIRE directive.

³⁶⁷ For general drafting advice, see the [Drafters’ Assistance Package \(DAP\)](#).

³⁶⁸ A sophisticated experimentation framework is referred to as a regulatory sandbox – testing innovations in a real-world environment subject to regulatory safeguards and support. See Tool #69 (*Emerging methods and policy instruments*) for more details.

- implementation plan addressing possible ICT challenges and by leaving the technical details for future implementing acts?
- ❑ contacting the [quality of legislation team](#) of the Legal Service for general advice on drafting?

4. DIGITAL-READY IMPACTS

The digital-ready impact questions listed in Tool #18 (*Identification of impacts*) can give guidance on important digital-ready impacts.

To detect all digital impacts, make sure that the stakeholder consultations explicitly cover digital aspects, where this is relevant. Consider as well any information gathered during the evaluation phase about whether more could be done for a successful digital transformation.

When performing the analysis of the policy options, consider modelling the digital impacts with the support of the JRC modelling competence centre³⁶⁹.

The assessment of the preferred option in impact assessments needs to cover the analysis of the 'digital by default' principle. This means that the preferred option should allow for delivering services digitally, thus be digital-ready.

When assessing different technical solutions, ask support from ICT experts³⁷⁰, who may benefit from the [ICT Impact Assessment Guidelines](#) developed by DIGIT and from [further guidance materials](#) on digital-ready impact assessments³⁷¹.

When a digital solution is a key element of the policy proposal, policymakers should consider running a **feasibility study on the selected technical scenarios** to inform the impact assessment. They may also pilot the preferred technical solution with interested Member States.

5. FURTHER RESOURCES

For more guidance on any of the digital components presented in this tool, policymakers are invited to visit the [digital-ready policymaking wiki](#).

Moreover, consider reaching out to the below-listed services:

Suggested service	Expected support	Topic
BPM@EC	Business process modelling	User-centric processes
UX office of DG DIGIT	Advice on delivering user-friendly digital solutions with the end-user in mind right from the start.	Digital policies
DG CNECT	Advice on the current digital policy environment and on potential links between the planned initiative and existing ones. Support designing and assessing policy options that fit for both the digital and the physical world.	
DG DIGIT	Advice on the Corporate IT Strategies and on the	

³⁶⁹ Models are currently used to quantify environmental, economic, and social impacts of policy options but could be extended to questions of digital transformation. See also Tool #61 and the [Commission's modelling inventory MIDAS](#).

³⁷⁰ When procuring external contractual support for the impact assessment, the terms of reference should specify the need for IT expertise and indicate this tool of the 'better regulation' toolbox as reference document.

³⁷¹ Like list of potential digital risks to consider or a decision supporting tool on interoperability.

	ICT and interoperability aspects of future public services and related digital solutions	
EC Data Catalogue	The Commission's internal data catalogue.	Reuse of data
data.europa.eu	The official portal for European data. A single point of access to a range of data produced by EU, national, regional, and local public administration, as well as by some international organisations.	
Data advisory service	Advice on data management and analytics	
Local Data Correspondents	The single point of contact for data management in your DG/service	
Data Protection Coordinators	Advice on personal data aspects	
Corporate IT Governance	Information on the opportunities and constraints of the current EC ICT ecosystem	Existing ICT landscape
Your DGs IRMs	DG's information resource manager (IRM), DG's IT systems.	
DG CNECT	Information on innovative digital technologies and their possible use. Help to increase the effectiveness of data collection and analysis of stakeholders' consultation processes (e.g. through 'big data' approaches or by pooling some open public data sources).	Innovative digital technologies
Legal Service - Quality of legislation	Advice on technology-neutral and clear legal drafting	Drafting clear rules for digital implementation
Further support		
One-stop shop for collaboration	Help to work in multidisciplinary teams	Multidisciplinary team
EU Policymaking Hub	Overview of the available support and training along the policymaking cycle	Policymaking process
JRC – competence centres for policymaking	Analytical tools, methods, and integrated solutions, covering among others the digital aspects of policymaking.	
Regulatory reporting community of practice	You can find help in this multidisciplinary community on how to set digital-ready reporting requirements.	
The EU Policy Lab	Creative space dedicated to bringing innovation in the European policy-making process.	Innovation
Digital innovation lab	Creative space dedicated to digital innovation.	

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDGs indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Gross domestic expenditure on R&D <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Research and development expenditure as a proportion of GDP • Number of science and/or technology cooperation agreements and programmes between countries, by type of cooperation • 17.6.2 Fixed Internet broadband subscriptions per 100 inhabitants, by speed 	 

TOOL #29. FUNDAMENTAL RIGHTS, INCLUDING THE PROMOTION OF EQUALITY

1. INTRODUCTION

Fundamental rights³⁷² afford basic legal protection for political, social, and procedural rights to individuals and legal entities. The [Charter of Fundamental Rights of the European Union](#) (the Charter) is an instrument of primary EU law that enshrines the fundamental rights people enjoy in the EU. It covers a wide range of rights and principles, such as human dignity, fundamental freedoms, equality, solidarity, EU citizens' rights and justice. All Commission acts and initiatives must comply with the Charter³⁷³. EU legal acts can be challenged before the Court of Justice of the European Union if they do not comply with the Charter.

To help implement this obligation, this tool gives an overview of salient points to consider when identifying and assessing impacts related to fundamental rights within impact assessments. This tool can also be used to assess impacts on fundamental rights in the context of the evaluation of an existing policy or legal instrument (especially in case the preceding impact assessment had to address fundamental rights issues).

Box 1. Fundamental rights

The Charter contains provisions on rights, freedoms and principles divided into six titles: Dignity, Freedoms, Equality, Solidarity, Citizens Rights, and Justice. The seventh title, General provisions, governs the interpretation and application of the Charter.

The Charter rights are relevant to all EU policies and to all EU institutions, bodies, and Agencies.

Some Charter rights are absolute and cannot be 'limited' or 'restricted', no matter how important the policy objective (see second point in box 2).

Other rights can be subject to limitations but only if such limitations respect the strict requirements set out in Article 52 of the Charter (see last two points in box 2 below).

2. STEP-BY-STEP ASSESSMENT

Aspects of fundamental rights may be of relevance in the problem definition³⁷⁴. This may be the case specifically where the Union intends to act to protect individuals against interferences with fundamental rights in the policy area concerned³⁷⁵.

³⁷² For pragmatic reasons, the impact assessment of initiatives with only an internal EU dimension should focus on the analysis of fundamental rights (guaranteed by the Charter of Fundamental Rights), while for initiatives with an external dimension the analysis should focus on human rights, which may be different to the fundamental rights guaranteed by a partner country, and which arise from international treaties and customs.

³⁷³ As expressed in the Charter of Fundamental Rights and other legal documents.

³⁷⁴ It should be recalled that the Charter of Fundamental Rights cannot form the legal basis for a legislative act. All Union legislative acts should respect fundamental rights and observe the principles recognised by the Charter, seek to ensure full respect for those rights and principles, and be implemented accordingly.

³⁷⁵ See Tool #13 (*How to analyse problems*)

Depending on the nature of the problem and the policy context, respect for fundamental rights may be presented as one of the general or specific/operational objectives. This will ensure that at every step of the impact assessment, the relevant aspects be consistently addressed from the perspective of these objectives (link between objectives and problem analysis, identification of policy options, assessment and comparison of options, future monitoring and evaluation activities).

To ensure an evidence-based assessment, questions on fundamental rights should be addressed during the early preparatory stage of any envisaged initiative, i.e. from the planning stage or at the latest when drafting the ‘call for evidence’. Stakeholder consultations and studies should include – wherever possible – collection of data on any potential impacts on fundamental rights. If an early screening suggests that fundamental rights might be or have been affected and further guidance is needed, one should consult the Legal Service, SG and DG JUST, which should also be invited to participate in the interservice coordination group.

The sub-section below highlights the importance of performing an in-depth analysis of the fundamental rights impacts of each option, to document carefully the reasons for discarding, retaining and/or modifying them, and their subsequent comparison.

For further details on this and other impact assessment steps or on ex post evaluation needs, please refer to the [operational guidance](#) mentioned below³⁷⁶.

3. ANALYSING IMPACTS OF POLICY OPTIONS ON FUNDAMENTAL RIGHTS

Policy options can have both positive and negative impacts on fundamental rights. In case of negative impacts, since limitations to fundamental rights can only be justified if they meet with the requirement of necessity and proportionality, a simple cost/benefit analysis is not sufficient when assessing impacts on fundamental rights of a policy option.

To ensure the use of correct methodology, all identified policy options should be screened against the fundamental rights checklist (see Box 2). In addition, the promotion of equality is addressed in a specific checklist, against which the identified policy options should also be screened.

Box 2. Fundamental rights checklist

- **What fundamental rights are affected?** Screening the envisaged policy options against the fundamental rights ‘key impact questions’ section in Tool #18 (*Identification of impacts*) provides a first indication of which fundamental rights may be concerned.
- **Are the rights in question absolute rights?** While the Charter does not explicitly list which rights are absolute, the case-law of the Court of Justice of the EU indicates that the prohibition of torture and inhuman or degrading treatment or punishment (Article 4), prohibition of child labour (Article 32) and prohibition of slavery or servitude (Article 5) are protected in absolute terms. If the conclusion is that the examined policy option limits an absolute right, **it should be discarded already at this stage** and a further analysis under the following points is not needed.
- **What is the impact of the various policy options under consideration on**

³⁷⁶ The operational guidance will be updated in 2021/2022

fundamental rights? This step aims at identifying any positive impacts (promotion of fundamental rights) or negative impacts (limitation of fundamental rights). The options might have both a beneficial and a negative impact, depending on the fundamental rights concerned (for example, a negative impact on freedom of expression and a beneficial one on intellectual property). Should the analysis reveal that the policy option would have no negative impact on fundamental rights or only positive impacts, there is no need for further analysis under the points below. If the opposite is the case, the following points should be considered for each individual limitation:

- Would the limitation of / negative impact on fundamental rights be **provided for by law** in a clear and predictable manner?
- Would any such limitation / negative impact:
 - genuinely meet an objective of **general interest** of the Union or **protect the rights and freedoms of others** (this step should identify the relevant objective of general interest or the rights and freedoms of others)?
 - be **necessary** to achieve the desired aim? (This step should examine whether the policy option is appropriate and effective for attaining the policy objective pursued without going beyond what is necessary to achieve it. Why is no equally effective but less intrusive measure available?)³⁷⁷
 - be **proportionate** to the desired aim?
 - **preserve the essence** of the fundamental rights concerned?

If the general interest objective indeed justifies maintaining a policy option impinging on one or several fundamental rights, the impact assessment needs to consider and develop appropriate **safeguards** to ensure that the negative impact would not amount to a violation of the fundamental right(s) concerned.

Box 3. Ensuring non-discrimination and promoting equality checklist

In addition to ensuring that EU legislation complies with fundamental rights as provided by the Charter (including its Article 21 on the prohibition of any form of discrimination), Articles 8 and 10 TFEU and the [UN Convention on the Rights of Persons with Disabilities](#) require the EU to aim to promote equality between women and men, to combat discrimination on grounds of sex, ethnic origin, religion or belief, disability, age, and sexual orientation and to ensure respect for the rights of people with disabilities. The following steps and questions should be considered when checking the impact of various policy options on equality:

- **Is the policy to be prepared people-related? Will it affect people's lives?** For many EU policies, the answer to these first questions is 'yes.' If so, the next step is to identify equality relevance in more detail.
- **Identifying equality relevance in more detail.** At this stage, it is important to check whether in the policy area in question, some parts of the overall population experience inequalities based on sex, ethnic origin, religion or belief, disability, age, or sexual

³⁷⁷ The European Data Protection Supervisor has produced [additional guidance materials](#) for application in the fields of access to documents and data protection.

orientation – or a combination of these characteristics – which could be addressed by the policy option in question. The following steps are useful:

- identify existing inequalities based on sex, ethnic origin, religion or belief, disability, age or sexual orientation in the respective policy area;
- analyse the causes and consequences of these inequalities;
- identify ways in which a policy initiative could address these inequalities.

For further information on how to do this, please refer to the Commission’s equality mainstreaming toolbox, in particular its [chapter 2 on equality mainstreaming across the policy-cycle](#) and [chapter 3 on equality data](#). Equality data are key tools to detect inequalities and monitor progress achieved through a specific policy option.

- **Assessing impacts.** Policy decisions that appear neutral may have a differential impact on specific groups, even when such impact was neither intended nor envisaged. Negative impacts leading to discrimination based on sex, race, colour, ethnic origin, religion, sexual orientation, age and disability are prohibited under Article 21 of the Charter and should be assessed accordingly. Furthermore, equality impacts of the policy options should also be assessed to see if an option is likely to affect the existing inequalities. The following questions should be considered:
 - Does the option have (directly or indirectly) a different impact on women or men? Is this a desired outcome or was it unintended? If the analysis reveals that the policy measure has a negative impact and leads to discrimination based on sex, the specific policy option shall be analysed in accordance with the checklist under Box 2, concerning potential limitations of fundamental rights.
 - Does the option promote equality between women and men? How?
 - Does the option have (directly or indirectly) a different impact on specific groups, such as people with a minority ethnic background, including Roma, religious communities, LGBTIQ people, children, older people, or persons with a disability? Is this a desired outcome or was it unintended? If the analysis reveals that the policy measure has a negative impact and leads to discrimination based on race, colour, ethnic origin, religion or belief, disability, age or sexual orientation, the specific policy option shall be analysed in accordance with the checklist under Box 2, concerning potential limitations of fundamental rights.
 - Does the option contribute to combating discrimination on grounds of sex, ethnic origin, religion or belief, disability, age, or sexual orientation? How?
 - Does the option ensure respect for the rights of people with disabilities in conformity with the UN Convention on the Rights of Persons with Disabilities? How? Depending on the initiative, this means checking whether the option ensures disability inclusive reforms of education, labour market and health sectors, accessibility of buildings and infrastructure, services and websites, as well as transition from institutional to community-based services.

4. FURTHER INFORMATION

While the [Charter](#) and its [Explanations](#) are the main reference documents, a number of other resources can be used to identify the rights that could be affected by a particular initiative:

- The Commission developed [operational guidance](#) on taking account of Fundamental Rights in Commission impact assessments. Specific guidance also exists for [trade related initiatives](#) and for [implementing the European Structural and Investment Funds](#) ('ESI Funds'). It is to be noted also that the [Regulation laying down common provisions for specific EU funds](#)³⁷⁸ provides for arrangements to ensure the compliance of EU funded programmes with the relevant provisions of the Charter.
- The [Commission's 2010 Charter strategy](#) sets out the Commission's approach to implementing the EU Charter of Fundamental Rights and can be a source of inspiration.
- The [Commission's 2020 Charter strategy](#) proposes specific actions to strengthen the application of the Charter.
- The [Commission's 2021 EU strategy on the rights of the child](#) sets out the Commission's approach to strengthening the protection and promotion of children's rights across EU policies (notably its [Annex 1](#)).
- The [Commission's EU Action Plan against racism 2020-2025](#) sets out [measures with which the Commission](#) will ensure that Member States fully implement relevant EU law and further strengthen the legal framework, if needed (link with Chapter 2.1 of the Charter).
- The [Commission's 2020 EU Roma Strategic Framework for equality, inclusion and participation](#) puts forward new targets and recommendations for Member States on how to achieve the key areas covered by the strategy.
- The [Commission's Gender Equality Strategy 2020-2025](#) presents policy objectives and actions to make significant progress **towards a gender-equal Europe** (notably its Chapter 5).
- The [Commission's LGBTIQ](#)³⁷⁹ [Equality Strategy 2020-2025](#) sets out a series of measures to step up action and to integrate LGBTIQ equality in all policy areas (notably, its Chapters 3 & 5).
- The [Commission's Strategy for the Rights of Persons with Disabilities 2021-2030](#) sets out measures to ensure the full participation of people with disabilities in society, on an equal basis with others in the EU and beyond.
- The [European e-Justice Portal](#) also contains relevant information on the application of the Charter.
- The [EU Agency for Fundamental Rights](#) (FRA) collects and analyses information on fundamental rights issues. Please liaise with DG JUST - Fundamental Rights Policy Unit to know whether the Agency could be of help with providing specific data.
- The [European Institute for Gender Equality \(EIGE\)](#) has developed a [step-by-step guide to gender impact assessments](#).
- The [European Data Protection Supervisor \(EDPS\)](#) can advise about ensuring compliance with rights to privacy and the protection of personal data.
- To develop a deeper understanding of any fundamental right guaranteed by the Charter, **the case law** of the Court of Justice of the European Union, of the European Court of Human Rights and when appropriate, the opinions and general comments of the UN

³⁷⁸ See in particular the horizontal enabling condition 'Effective application and implementation of the EU Charter of Fundamental rights' provided in Annex III of the Common Provisions Regulation.

³⁷⁹ LGBTIQ stands for lesbian, gay, bisexual, trans, intersex and queer people.

human rights monitoring committees should be consulted. The Fundamental Rights Agency's '[Charterpedia](#)' is a useful tool to obtain an overview of the Charter rights and of the relevant case law.

- **Other international instruments**, such as the [European Convention on Human Rights](#) or the UN [Convention on the Rights of the Child](#) are also relevant for interpreting the Charter on Fundamental Rights.
- The [UN Convention on Rights of Persons with Disabilities \(UNCPRD\)](#)³⁸⁰, is part of the EU legal order.

In accordance with Article 53 (Level of protection) of the Charter on Fundamental Rights nothing in the Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognised, inter alia in international agreements to which the Union or all the Member States are party, as it is the case of the UNCPRD.

5. SUPPORT

On Fundamental Rights, DG JUST Unit C.2 (Fundamental rights policy) can provide further assistance:

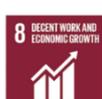
JUST-FUNDAMENTAL-RIGHTS@ec.europa.eu On methodological issues related to impact assessments and evaluations, the 'better regulation' team in DG JUST Unit 03 (Economic analysis and evaluation) can help;

JUST-03-IMPACT-ASSESSMENT-EVALUATION@ec.europa.eu

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

³⁸⁰ Council Decision of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities ([2010/48/EC](#)).

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • People at risk of poverty or social exclusion • Self-reported unmet need for medical care • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Population unable to keep home adequately warm • Gender employment gap • Population reporting occurrence of crime, violence or vandalism in their area • Perceived independence of the justice system <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Proportion of population covered by social protection floors/systems, by sex, distinguishing children, unemployed persons, older persons, persons with disabilities, pregnant women, new-borns, work-injury victims and the poor and the vulnerable • Proportion of population living in households with access to basic services • Proportion of total adult population with secure tenure rights to land, (a) with legally recognized documentation, and (b) who perceive their rights to land as secure, by sex and type of tenure • Proportion of countries where the legal framework (including customary law) guarantees women's equal rights to land ownership and/or control • Proportion and number of children aged 5–17 years engaged in child labour, by sex and age • Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law • Proportion of children aged 1–17 years who experienced any physical punishment and/or psychological aggression by caregivers in the past month • Number of victims of human trafficking per 100,000 population, by sex, age and form of exploitation • Proportion of young women and men aged 18–29 years who experienced sexual violence by age 18 • Proportion of victims of violence in the previous 12 months who reported their victimization to competent authorities or other officially recognized conflict resolution mechanisms • Unsentenced detainees as a proportion of overall prison population • Number of verified cases of killing, kidnapping, enforced disappearance, arbitrary detention and torture of journalists, associated media personnel, trade unionists and human rights advocates in the previous 12 months • Number of countries that adopt and implement constitutional, statutory and/or policy guarantees for public access to information 	         

TOOL #30. EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION

1. INTRODUCTION

This tool covers three categories within the broad category of social impacts: impacts on 1) employment, 2) working conditions, and 3) income distribution, social protection, and inclusion, including impacts on perspectives and life-situations of people in, or at risk of poverty³⁸¹.

Box 1. Things to keep in mind when assessing social impacts³⁸²

- Impacts are diverse, complex (affecting different population subsets, territories and economic sectors) and strongly connected with economic and environmental impacts.
- There may be trade-offs where social impacts point in different directions. Carefully compare these diverging impacts. A policy change could encourage the creation of new jobs in a sector/region while at the same time lowering job quality or wages for some workers in this (or another) sector.
- Always keep potential distributional effects in mind. Global (aggregate) figures could be misleading as they might hide controversial trade-offs.
- Always use a combination of qualitative and quantitative tools for your assessment as many social impacts might not be quantifiable and models available might rely on controversial assumptions.
- The most practical solution to a lack of EU-wide data and strong differences in labour markets and institutional contexts is in-depth research on 'typical' target groups or 'clusters' of Member States with similar characteristics.
- Positive social impacts often materialise only in the long run. When assessing impacts do differentiate between one-off and recurrent costs/benefits, as well as, between short-term and long-term impacts.
- When significant negative effects are identified, ask yourself whether there aren't ways to mitigate them. Possible solutions could include an exception for the most disproportionately affected stakeholders (e.g. vulnerable groups) or other mitigating measures, such as longer implementation periods, training and job search measures to support people losing jobs. Think about the ways to use the EU funds (e.g. European Social Fund Plus - ESF+ and European Globalisation Adjustment Fund for Displaced Workers - EGF).

³⁸¹ According to the Horizontal Social Clause of the TFEU (Art 9), the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health in defining and implementing its policies and activities.

³⁸² Contact DG EMPL 'better regulation' unit for further reference, information sources, background material and methodological issues.

2. WHO ARE THE RELEVANT STAKEHOLDERS?

In order to effectively *map stakeholders*, keep in mind those who might not be your usual interlocutors, especially those from *disadvantaged backgrounds* (like children from poor households or people with migration or minority ethnic or racial background), or those facing *multiple disadvantages* (like women living in rural areas with poor access to services and infrastructure).

In practice, it is useful to start by examining whether there are any systematic impacts on well-defined stakeholders (for instance by gender, age, income, disability, level of education and training, migration, or minority ethnic or racial background, or sexual orientation and gender identity, or by the place of residence like remote/rural areas with poor infrastructure). A gender perspective should always be considered. The assessment of potential impacts on gender should take into account the existing differences between women and men in the given policy field (e.g. gender pay gap). Various [European umbrella NGO networks](#) promote social inclusion, gender equality, and represent and defend the rights of people exposed to discrimination.

European social partners – employers' organisations and trade unions – should be specifically consulted in case of initiatives in **the field of social policy**³⁸³ and for **initiatives with social implications for the economy as a whole or for a specific sector**³⁸⁴. Contact [EMPL Social Dialogue Unit](#) in case you need more information about Sectoral Social Dialogue Committees, cross-industry social dialogue and social dialogue texts database.

Member States can be consulted via Employment Committee (EMCO) and Social Protection Committee (SPC). Contact EMPL Coordination Unit in case you need more information.

The identification of those stakeholders for whom there may be significant negative impacts may help foresee resistance and may point to mitigating measures to reduce negative impacts.

3. ARE IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION POTENTIALLY SIGNIFICANT?

To help identify potential impacts, sections 3.1 to 3.3 below include a few relevant *questions* accompanied by illustrative examples. Social impacts, positive as well as negative ones, often materialise in the long run, therefore it is important to differentiate between short- and long-term impacts. See section 5.1 for employment and social indicators and sources.

³⁸³ There are specific Treaty provisions for consulting social partners (management and labour), regarding initiatives in the field of social policy e.g. health and safety in the workplace, working conditions, social security and social protection of workers, and information and consultation (see Treaty Articles 153-155 TFEU, and particularly Article 153 TFEU on the policy fields concerned). This consultation process includes two stages: first, social partners are consulted on the general direction of an initiative; then, in a second stage, on the envisaged content (see Tool #10 (*Treaty-based social partner consultations and initiatives*))

³⁸⁴ If an initiative will create social implications for a sector for which a sectoral social dialogue committee exists, it shall be consulted (Article 2 of Commission Decision 98/500). If an initiative has social implications for the whole economy or for several sectors, social partner consultations can take the form of a dedicated hearing organised at services' level or of a political meeting at the level of Executive Vice-Presidents or Commissioners.

3.1. Impacts on the level of employment

Impacts on the level of employment can be expected whenever demand or supply for labour changes. For example, labour demand increases if companies want to employ more people due to increase in demand for their products. Labour supply increases when more people are available and willing to work.

The main question is **whether there will be more or fewer jobs (more or fewer hours worked) overall or for specific stakeholder categories, in a specific geographical area**. It will give you an indication whether a larger/smaller workforce will be needed and/or whether redistribution of labour is to be expected (e.g. between sectors or occupations).

The following questions and illustrating examples explore various dimensions of employment impacts.

(1) *To what extent are new jobs created or lost?*

Options improving access to funding for SMEs can create new industrial activity that can employ directly or stimulate indirect job creation through the purchases of goods and services from suppliers. Free trade agreements can create new jobs by increasing exports and demand for certain domestically produced goods but also destroy jobs by replacing other domestically produced goods or even services³⁸⁵ with imported ones. The impact on employment should refer to direct and indirect creation or loss of jobs, including short and long-term impact when possible.

(2) *Are direct jobs created or lost in specific sectors, professions, qualifications, regions or countries or a combination thereof? Which specific social groups are affected?*

Initiatives fostering greener energies might increase the need for certain skills (e.g. installation of photovoltaic panels) to the detriment of others (e.g. skills needed in extracting coal). Creation of jobs in new renewable sectors can be at the cost of employment in traditional extractive industries (skill-mismatch) and regionally unbalanced (e.g. jobs created at the off-shore wind farms and lost in coal mining regions). Jobs can be created or lost in male-dominated or female-dominated professions.

Reforming the common agricultural policy for wine growing is expected to have no employment impact in those Member States with (almost) no wine growing, very little impact in those Member States where the sector had already undergone significant reforms and significant impact in those Member States where such reforms had not yet taken place. However, depending on the respective structure (age of farmers, size of farms), these impacts can differ even in those countries.

(3) *Are there indirect effects which might change employment levels?*

New industrial activity can stimulate indirect job creation through increased purchasing power of newly employed workers (e.g. retail or leisure).

Initiatives fostering green energies might increase the need for certain skills but raise wages at the same time with a complex effect on employment levels. This might also increase the need for training and trainers leading to indirect employment impacts.

³⁸⁵ E.g. due to digital transition.

(4) *Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses?*

Delays in acknowledgement and certification of new qualifications or a lack of arrangements to provide for a transition can create significant employment problems.

Initiatives improving energy efficiency of buildings might increase demand for workers in construction sector with relevant skills. If the necessary skills are not available (e.g. lack of relevant educational/training programmes, non-recognition of skills acquired abroad) the effectiveness of the policy risks to be limited.

Transition between winning and losing sectors/occupations/skills/regions is not automatic. A worker losing a job in the car manufacturing or agriculture sector may not become a health or domestic service sector worker within a couple of months and without support/training. While analysis often implies easy adaptation processes, an important aspect of employment-related impacts requires explicit consideration for timing and sequencing of the intervention.

(5) *To what extent does the option influence the availability and willingness of workers/specific groups to work (i.e. supply of labour through labour market participation or labour market mobility)?*

Several factors can influence the supply of labour: tax and benefit systems, relative earnings, barriers to entry into profession/occupation, accessibility for persons with disabilities, work-life balance policies, work intensity and working conditions, length of working life, the occupational/geographical mobility of labour, migration policies.

An initiative aiming at regulating professions (e.g. by requiring a specific degree or special exam) can act as a barrier to entry, hold back the labour supply and limit occupational mobility, but it can at the same time support the safety and quality of the goods or services provided.

Work-life balance policies that help parents to balance professional and family responsibilities by increasing their availability/willingness to work and can have a positive impact on labour market participation of women.

Initiatives shortening the length of compulsory education, increasing the age of retirement, or supporting active ageing (like better ergonomics of working places, reskilling, ICT tools etc.) can increase the supply of labour of specific age groups and therefore total labour supply.

An initiative improving transport infrastructure and transport services can enhance the geographical mobility of workers by reducing the time and/or costs of travelling. More workers would be able to daily/weekly commute to cities/regions where jobs are available without the need to relocate and thus prevent depopulation of remote and rural areas. The geographical mobility of workers can be improved also through initiatives on property markets (e.g. affecting rents, conditions for mortgages etc.).

3.2. Impacts on working conditions

Impacts on working conditions are more difficult to capture. They often require a mix of qualitative and quantitative assessment and cover a broader range of outcomes, which may become tangible only in a medium to long term. Initiatives that e.g. enhance the creation of a business-friendly environment and liberalisation and/or deregulation of activities are likely to

have an impact on working conditions. In cases where value chains involve third countries, conditions of workers along the full value chain should be considered. This is particularly important for workers in industries in developing countries, as working conditions are often below European standards.

The following questions and illustrating examples explore various dimensions of impacts on working conditions:

(1) Does the option affect wages, labour costs and/or wage setting mechanisms?

Initiatives changing income taxation or social security systems can impact **wages and labour costs**³⁸⁶. Elements to be considered are: i) a relative dimension of wage: wage dispersion, changes in income-distance to another group of workers considered as reference group, or ii) its absolute dimension: wages, which are insufficient to allow for a decent standard of living.

Impacts on labour costs should be assessed in conjunction with changes in (labour) productivity. For example, initiatives introducing obligatory employers' training or health and safety requirements can increase labour costs. However, this may not be negatively correlated with the competitiveness of goods produced as those measures can increase the productivity of workers due to better skills and reduced absenteeism. While the costs might be relatively easy to estimate (e.g. prices of protective equipment, number of hours away from workplace dedicated to training), the benefits may be visible only in the longer term and are more difficult to quantify.

The **wage setting mechanism** affects the level or conditions of minimum wages, the coverage of workers by collective agreements and negotiating power of social partners.

(2) Does the option affect directly or indirectly employment protection, especially the quality of work contract or bogus self-employment³⁸⁷?

Employment contracts that don't provide for a minimum number of working hours and/or reduce job security make employees' income less predictable and lead to instable living conditions and uncertain career prospects. Initiatives aimed at facilitating technology-driven activities leading to new forms of work can open up employment opportunities to people further away from labour market but also reduce job security and predictability and also challenge the effective exercise of collective labour rights. Initiatives fostering entrepreneurship and self-employment can have a positive impact on job creation, but they can also undermine employees' rights and protection if the initiative leads to 'bogus self-employment' or to dependent self-employed persons in systems in which the recognition of their specificities, e.g. as to their social protection needs, is low.

³⁸⁶ Wages (or earnings) are the compensation that workers (employees) receive for their work. They safeguard labour income and are positively correlated with consumption. Net wages are calculated as a difference between gross wages, social contributions payable by the employee and any amounts which are due to government, such as income taxes. Labour costs are broader concept and reflect employers' expenditure on personnel. They include wages and salaries paid to employees, social contributions payable by the employer and other costs, such as taxes on labour, training costs, costs related to working cloths etc.

³⁸⁷ Bogus 'self-employed' or 'false self-employed' are formally self-employed but in practice employees. In some of these cases, workers are obliged to adopt a self-employed status while having a contract with a single firm that avoids paying social security payments.

Typically problematic contractual arrangements are: frequent use of short-term contracts, excessive use of traineeships, employment relations which do not give access to social security schemes, very short lay-off periods, excessively long probation periods, no fixed volume of working hours, involuntary and bogus self-employment, intensive use of temporary work agencies or subcontracting/outsourcing.

On the other hand, excessively protective employment protection legislation can adversely affect segmentation of the labour market with large differences in costs and rights between permanent and non-standard forms of work.

(3) *Does the option affect the risk of undeclared work?*

Undeclared work can take various forms, from completely undeclared work (e.g. a care assistant taking care for elderly people without signing any contract, or seasonal and temporary workers in agriculture without having a proper employment contract) to situations where only part of the work and income is undeclared (e.g. IT specialist working in a big company officially earning the minimum salary while receiving an additional amount by his employer 'cash-in-hand'). It has negative effects on workers (e.g. lack of security, reduced benefits, poor working conditions), employers (e.g. unfair competition) and on public finances (e.g. unpaid taxes and social security contributions).

Initiatives changing income taxation or social security systems, work or responsibilities of public administration (e.g. enhancing the frequency of checks by labour inspectorates), recognition of qualifications or initiatives in the area of migration are some of the examples that can affect the risk of undeclared work.

(4) *Does the option affect the work organisation?*

Work autonomy, level of teamwork and job rotation, pace of work and work intensity are important elements of work organisation. Work organisation can influence various aspects of working conditions (physical risk factors, work-related health and safety risks, work-life balance, or in general the satisfaction with working conditions) and therefore have an impact on labour productivity.

Liberalisation of activities (e.g. ground-handling in aviation sector) can stimulate growth and job creation but aggravate the working conditions of the workers (e.g. work in shifts or split work). Work organisation can change because of industrial restructuring but also with the introduction of new technologies. For example, the development of IT and the deployment of algorithmic management practices for recruiting, directing, and monitoring workers (or other ways of using artificial intelligence at work), and GPS tracking systems can reduce the work autonomy and increase the work intensity. Also, they need to be used cautiously to avoid negative impacts especially on vulnerable people such as people with disabilities. On the other hand, the IT development can support flexible working arrangements and, in some cases, contribute to better work-life balance.

(5) *Does the option affect health and safety at work?*

Health and safety at work³⁸⁸ encompasses several elements such as: safety and health aspects; organisation and adaptation of the workplace and working environment so as to ensure the

³⁸⁸ See also *Tool#32 (Health impacts)*, as health and safety at work is closely linked with general health impacts.

health and safety of workers; ensuring adequate personal protective equipment limiting exposure to potentially harmful agents or situations (including exposure to risks leading to musculoskeletal disorders; to physical agents such as noise or vibration; to radiation; to chemical agents, carcinogens and mutagens; to biological agents etc.), proper protective and preventive framework for work in a particularly challenging work environment/sector; or a combination thereof. Health problems do not only originate from physical strain at the workplace, but also from the overall psychological stress to which an employee is exposed. Therefore, aspects such as stress levels, tight/unsocial working hours and reconciling work and private life should also be considered, especially in view of an ever-growing digitalisation of the workplace and work-tools. The benefits of technology-enabled work (e.g. telework) should nonetheless be evaluated against the drawbacks of an increasingly blurry boundary between private and professional life, as well as a reduced ability for workers to 'digitally disconnect'.

Satisfying work and good working conditions constitute a value in itself, but their absence leads to discontent and can also produce significant negative effects on workers (e.g. death, disability, poor health, injuries, loss of present and future income, direct and indirect medical costs and rehabilitation costs); employers (e.g. absenteeism, lower productivity, production disturbances, damage to equipment and to a company's image, administrative and legal costs, negative impacts on insurance premiums); governments (e.g. sickness payments, increased health expenditure, increased social security expenditure (for disability or early retirement), tax revenue losses, direct and indirect medical and rehabilitation costs, administrative and legal costs).

Initiatives reducing regulatory burden by introducing, for example, less stringent requirements to monitor the working place, to guarantee preventive work clothes or to ensure preventive medical check-ups can increase health risks.

(6) *Does the option affect the social dialogue?*

Social partners (trade unions and employer's organisations) **determine** working conditions and carry out wage negotiations. Social dialogue between employers' and employees' representatives is an important mechanism for conflict resolution and can be a means to internalise external effects which take place at sectoral level.

Social dialogue within a company can be impacted by initiatives that, for example, exempt SMEs from ensuring the representation of workers in the management. Attention needs also to be paid to the extent to which the option affects the autonomy of social partners in the areas for which they are competent. Does it, for example, affect the right of collective bargaining at any level or the right to take collective action?

Another issue that might need to be considered is the impact on the transparency of workplace-level employment relationships. For instance, some initiatives aimed at facilitating technology-enabled work may lead to a de facto 'digitalisation of the workplace', which in turn causes a physical dispersion of the workforce, thus making it difficult for workers to collectively organise and for social partners to proactively reach out to them.

(7) ***Does the option affect access to vocational education and training and to career development/advice? How are different social groups affected³⁸⁹?***

Training / lifelong learning opportunities (including their availability and affordability) and returns to it (recognition of skill acquired in other companies or in other Member States) can influence career perspectives and employability of workers in the long run. Employers offering training opportunities can be more attractive among job seekers and thereby increase the pool of potential work candidates. Career advice can improve the match between job and worker, increase job satisfaction and productivity and reduce staff turnover. Tax reforms or financial incentives can have an impact on companies' willingness to invest in vocational education and training (VET) and career development.

Initiatives exploiting IT development and supporting distance learning can improve the availability of training opportunities for a large part of the population, but might be still unavailable to some, such as people with low incomes, persons with a minority racial or ethnic background, living in poverty or people living in remote and rural areas with inadequate access to digital infrastructure/broadband who can't afford to buy a computer or have an internet connection. Persons with disabilities may be disadvantaged in case accessibility of digital services is not ensured.

(8) ***Does the option help/endanger the effective exercise of labour standards in the EU?***

Labour standards largely rely on national legislation or social partner agreements. European level intervention can have an impact on these arrangements even without explicitly intending to do so, by e.g. setting new rules in an adjacent area; by changing the structure of a market; by introducing standards for consumers which could have – positive or negative – impacts on workers or by concluding external agreements (e.g. free trade agreements, international conventions).

The normative interpretation of these impacts, i.e. whether a change should be considered as improvement or not, depends on the context. In this sense, discussing and presenting these issues in an impact assessment report enhances the transparency of policy debates.

3.3. Impacts on income distribution, social protection, and inclusion

These impacts relate to social fairness considerations, including social inclusion and protection of people against various risk and needs throughout their lives. Such impacts may be particularly significant in interventions which affect the tax system or introduce changes to the transfer system. Most EU financial instruments (such as the Structural Funds, the Common Agricultural Policy), but also liberalisation or deregulation efforts, have income distributional impacts. Similarly, changes in legislation, for instance concerning equal opportunities/reconciliation or access to services for disabled people or people from disadvantaged backgrounds can affect their attitudes and their chances on the labour market. Changes in EU legislation can also indirectly impact the income distribution and social protection of workers in third countries, e.g. by creating a race-to-the-bottom situation. In a similar way, the analysis should cover the possible impacts on income of people working/living in the EU because of changes in labour costs outside the EU. Perpetuation of income and wealth inequality patterns should be avoided.

³⁸⁹ See also Tool #31 (*Education and training, culture and youth*)

The following questions and illustrating examples explore various dimensions of impacts on income distribution, social protection, and inclusion:

(1) Does the option affect people/households’ income and risk of poverty?

Disposable income is an important indicator of social status and of someone’s living standard. If it falls below a certain threshold, people will risk becoming poor and/or having to rely on social assistance. The **three dimensions of “poverty or social exclusion (AROPE)³⁹⁰”** comprise: very low work intensity and/or severe material and social deprivation and/or at-risk of poverty (relative poverty)³⁹¹.

As examples, initiatives leading to job losses (part 2.1 above) are very likely to have an impact on income and risk of poverty by increasing the number of unemployed or inactive people with low income and households with low work intensity. This is even more pertinent when there are few re-employment opportunities or the people losing jobs are from vulnerable groups (e.g. older workers, low qualified). Initiatives deteriorating working conditions (part 2.2 above) are also likely to have an impact on income and risk of poverty by increasing the number of people with low income when wages are reduced. If policies fostering green energies increase the price of energy this can increase household spending on energy and aggravate energy poverty.

(2) Does the option affect inequalities and the distribution of incomes and wealth?

Increasing income inequalities³⁹² threaten social cohesion and can be linked to several factors, such as wage dispersion, tax wedge or social protection systems.

Initiatives such as moving from direct taxation (e.g. taxing the income) to indirect taxation (e.g. increased VAT) raise the disposable income of certain stakeholders (the workers) but reduce that of the others towards poverty and negatively affect their chances to participate fully in society (inclusion). This may be counter-balanced by increased job opportunities created by the reduced labour cost. The overall impact on risk of poverty would have to consider the extent of such opportunities and the chances that the unemployed would be able to take advantage of them. A policy change may also have a distributional impact if existing inequalities are aggravated. If for example, only high skilled jobs are created this could increase the inequality with lower skilled people who already have more difficulties to find a job.

When assessing the impact on income inequality, consider also which segments of the income distribution would be affected (e.g. ‘relative impoverishment’ of the middle class).

³⁹⁰ AROPE – at-risk-of-poverty or social exclusion.

³⁹¹ **Work intensity** is the ratio between the number of months that household members of working age (with some exclusions) worked and the total number of months that could theoretically have been worked. Very low work intensity refers to situation where persons of working age (with some exclusions) living in the household worked less than 20.0% of their total potential in the previous 12 months. **Severe material and social deprivation** is the inability for a person to afford seven items out of a selection of 13 items of reference that are considered to be necessary or desirable to lead an adequate life **At-risk-of poverty (AROP)** rate is the share of people in the total population with an equivalised disposable income (after social transfers) below 60% of the national median equivalised income after social transfers. This indicator measures low income in comparison to other residents in that country, which does not necessarily imply a low standard of living.

³⁹² Income inequalities arise from distributional impacts on income. Income refers to equivalised disposable income.

(3) Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds?

Social services play a crucial role in improving quality of life and providing social protection against the risks and needs associated with unemployment, parental responsibilities, sickness and healthcare, invalidity, loss of a spouse or parent, old age, housing, and social exclusion. Social services are an important enabler of social inclusion in remote and rural areas contributing towards the reduction of inequalities in those areas.

Access to and adequacy of **social protection benefits** depends on the eligibility, duration and level of benefits, type of risks covered and rights to receive benefits when moving to another Member States beyond the obligatory rights. They will be likely affected by the initiatives that affect the organisation and financing of social protection systems (e.g. insurance vs solidarity; range of membership, private vs public provision; tax financed vs contribution based) as well as the cross-border provision of services, referrals across-borders and cooperation in border regions (e.g. provision of services by public employment services).

The changes would have to be assessed in view of their direct impact on the beneficiaries and on their behavioural impact on people who might leave or enter the scheme or other schemes. For instance, raising pension ages may encourage more people to join disability schemes. The increased prevalence of new forms of work (e.g. platform work) may impact the access and adequacy of social protection.

(4) Does the option affect the access to and quality of basic goods and essential services, particularly for those subject to social exclusion and from disadvantaged backgrounds?

Basic goods and essential services include, for instance, energy, water and sanitation, transport, financial services, and digital communications³⁹³, healthcare, education and training and housing. It might be important to assess the access to and quality of these goods and services especially for people not covered by social protection schemes and people living in remote and rural areas with inadequate access to those services.

Interventions increasing the price of basic good/services, e.g. energy prices, can aggravate material and social deprivation and energy poverty of certain categories of the population and exacerbate social exclusion and inequalities. On the other hand, initiatives aiming at increasing access to essential services, such as a bank account or internet can increase social inclusion. Social services of general interest can play a crucial role in improving life quality³⁹⁴.

3.4. Which impacts are potentially significant?

Among the five criteria to identify potentially significant³⁹⁵ impacts for more detailed assessment, the following three are especially relevant for social impacts:

³⁹³ A non-exhaustive list of essential services is provided in [principle 20 of the European Pillar of Social Rights](#).

³⁹⁴ https://employment-social-affairs.ec.europa.eu/policies-and-activities/social-protection-social-inclusion_en

³⁹⁵ i) The relevance on the impact within the intervention logic, ii) the absolute magnitude of the expected impacts, iii) the relative size of expected impacts for specific stakeholders, iv) the importance of impacts for

- **Relative size of expected impacts for specific stakeholders** (i.e. Are certain categories of stakeholders or regions/countries/sectors particularly affected?) For example, new rules (e.g. labelling, selling restrictions) regarding a particular product might have more serious consequences in terms of employment in those EU regions specialised in its production. Big job losses in a small region without viable alternatives for re-employment can be an example of a significant impact. The size of the EU population with no access to basic bank services is pretty modest. Still, regulations that would render those services more expensive/less accessible can have important negative consequences for that population (e.g. financial exclusion).
- **The importance of impacts for EU objectives and policies** – (i.e. Could the initiative undermine EU objectives in the social area?) E.g. initiatives that would lead to significant job losses, negatively impact health and safety at work or with significant impacts on households’ income could undermine efforts in building a fairer Europe and strengthening its social dimension in line with the principles of the [European Pillar of Social Rights](#)³⁹⁶. Such initiatives would also have a negative impact on the EU’s progress in achieving the SDGs.
- **Sensitivities and diverging views** - (i.e. How divergent are stakeholder views?) detailed assessment could be envisaged for potentially **politically sensitive issues**, such as impacts that could be considered as unfair (e.g. initiatives reducing tax burdens for companies and increasing those for workers).

4. HOW TO ASSESS IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION?

Given the diversity of impacts and affected stakeholders, start with a **systematic qualitative scoping**: i.e. go first through types of impacts and then stakeholders to be affected and in which way. Any assessment should focus on a **limited number** of impacts. A good and operational approximation is to identify three to six issues (combination of impact and stakeholders affected) that are the most important from a social perspective.

4.1. What to pay attention to in assessing social impacts?

Level of analysis and distributional impacts: The transition of employment between winning and losing sectors (or regions, qualifications, occupations) is not automatic. For employment and social impacts, it is important to understand where the adjustment occurs and therefore **net effects are not very informative**³⁹⁷. In the presence of important distributional effects, **global (aggregate) figures could be misleading as they might hide controversial trade-offs**. Disaggregated analysis can help you to look for alternative options or mitigating measures to minimise potentially negative impacts.

As an example, a trade agreement can be beneficial for the overall EU economy but have important opposite effects in different regions or sectors as well as the economy or specific sectors of the partner country. Likewise, liberalisation measures in the transport sector should

Commission horizontal objectives and policies and v) Sensitivities and diverging views. See step 2 in Tool #18 (*Identification of impacts*) for more details.

³⁹⁶ The European Pillar of Social Rights is accompanied by a ‘[social scoreboard](#)’ that monitors the implementation of the Pillar by tracking trends and performances across EU countries in three areas and feeds into the European Semester.

³⁹⁷ Net job changes are the difference between gross jobs created and destroyed (lost).

generally lead to lower prices for transport users but also to prohibitive prices for people living in remote areas. Moving from direct to indirect taxation raises the disposable income of certain population groups but reduces other groups to poverty and negatively affects their chances to participate fully in society. In such cases, calculating the average general impact on the total population could be misleading, and would be insufficient. Distributional impacts may for example vary by sex or age.

Different labour markets and institutional context: European countries have organised their labour markets and welfare states in different ways, relying to various degrees on market, family, and the State. The functioning of the labour market (e.g. social dialogue or labour market legislation) and different institutional settings can influence the direction and the magnitude of the social impacts. Those differences require an analysis at a national level or alternatively grouping of countries in clusters based on the similarity of their institutions. E.g. the transition of employment between winning and losing sectors is expected to be faster and more successful in countries with well-developed and efficient active labour market policies and public employment services. When a particular policy initiative is expected to have negative effects on job quality, Member States with strong union presence could face stronger opposition to it, but they could also be able to reduce the negative effects or secure mitigating measures via social dialogue. See (in particular) Eurofound for more information.

Sectoral and regional dimension: If the impacts are not economy-wide but concern a specific sector only, it is always better to refer to a [NACE](#) classification sector. When moving away from the NACE classification, consistent and reliable data is more difficult to get. However, if the impacts refer only to part of the sector, or parts of different sectors, it is reasonable to either adjust the NACE data source, or if possible, refer directly to those parts affected. For regional impacts it is essential to align with the [NUTS classification](#).

4.2. Can impacts be quantified and what is the availability of data?

A **quantitative analysis** can be easier to undertake when assessing impacts on **employment and income levels** as those impacts are quantitative in nature (e.g. number of jobs can be easily counted, wages, labour costs, disposable income are expressed in monetary units).

For assessing the impacts on income inequalities consider indicators such as income quintile share ratio (e.g. S80/S20) or the income share of the bottom 40% (S40). For overview of indicators see table “Relevant sustainable development goals (SDG) indicators” at the end of the tool.

In other areas, such as **working conditions**, **impacts are qualitative by nature and converting them into quantitative units will require the use of an indicator that acts as a proxy**³⁹⁸. E.g. the ‘number of occupational accidents’ can be used as a proxy to assess safety at work. Days of workers’ sickness in a certain sector, short-term contracts or part-time work indicate potentially problematic situations – however, this might also happen for other reasons (it is therefore crucial to understand the underlying causes or drivers). These indicators will be rather context specific – as for example in the situation of work contracts – and will normally be a compromise between accuracy and precision and the costs and time required to collect and process the necessary information.

³⁹⁸ See Tool #43 (*Monitoring arrangements and indicators*)

In some areas, you will most probably **analyse impacts qualitatively**. E.g. the impact on the access to social security services might be quantified (e.g. number of social services users), but the impact on its quality will be analysed qualitatively. Similarly, it will be difficult to quantify impacts related to social inclusion.

Complete, credible and EU wide comparable data is particularly important in the case of a quantitative analysis, but also your qualitative assessment will need to be underpinned with facts or examples. The availability of sound and up-to-date data will also condition the level of analysis. If impacts are concentrated on small groups, it will be difficult or impossible to find suitable data or a reasonable model. An inventory of the sources of data more relevant to the impacts covered in this tool is provided in section 4.2.

4.3. Using models in assessing social impacts?

If considerable social impacts are expected, a model should be used where possible.

Quantitative approaches to assessment range from relatively simple measurement, mainly based on past observations, to counterfactual analysis and up to highly complex formalised (and data-hungry) models, like Computable General Equilibrium (CGE) models or econometric models of the (world) economy.

The use of the model will be case-specific³⁹⁹. Some very well-known models, e.g. the input-output model, deliver results at a macro level and you will have to complement them with qualitative assessment to assess the distributional impacts. You may capture distributional impacts using augmented CGE models. If the expected impacts are restricted to certain sectors, a partial equilibrium model seems suitable to quantify those impacts. Otherwise, general equilibrium models might be more appropriate.

When using the models, pay attention to the **underlying assumptions about the labour market**. For example, Computable General Equilibrium (CGE) models generally assume full employment of all factors and perfectly competitive markets (which is far from the reality in many Member States' labour markets). In addition, there are strong differences among the Member States' institutional contexts related to the employment and social areas.

In complement to macro-economic models (useful to determine the impact on employment and wages), the use of micro-simulations (e.g. in the [Euromod](#) tool managed by Joint Research Centre) would be relevant to assess the impact of the option on income inequalities and the risk of poverty.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. Key EU-level data sources

- **The [European Union Labour Force Survey](#)** (EU LFS) is the most important survey for labour market data, providing monthly/quarterly/annual data on employment,

³⁹⁹ For further information on methods and models see Tools in Chapter 8. For an overview of models to be used for assessing social impacts see Annex 1 in *Review of Methodologies applied for the assessment of employment and social impacts* (2010) and table 4.3 in *Assessing the Employment and Social Impacts of Selected Strategic Commission Policies* (2009)

unemployment by sectors, age, qualification, sex, migrant background, per countries/regions. Micro-data are available upon request.

- **Other [labour market statistics at EUROSTAT](#)** are available on job vacancies, earnings, labour costs, labour market policy, labour disputes based on various surveys. Micro-data are available upon request.
- The **[European Working Conditions Survey](#)** enables monitoring of long-term trends in working conditions in Europe. Themes covered include employment status, working time arrangements, work organisation, learning and training, physical and psychosocial risk factors, health and safety, worker participation, work-life balance, earnings and financial security, as well as work and health. Micro-data are available upon request.
- The **[European Quality of Life Survey \(EQLS\)](#)** examines both the objective circumstances of European citizens' lives and how they feel about those circumstances and their lives in general. It looks at a range of issues, such as employment, income, education, housing, family, health, and work-life balance. It also looks at subjective topics, such as people's levels of happiness, how satisfied they are with their lives, and how they perceive the quality of their societies. European Foundation for the Improvement of Living and Working Conditions (Eurofound). Micro-data are available upon request.
- The **[European Company Survey](#)** (ECS) gives an overview of workplace practices and how they are negotiated in European establishments. It is based on the views of both managers and employee representatives. Micro-data are available upon request.
- For health and safety, Eurostat's statistical data on accidents at work, and work-related problems are available: **[European Statistics on Accidents at Work](#)** (ESAW), and the **LFS ad hoc modules on accidents at work** and **[European Occupational Diseases Statistics](#)** (EODS) and **Statistics on work-related health problems**.

Important information about occupational safety and health (OSH) management arrangements in enterprises can be drawn from the **[European Survey of Enterprises on New and Emerging Risks](#)** (ESENER), by EU-OSHA.

- The **[European Union Statistics on Income and Living Conditions](#)** (EU-SILC) collects comparable multidimensional micro-data on an annual basis on income, poverty, social exclusion and living conditions. Micro-data are available upon request.
- The **[European system of integrated social protection statistics](#)** (ESSPROS) provides a coherent comparison between European countries on social benefits to households and their financing.
- The **[Continuous Vocational Training Survey](#)** (CVTS) provides comparable statistical data on enterprises' investment in the continuing vocational training of their staff. Continuing vocational training (CVT) refers to education or training measures or activities which are financed in total or at least partly by the enterprise (directly or indirectly). Information is grouped around the following topics: provision of courses and other forms of CVT, CVT strategies, participants, costs, time spent in CVT courses, characteristics of CVT courses, and assessment of CVT activities. The sixth Continuous Vocational Training in Enterprises Survey conducted in 2020 is the most recent available wave of data collection. Micro-data are available upon request.
- The **[Adult Education Survey](#)** (AES) covers participation in education and lifelong learning activities (formal, non-formal and informal learning). The following information is available: participation, volume of instruction hours, characteristics of the learning

activities, reasons for participating, obstacles to participation, access to information on learning possibilities, employer financing and costs of learning and self-reported language skills. The fourth Adult Education Survey, conducted in 2022/2023, is the most recent available wave of data collection.

- [Skills forecast by CEDEFOP](#) provide comprehensive information on the future labour market trends in Europe looking at employment growth, developments in sectors, the types of job opportunities that may emerge, changes in qualification levels and demographic trends. Micro-data are available upon request.
- **The [Programme for the International Assessment of Adult Competencies \(PIAAC\)](#).** The Survey measures the key cognitive and workplace skills. It includes 3 elements: direct-assessment of skills (literacy, reading, numeracy, problem solving in technology-rich environment), collection of information about the skills use (the survey asks adults how intensively and how frequently they use cognitive, interaction and social, physical and learning skills at work), and background information (e.g. education, social background, engagement with literacy and numeracy and ICTs, languages, current activity of respondents, employment status and income, health status, volunteering, political efficacy, and social trust). Micro-data are available upon request.
- [World Input-Output Database](#) (WIOD) allows analysing impacts of the global value chain on skilled and non-skilled labour demand across EU countries and 15 other major countries in the world for the period from 2000 to 2014.
- [EUKLEMS](#) database which allows the analysis of productivity and growth. The EU KLEMS Release 2019 provides a database on measures of economic growth, productivity, employment, capital formation, and technological change at the industry level for all European Union member states, Japan, and the US. In addition, it provides supplementary indicators on intangible assets.
- Cross-country intangible investment data website, [INTAN-INVEST](#) is an open access database on intangible assets that allows the linking of employment data at macro level.

5.2. Other useful sources

This is a non-exhaustive list of potentially useful sources in the area of employment, working conditions and income distribution and inequality

- [Employment, Social Affairs & Inclusion Directorate General](#) (DG EMPL) – It coordinates and monitors national policies; promotes the sharing of best practices in fields like employment, poverty and social exclusion and pensions; makes laws and monitors their implementation in areas like rights at work and coordination of social security. It provides information and analysis. It provides analysis of various employment and social topics as well as descriptions of EU-funded projects.
- [Eurofound](#) – European Foundation for the improvement of Living and Working Conditions (EU decentralised agency). It provides information, advice and expertise on living and working conditions, industrial relations and managing change in Europe.
- [Cedefop](#) – European Centre for the Development of Vocational Training (EU decentralised agency). It provides information, advice and expertise on vocational education and training, identification of skills needs, understanding of qualifications and development of lifelong learning.

- **OSHA** – European Agency for Safety and Health at Work (EU decentralised agency). It develops, gathers, and provides reliable and relevant information, analysis, and tools to advance knowledge, raise awareness and exchange occupational safety and health (OSH) information and good practice which will serve the needs of those involved in OSH.
- **EIGE** (EU decentralised agency) – European Institute for Gender Equality. It contributes to the promotion of gender equality, including gender mainstreaming, in all European Union policies and the resulting national policies, and the fight against discrimination based on sex, and raise Union citizens' awareness of gender equality by providing technical assistance to the European Union institutions, in particular the Commission, and the authorities of the Member States.
- **European Social Policy Network** (ESPN) provides the Commission with independent information, analysis, and expertise on social policies
- **Social Scoreboard** – This monitoring tool of the European Pillar of Social Rights screens employment and social performances of EU Member States.
- **Europe Sustainable Development Report** (ESDR) is an independent quantitative report on the progress of the European Union and its member states towards Sustainable Development Goals (SDGs) which also measures spillover effects on third countries.
- **EDE – European Disability Expertise** – Experts' reports on legislation, policy and the situation of persons with disabilities including in the area of employment and transition from education to employment of persons with disabilities.
- **Skills Intelligence** (EC/CEDEFOP) is a central access point for data, information and intelligence on skill needs in occupations and sectors that provides a European perspective on trends in skill supply and demand and possible skill mismatches, while also giving access to national data and sources.
- **ILO** – International Labour Organisation brings together governments, employers, and workers representatives of 187 member States, to set labour standards, develop policies and devise programmes promoting decent work for all women and men. ILO provides good quality data and analysis of various employment and social topics.
- **OECD** – Organisation for Economic Co-operation and Development brings together 34 Member States and provides a forum in which governments can work together to share experiences and seek solutions to common problems. OECD provides good quality data and analysis of various employment and social topics available in their [library](#).

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant Sustainable Development Goal (SDG) indicators	SDGs
<p><i>EU indicators</i></p> <ul style="list-style-type: none"> • People at risk of poverty or social exclusion • People at risk of income poverty after social transfers • Severely materially deprived people • People living in households with very low work intensity • In work at-risk-of-poverty rate • Self-reported unmet need for medical care • Adult participation in learning • Gender pay gap in unadjusted form • Gender employment gap • Inactive population due to caring responsibilities by sex • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Final energy consumption in households per capita • Population unable to keep home adequately warm • Young people neither in employment nor in education and training • Long-term unemployment rate • People killed in accidents at work • Purchasing power adjusted GDP per capita • Disparities in adjusted gross disposable income of households per capita • Relative median at-risk-of-poverty gap • Income distribution <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Proportion of population living below the national poverty line, by sex and age • Proportion of men, women and children of all ages living in poverty in all its dimensions according to national definitions • Proportion of population covered by social protection floors/systems, by sex, distinguishing children, unemployed persons, older persons, persons with disabilities, pregnant women, newborns, work-injury victims and the poor and the vulnerable • Proportion of population living in households with access to basic services • Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population) • Proportion of youth and adults with information and communications technology (ICT) skills, by type of skill • Parity indices (female/male, rural/urban, bottom/top wealth quintile and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated • Whether or not legal frameworks are in place to promote, enforce and monitor equality and non-discrimination on the basis of sex • Proportion of population using safely managed drinking water services • Proportion of population with access to electricity • Proportion of population with primary reliance on clean fuels and technology • Proportion of informal employment in non-agriculture employment, by sex • Average hourly earnings of female and male employees, by occupation, age and persons with disabilities • Unemployment rate, by sex, age and persons with disabilities • Frequency rates of fatal and non-fatal occupational injuries, by sex and migrant status • Level of national compliance with labour rights (freedom of association and collective bargaining) based on International Labour Organization (ILO) textual sources and national legislation, by sex and migrant status • Proportion of people living below 50 per cent of median income, by sex, age and persons with disabilities 	

Relevant Sustainable Development Goal (SDG) indicators	SDGs
<ul style="list-style-type: none">• Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law• Labour share of GDP, comprising wages and social protection transfers• Proportion of population that has convenient access to public transport, by sex, age, and persons with disabilities• Proportion of cities with a direct participation structure of civil society in urban planning and management that operate regularly and democratically	

TOOL #31. EDUCATION AND TRAINING, CULTURE AND YOUTH (ETCY)

1. INTRODUCTION

Investing in a high level of education and training, culture, and youth has positive impact on individuals (e.g. higher chance to be employed) and the economy/society as a whole (higher productivity, innovation capacity, competitiveness, social cohesion, and sustainable growth). Education and training fuels employability, productivity and adaptability, and improves the ability of an economy to generate and absorb innovation. It can also foster important values such as democratic engagement, sense of citizenship, tolerance, solidarity, and European belonging. Any measure that helps improving the efficiency and performance as well as the inclusiveness of education and training systems (expressed, for example, as higher skills, better qualifications or a lower share of school drop-outs including for disadvantaged groups of learners) helps Europe to sustain economic growth and social benefits. EU policies concerning e.g. trade, foreign investment, and migration, might also impact educational outcome in third countries.

Box 1. Relevant provisions of the Treaties

- Article 6 TFEU states that the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, among others in (c) culture; (e) education, vocational training, youth, and sport.
- Article 9 TFEU obliges the EU to consider the requirements linked to a **high level of education and training** in defining and implementing its policies and activities.
- Article 3.3 TEU invites EU to “respect its rich **cultural diversity** and ensure that Europe’s cultural heritage is safeguarded and enhanced” and Art 167.4 TFEU invites EU to “take **cultural aspects** into account in its action under other provisions of the Treaties”
- Article 165 TFEU stipulates that the Union shall contribute to the development of quality education by encouraging cooperation between Member States and, if necessary, by supporting and supplementing their action, while fully respecting the responsibility of the Member States for the content of teaching and the organisation of education systems and their cultural and linguistic diversity.
- Article 166 TFEU concerns the EU implementing a vocational training policy that shall support and supplement the action of Member States while fully respecting the responsibility of the Member States for the content and organisation of vocational training.

2. ARE IMPACTS ON ETCY POTENTIALLY SIGNIFICANT?

To identify potential impacts on ETCY a few key questions should be asked regarding each area. These can be interlinked and can be of different magnitude, one-off or recurrent in relation to the transitory or permanent effects that take place. In addition, a distinction between direct and indirect impacts should be made.

2.1. Education and training

- *Is the initiative/policy designed to contribute to the achievement of a high level of education and training? Is there any impact on education and training systems, their financing, performance, or efficiency? Is there an impact on institutional autonomy, academic freedom, or integrity?*
- *Does the initiative contribute to mobility of students, learners and teachers, and/or promote deeper cooperation among educational institutions?*
- *Does the option contribute to implementing lifelong learning?*
- *Does the initiative have an impact on access to education and training and equitable outcomes (from early childhood to adult learning) especially for learners from disadvantaged backgrounds or learners from remote and rural areas with inadequate access to digital infrastructure and insufficient access to quality service (including quality education institutions)?*
- *Is the inclusiveness and accessibility for learners with disabilities considered?*
- *Does the option contribute to preventing or remediating early school leaving?*
- *Does the option have an impact on educational outcomes especially for learners from disadvantaged backgrounds?*
- *Does the initiative contribute to social inclusion or non-discrimination in education and training?*
- *Does the initiative promote gender equality in education and training?*
- *Does the option promote educational institutions' service to society? Does it encourage cooperation with business, local governments, and civil society?*
- *Does the initiative contribute to enhancing civic and intercultural competences?*
- *Does the option have an impact on the need for individuals (or groups of individuals) to upgrade their level of knowledge, skills and competences, as well as their ability to sustain employment, growth and innovation, and if so, does the option envisage measures to address those needs?*
- *Does the option affect the access to skills formation? Does it impact on the skills used by individuals (e.g. by increasing the relevance for labour market needs, by improving the visibility and comparability of skills and qualifications, etc.)?*
- *Is the quality of teaching both in formal and informal learning settings affected by a policy option?*

The initiatives that enhance the accessibility of people to acquire key competences can improve access to good jobs and fuller participation in society. Initiatives that affect the quality and relevance of skills formation (e.g. vocational training) facilitate the transition to employment and maintain and update the skills of the workforce. Initiatives that can impact on validation and recognition of skills and qualifications, increase the use of acquired skills and foster labour market mobility both internally and abroad. Initiatives that promote learning mobility, cooperation of European education institutions and their role in their local communities, may contribute to high quality learning, innovation capacity of education, and development of democratic societies.

Impacts on different education and training sectors need to be considered. These include pre-school, primary/secondary school, vocational education and training (VET), higher education, adult learning, non-formal learning, e.g. through youth work. These impacts need to be considered in the light of different societal groups/age cohorts, regions, and sectors.

Screening should not be restricted to a particular societal group or age cohort but should comprise (a) societal groups with different background and living conditions, such as minority racial or ethnic background, or migrant background, (b) learners with different abilities, (c) different regions/countries and (d) different economic sectors.

2.2. Culture

– *Is there an impact on cultural diversity?*

The 2005 UNESCO convention on the protection and promotion of cultural diversity, to which the EU is a party, defines cultural diversity as the manifold ways in which the cultures of groups and societies find expression. These expressions are passed on within and among groups and societies.

– *Is there an impact on cultural heritage?*

The Treaties require the EU to safeguard and enhance Europe’s cultural heritage and to “contribute to the flowering of the cultures of Member States, while respecting their national and regional diversity and at the same time bringing common cultural heritage to the fore”. The Treaty also recognises the specificity of heritage for preserving cultural diversity and the need to ensure its protection in the Single Market. Cultural heritage is both tangible (buildings, sites, etc.) and intangible (traditions, music etc.), and it includes landscapes. It may for example be affected by EU initiatives on environmental protection, transport, or energy efficiency (impact on historic buildings, natural landscapes). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

– *Are individuals’ access to and participation in cultural and creative activities affected? Is accessibility for persons with disabilities considered?*

Participation in culture is a fundamental right⁴⁰⁰. It usually covers both attendance (passive) and participation (active) in cultural activities, and is measured through quantitative and qualitative surveys, including household expenditure surveys, to gauge the economic consumption of culture.

– *Is there an impact on cultural and creative sectors?*

Possible impacts on the cultural and creative sectors could, among others, include legal aspects (e.g. copyright, intellectual property rights), financial (e.g. state aid, VAT), economic and social aspects (e.g. employment).

2.3. Youth

– *How to reach out to young people in consultations and decision-making?*

⁴⁰⁰ See Art. 27 of [Universal Declaration of Human Rights](#)

As per the TFEU, young people should be encouraged to participate in democratic life⁴⁰¹.

Young people often stand apart when it comes to their civic and democratic engagement; they tend to be under-represented in traditional forms of representation and decision-making, but they are active and have opinions frequently expressed in various ways, including loose movements and social media actions.

The Commission supports a [platform of youth organisations](#) and upholds an [EU Youth Dialogue](#) to facilitate the mobilisation and targeting of young people.

- *Is there an impact on social inclusion and integration of youth? Are the needs of young people from disadvantaged backgrounds and of young persons with disabilities duly considered?*

Provided that youth can be particularly prone to certain measures during their transitional phase to adulthood and can often face risk of exclusion (for example youth in rural and remote areas with inadequate digital infrastructure is prone to higher risk of social exclusion than their cohorts living in urban/cities areas), insufficient socio-economic integration and negative impact on well-being, analysis of how these can affect young people is necessary to avoid possible negative outcomes.

- *Is there an impact on learning opportunities in respect to youth?*

Young people can potentially benefit from learning opportunities that exist outside school or higher education, for instance through leisure time activities, youth clubs or volunteering.

- *Is there an impact on labour market, continuity of transition between education and professional performance in respect to youth?*

Aspects such as effects on activation of young people in terms of employment and self-employment, period between leaving education and finding a first job, transition from internships to work contract, as well as potential impacts on population of young people not in employment, education and training (NEET), and vulnerable young people should be considered in this part.

Box 2. Policies known to have impacts on ECTY

Education and training

- Changes in expenditure scheme – e.g. reallocation of spending from higher to lower levels of education, expanding coverage in specific regions, low-income areas.
- Changing financing scheme – e.g. introduction of school fees, switching to/from community to state financing providing incentives for individuals or enterprises to get involved in education and training.
- Systemic changes – e.g. changing governance structures in education and training to involve social partners in organisation, delivery and financing of learning; introducing reforms in schooling material, altering school systems, targeting specific studying programmes (increasing numbers of students on vocational education and training)

⁴⁰¹ Under Article 165 TFEU, the EU shall encourage youth participation in democratic life in Europe. It could be for example, participation in social and civic activities and organisations, volunteering, opportunities to express opinions in decision-making processes

<p>(VET), reducing numbers of students of particular specialisation at universities).</p> <ul style="list-style-type: none"> – Policies influencing fiscal stability, as they can limit public resources and investments in education. – Policies related to the digital and green transitions, innovation, employment, social inclusion, industrial policy, cohesion, and sustainable development. – Policies reforming digital markets, economy, and society – the potential of ICT to enhance the way people and institutions teach and learn⁴⁰². – Social policies and inclusion can help disadvantaged families (both younger and older age groups) participate or not in education, policies on maternity/parental leave can influence decisions to put children in crèche as well as gender policies. – Migration and border control policies might prevent student exchanges and/or influence knowledge, skills, and competence shortages.
<p><i>Culture</i></p>
<ul style="list-style-type: none"> – Policies related to digital transformation, innovation, employment, education, social inclusion, cohesion, and sustainable development. – Policies impacting cultural and creative sectors, such as EU laws on intellectual property rights, VAT or state aid. – Policies impacting cultural heritage – for example the Directive on the return of cultural objects unlawfully removed from the territory of a Member State (recast), legislation on energy efficiency (impact on historic buildings), legislation on green deal (impact on cultural and natural heritage).
<p><i>Youth</i></p>
<ul style="list-style-type: none"> – Policies impacting youth participation in democratic life and civic engagement in solidarity. – Policies impacting education and learning. – Policies impacting labour market. – Policies impacting health and well-being. – Policies impact youth inclusion and fight against poverty.

3. HOW TO ASSESS IMPACTS ON ECTY?

The following section aims at describing how to measure impacts that are significant in the areas listed above. The suggestions provided outline the most widely used methods of assessment including illustrative examples of possible impacts in some areas. Some of the indicators may overlap.

3.1. Education and training

European education and training systems are monitored through qualitative and quantitative indicators and targets, as adopted in the Resolution on a strategic framework for European

⁴⁰² See Tool #28 for guidelines on digital-ready policymaking.

cooperation in education and training towards the European Education Area and beyond (2021-2030)⁴⁰³.

Assessing impacts on education and training must consider different components:

– *The specificity of national education and training systems*

Evidence suggests that significant differences persist in the effectiveness of national education and training systems (young adults with nominally equivalent levels of educational attainment from different Member States scoring with considerable differences in competence tests).

– *The effects of expenditure in education – investing in skills, qualification, and new technologies*

Investing in people through providing better education and skills will raise productivity, employability and will generate economic growth, social benefits, and prosperity in general.

Statistics on these can be found at different levels of aggregation (national, regional, level of education, private/public), providing insight on expenditure levels both per student and overall. It is important to measure in monetary terms how the various stages of learning processes are supported and how they interact with investment in skills. In addition, it is useful to gather statistics on investing in new technologies serving learning processes paving the way for smart innovation.

– *Levels of literacy, numeracy, and digital numeracy*

Levels of literacy, numeracy and digital numeracy significantly affect a population's potential to contribute to a developed society, providing a basis for economic well-being and equity. The basic skills target is used to monitor this.

– *Level of knowledge, skills, and competences*

Increasing the level of knowledge, skills and competences of individuals has a great potential to create social value, to drive innovation and entrepreneurship and to reinforce Europe's strong social foundations. Demand and supply for skills and competences are ultimately guided by demographics, labour force quality and participation in education and training. Educational outcomes tend to converge towards high levels of skills and competences in general, and on science, technology, engineering, and mathematics (STEM) fields in particular. The digital transformation of the economy, the changes in work organisation and the dynamics in sectoral specialisation create new demands for skills leading to skills gaps and mismatches with the needs of the labour market.

Information on levels of knowledge, skills and competencies can serve as essential guidance for analysis of potential impacts⁴⁰⁴. Equally important is to assess if an initiative has an impact on the visibility and comparability of skills and qualifications (e.g. validation/recognition) and therefore on the opportunities for individuals to use the acquired skills in the labour market (either in the home country or abroad).

– *Level of progress on early childhood education and care*

⁴⁰³ <https://ec.europa.eu/eurostat/web/education-and-training/policy-context>: on Basic skills, Digital skills, early childhood education and care, early leavers from education and training, tertiary educational attainment, vocational education, and adult learning.

⁴⁰⁴ See also https://ec.europa.eu/education/policies/school/key-competences-and-basic-skills_en

Early childhood education and care refers to teaching and focusing on young children as regards the care aspect and development of social skills in the period before starting compulsory primary education. EU guidance is available to monitor quality in the quality framework on ECEC⁴⁰⁵.

– *Tertiary education attainment*

A high level of tertiary education attainment is viewed as one of key ways to promote a well-developed society, fostering growth and innovation, despite the fact that there is some evidence of skills mismatches in terms of those with a tertiary education being employed on positions requiring lower qualifications.

– *Adult participation in lifelong learning*

To foster coherence of learning processes it is necessary to support lifelong learning as a continuum of human development. Furthermore, higher levels of participation in lifelong learning impacts positively on work performance.

– *Teachers and educators*

Quality of teaching is essentially influenced by preparedness of teachers and the attractiveness of the teaching profession. Here, important areas are improving entry routes to, and the quality and relevance of, initial teacher training; ensuring attractiveness of the teaching profession and diverse career pathways; improving teachers' access to high-quality continuing professional development and empowering teachers to practice innovative and inclusive teaching.

– *Early school leavers statistics*

High levels of early school leavers adversely affect the transition from school to work, with unemployment levels among early leavers being considerably higher than average.

– *Inclusiveness of education*

To foster equality among students and to facilitate access and accessibility to education and training for every individual, it is necessary that the different policy measures, relevant for education, all foster social inclusion. It is important to consider how individualised support, scholarships and contributions are provided for particular groups of students and how services are provided for students with disadvantaged background and students living in the areas that face disadvantages in terms of accessing quality education, flexible educational pathways, recognition of prior learning and short learning options. Different aspects like gender equality, migrant, or minority ethnic or racial background, disability, should be considered. The provision of scholarships and access for citizens from developing countries to education and training in the EU, in particular European universities can create positive impact on sustainable growth in third countries.

Data on students' social situation is provided by the Erasmus+ funded Eurostudent survey. Eurostat collects data on gender aspects.

– *Statistics on recent graduates' participation in the labour market*

Better transition of young adults into labour market may be facilitated in several different ways, including by provision of high-quality traineeships, apprenticeships and dual

⁴⁰⁵ https://ec.europa.eu/education/policies/early-childhood-education-and-care_en

vocational education and training systems. Activating learning environment, work-based learning, and cooperation of education institutions with the local community and with employers may all foster labour market transition.

Data may be found in graduate tracking surveys⁴⁰⁶, and in European data collections like the Labour Force Survey.

3.2. Culture

When carrying out an assessment of impacts on culture, and in accordance with the list above, the following aspects should be considered:

– *Cultural diversity*

EU initiatives which may result in reducing consumer choice in cultural goods can, for example, have an impact on cultural diversity, e.g. merger between large music and internet companies or of large audio-visual companies could reduce consumer choice in music or film.

– *Cultural heritage*

Cultural heritage is both tangible (buildings, sites etc.) and intangible (traditions, music etc.), and it includes landscapes. It may, for example, be affected by EU initiatives on environmental protection or energy efficiency (impact on historical buildings). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

– *Participation in culture*

Economic policies can affect cultural activities. As an example, new EU initiative on VAT or on crowdfunding can have an impact on the way cultural sector is funded by public or private means; broadband availability affects access to culture (e.g. online collections/event tickets); or reduced funds for cultural events/sites raises prices, or causes closure⁴⁰⁷. Including cultural actors from third countries and facilitating global cultural exchange can have positive impact on the diversity of artistic expressions.

– *Cultural dimension of sustainable development*

The implementation of the [2030 Agenda on sustainable development](#) and the achievement of the SDGs directly concern the culture sector (impact on cultural activities and cultural offers) and cultural policies and actions contribute in many ways to achieving the SDGs (most of the 17 SDGs).

3.3. Youth

Young people⁴⁰⁸ are particularly prone to certain measures, which might affect their transition from dependent childhood to adulthood in terms of social and economic integration, social inclusion, well-being, and labour market. Impacts on employment, social conditions and education of this group can often be of higher magnitude compared to other

⁴⁰⁶ <https://op.europa.eu/en/publication-detail/-/publication/c5669b4b-6adb-11eb-aeb5-01aa75ed71a1>

⁴⁰⁷ [Eurobarometer on Cultural access and participation](#)

⁴⁰⁸ Definitions of young people vary; the EU Youth Strategy does not operate with an official definition for the specific period in life when a person is considered to be ‘young’. This definition varies from one Member State to another and the age to consider differs with time and socio-economic development. Age range 15-29 is often selected for statistical purposes at EU level.

cohorts thus this aspect should be considered when measuring such impacts. For a specific example on assessment of impacts, see Box 3.

Young people’s attitudes and actions regarding democratic engagement and expressing their views tend to differ from other generations. Measures can have an impact on young people’s ability and interest to participate in social/civic activities, such as volunteering, or to get involved in decision-making that directly affects them. In case young people’s views are sought, a targeted and focused consultation through established youth channels could be undertaken.

As a part of the everyday life of the majority of European youth, formal education and training, non-formal learning (courses outside school, etc.) or informal learning by engaging in meaningful activities (e.g. solidarity activities, voluntary work) play an important role in development of young adults. Thus, for those policy options which affect aspects of educational activities, it will be necessary to estimate the impacts of these effects on youth development. For detailed list of corresponding impacts on education and training, please see above.

Box 3. Example of cost-benefit assessment in the Youth Guarantee approach

- The [Youth Guarantee](#) approach is tackling youth unemployment with assuring that all young people under 30 get a good quality and concrete offer (e.g. job, apprenticeship, traineeship) within 4 months from either leaving formal education or becoming unemployed⁴⁰⁹.
- See [The European Pillar of Social Rights Action Plan \(europa.eu\)](#)
- In the [study](#), a cost-benefit analysis is included with estimates on what are current costs of leaving young people not in employment, education or training and what would the costs of implementation of the Youth Guarantee.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

The basic data and information sources that can help in assessing the policy impacts in areas of education, culture, and youth (ECY) are outlined below. Background materials and guidance can be found on internal [DG EAC web pages](#) or via the EU Youth Coordinator (EU-YOUTH-COORDINATOR@ec.europa.eu).

4.1. Education and training

The core quantitative information and data required are described and further annually assessed in the [European Education and Training Monitor](#). This annual report illustrates, in a succinct document, the evolution of education and training systems across Europe. It considers the European Education area targets and indicators, as well as recent studies and policy developments.

⁴⁰⁹ As part of the new headline target on employment, the social pillar action plan sets the following target: ‘decrease the rate of young people neither in employment, nor in education or training (NEETs) aged 15-29 from 12.6% (2019) to 9%, namely by improving their employment prospects.’ See [The European Pillar of Social Rights Action Plan \(europa.eu\)](#)

Additional useful sources of information include:

- **Eurostat** – data on participation rates, staff, financing, investment, training, ICT related to education, educational attainment, exposure to work-based learning, participation in adult learning, continuing vocational training, etc. ([UNESCO OECD Eurostat \(UOE\) joint data collection](#), [Labour Force Survey](#), [Adult Education Survey](#), [Continuing Vocational Training Survey](#)); the indicators to monitor the **Sustainable Development Goals**, more specifically (but not exclusively) the indicators to measure SDG 4 (Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all)⁴¹⁰.
- **DG EAC - Erasmus+** – data on mobile vocational education and training learners;
- **OECD** – information on teachers and their professional development (TALIS), annual study on students' performance (PISA), assessment of adults' skills (PIAAC);
- **EURYDICE** – data and analyses of the European education landscape, national descriptions, comparative thematic analyses, evidence-based reviews on specific issues, quantitative indicators and secondary analyses, trends and reforms;
- **CEDEFOP** European Centre for the Development of Vocational Training (EU decentralised agency) – indicators and annual studies on vocational education and training, thematic secondary comparative analyses and skills forecasts;
- **CRELL** (JRC) - [Centre for Research on Education and Lifelong Learning](#) – secondary comparative analyses on education and lifelong learning using the results from large scale surveys, conceptual work on the definition of indicators and prospective analyses;
- [JRC Human capital and employment](#) – develop scientific evidence to support policy making in the areas of learning and education; quantitative and qualitative methods, socio-economic impact assessment, behavioural insights and data analytics;
- **EENEE** – analysis and reports by network of experts in the field of economy of education and training;
- **NESET** – analysis and reports by network of experts in the field of equity in education and training.
- Other interesting sources of information are the UNESCO Global Education Monitor (GEM) Report, EASNIE (European Agency for Special Needs and Inclusive Education) as regards learners with disabilities, ETF (European Training Foundation).

4.2. Culture

- Cultural diversity: [2005 UNESCO convention on the protection and promotion of the diversity of cultural expressions](#);
- Participation in culture: [2013 Eurobarometer on cultural access and participation](#); Household expenditure surveys;
- Public policy in the area of culture, including funding: [2013 EENC report on trends in public funding for culture](#);

⁴¹⁰ [SDG 4 - Quality education - Statistics Explained \(europa.eu\)](#)

4.3. Youth

- The EU Youth Strategy provides common objectives and a detailed work plan for Commission and Member states in the field of youth. It also includes the eleven European youth goals that have been designed by young people in one of the latest cycles of the EU Youth Dialogue. These goals identify cross-sectoral areas that affect young people's lives and point out challenges, and the Council has agreed that the EU Youth Strategy should contribute to realising this vision of young people.
- The EU Dashboard of Youth Indicators provides some 41 indicators across different sectors that provide a comprehensive picture to illustrate the situation of young people. It is being updated in 2020 with the help of an expert group, which is also developing policy indicators. The core data on young people can be accessed via Eurostat youth dataset. The Youth Guarantee contains an indicator framework on youth employment⁴¹¹.
- The Youth Wiki is an online encyclopaedia in the area of national youth policies in Europe. The platform is a comprehensive database of national structures, policies and actions supporting young people.
- EU Youth Reports every three years describe relevant policy measures taken in support of young people and an analytical overview of the situation of young people, at EU level and in Member States⁴¹².
- Additional sources of information include reports from Expert groups set up by the Council of Youth Ministers on the contribution of non-formal learning and youth work to youth development:
 - [Expert group on the contribution of youth work in the context of migration and refugee matters](#)
 - [Expert group on the contribution of youth work to preventing marginalisation and violent radicalisation](#)
 - [Expert group on developing digital youth work](#)
 - [Expert group on the 'contribution of youth work and non-formal and informal learning to address the challenges young people are facing, in particular the transition from education to employment'](#)
- The study on the value of youth work depicts the contribution of youth work in different fields of action relevant to young people.
- Flash Eurobarometer surveys regularly address the opinions and engagement of young people:
 - 478 “How we build a stronger more united Europe: the views of young people” (2019);
 - 455 “European Youth” (2017);
 - 395 “Youth in Europe” (2014);

⁴¹¹ <https://ec.europa.eu/social/main.jsp?catId=1143&langId=en#YGIF>

⁴¹² https://europa.eu/youth/strategy/library_en

- 375 “European Youth: Participation in Democratic Life” (2013);
- 319 “Youth on the Move” (2011).

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Early leavers from education and training • Tertiary educational attainment • Participation in early childhood education • Underachievement in reading, maths and science • Employment rate of recent graduates • Adult participation in learning • Young people neither in employment nor in education and training • People at risk of income poverty after social transfers <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Proportion of children and young people (a) in grades 2/3; (b) at the end of primary; and (c) at the end of lower secondary achieving at least a minimum proficiency level in (i) reading and (ii) mathematics, by sex • Proportion of children under 5 years of age who are developmentally on track in health, learning and psychosocial well-being, by sex • Participation rate in organized learning (one year before the official primary entry age), by sex • Participation rate of youth and adults in formal and non-formal education and training in the previous 12 months, by sex • Proportion of youth and adults with information and communications technology (ICT) skills, by type of skill • Parity indices (female/male, rural/urban, bottom/top wealth quintile and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated • Proportion of population in a given age group achieving at least a fixed level of proficiency in functional (a) literacy and (b) numeracy skills, by sex • Extent to which (i) global citizenship education and (ii) education for sustainable development, including gender equality and human rights, are mainstreamed at all levels in (a) national education policies; (b) curricula; (c) teacher education; and (d) student assessment • Proportion of schools with access to (a) electricity; (b) the Internet for pedagogical purposes; (c) computers for pedagogical purposes; (d) adapted infrastructure and materials for students with disabilities; (e) basic drinking water; (f) single-sex basic sanitation facilities; and (g) basic handwashing facilities (as per the WASH indicator definitions) • Volume of official development assistance flows for scholarships by sector and type of study • Proportion of teachers in: (a) pre-primary; (b) primary; (c) lower secondary; and (d) upper secondary education who have received at least the minimum organized teacher training (e.g. pedagogical training) pre-service or in-service required for teaching at the relevant level in a given country • Proportion of youth (aged 15–24 years) not in education, employment or training NEET • Proportion of people living below 50 per cent of median income, by sex, age and persons with disabilities • Total expenditure (public and private) per capita spent on the preservation, protection and 	     

Relevant SDG indicators	SDGs
<p>conservation of all cultural and natural heritage, by type of heritage (cultural, natural, mixed and World Heritage Centre designation), level of government (national, regional and local/municipal), type of expenditure (operating expenditure/investment) and type of private funding (donations in kind, private non-profit sector and sponsorship)</p> <ul style="list-style-type: none"> • Proportions of positions in national and local institutions, including (a) the legislatures; (b) the public service; and (c) the judiciary, compared to national distributions, by sex, age, persons with disabilities and population groups • Proportion of population who believe decision-making is inclusive and responsive, by sex, age, disability and population group 	

TOOL #32. HEALTH IMPACTS

1. INTRODUCTION

Human health is a fundamental value and an investment in economic growth and social cohesion. Improving people’s health is improving their quality of life. Healthy people are less likely to be socially excluded and much more easily employable. A healthy workforce costs less and is more productive, and reduces the burden on healthcare services and health systems. Resilient and efficient health systems contribute to the optimisation of health spending, public and private. Healthcare services and health industries (pharmaceuticals, medical devices, and health research) are a key knowledge-intensive economic sector that enables to maintain and improve public health and creates jobs. The Treaty (Article 168 TFEU) states that a “*high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*”, which also relates to the approximation of laws in the single market (Article 114 (3) TFEU). Furthermore, the Charter of Fundamental Rights (art. 35) establishes that “everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.”

This tool is focussing on human health. When you need to consider impacts on animal welfare you can contact SANTE-CONSULT-G5@ec.europa.eu for advice.

2. TYPES OF HEALTH IMPACTS AND THEIR SIGNIFICANCE

Many EU policies have the potential to result in health impacts. Such impacts must be assessed during the policymaking process.

Health impacts are gains or losses that need to be identified⁴¹³ early in the policy making process. Health gains are always intended for policies with health as an objective (i.e. health and food safety, occupational health and safety) while losses are often unintended and might be the result of initiatives where health is not an objective or where the intervention needs to strike a balance between conflicting or different interests (e.g. transport, trade etc.). Unintended health impacts may not always be anticipated in an impact assessment but should be analysed in an evaluation.

Health gains consist mostly in the improvement of the health status of individuals or populations⁴¹⁴, or in the improvement of national health systems’ performance and sustainability (including their resilience during health crises).

Health losses may be generated by a policy initiative for some groups of people (e.g. limited access to healthcare for elderly people in case of digitalisation of services, difficulty in access to cross-border care by telemedicine in case of limited reimbursement policies). Health losses are generally unintended or the result of a trade-off in the policy design.

Health gains and losses can be direct or indirect. A policy initiative can generate direct health gains such as increased life expectancy or reduction of prevalence/incidence of a disease in specific or wider population groups. For example, the [Asbestos at Work Directive](#) or the [Tobacco Products Directive](#). The first protects workers from the risks related to asbestos exposure at work that may cause serious diseases while the second governs the

⁴¹³ Tool #18 (*Identification of impacts*)

⁴¹⁴ Other examples: health/quality of life, reduction of prevalence/incidence of disease, improved life expectancy, decrease of mortality and morbidity, etc.

manufacture, display, and sale of tobacco and related products protecting consumers across the EU from tobacco use which is a leading health risk factor. An indirect health gain is, for example, a decrease in morbidity and mortality generated by the modification of the socio-economic⁴¹⁵ and environmental determinants of health. Typically, reducing energy poverty in underheated dwellings could reduce mortality amongst people from vulnerable groups during winter, improvements in road safety reduce the number of accidents and the number of people injured in road accidents. Improving air quality can affect our health with both long- and short-term effects, given that reducing urban outdoor air pollution decreases the risk of acute (e.g. pneumonia) and chronic (e.g. lung cancer) respiratory disease as well as cardiovascular disease.

Direct health losses to people such as loss of work capacity/increase in disability may be generated by policies not ensuring a sufficient level of health protection, while indirect health losses may be generated by policies such as subsidising the cultivation of tobacco or governing the use of nanomaterials in products (due to existing risks and emerging hazards). Losses to health systems may be determined directly or indirectly by several policies not primarily addressed at the healthcare systems, which nonetheless influence the rules that relate to the provision and quality of healthcare services by impacting on their staff, equipment, communication, and infrastructure. For example, policy on the protection of personal data which may prohibit under certain conditions the processing of specific categories of data in some instances.

For all identified potential health impacts it should be examined if **specific population groups** (for instance risk groups such as children, persons with disabilities, pregnant women, older people, LGBTIQ people, people with a minority ethnic or racial background, low-income groups) or specific geographical areas are affected differently and disproportionately by the intervention, resulting in increased (or reduced) inequalities in health status⁴¹⁶.

The significance of health impacts depends on the policy initiative, and it is a case-by-case assessment made at an early stage of the design of an intervention taking into account all relevant factors⁴¹⁷. In any case, the outcomes of the stakeholder consultation should contribute to the identification of significant impacts. The specific expertise of health stakeholders may prove valuable in identifying and properly assessing those impacts.

3. HOW TO APPROACH THE ASSESSMENT OF HEALTH IMPACTS?

When designing EU initiatives, potential health impacts should be identified together with other potential socio-economic impacts. Before establishing whether those impacts are significant or not, the *health relevance* of the initiative as well as its interplay with health policies should be assessed. The *appraisal* of those impacts should allow for preparatory work in view of the selection of significant impacts and contribute to such selection, especially where the health relevance is uncertain, thus complementing the model in Tool #18 (*Identification of impacts*).

The depth of the analysis should be proportionate and consistent with the importance/type of initiative and the nature and magnitude of the expected impacts (e.g. legislative/non-legislative, REFIT initiative, implementing measures, etc.). This relates not only to the

⁴¹⁵ [2010 World Health Organization: A conceptual framework for action on the social determinants of health Discussion Paper Series on Social Determinants of Health, no.2 ISBN: 978 92 4 150085 2](#)

⁴¹⁶ Linked to this analysis is also the dimension of discrimination (e.g. in the access to healthcare) on grounds of e.g. racial, ethnic or social, religion, or belief, disability, age or sexual orientation.

⁴¹⁷ See the Tool #18 (Identification of impacts)

impact assessment process⁴¹⁸ but is also relevant during ex-post evaluations, irrespective of whether health impacts had been identified when the initiatives was adopted.

3.1. Establish the health relevance of a policy initiative

To decide if it is relevant or not to assess health impacts, it is to be considered:

- (a) how the initiative will impact (or has impacted) **health factors⁴¹⁹ and/or factors influencing the health systems capacity to deliver** and remain sustainable;
- (b) **how** these health factors or influencing factors, in turn, will **affect or have affected people's health and/or the performance of health systems.**

To accomplish this step evidence and knowledge on health determinants, their distribution in the population and relationship with health impacts, as well as health systems factors is required. The following checklist may facilitate the screening.

Box 1. Questions to help establish the health relevance of an initiative

1. ***Does the policy affect the Union's health objectives, as codified in the Treaty (Article 168 TFEU) and in relevant secondary legislation*** (e.g. on [cross-border health threats](#), [cross-border health care](#), [tobacco control](#), [pharmaceuticals](#) and [medical devices](#), or [substances of human origin](#))?

Major policies and initiatives with cross-sectoral impact (e.g.: agricultural, social, education, marketing/TV/digital/social media, taxation, or regional development) should, by default, be checked for their health impact.

2. ***Does the policy otherwise affect factors influencing people's health or the performance of health systems?***

The analysis should be directed at identifying the possible effects of the initiative on [health determinants](#) such as alcohol, tobacco, physical activity, nutrition (e.g. alcohol consumption is influenced by taxation or advertising/information placed on the label), on important health factors (e.g. air pollution or chemicals), or on the performance of health systems (e.g. new waste disposal rules in hospitals, university curricula for healthcare workers). [Social determinants of health⁴²⁰](#), namely poverty, and [commercial determinants of health⁴²¹](#) need also to be taken into consideration.

3. ***Does the policy affect the population as a whole or some population groups?***

The whole population; women; men; children; adults; older people; chronically ill; people with special needs people (e.g. physical or mental impairment, allergy; people with an addiction); unemployed; immigrants; refugees; single-parents; people with low income; homeless people; LGBTIQ; people with a minority ethnic or racial background; other groups.

⁴¹⁸ See Tool #12 (*How to apply proportionality to impact assessments*)

⁴¹⁹ European Health Indicators https://ec.europa.eu/health/social_determinants/indicators_en

⁴²⁰ Income and social protection; education; unemployment and job insecurity; working life conditions; food insecurity; housing, basic amenities, and the environment; early childhood development; social inclusion and non-discrimination; structural conflict; access to affordable health services of decent quality. https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1

⁴²¹ <https://www.who.int/bulletin/volumes/97/4/18-220087/en/> or [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(16\)30217-0/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(16)30217-0/fulltext)

3.2. Selection of significant impacts

Once the potential health relevance of the initiative is established, **significant impacts should be selected**. A series of questions (*Box 2*) might facilitate this work, which should **establish the relevance of the health impacts within the intervention logic, the absolute expected magnitude of those impacts, their relative size for specific stakeholders, their importance for the Union's objectives and policies**.

Box 2. Questions to help identify significant health-related gains and losses

Direct health impacts

- a) Does the option/initiative directly affect the health and safety of individuals/populations, including life expectancy, mortality, and morbidity?
- b) Does the option/initiative increase or decrease the likelihood of health risks due to substances or living organisms harmful to the natural environment?
- c) Does the option/initiative affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs?
- d) Are there specific effects on particular risk groups of people (determined by age, gender, disability, social group, mobility, region, etc.)?
- e) Does the option/initiative affect the quality and/or access to health services and/or the financing and organisation of health systems?
- f) Does the option/initiative affect the cross-border provision of services, referrals across-borders and cooperation in border regions?
- g) Does the option/initiative reduce health risks to people/patients (or create new ones) or does it affect their safety? For instance, by addressing the exposure to chemical substances (e.g. chemicals, pesticides in food, contaminants, etc.) or other factors (e.g. radiation, noise etc.) bearing an influence on the natural environment and the human body (e.g. air, soil and water quality, noise, unsafe consumer products).
- h) Does the option/initiative affect the effectiveness and sustainability of healthcare and long-term care services?
- i) Does the option/initiative affect the access of certain populations (including vulnerable ones) to medicinal products and information, health, or long-term care services, in particular by altering their availability, quality, affordability and cost?

Indirect health impacts

- a) Does the option affect the socio-economic and environmental health determinants (working environment, income, education and training, occupation, housing, nutrition, energy consumption, transport, etc.)?
- b) Does the option affect or the policy initiative has affected the factors influencing health systems capacity to deliver efficiently and effectively and remain sustainable?
- c) Does it affect health due to changes in the amount of noise, air pollution, reduced water or soil quality?
- d) Will it affect health due to changes in energy use and/or waste disposal?
- e) Does the option indirectly target population's lifestyle-related determinants of health such as diet, physical activity, use of tobacco, alcohol, or drugs?

If the answer is YES for any of the above, for those answer also the sub-questions:

- a) To what extent?
- b) Which groups of individuals are affected? Single population groups with same characteristics/living in a specific area etc.?

- c) What is the group’s size?
- d) Are all social groups affected or only some of them?

The questions above should be asked in relation to the various steps of the intervention logic: consider all key steps in the intervention that need to take place to achieve the objectives of the policy and consider how each of the steps may affect health objectives. Consider absolute and relative size of impacts (some impacts may be small in absolute terms, but they may be particularly significant for some specific group).

3.3. Assessment of impacts on people’s health

If health impacts qualify as significant, they need to be assessed⁴²². The assessment of health impacts should always *start from the qualitative dimension*, the core of which should be the discussion about the causal links involved in the impacts identified (direct and indirect). Draw information from relevant studies (in particular, peer-reviewed literature and previous Commission studies, impact assessments and evaluations) on which the analysis is based. Other relevant elements are the identification of the populations most affected, the rough size of those populations and the extent to which they are affected, the interplay among potential impacts as well as possible mitigation measures.

If sufficient relevant and robust data is available, *these arguments should be supplemented by a quantitative dimension*. The quantification of impacts should proceed from the most objective and robust measures to those that are more speculative and involve more assumptions. Such quantified impacts may be of many sorts, may be measured in different units, and may not be directly comparable among themselves. Special care should be taken to spell out uncertainties and caveats, whether these concern the reliability of sources, the assumptions made to bridge gaps in the existing data and/or analysis, or the passage from hard data to statistics and probabilities. Where quantifications are uncertain, they should be accompanied by a sensitivity analysis to make clear the range of possible values and to which parameters the analysis is most sensitive.

If proportionate, *quantification in terms of concrete outputs* (for example, not only direct indicators such as interventions performed or deaths avoided, but also indirect indicators such as absences from work, air pollution levels, etc.) *can be complemented by the monetisation of the health outcomes associated with them*. Several methodologies that can be used for this are reviewed below in section 3.

Monetisation needs to build on the causal analysis provided in the qualitative assessment and the primary data provided in the first step of quantification, but cannot be a substitute for them. Where appropriate, monetisation can be used to evaluate and compare different health outcomes (though even this may raise ethical issues, for example, if comparing outcomes which do not affect all population segments uniformly). Any monetisation of health outcomes should be *presented with all appropriate caveats* and should be seen above all as a way of illustrating the scale of a problem, or for differentiating between policy options, and not as in itself the principal basis for a final policy decision.

The **identification of the most appropriate methodology or mix of methodologies** to use will depend on the characteristics or nature of the options under assessment⁴²³. The

⁴²² See Tool #18 (Identification of impacts) and Tool #12 (How to apply proportionality to impact assessments)

⁴²³ For an example of choice of indicators, please see: “[Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task](#)”

availability of data and information, their granularity and the costs and time needed for gathering such data and information will influence the approach taken. Quantification of health impacts should only be used where proportionate. To assess impacts on health, it is in any case necessary to have at least a general knowledge of health policies and health systems and to identify the populations and the timeframe concerned. Health systems are defined as those systems that aim to deliver healthcare services to patients – be they preventive, diagnostic, curative, and palliative – whose primary purpose to improve health⁴²⁴.

DG SANTE can assist in identifying appropriate health policy stakeholders at EU level, who would be able to help determining or evaluating a possible impact on health. For health impacts related to environmental impacts, DG Environment can assist in identifying appropriate stakeholders at EU level.

3.4. Assessing the impacts of health risk management measures

In some instances, in line with the Treaty, the legislator has empowered the Commission to act as a risk manager and adopt measures or actions with the aim to eliminate, reduce or avoid a risk to health, **based on a sound assessment of the risk in question**⁴²⁵. The powers thus granted are subject to specific processes and conditions, which define the discretionary margin of the Commission acting as risk manager, including where it is recognised that risk assessment alone cannot provide all the information on which a risk management decision should be based and other factors relevant to the matter under consideration should be considered.

In such cases the most important limitation of the Commission decision-making powers is represented by the objective of the risk management measures or actions (i.e. ensuring a high level of health protection), which frames and therefore may limit the discretionary power of the Commission.

In the light of the nature of those objectives, health considerations are necessarily considered first and shape the design of the content of those measures or actions. The margin of discretion of the Commission in such cases is utilised to consider 'how' (not 'whether') to act in pursuit of the health objective mandated by the legislator.

In specific cases, the risk management measures on health-related matters may be subject to an impact assessment (in line with 'better regulation' requirements, see Tool #14 (*Risk assessment and management*)) to support the decision to be made on how to pursue the health objective. This should happen when 1) the context allows sufficient room for manoeuvre for the Commission and different viable options are available to manage the identified risk, 2) those options are expected to have significant impacts that impact stakeholders to different extent and 3) there is no urgency.

Should an impact assessment be required on the basis of the above considerations, it should always be proportionate to the need of comparing different ways of achieving the mandated health objective and consider the timely adoption of the risk management decision to minimise health risks.

⁴²⁴ Commission Communication, [On effective, accessible and resilient health systems](#), COM(2014) 215 final

⁴²⁵ See Tool #14 (Risk assessment and management)

3.5. Approaches and methods to assess health impacts

Choosing the right methodology for assessing health impacts depends on the policy context and on the nature of the policy initiative at hand. First, it is recommended to check how the same or similar potential health impacts have already been dealt with [in existing Commission impact assessments](#)⁴²⁶, at Member State level or by third parties more generally⁴²⁷. The evaluation of health impacts in a retrospective evaluation should take the assessment in the impact assessment as a starting point.

Qualitative methods provide an insight into how an intervention or a policy option leads to a health impact and which factors influence this impact. Quantitative methods provide information on the extent of a health impact, for example, based on dose response functions. This means quantifying the health benefits such as healthy life years gained, the monetary estimates of social wellbeing and costs to the health system.

Qualitative approach

Qualitative analysis allows for demonstrating causality. In both an impact assessment and an evaluation, *the starting point for the assessment is the intervention logic* which describes how and why a desired change is expected to happen, i.e. a theory of change. This *theory needs to be tested and evaluated* to see if it fits the data available and that assumed causal links are correct. This will involve both looking for evidence which could prove or disprove the causes that have been hypothesised and exploring evidence which might point to other possible causes that lie outside the theory of change from which the assessment departs. Several methods have been developed which can help make such qualitative analysis⁴²⁸ highly rigorous, even if alternative hypotheses can rarely be tested at scale in the real world.

Only once we have good reason to believe that the assumed outcome is (or will be) a result of the intervention, and did not arise independently of, or even despite, the actions taken, should we continue to put a figure (or a price) on an outcome. The more removed the expected impact is from the actions taken in steps necessary to reach it, the more important it is to establish a high level of confidence in the causal relationships being asserted. This is especially true in the case of health impacts at population level, where both causes are often multi-factorial, and subject to non-linear, systemic effects.

Just as real-world *causality is complex, so the process of testing and refining the intervention logic will most often be an iterative one*. This may include an initial survey of already-available quantitative data to see if it seems, *prima facie*, compatible with the linkages proposed, or would rather suggest the presence (or even dominance) of other factors that have not yet been considered.

Quantitative approach

A quantitative approach can establish the scale of an impact and enable comparisons between different options in an impact assessment. It also allows assessing the extent to which health objectives have been achieved in a retrospective evaluation.

⁴²⁶ For example: [Protection of workers from the risks related to exposure to carcinogens or mutagens at work](#); [Stepping up Europe’s 2030 climate ambition Investing in a climate-neutral future for the benefit of our people](#); [Trans-fat, other than trans-fat naturally occurring in fat of animal origin](#); [Clean Air](#);

⁴²⁷ See for instance the “Public health England” website that provides a gateway to Health Impact Assessments (www.apho.org.uk/default.aspx?RID=44539)

⁴²⁸ The Magenta Book: <https://www.gov.uk/government/publications/the-magenta-book>

Monetary and non-monetary quantitative methods can be used to assess direct and indirect health impacts⁴²⁹. The non-monetary methodologies quantify the health benefits of a given intervention without monetising it; to compare different interventions for the same specific health problem using cost and health outcomes (cost-effectiveness analysis) or in cases in which it is needed to compare different interventions for different health problems (cost-utility analysis)⁴³⁰. The monetary methodologies can present a comparison of costs and benefits, although such analysis may not always prove to be possible or the most appropriate when evaluating options affecting human health.

There are areas in which quantification is particularly complex or where it is inherently difficult to predict with accuracy the potential costs/benefits of a policy option (e.g.: regarding introduction of new products, services, or technologies). In this case, quantitative assessments may be presented as ranges to consider the possible margin of error or uncertainty associated with forecast costs and benefits.

Non-monetary quantitative methods

Health gains for people are measured for example with the following methods: *Quality Adjusted Life Years* (QALY)⁴³¹ and *Healthy Life Years* (HLY)⁴³².

Health losses are measured amongst other by: *Disability Adjusted Life Years* (DALY)⁴³³ and *Years of potential life lost* (YPLL)⁴³⁴.

The benefits of health technologies are relevant in terms of health impacts for both individuals and health systems. The European Network for Health Technology Assessment (EUnetHTA) elaborates methodological guidelines for health economic evaluations (including a reflection on discounting)⁴³⁵. Discount rates used for QALYs / YPLL tend to differ (also per jurisdiction). Therefore, cost-effectiveness findings are sensitive to changes in the discount rates⁴³⁶. The latter observation also has implications in terms of generational equity impacts (higher discount rates will for instance imply a lower value attributed to preventative care).

Monetary quantitative methods

Among others, two types of methods could be used, the preference-based, and accounting-style ones, however their use can raise ethical concerns and criticism. It should be clear that they cannot – and do not seek to – place a monetary value on life.

⁴²⁹ 2016 Milan Ščasný and Vojtěch Máca Monetary and Non-Monetary Measures of Health Benefits from Exposure Reduction https://link.springer.com/chapter/10.1007%2F978-3-319-43142-0_7/

⁴³⁰ <https://yhec.co.uk/glossary/cost-utility-analysis/>

⁴³¹ *Quality Adjusted Life Years* (QALY) using available information on objective improvements in health/quality of life (QoL) and combines it with the duration of that improvement. QALY is commonly used in economic evaluations of specific health interventions (e.g. medicines development). For an example of the use of QALY, see [sec\(2008\) 2163](#) and [sec\(2008\) 2956](#).

⁴³² *Healthy Life Years* (HLY) indicates (gain?) the number of years a person of a certain age can expect to live without disability. In 2012, HLY at birth in the EU was at 61.3 years for males and 61.9 years for females.

⁴³³ Disability Adjusted Life Years (DALY) measures. Originally a measure of the burden of disease, DALY is the number of quality adjusted years lost because of illness/disability in comparison to the benchmark scenario (in general good health status without disability). It is also used to estimate the cost-effectiveness of interventions in terms of cost per DALY.

⁴³⁴ https://ec.europa.eu/eurostat/statistics-explained/index.php/Preventable_and_treatable_mortality_statistics

⁴³⁵ https://eunetha.eu/wp-content/uploads/2020/03/EUnetHTA-JA3WP6B2-5-Guidance-Critical-Assessment-EE_v1-0.pdf

⁴³⁶ E.g. UK discount rate (<https://yhec.co.uk/glossary/discount-rate/>)

The aim of the preference-based methods is to compare the benefits of different policy options by placing an implicit monetary value on health benefits as is, for example, often done in the transport sector to inform decision on safety measures. These methods analyse individuals' stated or revealed preferences with respect to small changes in low-probability risks. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to saving time.

The *preference-based methods* measure the individuals (or populations) willingness-to-pay (WTP) and/or willingness-to-accept (WTA) compensation for a preferred policy choice of the intervention logic or for a worsening of certain conditions, respectively⁴³⁷. The preference for health gains is measured for example with methods such as: the *Value of Statistical Life* (VOSL)⁴³⁸ and the *Value of Statistical Life Year* (VOLY). The European Chemicals Agency (ECHA) has developed reference WTP values for the monetisation of health endpoints by Member States (when preparing 'restrictions' on the use of chemicals)⁴³⁹.

- The Value of Statistical Life (VOSL) is derived by investigating individuals' WTP for a lower risk of mortality, divided by that risk reduction. The OECD has undertaken both a literature review and primary analysis to better understand the right values to use in policymaking. It proposed a range for the average adult VOSL for the EU of USD 1.8 million – 5.4 million (2005-USD), with a base value of USD 3.6 million. These base values and ranges are currently being updated as new VOSL primary studies are conducted (contact DG Environment for details)
- The Value of Statistical Life Year (VOLY) measures more generally the WTP for an increase of one additional year of life expectancy⁴⁴⁰.

The *accounting style methods* measure only certain aspects of health impacts on individuals and health systems and should be therefore treated with extreme caution. Such methods are *Cost of Illness (COI)*⁴⁴¹. The Cost of Illness method comprises only the medical expenses related to the incidence of an illness. If an option lowers the rate of occurrence of an illness the saved medical expenses constitute a benefit. Conversely, if an option leads to an aggravation of a health situation, one can state the associated relevant costs. However, the

⁴³⁷ See Tool #57 on (Methods to estimate costs and benefits)

⁴³⁸ The VOSL measures a *gain* and is derived by investigating individuals' *WTP for a lower risk of mortality*, divided by that risk reduction. As such, the VOSL method does not measure the value of a life *per se*, instead it puts a monetary value on the willingness to accept slightly higher or lower levels of risk. For more in-depth analysis of the Value of a Statistical Life, including a discussion of VOLY, see: http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01. For an example of use of VOLY and VSL in a recent cost-benefit analysis on air quality effects on health, see: http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP_CBA_corresponding_to_IIASA11_v2.pdf

⁴³⁹ https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

⁴⁴⁰ The VOLY measures more generally the WTP for an increase of one additional year of life expectancy. However, as the VOLY is deemed constant across lifetime, assessments using VOLY and VOSL can produce conflicting results according to the demographics of the population considered. http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmenthealthandtransportpolicies.htm#Executive_Summary

⁴⁴¹ Cost of illness (COI) is defined as the value of the resources that are expended or forgone as a result of a health problem. It includes health sector costs (direct costs), the value of decreased or lost productivity by the patient (indirect costs), and the cost of pain and suffering (intangible costs).

usefulness of this method is limited as it often does not include other indirect costs to society such as loss of hours worked, or how people value their own health.

In all circumstances, it is advisable to mention both the quantitative and monetary estimates. For example, the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

In any case, the monetary results (costs and benefits) should be discounted, and sensitivity analysis should be performed to see how changes in the parameters affect the results.

4. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Healthy life years at birth • Share of people with good or very good perceived health • Smoking prevalence • Death rate due to chronic diseases • Standardised preventable and treatable mortality (sdg_03_42) • Self-reported unmet need for medical care • Obesity rate • People killed in accidents at work • Population living in households considering that they suffer from noise • Road traffic deaths • Exposure to air pollution by particulate matter <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Mortality rate attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease • Suicide mortality rate • Coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for substance use disorders • Harmful use of alcohol, defined according to the national context as alcohol per capita consumption (aged 15 years and older) within a calendar year in litres of pure alcohol • Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population) • Proportion of population with large household expenditures on health as a share of total household expenditure or income • Mortality rate attributed to household and ambient air pollution • Mortality rate attributed to unsafe water, unsafe sanitation and lack of hygiene (exposure to unsafe Water, Sanitation and Hygiene for All (WASH) services) • Mortality rate attributed to unintentional poisoning • International Health Regulations (IHR) capacity and health emergency preparedness • Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law 	  

TOOL #33. CONSUMERS

1. INTRODUCTION

Many EU policies directly affect EU citizens in their everyday life as consumers. It is obviously the case each time a policy concerns retail markets of goods and services. Other policies affecting supply chains or mobility also have an impact on consumers, and therefore a holistic view of the consequences for consumers is essential in deciding on the best societal choices while ensuring a high level of consumer protection, as required by Article 38 of the Charter of Fundamental Rights.

Box 1. Legal basis

The Treaty establishes that “*consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities*” (TFEU, Article 12), and that “... *the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.*” (TFEU, Article 169)

In addition to the Treaty-based legal provisions (see Box 1), in line with the Commission’s political priorities⁴⁴², relevant initiatives should aim at empowering consumers in the green and digital transitions. A New European Consumer Agenda⁴⁴³ adopted in November 2020 elaborates how these priorities will unfold across the different policy areas and on how to increase consumer protection and resilience during and after the Covid-19 pandemic.

Accounting for more than half of EU’s Gross Domestic Product, consumer spending is a powerful economic lever that will have to play its role in Europe’s recovery from the downturn caused by the pandemic. Positive impacts on consumers can be an important argument in support of new policy initiatives, especially to offset possible increases in costs for businesses.

While the section below mostly refers to ex-ante impact assessments, this tool can also be used to assess the impacts on consumers in the context of evaluating existing policy or legal instruments.

2. THE KEY QUESTIONS FOR ASSESSING CONSUMER IMPACTS

The EU common legal definition of ‘*consumer*’ means any ‘*natural person who is acting for purposes which are outside his trade, business, craft or profession*’.

In some situations, impacts on businesses might serve as a proxy for consumer impacts that are ultimately passed on to consumers. While in some circumstances **consumers** might best be thought of as individuals, in other cases **households** may be a more relevant unit to consider, including the potential role of children as particularly vulnerable consumers or as influencing purchasing decisions.

⁴⁴² https://ec.europa.eu/info/priorities_en

⁴⁴³ Commission Communication, [New Consumer Agenda - Strengthening consumer resilience for sustainable recovery](#), COM(2020) 696 final

A common understanding of **consumption** is a prerequisite for an adequate assessment of impacts on consumers. This term can relate to durable or non-durable products and services. The three phases of consumption are: **procurement** (purchase, inheritance, borrowing, exchange, etc.), **use** and **disposal**. The key aspect to consider is the relationship between a consumer and a professional supplier of a good or a service. This relation does not necessarily involve a payment in money. For example, online services provided ‘for free’ (but in exchange for personal data) also have an important consumer aspect.

When screening for potentially significant impacts on consumers, the following questions should be asked:

(1) *Would the policy option affect consumers’ ability to benefit from the four fundamental freedoms of the internal market?*

Attention should be paid to ensuring equal access to retail goods and services, the ability to move freely, access to various services at distance and the possibility to purchase cross-border financial products. Particular attention should be paid to any possible discrimination or other barriers based on nationality or place of residence (the non-discrimination principle⁴⁴⁴).

(2) *Would the policy option affect the prices, quality, availability, or choice of consumer goods and services?*

Increasing competition and decreasing costs for businesses will likely lead to lower consumer prices, more choice of goods and services and possibly also better quality (such as longer product lifetime).

(3) *Would the policy option affect consumer information, knowledge, trust, or protection?*

Policies reducing asymmetric access to information⁴⁴⁵ or excessive costs of accessing information may remedy a market failure, allow consumers to make better-informed decisions, reduce the scope for unfair practices by traders and generally increase consumer trust and protection. Similarly, knowledge of consumer rights, awareness of and trust in redress mechanisms are key to ensuring that consumers fully benefit from the legal protections available.

(4) *Would the policy option affect the safety of consumer goods and services?*

Consumer products sold in the EU are subject to high safety standards and consumers are entitled to expect that all the products they buy are safe. Market surveillance data from competent national authorities shows, however, that in certain cases (mostly imported) products reach the market before they are notified as unsafe and withdrawn, thus creating a safety risk to consumers.

(5) *Would the policy option contribute to more sustainable consumption patterns?*

More sustainable consumption is a key lever to achieving the EU’s sustainability goals. Policies affecting different segments of the consumption process – from the supply chain to

⁴⁴⁴ Directive of the European Parliament and of the Council on services in the internal market 2006/123/EC OJ L 376, 27.12.2006, p. 60, art. 20.

⁴⁴⁵ Extreme examples of asymmetric access to information are unfair commercial practices, such as providing misleading information via labelling, advertising or other means. They are prohibited by the Unfair Commercial Practices Directive 2005/29/EC.

distribution, to marketing and post-marketing, maintenance, repair, and recycling – can help promote more sustainable consumption patterns. For instance, logos, labels, and product claims on a product or in its advertising can all influence consumer choices in the marketplace; they can help consumers assess and compare products and guide them towards healthier, more sustainable, and responsible ways of consuming.

(6) *Would the policy option impact consumers in the digital environment?*

With digitalisation being a powerful trend, the Internet continues to show a lot of potential for giving consumers a stronger voice. At the same time, it creates challenges for the effective protection of consumer rights. As a rule, policies that improve the transparency of digital markets, ensure a fair treatment of consumers, reduce misleading marketing practices, online fraud and scams, and tend to have a positive impact on consumers.

(7) *Would the policy option impact vulnerable consumers?*

Consumer vulnerability means belonging to a socio-economic group likely to be less empowered or lacking full capacity to operate successfully in the marketplace as consumers⁴⁴⁶. Consumer vulnerability is a dynamic concept, and every consumer may become vulnerable in certain situations, e.g. due to changes in life situations or because of the complexity of goods, services or marketing practices that make it difficult to verify the validity of their choice⁴⁴⁷. Commercial practices that are likely to materially distort the economic behaviour only of a clearly identifiable group of consumers who are particularly vulnerable because of their mental or physical infirmity, age or credulity, in a way which the trader could reasonably be expected to envisage shall be assessed from the perspective of the average member of that group⁴⁴⁸.

3. HOW TO ASSESS IMPACTS ON CONSUMERS

A broad array of analytical methods, concepts and tools can be used in combination to answer the seven questions listed above. The key concepts for measuring consumer impact are: (i) consumer welfare, (ii) consumer detriment, (iii) consumer conditions, and (iv) consumer vulnerability.

3.1. Consumer welfare

Consumer welfare refers to the individual benefits derived from the consumption of goods and services. It is typically measured by calculating the consumer surplus, i.e. the difference between what a consumer is willing to pay for a good or service and what he/she actually has to pay. When summed across all consumers, consumer surplus is a measure of aggregate consumer welfare⁴⁴⁹. Distributional impact among different categories of consumers should also be considered.

⁴⁴⁶ This can be due to e.g. low income, low education, disabilities, diseases or specific behaviours such as credulity or addictive behaviour, developmental stages that may affect comprehension, reasoning and judgement (children, adolescents and the elderly).

⁴⁴⁷ E.g. because of a lack of technological expertise, time pressure, cognitive overload, lack of transparency of offers, lack of easily available, understandable and balanced information, or ignorance concerning the long term effects of product use.

⁴⁴⁸ Unfair Commercial Practices Directive 2005/29/EC OJ L 149, 11.6.2005, p. 27, art. 5(3).

⁴⁴⁹ In theory, individual welfare is defined by an individual's own assessment of their own satisfaction, given prices and income. Exact measurement of consumer welfare therefore requires information about individual preferences <http://stats.oecd.org/glossary/detail.asp?ID=3177>.

The EU Single Market, globalisation and digitalisation of markets allow consumers to benefit from a much wider choice of products. Market studies of the Consumers Directorate of DG JUST estimate these consumer welfare gains⁴⁵⁰.

Recent advances in behavioural economics have stressed the importance of factors such as the limits of consumer rationality and self-interest, incoherent preferences, limited ability to access, absorb and analyse information, etc. All of these affect how consumers make choices in the marketplace, which in turn impacts consumer welfare.

Behavioural studies⁴⁵¹ show how people make actual choices, based on rigorous observation of behaviour rather than assumptions. Policy design should consider well documented consumer biases, such as the ‘status quo bias’ (letting the default rule determine our decision), ‘myopia’ (choosing a small reward today over a larger one later) or ‘loss aversion’ (preference towards avoiding loss over acquiring gains). For more information on behavioural impacts, see Tool #69 (*Emerging methods and policy instruments*).

3.2. Consumer detriment

Consumer detriment is a measure of harm (whether financial, time loss, health, or quality of life, etc.) that consumers may experience when market outcomes fall short of their potential. Consumer detriment can be structural or personal (see Box 2). An operational method for measuring personal consumer detriment was developed and tested by the Consumers Directorate of DG JUST⁴⁵².

Box 2. Types of consumer detriment

- **Structural detriment** — the loss of consumer welfare (measured by consumer surplus as described above) due to market failure or regulatory failure, as compared to well-functioning markets. The reduction of structural consumer detriment is very relevant to look at in e.g. competition policies (such as antitrust policy) or internal market policies aimed at reducing barriers to cross-border trade.
- **Personal detriment** — the personal experience of those consumers for whom something goes wrong (rather than to all consumers on aggregate), benchmarked against reasonable expectations. This will generally be assessed through surveys inquiring on financial and non-financial detriment (e.g. time loss, psychological detriment). When consumers obtain redress from the retailer (e.g. a replacement product, refund or compensation) this may partly or wholly offset the detriment suffered.

⁴⁵⁰ E.g. the potential from increased e-commerce and a fully functioning internal market in *Consumer market study on the functioning of e-commerce and internet marketing and selling techniques in the retail of goods*.

⁴⁵¹ The behavioural studies with a consumer focus carried out in recent years are available at: https://ec.europa.eu/info/policies/consumers/consumer-protection/evidence-based-consumer-policy/behavioural-research_en

⁴⁵² See the 2017 *study on measuring consumer detriment in the EU* and the *operational guidance for measuring personal consumer detriment*.

3.3. Consumer conditions

Better consumer conditions contribute to maximising consumer welfare. The conceptual framework⁴⁵³ for measuring consumer conditions has been based on three main dimensions: (i) knowledge of rights and trust among market players⁴⁵⁴; (ii) traders' compliance with consumer legislation and its enforcement; and (iii) consumer complaints and resolution of disputes between consumers and retailers. These dimensions follow the logic of the three main stages of a transaction (before, during, and after) between a consumer and a retailer.

3.4. Consumer vulnerability

The Consumers Directorate of DG JUST developed an evidence-based definition of consumer vulnerability according to which a vulnerable consumer is one who, as a result of socio-demographic characteristics, behavioural characteristics, personal situation or market environment: (i) is at higher risk of experiencing negative outcomes in the market; or (ii) has limited ability to maximise their own well-being; or (iii) has difficulty in obtaining or assimilating information; or (iv) is less able to buy, choose or access suitable products; or (v) is more susceptible to certain marketing practices. This definition was operationalised in measuring consumer vulnerability across key markets in the EU⁴⁵⁵.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

To build a knowledge base, the Consumers Directorate of DG JUST gathers relevant information by monitoring markets and national consumer conditions and by studying consumer behaviour. How the Single Market works for consumers is monitored in two stages: (i) identifying malfunctioning markets and horizontal issues of concern through the Consumer Scoreboards; and (ii) in-depth analysis of these markets and issues through market studies to identify the main problems and suggest policy solutions. Behavioural tests allow comparing alternative policy options and tailoring interventions based on consumer response. This work is underpinned by the development of methodological tools, e.g. for measuring consumer detriment.

The information, data sources, and methodological tools presented below should be seen as a starting point for analysis rather than an exhaustive list of resources:

- The [Consumer Scoreboards](#) track the performance of key consumer markets and benchmark overall consumer conditions in EU Member States. The main data sources for the Scoreboards are the EU-wide [Market Monitoring Survey](#) and the [consumer and retailer surveys](#).
- Findings of [in-depth studies](#) of underperforming sectors and of cross-cutting issues have influenced policy with tangible benefits for EU consumers. Market studies⁴⁵⁶ can be carried out through the [Framework contract for Consumer Market Studies](#).

⁴⁵³ A detailed presentation of the conceptual framework for consumer conditions is available at https://publications.jrc.ec.europa.eu/repository/bitstream/JRC93404/2015-10-12_consumer_conditions_final_report.pdf

⁴⁵⁴ Knowledge of consumer rights, trust in retailers and in relevant institutions, in redress mechanisms, in product safety, in environmental claims, and confidence shopping online.

⁴⁵⁵ See the 2016 [study on understanding consumer vulnerability in the EU's key markets](#)

⁴⁵⁶ These studies allow data gathering through consumer opinion surveys, stakeholder surveys, the collection of prices for goods/services, surveys based on mystery shopping methodology and behavioural experiments.

- The [2017 study on measuring consumer detriment in the EU](#) developed a detailed step-by-step [operational guidance](#) for scientifically sound and resource efficient assessments of personal consumer detriment in markets across the EU, and tested it in six selected markets⁴⁵⁷.
- [Applying Behavioural Sciences to EU Policymaking](#) covers issues to consider when incorporating behavioural insights into the design, implementation, and monitoring of policies. Ex-ante behavioural testing of the effectiveness of policy interventions can be carried out through the [Framework Contract for the Provision of Behavioural Studies](#). The issues that policy officers need to be aware of when carrying out such behavioural testing are outlined in [Seven Points to Remember when Conducting Behavioural Studies in Support of EU Policymaking](#). All the recent [behavioural studies](#) on consumers are available online.

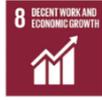
Helpdesk for assessing consumer impacts:

JUST-03-IMPACT-ASSESSMENT-EVALUATION@ec.europa.eu

If impacts on consumers are likely to be significant, DG JUST should be invited to participate in the interservice coordination group preparing the impact assessment and policy initiative.

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Consumption of hazardous and non-hazardous chemicals <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Indicator of food price anomalies • (a) Number of commercial bank branches per 100,000 adults and (b) number of automated teller machines (ATMs) per 100,000 adults • Proportion of adults (15 years and older) with an account at a bank or other financial institution or with a mobile-money-service provider • Number of parties to international multilateral environmental agreements on hazardous waste, and other chemicals that meet their commitments and obligations in transmitting information as required by each relevant agreement • Hazardous waste generated per capita and proportion of hazardous waste treated, by type of treatment • Number of companies publishing sustainability reports • Extent to which (i) global citizenship education and (ii) education for sustainable development (including climate change education) are mainstreamed in (a) national education policies; (b) curricula; (c) teacher education; and (d) student assessment 	  

⁴⁵⁷ The methodology for measuring personal consumer detriment was tested in the following markets: mobile telephone services; clothing, footwear, and bags; train services; large household appliances; electricity services; and loans, credit, and credit cards.

TOOL #34. TERRITORIAL IMPACTS

1. INTRODUCTION

The European Commission recognizes that the impacts of Union legislation may be different across local and regional levels and for public authorities⁴⁵⁸.

Impact assessments and evaluations should systematically consider territorial impacts when they are relevant and there are indications that they will be significant for different territories of the EU. Thanks to territorial impact assessments (TIA) and rural proofing⁴⁵⁹, the needs and specificities of different EU territories can be better considered (for instance of urban⁴⁶⁰/rural areas, cross-border areas⁴⁶¹ and the EU outermost regions⁴⁶²) to facilitate cohesion across the Union.

Living conditions as well as industrial structures, infrastructure endowment, patterns of land use, and geographical conditions vary substantially across the EU. EU's cohesion and regional policies are designed to mitigate these differences and ensure that poorer regions and territories have means to address regional challenges. Despite good progress in convergence across Europe on many parameters, there is still significant dispersion within the EU. Still many sectoral policy measures address specific territorial areas or have specific consequences concentrated in certain territories of the EU (i.e. insular areas). For example, efforts to ensure more sustainable fishing is likely to have spatially differing impacts which vary according to the distribution of fisheries and their conservation status. In addition, the reduction of poverty and social exclusion is a common objective, but the extent of the problem varies a lot across countries and regions.

The territorial dimension may be relevant for impact assessments for many sectoral legislative proposals and initiatives for two reasons:

- First, the impacts associated with the problem are often heterogeneously distributed across the EU. This means that the design of effective policy options will also bring about an uneven geographical distribution of impacts (costs and benefits);
- Second, a policy option may act unevenly to produce heterogeneous territorial impacts even where a problem is not necessarily unevenly distributed across the territory of the EU.

In policy cases where there is no specific territorial dimension, obviously there is no need for a detailed assessment of the territorial impacts.

Territorial impact assessments are looking into all thematic aspects of impact assessments (economic, social, and environmental) by translating them into the territorial setting (regions).

⁴⁵⁸ Commission Communication: [The principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking](#), COM(2018) 703

⁴⁵⁹ Commission Communication, The Future of Food and Farming, [COM\(2017\) 713](#) and Commission Communication: A Long Term Vision for Rural Areas, [COM\(2021\) 345](#)

⁴⁶⁰ Pact of Amsterdam: Urban Agenda for the EU (2016) and Council Conclusions on an Urban Agenda for the EU (24.6.2016)

⁴⁶¹ Commission Communication: Boosting growth and cohesion in EU border regions, [COM\(2017\) 534](#)

⁴⁶² defined in Article 349 TFEU, which provides for the adoption of specific legislative measures for the EU nine outermost regions across EU policies, taking into account their permanent constraints.

2. HOW TO ASSESS IMPACTS OF POLICY OPTIONS ON TERRITORIES

One first step is to allow for more active engagement of local and regional authorities in consultation processes. This is an essential element of improving the quality of assessments of territorial impacts. Local and regional authorities should help identify such potential impacts in their consultation responses and feedback on the ‘call for evidence’.

The Committee of the Regions and its network of regional hubs (RegHub)⁴⁶³ can help disseminate information about consultations by reaching out to its members.

The impact on territories can be assessed using qualitative and quantitative methods, as well as specific tools developed to support impact assessments or the consultation process.

The approach relies on a description of the spatial distribution of four items:

- 1) The degree to which the problem or driver to be addressed is concentrated in some types of areas (i.e. rural/urban), Member States or regions;
- 2) The capacity of EU policies to respond to the problem/implement the policy;
- 3) The degree to which stakeholders indicate a need for a policy response in the relevant areas and regions;
- 4) The effectiveness of the policy response and its potential impact.

In some cases, the risk of asymmetric territorial impact is obvious. In other cases, only experts familiar with the issue can assess the risk of such asymmetric impacts. Deciding whether that is the case for a given policy or legislative proposal however is not always easy as no policy will affect all regions throughout the European Union exactly to the same extent.

For that reason, when a preliminary screening of impacts⁴⁶⁴ shows that territorial impacts are relevant, the [TIA necessity check](#)⁴⁶⁵ will help assess the need of a more in-depth analysis of such impacts.

Through a series of five steps this online tool will help you decide whether a TIA is useful for a legislative proposal/initiative. It is recommended to use the tool in:

- the ‘call for evidence’ phase, to determine if a TIA should be part of the impact assessment based on the initial idea for the proposal, and/or
- the impact assessment phase, to determine if based on the more concrete idea for the proposal, a TIA might have become advisable even if it was not considered necessary at the ‘call for evidence’ phase.

Box 1 presents examples of cases where territorial impacts were relevant.

⁴⁶³ The European Committee of the Region’s (CoR) Network of Regional Hubs ([RegHub](#)) is a network of European regions and cities that evaluates the implementation of EU policies.

⁴⁶⁴ In line with Tool #18 (*Identification of impacts*)

⁴⁶⁵ Developed by DG REGIO and the [ESPON](#) Cooperation Programme, which aims to support the effectiveness of EU policies through the production, dissemination, and promotion of territorial evidence. It is co-financed by the European Regional Development Fund.

Box 1. Examples of territorial impacts**1. Commission initiative responds to an uneven problem but acts evenly on the territories of the EU**

Example: The [Clean Vehicle Directive](#) – stipulating minimum standards with respect to emissions and technical specifications of the public procurement of vehicles for public use (e.g. public transport, waste collection, etc.). In that case, the application is territorially evenly distributed, but the problem is different in agglomerations (big cities) due to the higher population and vehicle density and in rural areas where public transport is more scattered and people are more dependent on individual vehicles.

2. The initiative responds to an even problem but acts unevenly on the territories of the EU

Example: [EU Climate and Energy framework](#) – this policy package combines measures to successfully achieve the binding overall EU targets for reduction in greenhouse gas emissions, increased share of renewable energy and increased energy efficiency by 2030. The underlying problem is the need to fulfil the commitments made under the Paris Agreement, which are equal for all Member States. In implementing the framework, individual targets for Member States are set, thus representing an uneven policy action.

3. The initiative responds to an uneven problem and acts unevenly on the territories

Example: [EU Cohesion Policy](#) – funding made available through the European Structural and Investment Funds in order to reduce disparities between regions and to promote the overall balanced development of the territories. The problem addressed are the regional disparities, which are inherently unevenly distributed. The funding framework allows for different EU co-financing rates based on regional characteristics and shifts a larger share of overall funding towards specific regions or areas facing specific constraints.

4. The initiative responds to an even problem and acts evenly on the territories

Example: **Emission Trading System** – carbon dioxide (CO₂) emissions are a universal problem all over the EU (with certain peaks and dumps in areas with high/low human activities – e.g. urban agglomerations vs. unpopulated territories). The [Emission Trading System](#), which is a cornerstone of the EU’s policy to combat climate change and its key tool for reducing greenhouse gas emissions cost effectively, applies throughout the EU – with a current exemption for flights between airports in the EU outermost regions and other EU/EEA airports – and certificates can be traded freely with no specific national or regional provisions.

A correct assessment of the territorial dimension of the problem will help shaping properly targeted policy options. It can also avoid conducting policies in those areas and regions where no policy response is needed. This could create direct or indirect costs.

The relevant territorial unit or grouping may vary from case to case and should be proportional to the question at hand. It could be specified at the Member State level or in terms of geographical characteristics such as for instance urban or rural areas, coastal areas, island and the EU outermost regions, mountainous regions, cross border regions or densely versus very low populated areas. In other cases, there may be a need for singling out those administrative regions, which are disproportionately affected by a certain policy measure.

3. CHARACTERISING THE PROBLEM

Spatially relevant statistics and information are routinely collected, aggregated, and made available by local and regional authorities, Member States, the Commission and other EU agencies and bodies (see section 8 for some examples). This can be used to characterise a particular problem and to understand whether the problem is characterised by territorial impacts which are unevenly distributed across the Union.

Box 2. Examples where the problem is spatially uneven

- The sensitivity of terrestrial and aquatic ecosystems to acid rain varies across the Union as a function of the underlying geological rock and soil types which means that some air pollution emissions sources contribute more to the environmental damage than others once transport in the atmosphere is considered. The ecosystem sensitivity can be mapped.
- Measurement by the Member States show that the quality of bathing waters and rivers varies across the Union this can be overlaid with spatial information about the various economic activities, which occurs in river basins across the Union.
- The relative wealth of regions in the Union varies significantly, which is considered of in the Union's cohesion and State aid policies. Similarly, unemployment varies significantly across the Union.
- Educational attainment strongly varies across the EU, some regions having more than 70% of their population with tertiary education while in others this share is less than 15%.
- Susceptibility to a changing climate will vary across the Union. Some regions will be susceptible to flooding, encroachment of the sea, hurricanes, and other extreme weather events whilst others are sensitive to reduced rainfall and drought.

If the nature of the problem is spatially varying, then it is important to characterise this early in order that policy options can be designed properly but also to be able to assess the territorial impacts associated with each of the policy options.

A '**territorial baseline**' can be constructed to show how the problem is likely to evolve in the absence of policy intervention. The magnitude of the issue can be further elaborated thanks to the Annual Regional Database of the European Commission⁴⁶⁶ (**ARDECO**). It is a comprehensive territorial database of layers and statistics at various levels, with long time-series demographic and macro-economic indicators for EU regions, geo-referenced population⁴⁶⁷ and detailed maps of land use/cover and services⁴⁶⁸.

If data allows, a projection should be made to show to what extent the problem is likely to grow in the future. Projections with a sub-national component including demographic, economic and land use projections can help to show the likely evolution of the issue at stake.

If the spatial distribution of an issue cannot be measured directly, it can sometimes be derived from case studies or the scientific literature. In some cases, another measure with a similar

⁴⁶⁶ https://knowledge4policy.ec.europa.eu/territorial/ardeco-online_en

⁴⁶⁷ <https://ec.europa.eu/eurostat/web/gisco/geodata/reference-data/population-distribution-demography/geostat>

⁴⁶⁸ <https://ec.europa.eu/jrc/en/publication/luisa-base-map-2018>

spatial distribution can be used as a proxy indicator. For example, opening up trade in textile sector may mean that regions with an uncompetitive textile industry will see high redundancies in that sector. If no data is available on the regional competitiveness of the textile industry, regional employment growth in that sector may help to assess which regions could be more vulnerable.

4. MODELLING INTERACTIONS

A model can support an impact assessment, especially if the policy addresses a problem driver that is strongly linked to other issues. For example, trade policy can have an impact on the agricultural sector or new transport infrastructure can influence economic growth and land use changes. The Joint Research Centre has developed six models⁴⁶⁹ with a sub-national component, including RHOMOLO, LUISA, and TRANSTOOLS.

5. TOOLS TO SUPPORT THE QUANTITATIVE ANALYSIS

[ESPON](#) has developed [ESPON TIA Tool](#) (a web application) to get a quick indication of the possible territorial impacts of policy options. With the ESPON TIA Tool one can assess policy impacts using a vulnerability approach. This approach uses three elements: exposure, sensitivity, and impact. The tool combines local/regional expert knowledge on the *exposure*⁴⁷⁰ of specific regions to the impacts gathered in a workshop with a set of statistical data describing the *sensitivity*⁴⁷¹ of the EU regions to possible policy impacts.

In the process of the assessment of territorial impacts, the ESPON TIA tool produces maps that visualise the impacts on the various territories and serve as input for discussion among the experts. These maps are useful for policy considerations and for enriching an impact assessment report. The tool allows to do a TIA for Europe as a whole, but one can also focus on EU Member States only or on cross-border regions, urban, rural, outermost areas or make a composition of regions of their choice (i.e. coastal etc.). Its main advantage is the possibility to conduct a TIA with a reasonable time (workshops with experts takes half a day) and resource frame and apply it in a horizontal way combining all thematic aspects of impact assessments (economic, social, environmental) as well as governance aspects by translating them into the territorial setting (regions). It may be used in the 'call for evidence' phase as well as in the impact assessment phase. ESPON TIA Tool can also be used for evaluations.

For territorial impact analysis at the regional (NUTS2) level, the model [RHOMOLO](#) developed by the Joint Research Centre and DG REGIO can be used to analyse the impact on economics outcomes such as GDP, employment, investments, prices, exports and wage. There is a simplified web version of the model that can be used as a first approximation of the impact of policies affecting total factor productivity, labour productivity or transport costs. For more complex impact assessment exercises, DG REGIO and JRC can be contacted to run tailored simulations.

For policies with an expected impact mainly at the sub-regional level or when regional boundaries are crossed by the same policy without affecting whole regions, the JRC can provide support to the impact assessment through the [LUISA Territorial Modelling Platform](#) that allows producing projection at high spatial granularity and also to define and implement what-if scenarios.

⁴⁶⁹ See the [Modelling Inventory and Knowledge Management System \(MIDAS\)](#)

⁴⁷⁰ i.e. the potential strength and normative direction of the policy effect on the regions

⁴⁷¹ i.e. the existing territorial condition of the region

6. CONSULTATIONS CAN HELP REVEAL ASYMMETRIC TERRITORIAL IMPACTS

The stakeholder consultation process envisaged in the impact assessment can be used to collect evidence and information about the issue to be addressed and the impact of the policy option on different EU territories. Therefore, services must make an effort to reach out to stakeholders from different territories (urban, rural, cross border, coastal, insular, mountainous, sparsely populated etc.) and from the EU outermost regions. Stakeholders from different territories may have access to more information and thus be in a good position to judge the risk of an asymmetric territorial impact. Therefore, the consultation (public or targeted) could include question/s to check whether the public or the stakeholders expect the legislative proposal/initiative to have an asymmetric impact.

Box 3. Sample questions to include in public/targeted consultations

- According to your knowledge and information, is this problem concentrated in certain areas, regions, or Member States?
- Do you expect that this policy will have a disproportionately large impact on certain areas, regions, or Member States? If yes, please indicate which ones and why.

Under the 'Protocol on Cooperation between the Commission and the Committee of the Regions' (2012) the 'Commission services may ask for support from the Committee in preparing its assessment'. This may be particularly useful if the consultation investigates asymmetric impacts on regions or local authorities.

7. HOW TO MINIMIZE ANY NEGATIVE IMPACTS ON TERRITORIES

Considering potential asymmetric territorial impacts can increase the effectiveness and the efficiency of the policy. It can increase political support for a policy, boost the benefits while addressing excessive spatial concentrations of the costs.

If costs are distributed in a highly asymmetric manner, the policy could be adjusted to reduce the costs of the policy on the most affected regions. If the policy itself cannot be adjusted, mitigation measures including the creation of another instrument to reduce the burden on these regions or areas should be investigated. The territorial assessment can also help the relevant regions and areas by making them aware of the EU policies under development so that they will be able to prepare and take most advantage of the policy once implemented.

Three short examples can illustrate how negative territorial impacts can be reduced:

1. Reducing the concentrations of an airborne pollutant in cities to uniform level within a single deadline may be more difficult to achieve in some cities than others. Concerns about such difficulties may lead to pressure to allow higher concentrations. Assessing territorial impacts could identify such risks and ensure that the EU policy would be able to allow cities with very high concentrations a longer time frame – based on clear criteria – to reach the necessary quality threshold, should they so wish.
2. State aid policy also differentiates its approach according to the level of development of a region and to the size of the market. For example, different possibilities to award State aid apply to areas with an abnormally low standard of living, to insular, mountain and to the EU outermost regions and regions with low population density.

3. Growing global trade integrations tends to benefit the EU, but some regions specialised in a sector vulnerable to further trade integration/globalisation may face a high number of redundancies.

Policies can be adjusted in five ways to address highly asymmetric territorial impacts:

1. Adjust the policy for the entire Union or some of its parts (as for example State Aid policy does);
2. Grant more time to implement a policy in some parts of the Union (as was done for the urban wastewater directive during the accession negotiations);
3. Exempt those parts of the Union which are unaffected by the problem from the policy;
4. Use existing policies to address asymmetric territorial impacts (for example by using Cohesion Policy, etc);
5. Create a new instrument to address asymmetric territorial impacts if/when they arise (for example the European Globalisation Adjustment Fund).

8. INFORMATION SOURCES AND BACKGROUND MATERIAL

- Assessing territorial impacts: operational guidance on how to assess regional and local impacts within the Commission Impact Assessment system, [SWD \(2013\) 3 final](#)
- [TIA Necessity Check](#) can be used by Commission services to self-assess if a legislative proposal may require TIA
- Units B1 and 03 in DG REGIO provide assistance and training to other DGs on TIA
- Training on TIA methodologies and tools via [EU Learn - REGIO - Territorial Impact Assessment - ESPON TIA Quick check tool \(europa.eu\)](#)
- Examples of Territorial Impact Assessments contracted in the framework of IA with the support of DG REGIO: [Regulation on minimum requirements for water reuse TIA report](#)
- **Local typologies:** [Cities and their commuting zones](#); The [degree of urbanisation](#) can be visualised interactively using the [statistical atlas](#) (General and regional statistics, chapter 14). **Sub-national data sources:** Eurostat has been expanding its sub national data offer in the recent years in two dimensions, more domains covered and more detailed geographical levels see [Eurostat web page dedicated to sub-national statistics](#).
- In addition, Eurostat publishes [geographical information](#)⁴⁷² such as reference topographic layers and specific thematic layers.
- The LUISA-RHOMOLO combination for the evaluation of territorial impact of European policies⁴⁷³.
- The **JRC** develops geo-referenced datasets at European and global scale, many of which are relevant for regional or territorial analysis. These datasets cover themes as natural hazards and risk prevention, distribution of species, climate change, agriculture, land cover, soil data, etc. Contact the [JRC Knowledge Centre for Territorial Policies](#).

⁴⁷² GISCO - the Geographic Information System of the Commission <https://ec.europa.eu/eurostat/web/gisco>

⁴⁷³ [JRC Publications Repository - The LUISA-RHOMOLO combination for the evaluation of territorial impact of European policies \(europa.eu\)](#)

- The [Urban Data Platform Plus](#), the *de facto* standard repository for quantitative knowledge and indicators at all territorial levels in Europe.

9. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Settlement area per capita <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Ratio of land consumption rate to population growth rate • Proportion of cities with a direct participation structure of civil society in urban planning and management that operate regularly and democratically • Average share of the built-up area of cities that is open space for public use for all, by sex, age, and persons with disabilities. • Proportion of population living in cities that implement urban and regional development plans integrating population projections and resource needs, by size of city • Proportion of local governments that adopt and implement local disaster risk reduction strategies in line with the Sendai Framework for Disaster Risk Reduction 2015-2030. • Number of countries with national and local disaster risk reduction strategies. • Number of countries that have national urban policies or regional development plans that (a) respond to population dynamics; (b) ensure balanced territorial development; and (c) increase local fiscal space • Proportion of the rural population who live within 2 km of an all-season road • Proportion of the population living below the international poverty line by sex, age, employment status and geographic location (urban/rural) • Parity indices (female/male, rural/urban, bottom/top wealth quintile, and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated 	  

TOOL #35. DEVELOPING COUNTRIES

1. INTRODUCTION

Assessing the likely effects of different policy initiatives on developing countries is a requirement from Article 208(1) TFEU, which stipulates that the EU “*shall take account of the objectives of development co-operation in the policies that it implements which are likely to affect developing countries*”. This constitutes the legal basis of the concept more generally known as Policy Coherence for Development (PCD). Through PCD, the EU seeks to take account of development objectives in all its policies that are likely to affect developing countries, by minimising contradictions and building synergies. PCD is a fundamental element to progress towards EU’s development cooperation objectives, i.e. reduction and – in the long term – eradication of poverty, and key to implement the 2030 Agenda and its sustainable development goals.

As part of the EU’s commitment to ensure SDG implementation internally and externally, the assessment of potential impacts of internal EU policies and initiatives on third countries is crucial. Tool #35 must be applied in a manner that integrates the SDGs, given that they are a shared universal framework that provides a useful blueprint to assess in a comprehensive manner a range of impacts on developing countries.

When screening process indicates that impacts on developing countries will be significant, relevant targeted consultation should be planned in time and integrate in the overall stakeholder consultation strategy⁴⁷⁴. The targeted consultation, addressing relevant stakeholders in developing countries, should collect their views on expected likely impacts of the EU initiative.

If impacts are significant, a thorough assessment – as explained in this tool – is essential to ensure that the external dimension of the EU initiative is considered from the very start.

Developing countries are very heterogeneous in their social, political, and economic structure. While impacts on the most relevant countries will have to be established on a case-by-case basis, as a rule, the focus would be primarily on the impacts on Least Developed Countries and those countries most in need⁴⁷⁵.

While it can sometimes be cumbersome to identify potentially significant impacts and to distinguish between direct or indirect impacts, many of the EU measures that are likely to have an impact on developing countries are already well-known. See Box 1 below for a non-exhaustive list of these, compiled by OECD⁴⁷⁶.

Box 1. Measures known to have impacts on developing countries

Trade and finance:

- Regulatory measures in the management of EU production (e.g. fisheries) can affect exports and prices of products in developing countries, thereby distorting trade and

⁴⁷⁴ See Tool #51 (*Consulting stakeholders*)

⁴⁷⁵ An updated list of Developing Countries and Least Developed Countries can be found, respectively, at the World Bank’s and IMF’s official websites.

⁴⁷⁶ This list is based to a large extent on an OECD publication (2012). See OECD, Policy framework for policy coherence for development, WP n°1, 2012.

undermining the local production, food security and livelihoods in these countries;

- Tariff barriers or export subsidies for EU products (e.g. in agriculture) can affect the exports, commodity prices, and prices of processed products imported from developing countries to the EU and thereby undermine local production (for domestic or export markets), food security and livelihoods in developing countries;
- Measures regulating the behaviour of private actors such as multinational enterprises also active in developing countries; or measures impacting on the (re)distribution of value added along international integrated production chains (e.g. fair trade initiatives);
- Measures affecting movement of capital such as investment or remittances and the conditions of investment in developing countries, both in positive and negative ways (e.g. measures fighting tax evasion and dealing with tax havens);

Ensuring global food security:

- Regulatory measures regarding food safety and quality, animal welfare and environmental protection in the EU, which may present unintended non-tariff trade barriers to direct/indirect food exports into the EU from developing countries;

Making migration work for development:

- Initiatives affecting movement of people (e.g. migration policy) and conditions for travel of developing countries' citizens to and from the EU;

Strengthening the links between security and development:

- Measures affecting the attribution of development aid, investment or domestic resource mobilisation in developing countries;
- Measures and initiatives affecting fragile states or the EU intervention in international security issues;

Addressing climate change:

- Measures regarding climate change mitigation and achieving the international agreed warming limit level; measures affecting adaptation needs of developing countries.

2. HOW TO ASSESS THE IMPACTS ON DEVELOPING COUNTRIES

The scope and depth of the analysis will be determined, on a case-by-case basis, by the likely impacts of the proposed action.

When the screening process indicates that impacts on developing countries will be significant, consulting with developing countries stakeholders will be the main means to collect information. While the principles and requirements remain those of the 'better regulation' guidelines and relevant tools, the mechanisms need to be adapted to the reality of contexts, particularly for least-developed countries. While the lead DG will define the content of the consultation in cooperation with the interservice coordination group (ISCG), EU Delegations will define the most appropriate consultation activities and mechanisms⁴⁷⁷. While some stakeholders can be reached online, information will be mostly collected through direct consultations (e.g. interviews, workshops, meetings and seminars).

⁴⁷⁷ For details/examples see Tool #51 (*Consulting stakeholders*)

External expertise can be used to complement the consultation process, to gather evidence and conduct a more detailed, substantial and quantified analysis or/and qualitative analysis of the impacts of the EU policy proposed options⁴⁷⁸.

It is also important to consider factors potentially playing a role in the final negative/positive impact (e.g. other international actors, etc.) and determine whether it would be transitory or permanent. Furthermore, qualitative estimate of the main political risks should be provided (possible sources include comments/criticism on this or similar policy/measure by the European Parliament, the Council or civil society).

2.1. Guiding questions for a targeted consultation and/or qualitative and quantitative assessments

The table below presents the list of potential impact areas that should be screened to identify the most relevant impacts for subsequent, more detailed analysis. The guiding questions can also be considered when carrying out a targeted consultation and/or qualitative assessment⁴⁷⁹.

Category of impact	Potential impact areas and guiding questions
Economic impacts	Which developing countries are producing (and exporting to the EU) the goods/services affected? Are these least developed countries?
	What is the impact on proportion (esp. in value) of the trade between these developing countries and the EU, in particular regarding the trade balance of developing countries?
	What is the likely impact on price volatility?
	What are the impacts on proportion between the purchase of raw materials and finished products from developing countries?
	What are the impacts on domestic sectors development and infant industries?
	What is the impact on the competitiveness of exporters in developing countries in terms of intended or unintended trade barriers?
	What are the impacts on the initiative on intellectual property rights, standards, and technology and business skills in developing countries and on their capacity to trade their goods (towards the EU or among themselves)?
	What is the impact on food security for local population (e.g. by affecting the price of commodities or food in world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on the different population groups (urban vs. rural, small-vs. large-scale farmers and their livelihood)?
	What are the impacts on international and domestic investment flows (outflows and inflows including FDI) in the developing countries?

⁴⁷⁸ A qualitative analysis/overview of the impact of EU policy options on developing countries is a valid approach, especially when proceeding to a fully-fledged quantitative assessment is cumbersome (due to lack of data) or not proportionate (because the cost incurred in gathering such data would not be justified in the light of the magnitude of the initiative's likely impact).

⁴⁷⁹ These guiding questions could also support stakeholders in their analysis when participating in public or targeted consultations.

	What are the impacts on the private sector in developing countries (including competitiveness, access to finance, access to market)?
Social impacts ⁴⁸⁰	What are the impacts on labour market, e.g. quantitative impact on employment level, impact on the quality of employment (respect of labour standards, impacts on different groups of workforce – low-skilled vs. high-skilled workforce, wages, working conditions, discrimination, exploitation)?
	What are the impacts on main stakeholders and institutions affected by the proposal?
	What is the impact on poverty levels ⁴⁸¹ and income inequality in developing countries?
	What are the impacts on gender equality and on the most vulnerable groups of society, including persons with disabilities ⁴⁸² ?
	What is the impact on human rights ⁴⁸³ in the development countries?
	What is the impact on migrants, refugees, and other forcibly displaced populations? What is the impact on migration and mobility in developing countries (rural-urban or international)? What is the impact on EU aid allocation to developing countries (conditionality)?
	What is the impact on food security for the local population (e.g. by impacting on price of commodities or food on world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on different population groups (urban vs. rural, small- vs. large-scale farmers)?
	What is the impact on health systems at the regional and local level, in particular from a health security perspective and more generally from a human development one?
	What is the impact on the state's capacity to procure security to the population in the whole territory and its borders? What is the impact on cybersecurity?
Environmental impacts ⁴⁸⁴	How does it impact ecosystems (terrestrial, marine)?
	What is the impact on emission targets in developing countries?
	What is the impact on chemicals authorisation as well as on use and waste management?
	What is the impact on green economy development (e.g. on the adoption of green/circular practices) both globally and in partner countries?
	What is the impact on the low carbon technology transfer and its availability in developing countries?

⁴⁸⁰ See Tool #30 (*Employment, working conditions, income distribution, social protection and inclusion*)

⁴⁸¹ Those people that stay below the poverty line

⁴⁸² When analysing the impacts on persons with disabilities, consider the UN Convention on the Rights of Persons with Disabilities, to which the EU is a party (for example: accessibility of persons with disabilities to buildings, transport infrastructure and on-line services; access to employment and education; reduction of poverty; and deinstitutionalisation process).

⁴⁸³ See Tool #29 (*Fundamental rights, including the promotion of equality*)

⁴⁸⁴ For additional information see Tool #57 (*Methods to assess costs and benefits*) and Tool #36 (*Environmental impacts*)

	What is the impact on the biodiversity (mono-cropping, deforestation) and global or local food security?
	What is the impact on the management and use of natural resources, e.g. minerals, timber, water, land, etc.?

For qualitative assessments, a comprehensive literature review can provide the necessary elements for the assessment of the expected effects, which can be corroborated by means of focus groups or interviews.

2.2. Quantitative assessment

Whenever stakeholder consultation and/or qualitative assessment may indicate that a detailed, substantial and quantified analysis is advisable (e.g. for new regulatory proposals that substantially affect a specific production in developing countries), the analysis should be supported by detailed quantitative data to establish a causal link between the policy option and its impact and analytical tools that entail modelling techniques⁴⁸⁵.

No single analytical approach is recommended given the broad range of policy options that might need to be considered and the constraints on human and financial resources that might be available for the assessment. Moreover, several analytical/methodological approaches have been used in the past for similar types of policy option and each gives satisfactory results. More of different analytical tools can be used together to cover various elements at stake, with possibility of their combination. The various analytical approaches include:

- **Econometric analysis:** Gravity models have been widely used for estimating the impact of trade and non-trade barriers to trade (e.g. standards).
- **Computable General Equilibrium (CGE) models:** There are several well-established CGE models that can be used to yield results in ex-ante assessments. Results obtained from such models capture relations between different macro indicators providing full scale information on given economy be it on national or regional level. Widely used GTAP8 model serves in simulating world trade and production providing for assessment of likely impacts on economic performance after introduction of certain measure (change in tax rates, price levels, investment activity, consumption patterns, production technology, etc.)^{489,486}. For examples, see Box 2.

Box 2. Example of a modelling study

The CEPR Study used to simulate the likely effects of the Transatlantic Trade and Investment Partnership (TTIP) on the EU, which is based on the so-called GTAP8 model, is a good illustration of modelling studies that can potentially be used in impact assessments⁴⁸⁷. This is a well-established Computable General Equilibrium model to analyse tariff and non-tariff barriers to trade. If this model were to be applied to an appropriate level of aggregation (i.e. various groups of developing countries or, in special circumstances, individual developing countries), isolating trade diversion effects from other effects and substantiating important

⁴⁸⁵ For the list of plausible models see Tool #61 (*Simulation models*)

⁴⁸⁶ For a detailed description of the GTAP8 see, for instance, Aguiar, Angel H., McDougall, Robert A., and Narayanan, G. Badri (ed.), (2012), "Global Trade, Assistance, and Production: The GTAP 8 Data Base", Center for Global Trade Analysis, Purdue University

⁴⁸⁷ See http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

assumptions on other indirect effects towards the developing countries, it could prove to be a reliable tool for an assessment of the likely effects on developing countries. The responsible DGs could explore the opportunity of co-operating with the JRC to establish a sound application of this methodology to analyse and measure the impact of the proposed policy measures on the developing countries.

3. FOSTERING POLICY COHERENCE FOR DEVELOPMENT AND ASSESSING MITIGATING MEASURES

Choosing the appropriate policy option for reducing negative impacts in developing countries, while seeking positive synergies, is markedly important for the particularly vulnerable economies. From an array of mitigating measures those most effective for developing countries should be chosen.

Box 3. Examples of used mitigating measures

- The Common Agricultural Policy (CAP) post-2013 Regulation was accompanied by an evaluation framework to measure ex-post the performance of the CAP with the EU development cooperation objectives. This monitoring was based on appropriate indicators to provide a consistent and dynamic picture of performance of the CAP vis-à-vis its stated development objectives.
- When the Economic Partnerships Agreements were negotiated, several mitigating measures were envisaged, including:
 - At least 80% of customs import duties would be phased out by African Caribbean Pacific (ACP) Group of States over 12 years; following negotiations, the period was extended to 15 years (in some cases to 20 or even 25 years) and in one case a lower 75% threshold was accepted.
 - All export duties/taxes should be phased out; following negotiations, it was accepted that existing duties/taxes may continue, and new ones introduced in specific cases for development reasons, including industrial development, infant industry protection, and food security, environmental or fiscal reasons.
 - Exceptional difficulties should be dealt with traditional safeguard clauses: after negotiations, specific provisions were added to protect infant industries, food security and rural development, and bilateral safeguard clauses were provided for in cases of import surges from the EU, with lower triggers than those of multilateral safeguards under WTO rules.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

Examples of sources of information already available and on databases than can support the analysis of the different dimension of the IA on Developing Countries.

- **Tool knowledge already available.** To identify and obtain existing relevant sectoral studies, the lead service should contact in priority the DGs INTPA, RTD and JRC. Commissioning an expert study on given subject might also be an option (contact DG INTPA for available experts and use of relevant framework contracts). In addition,

relevant ex-post evaluations, previous impact assessments covering similar countries/sectors as well as provision of literature review can serve as good starting point.

- **Databases to support economic and social assessments.** The most comprehensive database in terms of coverage of cross-country, cross-time information on developing countries currently publicly available is the World Development Indicator database (WDI), which contains useful information on several dimensions of poverty (economic, protective, political, and human socio-cultural). As regards data on international prices, they can be found on the International Comparison Programme (ICP).⁴⁸⁸
- **Databases on Trade and FDI flows.** EUROSTAT, via the COMEXT database, has also extensive data on imports and exports of goods with developing countries. The UN COMTRADE can also be used to gather import data for the EU, as opposed to the actual export data from the developing countries (which can prove to be a great advantage as import values for developing countries are generally more reliable than export values. The UNCTAD and OECD have databases regarding foreign direct investments and DG TRADE also developed a market access database. The DAC OECD database reports complementary information on this. In terms of data on the measurement of standards/NTMS, the FP7 NTM project can be helpful.
- **Databases to support the environmental assessment.** As regards the environmental impacts on developing countries, relevant data can be found at the [United Nations Framework Convention on Climate Change](#) , the [Convention on Biological Diversity](#), [Global Climate Change Alliance](#) and the [Forest Law Enforcement, Governance and Trade](#).

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Contribution to the international 100bn USD commitment on climate related expending • Official development assistance as share of gross national income • EU financing to developing countries <p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Proportion of domestically generated resources allocated by the government directly to poverty reduction programmes • Proportion of government recurrent and capital spending to sectors that disproportionately benefit women, the poor and vulnerable groups • Total official flows (official development assistance plus other official flows) to the agriculture sector • Whether or not legal frameworks are in place to promote, enforce and monitor equality and non-discrimination on the basis of sex 	   

⁴⁸⁸ The ICP is a worldwide statistical exercise established at the end of the 1960s. Its objective is to compare the GDP of various economies to “... determine their relative size, productivity and material well-being”. This comparison is done using purchasing power parities.

Relevant SDG indicators	SDGs
<ul style="list-style-type: none"> • Proportion of countries with systems to track and make public allocations for gender equality and women's empowerment • Total resource flows for development, by recipient and donor countries and type of flow (e.g. official development assistance, foreign direct investment and other flows) • Mobilized amount of United States dollars per year between 2020 and 2025 accountable towards the \$100 billion commitment • Number of least developed countries and small island developing States that are receiving specialized support, and amount of support, including finance, technology and capacity-building, for mechanisms for raising capacities for effective climate change-related planning and management, including focusing on women, youth and local and marginalized communities • Foreign direct investment (FDI), official development assistance and South-South cooperation as a proportion of total domestic budget • Volume of remittances (in United States dollars) as a proportion of total GDP • Total amount of approved funding for developing countries to promote the development, transfer, dissemination and diffusion of environmentally sound technologies • Worldwide weighted tariff-average 	  

TOOL #36. ENVIRONMENTAL IMPACTS

1. INTRODUCTION

Environmental impacts are changes in the state of the environment due to anthropogenic activities (such as the use of resources or activities causing pollution) that may also affect human health.

Direct environmental impacts (so climate impacts, loss of biodiversity, resource use, etc.) have secondary (indirect) impacts on the economy and wider social wellbeing. Environmental impacts often affect not just the environment but through it:

- human health through impacts to our physical condition and well-being;
- economic activity through changes to production and services;
- social aspects through e.g. poverty alleviation and wealth distribution.

The 'better regulation' guidelines commit us to analysing the environmental impacts of all policies in a proportionate manner and following the 'do no significant harm' principle. This includes the identification of impacts, and, as far as possible, the quantification of positive and negative environmental impacts. This tool explains how to identify environmental impacts and is an introduction to Chapter 8 that provides approaches for determining their significance and trade-offs.

2. THE EU GREEN DEAL AND 'DO NO SIGNIFICANT HARM' PRINCIPLE

EU actions and policies should pull together to help the EU achieve a successful and just transition towards a sustainable future, in line with the objectives of the **European Green Deal**. Evaluations and impact assessments also systematically assess the relevance and coherence of current legislation with new priorities. To this end:

- **Stakeholder consultations** should explicitly cover environmental aspects where relevant. This can be done either with a reference in the 'call for evidence' and/or a set of questions in the public consultation or with targeted consultations reaching specific groups of stakeholders.
- **Evaluations** should look at whether the evaluated legislation or programmes had some impacts on the environment. This can concern either direct impacts or possible (in)coherence with overarching environmental goals (such as the European climate law) or (in)consistencies with other policies targeting the environment. All evaluations should ask the following evaluation questions:
 - Are there any identified issues that significantly harm the environment?
 - Is there any incoherence with the climate law?
 - If so, how they could be removed or minimised?

If the evaluation found that there could be potentially significant negative effects on the environment, but data were not available to quantify or fully assess the significant harm, the evaluation should conclude on the limitation of methodology, qualitatively

present the significant adverse effects, and include in the lessons learned the issues identified and the lack of data.

- **Impact assessments** should be clear if there will be environmental impacts, and what the trade-offs are between the environment and other objectives. This element should be clearly identified in the report and the proposal in the following way.

It is paramount that the options are consistent with the environmental objectives of the European Green Deal. In particular, the climate law⁴⁸⁹, states “*The Commission shall assess the consistency of any draft measure or legislative proposal, including budgetary proposals, with the **climate-neutrality objective** set out in Article 2(1) and the 2030 and 2040 targets before adoption, and include this analysis in any impact assessment accompanying these measures or proposals, and make the result of that assessment public at the time of adoption. The Commission shall also assess whether these draft measures or legislative proposals including budgetary proposals, are consistent with ensuring **progress on adaptation** as referred to in Article 5. In making its proposals, the Commission shall endeavour to align them with the objectives of this Regulation. In any case of non-alignment, the Commission shall provide the reasons as part of the assessment referred to in this paragraph.*” In cases when significant environmental harm cannot be avoided, options could include mitigating or compensatory actions. In any case, the analysis of options (in particular, the preferred option) should always clearly present the environmental assessment to allow for an informed policy decision.

The following, non-exhaustive list of questions helps to check the consistency of the legislative proposal with the ‘do no significant harm’ principle, when relevant.

- Does the policy have impact on any of the objectives of the European Green Deal?
- Are the options consistent with the objectives of the European Green Deal, including climate neutrality?
- Do the options consider all environmental impacts? What are the trade-offs? Are the global, non-EU environmental impacts considered?
- Do the options include incentives for cleaner production or consumption (e.g. information, market-based instruments, polluter pays principle)? Is the creation of new markets considered, allowing for the pricing of resources previously considered as without value, including instruments such as cap-and-trade schemes (e.g. ETS)?
- Is mitigation of possible negative environmental impacts considered? Has adaptation to changing environmental circumstances been considered?
- When relevant, are options analysed based on sector-specific resource modelling or a life-cycle assessment (see Tool #66) along the whole value chain? Have re-use, recycling, cascading uses, and circular economy been considered? Can less resource intensive alternatives lead to the same outcome?
- Will the options also limit or prevent environmental damage in the future with a rapidly changing context?

⁴⁸⁹ Regulation (EU) 2021/1119 of 30 June 2021 establishing the framework for achieving climate neutrality (European Climate Law)

- Do the options increase the EU’s leverage to improve the environmental practices of the trading partners?

A specific section of the preferred option chapter should transparently report if there are decisions that will cause significant environmental harm because of concerns over the costs of mitigation, or trade-offs between different environmental aspects (e.g. trade-offs between enhanced battery capacity for electro-mobility and the use of toxic and/or environmental damaging substances to obtain the enhanced capacity). These impacts should be transparently reported.

- The **explanatory memorandum** accompanying all legislative proposals and delegated acts will include a specific section explaining how each initiative upholds the ‘do no significant harm’ principle. An illustrative example of this can be found in the European Commission Proposal for a Regulation concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) 2019/1020, (COM(2020) 798/3)⁴⁹⁰.

3. WHAT ARE THE RELEVANT ENVIRONMENTAL IMPACTS?

3.1. Principles of environmental analysis

The identification of the likely significant environmental impacts is followed by a deeper assessment. The assessment can be qualitative if quantitative data are not available or not fully available.

Analysis of environmental impacts is often best done through a multi criteria analysis⁴⁹¹ (a pure cost-benefit or cost-effectiveness analysis is often difficult to be performed due to the character of impacts). This involves⁴⁹²:

- identifying the full extent of environmental impacts (what impacts are significant?);
- quantifying those impacts where possible (for example, km² of land converted, tons of waste or emissions and identify where they occur);
- monetising the costs and benefits of those impacts where possible.

3.2. What environmental impacts can be distinguished?

Tool #18 includes an identification of the main environmental areas on which a policy could have an impact. These can be overlapping and linked, e.g. a circular economy approach will normally reduce climate impacts. The different impacts of any option concern changes in the state of:

- climate;
- air quality;
- water quality and quantity;
- biodiversity;
- soil quality or resources and land use change or degradation;
- waste production and recycling;

⁴⁹⁰ [Proposal for a Regulation on batteries and waste batteries](#)

⁴⁹¹ https://europa.eu/capacity4dev/evaluation_guidelines/wiki/multi-criteria-analysis-0

⁴⁹² See Tool #62 (*Multi-criteria decision analysis*)

- zero pollution and toxicity;
- efficient use of resources (renewable & non-renewable);
- contribution to circular economy;
- the likelihood or scale of environmental disasters;
- international environmental impacts.

The enabling conditions to meet the objectives of the above-mentioned areas include:

- ensuring effective and efficient implementation of Union legislation on environment and climate;
- strengthening the integrated approach to policy development and implementation, including the link to social objectives;
- mobilising sustainable investments from public and private sources;
- ensuring that environmental policies and action are based on the best available scientific knowledge.

3.3. Key questions to identify potential impacts

First, what are the potential environmental impacts of the existing policy intervention (evaluation) or policy options (impact assessment) that need to be assessed? For evaluations this step is informed by impacts identified in the prior impact assessment or accompanying documents of the legislation or policy to be evaluated. However, possible unintended or unknown impacts could have occurred.

As a rule, environmental impacts occur both in the short term and in the long term. The immediate impact on the environment can be negligible, but the effect can be quite significant if the impact takes place over a longer period (the cumulative effect). The impacts can be interlinked and can be of different magnitude. They can be of local or of transboundary nature. Once the potential impacts are clear, a deeper assessment may need to follow (see section 4 below).

There are several **overarching questions** to consider:

- Is there a market failure linked to externalities (so polluters do not pay for the damage they do)? For example, does the policy affect economic incentives for reduction of greenhouse gases (e.g. first and second round incentives and price signals under the EU's emission trading system)?
- Is there a market failure linked to environmentally harmful subsidies that encourage pollution?
- What is the role of environmental technology and innovation in the problem and solving it?
- Are there issues related to implementation and enforcement of existing environmental legislation?

Moreover, the following, non-exhaustive questions can help identify potential direct or indirect impacts:

Climate change

- Does the policy contribute to the achievement of the 2030 climate target of at least 55% net greenhouse gas emission and the climate-neutrality objective by 2050?
- Does the policy affect the emission of ozone depleting substances (CFCs, HCFCs etc.)?
- Does the policy affect our ability to adapt to climate change? How does the policy affect our adaptive capacity, resilience, or vulnerability for climate change?
- Does the policy allow to increase carbon removals or preserve carbon stocks?
- Does the policy improve climate mainstreaming into other policy goals?
- With a view to achieving climate neutrality, i.e. equalisation of emissions and removals of greenhouse gases by 2050, does the policy ensure that no additional carbon lock-in is created?
- Does the policy create risks for climate resilience as referred to in Tool #14 (*Risk assessment and management*)?

Air quality

- Does the policy have an effect on emissions of harmful air pollutants that might lead to deterioration in the environment (crop yields, soil, forests or rivers etc.), affect human health, and damage buildings and cultural heritage?

Water quality and resources

- Does the policy decrease or increase the quality or quantity of freshwater and groundwater?
- Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)?
- Does it affect drinking water resources, and in particular their quality?

Biodiversity

- Does the policy affect natural capital and the ecosystem services?
- Does the policy reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)?
- Does it affect protected or endangered species or their habitats or ecologically sensitive areas?
- Does it affect the integrity and the conservation measures of Natura 2000 sites and for example split the landscape into smaller areas or in other ways affect migration routes, ecological corridors, or buffer zones?
- Does the policy affect the scenic value of protected landscape?

Soil quality and land use change and degradation

- Does the policy affect soil quality and result in a loss of soil carbon stocks, decline of soil biodiversity, compaction, sealing, landslides, acidification, contamination, salinisation or erosion?
- Does it lead to loss of available soil (e.g. through building or construction works i.e. land sealing) or increase the amount of usable soil (e.g. through land decontamination)?
- Does the policy lead to land use change, land take and bring new areas of land ('greenfields') into use for the first time?
- Does it affect land designated as sensitive for ecological reasons?
- Does it lead to degradation of land?

Waste production and recycling

- Does the policy affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of, or recycled?

Zero pollution and toxicity

- Is the product toxic? At what levels? Is it (bio)degradable? Does it accumulate in the bodymass?
- What are the sectors? Are there any non-toxic substitutes?

Efficient use of resources (renewable & non-renewable)

- Does the policy affect the use of renewable resources (fish, etc.) and lead to their use being faster than they can regenerate?
- Does it reduce or increase use of non-renewable resources (groundwater, minerals, etc.)?
- Does the policy affect the energy intensity of the economy?
- Is there a risk of a 'rebound effect' (e.g. improvement in resource efficiency is offset by an increase in consumption)?
- Is there an impact on the supply chain for key resources?

Circular economy

- Does the policy aim at maintaining the value of products, materials, and resources (understood as durability, reparability, reusability, or recyclability) for as long as possible by returning them into the product cycle at the end of their use, while minimising the generation of waste?
- Does the policy lead to verifiable additional sustainable production and consumption?
- Does the policy change the relative prices of environmentally friendly and unfriendly products?

- Does the policy promote or restrict environmentally (un)friendly goods and services through changes in capital investments, loans, insurance services, etc.?
- Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?

The likelihood and scale of environmental risks

- Does the policy affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions?
- Does it affect the risk of unauthorised or unintentional release or proliferation of organisms or products that might have an environmental impact (such as invasive species)?

International environmental impacts

- Does the policy have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?
- Does the policy promote the EU's sustainability objectives in third countries (Green Deal diplomacy)?

Environment and fairness

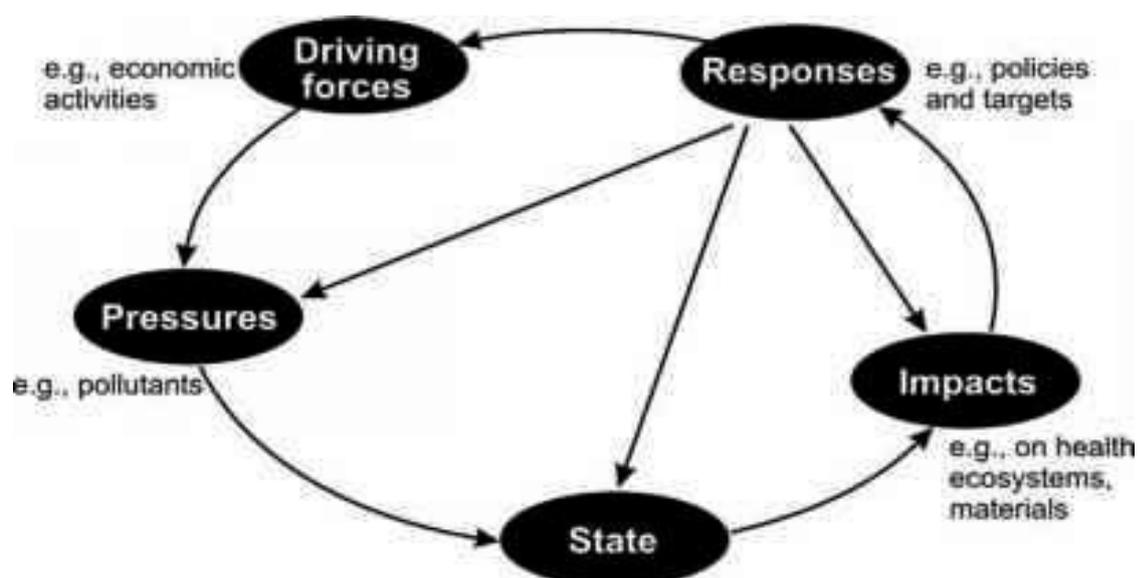
- Is the environmental policy socially just?
- Does the policy reduce social and regional inequalities with respect to environmental and health risks, and access to eco-system services?
- Does the policy disproportionately burden certain citizens (e.g. low-income or rural)? Are the benefits of the policy evenly distributed?

4. ASSESSMENT OF ENVIRONMENTAL IMPACTS

4.1. The DPSIR framework

DPSIR (drivers, pressures, state, impact and response model of intervention) is a causal framework for describing the interactions between society and environment – human impact on the environment and vice versa because of the interdependence of the components.

The DPSIR framework has been widely adopted by the European Environment Agency (EEA), an EU decentralised agency, acting as an integrated approach for reporting, e.g. in the EEA's State of the Environment Reports. The framework gives a structure to present the indicators needed to inform policy makers on environmental quality and the resulting impact of the political choices. According to the DPSIR framework there is a chain of causal links starting with 'driving forces' (economic sectors, human activities) through 'pressures' (emissions, waste) to 'states' (physical, chemical, and biological) and 'impacts' on ecosystems, human health and functions, eventually leading to political 'responses' (prioritisation, target setting, indicators). The mapping and assessment of ecosystems and their services (MAES) initiative is a collaboration between the European Commission, the EEA and Member States, which is based on the DPSIR framework.



4.2. Understanding market failures in the environment

Market failure occurs when the price mechanism fails to account for all the costs and benefits necessary to provide and consume a good. In the real world, it is not possible for markets to be perfect due to inefficient producers, externalities, environmental concerns, and lack of public goods. An externality is an effect on a third party which is caused by the production or consumption of a good or service, without being considered by the producer or consumer. Externalities can be positive (external benefit) or negative (external cost). The result is that producers or consumers do not behave in the socially most optimal way. Many (environmental) policies try to correct these externalities. Tools #13 (*How to analyse problems*) and #16 (*How to identify policy options*) explain how these market failures can be addressed in impact assessments.

A first example of market failures causing environmental damage is when economic actors are not fully accountable for the negative environmental externalities (or damage) their actions cause. Economic instruments (e.g. taxes) are often proposed as a solution to 'internalise' these externalities. A particular example of this is the **polluter pays principle**, where those who produce pollution should bear the costs of managing it to prevent damage to human health or the environment. For instance, a factory that produces a potentially poisonous substance as a by-product of its activities is usually held responsible for its safe disposal. The polluter pays principle is part of a set of broader principles to guide sustainable development worldwide. The polluter pays principle is included in the Treaties. Article 191(2) TFEU, "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on ... the polluter should pay*".

A second example of market failures in the environment is, the common case, when there is an **absence of market prices** for the environmental goods or services. The lack of market prices for environmental services does not mean that these goods have no value. Monetisation of environmental goods helps to create incentives to avoid environmental damage. Valuation techniques to assess the costs of environmental damage and benefits of environmental services are set out in Tool #57 (*Methods to assess costs and benefits*).

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- [International resource panel website](#)
- [European Environment Agency](#)
- [Mapping and Assessment of Ecosystems and their services](#)
- [Natural Capital Accounting](#)
- [REGIO guidelines on CBA](#)
- [Taxonomy Regulation](#)
- [Handbook on the external costs of transport](#)

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<p><i>EU indicators:</i></p> <ul style="list-style-type: none"> • Area under organic farming • Ammonia emissions from agriculture • Exposure to air pollution by particulate matter • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Population connected to at least secondary wastewater treatment • Biochemical oxygen demand in rivers • Nitrate in groundwater • Phosphate in riversWater exploitation index • Primary & final energy consumption • Energy productivity • Share of renewable energy in gross final energy consumption • Energy dependence • Share of busses and trains in total passenger transport • Settlement area per capita • Recycling rate of municipal waste • Consumption of hazardous and non-hazardous chemicals • Resource productivity and domestic material consumption (DMC) • Average CO2 emissions per km from new passenger cars • Circular material use rate • Generation of waste excluding major mineral wastes • Greenhouse gas emissions • Greenhouse gas emissions intensity of energy consumption • Global mean ocean surface acidity • Estimated trends in fish stock biomass • Assessed fish stocks exceeding fishing mortality at maximum sustainable yield (Fmsy) • Surface of marine sites designated under NATURA 2000 • Bathing sites with excellent water quality • Share of forest area • Surface of terrestrial sites designated under NATURA 2000 • Soil sealing indexEstimated soil erosion by water • Common bird index • Shares of environmental and labour taxes in total tax revenues 	       

Relevant SDG indicators	SDGs
<p><i>UN indicators:</i></p> <ul style="list-style-type: none"> • Prevalence of moderate or severe food insecurity in the population, based on the Food Insecurity Experience Scale (FIES) • Proportion of agricultural area under productive and sustainable agriculture • Number of plant and animal genetic resources for food and agriculture secured in either medium- or long-term conservation facilities • Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction • Mortality rate attributed to household and ambient air pollution • Proportion of population using safely managed drinking water services • Proportion of population using (a) safely managed sanitation services and (b) a hand-washing facility with soap and water • Proportion of wastewater safely treated • Proportion of bodies of water with good ambient water quality • Level of water stress: freshwater withdrawal as a proportion of available freshwater resources • Change in the extent of water-related ecosystems over time • Proportion of population with primary reliance on clean fuels and technology • Renewable energy share in the total final energy consumption • Energy intensity measured in terms of primary energy and GDP • International financial flows to developing countries in support of clean energy research and development and renewable energy production, including in hybrid systems • Passenger and freight volumes, by mode of transport • CO2 emission per unit of value added • Ratio of land consumption rate to population growth rate • Proportion of urban solid waste regularly collected and with adequate final discharge out of total urban solid waste generated, by cities • Annual mean levels of fine particulate matter (e.g. PM2.5 and PM10) in cities (population weighted) • Total expenditure (public and private) per capita spent on the preservation, protection and conservation of all cultural and natural heritage, by type of heritage (cultural, natural, mixed and World Heritage Centre designation), level of government (national, regional and local/municipal), type of expenditure (operating expenditure/investment) and type of private funding (donations in kind, private non-profit sector and sponsorship) • Number of countries with sustainable consumption and production (SCP) national action plans or SCP mainstreamed as a priority or a target into national policies • Material footprint, material footprint per capita, and material footprint per GDP • Domestic material consumption, domestic material consumption per capita, and domestic material consumption per GDP • Number of parties to international multilateral environmental agreements on hazardous waste, and other chemicals that meet their commitments and obligations in transmitting information as required by each relevant agreement • Hazardous waste generated per capita, and proportion of hazardous waste treated, by type of treatment • Number of companies publishing sustainability reports • National recycling rate, tons of material recycled • Number of countries implementing sustainable public procurement policies and action plans • Amount of fossil-fuel subsidies per unit of GDP (production and consumption) and as a proportion of total national expenditure on fossil fuels • Number of countries that have communicated the establishment or operationalization of an integrated policy/strategy/plan which increases their ability to adapt to the adverse impacts of climate change, and foster climate resilience and low greenhouse gas emissions development in a manner that does not threaten food production (including a national adaptation plan, nationally determined contribution, national communication, biennial 	  

Relevant SDG indicators	SDGs
<p>update report or other)</p> <ul style="list-style-type: none"> • Number of least developed countries and small island developing States that are receiving specialized support, and amount of support, including finance, technology and capacity-building, for mechanisms for raising capacities for effective climate change-related planning and management, including focusing on women, youth and local and marginalized communities • Index of coastal eutrophication and floating plastic debris density • Proportion of national exclusive economic zones managed using ecosystem-based approaches • Average marine acidity (pH) measured at agreed suite of representative sampling stations • Proportion of fish stocks within biologically sustainable levels • Coverage of protected areas in relation to marine areas • Number of countries making progress in ratifying, accepting, and implementing through legal, policy and institutional frameworks, ocean-related instruments that implement international law, as reflected in the United Nations Convention on the Law of the Sea, for the conservation and sustainable use of the oceans and their resources • Sustainable fisheries as a proportion of GDP in small island developing States, least developed countries, and all countries • Forest area as a proportion of total land area • Progress towards sustainable forest management • Proportion of important sites for terrestrial and freshwater biodiversity that are covered by protected areas, by ecosystem type • Proportion of land that is degraded over total land area • Coverage by protected areas of important sites for mountain biodiversity • Mountain Green Cover Index • Red List Index • Proportion of traded wildlife that was poached or illicitly trafficked • Progress towards national targets established in accordance with Aichi Biodiversity Target 2 of the Strategic Plan for Biodiversity 2011–2020 • Proportion of countries adopting relevant national legislation and adequately resourcing the prevention or control of invasive alien species <p>Official development assistance and public expenditure on conservation and sustainable use of biodiversity and ecosystems</p>	

TOOL #37. CUSTOMS ENFORCEMENT OF SECTORAL PROHIBITIONS AND RESTRICTIONS AT EU BORDERS

1. INTRODUCTION

The EU Customs Union is the operational arm of many EU policy measures at the Union borders: it controls goods arriving from third countries before they can enter the EU market or other movements of goods such as exports or transit. This applies not only to financial measures⁴⁹³ but also to 'sectoral legislation' aimed at protecting a variety of public interests such as health, safety, security, environment, cultural goods, intellectual property, or sanctions imposed in the framework of the Common Foreign and Security Policy (CFSP). Authorities responsible for the controls of Prohibitions & Restrictions (P&R) at EU external borders are designated by Member States and are in most cases Customs. As of April 2021, more than 300 pieces of EU legislation linked to Prohibitions & Restrictions⁴⁹⁴ require enforcement at EU borders. This already presents a huge workload for Customs even considering that controls are primarily risk-based.

Enforcement of Prohibitions & Restrictions may equally have significant impacts on economic operators. On the one hand, they may represent an additional cost⁴⁹⁵ as they must comply with numerous and sometimes complex legislation when declaring goods at EU borders, such as complying with product requirements, providing specific documentation or certificates. On the other hand, an ineffective enforcement of Prohibitions & Restrictions at EU borders may also have significant economic impacts on EU businesses as it may distort competition by putting EU economic operators at a disadvantage *vis-a-vis* non-EU economic operators not abiding to EU legislation.

This tool concerns the part of the 'sectoral legislation' requiring enforcement by Customs Authorities (hereinafter Customs) at the Union's external borders which is usually referred to as Prohibitions & Restrictions. It should be applied only for those cases involving P&R (entry, release for free circulation, exit, export or transit of goods or their placement under another customs procedure).

2. SCREENING OF OPTIONS AGAINST CUSTOMS' MANDATE

Options involving a role for Customs in the enforcement of P&R measures at the EU borders should be consistent with the mission and practices of customs authorities.

As shown in Box 1, customs need to enforce a multitude of sectoral legislation, while not being specialists. Therefore, they need clear instructions in the sectoral legislation. In consequence, the impact assessment should consider options that are viable from a customs perspective and that allow for an effective and efficient enforcement at EU borders.

⁴⁹³ Customs and trade measures cover among other customs duties, quotas, commercial policy measures, fishery conservation and management measures. For customs and trade legislation see Tool #27 (*External trade and investment*)

⁴⁹⁴ DG TAXUD is developing with the help of the lead DGs an integrated list of Prohibitions and Restrictions

⁴⁹⁵ In international rankings most EU Member States are listed as [best places to import goods into \(no cost](#), which is very good) but this is probably by comparing them to other countries; in reality all compliance bears a cost. An [OECD paper](#) assessing 5000 traded goods and 80 countries estimates that the ad valorem equivalent of a non-tariff measure (P&R), that is the proportional rise in the domestic price of the goods to which it is applied, can be as high as 15.9%; it is clearly not the case for the EU (because domestic goods would not allow such surge in prices) but this illustrates that the cost of compliance is non-negligible.

Box 1. Key provisions of the Union Customs Code⁴⁹⁶**Mission of customs authorities**

According to [Article 3](#), “Customs authorities shall be primarily responsible for the supervision of the Union’s international trade, thereby contributing to fair and open trade, to the implementation of the external aspects of the internal market, of the common trade policy and of the other common Union policies having a bearing on trade, and to overall supply chain security. Customs authorities shall put in place measures aimed, in particular, at the following:

- (a) protecting the financial interests of the Union and its Member States;
- (b) protecting the Union from unfair and illegal trade while supporting legitimate business activity;
- (c) ensuring the security and safety of the Union and its residents, and the protection of the environment, where appropriate in close cooperation with other authorities; and
- (d) maintaining a proper balance between customs controls and facilitation of legitimate trade.”

Customs role with regards to Prohibitions and Restrictions

When it comes to the enforcement of P&R at entry into and exit from the EU customs territory, [Articles 134 and 267](#) of the Union Customs Code foresees that, while they are under customs supervision, the goods “shall be subject to such prohibitions and restrictions as are justified on grounds of, *inter alia*, public morality, public policy or public security, the protection of the health and life of humans, animals or plants, the protection of the environment, the protection of national treasures possessing artistic, historic or archaeological value and the protection of industrial or commercial property, including controls on drug precursors, goods infringing certain intellectual property rights and cash”.

Cooperation and information exchange between customs and competent authorities and risk analysis

Effective control at EU borders requires cooperation between competent authorities and customs. [Article 47](#) of the Union Customs Code provides the general framework for such cooperation but the sectoral legislation needs to include provisions on the concrete interaction between customs and competent authorities which are adapted to the specificities of that legislation.

Furthermore, risk analysis is an important part of controls at EU borders. For risk analysis, the Customs Risk Management System allows among others to exchange relevant risk information between Customs in all Member States. Some sectoral legislation also lays down the principle of common risk analysis at the EU level. However, as Customs are only generalists, it is paramount to rely also on the expertise of sectoral authorities. The sectoral legislation should thus make explicit the form and scope of exchanges of risk information as well as the means of communication.

Framework and scope of customs enforcement at EU borders

Where Customs plays a role in the enforcement of sectoral legislation, this should precisely

⁴⁹⁶ Regulation (EU) 952/2013 laying down the Union Customs Code and its delegated and implementing acts

lay down its interactions with other framework or specific legislation and its exact scope. For example, when a sectoral legislation relates to product requirements, it should make explicit whether the framework legislation on product compliance (Regulation (EU) 2019/1020) applies in full or whether specific provisions for enforcement at the EU borders are included in the specific legislation, which should accordingly be dealt with as a *lex specialis*. Recital 6 of Regulation 2019/1020 indicates that: “*If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation.*”

In this regard, certain basic questions should systematically be considered when designing the options involving P&R measures:

- Does the option allow for a proper balance between customs controls and facilitation of legitimate trade? In other words, can the objective sought be attained by using different, more efficient, means?
- To render controls at EU border as effective as possible, has the option envisaged provisions related to cooperation between competent authorities and customs?
- Have you considered the possible compatibility of options with a horizontal legal framework for enforcement (see point 4)?

3. HOW TO ASSESS ECONOMIC IMPACTS OF SECTORAL POLICY ON CUSTOMS ENFORCEMENT OF PROHIBITIONS & RESTRICTION

Before designing new policy proposals or amending/revising already existing legislation with new provisions relating to entry, release for free circulation, exit, export or transit of goods, or their placement under another customs procedure, there is a need to assess the impacts of sectoral legislation on its enforcement at EU borders.

For this purpose, the following questions may provide guidance:

- 3.1. Does the new policy proposal require enforcement at EU borders?
 - If so, does it require enforcement at import, at export or both at import and export or under other customs procedures (e.g. transit, customs warehouse, inward processing)?
 - What type of protection should the measure provide (prohibition, restriction, technical requirement)?
 - If a measure is envisaged, how will it be managed (by requiring a licence/permit/certificate, due diligence, other?)

Customs enforces sectoral legislation by performing documentary checks that include the customs declarations and the supporting documents (certificates, licences, authorisations), in particular those required by the sectoral legislation, as well as by doing physical or laboratory controls on the goods themselves. Customs controls are based primarily on risk analysis, which allows selecting for control those consignments that present a higher risk of non-compliance. As the selection relies almost exclusively on IT processing of the customs declaration, the latter needs to contain all the necessary information and the necessary IT systems and interfaces shall be foreseen for an efficient and effective

enforcement. However, the customs legislation⁴⁹⁷ provides only a horizontal framework for customs enforcement of Prohibitions & Restrictions (see [Articles 134 and 267](#) above). The sectoral legislation should therefore lay down any specific requirement necessary for customs enforcement and then only its practical implementation will be coordinated with the customs processes and systems. This applies at distinct levels:

- First, the sectoral legislation should normally link any measure applicable at EU borders to the customs classification, thereby allowing for an easy identification of the goods and the applicable measures. Concretely, Customs identify goods via a code system ([6 digit HS, 8 digit CN or 10 digit TARIC](#)) that allows for a quick and precise identification of the goods and serves also as a gateway to the relevant control measures ([TARIC measures](#)).
 - Second, where necessary, the sectoral legislation should lay down all necessary requirements. For example, if customs have to check the existence of certificates or licences, the sectoral legislation should request economic operators to submit such supporting documents together with their customs declaration.
- 3.2. Will the new legislation require a new or upgraded IT systems or interfaces to:
- manage the implementation of the requirements at EU borders (e.g. setting up a new IT system or scaling up an existing system with new modules, new connectivity with other systems)? As long as this new/upgraded IT system is not available, will the new legislation be enforced efficiently and effectively enough? If yes, how?
 - monitor the trade at EU borders (e.g. setting up a new IT system or scaling up an existing system with new modules, new connectivity with other systems)?

Enforcement of sectoral legislation at the EU borders and cooperation between customs and competent authorities in the specific sectoral domain relies largely on IT systems. Their availability and interconnection are essential for an efficient and effective enforcement of Prohibitions & Restrictions.

The EU Single Window environment for customs is a digital solution for the exchange of electronic information between different sectoral authorities and customs. It enables the automated verification by customs of the non-customs regulatory formalities, managed in the Union non-customs systems, which are referenced in the customs declaration as evidence of compliance (e.g. certificates, authorisations, licences) and as well as quantity management⁴⁹⁸.

The Commission proposal on the EU Single Window Environment for Customs⁴⁹⁹ envisages also the business-to-government component, i.e. possibility for economic operators to fulfil customs and non-customs formalities via a single channel.

The possible incorporation of the sectoral measures in the EU Single Window Environment for Customs solution should be subject to the assessment of time needed for the development of the IT systems and the assessment of the related costs.

⁴⁹⁷ Regulation (EU) 952/2013 laying down the Union Customs Code and its delegated and implementing acts

⁴⁹⁸ The EU Customs Single Window Certificates Exchange System (EU CSW-CERTEX) introduced new functionalities, such as quantity management. The monitoring and managing the quantity of goods authorised by partner competent authorities in accordance with Union non-customs legislation is based on the information provided by customs authorities on the clearance of related consignments.

⁴⁹⁹ The EU Single Window Environment for Customs | Taxation and Customs Union; Subject to the approval of the legislative proposal, such channel would be enabled by 2031.

- 3.3. Does the enforcement of the new measure apply on the entire EU customs territory, or should exceptions apply?

The EU customs borders do not match exactly with the EU borders. The territorial scope of the EU Customs Union is defined in Article 4 of the Union Customs Code⁵⁰⁰. It should be read in conjunction with the UK Withdrawal agreement. UK including Northern Ireland are not part of the customs territory (Article 4 of the Protocol of Ireland/Northern Ireland) but, for goods entering Northern Ireland, EU legislation is applicable (Article 5(3) and (4) and Annex 2 of that protocol). The UK sovereign base areas in Cyprus are part of the customs territory of the Union (Article 2 of the Protocol Relating to the sovereign base areas of the United Kingdom of Great Britain and Northern Ireland in Cyprus). See summary table [here](#).

- 3.4. How severe should the prohibition, restriction or technical requirement be?

In other words, how dangerous would be the introduction in the EU customs territory of a good infringing the new measure, should it not be detected by customs? There are two aspects in connection to this question.

First, sectoral legislation may be complex and require specific facilities, equipment, and staff qualifications. The sectoral legislation should consider such elements and define proper mitigating measures. For example, whereas Customs are present at all EU borders (land, air, sea), it might be opportune to limit the entry into or exit from the EU to certain custom offices that have acquired or can acquire knowledge or expertise with the specific sectoral legislation and have at their disposal the necessary control equipment.

Second, depending on the goods’ risk profile, advance cargo information and risk analysis may be required to enable the early identification of threats and help Customs to intervene at the most appropriate point in the supply chain. The EU is implementing a new customs pre-arrival security and safety program, underpinned by a large-scale advance cargo information system – Import Control System 2 (ICS2). The ICS2 will collect data about all goods entering the EU prior to their arrival. Economic operators will have to declare safety and security data to ICS2, through the Entry Summary Declaration. The obligation to start filing such declarations will not be the same for all operators. It will depend on the type of services they provide in the international movement of goods.

4. HOW TO MINIMISE IMPACT ON (CUSTOMS) ENFORCEMENT AT EU BORDERS (MITIGATING MEASURES)

4.1. No involvement of customs in the enforcement at the Union borders

Where no enforcement at the Union borders or Customs involvement are necessary, no impact should obviously be analysed. This may be the case for example for sectoral legislation relating to requirements that could easily be enforced at a point in time when the goods are already made available in the market and for which non-compliance with the requirement would result only in remote risks to the interests at stake.

⁵⁰⁰ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (please ensure that you take the latest consolidated text as there were changes to the customs territory recently, not only in relation to the UK)

4.2. Relying on an existing framework to enforce sectoral legislation at EU borders

An easy way to limit the impacts of enforcement of sectoral legislation at the EU borders is to rely on an existing framework that provides already a collaboration mechanism with Customs. Two comprehensive frameworks are in place in the EU: *the product compliance framework* and *the official controls framework*. If one of these two frameworks provides a sufficient basis for the enforcement and no substantial change is necessary, the impacts on Customs may remain limited and require less effort for effectively implementing the sectoral legislation.

4.2.1. Product compliance framework

Regulation (EU) 2019/1020 applies to all products, whether manufactured or not, also including food and feed, medicines and products of human origin and products of plants and animals relating directly to their future reproduction when the goods qualify also as products.

It lays down rules and procedures to ensure a high level of protection of health and safety, in general and in the workplace, and protect consumers, the environment, public security and other public interest in the EU. As regards enforcement at the EU borders, Chapter VII of the Regulation⁵⁰¹ establishes the framework for controls on products imported into the EU.

4.2.2. Official controls framework

Regulation (EU) 2017/625 lays down the governance of the agri-food chain. As regards enforcement at the EU borders, it establishes an integrated approach to import controls. Common rules apply to controls carried out at borders on animals, products of animal origin, plants and other products and goods that must be checked before they enter the EU. The import control system is risk-based and targeted.

A list of animals and goods subject to systematic controls at the border has been established. Border Control Posts (BCPs) carry out border control tasks. Minimum requirements for facilities, equipment and staff qualifications apply throughout all border control posts.

All consignments to be presented at the border control posts must undergo documentary checks. Identity and physical checks are carried out at a frequency depending on the risk linked to the specific animals or goods. The criteria to determine and modify the frequency of rates has been established by the Commission.

In principle, all controls must be carried out at the border control post where the consignment arrives. However, the Commission is empowered to establish cases and conditions under which deviations from this principle are allowed.

A single standard document, the Common Health Entry Document (CHED), must be used by operators for the prior notification of consignments. It is transmitted to the border control post through a new integrated computerised system for official controls (Integrated Management System for Official Controls, IMSOC⁵⁰²).

The provisions require close cooperation among competent authorities, Customs and other authorities involved in the controls of animals and goods arriving from third countries to ensure timely exchange of relevant information. The Commission is empowered to detail the functioning of such cooperation.

⁵⁰¹ DG TAXUD can provide detailed explanations on the product compliance framework upon request.

⁵⁰² IMSOC allows the integration of all computerised systems (TRACES, RASFF, Europhyt, AAC) to optimise exchange of information, data and documents needed enforce agri-food chain rules.

4.3. Specific enforcement requirements

If the legislation relates to either products or the agri-food chain described above, these respective frameworks normally provide an appropriate and comprehensive organisation for controls on goods entering the Union market. Therefore, it is strongly advised to simply rely on these frameworks as their organisation of controls at the Union borders is already in place and the extension to another sector would be easier and only have limited impacts.

On the contrary, in all cases where:

- the relevant goods do not qualify as products or relate to the agri-food chain, or;
- even if they do, further or other specific provisions relating to the organisation of controls on goods entering the Union market are required,

the impact assessment should consider as a minimum the two following options and analyse their impacts in full coordination with DG TAXUD:

- Option 1: (partial or full) reuse of one of the existing organisations of controls under the frameworks described above;
- Option 2: establishment of a separate organisation of controls at the EU borders with specific provisions.

Specific provisions to consider for Option 2 include:

- control at the Union borders would cover in the first line goods declared for transit, export or any special customs procedure;
- control requires specific facilities, equipment and staff qualifications;
- specific control processes are necessary, such as the systematic involvement of a designated authority to clear each consignment;
- specific exchanges of information between the authorities concerned by the controls;
- specific information shall be provided in the customs declaration and therefore require integration in the customs classification systems for automated checks with specific parameters or databases;
- an authorisation (e.g. license scheme) is required and Customs should control it through automated checks of a sectoral database;
- specific reporting is necessary (e.g. for statistics);
- specific IT tools or interfaces should be used or developed.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

For further DG TAXUD support, documents and guidance:

- Consult [TAXUD Intracomm pages](#)
- Contact TAXUD by email: TAXUD-PROHIBITIONS-RESTRICTIONS@EC.EUROPA.EU

Chapter 4 – Compliance, implementation and preparing proposals

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TOOL #38. COMPLIANCE PROMOTION AND VERIFICATION TOOLS

1. INTRODUCTION

Compliance tools can be categorised according to several dimensions: a distinction can be made between:

- ‘*compliance promoting*’ tools, which are mainly used during the implementation period of the EU act, before expiry of the transposition deadline or date of application, and
- ‘*verification*’ tools, which help to identify and correct an instance of non-compliance. The latter are activated after the transposition deadline or the date of application of the EU act has been reached.

The following tools are included in the first category – *compliance promoting* tools:

- implementation strategies (drawn up by the Commission);
- implementation plans (drawn up by the Member States);
- networks, expert groups, committees, workshops;
- guidelines on interpreting and implementing EU law (Commission)⁵⁰³.

The following tools are included in the second category – *compliance verification* tools:

- explanatory documents (drawn up by the Member States);
- package meetings;
- compliance dialogues;
- guidelines on interpreting and implementing EU law (Commission);
- implementation reports;
- scoreboards and barometers;
- Commission controls (for instance, EU inspections, audits, financial corrections procedure);
- expert groups.

Some of the tools can be used both proactively and reactively (e.g. guidelines). In practice, both sets of tools complement each other.

For some of the tools, a definition already exists in specific EU acts (e.g. committees, expert groups).

2. COMPLIANCE TOOLS EXPLAINED

Given the use of certain tools in areas going beyond the monitoring and enforcement of EU law, the definitions below should be understood exclusively in the context of the use of such tools to help prevent and correct infringements:

- Implementation strategy drawn up by the Commission – An implementation strategy identifies the main challenges Member States will face in transposing and applying the EU legislation, as well as the tools that the Commission may use to carry out its monitoring activities, depending on the nature and content of the legal instrument. It should also list the various support actions which the Commission will provide to the Member States (i.e. the other compliance promotion tools to be used). Implementation strategies may also include Member States’ implementation plans – if communicated

⁵⁰³ See Tool #41 (*Guidance documents containing legal interpretation of EU law*)

to the Commission – and monitoring arrangements to track progress and report on the transposition or implementation of EU specific legislation (e.g. calendar of compliance assessment, enforcement actions and implementation reports). Such a strategy is drafted by the responsible DG after the Commission’s legislative proposal has been adopted by the co-legislators. It should include the issues of digital implementation where relevant.

- Implementation plans drawn up by the Member States – Member States may draw up their own implementation plans for a given EU legal act. These detail the implementation process at national level, identifying concrete actions to be taken by the different authorities at local, regional, or central level.
- Networks – The Commission may set up various networks composed of Member State authorities or other national bodies in charge of the implementation of specific EU law. Networks may also include stakeholder representatives.
- Expert groups – The Commission may set up expert groups to get advice on the application, implementation and transposition of EU law. Expert groups consist of stakeholder representatives, organisations or Member States’ authorities. They provide specific expertise in a given policy area. Expert groups do not take binding decisions, but may formulate opinions and recommendations or submit reports.
- Committees – An EU legal act may set up a committee to assist the Commission in the implementation and application of that specific legislation. They are composed of representatives of Member States and chaired by the Commission. Some of these committees (comitology) provide formal opinions on proposals for implementing acts. In some other cases, committees play an advisory role, acting as expert groups⁵⁰⁴.
- Workshops – The Commission may organise on an ad-hoc basis workshops to facilitate and promote the implementation of EU legislation. Workshops may be organised at a technical, political or judicial level (involving a Commissioner and/or high-ranking Member State officials).
- Guidelines on interpreting and implementing EU law, including interpretative Communications – This is written guidance to Member States on how to implement and apply certain EU legal instruments. Guidelines contain interpretation of EU law, which bind the Commission. The Commission may also address written guidance to stakeholders on how to implement/apply certain EU provisions. The Commission can issue guidelines, for example on digital platforms⁵⁰⁵, including digital compliance assessment tools⁵⁰⁶, reference architectures⁵⁰⁷ and data models⁵⁰⁸. Such guidelines must in principle be adopted by the Commission⁵⁰⁹. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.
- Explanatory documents – These documents, prepared by the Member States, explain the relationship between the components of a directive and the corresponding parts of the national transposition instruments. Such documents may take the form of

⁵⁰⁴ [Register of Commission expert groups and other similar entities \(europa.eu\)](#)

⁵⁰⁵ Example for Knowledge Base for the implementation of the INSPIRE directive: <https://inspire.ec.europa.eu/>

⁵⁰⁶ Example: <https://joinup.ec.europa.eu/collection/interoperability-test-bed-repository/solution/interoperability-test-bed>

⁵⁰⁷ Example: <https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/solution/eira>

⁵⁰⁸ Example: <https://joinup.ec.europa.eu/collection/eprocurement/solution/eprocurement-ontology>

⁵⁰⁹ See also Tool #41 (*Guidance documents containing legal interpretation of EU law*)

correlation tables spelling out the link between each provision or legal obligation set by the directive and the corresponding legal obligation transposed in the national legislation. Explanatory documents must accompany Member States' notification of their transposition measures⁵¹⁰. The Commission DGs use these documents when assessing (i) the compliance with the obligation to adopt and communicate complete transposition measures and (ii) the correctness the compliance of the national transposition measures⁵¹¹.

- Package meetings – These meetings are convened with individual Member States to discuss implementation issues and infringement cases in a given policy area. These may help to find solutions in compliance with EU law and should therefore take place regularly, whenever useful. Package meetings could be combined or organised together with other meetings with Member States (e.g. compliance dialogues)⁵¹².
- Compliance dialogues⁵¹³ – This refers to a systematic better law-making dialogue with the Member States on compliance with EU law and on broader enforcement issues and policy considerations, across the range of legislative areas. Compliance dialogues could be organised in different settings: bilateral meetings, meetings with groups of Member States with similar issues to be tackled, sectoral meetings on specific issues concerning all Member States. Compliance dialogues could also help to assess together with the Member States the effects of non-compliance on the country's economic performance in terms of growth and investments (e.g. by looking at compliance with EU law in the light of the country specific recommendations issued for the European Semester exercise). The responsible DGs should define the format of compliance dialogues and to initiate them. Carrying out such dialogues could be a resource-intensive exercise for both Commission and Member States. The criteria for establishing these dialogues and for identifying candidate Member States must be clear and transparent. Compliance dialogues do not exclude other specific dialogues with the Member States (such as package meetings or technical meetings).
- Implementation reports – An EU directive or regulation may require the Commission to prepare an implementation report focussed on the Member States' implementation measures. This describes the state of play based on available national legislation and monitoring data and provides information on progress against the legal obligations laid down in the EU legislation and for obligations of results against agreed timetables or objectives, to the extent possible and in the limits of the data available. It often has a wider scope than a purely legal compliance report, but nonetheless builds on existing conformity/compliance checking.
- Scoreboards and barometers – The Commission may publish scoreboards (or barometers) to enable the public to compare the performance of Member States in achieving specific goals, including regarding the correct and timely application and implementation of EU law in particular policy areas.
- Commission controls – In certain policy areas, where the Commission has specific investigative or controlling powers, its DGs may carry out on-the-spot checks, audits

⁵¹⁰ Judgment of the Court of Justice in *Commission/Belgium*, [C-543/17](#).

⁵¹¹ See Tool #39 (*Compliance assessment: explanatory documents, transposition and conformity checks*).

⁵¹² Action 22, [Long term action plan for better implementation and enforcement of single market rules](#), COM (2020) 94 final.

⁵¹³ These were set up by the Communication [EU law: Better results through better application](#), C (2016) 8600.

inspections or financial correction procedures⁵¹⁴. Their objective is to collect the information needed to verify compliance with EU legal obligations and verify that the EU funds are spent in line with all relevant financial rules.

3. REFERENCES

Contact point for compliance promotion tools: SG-UNITE-E-3@ec.europa.eu

⁵¹⁴ Technologies like blockchain offer the possibility for automated controls: <https://digital-strategy.ec.europa.eu/en/policies/ebsi>. On-the-spot checks can in some cases be replaced by the use of geo-spatial information. Example for such practices in agriculture: <https://ec.europa.eu/jrc/en/research-topic/agricultural-monitoring>

TOOL #39. COMPLIANCE ASSESSMENT: EXPLANATORY DOCUMENTS, TRANSPOSITION AND CONFORMITY CHECKS

1. A TWO-STAGE SYSTEMATIC APPROACH

When it comes to the compliance of national legislation with EU directives, a clear line is to be drawn between infringements for failure to notify national transposition measures and infringements for non-conformity. These two types of infringements are assessed by two distinct methods: **transposition checks** for the former and **conformity checks** for the latter. When assessing national transposition measures, **explanatory documents** allow the Commission to better understand how Member States transpose EU directives.

1.1. Explanatory documents

The explanatory documents, prepared by Member States, explain the relationship between the components of a directive and the corresponding parts of the national transposition instruments.

In its judgment of 8 July 2019 in Case C-543/17⁵¹⁵, the Court clarified the respective roles of the Member States and of the Commission in setting out the correlation between the provisions of a directive and the corresponding rules of national law. The Court held that, when notifying national transposition measures to the Commission, Member States must provide sufficiently clear and precise information and state, for each provision of the directive, the national provision(s) ensuring its transposition.

Thus, Member States must accompany their notifications of national transposition measures to the Commission by explanatory documents. It is no longer necessary to include, in the new directives, a recital recalling the requirement to provide such documents.

The explanatory documents should preferably take the form of correlation tables, but this is not an obligation. Explanatory documents do have to be sufficiently clear and precise to allow the Commission services to identify, for each provision of the directive requiring transposition, the relevant text of national transposition measure creating the corresponding legal obligation in the national legal order, whatever the form chosen by the Member State.

1.2. Transposition check

As Member States must transpose directives in a complete way, every obligation of the directive to be transposed should be covered by the check. Hence, the transposition check should ensure that the national transposition measures notified by the Member State cover each obligation contained in each article and sub-article/paragraph of the directive, including in its annexes where relevant.

In a first step, services carry out a *prima facie* check. In case of partial transposition, the services then, in a second step, clearly identify the provisions that have not been transposed or that have not been completely transposed.

⁵¹⁵ Judgment of the Court of Justice in Commission/Belgium, [C-543/17](#). Confirmed in C-550/18, Commission/Ireland, C-549/18, Commission/Romania and C-628/18, Commission/Slovenia.

Box 1. Examples of incomplete transposition

- The concept of completeness of transposition measures in terms of geographic scope is relatively straightforward⁵¹⁶. For instance, when, for federally organised Member States, certain regions have not yet transposed or are erroneously not covered by the national implementing measures, the directive is incompletely transposed in terms of geographic scope⁵¹⁷;
- The concept of completeness of transposition measures in terms of substantive scope means that every obligation of a directive should be reflected in the national transposition measures⁵¹⁸. Therefore, all obligations contained in a directive fall within the scope of the transposition check. For example, if a provision contains an obligation, and the subparagraphs contain specific non-optional derogations therefrom, both should be checked during the transposition check⁵¹⁹. Hence, if national transposition measures contain only the general obligation, but not the [non-optional] derogations, it is an evidence of incomplete (partial) transposition.
- Occasionally, Member States notify transposition measures that merely specify a framework for future implementation. For example, a Member State could notify a measure stating that: *The Minister decides on the methodology for calculating a building’s energy performance through a decree*. Nothing specific has been transposed, only the national authority responsible for transposition has been identified. These so-called ‘empty shell’ transpositions are to be considered as a lack of transposition.

The transposition check starts upon the expiry of the transposition deadline; it may even start before (to be decided by the competent service) if national transposition measures for individual Member States have been received in advance.

If Member States fail to notify the transposition measures by the deadline, an infringement procedure will be launched as soon as possible. In its judgment of 8 July 2019 in Case C-543/17, the Court clarified that the sanction scheme of Article 260(3) TFEU may also be applied to cases of partial failure to adopt and communicate transposition measures.

To facilitate and speed up the transposition checks, DGs should prepare a table indicating which articles, sub-articles or paragraphs include self-standing obligations that require transposition by Member States. The Legal Service should be consulted if a scope of a particular obligation is not clear.

⁵¹⁶ See the guidance in Box 48, SEC(2010)922/3.

⁵¹⁷ For an example, see Case [C-428/04, Commission v. Republic of Austria \[2006\]](#) ECR I-3325.

⁵¹⁸ See the guidance in Box 48, SEC(2010)922/3.

⁵¹⁹ For an example, see Case [C-350/02, Commission v. Kingdom of the Netherlands \[2004\]](#) ECR I-6213, para. 41, where failure to notify implementing measures for a sub-article (article a of directive 97/66/EC) is qualified as incomplete transposition.

Box 2. Under what conditions can the Commission launch or pursue an infringement procedure, if explanatory documents are missing?

- Member States are in breach of their obligation to notify measures transposing a directive if they failed to indicate in a sufficiently clear and precise manner which provisions of national law transpose which provisions of the directive. Without such information, the Commission is not able to verify whether the Member State has transposed the directive effectively and completely. The Commission can launch or pursue an infringement procedure based on Article 258 and 260(3) TFEU without having to analyse the notified transposition measures.
- Member States should no longer make 'bare notifications' of national laws, i.e. notifications that are not accompanied by explanatory documents.
- Such notifications, which do not indicate clearly for each provision of a directive which national provision ensures its transposition (no explanatory documents provided), should not be accepted by the Commission services, unless they are self-explanatory (e.g. appropriate level of clarity is provided in the notification as to which national provision corresponds to which directive's provisions).
- Refusing 'bare notifications' should be done with caution, in full respect of the principle of proportionality.
- The refusal should only cover the extent that sufficiently clear and precise information is missing. If, for example, a Member State gives such information with respect to several provisions of a directive but not with respect to others, the notification should be qualified as a partial failure to communicate, but not be completely discarded.
- Where a Member State has provided sufficiently clear and precise information on the transposition, the Commission should pursue only manifest gaps under the procedure provided for by Article 260(3). This is the case when, despite indications to the contrary given by the Member State, no corresponding transposition measure exists for a self-standing obligation of a directive.
- Any objection to the clear indications given by the Member States on the matching transposition measure requires a well-substantiated explanation in the subsequent infringement step that the Commission takes (letter of formal notice, reasoned opinion, or referral to the Court), beyond the mere identification of the transposition gap. In case of doubt, the debate as to whether the national transposition measure implements the directive sufficiently should be held in the context of a 'non-conformity' case under Article 258 TFEU alone.
- The Commission can launch or pursue an infringement procedure based on Article 258 and 260(3) TFEU for notifications of national transposition measures, which do not comply with the above standards and were submitted to the Commission after the Court's judgment in case C-543/17 of 8 July 2019.

The Commission aims at completing the transposition check within six months after the transposition deadline expires. If the Commission launches an infringement procedure for failure to communicate national transposition measures, the six-month period will start when the measures are notified.

1.3. Conformity check

This check entails the assessment of the compatibility of the national implementing measures with the directive's provisions/obligations, including definitions.

Box 3. Issues related to incorrect transposition or bad application

- The implementation of parts of provisions of directives that require subsequent administrative practice or judicial interpretation to be applied in specific cases should normally be assessed within the conformity check. This holds especially true for so-called 'open norms' that grant significant discretionary power to national administrations⁵²⁰.
- Frequently, directives contain provisions that require Member States to notify specific reports / action plans / facilities. These provisions often contain separate deadlines and are different from the general obligation to notify transposition measures. Non-compliance with such provisions should be classified as bad application, as opposed to a failure to notify⁵²¹. Therefore, they are not part of the transposition check.
- For directives requiring the setting-up of national enforcement bodies, structural issues with the national regulatory body should be examined during the conformity check⁵²².
- National definitions broader than definitions included in a directive do not, as such, qualify as non-conform, unless it is demonstrated that the use of an extensive definition could be the cause of practical difficulties or confusion in application of the directive's rules⁵²³.

As a rule, the conformity check should start only once the previous phase of the transposition check, including a possible infringement procedure for failure to communicate transposition measures, has been completed. Exceptionally, a conformity check may be started in parallel to an ongoing transposition check for well-defined parts of a directive which have been identified as being completely transposed and which are clearly distinct from the provisions that require transposition measures which have not yet been notified.

Box 4. Example on running the transposition check and the conformity check in parallel

A Member State notified transposition measures for almost all provisions of a directive and only residual, non-essential parts have not been transposed. In this case, it is appropriate that the conformity check can already start for the well-defined parts of a directive, which have been identified as being completely transposed.

The Commission aims at completing the conformity check within 16 to 24 months from the date of the communication of the national transposition measures.

⁵²⁰ Open norms are those rules that depend for a large extent on judicial interpretation and that enable judges to administer justice in individual cases; examples of open norms are terms such as 'unnecessary', 'disproportionate', 'fair', 'adequate' and 'requisite legal standard'.

⁵²¹ For an example, see provision 11(1) of [Directive 2000/60/EC](#).

⁵²² For an example, see article 3 of [Directive 2002/21/EC](#).

⁵²³ See Case C-281/11, Commission v. Poland, EU:C:2013:855.

If during this subsequent conformity check the service finds that the Member State has not notified all the measures necessary for full transposition, the service should launch an infringement procedure for late notification in relation to the parts that are missing⁵²⁴.

Reports on conformity assessment from external contractors need to be verified by the Commission; any final decision that is taken based on such reports should be the result of an independent assessment by the Commission services.

Given that compliance studies may feed into infringement proceedings, they should not be published or disclosed before the compliance check is completed and a decision whether to pursue the matter or not is made. Requests for access to such studies will be assessed in the context of Article 4(2), third indent of Regulation No 1049/2001⁵²⁵.

Compliance assessment should finally feed into the evidence base used for effective evaluation; therefore, the conformity check should lead to a clear tangible result in the form of a written document containing the assessment results.

Several challenges in the implementation phase stem from historical reasons. Some information may be lost over time. It would be extremely useful for those who deal with compliance checks to know difficulties linked to the design of the legal instrument, foreseeable shortcomings in the concrete enforcement on a daily basis, articles that were subject to more intense debate and interpretation, as well as articles that resulted from a political compromise and that may generate interpretation difficulties. If the service / team of desk officers that ensures the conformity checks is different from the service, which has drafted and negotiated the directive or discussed with national authorities during the transposition period, DGs must put in place appropriate arrangements.

This can be achieved in different ways, depending on the organisation of each department. Useful tools are:

- hand-over notes detailing the challenges faced during the preparation and the negotiation phases;
- co-ordination mechanisms, such as task forces involving policy and enforcement units;
- integrated units covering all the activities of the policy cycle for a specific piece of legislation.

2. REFERENCES

For any queries on compliance assessment, please contact SG.E3 - SG-UNITE-E-3@ec.europa.eu

⁵²⁴ SEC(2010)923/3 Box 48

⁵²⁵ See especially Case [T-111/11, ClientEarth v. European Commission \[2013\]](#), n.y.r; Case [T-29/08, LPN v. Commission \[2011\]](#) ECR II-6021; Case [T-36/04, API v. Commission \[2007\]](#) ECR II-3201; Case [T-109/99, Petrie and Others v. Commission \[2001\]](#) ECR II-3677; Case [T-105/95, WWF v. Commission \[1997\]](#) ECR II-313.

TOOL #40. DRAFTING THE EXPLANATORY MEMORANDUM

1. WHEN IS AN EXPLANATORY MEMORANDUM NECESSARY?

All Commission proposals and delegated acts should include an explanatory memorandum.

For delegated acts, a simpler form is used covering: (i) the context of the delegated act; (ii) consultations prior to the adoption of the act; (iii) legal elements of the delegated act.

2. WHAT IS THE PURPOSE OF THE EXPLANATORY MEMORANDUM?

The purpose of the explanatory memorandum is to explain the reasons for, and the context of, the Commission's proposal drawing on the different stages of the preparatory process. It presents the results of the 'better regulation' processes and tools used to prepare the initiative, including opportunities for legislative simplification and reducing unnecessary regulatory costs. It also serves as a basis for the examination of the proposal by national Parliaments under the subsidiarity control mechanism (Protocol No. 2 to the Treaties).

The explanatory memorandum should be available in the same languages as the proposal it introduces. In principle, it should not exceed 15 pages, although in particularly complex cases a longer text may be justified. The explanatory memorandum is transmitted to the other institutions together with the accompanying act and is available to the public through [EUR-Lex](#). The explanatory memorandum is not published in the Official Journal and has no legal effect.

The explanatory memorandum should not be confused with the recitals, which are part of the act itself, which will be published in its entirety in the Official Journal.

The explanatory memorandum ensures the transparent exercise by the Commission of its right of initiative. Therefore, it should be reader-friendly, clearly worded, concise, and written with the non-specialist in mind. Commission services can seek the advice of DGT-EDIT during the interservice consultation⁵²⁶.

3. THE CONTENT OF THE EXPLANATORY MEMORANDUM⁵²⁷

The explanatory memorandum should satisfy all applicable requirements, including those following from Protocol No. 2 on the application of the principles of subsidiarity and proportionality, the Interinstitutional Agreement on Better Law-Making and the Commission's 'better regulation' agenda.

The Commission should summarise in the explanatory memorandum the following:

- the context of the proposal,
- how it complies with the principle of conferral (i.e. reasons for the choice of legal basis) and with the principles of subsidiarity and proportionality,
- explain the choice of the legal instrument.

⁵²⁶ DGT-EDIT can be included in the list of DGs consulted during the interservice consultation.

⁵²⁷ The template presented in this tool is not entirely appropriate for proposals adopted under Article 218 TFEU. Specific templates should be used which will be available on GoPro following the revision of the current Vademecum on the external action of the European Union: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/External+representation+of+the+EU>

- how it complies with the 'better regulation' principles, as well as with the fundamental rights. Generally, proposals are subject to fitness checks or evaluations of the existing policy framework, where relevant, to an impact assessment and scrutiny by the Regulatory Scrutiny Board and informed by stakeholder consultations. The results of this preparatory work should therefore be reflected in the explanatory memorandum.

(1) CONTEXT OF THE PROPOSAL

- Reasons for and objectives of the proposal:
 - Describe the reasons behind the proposal and/or the problem(s) that the proposal intends to tackle (e.g. obstacle to free movement, dangerous products, environmental pollution).
 - State if this is a REFIT initiative⁵²⁸.
 - State the relevant institutional background of the proposal (e.g. mandate from the European Council, undertaking by the Commission to revise an act, Commission work programme, reply/reaction to a legislative initiative resolution of the EP, reply/reaction to a European Citizens' Initiative).
- Consistency with existing measures in the area:
 - Mention any important Union measures and initiatives already undertaken in the relevant area (existing legislation, linked policy proposals, white papers) or comparable relevant initiatives in the Member States.
 - Provide a clear description of the similarities and differences of the proposal as compared with existing acts (e.g. different field of application, complementarity).
 - Explain the timing of the proposal (why the proposal is presented now) and the sequencing of proposals related to the same policy sector.
- Consistency with other Union policies
 - Mention links with other Union policies, in particular in cases of 'mainstreaming', where significant and relevant (economic, competition, employment, environment, equal opportunities and gender equality, external implications of the policy on third countries, etc.). Keep this part concise and avoid overlaps with the 'impact assessment' section.

(2) LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- Legal basis

In accordance with the Interinstitutional Agreement on Better Law-Making⁵²⁹, the Commission should justify the legal basis of the proposal in a clear and complete way, especially where it would seem that several options exist.

⁵²⁸ See Tool #2 (*The Regulatory fitness and performance programme (REFIT) and the Fit for Future Platform*)

⁵²⁹ Interinstitutional agreement of 13 April 2016 on Better Law-Making, [EUR-Lex - 32016Q0512\(01\) - EN - EUR-Lex \(europa.eu\)](#)

- Explain what the legal basis of the proposal is. When several feasible options seem to exist, justify the choice based on objective criteria.
- Clarify whether the concerned policy area falls under an exclusive or shared competence or under other categories of competence (support and coordination competences).

- Subsidiarity and proportionality:

Demonstrating compliance of the proposal with the principles of subsidiarity and proportionality is a fundamental part of the explanatory memorandum. Refer to the main elements of the subsidiarity [grid](#)⁵³⁰. Avoid standard, general phrases that merely state that the proposal respects these principles. Aspects to include:

- Subsidiarity (the subsidiarity principle does not apply in areas where the Union has exclusive competence)
 - Explain what the Union dimension of the problem is. While respecting Union law, are well-established national arrangements and special circumstances applying in individual Member States respected?
 - Necessity test: Why can the objectives of the proposal not be adequately achieved by Member States? Is the scope of action limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?;
 - Effectiveness test: What is the most effective solution – that achieved by Union action or that achieved by possible national means? What specific EU-added value is expected by the envisaged Union measure and what would be the cost of taking no action at all?

- Proportionality

Explain the scope of chosen policy option:

- Does the option go beyond what is necessary to achieve the objective satisfactorily?
- Will the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?

- Explain the choice of instrument:

- Has the simplest form of Union action (instrument) been chosen?; is this choice consistent with the pursued objective and effective enforcement? Where appropriate, it should also be justified why a recast is or is not proposed⁵³¹.
- Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?

⁵³⁰ See Tool#5 (*Legal basis, subsidiarity and proportionality*)

⁵³¹ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Recasting>

(3) **RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

In support of evidence-based policymaking, the Commission should explain the preparatory analytical work undertaken, including evaluations and fitness checks of existing provisions, stakeholder consultations, the collection and use of expertise and impact assessments⁵³². Clearly describe any approved exemption from procedural requirements of the ‘better regulation’ and provide the justification. **If no evaluation or fitness check, consultation activity or impact assessment have been undertaken, this section should explain why.**

The section should provide a short overview of the main findings and how they have been taken account in the final proposal – for further details, references should be made to the relevant evaluation, impact assessment reports or staff working documents and to the Regulatory Scrutiny Board’s opinion, where relevant.

- Evaluation/fitness check and related opinions of the Regulatory Scrutiny Board (RSB)
 - Summarise the results of any evaluations/fitness checks of existing measures related to the policy objectives, clarifying the link to the identified problems that the proposal aims to tackle. Provide relevant links to available staff working documents, studies or reports;
 - In the case that the RSB issued an opinion on the evaluation/fitness check (or made comments related to the evaluation/fitness check included in the related IA report), summarise the Board’s findings and explain how they were taken into account;
- Stakeholder consultation
 - Describe the consultation(s) carried out and the tool(s) used (public consultation, consultation targeted at pre-selected organisations, hearings, etc.).
 - State briefly the main sectors and/or institutional bodies from which responses have been received, giving an objective and balanced summary of their answers. Avoid vague wording such as “the associations consulted broadly welcomed this initiative”. Provide link to published consultation results/reports (e.g. on ‘[Have Your Say](#)’ portal).
 - Summarise how the results of the consultation were considered in the proposal and, where appropriate, explain where the Commission’s views diverged and why;
- Use of expertise

If the Commission has relied on expertise⁵³³, describe the methodology used, the range of expertise consulted, the advice received, how expertise was taken into account and, where appropriate, indicate how to access any publicly available information (e.g. website).

- Impact assessment and opinion of the Regulatory Scrutiny Board

⁵³² <https://ec.europa.eu/info/sites/info/files/working-methods.pdf>. The explanatory memorandum will present the better law-making dimension and how the Commission plans to address the burdens added or reduced for business and citizens.

⁵³³ See Tool #4 (*Evidence-informed policymaking*)

A summary presentation of the main elements of the impact assessment (IA) process serves to strengthen the motivation underlying the proposed policy choice, and to show that the careful assessment of the policy options and significant impacts have been fully considered by the Commission. Given that some elements of the impact assessment process are reported on under other sections in the explanatory memorandum, this section should focus on the assessment of policy options and their significant impacts, as set out below.

- Where relevant, explain why the proposal is not supported by an impact assessment⁵³⁴. If the College has chosen not to undertake an impact assessment, the reasons therefore should be explained.
- Reference should be made to the initial political validation, the ‘call for evidence’ in which the need for an impact assessment has been addressed and also to the ‘better regulation’ guidelines;
- Provide the links to the IA summary and the final opinion of the Regulatory Scrutiny Board. Where no positive opinion was issued, a clear justification should be given for proceeding with the initiative;
- Summarise the main content of the Regulatory Scrutiny Board’s opinion and explain clearly how the opinion was taken into account.
- Explain which policy options were examined, how they compare and why the final proposal was the preferred policy choice.
- Describe the main economic, social, and environmental impacts of the preferred option, who would be affected and how.
- Summarise the key findings of the impact assessment (or ex-ante evaluation) relevant to the sustainable development goals (SDGs)⁵³⁵, based on the analysis presented in Annex 3 of the impact assessment (or the relevant analysis in ex-ante evaluation).
- Explain how the proposal upholds the ‘do no significant harm’⁵³⁶ and ‘digital by default’⁵³⁷ principles and contributes to achieving the European way for a digital society and economy.
- Explain the consistency of the draft measure or legislative proposal, including budgetary proposals, with the climate-neutrality objective set out in European Climate Law⁵³⁸, Article 2(1) and the Union 2030 and 2040 targets before adoption, as included in the impact assessment accompanying these measures or proposals. Also include the assessment whether these draft measures or legislative proposals, including budgetary proposals are consistent with ensuring progress on adaptation as referred to in Article 5. In any case of non-alignment, the Commission shall provide the reasons.
- Explain, where relevant, how the Commission screened and assessed territorial impacts in its proposals and accompanying explanatory memoranda⁵³⁹.

⁵³⁴ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁵³⁵ See Tool #19 (*Sustainable development goals*)

⁵³⁶ See Tool #36 (*Environmental impacts*)

⁵³⁷ See Tool #28 (*Digital-ready policymaking*)

⁵³⁸ Regulation(EU) 2021/1119 of 30 June 2021 establishing the framework for achieving climate neutrality (European Climate Law)

⁵³⁹ See Tool #34 (*Territorial impacts*)

- Quantified estimates of the impacts should be provided wherever possible, and reasons given where this is not possible;
 - If the final policy proposal deviates from the options assessed in the impact assessment, clarify in which way it deviates from these options and the likely impacts of this change. If there are additional costs created by the measure that have not been considered in the IA (particularly on SMEs), they should also be analysed and reported. Indicate if the final choice will reduce burden as compared to the preferred option of the IA.
- Regulatory fitness and simplification (REFIT)

This section aims at providing specific and clear information on the regulatory fitness of the final proposal and the extent to which regulatory burdens are minimized and proportionate to the objective to be achieved. **All revisions of existing legislation should assess the potential to simplify the legislation and to identify the potential to reduce any unnecessary regulatory costs. Quantification should be presented wherever possible. This REFIT-related work should be based on impact assessments and/or evaluations and fitness checks that support the initiative.**

The European Parliament and the Council are encouraged to take account of the burden reduction objective in their legislative work and the Member States in respect of their transposition and implementation of the legislation at national level.

This section of the explanatory memorandum should outline, in particular:

- If the proposal includes a revision of existing legislation and if the possibility to simplify the legislation and/or reduce unnecessary costs has been identified, then the explanatory memorandum should explain how these possibilities will be exploited by the proposal without undermining the achievement of the objectives of the legislation.
- Wherever pertinent, a **burden reduction objective**⁵⁴⁰ included for tackling unnecessary regulatory costs should be presented for the specific legislation. This should be based on the REFIT-related findings of the impact assessment and any earlier evaluation or fitness check.
- Quantified information should be presented, whenever possible.
- The Fit for Future Platform's opinion and how it was used in the impact assessment, evaluation or fitness check should be highlighted, where relevant.
- Who will be affected and how? What will the affected parties have to do to comply and what will public authorities have to do to ensure compliance?
- Why microenterprises are not exempted from the scope of the initiative, and whether there is a lighter regulatory regime for SMEs generally⁵⁴¹;
- How the expected compliance costs for SMEs and any other relevant stakeholders have been minimised, providing quantitative estimates, to the extent possible;
- How any negative effects on sectoral EU competitiveness or on international trade have been minimised;

⁵⁴⁰ See COM (2017) 651

⁵⁴¹ See Tool #23 (*The 'SME test'*) for examples of mitigating measures for SMEs.

- How the proposal is digital-ready and consistent with the operation of the internet, social media, and other digital developments. Will the proposal operate effectively in both the digital and physical worlds?⁵⁴²;
- **If there is no scope to simplify or reduce regulatory costs a short justification should be provided.**
- Fundamental rights

Where the proposal has significant consequences for fundamental rights, explain how the fundamental rights obligations have been met⁵⁴³. Where relevant, specify significant gender equality impacts and data protection aspects⁵⁴⁴.

(4) BUDGETARY IMPLICATIONS

Briefly outline the budgetary implications of the initiative (if any) and, where appropriate, refer to the ‘financial statement’ showing the budgetary implications and the human and administrative resources required.

(5) OTHER ELEMENTS

- *Monitoring, evaluation, and reporting arrangements:* Reference should be made to the compliance tools associated with the measure and a concise description should be given of the monitoring, evaluation and reporting framework proposed to assist the Commission with the implementation and application of the proposed act and with the reporting on its performance.
- *Variable geometry:* In case of proposals under Title V of Part Three of the TFEU (justice and home affairs), particular arrangements apply to the Ireland (protocol 21), Denmark (Protocol 22) and to different EU Member States and associated countries depending on their participation in Schengen (protocol 19). The implications of the proposal on these countries should be explained where relevant.

(6) DETAILED EXPLANATION OF THE SPECIFIC PROVISIONS OF THE PROPOSAL

In addition to the general explanation of the reasons for the Commission proposal, more information should be provided on the various provisions, with a commentary on each chapter or article. Such a commentary may focus on selected key articles including those provisions intended to simplify the legislation or tackle unnecessary regulatory costs. This text should have added value for the future interpretation of the proposed act. A more detailed commentary may be useful for explaining any new ideas in the proposal (in particular if such an explanation goes beyond the general framework of the explanatory memorandum). An article-by-article commentary may be very useful in case of doubts on the interpretation of a particular provision. Where the proposal codifies or replaces an existing text, the detailed

⁵⁴² See Tool #28 (*Digital-ready policymaking*)

⁵⁴³ See Tool #29 (*Fundamental rights, including the promotion of equality*)

⁵⁴⁴ Including if the European Data Protection Supervisor and European Data Protection Board have been or will be consulted. See Article 42, Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

commentary may indicate those provisions from the existing text that are taken over (or codified) in the proposal.

TOOL #41. GUIDANCE DOCUMENTS CONTAINING LEGAL INTERPRETATION OF EU LAW

1. INTRODUCTION

Commission documents frequently provide guidance to Member States and/or stakeholders in applying and implementing EU law. Such guidance may contain interpretation of EU law⁵⁴⁵. In such cases, according to the case law⁵⁴⁶ of the Court of Justice of the European Union, Commission guidance documents may produce legal effects, i.e. they may legally bind the Commission⁵⁴⁷.

Guidance documents are any texts with guidance on how Member States and/or stakeholders are to apply EU legal instruments. Guidance on the interpretation of EU legal instruments may bind the Commission and must in principle be adopted by the College of Commissioners.

2. GUIDANCE DOCUMENTS CONCERNED

College endorsement is required for guidance documents that contain interpretation of EU law, including interpretation provided in the framework of compliance promotion tools⁵⁴⁸, unless such documents are part of the Commission's normal administrative operations.

Box 1. Interpretation of EU law

Interpretation of EU law means that the document sets out a position on how one or more EU law provisions should be interpreted and/or applied. This is typically the case when, for example:

- an EU law provision can be understood in various ways and the guidance document sets out the Commission's understanding (or defines the Commission's interpretation);
- the guidance document clarifies whether a certain activity falls under the scope of a given EU legal instrument;
- the Commission adjusts its earlier position after a Court judgment⁵⁴⁹.

⁵⁴⁵ The Commission has an autonomous power to issue guidance documents (Article 292 TFEU referring to the Commission's power to issue recommendations) so the legislator may not impose obligation to issue guidance. Frequently, however, legislative measures contain such obligations. See, for example, Annex I, points (a) and (b), to Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions.

⁵⁴⁶ See, for example, Case T-472/12 *Novartis v Commission*, point 67; Case T-376/12, *Greece v. Commission*, point 108; Joined Cases T-61/00 and T-62/00, *APOL*, point 72. See also the Opinion of AG Mazak in case C-527/07, point 37.

⁵⁴⁷ Therefore, staff working documents should, as a rule, not include such guidance. See the joint note from the Legal Service and the Secretariat-General in relation to the use of staff working documents (SEC(2013)663, Ares(2014)642944).

⁵⁴⁸ See Tool #38 (*Compliance promotion and verification tools*).

⁵⁴⁹ Examples: [The Practical Guide on Posting of Workers](#); [Guidance on the interpretation and application of Council Directive 93/13/EEC on unfair terms in consumer contracts](#); [Guidance on the application of exemptions under the Environmental Impact Assessment Directive \(C/2019/8014\)](#). Examples of guidance documents can be found in the Commission's annual reports on monitoring the application of EU law.

Services should assess on a case-by-case basis and based on the content of the document whether it contains interpretation of EU law and whether interpretation goes beyond the Commission's normal administrative operations. The services' contact points in the Legal Service and or the Secretariat-General (SG Infractions) may assist in identifying whether this is the case.

The following documents are not considered guidance documents containing legal interpretation going beyond the Commission's normal administrative operations:

- guidelines used only internally;
- documents of a factual nature illustrating best practices;
- documents that contain only information on the existence of EU law provisions or merely paraphrase their contents (such as basic explanation given in a simplified, citizen-friendly way) or on their application (such as defined in the compliance tools⁵⁵⁰).

As part of their normal administrative operations, the Commission services have regular contacts with Member States' administrations and other stakeholders. In this context, the Commission services are frequently requested to provide *ad hoc* interpretation of legal provisions or technical advice on the practical application of those provisions.

In so far as the interaction with the Member States does not take the form of general guidance on the legal provisions or remains at a very technical level, or when the interpretation presented merely confirms a Commission position already approved by the College, the requirement to seek College endorsement does not apply.

For example, this may be the case where services are requested to clarify the interpretation of certain legal provisions during expert group meetings, committees⁵⁵¹ or in bilateral contacts with a Member State's administration or any other meetings with one or more Member States or stakeholders⁵⁵².

Whenever a formal written reply is provided (for example, in the summary minutes of an expert group meeting, in letters or in e-mails with more than ephemeral significance, or Q&As published on sites accessible to relevant Member State authorities⁵⁵³), the service should mention that the reply reflects the position of the Commission services and does not commit the Commission. In those cases, the following disclaimer should be added:

"This [...] was prepared by/ expresses the view of the [Commission services/ DG ...] and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law."

The Legal Service must be consulted on the envisaged interpretation of EU law and will help, if needed, to determine whether the envisaged action is covered by this note. The Legal Service may also assist in specific cases where submitting general guidance documents to College endorsement raises particular problems.

⁵⁵⁰ A collection of statistical and factual information on, for example, how a certain directive has been implemented so far across the Member States.

⁵⁵¹ This includes meetings of comitology committees or non-comitology committees (e.g. the European Social Fund Committee).

⁵⁵² This is the case, for instance, for monitoring committee meetings of European Structural and Investment Funds, where the Commission participates in an advisory capacity.

⁵⁵³ Example: Coronavirus Response Investment Initiative Platform

3. PREPARATION AND FORMAT

In preparing guidance documents, services should check if any of the ‘**better regulation**’ **requirements** are to be applied⁵⁵⁴. Guidance documents falling under the scope of Decide should have the appropriate planning entry and political validation before preparatory work begins⁵⁵⁵. Guidance documents are normally subject to an **interservice consultation**⁵⁵⁶.

A guidance document containing an interpretation of EU law to be used by Member States, stakeholders and the general public is to be adopted by the Commission in the form of a Commission interpretative Communication or Notice (with a ‘C’ serial number). It should be adopted in all official EU languages and published in the C series of the Official Journal.

In those cases where the guidance document exclusively concerns interinstitutional relations⁵⁵⁷, it should be adopted by the Commission as a Commission ‘Communication’ (with a COM serial number) addressed to the other institutions and published on EUR-Lex⁵⁵⁸. Such Communication may be adopted in the three working languages, but its publication requires translation into all official EU languages.

In choosing the format for the guidance document, it is recommended that services consider that Commission communications (contrary to Commission notices) may not extend to more than 15 pages (unless agreed with the DGT). Detailed information on the procedures necessary to issue these documents is provided on GoPro⁵⁵⁹.

Where documents contain both factual information and interpretation of legislative provisions and the scope and length of the document so justifies, the factual information may be set out in a staff working document accompanying the Commission communication or Commission notice.

Such Commission guidance documents containing interpretation of EU law should have a disclaimer to clarify that it is ultimately for the Court of Justice to ensure the uniform interpretation of EU law. The following sentence should be added in the document:

“This [...] is intended to assist [citizens and businesses/ national authorities] in the application of this [EU legislation]. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.”

Regarding guidance documents which have already been made public (or released to third parties), services are requested to follow these guidelines once they decide to revise/update the interpretation of EU law in these documents.

⁵⁵⁴ For example, an impact assessment may be needed.

⁵⁵⁵ See Tool #6 (*Planning and political validation of initiatives*)

⁵⁵⁶ To note that documents that are not adopted by the College (staff working documents) should also be submitted to an interservice consultation, see LS/SG note mentioned above.

⁵⁵⁷ For example, Commission Communication of 9 December 2009 - Implementation of Article 290 of the Treaty on the Functioning of the European Union (COM(2009)673 final).

⁵⁵⁸ It is to be noted that in certain languages, no distinction is made between a Commission interpretative notice and a Commission interpretative communication (for example, in French, both documents will be entitled ‘communication’).

⁵⁵⁹ [https://eceuopa.eu.sharepoint.com/:u:/r/sites/gopro/SitePages/Autonomous-acts\(1\).aspx?csf=1&web=1&e=ZLOnEu](https://eceuopa.eu.sharepoint.com/:u:/r/sites/gopro/SitePages/Autonomous-acts(1).aspx?csf=1&web=1&e=ZLOnEu)

TOOL #42. DELEGATED AND IMPLEMENTING ACTS

1. INTRODUCTION

The vast majority of EU legal acts are adopted by the Commission in accordance with powers conferred on it by the legislator in basic legislation, either in accordance with Article 290 (delegated acts) or Article 291 (implementing acts) of the Treaty on the Functioning of the European Union⁵⁶⁰. The institutions agreed non-binding delineation criteria in 2019⁵⁶¹ to guide the choice between the two instruments.

A legislative act may grant the Commission powers (‘empowerments’) to adopt delegated acts: legal acts of general application to supplement or amend certain non-essential elements of a legislative act. The Interinstitutional Agreement on Better Law-Making⁵⁶² between the European Parliament, the Council and the Commission and the **Common Understanding on Delegated Acts**, as annexed to it, set out the practical arrangements and commitments of the institutions on the exercise of these powers.

Empowerments for implementing acts are used where uniform conditions for implementing legally binding Union acts are needed. The rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers have been laid down in the Comitology Regulation⁵⁶³. Implementing powers shall be conferred on the Commission in the legally binding acts concerned.

Guidelines for the Commission services are in place providing detailed explanations on how empowerments for delegated and implementing acts should be included in basic acts, how the empowerments should be used, how delegated and implementing acts should be prepared and how the respective control mechanisms work⁵⁶⁴.

‘Better regulation’ principles apply to the preparation of delegated and implementing acts as specified in this tool. The key principles are explained below.

2. REQUIREMENTS THAT APPLY TO DELEGATED AND IMPLEMENTING ACTS

Standard clauses must be used when including empowerments for delegated and implementing acts in basic acts. For delegated acts these standard clauses have been agreed between the institutions in the appendix to the Common Understanding on Delegated Acts. For implementing acts, templates for the empowerments are set out in the Drafters’ Assistance Package (DAP)⁵⁶⁵.

⁵⁶⁰ An important number of acts are also still adopted under the regulatory procedure with scrutiny (RPS), set out in Article 5a of Council Decision 1999/468/EC. ‘Better regulation’ principles apply to these measures as well.

⁵⁶¹ The delineation criteria were negotiated and agreed between the Parliament, Council and Commission pursuant to a commitment to that end in point 26 of the Interinstitutional Agreement on Better Law-Making. The criteria are published in OJ 2019/C 223/01.

⁵⁶² [Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making](#) of 13 April 2016 (OJ L 123, 12.5.2016, p. 1)

⁵⁶³ Regulation (EU) 182/2011, OJ L 55, 28.2.2011, page 13.

⁵⁶⁴ Guidelines on Delegated and Implementing Acts, [SEC\(2020\)361](#).

⁵⁶⁵ <https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=dap&title=Home>

The **use of empowerments must be properly planned**. Basic acts often contain several empowerments, sometimes with an obligation for the Commission to act by a specific time and may contain reporting obligations relating to delegated acts.

Delegated and implementing acts should be entered in **Decide planning**, either as 'politically sensitive and/or important' (PSI) initiatives (at the latest 12 months before planned adoption date) or as non-politically sensitive and/or important, as for any other initiative⁵⁶⁶.

A **'call for evidence'**⁵⁶⁷ should be prepared for all delegated and implementing acts identified as PSI initiatives.

Impact assessments should be prepared for delegated and implementing acts when the expected economic, environmental, or social impacts of EU action are likely to be significant and the Commission has a margin of discretion regarding the content of the act⁵⁶⁸. The principle of proportionate analysis applies and the appropriate level and focus of the impact assessment is linked to the type of policy initiative. The impact assessment should be sent to the Regulatory Scrutiny Board for its scrutiny in the usual way⁵⁶⁹. Once the impact assessment report has received a positive opinion from the RSB, it should accompany the implementing act or delegated act as part of the interservice consultation.

Whenever **broader expertise** is needed in the early preparation of delegated and implementing acts the Commission will make use of expert groups, consult targeted stakeholders and carry out public consultation, as appropriate⁵⁷⁰.

Whenever Commission services share early drafts of acts or measures or other preparatory documents with Member State representatives in the relevant committee or expert groups, it must be absolutely clear that these documents are in no way endorsed or adopted by the College⁵⁷¹.

An **interservice consultation** must be carried out, followed by publication for a **4-week public feedback** with certain exceptions⁵⁷².

Where applicable **notifications** of drafts under the Agreement on Technical Barriers to Trade (TBT) or the Agreement on the application of Sanitary and Phytosanitary measures (SPS) in the WTO framework need to take place.

Subsequently, delegated acts are adopted by the Commission and implementing acts are submitted to the committee for an opinion and then adopted by the Commission (if the committee opinion allows).

When the basic acts provides for such a possibility, in the relevant (and duly justified) cases an urgency procedure can be applied for both delegated and implementing acts, allowing them to be adopted and enter into force immediately. However, the control mechanisms (see below) remain applicable post-adoption.

⁵⁶⁶ See Tool #6 (*Planning and validation of initiatives*)

⁵⁶⁷ See Tool #6 (*Planning and validation of initiatives*) and Tool #7 (*What is an impact assessment and when it is necessary*)

⁵⁶⁸ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁵⁶⁹ See Tool #3 (*Role of the Regulatory Scrutiny Board*)

⁵⁷⁰ See Chapter VII on stakeholder consultations

⁵⁷¹ For practical guidance please see <https://webgate.ec.europa.eu/fpfis/wikis/x/fwIUCQ>

⁵⁷² See Chapter VII on stakeholder consultations

2.1. Delegated Acts

Delegated acts need to be prepared in line with the commitments in the Interinstitutional Agreement on Better Law-Making and in the **Common Understanding**, in particular **Member State experts must always be consulted on draft delegated acts** and the **European Parliament and the Council must receive all documents sent to Member State experts** and can send experts to **participate in expert groups** or ad hoc meetings preparing the delegated acts.

Expert groups assisting in the preparation of delegated acts are subject to the rules applicable to expert groups⁵⁷³.

Delegated acts must include an explanatory memorandum⁵⁷⁴.

A basic act may contain several empowerments for delegated acts. On the condition that the Commission provides objective justifications based on the substantive link between two or more empowerments contained in a single legislative act, and unless the legislative act provides otherwise, empowerments may be **bundled**. Consultations in the preparation of delegated acts also serve to indicate which empowerments are considered to be substantively linked (see Interinstitutional Agreement on Better Law-Making, point 31 and Guidelines on Delegated and Implementing Acts, points 130-133). A single delegated act may not be based on empowerments from different basic acts.

After adoption of the delegated act by the Commission, the European Parliament and the Council have the right to object (*two months, generally*). If they do not or if they inform the Commission before the objection period expires that they are not going to object, the delegated act can be published and enters into force.

In case of objection, the Commission must decide on the next steps to take.

The [Register of delegated and implementing acts](#) provides an overview of all the steps in the lifecycle of delegated and implementing acts, from planning to publication in the Official Journal. Draft and final delegated acts and draft and final implementing acts and their progress in the internal decision-making process can be found in the related bibliographic page for the relevant legal acts, under the 'Internal Procedure' tab⁵⁷⁵, in EUR-Lex⁵⁷⁶.

2.2. Implementing Acts

Implementing acts need to be prepared and, where provided for by the basic legal act, submitted to Member State control in the respective committee in accordance with the Regulation laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers – the Comitology Regulation⁵⁷⁷.

⁵⁷³ See rules on expert groups: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Expert%20groups>

⁵⁷⁴ See Tool #40 (*Drafting the explanatory memorandum*)

⁵⁷⁵ For further details, see the Frequently asked questions in EUR-Lex: <https://eur-lex.europa.eu/content/help/faq/intro.html>

⁵⁷⁶ <https://eur-lex.europa.eu/homepage.html>

⁵⁷⁷ Regulation (EU) 182/2011, OJ L 55, 28.2.2011, p.13.

The European Parliament and the Council are informed through the [Comitology Register](#). The European Parliament and the Council have a scrutiny right until adoption which is limited to the exceedance of the implementing powers provided for in the basic act (Art. 11 of the 'Comitology' Regulation). The exercise of this right does not prevent the Commission from adopting the draft implementing act, however in case the European Parliament or the Council indicate that in its view the draft act exceeds the implementing powers, the Commission shall review the draft implementing act (taking into account the position expressed) and inform whether the draft act is maintained, amended or withdrawn.

3. FURTHER READING AND REFERENCES

- [OJ L 55, 28.2.2011](#), page 13
- [GoPro pages](#)
- Guidelines on Delegated and Implementing Acts, [SEC\(2020\)361](#)
- [Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016](#) (OJ L 123, 12.5.2016, p. 1)
- [Non-Binding Criteria for the application of Articles 290 and 291 of the Treaty on the Functioning of the European Union](#) — 18 June 2019, OJ 2019/C 223, page 1.
- [Register of delegated and implementing acts](#)
- [Comitology Register](#)

Chapter 5 – Monitoring the application of interventions

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TOOL #43. MONITORING ARRANGEMENTS AND INDICATORS

1. WHAT IS MONITORING?

Monitoring is a continuous and organised process of systematic data collection (or access) throughout the life cycle of an initiative⁵⁷⁸ to oversee its progress. Monitoring is necessary to generate information that feeds into future evaluation and impact assessments and to provide solid evidence base for policymaking. Monitoring generally involves tracking progress with respect to previously identified targets or objectives. While monitoring most frequently uses quantitative data, using qualitative data is also possible.

Monitoring is therefore necessary and can be used for a variety of purposes. Some of the most frequent reasons for monitoring include:

- understanding of how initiatives are proceeding; it can serve as an early warning system, for instance in case of weak progress of an initiative or unexpected or unintended findings, when it may suggest a need for subsequent corrective adjustments;
- evidence-informed policymaking, by tracking and reporting on implementation progress against objectives and targets and enhancing accountability;
- addressing external requirements for compliance and control, such as stakeholders' demands for reporting and accountability;
- effective communication to wider stakeholders, ensuring transparency on EU initiatives and helping to explain the progress towards policy goals.

It is important to note that monitoring data could sometimes capture changes that are both due to the EU initiative *and* to other factors.

Monitoring is an integral part of the evaluation. Monitoring aims to track systematically the progress of an initiative during its implementation. It is one of the sources that informs the evaluation, which entails a more encompassing and in-depth retrospective assessment of whether the initiative actually achieved its objectives and how. Evaluation also assesses whether the objectives have been met efficiently (i.e. at least cost), as well as the reasons for its success or otherwise. Evaluation also captures the causality between the effects and the evaluated initiative, which is not the case for monitoring.

Monitoring and evaluation are complementary as they aim to check whether policy objectives are being achieved. For instance, to monitor progress towards objectives, one must measure inputs (such as actual expenditure of funds), outputs (such as numbers of individuals/firms affected), results and impacts related to the intervention logic, to the extent of available data; this information is one of the sources necessary for the more in-depth analysis in the evaluation. Moreover, monitoring may also collect data on other contextual indicators like macroeconomic conditions, such as unemployment in the local labour market, which may be facilitating or blocking the initiative from bearing its intended effects. The same contextual indicators might be useful in evaluation.

The implication of this observation is that **monitoring can be used to collect data for the evaluation** on inputs, outputs, results, impacts and contextual information. One limitation

⁵⁷⁸ 'Initiative' refers to policy, legislation or spending programmes and financial instruments.

occurs when the initiative takes a long time before some of its effects start to materialise or when changes in the policy cannot be attributed solely to the initiative; in this case, the monitoring may not capture the intended effects of the policy. However, the data collected by the monitoring could be used by the evaluation even if the effect may have not materialised or it is impossible to precisely distinguish the attribution of effects. A good practice that can limit the problem of the time lag between the initiative materialisation and measuring its effects is that monitoring is done on an ongoing basis, even beyond programming periods, to ensure data collections based on a stable framework and long time-series. This will improve data availability and eventually the evaluations quality.

Monitoring and evaluation arrangements should be analysed in the impact assessment report, for the preferred option if one is specified or otherwise based on the initiative's objectives⁵⁷⁹. This part of the impact assessment should inform the legal provisions on monitoring and evaluation to be included in the proposal itself⁵⁸⁰. Main elements may include **indicators** and/or **regulatory reporting requirements**⁵⁸¹. Reporting requirements are a prerequisite to ensure the timely monitoring of EU initiatives⁵⁸². The monitoring and evaluation arrangements that were initially identified in the impact assessment will need to be reflected in the Commission's proposal. They might have to be revisited again later to reflect changes to the proposal made in the legislative process to avoid that the indicators initially chosen no longer reflect objectives of the initiative.

2. SETTING UP A MONITORING SYSTEM

Given that monitoring is a systematic process to track progress and generate information for evaluation, arrangements need to be set-up for collecting, processing, and using/reusing data.

Setting up a monitoring system could benefit from IT support. Digitalisation will lead to simplification, burden reduction and less errors only when the monitoring processes and related data flows are well considered and streamlined in advance. To this end, it is important that policy officers consider the use and the reuse of IT systems and reuse of data, whenever possible as well as data protection aspects⁵⁸³.

Capabilities of such an IT system⁵⁸⁶ could include:

- cataloguing data collection requirements (frequency of data provision, actors, etc.);
- collecting or harvesting data;
- data storing;
- data quality assurance, including (automatic) validation;
- data processing and analysis;
- database interoperability;
- data visualising⁵⁸⁴, sharing and disseminating results;
- data access and discovery (for example by making available metadata or referencing your data on data.europa.eu).

⁵⁷⁹ See Tool #11 (*Format of the impact assessment report*)

⁵⁸⁰ See Tool #43 (*Legal provisions on monitoring and evaluation*)

⁵⁸¹ Regulatory reporting is the provision of periodical structured or unstructured data (qualitative or quantitative) from concerned Member States, private and public organisations to competent authorities (at EU or national level).

⁵⁸² For more guidance, visit the Commission's [Regulatory Reporting Community of Practice](#)

⁵⁸³ For example, local data correspondents or local IT services can provide more information.

⁵⁸⁴ <https://data.europa.eu/apps/data-visualisation-guide/>

The following sections describe the different steps for setting up a monitoring system.

2.1. Identify what to monitor

An initiative should be monitored during its lifecycle, from the **implementation** and **application** to the **compliance and enforcement**. The initiative objectives define what to monitor. What can be and needs to be monitored depends to some extent on whether the initiative is a regulatory proposal, a spending programme or other (for example a strategy). However, it can be helpful to think of monitoring an initiative in terms of inputs, outputs, results, and impacts, which should be aligned to the intervention logic – see figure 1.

- (1) **Inputs:** often money and material resources, for example any budget executed, human resources allocated. While inputs can be easily monitored, they give no indication of the outputs or impacts of the initiative;
- (2) **Outputs:** the immediate tangible and countable products/services produced because of the initiative. For regulatory initiatives, outputs will concern their implementation and application, e.g. the transposition into the national laws of the Member States in case of a directive and, more generally, adoption of measures that are necessary to comply with the regulatory requirements and to enable the legislation to be effectively applied by Member States or others. This may also concern monitoring compliance and enforcement (for example, extent of compliance by businesses, measurements taken, inspections carried out, court cases pursued). Outputs are directly connected with the operational objectives of the initiative, and hence, they are a reasonable measure of progress. They will be measurable in a short elapse of time (low data lag) and are influenced less by external factors.

Examples: *Kilometres of roads built, scholarships awarded, consultancy services developed, standards developed, databases created, labelling requirements implemented, number of SMEs supported, websites created, etc.*

- (3) **Results and impacts:** results match the immediate direct effects of the initiative with particular reference to the direct addressees. If an initiative aimed to support SMEs, a result might be the number of jobs created in the supported SMEs. Impacts concern the long-term wider effects on society, environment, etc., beyond those directly affected by the initiative. The distinction between results and impacts may sometimes be difficult to define, depending on the intervention logic. It is also often challenging to link the initiative to impacts. A variety of factors may be involved, and it could be difficult to differentiate between correlation, causality and incidental. For impacts, the data lag is higher for results and even more so than for outputs.

Examples: *Improvement in median income, or an overall increase in employment rate; safety incidents at EU level; tax compliance; innovations/new products generated in the sector; time saved by users of a road; survival rate of businesses; consumption of low fat, low sugar food; mutual recognition of nationally approved products; permissions/derogations granted; bans introduced; e-invoices exchanged cross-border; tax declarations filed, reduction of inputs (e.g. fertilisers and pesticides), etc.*

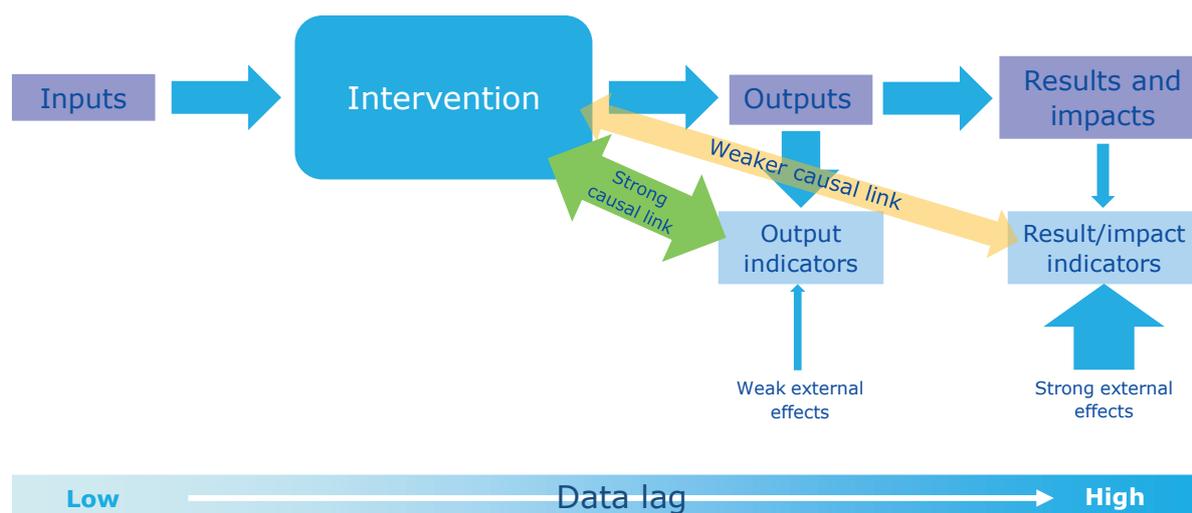


Figure 1: System view of an initiative

In addition to monitoring progress of an individual initiative, **contextual information**⁵⁸⁵ should also be collected. Contextual information refers to developments that are not intentionally related to the individual initiative, although they may influence it or be influenced by it, such as the economic growth, break-through (emerging) technologies, new behavioural patterns etc.

Results and impacts are ultimately the most relevant measures of performance of an initiative (whether financial programme or other), since they relate to finding the answer to the most important question: *is the initiative actually achieving what it set out to do?* It is the role of the evaluation to analyse this. In particular, two aspects complicate answering this question.

The first relates to the aspect of **causality**. Results and impacts usually relate to changes that are influenced by a wide range of factors, of which the initiative is only one.

For example, impacts on employment rates, health, innovation, and agriculture can be influenced by national policies, other initiatives, global context and many other factors. For example, in the agricultural case, suppose that the digitalisation intervention was implemented during a time of ideal weather. The productivity in the area in which the digitalisation intervention was implemented increased over previous years. However, is the productivity increase a result of the intervention? Or is it caused by other factors, such as increased rainfall, lack of frost-spell, etc.?

It is usually hard to know to what extent a change in a result/impact indicator is due or can be attributed to the initiative or to something else. To separate the effect of the initiative from other effects, appropriate evaluation methods should be used, such as counterfactual analysis. This requires detailed data and designing monitoring (and evaluation) from before the start of the initiative. A possible partial answer to this problem is to collect also contextual indicators on other drivers of the monitored phenomenon.

The second aspect relates to **timeliness**: depending on the initiative, it can take several years or more before it can actually have an impact, and even longer before that impact can be measured. Before that point, other indicators must be used.

⁵⁸⁵ ESTAT can be consulted for further details on contextual information.

For these reasons (causality and timeliness), measuring outputs and results (to a certain extent), is often more suitable for monitoring the progress of an initiative. Most results and impacts are analysed via evaluation.

2.2. Indicators

Indicators are a key part of a monitoring system. Generally, an indicator is a quantitative or qualitative indication of how close an initiative is to achieving its set goal; it is a factor or variable used to measure aspects of policy or programme progress. Indicators must be linked with the objectives of the initiative, and they must relate to different stages of the initiative (inputs, outputs, results, and impacts) (see section 2.1). Indicators could help analyse and compare performance across population groups or geographic areas and can be useful for informing the policy cycle. They set requirements on data that needs to be collected.

Indicators can give only one perspective of the performance of an initiative, depending on the type of indicator selected, timing, data, external influences, and other factors. It is important therefore to select a set of indicators carefully, be aware of their limitations and possible burden for their data collection. Indicators should be selected in such a manner to provide relevant and reliable information at an affordable cost. Attention must be paid also to the chosen set of indicators to avoid an unintended negative impact on the actual delivery of an initiative. For example, choosing an indicator reflecting shortening the waiting time in health care sector to monitor the progress towards improving access to healthcare may introduce pressure to shorten the waiting period with a negative impact on treatment quality.

Defining indicators should include the description of what exactly they are measuring, metadata and qualitative analysis, as appropriate.

There is no clear-cut rule on the appropriate level of detail for indicators. This will depend on the type of initiative, the complexity of the intervention logic and the hierarchy of objectives constructed for a particular initiative. In principle, however, the smarter the policy objective⁵⁸⁶, the easier to define a corresponding indicator.

Indicators should be chosen based on a set of clear criteria. To the extent possible, all indicators should be **RACER**, which means:

- (1) **Relevant**, i.e. closely linked to the objectives to be reached;
- (2) **Accepted** (e.g. by staff, stakeholders). The role and responsibilities for the indicator need to be well defined. For example if the indicator is the handling time for a grant application and the administrative process is partly controlled by Member States and partly by the EU, then both sides would assume only partial responsibility.
- (3) **Credible** for non-experts, unambiguous and easy to interpret;
- (4) **Easy to monitor** (e.g. at low cost and with acceptable administrative burden);
- (5) **Robust** against manipulation (e.g. if the target is to reduce administrative burdens to businesses, the burdens might not be reduced, but just shifted from businesses to public administration).

However, on top of the RACER criteria, other important criteria should be considered:

⁵⁸⁶ See Tool #15 (*How to set objectives*)

- (6) **Attributable:** changes in the indicator should be attributable to the initiative. There should be a clear causal link, unless the indicator is to be used for contextual information only;
- (7) **Data** should be easily/readily available and of a good quality, ideally at national/regional level if appropriate;
- (8) **Timeliness:** Indicators should capture the effects due to the initiative within a reasonable length of time, taking into account also the frequency of capturing or measuring the indicators;
- (9) **Baseline and target:** for monitoring progress, it is important to clarify the link to the relevant policy objective, have baseline (starting point) and explained target values to put the indicator value into context, for example which assumptions are used to derive the target from the baseline;
- (10) **Metadata:** Indicators definition should come with the unit of measurement, the source of the data, frequency of data collection and any other relevant information to facilitate data sharing, use and reuse, and aggregation.
- (11) **Data protection legal framework.**

Table 1: Examples of links between objectives and indicators

Objectives	Indicators
To develop and provide global satellite-based radio navigation infrastructures and services ⁵⁸⁷	<ul style="list-style-type: none"> • Cumulative number of operational satellites • Version of deployed terrestrial infrastructure • Number of services implemented
Strengthen sustainable innovation ecosystems and bring new solutions to the market ⁵⁸⁸	<ul style="list-style-type: none"> • No. of product innovations (goods or services) launched on the market • Start-ups supported and survival rate
Ensure interoperability and continuity of Cooperative Intelligent Transport Systems (C-ITS) services across the EU ⁵⁸⁹	<ul style="list-style-type: none"> • Number of C-ITS stations deployed • % of road network type covered by C-ITS services • Standardisation and profiling of new C-ITS services and communication methods • Revisions of the specifications to consider technological progress

It is usually not possible to find indicators that perfectly meet all criteria. Some quantities are particularly difficult to measure, such as illegal migration, counterfeits, social inclusion. In these cases, proxy indicators may need to be used. For example, in agricultural sector the actual use of pesticides by farmers could help measuring their effect on biodiversity (i.e.

⁵⁸⁷ <https://ec.europa.eu/budget/library/biblio/documents/2019/WD%20I%20with%20covers.pdf>

⁵⁸⁸ <https://ec.europa.eu/transparency/regdoc/rep/10102/2019/EN/SWD-2019-330-F2-EN-MAIN-PART-1.PDF>

⁵⁸⁹ <https://ec.europa.eu/transparency/regdoc/rep/10102/2019/EN/SWD-2019-96-F1-EN-MAIN-PART-1.PDF>

pollinators). It is nevertheless difficult to monitor it. A proxy could be the sales of pesticides, which provide an indication of the maximum amount of pesticides potentially used.

It is in any case always important to understand and explain the limitations of the indicators and of the monitoring in general.

Where impacts concern complex multidimensional concepts such as wellbeing or innovation, *composite indicators* may be a useful tool. Composite indicators aggregate a set of indicators into a single measure, such as country ratings and well-being indicators but also ratings of financial institutions and instruments. However, as they often use predefined weight values, they may be difficult to interpret and are usually more suitable for assessing the broad context rather than specifically tracking the progress of an initiative⁵⁹⁰.

At the end of the process, it might be useful to summarise the system of indicators and monitoring in tabular form:

General/Specific/Operational objective	Indicator	Definition	Type of indicator	Unit of measurement	Data source	Frequency of measurement	Baseline	Target	Data quality rating

For issues on **indicators and composite indicators**, the European Commission's *Competence Centre on Composite Indicators and Scoreboards* (based at JRC) can provide support⁵⁹¹.

2.3. Check any existing data and data arrangements

Before designing a monitoring system, one should first assess whether any existing monitoring and evaluation systems can be used, either those developed and used for earlier versions of the initiative or for related initiatives⁵⁹². Consider the following:

- **What data is already being collected and how is it used?** By whom is the data used and for which purpose?⁵⁹³ Is the data needed and sufficient for monitoring the implementation progress of the new initiative? If not, why not? Is the data used or can it be used for other purposes, including by considering data protection aspects? Is some relevant data already being collected in the context of monitoring other initiatives?
- **How is data collected?** To what extent do monitoring structures already exist? Are they interoperable? By whom is data collected (e.g. the Commission, Member States, intermediaries such as Agencies, operators/beneficiaries) and with what regularity? Are the existing data format and data collection compatible with your monitoring needs?

⁵⁹⁰ Various categories of indicators exist, such as qualitative/quantitative, local/global, monetary-non-monetary, etc.

⁵⁹¹ jrc-coin@ec.europa.eu

⁵⁹² A first assessment of monitoring systems in place should be provided in the relevant evaluations.

⁵⁹³ Beware that collected data need to be analysed to turn them into useful information.

- **Is data relevant and timely and of sufficient quality?** (See the section 2.2 on indicator criteria for more details.)

Before proposing new monitoring structures and data requirements, it should be carefully assessed to what extent the existing data reflect the (new) objectives set. If data gaps are identified, the purpose for which the data will be used and whether it can be collected via existing monitoring structures need to be considered in detail. If the additional data collection implies significant administrative burden – be it for businesses, citizens, or public authorities – it should be measured through the EU Standard Cost Model⁵⁹⁴ and demonstrate that it is proportionate compared to the identified data (and policy) needs. The cost of setting up and maintaining a monitoring system should also be considered among the cost impacts of options⁵⁹⁵.

A possibility for streamlining the existing regulatory reporting requirements should always be considered to minimise additional administrative burden⁵⁹⁶, for example by pooling them across policies or simplifying via web-based electronic collection.

2.4. Identify data sources

Data for monitoring can be gathered from many sources⁵⁹⁷.

- Many legal measures contain provisions requiring the production of different documents and reports on the performance of an initiative at a given point in time⁵⁹⁸. Member States may have to report on what they have done in accordance with the initiative provisions or about the national progress; beneficiaries may have to provide data, or the Commission may assess its own actions or those of Member States. Examples include implementation reports on the current state of play in the implementation and application of the EU measure, interim and final evaluations. One should always consider whether these reporting arrangements could be made potentially less burdensome, for example by substituting data reporting with data access to the sources in Member States that already hold the data, under proper confidentiality clauses or data reuse.
- EU decentralised agencies and other EU bodies, the European Parliament, Member States, NGOs, think tanks and consultants, also produce reports on various aspects of EU activities or areas where EU initiatives combine with a range of other actions.
- Higher-level data and indicators relating to impacts and contextual information can be gathered via Eurostat, the OECD, the World Bank, the UN, and other international organisations.

⁵⁹⁴ See Tool #58 (*EU Standard Cost Model*)

⁵⁹⁵ See paragraph 22 of the Inter-institutional Agreement for Better Law-Making of 13 April 2016: *In the context of the legislative cycle, evaluations of existing legislation and policy, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action. To support these processes, the three Institutions agree to, as appropriate, establish reporting, monitoring and evaluation requirements in legislation, while avoiding overregulation and administrative burdens, in particular on Member States. Where appropriate, such requirements can include measurable indicators as a basis on which to collect evidence of the effects of legislation on the ground.*

⁵⁹⁶ This [guidance document](#) can help setting regulatory reporting requirements.

⁵⁹⁷ See Tool #4 (*Evidence-informed policymaking*)

⁵⁹⁸ It is important to note that if a legal obligation does not cover an indicator or the data collection, it might be very challenging to obtain the necessary information.

- In particular cases emerging technologies (such as earth observation or text mining) might be considered when automatically extracting information from text sources such as Twitter, worldwide news, large document corpora, etc. The European Commission's *Competence Centre on Text Mining and Analysis* (based at JRC) may offer support⁵⁹⁹.

When collecting data, attention should be paid to international classification and/or agreed definitions from scientific literature. Classification systems are tools that allow harmonised registration of data. The Commission uses international classifications to collect high-quality and harmonised/comparable data⁶⁰⁰.

2.5. Constructing a monitoring and evaluation framework

The general objective of a monitoring and evaluation framework should be to monitor the initiative effectively and efficiently, and provide relevant information for evaluation purposes, while ensuring that the framework does not create unnecessary administrative burden. The framework needs to be aligned with the needs of the policy objectives, but complexity should be kept to the minimum. Some general principles should be:

- Ensure that adequate (legal) provisions are in place to collect necessary high-quality data from Member States or from other parties, including by considering the possibility to adapt the indicators while the initiative is in place in function of their relevance⁶⁰¹. Data needs to be collected reliably and smoothly, and regularly reported in a standardised and interoperable manner (regulatory reporting requirements) to the extent possible. Ensure that the data collected are reusable.
- Set clear and functional monitoring and evaluation framework from the outset of the initiative or as early as possible in its life cycle. This implies carefully selecting a set of indicators, in function of the intervention logic and keeping in mind the data that will be necessary and when it is expected to become available.
- The selected indicators should cover all objectives of the initiative along the whole implementation cycle and levels of initiative (output, result, impact).
- Design indicators that will provide information relevant for improving the policy implementation and later on for the evaluation of the initiative.
- Choose the right indicators based on quality criteria (see section 2.2).
- Ensure the soundness and reliability of the proposed methods and instruments for collecting, storing, and processing the data.
- Make maximum use of existing data to save time and resources and increase coherence of results. Reporting requirements should only cover what is relevant and not available via other channels and once-only principle should be respected.
- Use reporting standards and formats to increase interoperability and ease sharing of data in the context of different policy areas, to the extent possible.

⁵⁹⁹ JRC-TMA-CC@ec.europa.eu

⁶⁰⁰ A good place to find relevant data is the data.europa.eu – the official portal for European data, a single point of access to data produced by EU, national, regional, and local public administration, as well as by some international organisations.

⁶⁰¹ See Tool #44 (*Legal provisions on monitoring and evaluation*)

- Automate as much as possible with the use of (existing) IT tools to shorten data collection and processing time.
- Clarify and assign responsibilities for data management, collection, processing, and quality assessment (data governance).
- Be transparent towards stakeholders and make data publicly available where possible and according to the data protection framework, preferably as *open data* (according to the principles of the European Interoperability Framework⁶⁰²).

⁶⁰² [European Interoperability Framework](#)

TOOL #44. LEGAL PROVISIONS ON MONITORING AND EVALUATION

1. INTRODUCTION

An act of Union law should be evaluated, and the results used to inform any new initiative to modify it. The evaluation of existing legislation is an integral part of the policy cycle.

The Interinstitutional Agreement on Better Law-Making⁶⁰³ sets out the commitment of the European Parliament, Council and Commission to consider establishing reporting, monitoring, and evaluation provisions in a systematic way in legislation.

Box 1. The 2016 Interinstitutional Agreement on Better Law-Making

- §21: The Commission will inform the European Parliament and the Council of its multiannual planning of evaluations of existing legislation and will, to the extent possible, include in that planning their requests for in-depth evaluation of specific policy areas or legal acts. The Commission’s evaluation planning will respect the timing for reports and reviews set out in Union legislation.
- §22: In the context of the legislative cycle, evaluations of existing legislation and policy, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action. To support these processes, the three Institutions agree to, as appropriate, establish reporting, monitoring and evaluation requirements in legislation, while avoiding overregulation and administrative burdens, in particular on Member States. Where appropriate, such requirements can include measurable indicators as a basis on which to collect evidence of the effects of legislation on the ground.
- §23: The three Institutions agree to systematically consider the use of review clauses in legislation and to take account of the time needed for implementation and for gathering evidence on results and impacts.

When proposing monitoring and evaluation clauses in Union legislation, it is important to consider that good quality ex-post evaluations⁶⁰⁴ of legislation cannot be performed too soon after its entry into force because its implementation must be sufficiently advanced to measure or assess its effects and to have information available about its actual performance.

Still, the legislator often incorporates ‘review clauses’ in Union legislation which request the Commission to undertake reviews (e.g. of specific clauses) or develop certain elements (e.g. those that could not be agreed in co-decision) with deadlines that are too short for a rigorous evaluation based on information gained from the application of the legislation.

To guide DGs on how to draft monitoring and evaluation clauses when preparing Commission proposals, this tool discusses various ex-post review systems⁶⁰⁵ that the DGs may include in the monitoring and evaluation clauses, their expected outcome and indicative timing.

⁶⁰³ OJ L123, 12 May 2016, p. 1.

⁶⁰⁴ See Tool #45 (*What is an evaluation and when it is required*)

⁶⁰⁵ This guidance also responds to the observations and recommendations in the framework of the ECA report on ex-post review of EU legislation on 12/06/2018ECA, in so far as considered relevant and acceptable.

2. WHAT IS A MONITORING AND EVALUATION CLAUSE?

Monitoring and evaluation clauses are provisions in Union legislation defining when and how the changes required by the legislation will be monitored and the effects of the legislation will be evaluated. The aim of monitoring and evaluation clauses is to ensure that appropriate arrangements are put in place early on to track **progress and evaluate the performance of Union legislation**.

A comprehensive monitoring and evaluation clause describes the information to be collected and its purpose, who is to collect the information and how and when it is to be collected and, on that basis, when to produce the evaluation or implementation report⁶⁰⁶ of the legislation. The scope of monitoring and evaluation clauses can vary greatly depending on the context of the legislation. It is guided by the analysis in the impact assessment⁶⁰⁷. The simplest cases only require reports to be prepared by the Member States or the Commission (or both) by a certain date. More complex legislation may include specific measurable indicators and require information to be collected and reported by stakeholders, public authorities, or both.

In principle, the Commission does not need any empowerment to establish a programme for monitoring the outputs, results, and impacts of legislation. Schemes for reporting may be autonomously determined by the Commission. Where it is necessary to provide for specific reporting obligations for national authorities or other stakeholders, they need to be specified in the monitoring and evaluation clause of the legislative act.

When it is impossible to spell out in the legislation what exactly will be needed from the Member States or other stakeholders (for example, due to time constraints or level of detail), the clause could contain an empowerment for the Commission to specify those requirements by adopting an implementing act (when such act would specify criteria that are already set out in the legislative act) or a delegated act (when such act would actually set out such criteria). Alternatively, the Commission may opt for including in its proposal a provision according to which it will be for the Commission to establish a detailed programme for monitoring the outputs, results, and impacts of the legislation, in which it will set out the means by which and the intervals at which the data and other necessary evidence will be collected. Such programme could then specify the action to be taken by the Commission and/or by the Member States in collecting and analysing the data and other evidence. Such alternative provision, which does not contain any empowerment to adopt an implementing or a delegated act, could be sufficient in those cases where there may be no need to impose specific data collection requirements on the Member States.

For funding programmes, monitoring and evaluation are tasks inherent to the Commission's powers of budget implementation under the Treaties. In such case, the data necessary for the monitoring and evaluation should normally be available from the reporting obligations laid down in the grant agreements or contribution agreements signed with beneficiaries or recipients, without any need for specification in the legislative act. In principle, there is no need either to adopt any other elements regarding the monitoring and evaluation framework (such as indicators) in the legislative act or in implementing/delegated acts. Still, in the

⁶⁰⁶ See section 3, points 3 and 4, below.

⁶⁰⁷ See Tool #11 (*Format of the impact assessment report*) and Tool #43 (*Monitoring arrangements and indicators*)

proposals for spending programmes/funds under the 2021-2027 Multiannual Financial Framework, standardised articles on monitoring and evaluation were included systematically. To ensure effective assessment of the progress made under the programmes/funds towards the achievement of their objectives, the Commission is empowered to adopt delegated acts to review or complement the indicators included in the regulations, where considered necessary, and to supplement the regulations with provisions on the establishment of a monitoring and evaluation framework. In this context, delegated acts should be adopted whenever DGs are to set up monitoring and evaluation frameworks **for the main elements establishing those frameworks** (such as indicators and corresponding reporting obligations, which are not already covered by the basic act). The DGs should develop the concrete monitoring and evaluation frameworks for the programme/funds, which should be submitted for inter-service consultation, where appropriate, and will generally be finalised as a staff working document.

Monitoring and evaluation arrangements should be analysed in the impact assessment report given the potential impacts that may follow from the requirements imposed – for example regarding the data collection. For the preferred option, if one is specified, operational objectives and the corresponding monitoring indicators should be identified as well as what would be monitored⁶⁰⁸, from when will the monitoring start, by whom and how the results will be used, and when the future evaluation will be undertaken⁶⁰⁹. The analysis should inform the drafting of the monitoring and evaluation clauses to be included in the proposal. When conducting the monitoring and evaluation, the DGs should set-up and apply the monitoring and evaluation arrangements as following from the final legislative text as far as possible, in the light of the needs and purposes initially identified in the impact assessment⁶¹⁰.

Subsequently, any evaluation of legislation should review its monitoring and evaluation arrangements, as already defined in the impact assessment, and consider the information provided in the implementation report or review reports.

3. ISSUES TO CONSIDER WHEN PREPARING MONITORING AND EVALUATION CLAUSES

(1) *The Commission's right of initiative*

It is the Commission's right pursuant to the Treaty to decide whether and when to present a proposal to the legislator to take action or amend existing Union acts. Monitoring and evaluation clauses proposed by the Commission should not contain therefore any commitment to present any new proposal in the future.

The Commission should evaluate the performance of existing legislation and then assess based on the evidence collected and in conformity with the 'better regulation' guidelines, whether any modification to that legislation is necessary. There may however be circumstances where the Commission needs to act before it has been possible to carry out any

⁶⁰⁸ For example, for initiatives that are 'highly relevant' for SMEs, the impact assessment report could consider specific indicators to monitor the impact of the preferred option on SMEs.

⁶⁰⁹ Including by considering for example in the case of expenditure programmes or funds, the timing for interim and final evaluations.

⁶¹⁰ See Tool #43 (*Monitoring arrangements and indicators*)

evaluation and the Commission should be free to do so in the exercise of its right of initiative⁶¹¹.

(2) *Consider how to monitor and evaluate the legislation*

The monitoring and evaluation arrangements section of the impact assessment report accompanying the Commission proposal should be the starting point for preparing evaluation and monitoring clauses. This section of the report describes how the impacts of the EU legislation will be monitored and evaluated in the light of the objectives, what indicators will be used and when and what information might be needed in addition to that which is already available. Before drafting the proposal, you will have to consider the principles to constructing a monitoring and evaluation framework⁶¹² and the following aspects:

- Should there be mandatory provisions regarding data collection – regulatory reporting requirements⁶¹³ – define who will collect the data, when, how often, where it will be stored, how it will be transmitted, accessed or reused, etc.);
- What will be the role of the Member States, the stakeholders, the Commission or any relevant EU decentralised agencies or other EU bodies?;
- Are any new reporting requirements clear and proportionate to the scope and objectives of the legislation⁶¹⁴? What are their costs and how will they be covered?
- Consider whether specific aspects of the legislation are particularly important so that they need to be directly referenced in the monitoring and evaluation clauses to ensure a sufficient focus on these aspects. It is however good practice to cover all elements of the legislation for monitoring and evaluation purposes;
- Ensure that the legislation will be evaluated fully, at the appropriate time.

Ultimately, the evaluation of the legislation will result in an evaluation report (in the form of a staff working document) prepared by the lead DG or service and possibly accompanying a formal Commission report to the legislator, the Economic and Social Committee and/or the Committee of the Regions, as necessary.

(3) *Timing of the evaluation*

An ex-post evaluation can only be useful if there is enough practical experience and performance-related information. Results and impacts take time to materialise.

As a rule of thumb, an ex-post evaluation requires data on the application of the legislation over a period of at least three to four years. In setting the period on which an evaluation is to be provided, account must be taken also of the transposition, implementation and application deadlines, the moment when the key elements of the legislation will be applied in practice, as well as any time needed for the collection of data, for the evaluation and for the reporting.

Due consideration needs to be given to the time needed to carry out the evaluation, including the drafting of the report, where relevant, interservice consultations and the process for adoption of the report to the legislator, if the legislation provides for such a report. Ex-post

⁶¹¹ See Tool #40 for guidance regarding the explanatory memorandum

⁶¹² See Tool #43 (*Monitoring arrangements and indicators*) for detailed information.

⁶¹³ For more guidance on regulatory reporting requirements, consult [the regulatory reporting wiki](#).

⁶¹⁴ This [guidance document](#) can help you in setting clear regulatory reporting requirements.

evaluations should not be required more frequently than every 5 to 8 years after transposition, application, or implementation, as it is important that the requirements do not impose unnecessary burdens.

(4) Other intermediate reports

The lead DG should also consider carefully whether it may be useful for the Commission to also prepare a report on the Member States' implementation of the legislation based on the data available before the actual evaluation is carried out.

As indicated in the table below, such implementation report should be produced by the Commission within 1 to 3 years. It should be noted that this intermediate product cannot be considered as a substitute for a comprehensive, fully-fledged evaluation and cannot inform on its own a possible revision of the legislation.

The DGs should consider that monitoring or evaluation clauses proposed by the Commission do not contain any commitment to present any new proposal, as explained above.

Report type	Timing (after transposition, application or implementation)	Content	Who
Implementation report	1-3 years	An EU directive or regulation may require the Commission to prepare an implementation report focussed on the Member States' implementation measures. This describes the state of play based on available monitoring data and provides information on progress against agreed timetables, targets, or objectives, to the extent possible and in the limits of the data available. It often has a wider scope than a purely legal compliance report, but nonetheless builds on existing conformity/compliance checking.	Commission based on information from Members States or other parties.

In order to ensure consistency across policy areas, when drafting monitoring and evaluation clauses, the DGs should use the terminology indicated above (i.e. 'implementation report') and not refer to any 'application', 'transposition' or 'monitoring' report⁶¹⁵.

Similar to the requirements for an evaluation, the implementation report should always describe the methodology used (i.e. including data collection and analysis tools), a justification of its choice and the limitations.

Thought also needs to be given as to how often an implementation report should be produced. It is important that the requirements do not impose unnecessary burdens and the implementation report(s) do not overlap between them and with the evaluation of the legislation.

⁶¹⁵ Some of these terms are currently used in existing review clauses.

The legislator might require a **review report on specific provisions of the legislation**, shortly after its adoption or implementation, i.e. less than 3 years. The DGs should note that a review report should be based on the available monitoring data regarding the specific provisions of the legal act, which sometimes only allows for a general description of the state of play. When the data available are limited, such report can only explain *what* has happened rather than *why*. Such report should clearly explain data availability issues and limitations. Depending on the availability of data, the report may not be a sufficient basis for proposing a revision of the entire legislation. However, it may **inform a revision of the specific aspects reviewed**. Its timing should be carefully considered in the light of the timing of the implementation report, where such a report is envisaged, and the timing of the evaluation, in order to avoid administrative burden and overlaps.

A review report should not be confused with an evaluation. Where the legislation requires an implementation report as well as an assessment of the effects of certain provisions, this should not prevent the DGs, where sufficient data are available, to carry out a fully-fledged evaluation.

4. EXAMPLES OF MONITORING AND EVALUATION CLAUSES

The Commission's 'better regulation' policy requires Union legislation to be evaluated. In specific cases, a legislative act may also require the Commission to monitor, review or evaluate specific aspects of the act. However, the European Parliament, Council and the Commission have agreed to consider a more systematic approach⁶¹⁶. Accordingly, the Commission should include in its proposals what it considers to be appropriate approach for the monitoring and evaluation of the legislation concerned and defend that approach in further institutional negotiations to ensure consistency across the *acquis* as regards monitoring and evaluation.

There is no single template for monitoring and evaluation clauses that may be applied in every case. The table below contains templates for evaluation and monitoring clauses. In every specific case, their wording should be adjusted to the needs of evaluation and monitoring (including the list of data/information, which should be collected). An evaluation and monitoring clause may take elements from different templates. For instance, an evaluation and monitoring clause may require Member States to collect certain data, based on which the Commission is required to produce an implementation report followed by an evaluation, once sufficient information on the performance of the legislation has been obtained.

4.1. Examples of evaluation and monitoring clauses

Box 2. Examples of evaluation and monitoring clauses	
Evaluation	<p>No sooner than [five] years after the date of [application/transposition/implementation] of this [Regulation/Directive], the Commission shall carry out an evaluation of this [Regulation/Directive] and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.</p> <p>Member States [<i>or other parties</i>] shall provide the Commission with the information necessary for the preparation of that report.</p>

⁶¹⁶ Interinstitutional Agreement on Better Law-Making, OJ L123, 12 May 2016, p1.

<p>Implementation report</p>	<p>By [xx/yy/zzzz] at the latest, the Commission shall present a report on the implementation of this Directive to the European Parliament, the Council and the European Economic and Social Committee.</p> <p>Member States [<i>or other parties</i>] shall provide the Commission with necessary information for the preparation of that implementation report.</p>
<p>Monitoring– monitoring programme*</p> <p><i>*such a clause could be used when the monitoring arrangements (for example data, indicators and data collection) are not sufficiently detailed in the impact assessment, DGs cannot include them at the time of the proposal and require more time to define them after the proposal is adopted.</i></p>	<p>By [xxx] at the latest, the Commission shall establish a detailed programme for monitoring the outputs, results and impacts of this [Regulation/Directive].</p> <p>The monitoring programme shall set out the means by which and the intervals at which the data and other necessary evidence will be collected. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.</p>
<p>Monitoring - specific requirements</p>	<p>Member States shall regularly monitor the application of the [Regulation/Directive] based on the following indicators⁶¹⁷:</p> <ul style="list-style-type: none"> - X - Y - Z <p>Member States shall organise the production and gathering of the data necessary to measure the change in the indicators described in [paragraph x.x] above, and shall supply that information to the Commission on a [yearly/b-annual/monthly basis].</p>

4.2. Recitals

In the Commission’s proposal, it may be useful to provide further explanations on the monitoring and evaluation clauses through a corresponding recital. The following examples may be useful:

<p>Box 3. Examples of recitals</p>	
<p>Evaluation</p>	<p>The Commission should carry out an evaluation of this [Regulation/Directive] [add reasons why].</p>
<p>Data collection</p>	<p>Information should be collected in order to assess the performance of the legislation against the objectives its pursues and in order to inform an evaluation of the legislation.</p>

⁶¹⁷ See Tool #43 (*Monitoring arrangements and indicators*)

Chapter 6 – How to carry out an evaluation and fitness check

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TOOL #45. WHAT IS AN EVALUATION AND WHEN IT IS REQUIRED

1. INTRODUCTION

Commission evaluations^{618,619} and fitness checks assess the performance of existing policies, programmes and legislation. This tool provides guidance to Commission officials on the application of the 'better regulation' guidelines, the definition of evaluation and fitness checks, the obligations to evaluate and the evaluation planning.

Box 1. What is an evaluation?

Evaluation is an **evidence-based judgement** of the extent to which an existing intervention is:

- effective in fulfilling expectations and meeting its objectives;
- efficient in terms of cost-effectiveness and proportionality of actual costs to benefits;
- relevant to current and emerging needs;
- coherent both internally and externally (with other EU interventions or international agreements); and
- has EU added value i.e. produces results beyond what would have been achieved by Member States acting alone.

Evaluation uses evidence to judge how well the intervention has performed so far compared to earlier expectations prior to implementation or compared to earlier projections made in the context of an impact assessment.

Evaluation goes beyond a factual assessment of *what* has happened it considers *why* something has happened; *how much change* can be attributed to the EU intervention and to *what extent this change meets original expectations/projections*. Evaluation **thus aims (where possible) to draw conclusions about the causal effects of the EU intervention on the actual outcomes/results⁶²⁰. Evaluation should also look at the wider perspective, seeking to identify (and learn from) any unintended or unexpected effects, whether positive or negative, which were caused by the EU intervention but not anticipated, for example in the impact assessment or in the act agreed by the EU co-legislators. Evaluation should provide an evidence-based assessment of whether the EU intervention continues to be justified or where**

⁶¹⁸ Throughout the 'toolbox' and 'guidelines', the term 'evaluation' is used to describe evaluations of programmes – often classified as interim, final, ex-post; evaluations of policies based on legal instruments or soft law – generally classified as interim because few policies have a set end-date; and fitness checks – evaluations of a group of interventions. If special consideration is required, this is mentioned in the text.

⁶¹⁹ EU decentralised agencies (e.g. EFSA, European Food Safety Authority) have their own legal personality are charged with a particular task (e.g. food safety). They are distinct from the Union Institutions (European Parliament, Council, European Commission, etc.) and have their own legal personality. Evaluations conducted by EU decentralised agencies follow the [Evaluation handbook for Agencies](#). EU executive agencies, on the other hand, are established by implementing decision; the European Commission delegates power for the implementation on its behalf and under its responsibility of Union programmes. Evaluations are governed by the Financial Regulation and the 'better regulation' guidelines.

⁶²⁰ As such, evaluation goes further than typical monitoring or audit activities. Monitoring looks at 'what' (what has occurred; what has been the output of the intervention). Compliance audit looks at 'how' (how the internal control systems have functioned and how resources have been used at the implementation level). Performance audit takes a broader look at the overall conduct of the work and its results.

lessons can be learned for improving. As such, evaluation forms the basis for a possible future revision of the intervention which will be further developed in an impact assessment.

Evaluation and fitness check

Evaluations can cover a single EU intervention or a group of interventions which have some relationship to each other (normally a common set of objectives or specific procedures, e.g. reporting) justifying a joint analysis. The latter kind of evaluation is called a **fitness check**. There are no set criteria to identify the scope of a fitness check – rather, the scope should bring together EU interventions whose evaluation as a group will contribute to a better understanding of the role played by the EU in achieving their related objectives and reacting to broader policy concerns. Although fitness checks to date have mainly considered groups of related legislative actions, it is possible to include within the scope of a fitness check any type of EU intervention, e.g. spending programmes, strategies, cross-cutting evaluations of EU decentralised agencies and other EU bodies. It is advisable to discuss the scope of the fitness check early in the preparatory process in an upstream meeting with the Regulatory Scrutiny Board.

A broad fitness check can provide a helicopter view on related policy interventions, assessing in particular coherence and opportunities for streamlining. However, it may prove to be challenging to establish and investigate the intervention logic, to identify good evaluation questions for certain evaluation criteria and find the appropriate point(s) of comparison. All fitness checks should pay particular attention to identifying and quantifying (to the extent possible) synergies (e.g. improved performance, lower costs, reduced burdens, simplification, automation/digitalisation) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies, implementation problems or obsolete measures) within the group of measures and help to identify the cumulative impact of the group of interventions, covering both costs and benefits.

Fitness checks can provide a more global picture of the burdens carried by businesses, citizens, and public administrations by looking at the cumulative incurred impacts of several legal acts. As such, they can help identify future simplification opportunities and quantify potential burden reductions, including by increasing digitalisation. When conducting a fitness check in a policy area, it is important to also consider the coherence in roles and tasks of relevant EU agencies and other EU bodies operating in that policy area. As such, a fitness check can help identify synergies including services sharing or reducing bureaucracy and can help derive lessons from the evaluation findings to inform decisions on potential mergers or closures of EU agencies (or other EU bodies) operating in this area.

Evaluation and the 'one in, one out' approach

In the implementation of the **'one in, one out' approach**⁶²¹ regarding the cost of EU legislation, evaluations and fitness checks will be important sources to identify possibilities for simplification and burden reduction without jeopardising net benefits. This REFIT⁶²² aspect should play a prominent role in the evaluation work, as far as possible based on quantification of costs and cost savings potential, applying the EU Standard Cost Model⁶²³ or other cost models. In the context of the 'one in, one out' approach, evaluations will verify initially estimated costs and benefits against actual outcomes, following co-legislators'

⁶²¹ See Tool #59 (*Cost estimates and the 'one in, one out' approach*)

⁶²² See Tool #2 (*The regulatory fitness programme (REFIT) and the Fit for Future Platform*)

⁶²³ See Tool #58 (*The EU Standard Cost Model*)

amendments and national implementation. Fitness checks of entire policy areas (rather than evaluations of specific legislative acts) are particularly useful in this regard. Apart from assessing the extent to which a policy initiative is achieving its objectives, they look at the cumulative impacts of legislation, overlaps and inconsistencies, and so give a more complete picture of the benefits brought to and burdens borne by businesses, individuals, and public administrations. Fitness checks can be tailored to look at specific elements, such as digitalisation opportunities, potential for removing unnecessary or overlapping reporting requirements, for simplifying authorisation systems.

Fitness checks of horizontal issues, such as reporting obligations have already been conducted in a limited number of policy areas (e.g. environment, agriculture, financial services) and they have identified significant potential to simplify the requirements and reduce reporting costs. The [fitness check of reporting and monitoring of EU environment policy](#) is a good example, the [fitness check of EU supervisory reporting requirements in EU financial services legislation](#) is another one.

Objectivity and independence

DGs may commission supporting studies from external contractors to help with certain aspects of the evaluation. The precise content of such outsourced work depends on the needs of each evaluation and the resources available. Studies generally present important information – but may only cover part of the overall picture. A study on its own cannot be considered as an evaluation that meets the Commission’s standards. Even where the scope of an external study covers the full scope of an evaluation, it does not represent the evidence-based judgements of the Commission services. An evaluation report in the form of a staff working document is required to bring together all the information and present the position of the lead DG⁶²⁴.

Box 2. Principles of objectivity and independence

An evaluation can be carried out internally by the Commission services or with the help of external contractors via a supporting study. Evaluation work whether undertaken in-house or outsourced to external parties – should respect the principles of objectivity and independence. The analysis in an evaluation can be considered objective and independent if it is based on all relevant information, it is conducted without influence or pressure by third parties and reports transparently on the positive and negative elements of the analysis.

The ‘better regulation’ function within the lead DG together with the interservice coordination group have a role to play in avoiding bias in evaluation reports. The ‘better regulation’ function within the lead DG should provide guidance to those conducting the evaluation and together with the interservice coordination group, they should ensure that no important or critical findings have been left out of the evaluation without explanation and that the conclusions of the evaluation are based on an objective reading of the data, clearly indicating the weaknesses of the evidence collected.

⁶²⁴ See Tool #49 (*Format of the evaluation report*)

2. WHAT ARE THE REQUIREMENTS TO EVALUATE?

Evaluation is an essential tool to help manage and inform revisions of existing EU legislation, policies, and programmes. The Commission is committed to regularly evaluate in a proportionate way all EU spending and non-spending activities with an impact on society or the economy. In line with the ‘**evaluate first**’ principle⁶²⁵, evaluation of EU intervention precedes work (i.e. the impact assessment) dealing with the revision of that (or related) intervention. In cases where political urgency may require a Commission proposal at short notice, evaluations may be carried out back-to-back with an impact assessment⁶²⁶.

When planning an evaluation, it is important to make a preliminary assessment of data needs and data availability⁶²⁷ and to consider how long the EU intervention has been operating. This will allow making clear from the start what the analysis will be able to deliver. Consideration also needs to be given to the time required to carry out the actual evaluation work⁶²⁸ with DGs taking a pro-active role in identifying evaluation needs and planning accordingly.

Many evaluations are mandatory by evaluation or assessment clauses in EU legislation⁶²⁹. Evaluations of spending activities need to comply with the requirements of the Financial Regulation. Evaluations may also be necessary due to the application of a sunset clause⁶³⁰.

Review clauses are also common⁶³¹ – requiring work with backward and forward-looking elements. For example, a review clause may require that, by a certain date, the Commission produces an assessment of certain or all elements of an intervention together with, if appropriate, proposals for change. Often such clauses relate to very specific articles, or to the possibility of introducing new elements (e.g. broadening scope of application). Where sufficient evidence to carry out a meaningful evaluation is not available and no revision of the intervention is envisaged, services should consider carrying out a different exercise e.g. an implementation report instead.

For spending programmes, the **Financial Regulation**⁶³² requires an evaluation of all programmes and activities that entail significant overall spending⁶³³. These rules also apply in full to evaluations of EU agencies conducted or contracted out by the Commission. The evaluation requirements for projects or programmes financed by the (11th) European Development Fund (EDF) budget are laid out in [Council Regulation \(EU\) 2018/1877](#).

⁶²⁵ See section II.3 of the [European Commission 2019-2024 Working Methods](#)

⁶²⁶ See Tool #50 (*‘Back-to-back’ evaluations and impact assessments*) for more information on the specific processes to follow.

⁶²⁷ Section 9 of any associated impact assessment should include indications of monitoring and evaluation arrangements; See Tool #11 (*Format of the impact assessment report*) for further information.

⁶²⁸ See Tool #46 (*Designing the evaluation*)

⁶²⁹ See Tool #44 (*Legal provisions on monitoring and evaluation*)

⁶³⁰ See for instance as regards EU decentralised agencies point 60 of the [Joint Statement and Common Approach \(Parliament, Council & Commission\)](#), 2012

⁶³¹ See for instance Article 29 of the EU Regulation (2019/715) of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

⁶³² See the EU’s [Financial Regulation](#), particularly Article 34.

⁶³³ While the Financial Regulation does not define the level of the ‘significant spending’, the ‘better regulation’ guidelines define it indicatively as at least EUR 5 million.

In addition, for spending programmes financed by the EU budget, an obligation to evaluate is included in **Article 318 of the Treaty on the Functioning of the European Union (TFEU)**, which requires the Commission to establish an annual evaluation report of the Union's finances based on results achieved. Evaluation findings should also be properly reflected in the programme statements accompanying the draft budget proposal each year.

Further sector-specific evaluation requirements are also explicitly included in the EU Treaties in the area of justice, freedom and security; common security and defence policy; research, technological development and space; industry; employment; social policy and public health.

Box 3. Activities which need not necessarily be evaluated in the standard way

It may not be necessary to apply the guidelines fully when evaluating:

- Individual (pilot) projects, groups of projects or sub-activities where their findings will feed into an overarching evaluation. This is particularly relevant for (spending) programmes where there may be many projects or sub-activities that require some degree of assessment that has a narrower scope than evaluation as defined in these guidelines. It is also the case for external programmes where findings coming from evaluations of country programmes, specific delivery methods, tools or elements of certain themes, feed into larger or overarching evaluations including of legal instruments;
- EU executive agencies, where aspects of the agency's performance will be evaluated within the context of the associated programme⁶³⁴;
- EU decentralised agencies, where evaluation of the agency's performance is part of the evaluation of the policy area concerned (fitness check)⁶³⁵;
- A limited set of actions within an EU intervention which are not expected to lead to changes to the wider intervention e.g. a directive which contains a clause requesting the Commission to evaluate, review or assess the definition of X after one year and decide if it is appropriate;
- Performance at an early point in the implementation of an intervention, when information on the longer-term changes (results and impacts) is not yet available (in this case an implementation report is more appropriate);
- The internal administrative policies of the Commission (translation, interpretation, human resources and security, the Publications Office and certain areas of Eurostat).

Such work, which would not generally constitute an evaluation, should nonetheless broadly follow the concepts and principles of evaluation presented here. In the above cases, a more proportionate approach should be applied; in general, a separate Decide planning entry, a 'call for evidence' or evaluation report in the form of a staff working document (SWD) might not be required and/or the consultation strategy and evaluation criteria could cover a lesser scope. **Where a Directorate-General has doubts about the degree of application and the steps that should be followed, they should discuss the approach with the Secretariat-General**, preferably during the annual discussions establishing the evaluation

⁶³⁴ Legal provisions on evaluation of executive agencies are set out in [Council Regulation \(EC\) No 58/2003](#) of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes (Article 25).

In addition, Commission Decision C(2014) 9109 final sets out guidelines on executive agencies

⁶³⁵ Without prejudice to the individual evaluation clauses inserted in most of the agencies' founding acts and Article 29 of Regulation (2019/715).

planning.

Proportionality of evaluation

The ‘evaluate first’ principle applies to all EU interventions (policies, programmes, and legislation) prior to revising. Nevertheless, the scope and depth of the analysis should be **proportionate** to the importance of the EU intervention. Setting the appropriate depth and scope of the analysis implies deciding on:

- resources and time allocated to the overall evaluation process, including data collection, preparing the ‘call for evidence’, organising consultation activities, conducting external studies, drafting the evaluation report or fitness check in the form of a SWD;
- the importance and priority given to the intervention (e.g. political guidelines, Commission work programme, operational and strategic decision-making needs, contribution to the sustainable development goals);
- specific factors, such as: the type of intervention e.g. regulation, directive, decision, recommendation, communication; the timespan of implementation and associated data availability; its magnitude and complexity; the significance and nature of the intervention’s expected or observed impacts.

It is the **responsibility of the lead DG, in cooperation with the interservice coordination group**⁶³⁶, to determine the level of analysis, considering all relevant factors as well as any constraint in the availability of time, resources and data. Setting the right level of analysis is likely to be an **iterative process**. First indications should be provided in the ‘call for evidence’⁶³⁷.

Evaluation analyses and findings should be fully exploited in related impact assessments conform with the ‘evaluate first’ principle. Furthermore, fitness checks and relevant evaluations should be included in reporting exercises, e.g. in the DG’s annual activity reports, strategic and management plans, programme statements, the Annual Management and Performance Report.

3. EVALUATION PLANNING & THE FIVE-YEAR ROLLING EVALUATION PLAN

Good evaluation planning is a critical step to ensure the availability of evaluation results that will feed back into the policymaking cycle. Evaluation activities should be planned in a transparent and consistent way so that the relevant evaluation findings are available in due time for operational and strategic decision-making. They are also an important tool in improving organisational learning, ensuring transparency, and demonstrating the accountability of the Commission.

⁶³⁶ See Tool #48 (*Conducting the evaluation*) describing the role of the interservice coordination group.

⁶³⁷ See Tool #51 (*Consulting stakeholders*)

The Commission's organisational framework for evaluation is decentralised, making individual Directorates-General responsible for planning and conducting evaluations of all of their activities over time. The choice of structure is at the discretion of each Directorate-General, reflecting its needs and requirements.

Each Directorate-General should ensure that:

- A periodic evaluation of EU interventions or EU decentralised agencies or other EU bodies under its responsibility is done. Under the '**evaluate first**' principle, evaluation findings and lessons learned should feed into the decision-making cycle, backing up proposals for change and revision. Evaluation findings should, where available, be included in the 'call for evidence' for new initiatives.
- Appropriate monitoring and evaluation activity is planned at the time of adoption of each initiative⁶³⁸ to develop or amend EU action (in general such arrangements are first set out in the relevant impact assessments). It is strongly recommended that the associated work is then entered into the evaluation planning, ensuring that deadlines set in legislation are met.
- Relevant evaluation results are available to feed into the Annual Management and Performance Report⁶³⁹. These results are presented in the Annual Activity Reports drawn up by Directorates-General and in the annual Programme Statements prepared to justify resource allocation in the draft budget, both of which provide a key source of information for the Annual Management and Performance Report.

Regular screening of responsibilities

It is recommended that each Directorate-General screens regularly the legislation falling under its responsibility to identify:

- legal obligations to carry out an evaluation (including under the EU Financial Regulation) or any kind of requirement to review or produce a report⁶⁴⁰, considering whether a full evaluation would be timely and appropriate⁶⁴¹;
- when individual interventions were evaluated last and ensure evaluations are available in a timely manner to feed into the next steps in the policymaking cycle;
- the potential to carry out fitness checks (i.e. cross-cutting evaluations);
- the potential for burden reduction, cost savings and simplification in the context of the REFIT programme and the 'one in, one out' approach⁶⁴²;
- other feedback provided on interventions, including any recommendations from the Fit for Future platform, complaints, infringements or SOLVIT cases⁶⁴³ which might imply problems with implementation, application, or performance.

⁶³⁸ The 2016 Interinstitutional Agreement on Better Law-making envisages a systematic approach to evaluation and monitoring in basic acts: See Tool #44 (*Legal provisions on monitoring and evaluation*).

⁶³⁹ See Financial Regulation, Article 247 Integrated financial and accountability reporting

⁶⁴⁰ For example, report from the Commission to the European Parliament and the Council, implementation report, etc.

⁶⁴¹ The European Parliament produces a [rolling check list of review clauses in EU legislation](#).

⁶⁴² The general idea of the 'one in, one out' approach is to systematically and proactively seek to reduce burdens imposed by existing legislation when introducing new burdens. The role of evaluations will be to verify initially estimated costs and benefits against actual outcomes.

Rolling evaluation plan

The planning of evaluation activities of individual Directorates-General takes the form of a (minimum) five-year indicative rolling programme, where the plan is broadly fixed for the first two years and stays more indicative for later ones, providing an overview of the structure and coverage of the evaluation policy. The plan is submitted through the [interinstitutional studies database](#) and should respect the relevant instructions.

The update of the interinstitutional studies database is under the responsibility of each Directorate-General. In the management plan, the Director-General certifies that the studies database is up to date and includes all evaluations and studies on a 5-year rolling base. But the database is a living tool to follow evaluations or any other study in its life cycle, from the launch to the completion and needs to be kept up to date. It therefore requires regular updating to be effective, in particular regarding the links to deliverables published by the Publications Office of the EU or *Decide* references of the documents.

All Directorate-General's policy areas, including both spending and non-spending interventions, should over time be proportionally covered in the rolling evaluation plan.

The Secretariat-General compiles the evaluation plans of individual Directorates-General into a single Commission evaluation plan which is published on a central website⁶⁴⁴. This ensures transparency, enhancing stakeholder access by publicising what is being and will be evaluated when and thus further enabling their participation.

Each Directorate-General should indicate a central evaluation contact (for example a functional mailbox address), which is responsible for answering questions from stakeholders on the planning, timing, and progress of work on evaluations all year round. The evaluation plan will be a key input to the Regulatory Scrutiny Board's decision on which evaluations it will review.

Timing of evaluations in the policy cycle

While the evaluation plan lists all the evaluations scheduled by a Directorate-General during a (minimum) five-year period, the timing of the evaluation (i.e. when it starts and ends) is a key element of the overall plan. Timing is a crucial factor affecting the use of evaluation in the decision-making process; it should enable the results to feed into further preparations for the design, renewal, modification, or suspension of activities. Both planning and timing need to be aligned with political priorities and while there may always be emergencies, good management of these elements helps to ensure that reasonably up-to-date evaluation material is always available for part of the EU acquis.

Evaluation planning should consider the life cycle of the intervention, legal obligations and the operational and strategic decision-making needs of the DG. Often, evaluation planning starts by looking at when the findings are required (e.g. to meet a legal obligation, or to feed into a policy proposal) or when reporting by Member States is due.

Planning for evaluations of *spending initiatives* covered by the multi-annual financial framework (MFF) or the European Development Fund (EDF)⁶⁴⁵ is generally defined in the

⁶⁴³ See www.SOLVIT.eu or contact solvit@ec.europa.eu

⁶⁴⁴ See http://ec.europa.eu/smart-regulation/evaluation/index_en.htm [to upd]

⁶⁴⁵ A different set up applies for the European Structural and Investment Funds.

legal basis, predefining the timing of the different evaluations within the seven-year funding cycle as well as the nature and number of contributions and reports that are expected. To allow the interim evaluation findings to feed into ex-ante evaluations (or impact assessments)⁶⁴⁶ for the subsequent programming period, the interim evaluation results are generally scheduled for delivery around the fourth year of the programming period. Most (ex-post) evaluations are expected to take place within four years of the end of the programming period.

Although the timing of the interim evaluations might potentially be too early to capture the full results and impacts, carrying out the evaluations later would not allow the evaluation findings to be used in impact assessments for the preparation of the subsequent programming period. Equally, there would be insufficient time for any improvements to the current programme to produce significant benefits (although the interim evaluation would allow to correct some implementation issues). To address this, bringing together the final evaluation of the preceding programme and the interim of the ongoing programme, provides a longer data set against which to evaluate performance⁶⁴⁷.

It is much harder to apply a uniform timetable to the evaluation of *non-spending activities* which follow a wide range of formats (e.g. regulation, directive, decision, recommendation, communication, trade agreement). Regulatory activities in particular, have very different policy cycles. For different reasons, Member States can be given relatively long or short periods to complete the transposition of an EU law into national legislation. In other instances, different policy areas and different interventions within one policy area take effect at different moments in time, with a corresponding delay in the arrival of change, etc.

Ideally, when planning for an evaluation of a non-financial intervention, sufficient time should have passed since its implementation to ensure **at least three years' worth of sufficiently full set of data**, meaning that the evaluation cannot be produced before the fourth year following implementation. This makes evaluation planning difficult if a given intervention is revised very frequently, for instance every three years, especially if new objectives are introduced or old ones refined. Even in such cases it is unlikely that the full range of actions are amended each time, so it should still be possible to schedule an evaluation after a given period. However, the scope of the evaluation may need to limit the analysis of certain aspects, reflecting the fact that they have been in place for a shorter duration.

The planning should also consider the need for public/targeted consultations under the 'call for evidence', as well as the duration of relevant administrative procedures, including public procurement of external studies⁶⁴⁸, validation by hierarchy, interservice consultation, preparation of submission/resubmission to the Regulatory Scrutiny Board. If the Regulatory Scrutiny Board decides to scrutinise an evaluation⁶⁴⁹, a minimum of four weeks should be added to the timing of that evaluation.

Resourcing

⁶⁴⁶ See Tool #9 (*Spending programmes, financial instruments, and budgetary guarantee*)

⁶⁴⁷ This works particularly well in cases where there is continuity in objectives and implementation between one funding cycle to the next.

⁶⁴⁸ Detailed guidelines to public procurement can be found on the [Commission's Internal Financial Website](#).

⁶⁴⁹ See Tool #3 (*Role of the Regulatory Scrutiny Board*).

Every operational DG should have a designated evaluation function which can take different shapes (ranging from one full-time equivalent responsible for evaluation to a central unit in the DG and all forms in between). Depending on the organisational model chosen by a Directorate-General, individual evaluations can be run by the evaluation unit, by the operational unit responsible for a particular intervention, or in the form of a joint collaboration between the DG's evaluation function and the operational unit(s). **Whether external contractors are used or not, evaluations require significant input from Commission staff** – both from the lead Directorate-General as from other Directorates-General represented on the interservice coordination group. The decision whether to use external contractors or not depends, amongst others, on the data available as well as resources and relevant expertise in-house.

Typical activities that can be contracted out to external contractors comprise data collection, (including all or some consultation activities), desk research, literature review, modelling, data analysis, synthesizing information, answering the evaluation questions.

The resources, both internal and external, allocated to an evaluation should be proportionate to the perceived importance and expected effects of an intervention, both in terms of its costs and the changes (benefits) it generated.

TOOL #46. DESIGNING THE EVALUATION

1. INTRODUCTION

Designing the evaluation means identifying the nature and sequence of tasks, assessing data and data collection methods and the range of analytical methods to be used to deliver the evaluation. Good design starts by identifying the purpose of an evaluation and identifying what is in scope (e.g. which interventions, which policy objectives and results, over what time period and for what geographical coverage) and what is not. This will influence the evaluation questions set and as a result, the methodology applied, and the data and research undertaken to answer robustly these questions. This will then affect who is assigned which tasks within the evaluation process.

As with any project, good planning and preparation is necessary to produce a high-quality final deliverable. Evaluation requires a critical, evidence-based assessment – using robust and reliable data drawn from a range of sources and analysed in an appropriate manner. Evaluations need to present a clear chain of logic between the data, analysis and conclusions and highlight any particular strengths or weaknesses. This does not happen by accident – but by design.

Other factors which will affect the design include: the political priority of the intervention(s) being evaluated; the timing of the evaluation within the intervention(s)' policy cycle; financial resources and personnel available. It is important to understand how such factors may influence the evaluation process to manage expectations about what the evaluation will realistically be able to deliver⁶⁵⁰.

The 'call for evidence'⁶⁵¹ should provide a first description of the context, purpose and scope of the evaluation and the proposed methodological approach. However, the level of detail provided should simply set the scene. Further detail should be developed during the evaluation process, allowing the appropriate work to be done and enabling the evaluation to meet its purpose.

For fitness checks and evaluations that are selected by the RSB for scrutiny, the Board is available to have an early and informal bilateral discussion with the lead DG(s) based on the 'call for evidence' in an upstream meeting⁶⁵². **The selection of evaluations for scrutiny is communicated to DGs in the second quarter of the year (T) and concern evaluations and fitness checks to be finalised in the next year (T+1).** Therefore, when planning the work, it is advisable to assume that the evaluation may be selected for scrutiny as this adds at least four weeks to the process. Since the Board scrutinises all fitness checks, their planning should factor in this process upfront⁶⁵³.

2. DESIGNING THE EVALUATION

When designing an evaluation, it is important to:

- (1) Clarify the **purpose** of the evaluation: deciding and clearly describing what the evaluation will deliver and how its findings will be used.

⁶⁵⁰ See also Tool #44 (*Legal provisions on monitoring and evaluation*)

⁶⁵¹ See Tool #51 (*Consulting stakeholders*)

⁶⁵² See Tool #3 (*Role of the Regulatory Scrutiny Board*)

⁶⁵³ Ibid

- (2) Define the **scope**: setting out clearly what will be evaluated. This may be in terms of interventions, measures or legal articles, time period, geographical coverage, particular effects or any other relevant aspect. The reader should understand what will be covered by the evaluation and what will not, and the reason why.
- (3) Explain the **intervention logic**: summarising how the intervention was expected to work (i.e. at the time of adoption by the Commission or later by the co-legislators, or at the time of implementation), including the underlying assumptions. The intervention logic can draw from any prior impact assessment or other documentation such as the explanatory memorandum, which justified the initial policy action.
- (4) Draft good **evaluation questions**: they should address the five evaluation criteria and any other aspect as relevant, also considering the feedback on the 'call for evidence' to the extent possible. Questions should cover all issues that are known to be of interest to the stakeholders.
- (5) Identify the **appropriate point(s) of comparison**: the different evaluation questions should be answered against relevant starting points (e.g. benchmarks) or expected achievements for example, comparisons may be drawn against the changes projected or expected under the preferred policy option (as in the impact assessment or changes since measurements made at the start of an intervention. Before doing such analysis, it may be necessary to update the original points of comparison to take on-board changes introduced by the co-legislators to the Commission's proposal.
- (6) Consider **appropriate data collection and analytical methods**: it is important that the evaluation is set up to collect and analyse a range of different data, using the appropriate data and methodologies to fill existing data gaps and to answer robustly the evaluation questions.

It is essential to clearly present the key design elements of the planned evaluation in the 'call for evidence' as this is the first public communication with interested stakeholders who may provide input to the evaluation work or wish to use the evaluation findings. Stakeholders may also provide feedback on the 'call for evidence' which could affect, in some instances, the evaluation design⁶⁵⁴.

2.1. Purpose of the evaluation

It is important to be clear from the start and state in the 'call for evidence' the purpose of an evaluation – to explain why the evaluation is being carried out, the sort of findings it is expected to provide and how these findings may be used.

Evaluations may be launched for specific reasons, such as:

- to ensure compliance with an article in the legal base or in the Treaties. This applies to many policies and is for instance mandatory for programmes carried out under the Multi-annual Financial Framework (MFF);
- to ensure compliance with the EU Financial Regulation;

⁶⁵⁴ Issues relating to the purpose or scope of an evaluation (for example concerns raised by stakeholders, input from other DGs or the RSB, lack of data, timetable) must be addressed by the lead DG early on, to prevent miscommunication and to ensure appropriate evaluation design. In the extreme case, it may be necessary to consider delaying the evaluation or agreeing that a different kind of analysis is acceptable.

- to identify efficiency gains, synergies and opportunities for more policy coherence; to identify potential for simplification and burden reduction in a specific area (fitness checks);
- to assess the role of existing EU interventions before bringing forward possible changes ('evaluate first') and to identify the problems that revisions will tackle;
- to identify opportunities for more streamlined/enhanced implementation; and
- to keep the EU law fit for purpose particularly when there are signs that the legislation is not performing as it should (e.g. high number of infringements or complaints).

All evaluations are required to explore the potential for simplification and burden reduction.

2.2. Scope

The scope of an evaluation also has a significant impact on the design and subsequent conduct of the evaluation. It is important to know from an early stage what will be in the scope of the evaluation and what will not. Any limitations to the scope identified upfront must be clearly justified in the 'call for evidence'.

Key factors affecting the scope relate to the coverage of:

- **an individual intervention or group of interventions:** the scope should be defined in terms of the EU intervention – the legislative act(s) and/or related programme(s), associated implementing and delegated acts, policy(ies), soft law (action plans, strategies, communications etc.) covered. Usually, all aspects of a given piece of legislation or an intervention will fall within the scope of an evaluation. There may be circumstances when particular aspects are excluded, e.g. due to lack of experience, something not having been tested perhaps due to a later than expected implementation date or because a given article is conditional on other activities that are not yet complete. Any significant constraints to the scope should be explained in the 'call for evidence' and reflected in the design. In the most extreme case, factors affecting scope may raise questions about whether the evaluation should be delayed or a different analysis undertaken.
- **geography:** all Member States, a subset, the wider EEA, third countries (incl. developing countries) etc.
- **period of time:** this could be the full period since the intervention was implemented or a shorter period depending on the purpose/timing of the evaluation such as from the end of the period covered by the last evaluation to the current day.
- **particular effects anticipated:** this may be affected by the time period covered as some effects may not have been expected to materialise at the time of the evaluation. It could also reflect the significance of the different effects expected and availability of data or the particular political and/or policy context.

The scope may be also influenced by any feedback on the (perceived) performance of EU action e.g. from stakeholders or monitoring. This may lead to the inclusion of action(s) where there is evidence of synergies (e.g. interventions working together to complement each other

or where data is re-used, simplifying demands on stakeholders) or of problems (e.g. targets not being met, low transposition or compliance, complaints). However, it may also be interesting to include in the scope action(s) where there is a theoretical or expected link but no apparent evidence indicating problems or successes. Just because 'all is quiet' does not necessarily mean 'all is working as expected'; it may, for example, in the worst case mean that the intervention is irrelevant or that there are significant loopholes.

When considering the scope of an evaluation, due attention should be paid to both the political and policy context of the intervention(s):

- Political aspects relating to context may reflect, for example, a particular emergency or a 'hot topic', which could significantly reduce the time available to conduct the evaluation, the depth or scope of analysis.
- Policy considerations may refer to the intervention being evaluated within the logic of the wider relevant policy framework or any relationship to other actions. Sometimes related actions will be considered under coherence – for example, an evaluation of EU environmental action relating to water may consider coherence with another EU environmental action relating to waste, or with a particular EU business related action. In other cases, the interactions and their coherence may be so important and integral to the policy that a fitness check is needed. For example, the Fitness Check of EU Freshwater Policy⁶⁵⁵ looked at six EU environmental actions in the area of fresh water, with further consideration under coherence of wider environmental issues such as waste and emissions controls, but also the common agricultural policy and regional policy.

There is a clear link between the purpose of an evaluation and its scope. If the scope of an evaluation is limited in some way, then it might not be able to fulfil its purpose and meet the expectations of decision makers and stakeholders.

Box 1. Considerations affecting the decision to do a fitness check

- There are no set criteria for defining the scope of a fitness check – consideration should be given to a range of factors including its purpose, context, timing, maturity of actions being considered for inclusion, data availability and resources.
- It is critical to define an acceptable/appropriate scope early. The EU interventions, which fall within the scope of a fitness check should interact together or have common objectives. Where this is not the case, it is likely that the work undertaken will deliver several evaluations of the separate interventions, rather than the desired synergy of a joined-up evaluation of the EU policy and its framework.
- When considering which EU actions to include in scope, careful consideration needs to be given to:
 - the interaction between purpose and scope. Increasing the scope by adding more EU actions might increase the time and resources required, but could deliver synergies, providing more useful findings and a more comprehensive overview of the EU's role in that policy area. However, expanding the scope and including more loosely connected actions may not provide much additional or important information. For

⁶⁵⁵ https://ec.europa.eu/environment/water/blueprint/fitness_en.htm

example, in the chemicals area, there is certain key central EU legislation (REACH, CLP regulation) relating to chemicals, but EU actions on chemicals also includes legislation on pesticides, medical devices, toys' safety and many others, which may or may not need to be included in the scope. Often, looking at EU framework directives and related legislation together delivers a good picture about the legislative framework in place.

- how long the various EU actions have existed and hence operated or not operated together.
 - the depth of analysis required – whether the interventions need to be assessed together (a fitness check) against all (five) criteria, or whether the focus would be on the criterion of coherence.
- Sectoral fitness checks look at how EU interventions affect a specific sector. They look at the same five criteria, but from the sectoral perspective. When designing a sectoral fitness check, it is crucial to consider the use of its possible results (conclusions and lessons learned) beforehand.

Many of the legal acts assessed in a sectoral fitness check apply to a wide range of sectors, not just the specific sector identified for a given sectoral fitness check. It is beyond the scope of a sectoral fitness check to perform a full evaluation of those acts. However, some qualitative (and to the extent possible, quantitative) data of the wider performance of those acts should generally be considered, to provide the appropriate context for the sectoral fitness check. For example, often a certain sector bears a higher proportion of the overall costs, whilst the benefits are to the wider society.

Sectoral fitness checks are likely to require a higher level of coordination across the different Commission services due to the varying legislation in the scope.

- In some cases, fitness checks can be targeted at specific aspects of the legislation in question, for example: reporting requirements, supervisory activities, processes. These fitness checks have a more prominent role in burden reduction and simplification.

2.3. The intervention logic

The intervention logic provides a (narrative) description and usually a diagram summarising how the intervention was expected to work. Put another way, it describes the expected logic of the intervention or chain of events that should lead to the intended change. An intervention is expected to be a solution to a problem or need – the intervention logic is a tool which helps to explain (and often visualise) the different steps and actors involved in the intervention, and their dependencies – thus presenting the expected 'cause and effect' relationships. The intervention logic is useful both as:

- a communication tool – facilitating discussion of the intervention with different parties, helping to identify differences in understanding or to clarify particular details;
- an analytical tool – identifying relationships and dependencies that were expected, based on certain assumptions made in the impact assessment (where one exists). For example, were certain activities expected to occur in parallel or sequentially? Were all activities expected to generate outputs or just some? Who was expected to do something? Was the expected 'output' from one person or entity an 'input' for someone else? A well-constructed intervention logic will help to identify the relevant evaluation questions.

Constructing the intervention logic means considering how different actors were expected to react, what actions were expected to be triggered by the EU intervention, how both actors and actions were expected to interact to deliver the promised changes over time and ultimately achieve the objectives of the EU intervention being evaluated. Given that an evaluation delivers a judgement on why and how the EU intervention has actually worked, compared to what was expected (i.e. at the time of adoption by the Commission or later by the co-legislators, or at the time of implementation), it is important to have this understanding from the start.

In practice, there is a link between the intervention logic of an evaluation and the intervention logic/problem tree of any preceding impact assessment. In the impact assessment, the problem tree typically describes (a) the problem and its drivers, (b) the general and specific objectives, and (c) all potential solutions (options) and how they are supposed to work. In the evaluation the intervention logic typically describes (a) the need for the intervention and (b) the expected outputs, results, and impacts of the intervention and (c) how they are supposed to be achieved. The intervention logic also considers external factors, which may influence both the expected performance of the EU intervention or generate some type of effects.

There are many possible formats or approaches to describe the logic of the intervention⁶⁵⁶ and the ‘better regulation’ guidelines do not mandate a particular approach.

In practice, a traditional starting point to describe the logic of the intervention is to consider the categories presented in Figure 1 below (i.e. needs, objectives, inputs, activities, expected outputs, results, impacts, external factors, other EU policies) and assess those using the five evaluation criteria⁶⁵⁷.

Whatever approach is used to describe the logic of the intervention, thought should be given to the following elements being reflected:

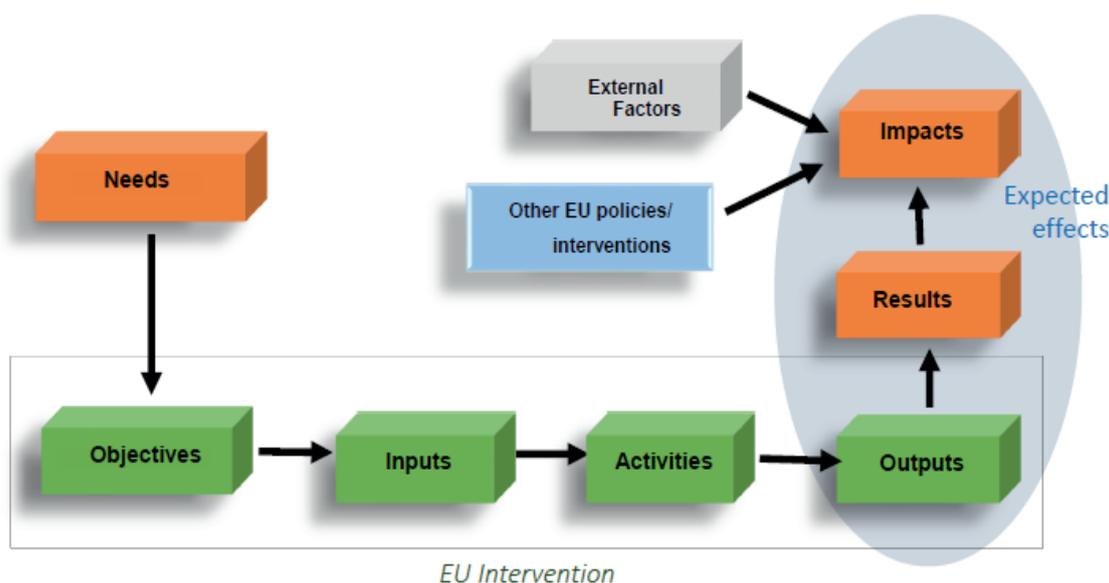
- What was the rationale for the intervention? What were the ‘**problems**’ or ‘**needs**’ that the intervention was meant to solve? → **Tip:** Look at relevant background documents to understand the context – these may include a previous impact assessment, associated studies, legal text (particularly the recitals) and associated explanatory memorandum. These may also be helpful in identifying key deadlines, milestones, and deliverables.
- How were the **objectives** expected to be achieved? What was the ‘positive desired situation’? What were the expected changes that the EU wanted to achieve?
- How were these changes to be achieved? What **inputs** were expected to be used? → **Tip:** Inputs can be a very encompassing term, covering for example resources such as staff, time, and equipment as well as the legal act. Which events (**activities**) were expected to happen?
- What was expected to be achieved in the short, medium, and long term (**expected outputs, results, impacts**)?

⁶⁵⁶ In evaluations, the concept of intervention logic combines elements from the Logframe approach and the Theory of Change. Both approaches are used to describe causal pathways in interventions and the mechanisms that enable them. The differences between the Logframe approach and the Theory of Change are not clear-cut and they are used in various definitions. In application, their meaning often overlaps.

⁶⁵⁷ See Tool #47 (*Evaluation criteria and questions*)

- Can any **external factors** be identified which may have influenced the performance of the EU intervention, or generated the same type of effects? Reality is complex and many other players and factors can intervene and influence a situation.

Figure 1: Simplified intervention logic

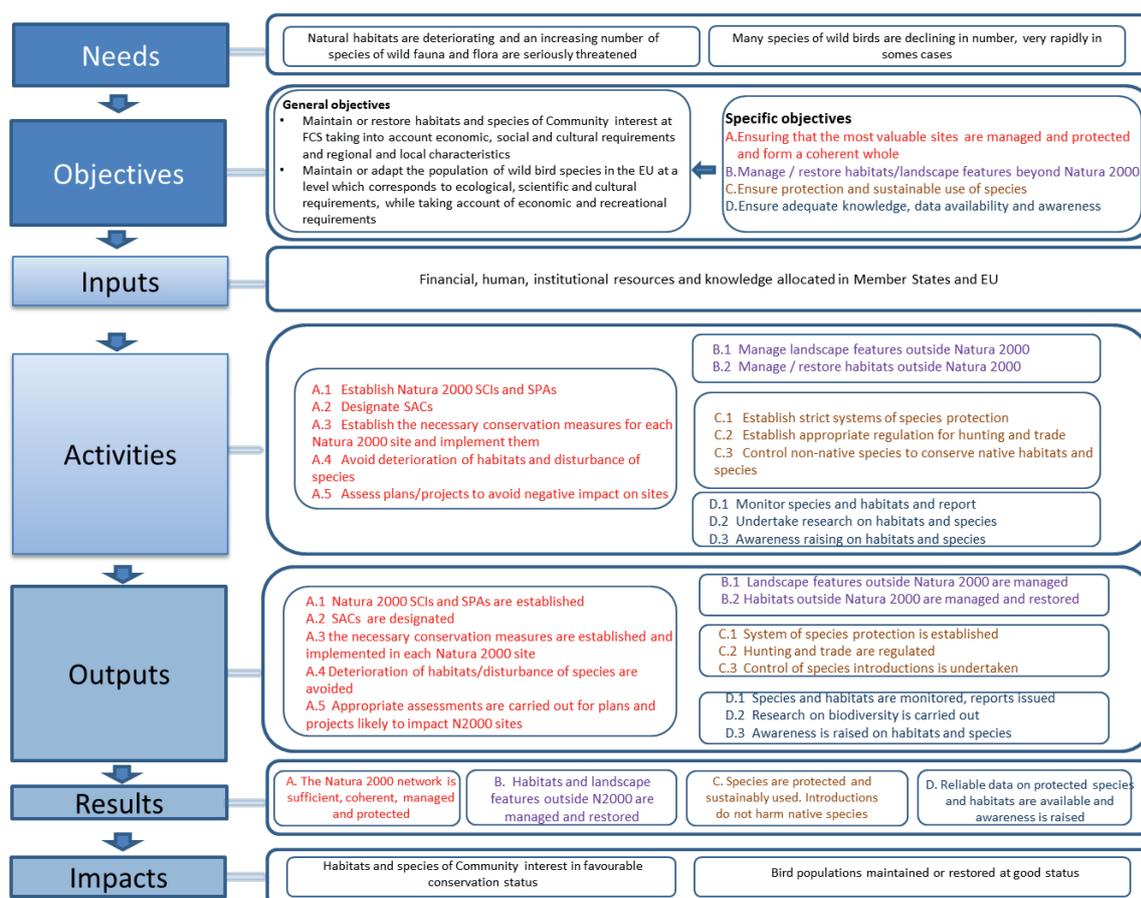


Moreover, the intervention logic (narrative part) could further describe:

- Who was expected to be involved? How were these entities expected to be involved – were they going to be affected by the intervention (positively or negatively)? Were they responsible for taking a particular action? Activities are often more tangible or visible.
- When was something supposed to happen? What was the expected order of activities or events? What was expected to happen at the same time (in parallel)? What was supposed to happen before or after something else (sequentially)? What changes were expected to be positive (benefits / cost savings) or negative (costs) and for whom? This consideration of changes over time (outputs/results/impacts) may then be linked to the hierarchy of objectives in the impact assessment.
- What obligations were set or what provisions were expected to be put in place? For the evaluation of legislative actions, many of the required actions are identified in the articles of the legal act. These physical ‘inputs’ are often translated into monetary values, leading to a broader consideration of what has been needed to achieve objectives and possibly to considerations of costs and benefits. For example, costs and benefits related to changes in employment practices made by an employer to comply with an EU law, or costs incurred by a Member State due to new reporting obligations may start with a consideration of training needs, time taken to train, new systems bought, etc.

A typical example of an intervention logic included in a Commission evaluation staff working document is presented below.

Intervention logic for the Birds and Habitats directives:



It is important to check the draft intervention logic with the interservice coordination group, to see whether it ‘flows’ and is truly ‘logical’, describing the appropriate causal pathways. It is also important to check whether appropriate attention has been given to all the elements which influenced the design of the intervention, including changes made during the adoption process.

In terms of the process, a first (rough) draft intervention logic (design phase) should be developed by the lead DG and discussed with the interservice coordination group ideally **at its first meeting**. It can also be useful to test it out both with colleagues who understand the intervention, and with people who have little familiarity with the subject.

It is recommended that a first (rough) draft intervention logic is included in the terms of reference for external work, and contractors are asked to either (a) demonstrate their understanding and evaluation skills by providing a more elaborated version, and/or (b) develop and test with various stakeholders the shared understanding of the draft intervention logic, and/or (c) develop the final intervention logic which provides, among other things, for the actual effects (i.e. actual outputs, results, impacts).

A good understanding on how the intervention was expected to work, including the underlying assumptions is essential for identifying good evaluation questions.

2.4. Drafting good evaluation questions

Establishing the intervention logic is useful in identifying specific and robust evaluation questions linked to the initial expectations of the policy intervention. Robust evaluation questions encourage critical analysis. By defining and sharing the questions early in the process, the Commission services clarify what they intend to analyse and invite interested parties to provide relevant contributions. These questions will then influence the design and conduct of the subsequent steps, and their answers will feed the narrative of the evaluation report.

Questions should be worded in a way that forces the evaluator to provide a complete, evidence-based answer that improves understanding of the performance of the EU intervention against the five evaluation criteria. Answers should go beyond providing a yes/no answer based on simple description and to look at what the links were between the changes observed and the original intention of the EU intervention(s). This tends to mean that evaluation questions are 'causal' or 'normative', but they also need to be 'critical'. Moreover, evaluation questions should draw from the intervention logic, assessing for example whether the expected outputs, results and/or impacts were achieved effectively and efficiently, or whether needs and objectives are still relevant, etc⁶⁵⁸.

Broad, generic questions based on the criteria themselves, such as *How effective has the EU action been?*, should be approached with a number of more detailed, specific questions e.g. *What factors linked to the Directive have most influenced progress?*, *To what extent have the arrangements set out in Article 7 been able to influence progress towards the objectives of the Directive?* Although general questions are important as they allow the analysis to follow the collected evidence, which can often unearth unexpected or unintended changes, this is only true if these general questions are made more specific.

Specific questions allow issues raised during adoption or implementation to be further investigated, e.g. in relation to detailed arrangements that caused strong debate and a compromise solution to be adopted, or based on feedback from stakeholders that a given article is problematic or a procedure is difficult. It is important that such questions reflect the level of progress and performance expected at the time of the evaluation. For example, if at the time of the evaluation no businesses have completed a certification process specified in the respective EU legislation, there should be no evaluation questions about how well the specified process has worked⁶⁵⁹; instead, if not obvious, the evaluation question should be on the cause of this outcome.

When considering the questions to ask it is also important to think about the usefulness of an answer, and the feasibility of obtaining an answer. This again links back to considerations of scope and purpose. The availability of data to provide evidence to answer the question is also a relevant consideration.

2.5. Point(s) of comparison

The evaluation aims to capture the change that an intervention has brought over time. To do this, it needs to compare actual performance against one or more points of comparison.

⁶⁵⁸ See Tool #47 (*Evaluation criteria and questions*), Figure 1 on a simplified view of the intervention logic and the 5 evaluation criteria

⁶⁵⁹ See Tool #47 (*Evaluation criteria and questions*).

Where there is a prior impact assessment, the expected results and impacts of the preferred policy option should be the preferred point(s) of comparison. To the extent possible and proportionate, these may need to be adapted to create an evaluation point of comparison, **reflecting any relevant changes since the IA was published** (such as significant changes during the legislative process). Ideally, such point(s) of comparison are already quantified in the impact assessment⁶⁶⁰ or can be quantified (e.g. expected level over time of pollution or emission of certain substances; level of employment). As a minimum, a qualitative description of what was expected to happen should be given (e.g. description of expected trends in nature, levels of education in society etc).

Where no prior impact assessment exists, the evaluation will usually have to build its own point(s) of comparison for example based on existing data measuring the situation at or around the time the EU action started. Where there is no existing data measuring the situation at or around the time the EU action started, this may have to be a qualitative description.

In other instances, there may be one or more figures which do provide some information relevant to the situation (e.g. level of a certain chemical before EU intervention; level of employment). A reasonable starting point for constructing a point of comparison for the evaluation would then be to take this information and reflect on how it might have continued over the period being evaluated, had there been no policy change. For example, is it realistic to assume a constant level of performance over this period (number does not change)? Or was some level of increase or decrease more likely? How big an increase or decrease? This might allow a reasonable point of comparison to be created. In doing this, it will be important to state clearly the assumptions being made (e.g. constant performance, decline of 10% a year in line with global trend, etc).

Other useful points of comparison that could be investigated for relevance and applicability include:

- Another scenario or benchmark, such as the situation prior to implementation, an earlier programme, or systems in countries outside EU.
- Different performance ('policy-on') or counterfactual ('policy-off') scenarios may be used, based on clearly stated assumptions. For instance, a common counterfactual scenario would be to consider the situation where the Union does not act⁶⁶¹.
- Other benchmarks may also be identified or exist for the policy context. They may be used for comparison, to provide additional context or as an aid to interpreting the change identified. For example, there may be benchmarks for certain types of cost, durations of processes which can be drawn from industry or from other countries. Often this type of benchmarks are concrete, actual figures or levels of performance which have been achieved – rather than aspirations or predictions.

⁶⁶⁰ The predictions from the impact assessment are generally the estimated costs and benefits. This will provide an insight into how actual developments compare to what was expected at the time. The original impact assessment predictions may need to be updated to address changes introduced during the discussions with the co-legislators.

⁶⁶¹ As EU policies operate in a complex environment influenced by a wide range of factors falling outside the scope of the EU intervention, it requires effort and resources to identify a robust counterfactual scenario. For more information on counterfactual scenarios see Chapter VIII – Tool #68 (*Methods for evaluating causal effects*)

Evaluations may have several points of comparison. This depends on the evaluation criterion to be assessed. For example:

- When assessing relevance, the suitable points of comparison are the original needs and objectives behind the EU intervention and new needs arising from changing policy objectives or upcoming technological, social, environmental, or economic changes and the use of strategic foresight information.
- When assessing coherence, suitable points of comparison could include looking at the changes in coherence between the start and end of the period being evaluated or, if applicable, information from the impact assessment (i.e. assessment of coherence of preferred policy option). They could also include looking at existing or new national or international actions.
- When assessing the EU added value, the comparison involves consideration of performance against a projection of how the situation was expected to evolve without the EU intervention (a defined counterfactual, or some estimate of the cost of the Union not acting – 'the cost of non-Europe'). Often such analysis assesses whether the subsidiarity arguments put forward before the intervention (as presented in a prior impact assessment, or other accompanying documents such as the explanatory memorandum) were valid and whether the expected changes resulting from EU action were delivered.
- When assessing effectiveness and efficiency, suitable points of comparison could include looking at what was expected to have happened at this point, including comparison with the stated specific and operational objectives (and targets if applicable) as in the impact assessment, explanatory memorandum etc; or another scenario or benchmark, such as the situation prior to implementation, an earlier intervention, groups that did not participate or benefit from the intervention, or similar systems in countries outside the EU.

For consistency purposes, **the source for identifying points of comparison** should ideally stay the same for addressing all evaluation criteria (e.g. the prior impact assessment, the situation at or around the time the EU action started, etc).

When deciding on the appropriate point(s) of comparison possible, consideration should be given to:

- **availability of data:** Does the impact assessment contain information reflecting the adopted intervention? Is data available to judge if these projections need to/can be updated? Are there other 'benchmarks' from EU/non-EU countries or organisations that can be used to assess performance? Could the UN sustainable development goals and targets be used as benchmarks? Are other relevant data available that can describe the situation before the intervention? Is it feasible to collect them? Has monitoring been conducted since the intervention started (allowing a robust assessment of actual change over time)?
- **relevance of the points of comparison:** different sources for extracting comparison points may be more useful, depending on the different evaluation criteria and/or the exact evaluation question posed. However, different sources for extracting comparison points may be very difficult to manage and can create some arbitrary conclusions.

After identifying the appropriate point(s) of comparison, it is necessary to consider what type of analysis is possible. At the very least, comparison should enable the evaluator to judge whether change has occurred and to decide whether it is a change in the desired direction (e.g. increase or decrease) and to what extent as a consequence of the intervention. When causal analysis⁶⁶² is not possible or only at disproportionate cost in terms of data collection and resources, EU evaluations have to rely on qualitative, reasoned arguments (backed by the appropriate quantitative and qualitative evidence) about the likely role/contribution of an EU intervention to the changes observed.

There is growing expectation to find ways to reliably quantify the impacts of EU interventions and efforts should be made to aim for high quality causal evidence⁶⁶³.

2.6. Methodologies and data

The methodology of an evaluation should consist of a combination of tools and techniques assembled to provide answers to its evaluation questions.

Data availability and quality of data will play a key role in deciding which analytical methods can reliably be applied. It will also influence consideration on who will be assigned which tasks – what will be done by Commission staff and what will be contracted out.

The time and budget allocated to the evaluation will have a significant influence on both the methods chosen and the data collected. The lead DG may also wish to contact the JRC who can advise on data sources and methods that might be used for the evaluation. In particular, the JRC is developing knowledge-management services bringing together data collected during earlier evaluations, impact assessments and studies⁶⁶⁴. It can also help in reviewing existing evidence in international specialised literature.

It is also important that evaluations clearly state the challenges that have been encountered and resulting limitations in the certainty or accuracy of the findings, particularly as these vary greatly from case to case.

When considering human resources, it should be kept in mind that desk officers in the Commission involved in evaluation are not expected to become experts in the many tools and techniques available for use in evaluation. Such expertise is generally available in the DG's evaluation / 'better regulation' function, economic analysis function, from the JRC and/or from external contractors. However, it is still necessary to have a general understanding of various approaches to data collection and analytical methods, in order to:

- ensure the focus is only on relevant data, which helps to answer the evaluation questions;
- recognise the strengths and limitations of the methods proposed;

⁶⁶² Causality, in the context of evaluation, checks the plausibility of the expected chain of events whereby the EU intervention was expected to alter behaviours and create the expected changes (e.g. as identified in a preceding impact assessment) or any other unintended or unexpected changes. It seeks to establish a relationship between an intervention and the observed changes in the issues which the intervention addressed. See also Tool #68 (*Methods for evaluating causal effects*)

⁶⁶³ See also Tool #4 (*Evidence-informed policymaking*)

⁶⁶⁴ https://knowledge4policy.ec.europa.eu/microeconomic-evaluation_en

- understand which methods can be combined, to ensure that the data is based on several sources of information and that the analysis is drawn from several perspectives (triangulation);
- estimate whether a contractor's offer to use a certain set of methodologies in an evaluation is realistic in view of the reliable data, time, and budget available.

When performing an evaluation not supported by any external (contracted out) work, it is equally important to have a reasonable overview of such aspects, before acquiring a deeper understanding of the methodologies selected for use.

It is important to consider ways to design the evaluation **so that it is possible to triangulate data and modelling results from different sources**. When thinking about the data needed for an evaluation, **it is necessary to look first at what is already available** – for example, from existing monitoring and reporting arrangements or studies which have been conducted, **including any prior impact assessment**, explanatory memorandums or staff working documents accompanying the policy measure under evaluation. A key source of information, which is often overlooked, is to **check what evidence-based complaints (if any) have been received from stakeholders and interested parties**. For evaluations involving legislative interventions, it is also important to **check whether any infringements have been detected** and to investigate the underlying reasons for the alleged violation. Both these sources of information can provide significant insight into the actual and perceived performance of the intervention being evaluated. Equally, in policy areas related to the four freedoms of the single market, the SOLVIT database might provide additional information.

Once this stock-take of existing data has been carried out, it will be easier to identify new data which will need to be collected and to consider the mix of objective (quantitative) and subjective (qualitative) data. Reduction to either only objective or only subjective data for the whole evaluation work is not optimal. Objective data often comes from statistical reports, monitoring, or modelling (although the degree of objectivity will be affected by the assumptions underpinning the model), while subjective data is generally opinion based. All evaluations require a consultation strategy presenting consultation scope and objectives, identification of stakeholders, envisaged consultation activities, their timing and language regime⁶⁶⁵.

Efforts should be made to improve the degree and quality of quantification and modelling provided in evaluations and fitness checks and to put a number (or a range) on the costs, benefits and value delivered by the EU intervention⁶⁶⁶.

Whether evidence is quantitative or qualitative, every evaluation should include an assessment of limitations and uncertainties of the evidence (e.g. due to poor data availability, assumptions or modelling issues), as well as mitigation measures used to remedy such limitations. Building on this assessment, the evaluation should also conclude on the robustness of findings and conclusions made.

The information on data collection and analytical approach is brought together in an 'evaluation matrix'. This identifies for each evaluation question per criterion:

⁶⁶⁵ See Chapter VII on Stakeholder consultation

⁶⁶⁶ See Tool #57 (*Methods to assess costs and benefits*)

- the ‘success’ or ‘judgement’ criteria (i.e. points of comparison) against which the answer to the question can be assessed;
- associated indicators and/or targets, which may be both quantitative and qualitative;
- data necessary to fill the indicators and provide information for the success/judgement criteria – this should consider not just the type of data, but which stakeholders it involves, whether it is already available or needs to be collected (and how this might happen), time required / feasibility to collect. Where questions have the same sources of data, this may suggest a way to cluster them; where questions require specialised data, the resource implications should be considered;
- analytical methods for turning data into necessary indicators or information – again considering how this can be done, who will do it, time required / feasibility to do etc. This may then lead to consideration of data collection and analysis methods (and can also be used to inform decisions on the work to be contracted out and its possible value).

Example of an evaluation matrix:

To what extent do the provisions of Directive 92/83/EEC ensure proper functioning of the internal market?

Question	Sub-question	Judgement criteria	Indicator	Data sources
1.1 To what extent does the Directive ensure legal certainty and clarity with regards to the classification of alcohol and alcoholic beverages for excise purposes?	1.1a Which products are difficult to classify (e.g. because they could, arguably fall within several excise categories)?	The applicable rules result in difficult and/or unclear classifications of alcoholic beverages	Classification of alcoholic products that do not fall into one clear category, such as mixtures of fermented beverages and spirits, alcopops containing cleaned-up alcohol, cream liqueurs, mead, by the Member States. Other reported instances of alcoholic products whose excise classification was difficult	Survey to national tax authorities Survey to economic operators Reported statistics Studies /papers
	1.1b Do the ambiguities post Siebrand (C-150/08) still cause problems in this area?	Degree to which classification of concerned products follows the criteria laid down in the judgement	Classification of products containing a mixture of fermented and distilled alcohol products by the Member States The interpretation of the ‘essential character’ or particular products	Survey to national tax authorities Survey to economic operators Reports and studies

Chapter 8 provides information on available methodologies for evaluation. The European Commission’s Competence Centre on Microeconomic Evaluation (JRC) can provide advice on appropriate evaluation methods and data, where needed.

2.7. The evaluation design checklist

The following step-by-step approach can be used to assist the lead DG and the interservice coordination group in designing the key elements of the evaluation / fitness check and monitor the level of completion for each step. For evaluations and fitness checks selected for scrutiny, the checklist may also be used to structure the discussion with the Regulatory Scrutiny Board in the upstream meeting⁶⁶⁷.

⁶⁶⁷ See Tool #3 (Role of the Regulatory Scrutiny Board)

Evaluation design – a step by step approach (‘evaluation design checklist’)



TOOL #47. EVALUATION CRITERIA AND QUESTIONS

1. INTRODUCTION

All evaluations and fitness checks should base their analysis on the evaluation criteria of **effectiveness, efficiency, coherence, relevance, and EU added value of the intervention**, or provide due justification why this is not the case⁶⁶⁸. Additional criteria beyond these five can be added, if at all necessary. This also needs to be duly justified.

The evaluation criteria should structure the analysis and ensure it is comprehensive. The evaluation needs to report on them⁶⁶⁹, but the purpose of the analysis should be to draw operational conclusions and lessons learned that can feed into future initiatives.

Evaluations and fitness checks should always assess the economic, social, and environmental impacts of EU interventions (expected or unexpected) with, where relevant, particular emphasis on those impacts identified in a previous impact assessment.

The degree of analysis conducted for each criterion should be proportionate: it depends on the **intervention** being evaluated, the **timing** of the evaluation and the adequacy and reliability of the **data**. Often this will mean that for some criteria new data will need to be collected, analysed, and compared with other findings; while for others, a short summary can be presented based on existing reports and information.

For example, at an 'early' stage in the intervention's lifecycle, it may not be necessary to judge the relevance criterion in any depth. If it is only a short time since the intervention has been implemented, it may be fair to assume the continued relevance of the action and hence simply restating previous arguments should suffice; alternatively, stakeholder feedback may be the only indicator of whether needs have changed and some summary presentation of their (unchanged) opinions may also be sufficient. Equally, EU added value may be difficult to judge in the early years, particularly if the intervention concerns setting up new EU decentralised agencies or other EU bodies or putting in place a framework. In these cases, confirming the validity of the (theoretical) EU added value may be as much as is reasonably possible at that time.

Establishing the intervention logic is usually helpful in identifying specific evaluation questions, based on the evaluation criteria. As mentioned in the tool on designing the evaluation (Tool #46), there is a need to ensure that all evaluation questions focus on providing useful information such as information on the changes the intervention sought to achieve, investigating particular intervention characteristics or factors, which have (not) worked. It is also advisable not to have too long a list of evaluation questions at the start of an evaluation as it may be too constricting and prevent the analysis from 'going where the data leads'. Whilst evaluation sub-questions can be developed early in the evaluation process, e.g. to help define a particular question, or drill down on specific areas, this may also happen at a later stage in response to evidence collected. In this regard, it is important to give the

⁶⁶⁸ The evaluation of a single intervention may on an exceptional basis omit one or two of the five evaluation criteria. An exception must be granted, and clear justification for such omission must then be provided in the evaluation roadmap and repeated in the final evaluation report. Fitness checks always consider the five criteria.

⁶⁶⁹ [Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-making](#)

evaluator the flexibility to develop additional questions or sub-questions later in the process as they see fit.

Depending on the specific evaluation there may be overlaps between the criteria – for example, for relevance and EU added value. **It is generally more important to identify a good set of evaluation questions, than to be too concerned about how to categorise the question as long as the different criteria are addressed.**

It is advised to discuss the evaluation questions with the interservice coordination group. The evaluation questions can either be set at the time that the 'call for evidence' is published or discussed at the first interservice coordination group meeting and defined shortly thereafter. These questions will then influence further the design and conduct of the subsequent steps; they should be reported in Annex III of the evaluation report that takes the form of a staff-working document⁶⁷⁰.

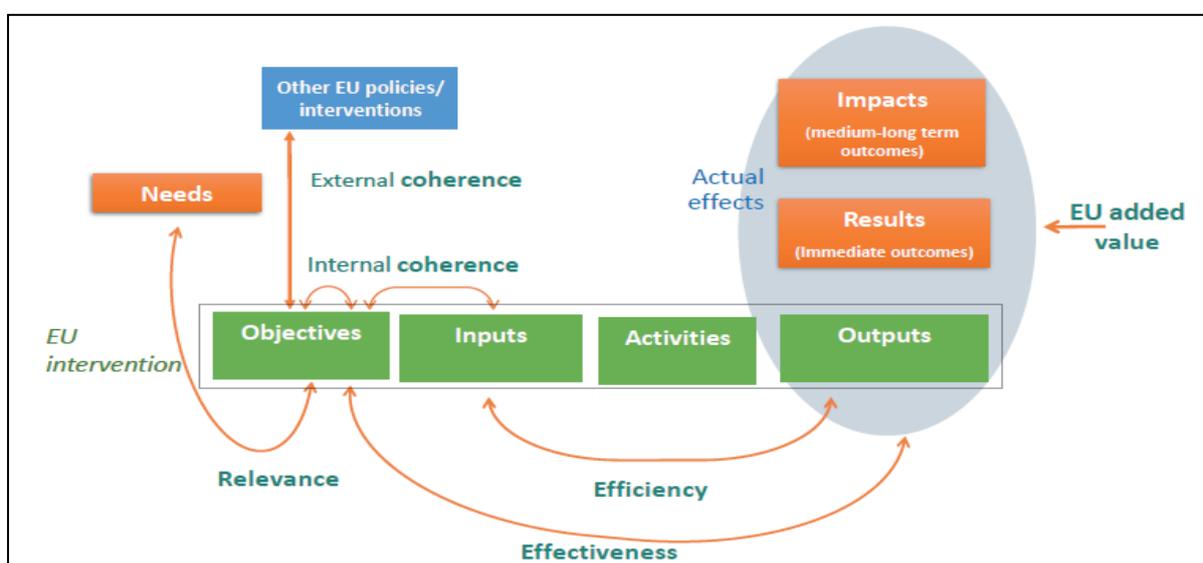


Figure 1: Simplified view of the intervention and the 5 key evaluation criteria

2. EFFECTIVENESS

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives. The evaluation should form an opinion on the progress made to date and the role of the EU action in delivering the observed changes. If the objectives have not been achieved, or things are not on track, an assessment should be made of the *extent* to which progress has fallen short of the target and what factors have influenced *why* something has not been successful or *why* it has not yet been achieved. To this end, the effectiveness analysis should seek to identify the factors driving or hindering progress and how they are linked (or not) to the EU intervention.

The **effectiveness analysis should look closely at the benefits of the EU intervention as they accrue to different stakeholders**⁶⁷¹. It should identify what factors are driving these benefits and how these factors relate to the EU intervention.

⁶⁷⁰ See Tool #49 (*Format of the evaluation report*)

⁶⁷¹ See also Chapter VIII *Methods, models and costs and benefits*.

Consideration should also be given to whether the objectives can still be achieved on time or with what delay. The analysis should also try to identify if any *unexpected* or *unintended* effects have occurred. The analysis needs to consider how the observed changes may be linked to the actions triggered by the EU intervention. Ultimately, the analysis of effectiveness should provide an answer on whether the EU action has successfully achieved its objectives.

Box 1: Typical examples of questions about effectiveness

- How successful has the EU intervention been in achieving (or progressing towards) its objectives? To what extent were the expected changes resulting from EU action delivered?
- What have the quantitative and qualitative effects of the intervention been? Are they as expected when introducing the intervention?
- What external factors have affected progress towards the objectives and how are they linked to the EU intervention?
- If the objectives have not been achieved yet, can the objectives still be achieved in time? If not, with what delay?
- Are there any unexpected or unintended effects that have occurred, and which drove or hindered progress? What can explain these effects?

Points of comparison to consider

In many cases, performance can be identified from monitoring data covering the relevant period. This can then be compared to a relevant point of comparison⁶⁷² such as:

- What was expected to have happened at this point (based on the adopted proposal, drawing on the appropriate information from a prior impact assessment or other relevant documents, such as the explanatory memorandum), including comparison with the stated specific and operational objectives (and targets if applicable); or
- Another scenario or benchmark, such as the situation prior to implementation, an earlier intervention, groups that did not participate or benefit from the intervention, or similar systems in countries outside the EU.

3. EFFICIENCY

Efficiency considers the resources used by an intervention for the given changes generated by the intervention (which may be positive or negative). Differences in the way an intervention is approached and conducted can have a significant influence on the effects, making it interesting to consider whether other choices (e.g. as demonstrated via different Member States) achieved the same benefits at less cost (or greater benefits at the same cost).

Efficiency analysis should look closely at the costs of the EU intervention as they accrue to different stakeholders⁶⁷³. It should identify what factors are driving these costs and how these factors relate to the EU intervention. The purpose of the assessment of efficiency is to

⁶⁷² For more information on various points of comparison, see Tool #46 (*Designing the evaluation*)

⁶⁷³ See also Chapter VIII on *Methods, models and costs and benefits*

show that resources are used to their best and therefore that the costs generated are strictly necessary to reach the policy objectives. If this is not the case, the potential for simplification is to be highlighted in this analysis.

The efficiency analysis should also compare the identified costs with the benefits that were identified under the effectiveness criterion. As a rule, the benefits of EU interventions are expected to exceed the costs they generate. However, in specific cases, costs might exceed benefits in the short term, with net benefits occurring with a lag. Furthermore, those who bear the costs do not always reap the benefits. This is often the case for safety, health, environment, climate, or consumer protection policies. The evaluation should take into consideration such lags and identify such distributional effects and assess whether they were expected or not. Efforts should be made to address in quantitative terms benefits and costs arising from the intervention.

All evaluations are required to explore the potential for simplification and burden reduction. Typical efficiency analysis will measure administrative and regulatory burden and look at aspects of simplification, which is important for ALL evaluations. Where appropriate, evaluation findings should pinpoint areas where there is potential to reduce inefficiencies, particularly unnecessary regulatory costs, and simplify the design and implementation of the intervention. The full efforts to support and perform an intervention can be broken into different categories such as adjustment costs, administrative costs, fixed costs, running costs, etc⁶⁷⁴.

'Better regulation' and particularly the REFIT programme (commitment on simplification) place a strong emphasis on identifying and where possible measuring (i.e. if possible, quantifying or monetising) the costs and benefits of EU interventions⁶⁷⁵.

Tailored fitness checks, for example those that look at specific reporting requirements, have a strong simplification and burden reduction potential. The efficiency assessment should look particularly at the angle of reducing overlaps, inconsistencies but also at alternative ways of performing the required action(s), such as the scope for simplification.

A cumulative cost assessment (CCA)⁶⁷⁶, although providing inputs into the evaluation process, is not sufficient on its own to provide the required full picture in terms of the efficiency of the EU intervention. As such, it cannot be "the sole basis for policy recommendations"⁶⁷⁷. To serve as an instrument for the policymakers, CCAs need to be put in the context and CCAs need to be supplemented by the analysis of the corresponding benefits arising from the EU legislation⁶⁷⁸.

Assessing costs and benefits may be (methodologically) easier for spending programmes which have well defined stakeholders, systems, etc. Doing this with precision at EU level can be difficult since obtaining robust, good quality data to use in the evaluation of costs and benefits may be challenging, particularly across all Member States which may have

⁶⁷⁴ See Tool #56 (*Typology of costs and benefits*)

⁶⁷⁵ See Tool #2 (*The Regulatory fitness programme (REFIT) and the Fit for Future Platform*); and Tool #57 (*Methods to assess costs and benefits*)

⁶⁷⁶ CCA are studies that aim to estimate the overall regulatory burden on a particular sector. In the EU context, the CCAs will look at the costs arising from the EU regulations.

⁶⁷⁷ Page 15, [Regulatory Fitness and Performance: State of Play and Outlook; COM \(2014\) 368 final](#)

⁶⁷⁸ Further discussion on costs and benefits analysis in the context of CCA is provided in the Tool #57 (*Methods to assess costs and benefits*)

implemented legislation in a variety of different ways and at different points in time. However, sufficient efforts should be dedicated to this task, given its importance.

Table 1: Approach towards efficiency analysis in specific cases

	Costs				Benefits					Benefits and costs have same scope and are directly comparable?
	Specific to the sector	To all affected sectors	General welfare/ Costs to society	Overall cost of a policy	Specific to the sector	To all affected sectors	General welfare / Benefits to society	Of a specific policy	Overall benefit of a policy	
Evaluation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fitness check	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sectoral fitness check	Yes	No	No	No	Yes	No	No	Partial	Partial	Possibly
Cumulative cost assessment	Yes	Possibly	Possibly	Possibly	No	No	No	No	No	N/A

Box 2. Typical examples of questions about efficiency

- What are the costs and benefits for different stakeholders? Were the costs and benefits of the intervention distributed as expected among them? What could explain the differences (if any)?
- To what extent are the administrative and/or adjustment costs of the intervention justified, given the changes/effects it has achieved?
- Have the changes/effects of the intervention been achieved at initially expected costs or were these costs different for whatever reason? What could explain the differences (if any)?
- To what extent do factors linked to the intervention, influence the efficiency with which the observed achievements were attained? What other factors influence the costs and benefits?
- Have any inefficiencies been identified? Could the intervention have been done in a more efficient way? What is the simplification and cost reduction potential of the intervention?
- If there are significant differences in costs (and benefits) between Member States, sectors, etc., what is causing them? Were they expected?
- How timely and efficient is the intervention’s administrative process (e.g. for reporting and monitoring)?
- For spending programmes, how efficient was the governance of the programme?
- For decentralised agencies, to what extent has the governance structure of the agency supported its ability to perform its tasks, having regard to its size, composition, organisation and working processes? To what extent were their activities effectively resourced?

Points of comparison to consider

Points of comparison for efficiency are usually quantitative. In many cases, performance can be identified from monitoring data covering the relevant period. This can then be compared to a relevant point of comparison⁶⁷⁹ such as:

- What was expected to have happened at this point (based on the adopted proposal, drawing on the appropriate information from a prior impact assessment or other relevant documents, such as the explanatory memorandum), including comparison with the stated specific and operational objectives (and targets if applicable); or
- Another scenario or benchmark, such as the situation prior to implementation, an earlier intervention, groups that did not participate or benefit from the intervention, or similar systems in countries outside the EU.

4. RELEVANCE

Relevance looks at the relationship between the needs and problems at the time of introducing the intervention and during its implementation. **Relevance should also look at the relationship between the current and future needs and problems in the EU and the objectives of the intervention.** Relevance analysis requires a consideration of how the objectives of an EU intervention (legislative or spending measure) correspond to wider EU policy goals and priorities. Analysis should identify if there is any mismatch between the objectives of the intervention and the current and the foreseeable future needs or problems. For example, 'problem drivers'⁶⁸⁰ identified in the impact assessment may now be obsolete; circumstances may have changed, and the needs and problems now may not be the same as the ones looked at when the intervention was designed.

Relevance analysis is very important – because if an intervention does not help address the current and the likely future needs or problems (on the basis of new objectives) then it does not matter how effective, efficient or coherent it is – it may no longer be appropriate (this is why relevance is sometimes called the 'kill' criterion!). The relevance analysis may also consider future needs or problems identified on the basis of trends and foresight analysis. This is key information that will assist policy makers in deciding whether to continue, change or stop an intervention and also explains the strong link between relevance and the criterion of EU added value – which assesses whether action continues to be justified at the EU level.

Box 3. Typical examples of questions about relevance

- To what extent did the scope and objectives of the intervention remain relevant over the implementation period?
- How did the objectives of the intervention (legislative or spending measure) correspond to wider EU policy goals and priorities?
- To what extent is the intervention still relevant in view of the objectives? How well do

⁶⁷⁹ For more information on various points of comparison, see Tool #46 (*Designing the evaluation*)

⁶⁸⁰ See Tool #13 (*How to analyse problems*)

the (original) objectives of the intervention still correspond to the needs within the EU?

- To what extent do the needs/problems addressed by the intervention continue to require action at EU level?
- How well adapted is the intervention to the technological or scientific progress that has appeared since its introduction? How well adapted is the intervention to social, environmental changes or developments related to implementation, reporting and compliance?
- Have the circumstances changed in the meantime so much that the intervention has to change/adapt to them over time?
- How relevant is the intervention to EU citizens? Will it continue to be relevant for them in the near future?
- For decentralised agencies, how have the agency’s activities contributed to the achievement of the overall EU policy objectives and priorities, and how well have they been able to respond to the needs of their stakeholders?

Points of comparison⁶⁸¹ for relevance are usually more qualitative. It is necessary to think about what the needs and objectives behind the EU intervention were and compare them to the current situation. It is also advisable to consider how the situation is likely to develop in the future (e.g. based on new political priorities and objectives, anticipated or upcoming technological, social, environmental or economic changes, and the use of strategic foresight information). In addressing the question of continued relevance, it may be useful to look at how megatrends (such as demographic change or digitalisation of services) may impact the intervention. Information on foresight approach and related instruments can be found in Tool #21 (*Strategic foresight for impact assessments and evaluations*).

5. COHERENCE

The evaluation of coherence involves looking at how well (or not) different interventions, EU/international policies or national/regional/local policy elements work together. It may highlight areas where there are synergies which improve overall performance or which were perhaps not possible if introduced at national level; or it may point to tensions e.g. objectives which are potentially contradictory, overlapping or approaches which are causing inefficiencies.

Checking **‘internal’ coherence** means looking at how the various components of the same EU intervention operate together to achieve its objectives, e.g. the different articles of a piece of legislation, different actions under an action plan. Checking **‘external’ coherence** means that similar checks can be conducted in relation to other (‘external’) interventions, at different levels: for example, between EU interventions within the same policy field (e.g. a specific intervention on drinking water and wider EU water policy) or in areas which may have to work together (e.g. water policy and chemicals policy, or chemicals and health and safety). Where relevant, analysis of coherence may involve checking whether interventions are in line with the objectives of the European Green Deal, or whether the intervention is consistent with the overarching environmental goals (such as the Climate Law) or other policies targeting the environment⁶⁸². At its widest, external coherence should also look at compliance with

⁶⁸¹ See Tool #46 (*Designing the evaluation*)

⁶⁸² See Tool #36 (*Environmental impacts*)

national policies or international agreements/declarations (for example EU labour market interventions might be looking into coherence with ILO conventions), in particular the UN sustainable development goals or EU interventions in developing countries.

The focus on coherence may vary depending on the type of evaluation **and is particularly important in fitness checks**, where coherence analysis will look for evidence of synergies or inconsistencies between policies in a related field that are expected to work together. Even when evaluating an individual intervention, it is important to check coherence with other interventions which have the same or similar objectives.

When assessing coherence, comparison with other scenarios is predominantly qualitative. Suitable points of comparison⁶⁸³ could include looking at changes in coherence between the start and end of the period being evaluated or, if applicable, information from the impact assessment (i.e. assessment of coherence of preferred policy option). They might also include looking at existing or new national or international actions, including the UN sustainable development goals that have been adopted in 2015 and are now at the heart of the Commission's policymaking. The level of coherence being evaluated (e.g. internal to a given EU action, within a given policy field, wider EU policy or wider global context) could also affect the comparison point and degree of analysis possible.

Box 4. Typical examples of coherence questions

- To what extent is this intervention coherent with other EU and national interventions that have similar objectives⁶⁸⁴?
- Does the intervention comply with the green oath to 'do no significant harm', and could it help respond better to significant harm?
- To what extent are the various elements of intervention coherent with one another?
- To what extent have the various elements of intervention generated synergies and/or compensated possible trade-offs among them?
- To what extent is the intervention coherent with (current) wider EU policies and priorities (e.g. Commission policy priorities)?
- To what extent is the intervention coherent with international obligations, including the SDGs?
- For decentralised agencies, to what extent has the agency coordinated its work and made best use of existing resources with other relevant bodies, governmental institutions, and agencies active at EU, national and international level carrying out similar tasks? To what extent were inappropriate overlaps of mandates avoided?

6. EU ADDED VALUE

EU added value⁶⁸⁵ looks for changes that are due to the EU intervention, over and above what could reasonably have been expected from national actions by the Member States. In many

⁶⁸³ See Tool #36 (*Environmental impacts*)

⁶⁸⁴ Outline these objectives to make the question less abstract.

⁶⁸⁵ For further information see [SEC\(2011\) 867 final "The added value of the EU budget"](#).

ways, the evaluation of EU added value brings together the findings of the other criteria, presenting the arguments on causality and drawing conclusions, based on available evidence, about the performance of the EU intervention.

Under the principle of subsidiarity (Article 5 Treaty on European Union), and in areas of non-exclusive competence, the EU should only act when the objectives can be better achieved by Union action rather than action by the Member States. It requires consideration of the added value of EU action compared to that of other actors⁶⁸⁶. **EU added value analysis should, where applicable, respond to the subsidiarity analysis conducted in any related IA.**

In practice, the EU added value in evaluations should assess retrospectively whether the subsidiarity analysis was valid, and the policy remains fit for purpose. The EU added value assessment provides the verification of compliance with the subsidiarity principle, based on information and analysis of impacts that actually occurred.

The sources and nature of the EU added value vary from intervention to intervention. It is useful to distinguish the European added value of an EU policy measure in general (such as an EU regulation to foster the single market) and that of an EU spending programme per se. In both cases, EU added value may be the result of different factors: coordination gains, legal certainty, greater effectiveness or efficiency gains, complementarities, synergies, etc. In all cases, concluding on the continued need for the intervention at EU level may be difficult as the measurement of EU added value is challenging.

In areas where the EU has exclusive competence⁶⁸⁷, the appropriate answer to the question of EU added value may simply involve re-stating the reasons why the EU has exclusive competence⁶⁸⁸ or may already be answered by the efficiency and effectiveness analysis.

When assessing the EU added value, the comparison⁶⁸⁹ involves consideration of performance against a projection of how the situation was expected to evolve without the EU intervention (a defined counterfactual⁶⁹⁰, or some estimate of the cost of the Union not acting – ‘the cost of non-Europe’). Often such analysis is qualitative, analysing whether the subsidiarity arguments put forward before the intervention (as presented in a prior impact assessment, or other accompanying documents such as the explanatory memorandum) were valid and whether the expected changes resulting from EU action were delivered. It may also be appropriate to analyse whether any contextual change or other factors affected the assumption that such change could only be generated by EU level action.

Key steps for assessing EU added value in an evaluation:

- Check whether the explanatory memorandum or impact assessment accompanying the Commission’s legislative proposal contain adequate justification regarding compliance with the principle of subsidiarity.

⁶⁸⁶ See also Tool #5 (*Legal basis, subsidiarity and proportionality*)

⁶⁸⁷ Article 3 TFEU of the Lisbon Treaty defines the following areas as exclusive EU competences: the competition rules within the internal market, the customs union, the common commercial policy, monetary policy for the Euro countries, the conservation of marine biological resources under the common fishing policy and the conclusion of international agreements.

⁶⁸⁸ See Tool #5 (*Legal basis, subsidiarity and proportionality*)

⁶⁸⁹ See Tool #46 (*Designing the evaluation*)

⁶⁹⁰ See Tool #68 (*Methods for evaluating causal effects*)

- Formulate appropriate questions to check whether the subsidiarity justification in the IA or explanatory memorandum is still valid and whether the expected results have materialised. The subsidiarity grid that supports a proposal may be also used to identify relevant questions. Indicative examples of this set of questions are also included in Box 5 below.

Box 5. Typical examples of questions on EU added value

- Are the subsidiarity arguments put forward in a prior impact assessment, or other accompanying documents such as the explanatory memorandum or subsidiarity grid, still valid?
 - Could the objectives of the policy have been achieved sufficiently by the Member States acting alone?
 - Would national action or the absence of EU level action significantly damage the interests of other Member States?
 - In the absence of EU level action, to what extent would Member States have had the ability or possibility to put in place appropriate measures?
 - In case the initial problem and its causes (e.g. negative externalities, spill over effects) varied across the national, regional and local levels, did the EU level action help establish a level playing field?
 - Were there significant/appreciable transnational/cross-border aspects being tackled? Could these be quantified?
 - Were there clear benefits from EU level action?
 - Were there economies of scale and services sharing? Were the objectives met more efficiently at EU level than they would have been met by Member States acting individually (larger benefits per unit cost)?
 - Did the functioning of the internal market improve?
 - Were there benefits in replacing different national policies and rules with a more homogenous policy approach?
 - Did the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, local, and regional levels)?
 - Were some Member States more affected than others? If so, to what extent have these differences been offset, or have they created negative net trade-offs between the Member States?
 - Was there improved legal clarity from implementing EU legislation?
- Could the identified results/outputs/impacts have been achieved without EU intervention?
- Is it still valid to assume that the objectives of the intervention can best be met by action at EU level?
- What would be the most likely consequences of stopping or withdrawing EU intervention?
- What is the additional value resulting from the EU intervention(s), compared to what could reasonably have been achieved (in terms of effectiveness and efficiency) by Member States acting at national and/or regional levels?

7. THE USE OF ADDITIONAL EVALUATION CRITERIA

There are cases where the legal basis (or the specific nature of the intervention) requires the **use of additional evaluation criteria**. The most common additional criteria evaluated by the Commission are listed below. Most of these can be addressed through evaluation questions under the existing five compulsory criteria. Therefore, unless the legal basis of an intervention explicitly requires reporting on an additional criterion, every effort should be made to address additional criteria as part of the five compulsory ones. For example:

- **utility:** To what extent do the changes or effects of an intervention satisfy (or not) stakeholders’ needs? How much does the degree of satisfaction differ across different stakeholder groups? Utility could be addressed through evaluation questions under the relevance and/or EU added value criteria.
- **complementarity:** To what extent do EU policies and interventions support and usefully supplement other policies (in particular those pursued by the Member States)? Complementarity could be addressed through evaluation questions under the coherence criterion.
- **coordination:** To what extent are **interventions** organised to maximise their joint effects to better achieve objectives, e.g. by mobilising resources combined with harmonising measures? Coordination could be addressed through evaluation questions under the coherence and/or efficiency criteria.
- **equity:** How fairly are the different effects distributed across the different stakeholders/regions/genders / social groups⁶⁹¹? Equity could be addressed through evaluation questions under the effectiveness criterion.
- **sustainability:** *How likely are the economic and/or social and/or environmental effects to last after the intervention ends?* It is often hoped that the changes caused by an intervention will be long-lasting. It can be important to test this expectation for interventions, which have a finite duration, such as particular programmes. Sustainability could be defined as an objective and addressed through evaluation questions under the effectiveness criterion, given that it is related to the durability of the effects. Sustainability could also be a crosscutting criterion not limited to durability of the policy effects. For example, sustainability of the economy, the environment or the social fabric when implementing the intervention. In this case too, sustainability could be defined as an objective and addressed through evaluation questions under the effectiveness criterion (e.g. to what extent have the intervention fostered a sustainable use of the natural resources while achieving its objectives?).
- **acceptability:** To what extent can we observe changes in the perception of the intervention (positive or negative) by the targeted stakeholders and/or by the general public? Acceptability could be addressed through evaluation questions under the effectiveness criterion, as it is related to the degree of acceptance of the effects.

Care needs to be used to avoid the multiplication of criteria, which may have limited added value and make the evaluation analysis repetitive. **The use of additional criteria needs to be duly justified.**

⁶⁹¹ Such as for example low-income groups, persons with a minority ethnic or racial background, persons with disabilities etc.

8. GOOD PRACTICE TIPS

- Evaluation questions should be worded in a way that forces the evaluator to go beyond an answer based on simple description. Questions that start with 'how', 'why', 'to what extent' are more likely to ensure that the answer provided looks at what the links were between the changes observed and the EU intervention(s). Questions that start with verbs such as 'do' the directives...? 'Are' the directives providing...? should be avoided as they tend to provoke yes/no answers, or they should be accompanied with a request to explain.
- If necessary, use clarifications or sub-questions to define specific elements for the evaluator to consider in answering the evaluation questions (e.g. in answering the question, special attention should be paid to ...)
- Dare to ask the difficult question, including those that may challenge current policy.
- Try not to have too many evaluation questions. Sometimes it is necessary to have very specific questions, other times it is better to have a more generic set and see where the data/analysis leads. There is always a trade-off between the number of questions and the depth of analysis that can be conducted, especially across all Member States.
- Check any prior impact assessment to see what issues were addressed and what expectations were presented. Where necessary compare the proposal accompanying the impact assessment to the final actions adopted/introduced and try to identify where amendments to the Commission proposal may have changed the intervention logic described in the impact assessment.
- Encourage consideration of the 'end-user' perspective. End users are most affected by actions triggered due to EU interventions – they have practical experience of what has happened on the ground and may have a different perspective from policy makers, governments, NGOs, etc.
- Evaluation questions, which guide the work of the evaluator, are often worded in a technical way, using terminology that makes sense within the Commission, but which requires further explanation (simplification) to many stakeholders. **It is strongly recommended to avoid using the evaluation criteria as such in formulating questions** that look for input from stakeholders. Instead, 'translate' the criteria into more manageable and understandable concepts, particularly for consultation, data gathering exercises and for drafting the report. For example, rather than referring in an abstract manner to the 'objectives of the policy' describe the objective in more common terms – so ask 'What progress has been made towards increasing the availability of funding to small and medium sized businesses'?

TOOL #48. CONDUCTING THE EVALUATION

1. INTRODUCTION

When the planning and designing is over, the actual evaluation work starts. **The final product of this process is the evaluation report, which takes the form of a staff working document written by the lead Directorate General(s) for all evaluations and fitness checks⁶⁹².**

The support work for an evaluation can be outsourced to external contractors and/or draw on the (internal) work of Commission services including services offered by the JRC. External support work may involve one or several studies (contracts). The evaluation report brings together all work⁶⁹³ carried out during the evaluation process.

For all work conducted as part of the evaluation, the evaluation manager⁶⁹⁴ and the interservice coordination group (ISCG) have a particular role to steer the project and improve its quality at all key steps. Where there is external work, this may include advising contractors, supervising their work (and hence its quality), and enforcing the timetable.

It is important to constantly check the quality of the work being undertaken, ensuring that it is evidence-based and free from bias. Thorough, robust and reliable research, data collection and analysis, are core activities to conducting high-quality evaluation and drawing appropriate evaluation findings and conclusions. Robust and reliable results can be delivered only by objective evaluations. Every effort should be made to ensure the transparency of the evaluation – both in terms of how it progresses (e.g. involvement of ISCG, working group, stakeholders) and when reporting (e.g. in terms of collection and use of data, analysis and results). Any limitations to the method applied or the data collected should be clearly discussed over the course of the evaluation, addressed where possible and described in the final report.

Equally, care should be taken to spot weaknesses in:

- the data: e.g. do they come from a reliable source? Have enough respondents replied? Do we not overly rely on only one data source?;
- the analysis: e.g. are the survey questions clear and simple? Do they cover a sufficient time period and identify any trends? Can the modelling be repeated?
- the timing of the evaluation: e.g. have expected impacts been reasonably materialised?

⁶⁹² See Tool #49 (*Format of the evaluation report*)

⁶⁹³ The vast majority of evaluations involve external contractors in some way. They can be commissioned for all or some tasks such as:

- collecting and analysing the relevant evidence (including consultation work);
- developing analytical models and running them;
- providing ‘first’ answers to some/all evaluation questions;
- presenting evidence-based conclusions.

The terms of reference (ToR)/Technical Specifications are written by the Commission services and set out the work that a contractor is required to do.

⁶⁹⁴ The policy officer responsible for the evaluation and/or the evaluation function/unit of the lead DG.

Box 1. Conducting an evaluation – key principles

- The ISCG and the evaluation manager play a key role in assuring the quality of the overall evaluation.
- A public consultation for an evaluation is not always necessary. It is at the discretion of a Directorate-General whether public consultation is needed to support an evaluation. In all cases, appropriate targeted consultation activities should be carried out. For evaluations of broad public interest and for fitness checks, a public consultation is highly recommended
- The evaluation methodology should follow that identified in the design phase (including any commitments in associated Terms of Reference/Technical Specifications) or explain why this has not been possible.
- All evaluations should consider the evidence base built up over earlier parts of the policy cycle and in particular any prior impact assessment, where appropriate.
- All evaluations should make credible efforts to obtain data from a wide range of qualitative and quantitative sources and distinguish between the opinion of, or data from, vested interests and independent sources. Where possible, it is recommended that the supporting data substantiating the evaluation assessment is available in an easily accessible format.
- Particular effort should be made to access and reuse data that is already collected, for instance by ESTAT, or by public services in Member States for administrative purposes (admin data).
- Proportionate effort should be made to quantify costs and benefits, reflecting the role of the intervention being evaluated and external expectations or discussions (e.g. where there has been significant debate or disagreement between stakeholders in relation to actual costs or benefits delivered). Where this is not possible, a clear explanation of the efforts made, and the restrictions encountered should be given.
- Ethics and integrity concepts should be respected. Any conflicts of interest should be reported to the appropriate actor in the Directorate-General and Secretariat-General.
- Evaluations should be evidence based and adhere to the principles of objectivity and independence⁶⁹⁵.

2. THE ROLE OF THE EVALUATION INTERSERVICE COORDINATION GROUP

Interservice coordination group (ISCG)

The ISCG must be involved in all key steps of the evaluation following validation until the launch of the interservice consultation on the evaluation report and if applicable, the associated executive summary. It may be consulted on any associated report/communication to the European Parliament and Council. When applicable, the group should discuss the draft evaluation report prior to its submission to the Regulatory Scrutiny Board (RSB). The minutes from this discussion are submitted to the Board⁶⁹⁶.

⁶⁹⁵ See Tool #45 (*What is an evaluation and when it is required*)

⁶⁹⁶ See Tool #3 (*Role of the Regulatory Scrutiny Board*) for the list of documents submitted to the Board

Who?	<p>The group is led by the relevant lead DG or service. A representative of their evaluation function / 'better regulation' support unit must also be included in the ISCG.</p>
	<p>DGs with policies linked to the subject of the evaluation or likely to be affected by the evaluation should be invited to participate. A representative from the Secretariat-General must be invited.</p>
	<p>By definition, the ISCG is an internal Commission group, made up of representatives from DGs. However, this does not prevent consultation with other groups in consideration of their knowledge and expertise, which include non-Commission staff (e.g. from EU decentralised agencies and other EU bodies, Member States, academia) which could also provide advice and information. This is particularly relevant when a partner DG is evaluating an EU decentralised agency. In such a case, it is important to involve representatives of the agency in the evaluation process, but they will not be a member of the ISCG. One way to do this would be to create an ISCG, but to discuss relevant aspects of the work in an additional, wider group (identified at the discretion of the lead DG), which includes both the ISCG members and agency representatives. Further examples of such groups include Member State advisory committees, academic or reference panels.</p>
	<p>In addition, DGs with core expertise in specific areas, such as economic analysis (e.g. ECFIN), scientific research and analytical models (e.g. JRC, RTD), social impacts (e.g. EMPL), SMEs, competitiveness (e.g. GROW), environment (e.g. ENV), fundamental rights (JUST), development cooperation (INTPA), innovation (RTD), digital/ICT (CNECT and DIGIT)⁶⁹⁷, should also participate where appropriate to ensure that the evaluation calls upon all relevant expertise in the Commission.</p>
	<p>The invitation to set up an ISCG should take the form of a note from a senior manager of the lead DG to those of the identified DGs asking to nominate a representative.</p>
	<p>Existing ISGs can be used to steer the evaluation work particularly where such a group has been used to conduct a prior impact assessment or to provide advice to policy development.</p>
	<p>Consultants may be invited to make presentations regarding supporting studies or contracts but should leave the meeting when substantive discussions take place between ISCG members. The lead DG should make sure the confidential nature of internal ISCG discussion remains protected.</p>
Why?	<p>An effective ISCG can significantly increase the credibility of an evaluation. By ensuring that different perspectives are discussed, analysed, and reported it improves the quality of the evaluation, helps to ensure coherence with other policies and demonstrates an open and transparent approach to critically analysing performance and delivery. Involving other services should also anticipate (and solve) problems that could emerge later in the process (e.g. during interservice consultation). Colleagues from other areas or with diverse professional profiles are a good test of whether your arguments are clear and easy to follow.</p>

⁶⁹⁷ See Tool #28 (*Digital-ready policymaking*)

	<p>The ISCG encourages a pooling of knowledge and brings together a range of different perspectives. The mix of policy/operational experience and evaluation expertise should prevent biases from taking over the evaluation and encourage critical judgement.</p>
	<p>The ISCG is the best way to ensure that a DG's views are considered by the lead DG. It is important, therefore, to plan participation well in advance and, to the extent possible, for members to participate pro-actively. As far as possible, make sure the position expressed in an ISCG is representative of the position your DG is likely to take during ISC.</p>
<p>When?</p>	<p>An ISCG can be established/convened as soon as the evaluation has been included and validated in Decide⁶⁹⁸.</p> <p>The ISCG should meet as many times as needed to cover the important elements of the evaluation. When the evaluation is to be submitted for scrutiny, the ISCG should also discuss the final draft prior to its submission to the Board.</p> <p>More meetings or consultation of the ISCG in writing can also be envisaged, particularly in the case of complex evaluations running over a long period. Meetings may also follow the timing of other milestones such as an external study or a stakeholder consultation. It is important to remain mindful of the workload this generates for other services.</p>
<p>How?</p>	<p>The first meeting of the ISCG should discuss the intervention logic, evaluation questions and other elements affecting the design/conduct of the evaluation including the consultation strategy. It is recommended that the 'call for evidence' is also discussed in the first meeting, together with the consultation strategy. Ideally, the evaluation questions will be finalised shortly after this meeting. It is good practice to share information and record decisions on these key elements in written format.</p> <p>The ISCG must steer the evaluation through subsequent key phases (e.g. design /conduct, including consultation, studies and evaluation report that takes the form of a staff working document), providing input and information and ensuring the quality, impartiality and usefulness of the final product.</p> <p>The ISCG should also be involved in the preparation of terms of reference/technical specifications for external studies and, as part of this, drawing up the scope of possible modelling work. The ISCG <u>should be involved</u> in the design of stakeholder consultation strategy and any consultation documents. It should discuss any feedback received from stakeholders on the 'call for evidence'. It should always discuss intermediate findings, e.g. deliverables and quality of modelling work or supporting studies, and drafts of the evaluation report.</p> <p>The ISCG is not involved in any strict procurement-related activity in the context of the evaluation work.</p> <p>Meetings should be well prepared with <u>invitations and documents being circulated in principle at least one week in advance</u>. Similarly, ISCG members should be given <u>at least one week since they received them</u> to provide written comments on the documents. Minutes of meetings should be prepared which</p>

⁶⁹⁸ See Tool #6 (*Planning and validation of initiatives*)

	record transparently and accurately the views of the ISCG members. The minutes of the last ISCG meeting should be attached to the covering note if the draft evaluation report is submitted to the RSB.
	The lead DG is recommended to establish a collaborative workspace for sharing documents which facilitates more flexible participation by DGs.

3. KEY PROCEDURAL STEPS

The time needed to prepare an evaluation will vary from case to case. Sufficient time needs to be allocated to ensure that the evaluation can be conducted according to these guidelines and, where necessary, the Commission can report to the European Parliament and Council by the date set in the legal base. Where an evaluation is linked to a (review) clause that invites the Commission to present new proposals by a certain date, care must be taken to ensure that the planning allocates sufficient time for the evaluation and the impact assessment. Good planning also implies taking account of the time needed to meet the various procedural requirements, including scrutiny by the Regulatory Scrutiny Board, political validation to launch the interservice consultation and the time needed for translations.

Box 2. The key steps in an evaluation

1. **Political validation:** generally evaluations to be conducted by a Directorate-General are approved during the management plan process. At an appropriate point in time, each individual evaluation is introduced and validated in Decide⁶⁹⁹;
2. **Establish an interservice coordination group (ISCG)** to steer the evaluation;
3. Draft the **'call for evidence'**, for consultation with the ISCG and agreement with the Secretariat-General. Finalise the consultation strategy with the ISCG, including the 12-week internet-based public consultation, where applicable;
4. **Steer and conduct the evaluation work** which may involve managing supporting studies by contractors. Involve the ISCG as appropriate throughout the conduct of the evaluation work;
5. Prepare the **evaluation report**⁷⁰⁰ that responds to the issues in the 'call for evidence', presents the analysis, and answers the evaluation questions. Where applicable, prepare an **executive summary** presenting the findings of the evaluation report⁷⁰¹;
6. For those **evaluations selected for scrutiny**, submit the draft evaluation report together with the supporting documents to the Regulatory Scrutiny Board⁷⁰². **Address the Board's comments** and incorporate them into a revised version prior to launching the interservice consultation. Where the opinion is negative, the DG has an option to resubmit an amended report to the Board;
7. Launch the **interservice consultation**;
8. **Publish** the evaluation report and any supporting contractors' (final) study. **Where required by the basic legal act**, transmit the evaluation to the Parliament and the

⁶⁹⁹ See Tool #6 (*Planning and validation of initiatives*)

⁷⁰⁰ The evaluation report takes the form of staff working document outlined in Tool #49

⁷⁰¹ For exceptions to the preparation of the executive summary, see Tool #49.

⁷⁰² See Tool #3 (*Role of the Regulatory Scrutiny Board*) for the list of documents submitted to the Board

Council together with a short Commission report/communication;

9. **Disseminate the evaluation findings** as appropriate and identify any **appropriate follow-up actions** to put into practice the lessons learned and capitalise on the evaluation findings. Feed the evaluation findings into the next step of the decision-making cycle (Annual Activity Reports, Annual Management Plans, impact assessments for revisions, etc.)

TOOL #49. FORMAT OF THE EVALUATION REPORT

1. INTRODUCTION

The evaluation report takes the form of a staff working document (SWD)⁷⁰³. The report is the final output and key deliverable of the evaluation process, presenting the evidence-based judgement of an EU intervention or set of EU interventions for fitness checks.

The lead DG should present the conclusions of the evaluation in a way that is useful to policymakers and that can serve as a basis for future policy development. The report also serves to communicate to stakeholders the methods, evidence base and analyses applied when evaluating the EU intervention. The drafting of the evaluation report in the form of a staff working document falls under the exclusive responsibility of the European Commission services.

The report should tell an evidence-based story of the EU intervention. Like the impact assessment report, the evaluation report should answer a set of key questions in separate sections. Any limitations to the robustness of the process and evaluation findings must be analysed in the report. The process and methodology used to undertake the evaluation should be described and detailed. Throughout the report all evidence should be clearly presented, referenced and, if possible, hyperlinked. DGs must use the standard format described below for the report, which will ensure consistency across the Commission.

Evaluations may draw on a range of sources and methods, including legal analysis, statistics, expert opinions, external supporting studies, surveys, consultations, case studies, analytical models⁷⁰⁴. Where evaluations are largely based on the work of external contractors (e.g. supporting studies), the evaluation report should draw on this work, but it is the lead DG that takes ownership of the findings and conclusions of the evaluation. If there are reasons why the lead DG thinks there are different answers or draws different conclusions to those of the external contractor, this should be brought out in the report, together with the necessary supporting justification – either by showing why they interpret the evidence differently, or by bringing in additional information.

2. WHY IS THE EVALUATION REPORT IMPORTANT AND HOW IS IT STRUCTURED?

The evaluation report is the key document that will inform stakeholders and policymakers on the outcome of the evaluation, presenting the judgements and lessons learned. The evaluation report is expected to tell the story of what has been achieved with a particular EU intervention and how it was achieved (or not) in narrative form. **It should be written by the lead DG** irrespective of whether it draws or not on an external supporting study. It is the response to the issues raised in the 'call for evidence' and answers the questions of the evaluation (see Box 1 below). It is also the basis for any follow-up action, such as revision of legislation. It can provide an indirect feedback mechanism acknowledging the contributions that stakeholders and experts have made throughout the process. With the evaluation report, Commission services take ownership of the evaluation work.

⁷⁰³ The evaluation report or fitness check in the form of a SWD is hereafter shortened as 'the report' unless specified otherwise.

⁷⁰⁴ See Tool #4 (*Evidence-informed policymaking*).

The report should be a self-standing document that follows the standard structure set out below, to ensure consistency across Commission services. It should be written using non-technical language with non-expert readers in mind and should provide the reader with a complete picture of the main issues and findings. More detailed information or explanations, including on the methodologies used, should be provided in the relevant annexes.

An evaluation report should be accompanied by an executive summary as a stand-alone document. An executive summary is not needed when the Commission provides a report to the European Parliament and the Council.

Box 1. Mandatory elements of the evaluation report

- The evaluation report should contain:
 - A critical, evidence-based judgement of the EU intervention, based on a range of data and analysis. It should be presented in narrative form ('story') guided by the evaluation questions which the evaluation intended to address.
 - The answers to the following questions that make up the intervention's assessment 'story':
 - What was the expected outcome of the intervention?
 - How has the situation evolved over the evaluation period?
 - Evaluation findings:
 - To what extent was the intervention successful and why?
 - How did the EU intervention make a difference and to whom?
 - Is the intervention still relevant?
 - What are the conclusions and lessons learned?
 - A clear chain of logic between the evidence, analysis and findings, the answers to the questions and the conclusions drawn.
 - Clear conclusions based on the evidence collected which generates useful information for future policy decisions and which helps the organisation to learn.
 - Annexes on (I) procedural information, (II) methodology and analytical models used, (III) evaluation matrix and answers to the evaluation questions, (IV) overview of benefits and costs and, where relevant, table on simplification and burden reduction and (V) stakeholder consultation-synopsis report.
 - A summary of the changes introduced following the opinion of the Regulatory Scrutiny Board (RSB) if the evaluation report has been scrutinised (to be included in Annex I on procedural information).
- All contractors' final studies (plus other relevant interim deliverables from external work) and the evaluation report should follow the appropriate corporate publication requirements⁷⁰⁵.
- Non-confidential data used in the evaluation or supporting studies should be publicly available.

⁷⁰⁵ See section 7 below and GoPro for additional information on publication requirements.

The evaluation report presents in a self-standing and non-technical manner the process, evidence, analysis, conclusions, and lessons learned. **The evaluation report should not be longer than 50 pages of text accompanied by annexes as appropriate.** Even where the full body of work described in the 'call for evidence' has been outsourced to contractors, who have written up their process and findings as a separate study, the evaluation report must provide sufficient detail, enabling the reader to follow the evidence and logic and understand the answers and conclusions without having to read the contractors' report or any other supporting materials.

Underlying data, statistics, information, expert contributions, and stakeholder views should all be referenced, particularly where choices are made, or conclusions are drawn based on them. Whenever possible, direct hypertext internet links should be provided.

Stakeholder views should be integrated throughout the text of the evaluation report. A description of the views of the different stakeholder groups should be included and any differences within or across such groups should be highlighted. A separate Annex should contain the analysis of the stakeholder consultation.

The evaluation report template and executive summary cover page can be downloaded from [GoPro](#).

3. DETAILED STRUCTURE AND CONTENT OF THE EVALUATION REPORT AND ITS EXECUTIVE SUMMARY

The 'better regulation' criteria of effectiveness, efficiency, relevance, coherence, and EU added value serve to organise the analytical part of the evaluation work and collect the factual evidence on these criteria. The results of the data collection feed into the evaluation report and help draft the 'story' of EU intervention. The evaluation report should tell what was achieved and how the EU intervention helped this happen, but also what was not achieved, why so and what lessons were learned.

To the extent possible, the report should ensure a strong link between the retrospective evaluation and any prior impact assessment. Evidence on what was achieved and not achieved and how EU intervention made this happen is crucial information feeding into the problem definition and baseline option of any future impact assessment. Conversely, the discussion on what success was expected to look like (as in a prior impact assessment, explanatory memorandum, etc.) provide the starting point for the evaluation.

The evaluation report should follow the structure presented below. Each section provides further guidance on the issues to be covered.

Section 1 – Introduction

Section 1 explains the purpose and scope of the evaluation / fitness check. Issues to be addressed in this section are:

Purpose and scope of the evaluation / fitness check

- *What is the purpose of the evaluation / fitness check (refer to the legal basis of the EU intervention being evaluated, TFEU article, etc.), what will the evaluation / fitness*

check deliver and how will its results be used (e.g. to fulfil a legal obligation, provide the basis for a possible future IA, to improve application)?

- *What are the main issues the evaluation addresses (check legal obligations besides 'better regulation' requirements; check consistency with the text in the 'call for evidence')?*
- *What evaluation criteria are applied (noting that all evaluations should investigate effectiveness, efficiency, relevance, coherence, and EU added value of the EU intervention)? To what extent are the five compulsory criteria covered?*
- *A few, concise sentences informing about the methodology applied, its robustness and its limitations. Methodological information on how the evaluation was conducted is to be detailed in the Annex II to the evaluation report.*
- *What time period does the evaluation cover (from the start of the intervention until now; when covering a different time period, explain why)?*
- *What geographical scope does the evaluation cover? (if not all Member States and if other countries, explain why).*
- *Which related implementing / delegated acts does the evaluation cover? If they are not covered, explain why.*

Section 2 - What was the expected outcome of the intervention?

Section 2 explains the rationale for the intervention at the time it was prepared/adopted, i.e. the problem or the needs the EU was trying to address and its underlying causes, what it expected to achieve and how that achievement was to be assessed (the intervention logic). It should draw to the extent possible on the impact assessment report (if available), the explanatory memorandum and the preamble of the final legal text. It should also include the points of comparison against which the intervention will be assessed.

Issues to be addressed in this section are:

Description of the intervention and its objectives

- *Explain the logic of the intervention being evaluated and establish the link with the preceding impact assessment (if any). Clarify to what extent the analysis in the impact assessment is still relevant (depending on what was finally adopted).*
- *Provide a brief description of how the intervention fitted in the wider policy framework (in the past).*
- *Include, wherever possible, a reference to the UN sustainable development goals (SDGs) that the intervention aimed to address and sketch which SDG-related insights the evaluation can provide⁷⁰⁶.*
- *Provide a brief description of the problems and/or needs the intervention was intended to solve.*
- *Provide a brief description of the objectives that were agreed upon to solve/address the problems/needs.*

⁷⁰⁶ See Tool #19 for more guidance on sustainable development goals and references to the available toolkit.

- *Provide a brief description of the expected achievements at the time of the evaluation in terms of outputs, results, and impacts.*
- *Provide a brief description how the actions of the intervention were ultimately expected to deliver on the objectives (i.e. what success was expected to look like).*

Summarise this information in a descriptive text, preferably supported by an intervention logic diagram. It should connect the needs (i.e. problem definition in the impact assessment or in the explanatory memorandum), with the objectives, the intervention’s actions and the expected achievements in terms of outputs, results and impacts. It is generally helpful to use a graphical representation (visual aid) illustrating how the different components were expected to fit together⁷⁰⁷. This should also refer to potential external factors influencing the expected achievements.

Point(s) of comparison

- *Describe what the situation was like before the intervention started, how it was expected to develop and/or any other relevant points of comparison.*
- *Use all relevant information from the preceding impact assessment (if any), analytical documents accompanying the legal proposal and/or the explanatory memorandum.*
- *Describe the point(s) of comparison against which you will assess your intervention. You may need to use different points of comparison for assessing the different evaluation criteria and should clearly explain the choice made.*
- *Use tables / graphs / other visual aids as necessary to help the reader understand the text.*

This discussion should draw on the prior impact assessment if available (but updated to reflect changes during the adoption process) and/or the explanatory memorandum. The discussion should cover in particular the situation linked to the problems/needs the intervention was intended to solve (a quantitative description should be provided as far as possible). This should facilitate a comparison with the current situation and should therefore cover as far as possible the same parameters/indicators that are used to describe the state of play in the following section (Section 3).

Section 3 - How has the situation evolved over the evaluation period?

Section 3 explains the state of play in implementing the EU intervention (both legally and on the ground) and presents what has happened so far. The presentation in this section should be factual as in Section 2 (‘What was expected to be achieved?’). Any judgements on the findings should not be presented here but in Section 4 (‘Evaluation findings’).

Issues to be addressed in this section are:

Current state of play

- *Explain how the intervention has been implemented, summarising which Member States have done what and what problems/infringements have been identified.*

⁷⁰⁷ See Tool #46 (*Designing the evaluation*)

- *In case of delays in implementation, explain what happened and consider the impact of delays on the implementation.*
- *Describe the current situation from the start of the period under evaluation: what has happened in quantitative and qualitative terms. Consider the monitoring arrangements put in place and use the different indicators to report.*
- *If unexpected or unintended changes have been identified, explain what they are and whether there have been 'knock-ons' in other areas due to this intervention.*
- *Outline any external factors or market developments that have impacted the implementation of the intervention.*

It is not necessary to present in this section all the evidence collected; this can be done in an annex. However, clear references and hyperlinks should be added, signposting where further details/information can be found.

Use tables / graphs / other visual aids as necessary to illustrate the current situation.

Be aware that there is a need to balance the data presented here (and earlier in Section 2) in a descriptive format, with later analysis in Section 4 ('evaluation findings'). Cross-referencing may assist in avoiding unnecessary repetition.

By the time readers reach the end of this section, they should be able to understand what the intervention was expected to achieve and by when; how that was expected to happen (intervention logic); and what the situation is now (factual information). They should also understand the general approach taken for the evaluation and any limits that have been identified, providing them with a context for the subsequent analysis and managing their expectations about the level of detail and sophistication that will be provided.

Section 4 - Evaluation findings (analytical part)

4.1. To what extent was the intervention successful and why? *[Related criteria to assess: effectiveness, efficiency, coherence]*

4.2. How did the EU intervention make a difference and to whom? *[Related criterion to assess: EU added value]*

4.3. Is the intervention still relevant? *[Related criterion to assess: relevance]*

Section 4 deducts a critical, unbiased, and evidence-based judgement on the success (or failure) of the intervention and reports on it. It also describes the critical success (and/or failure) factors, which may feed in the discussion on lessons learned and suggestions for improvement for future policy design.

Section 4 should be analytical, and the narrative should **clearly encompass the five evaluation criteria**. All three questions above should be answered.

The evidence and argumentation leading to an answer should be clearly presented and their association to the evaluation criteria clearly referenced. Text and arguments should be self-standing and accessible to non-expert readers. Reference to the relevant evaluation criterion (or criteria) should be explicit in the narrative.

Section 4 should compare the expected situation (described in Section 2 – ‘*What was expected to be achieved?*’) with the actual situation (described in Section 3 ‘*How has the situation evolved during the evaluation period?*’). The evidence gathered on the questions addressing the ‘better regulation’ criteria⁷⁰⁸ should feed into this section to substantiate the discussion with the necessary evidence base.

Question 4.1 – To what extent was the intervention successful and why? [*Related criteria to assess: effectiveness, efficiency, coherence*]

‘**Success**’ is assessed in terms of the extent to which an intervention achieves its objectives⁷⁰⁹:

- **effectively**;
- **efficiently**; and
- in **coherent** way.

The evidence gathered to answer the questions addressing these three evaluation criteria⁷¹⁰ should feed into the narrative here. Arguments supporting the narrative should be clearly presented and their association to any of the three evaluation criteria clearly referenced.

More detailed analysis by criterion could be documented in Annex III (*Evaluation matrix and answers to the evaluation questions*) to the evaluation report.

Under the effectiveness and efficiency discussion, efforts should be made to address in quantitative terms benefits and costs arising from the intervention.

In case the evaluated intervention concerns an EU initiative that was considered as ‘relevant’ or ‘highly relevant’ for SMEs at the impact assessment phase (see section 2 of the ‘SME test’ - Tool #23) or these impacts emerged afterwards, the evaluation should also cover the effectiveness and efficiency of the intervention for SMEs.

The analysis of efficiency should cover administrative and adjustment costs, and aspects of simplification – these are important for all evaluations. Where appropriate, evaluation findings should pinpoint areas where there is potential to reduce inefficiencies (particularly unnecessary costs) and simplify the intervention by considering e.g. the use of digital solutions.

The proportionality of costs and benefits should be assessed. Actual costs and benefits should be outlined in Annex IV, in the ‘Overview of benefits and costs’ table and, where relevant, the separate table on ‘Simplification and burden reduction’.

Indicative questions for addressing each of these three criteria are provided in Tool #47 (*Evaluation criteria and questions*)

⁷⁰⁸ See Tool #47 for indicative questions by criterion. All relevant analysis and answers to such questions should be documented in Annex IV (‘Evaluation matrix and answers to the evaluation questions by evaluation criterion’)

⁷⁰⁹ As outlined in the intervention’s legal act and/or any prior impact assessment. In the latter case, if co-legislators’ amendments affect the initial objectives presented in the impact assessment, the initial objectives should be updated accordingly.

⁷¹⁰ See Tool #47 (*Evaluation questions and criteria*).

Question 4.2 - How did the EU intervention make a difference and to whom? [*Related criterion to assess: EU added value*]

Answering question 4.2 ('How did the EU intervention make a difference and to whom?') goes beyond re-stating the legal reasons/objectives presented in section 1 ('Purpose and scope of the evaluation') and should strive to present an ex-post evidence-based assessment of the EU intervention in the policy under evaluation. There are two broad approaches on **EU added value**:

- In areas not falling within its exclusive competence, the Union shall only act if the objectives being pursued cannot be sufficiently achieved at Member State policy level (COM(2018)703 final). This implies there is a 'cost of non-Europe' due to the scale, scope, costs, and efforts, organisational or transnational effects of the envisaged action. The evaluation could investigate to what extent the 'cost of non-Europe' can be determined in the intervention area. A counterfactual evaluation methodology⁷¹¹ is one possibility.
- Making an evidence-based case for EU intervention can also be approached by assessing the intervention's 'EU added value'. EU added value is the value that results from an EU intervention which is additional ('above and beyond') to the value that would have been otherwise created by Member States individually. The changes should be reasonably argued, and if possible, factually demonstrated to have arisen from EU intervention. The focus is not so much on the costs (of 'no Europe'), but on the gains (of 'having Europe').

The narrative in this part should **explain clearly to whom the EU intervention made a difference** (e.g. EU people, businesses etc.). Where relevant it should provide an assessment of the EU added value in different territories (rural, urban, cross-border, outermost regions).

Indicative questions for addressing the EU added value are provided in Tool #47 (*Evaluation criteria and questions*)

Question 4.3 - Is the intervention still relevant? [*Related criterion to assess: relevance*]

The evaluation should look at the objectives of the intervention and see how well they reflected and most importantly, they still reflect current and future needs (continuing relevance). This is key information that will help policymakers decide whether to maintain, adjust or terminate the intervention.

The narrative here should highlight any mismatch between the original objectives and current and future needs and problems (also considering elements of foresight) and the reasons for it.

To facilitate answering question 4.3 ('Is the intervention still relevant?') the analysis could draw from the questions provided in Tool #47 under the **relevance** criterion. In addressing the question of continued relevance, it may be useful to look at how megatrends (such as demographic change, digitalisation) may impact the intervention. Information on foresight approach and related instruments can be found in Tool #20 (*Strategic foresight for impact assessments and evaluations*).

Practical tips: Use the information collected to analyse how far the outputs and outcomes observed match the expectations stated when the intervention was adopted, referencing the

⁷¹¹ See Chapter VIII Tool #68 (*Methods for evaluating causal effects*)

intervention logic as appropriate and showing whether the logic has been followed as expected or not. Consider the impact of delays in implementation. Bring together different sources of data (clearly referenced so that the reader can investigate further if they wish) and assess what/how new developments and external factors might influence the future relevance of the intervention. Ensure triangulation of data (i.e. its verification by comparing several sources).

Presentation should be clear, concise, and understandable to the non-expert reader. If there is insufficient data or evidence to answer one or more questions related to the evaluation criteria, this should be clearly stated and linked to the limitations under Section 1 above (brief reference) and to the Annex II on methodology (more comprehensive reference).

Answers to all evaluation questions that were agreed with ISCG should explicitly feed in the relevant parts of this section. The level of analysis should not be compromised; section 4 of the evaluation report should present the findings derived from the questions related to the five criteria⁷¹² and provide appropriate substantiation throughout. The evaluation matrix and, where relevant, more details on answers to evaluation questions by criterion should be presented in Annex III.

Question 4.1 '*To what extent was the intervention successful?*' requires discussion of three evaluation criteria (effectiveness, efficiency, coherence) in one narrative. The building blocks of this narrative could be by criterion, discussing efficiency and effectiveness together (cost-effectiveness), discussing coherence more prominently in the case of a fitness check, or providing a more comprehensive narrative that blends the three criteria. In case a more comprehensive narrative is selected and there is no clear distinction among the three criteria, then the answers to their specific evaluation questions should be provided in Annex III ('*Evaluation matrix and answers to evaluation questions by criterion*'), to provide the reader with all relevant detail on the evidence base informing this narrative.

Section 5 - What are the conclusions and the lessons learned?

An important purpose of evaluations is to enable the organisation to learn and to raise critical policy issues for the attention of the political level. Information reported in the previous sections serves to feed this section to present the conclusions of the evaluation results. Section 5 should focus at least on the following three areas:

Describe what elements of the **EU intervention are working or not** and why.

- Did the intervention achieve its objectives? Did its actual performance match the expectations? Did the intervention generate unintended effects? Were these positive or negative effects, and for whom? Was the intervention more/less costly than expected, and if so, why? Etc.

Summarise what has been **specific about the EU role** in this particular intervention that could not have been achieved without EU involvement.

- Did the EU bring actors together to work on shared solutions that would not have happened otherwise? Did the efficiency of public finances increase because of

⁷¹² See Tool #47 (*Evaluation criteria and questions*)

achieved economies of scale and scope? Did the EU involvement help safeguard key EU interests? Etc.

Present credible **evidence-based lessons** and, where possible, suggested areas for improvement.

- What are the lessons that can be derived from this primarily backward-looking exercise? Do these lessons indicate a continuation of the problems/needs that triggered EU intervention in the past? Do these lessons indicate a lack of coherence that hinders the performance irrespective of a sound logic of intervention? Did the intervention trigger changes in the target group that need to be considered for future policy design? Do these lessons need to be addressed or will resolve over time? Etc.

Given that all evaluations need to investigate how to simplify and cut burdens, clear reference should be made to **lessons relating to (REFIT) issues** such as regulatory or unnecessary burden, simplicity/complexity, identification of efficiencies/inefficiencies, achievement of objectives at low/high (appropriate/reasonable) costs.

The **conclusions** should be written in such a way that policy makers can use them as a basis for future policy development but respecting the limits of a staff working document. For example, the evaluation report **should not make any commitment for future action or direction of action**. It is important to present the lessons learned and include a systematic screening of the evidence, indicating which findings match expectations, which findings are too preliminary to conclude (wait and see) and what does not work.

Finally:

- There should be a clear and logical progression between the description of what has been achieved presented in section 3, the answers to the questions in section 4 and the conclusions being drawn in section 5. No new detail or issue should be presented in the conclusions section – such information should always be presented in the preceding sections first. Related to this, avoid confusion by taking care to use consistent terminology throughout the evaluation report.
- Where relevant, references should be added and/or comments inserted from the stakeholder consultations (public consultations, targeted consultations, workshops with stakeholders, etc.).

Annexes that must be included in the evaluation report

Annexes are used to present additional technical material particularly to support the information presented in the main body of the report (e.g. a more detailed description of the concerned market or monitoring indicators). Annexes should not be excessively long, be restricted to information which is relevant and contain references and hypertext links to external information sources wherever possible (rather than reproducing the material in the report itself).

The following annexes are required:

- Annex I. Procedural information
- Annex II. Methodology and analytical models used

- Annex III. Evaluation matrix and answers to the evaluation questions (by criterion)
- Annex IV. Overview of benefits and costs and, where relevant, table on simplification and burden reduction
- Annex V. Stakeholders consultation - synopsis report

Annex I. Procedural information

- Identify the lead DG; the *Decide* reference and if relevant the Commission work programme reference;
- Describe any exceptions from the usual procedural requirements of the 'better regulation' guidelines together with an appropriate justification;
- Organisation and timing: provide the general chronology of the evaluation or fitness check and specify which DGs participated in the steering group (ISCG) and how many meetings of the group were held;
- **Consultation of the Regulatory Scrutiny Board (if relevant).** Briefly explain how the Board's recommendations have led to changes compared to the earlier draft. This should be presented in tabular format – the first column identifying the Board's recommendation and the second column how the report has been modified in response;
- Explain which **evidence** has been used in the evaluation or fitness check together with sources and any issues regarding its quality (i.e. has the information been quality assured?);
- **External expertise.** Describe how expert advice has been used in the process, including scientific expertise and/or use of Commission expert groups or expertise from the EU decentralised agencies and other EU bodies. Outline any studies/work carried out by external contractors, with references and internet links.

Annex II. Methodology and analytical models used

- Provide a transparent account of what has been done, by whom (external contractor, Commission), any changes from the original plan (set out in the 'call for evidence') and any mitigating measures taken.
- List any known limitations, e.g. data, timing, etc. and explain the mitigating measures taken. Provide an overall analysis of the reliability of the available data.
- Provide a critical assessment of the work carried out by the external contractor, which allows an understanding why you agreed or disagreed with their conclusions.
- Provide a more elaborate description of the process as well as details relating to the methodologies applied (e.g. studies carried out/used, sources of data, models, stakeholder consultation).
- Explain any uncertainty in the analytical results and the robustness of the results to changes in underlying assumptions or data inputs. It should also be clear how such uncertainty has been addressed or minimised in the analytical work.
- Explain the steps taken to assure the quality of the analytical results presented in the evaluation.

- When the evaluation relies on modelling or other analytical techniques, this Annex should include the following additional information, for any model used:
 - brief description of model structure and modelling approach with any key assumptions, limitations and simplifications;
 - intended field of application and appropriateness for the specific analysis presented;
 - model validation and peer review with relevant references; This may include the extent to which the model/technique and input data / results have been discussed with external experts;
 - citation of input data following good practices for data citation for maximum transparency;
 - explanation of the likely uncertainty in the model results and the likely robustness of model results to changes in underlying assumptions or data inputs;
 - explanation as to how uncertainty has been addressed or minimised in the modelling exercise with respect to the policy conclusions;
 - the steps taken to assure the quality of the modelling results presented in the report.

A concise description of the point(s) of comparison used in any modelling exercise in terms of the key assumptions, key sources of macroeconomic and socio-economic data, the policies and measures they contain and any assumptions about these policies and measures (such as the extent to which they are deemed implemented by the Member States, or their estimated impact following implementation).

Where the point(s) of comparison is not the preferred option identified in a prior impact assessment, the reasons for this should be clearly explained, including any related changes introduced during the adoption process.

Annex III. Evaluation matrix and, where relevant, details on answers to the evaluation questions (by criterion)

The evaluation matrix serves to help organise the evaluation work by:

- translating each of the five 'better regulation' criteria into evaluation questions about the EU intervention under investigation;
- describing per question the data sources that will be consulted to answer the evaluation questions;
- indicating per question the success criteria (i.e. points of comparison) to enable the judgment whether the intervention was successful;
- defining per success criterion the indicator(s) and describe what the indicator(s) will measure (either quantitatively or qualitatively).

The annex should include the evaluation matrix that serves as the organising framework of the evaluation work and factual answers to the questions by evaluation criterion agreed with the ISCG. All the evaluation criteria – effectiveness, efficiency, relevance, coherence, and EU added value – should be addressed in the evaluation matrix, unless a substantiated reason is provided. The analysis and evidence in this Annex provide the main points substantiating the assessment in section 4 – Evaluation findings.

Questions and their respective evidence-based answers could be presented one by one. It is recommended that this is done separately for each evaluation criterion – effectiveness, efficiency, relevance, coherence, and EU added value. **The coverage allocated to each criterion will vary depending on its importance and the depth of the evidence/analysis presented in the main text of the evaluation report.**

For example, in case there is no clear distinction among the criteria of effectiveness, efficiency, coherence when answering Question 4.1 '*To what extent was the intervention successful?*', then the answers to their specific evaluation questions should be provided in this Annex, to provide the reader with all relevant detail on the evidence base informing this narrative.

When external support studies exist, answers to the questions in the evaluation matrix can be concise but factual with reference to these studies for reporting in full. For other cases, answers to the questions in the evaluation matrix must provide sufficient detail, enabling the reader to follow the evidence and logic and understand the answers.

Any differences between the actual evaluation matrix used and the one created at the start of the evaluation (design phase) should be used to inform Annex II (section on limitations).

Annex IV. Overview of benefits and costs and, where relevant, table on simplification and burden reduction

Annex IV is a record of the resources used by an intervention and the changes generated by it (i.e. an assessment of costs and benefits). All costs and benefits that can be linked to the intervention, as identified by the evaluation, should be summarised clearly in a tabular format. An indicative structure for this table is provided below. The structure of the table can be adjusted as the evaluation sees fit, but in all cases, **costs should be classified according to the EU Standard Cost Model**⁷¹³.

⁷¹³ See Tool #58 (*EU Standard Cost Model*)

Table 1. Overview of costs and benefits identified in the evaluation ¹									
	Citizens/Consumers		Businesses		Administrations		[Other...] _ specify		
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	
[Cost or Benefit description]:									
Mark the type of cost/benefit, each on a separate line: Costs: Direct compliance costs (adjustment costs, administrative costs, regulatory charges) Enforcement costs: (costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/infraction) Indirect costs (indirect compliance costs or other indirect costs such as transaction costs) Benefits: Direct benefits (such as improved well being: changes in pollution levels, safety, health, employment; market efficiency) Indirect benefits (such as wider economic benefits, macroeconomic benefits, social impacts, environmental impacts)	Type: Choose one-off or recurrent	Provide the monetary value	Where no quantification is possible, please provide ranges or explain the reasons why	Provide the monetary value	Where no quantification is possible, please provide ranges or explain the reasons why	Provide the monetary value	Where no quantification is possible, please provide ranges or explain the reasons why	Provide the monetary value	Where no quantification is possible, please provide ranges or explain the reasons why

In case the evaluation has identified (measurable) potential for simplification and burden reduction, this should be summarised in a separate table. An indicative structure for this table is provided below. The structure of the table can be adjusted as the evaluation sees fit, but in all cases, costs should be classified according to the EU Standard Cost Model.

TABLE 2: Simplification and burden reduction (savings already achieved)								
Report any simplification, burden reduction and cost savings achieved already by the intervention evaluated, including the points of comparison/ baseline where available (e.g. REFIT savings predicted in the IA or other sources).								
	Citizens/Consumers/Workers		Businesses		Administrations		[Other...] _ specify	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Title ¹ :...								
Type: One-off / recurrent (select)	Provide the estimated monetary and quantitative value (point value or range)	If no monetisation/quantification is possible, please explain here the reasons. Qualitative analysis on simplification benefits provides important information and should be inserted here.						
PART II: II Potential simplification and burden reduction (savings)								
Identify further potential simplification and savings that could be achieved with a view to make the initiative more effective and efficient without prejudice to its policy objectives ² .								
	Citizens/Consumers/Workers		Businesses		Administrations		[Other...] _ specify	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Description:...								
Type: One-off / recurrent (select)								

Annex IV should be filled in as far as possible, to provide a systematic presentation of the costs and benefits which have been identified and assessed during the evaluation process. As a minimum, Annex IV should include an explanation of the cost/benefit and a qualitative summary of the information collected. As far as available, Annex IV should include both:

quantitative data (e.g. time taken, person days, number of records/equipment/staff etc. affected or involved) and monetisation (in euro) of the costs/benefits.

For all information presented, it should be clear whether it relates to all Member States or is drawn from a subset. Cross-references to the source and assumptions behind any figures should also be provided.

Where there is a prior impact assessment, the table should contain, as a minimum, the same costs/benefit categories identified in it, to enable straightforward comparison between expected (as in the impact assessment) and actual (as in the evaluation) costs and benefits.

Annex V. Stakeholder consultation – synopsis report

This annex summarises all stakeholder consultation activities undertaken for the evaluation or fitness check. The content and format of this annex is outlined in Tool #54 (*Analysing data and informing policymaking*).

The Executive Summary

An evaluation report should be accompanied by an executive summary – a reader-friendly **stand-alone** staff-working **document**. Thus, a non-technical style should be applied, providing the full picture of the evaluation and any technical terminology and jargon should either be adapted or explained for a non-expert reader. The executive summary may follow the structure of the evaluation report.

The executive summary should be short (max 4-5 pages) and be available in English, French and German.

An executive summary is not necessary when the Commission provides a report to the European Parliament and the Council.

4. GOOD PRACTICE TIPS FOR DRAFTING THE EVALUATION REPORT

- Given the importance of providing a good evidence base, all data and analysis should be clearly sourced and where necessary further detail provided in an annex.
- To be credible, evaluations need to state the findings clearly and objectively, i.e. avoid picturing too rosy a picture or not avoid being critical where relevant. The evaluation is a primarily backward-looking exercise. Therefore, findings and conclusions must be phrased so that it is clear what has been achieved and what is lacking. Avoid replacing this backward-looking angle by forward looking recommendation for future inclusion, e.g. recommending a specific improvement when a lack of something has been observed. Care needs to be taken so that the phrasing of conclusions, lessons learned and suggested areas for improvement do not go beyond the limits of an evaluation report.
- The executive summary and the conclusions section of the evaluation report should both contain clear statements on the robustness and reliability of the data and analysis which form the basis of the evaluation, to reflect the common practice of reading either of them first.
- Compare what is being delivered in the final evaluation to what was agreed in the 'call for evidence'. It is easy to promise everything at the start of an evaluation and then find

that it is not possible to deliver. Such limitations or variances from the plan should be clearly written up in the evaluation report.

- In cases where several evaluations of a repetitive nature with very similar content and structure are carried out (e.g. in case of certain funding instruments) it may be possible to cover them in a single evaluation report. This approach would need to be agreed in advance with the SG on a case-by-case basis.

5. THE EVALUATION REPORT AND ANY ASSOCIATED REPORT/COMMUNICATION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

The evaluation of legislation may be based on a reporting/review/evaluation clause in a legal act which obliges the Commission to review or evaluate the legislation after a certain time and to provide the European Parliament and the Council with a report (or Communication – hereafter, just 'Commission report')⁷¹⁴.

In cases where the legislation requires such a Commission report (i.e. one adopted by the College), the evaluation report should be linked to and support the Commission report. This should help keep the main text of the Commission report concise (maximum 10-15 pages is recommended). Where the Commission reports formally to the European Parliament and the Council, it is sufficient to organise one single interservice consultation covering both the Commission report and the evaluation report.

Where there is no legal obligation for the Commission to report formally to the co-legislator, the lead DG can still decide to do so because of the dissemination value and use made by many stakeholders of such documents. It is sufficient to organise one single interservice consultation covering both the Commission report and the evaluation report.

The evaluation report describes the Commission services' approach, analysis, and conclusions to the evaluation. Such an evaluation report is an analytical document, drawing conclusions underpinned by factual information and analysis.

In contrast to the evaluation report, a formal report to the co-legislator can also set out any political message about the evaluation and indications of next steps. This Commission report can be a shorter, self-standing document, referring to more detailed indications in the evaluation report. It should provide clear indications on all key aspects of the evaluation including, if appropriate, political responses to the conclusions of the evaluation. This Commission report is not submitted to the RSB⁷¹⁵.

6. 'BACK-TO-BACK' EVALUATIONS AND IMPACT ASSESSMENTS

For 'back-to-back' evaluations and impact assessments, the evaluation findings can be presented as an annex to the impact assessment report, unless the evaluation has been selected for separate scrutiny by the RSB⁷¹⁶.

⁷¹⁴ See Tool #44 (*Legal provisions on monitoring and evaluation*)

⁷¹⁵ The RSB provides an objective assessment of the quality of the work of the Commission services in relation to the evaluation, and hence this is based on the Commission services' evaluation report or fitness check (in the form of a staff working document).

⁷¹⁶ See Tool #50 (*'Back-to-back' evaluations and impact assessments*)

7. COMMUNICATING THE FINDINGS FROM THE EVALUATION REPORT AND THE EVALUATION EXERCISE TO THE PUBLIC

Communicating and promoting the evaluation exercise and its findings to the widest possible audience is of paramount importance.

A dissemination plan could be drawn up from the early stages of the design. It should list the different interested audiences as well as identify the appropriate messages you want to convey to suit what your different audiences would be most interested to know. Commission services are also encouraged to seek guidance from their respective communication units, if applicable.

To maximise transparency and access, all relevant supporting deliverables from any external work and the evaluation report should be widely disseminated. The following files related to the evaluation must be published on the '*Have Your Say*' web portal:

- the 'call for evidence';
- the evaluation report with annexes and (if applicable) its executive summary (in English, French and German);
- the factual summary report of the public consultation (if applicable);
- the opinion(s) of the Regulatory Scrutiny Board (if applicable).

In addition to the publication on '*Have Your Say*', DGs can establish a dedicated webpage for each evaluation or fitness check within their associated general policy pages. Such pages can act as a communication tool, bringing together information and providing an update of progress both during the evaluation and after.

Apart from the publication of the evaluation report, the supporting documents, the related material and of any news items or press releases of the evaluation exercise, DGs should make use of a vast array of communication means to better disseminate the evaluation findings to their different audiences. For example, DGs are encouraged to widely disseminate the evaluation results in the social media and to not rely only on the reports and documents published on '*Have Your Say*' or on their own dedicated webpage.

The terms of reference (or technical specifications), all contractors' final reports (and other relevant interim deliverables from external work) and evaluation reports/fitness checks in the form of staff working documents should be published in a manner compliant with [corporate guidelines](#).

Where contractors are involved, it may be desirable to ask them to provide findings in different formats (e.g. PowerPoint presentations or videos, leaflets, different documents, using social media) to facilitate dissemination of evaluation exercise and/or its findings.

8. FEEDING EVALUATION FINDINGS INTO THE DECISION-MAKING PROCESS

For an evaluation to fulfil its purpose, results must feed into the decision-making process, ensuring that lessons are learned and communicated.

Further to the dissemination of the evaluation report and the evaluation exercise, the evaluation results and lessons learned should feed into the DGs Annual Activity Reports.

- Related follow-up actions (such as decisions to undertake an impact assessment, improve guidance) should be identified in the Annual Management Plans of the Commission services.
- As a part of ensuring transparency and accountability for EU actions, it is recommended that the Directorate-General(s) concerned convene, within a reasonable time of the completion of the evaluation report, upon any follow-up actions with senior management. It is good practice that the unit in charge of the evaluation provides an (annual) progress update against the follow up actions identified. If necessary, the REFIT Scoreboard should be updated.
- Follow-up action plans may be drafted to set out actions planned resulting from the evaluation and their indicative timetable. It is equally important to be clear where no action is envisaged and explain why that is the case. The document should distinguish between policy follow-up (major policy changes requiring Commissioner/College endorsement) and administrative/organisational follow-up. Where it takes the form of a staff working document, no commitments should be taken for the Commission. The degree of commitment presented in the follow-up document will also depend on several factors including the timing of its publication in respect to the Commission's strategic planning and programming cycle (e.g. commitments made in management plans, Commission work programme). It should in no case pre-empt results of a possible impact assessment.

TOOL #50. 'BACK-TO-BACK' EVALUATIONS AND IMPACT ASSESSMENTS

1. INTRODUCTION

Usually, evaluations and impact assessments are conducted sequentially so that the results of the evaluation can be fully used in the subsequent impact assessment. This requires appropriate advance planning and may not always be possible. When necessary, evaluations and impact assessments may be launched at the same time and carried out (in a so-called 'back-to-back' manner) as a single process.

The intention to conduct a 'back-to-back' evaluation / impact assessment must be clearly specified when the initiative is presented for political validation.

2. THE 'BACK-TO-BACK' PROCESS

(1) 'Call for evidence'

The 'call for evidence' will cover elements of the evaluation and of the impact assessment⁷¹⁷. The 'call for evidence' template for 'back-to-back' evaluations / impact assessment is available on [GoPro](#).

(2) Interservice coordination group

A single interservice coordination group (ISCG) should be set up. This is chaired by the Secretariat-General for important or politically sensitive initiatives or by the lead DG or service.

(3) Conduct

The evaluation and impact assessment work will follow the usual steps. Any external work conducted to support the evaluation and/or impact assessment will be steered and discussed with the ISCG.

(4) Stakeholder consultation

A single consultation strategy⁷¹⁸ can be prepared. This strategy should be revised and adapted throughout the process to ensure that the necessary work is conducted to gather information from all the identified stakeholder categories to meet the evaluation and impact assessment requirements.

As usual, the consultation strategy should include a range of appropriate consultation activities. One single public consultation can be used to support the 'back-to-back' evaluation and impact assessment. The public consultation should have a good mix of backward-looking and forward-looking questions that address existing performance and the design of the new initiative.

⁷¹⁷ See Tool #51 (*Consulting stakeholders*)

⁷¹⁸ See Tool #52 (*The consultation strategy*)

Only one synopsis report⁷¹⁹ needs to be drafted as part of the impact assessment report. If the Regulatory Scrutiny Board has selected the evaluation for scrutiny, the same synopsis report should be attached to the evaluation.

(5) 'Back-to-back' reports

For 'back-to-back' evaluations and impact assessments, the results of the evaluation will usually be presented as an annex to the impact assessment report. This annex will follow the full structure of an evaluation report. Compulsory annexes accompanying the evaluation, when overlapping with those of the impact assessment (e.g. procedural information, methodology, stakeholder consultation) as well as the executive summary should be reported once. The introductory part of the evaluation could explain why a 'back-to-back' approach was taken and identify any limits or issues caused by overlaps in conducting the evaluation and impact assessment.

(6) Regulatory Scrutiny Board

For 'back-to-back' evaluations with an impact assessment, in which the evaluation has been selected for separate scrutiny by the RSB, the Board will issue a separate opinion on the evaluation. In such cases, a separate evaluation report is always required as well as a separate slot in the Board's meetings plan. If there are imperative and well-justified timing constraints, the RSB may consider the evaluation report and the impact assessment report at the same meeting but in two separate slots.

For back-to-back evaluations, in which the evaluation has not been selected for separate scrutiny by the RSB, the evaluation will be annexed to the impact assessment report, or, at the discretion of the lead DG, it may be presented as a self-standing report. In either case, the findings of the evaluation will be scrutinised by the RSB as part of its scrutiny of the impact assessment report.

3. POINTS OF ATTENTION

A 'back-to-back' approach allows the evaluation and impact assessment of an EU intervention to be carried out in a single process, quite often with support of a single external study contract, which allows for efficient use of time and resources. Services should however not be tempted to run the two parts in parallel. This would prejudice the outcomes of the evaluation and could lead to low(er) quality of analysis, most often because the problem(s) would be ill-defined.

It is imperative to allow for sufficient time for the evaluation part to thoroughly examine the intervention according to the five evaluation criteria. This should lead to a proper diagnosis of the areas and problems to be tackled in the subsequent revision of the EU intervention. A thorough assessment as part of the evaluation stage leads to conclude on lessons learned that provide a solid basis for the problem definition on which to base the different steps of the impact assessment stage. Therefore, the problem definition in the impact assessment cannot be finalised until at least tentative evaluation conclusions are available.

The handling of the evaluation and impact assessment in one single process, if done properly as explained in the previous paragraph, will enhance the consistency of the two steps and has

⁷¹⁹ See Tool #54 (*Analysing data and informing policymaking*)

the advantage that it is easier to handle external communication on the different steps and the public consultation. Stakeholders and the public will easier understand the whole process and will be able to contribute at the same time on what worked (less) well and where they see room for improvement for the future.

Chapter 7 – Stakeholder consultation

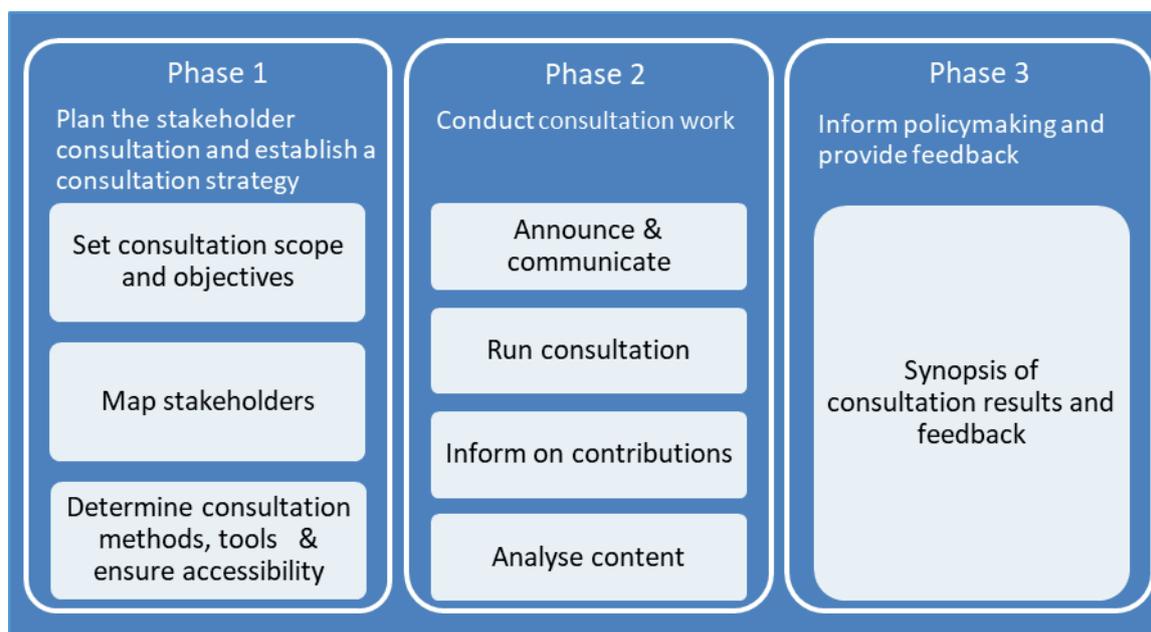
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TOOL #51. CONSULTING STAKEHOLDERS

1. INTRODUCTION

Under the sixth political priority 'A new push for European democracy', the Commission is committed to giving Europeans a stronger role in decision-making. Citizens should play an active part in setting the priorities and the level of ambition. The Commission is committed to promote the participation of Europeans and civil society in the policymaking activities and to ensure the transparency and the legitimacy of the policymaking process.

Consulting stakeholders is an important instrument to collect information for evidence-based policymaking. Their views, practical experience and data will help deliver higher quality and more credible policy initiatives and evaluations.



The Commission's consultation system offers stakeholders many opportunities to contribute to policymaking such as on:

- The Commission's initiatives (policies, legislation, or evaluations of existing policies) through 'calls for evidence'⁷²⁰.

The '**call for evidence**' is a streamlined, inclusive, and simple system which combines feedback to the 'call for evidence' document and a public consultation, where applicable. It is published on the web portal '*Have Your Say*'⁷²¹, the entry point for all contributions to the Commission's legislative proposals, evaluations/fitness checks, communications etc.

The 'call for evidence' document is translated in all EU languages.

- **Legislative proposals** once they have been agreed on by the Commission.

⁷²⁰ 'Evidence' refers to multiple sources of data, information, and knowledge, including quantitative data such as statistics and measurements, qualitative data such as opinions, stakeholder input, conclusions of evaluations, as well as scientific and expert advice.

⁷²¹ '*Have Your Say*' is the web portal through which stakeholders, including members of the public, scientific and technical experts, can contribute to initiatives as they take shape before and after adoption by the Commission.

- Draft acts that add or amend aspects of existing laws (**delegated acts**), or set out rules to make sure Member States implement EU legislation in the same way (**implementing acts**) as well as on draft measures subject to regulatory procedure with scrutiny (*RPS/PRAC measures*).
- Suggestions to simplify existing EU laws in '[Have Your Say: Simplify!](#)'

2. 'CALL FOR EVIDENCE'

2.1. Introduction

The 'call for evidence' consists of a 'call for evidence' document that describes an initiative and, where relevant, a public consultation questionnaire (for the initiatives that need one).

The 'call for evidence' is the Commission's main opportunity to explain to the public and stakeholders why a particular initiative, evaluation, or fitness check is being prepared, what it aims to achieve and to gather their views.

Stakeholders and the public are invited to:

- a) give their feedback on the 'call for evidence' document, which explains the Commission's understanding of the problem and possible solutions, and to
- b) respond to a public consultation questionnaire (for the initiatives that need one) to share their views and any relevant information they may have.

Box 1. Feedback vs. consultation

In the context of the Commission's 'better regulation' policy, collecting feedback under the feedback mechanisms differs from collecting input under consultation.

- 1) The collection of feedback offers an opportunity for stakeholders to express general views on a specific document (a 'call for evidence' document, draft secondary legislation, legislative proposals and accompanying impact assessments, established legislation), not based on specific questions or consultation background documents.
- 2) Consultation is a formal process for collecting input and views from stakeholders on new initiatives⁷²², evaluations / fitness checks, communications, Commission documents launching a consultation process, green papers, etc. It is structured and based on specific questions and/or consultation background documents. When consulting, the Commission proactively seeks evidence (facts, views, opinions) on a specific issue.
- 3) There is a specific formal procedure regarding the EU recognised social partners' consultation under the Treaty (see Tool #10 (*Treaty-based social partner consultations and initiatives*)).

Commission services are required to launch a 'call for evidence' for its legislative proposals, evaluations, and fitness checks. Below are the four distinct types of the 'call for evidence' documents; further details on these distinct 'call for evidence' types are provided in section 2.2.

⁷²² Including revision of existing legislation

- i. 'call for evidence' for an initiative without an impact assessment
- ii. 'call for evidence' for an impact assessment
- iii. 'call for evidence' for an evaluation/fitness check
- iv. 'call for evidence' for an evaluation/impact assessment run in parallel

The templates for the different types of 'call for evidence' are available in [GoPro](#). 'Calls for evidence' are published in all EU languages.

There are two different situations:

- A) When a public consultation is also carried out;
 - B) When a public consultation is not carried out (for initiatives that do not need one, as specified below).
-
- A) When a public consultation is carried out, it is, by default, done simultaneously with the launch of the 'call for evidence'. The overall duration of publication on '[Have Your Say](#)' web portal for feedback and contributions is 12 weeks⁷²³. It is possible however to publish the public consultation at a later stage if services still want to seek feedback on the 'call for evidence' document. In this case, the 'call for evidence' document is normally published for feedback for 4 weeks. Then, a public consultation is launched, after the related 'call for evidence' document, for 12 weeks. If the public consultation is not ready when the 'call for evidence' is launched it can be uploaded later, provided that 12 weeks of public consultation are preserved.
 - B) When not associated with a public consultation, the 'call for evidence' document is open for feedback for 4 weeks. It is still translated in all EU languages and clearly explains, in the section on 'better regulation' instruments, how stakeholders' input will be sought.

All these steps are detailed below.

2.2. Planning a 'call for evidence'

Creating the Decide planning entry

- 1) All initiatives – 'Politically sensitive and/or important', 'Non-politically sensitive and/or important' and 'Evaluations / Fitness Checks' must be encoded in Decide planning. 'Politically sensitive and/or important' initiatives and fitness checks and evaluations must be accompanied by a 'call for evidence'⁷²⁴ unless an exception is granted⁷²⁵.
- 2) For reporting and publication purposes, it is important to use the right 'call for evidence' template when encoding the description of the 'call for evidence' to be published on the '[Have Your Say](#)' web portal in Decide planning. All templates are available on [GoPro](#). The types of 'call for evidence' templates to be used are:
 - i. **'call for evidence' for an initiative (without an impact assessment)**: The 'call for evidence' document for politically sensitive and/or important initiatives describes the problem to be tackled and the objectives to be achieved, explains why EU action is needed, its added value and outlines alternative policy options.

⁷²³ During the summer holidays, this period is usually extended to 14 weeks.

⁷²⁴ For Agreements concluded by the social partners pursuant to Article 155 TFEU, no 'call for evidence' is necessary.

⁷²⁵ See Tool #1 (*Principles, procedures and exceptions*)

- ii. **'call for evidence' for an impact assessment:** The 'call for evidence' document for politically sensitive and/or important initiatives describes the problem to be tackled and the objectives to be achieved, explains why EU action is needed and its added value, and outlines alternative policy options. The 'call for evidence' document for an impact assessment sets out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives, the options, as well as the likely impacts of each option, including the identification of the relevant sustainable development goals affected by the initiative⁷²⁶. It is mandatory to include a 12-week internet-based public consultation⁷²⁷.
- iii. **'call for evidence' for an evaluation/fitness check:** The 'call for evidence' document for evaluations and fitness checks⁷²⁸ specifies the scope of the evaluation and the issues to be examined in the context of an evaluation. For evaluations of policies and programmes of broad public interest and for fitness checks, a public consultation is highly recommended.

Upon decision of the lead DG, the ISCG should be consulted whether a public consultation is needed to support an evaluation 'call for evidence'.

- iv. **'call for evidence' for an evaluation and an impact assessment run in parallel:** Usually evaluations and impact assessments are conducted sequentially so that the results of the evaluation can be fully used in the subsequent impact assessment. However, this requires appropriate advance planning and may not always be possible. When necessary, evaluations and impact assessments may be launched at the same time⁷²⁹ and consultations are carried out as a single 'call for evidence'. A public consultation, with backward and forward-looking questions, must be associated with the 'call for evidence' for an evaluation and an impact assessment run in parallel, unless a derogation⁷³⁰ is granted⁷³¹.

Approval

- 3) A 'call for evidence' should be finalised by the lead DG together with the Secretariat-General. The lead DG should consult with the pertinent DGs prior to submitting the documentation to the Secretariat-General. It is recommended to share the 'call for evidence' with and consult the ISCG members (if an ISCG is established).
- 4) All documents in a 'call for evidence' should be written in plain language – short and simple sentences with no EU jargon. The DG should ensure that the draft 'call for evidence' documents are edited by the DGT EDIT team, before being submitted to the Secretariat-General via Decide for approval⁷³². For politically sensitive and important documents, the DGT EDIT team will edit both the description of the 'call for evidence' as well as the related public consultation.
- 5) The draft 'call for evidence' document and public consultation questionnaire must be submitted to the Secretariat-General via Decide once political validation has been granted

⁷²⁶ See Tool #19 (*Sustainable development goals*)

⁷²⁷ Public consultations on very technical issues of little interest for the general public can be avoided, where a targeted consultation of stakeholders is a better means of collecting the necessary evidence.

⁷²⁸ Including 'call for evidence' for an ex-ante evaluation required by the Financial Regulation.

⁷²⁹ See Tool #50 (*'Back-to-back' evaluations and impact assessments*)

⁷³⁰ See Tool #1 (*Principles, procedures & exceptions*)

⁷³¹ Draft findings of the evaluation can be used, if available on time, for the public consultation covering the impact assessment and evaluation

⁷³² The 'call for evidence' should be sent via email to the DGT EDIT functional mailbox.

for the initiative. When submitting the documentation to the Secretariat-General, the lead DG should update the Decide entry with the pertinent information for the initiative⁷³³. Publication can be done only once per initiative and is irreversible. It is therefore compulsory, before triggering the publication of the 'call for evidence' that the appropriate political approval is given.

Gathering feedback and views on the 'call for evidence' on the 'Have Your Say' web portal

- 6) The description of the 'call for evidence' document is published on the '[Have Your Say](#)' web portal with the date of publication indicated. The document can be considered as reflecting the Commission's thinking at the time of publication; it does not need to be reviewed or updated.
- 7) The related public consultation questionnaire consists of a set of questions for citizens as well as a set of more specialised questions, where relevant, for experts in civil society organisations, business, public authorities, academia etc. Position papers, letters, informal text contributions and other types of contributions may also be submitted by respondents. For transparency, all received contributions will be published on the '[Have Your Say](#)' web portal.
- 8) The 'call for evidence' public consultation questionnaire must be developed using the EU Survey template and in line with the guidance provided in Tool #53 (*Conducting consultation activities*).
- 9) The document describing the 'call for evidence' should not exceed 4-5 DGT pages. When a public consultation is included or launched at a later stage, the public consultation questionnaire should remain at 10 DGT pages maximum. Longer questionnaires do not attract enough attention.
- 10) A 'call for evidence' document is available in all EU languages⁷³⁴.
- 11) The public and stakeholders can provide feedback on the 'call for evidence' document and share their views in the related public consultation directly on the '[Have Your Say](#)' web portal. This allows comments to feed usefully into the further preparatory work of the initiative, including the preparation and management of external studies and contracts^{735,736}.
- 12) Feedback comments and suggestions to the 'call for evidence' which contradict the [rules in place for providing suitable content](#) must be removed. Such feedback may contain abusive, obscene, vulgar, slanderous, hateful and xenophobic, off-topic language, unrelated to the proposed legislation, or could be linked to illegal or pirated software etc. The lead DG must keep a detailed track of such feedback comments and suggestions as well as of the grounds on which they were removed.
- 13) Data protection requirements must be considered throughout the consultation, analysis, and publication of contribution processes. Refer to Tool #55 (*Horizontal matters –*

⁷³³ Include a 'Go Pro link' with guidance to DGs: "General information' tab in Decide: Include a short title and summary in line with the guidance provided by DGT. Ensure that one of the contact names included on this page is the person responsible for the 'call for evidence'; 'Stakeholder consultation' tab in Decide: Include a link to the EU survey BRP generated public consultation".

⁷³⁴ Except for very technical initiatives and specialised questionnaires where such an effort would be disproportionate to the expected input. Translations into Irish are available as of 1 January 2022.

⁷³⁵ See Tools #52, #53, and #55 on stakeholder consultation.

⁷³⁶ The consultation strategy (in a succinct form, should be included in the 'call for evidence')

publication of responses, data protection, access to documents and transparency register) concerning data protection requirements.

Reporting back to stakeholders on feedback and views received

- 14) A 'factual summary report' summarising the key elements of the public consultation associated with the 'call for evidence' must be published within 8 weeks⁷³⁷ of the closure of the public consultation⁷³⁸, along with the contributions to the public consultation on the '[Have Your Say](#)' web portal.
- 15) DGs should ensure that the feedback comments and views received in a 'call for evidence' are considered in the process of policy preparation or evaluation work. No formal translation of the feedback comments or the contributions is required, and no specific replies are required from the Commission in response to individual feedback and contributions received.
- 16) Feedback and contributions to all consultation activities (public or targeted) should be summarised and referred to in the 'synopsis report'⁷³⁹. The report should also explain how and to which extent the stakeholder views have been considered in the final initiative/evaluation. For transparency reasons, the synopsis report⁷⁴⁰ should also mention the number of removed feedback comments and suggestions.

IT issues

Any questions or concerns related to IT issues with the launch or follow up to a 'call for evidence' should be addressed to the [EC HELPDESK IT](#) who will assign it to the appropriate IT team.

2.3. Considerations when drafting a 'call for evidence' document

Describing the problem

Defining the problem correctly is probably the single most important step in the preparation of a new initiative because if the problem (and its causes) is poorly understood then it will be difficult to design policies that will be effective on the ground. The tool on how to define problems should be consulted before drafting the 'call for evidence'⁷⁴¹.

These problems should be quantified where possible and at least in the impact assessment report if it is not yet possible to provide quantitative information in the 'call for evidence'.

In the context of an evaluation briefly describe the expected role and original objectives of the EU intervention(s) being evaluated. Explain why the intervention(s) is (are) being evaluated (e.g. legal requirement). There is no need to provide a fully developed intervention logic at this point, but the non-expert reader should be able to understand in broad terms, what the initiative was expected to achieve (its policy objectives) and how this was expected to happen.

⁷³⁷ The 8-week timeframe is indicative for public consultations with large number of responses.

⁷³⁸ See Tool #54 (*Analysing data and informing policymaking*) and #55 (*Horizontal matters – publication of responses, data protection, access to documents and transparency register*)

⁷³⁹ See Tool #54 (*Analysing data and informing policymaking*)

⁷⁴⁰ The synopsis report is a detailed, qualitative analysis of all consultation activities. For further information see Tool #54 (*Analysing data and informing policymaking*)

⁷⁴¹ See Tool #13 (*How to analyse problems*)

Objectives

As an **impact assessment** supports the preparatory work, the 'call for evidence', including the public consultation, should cover, as appropriate, the four key elements of an impact assessment: the problem to be tackled, subsidiarity and the EU dimension to the problem, the policy options and their likely impacts. In addition, it should also address the scope for regulatory cost reduction and simplification measures not affecting the achievement of objectives as well as environmental and digital aspects when relevant.

If an **evaluation** or **fitness check** is carried out, the 'call for evidence' should contribute to the subsequent analysis of the five evaluation criteria: effectiveness, efficiency, EU added value, relevance, and coherence. Explain what the evaluation will deliver and how its results will be used. The scope should set out clearly what actions, time period and geographical area will be covered by the evaluation and what will not (with any associated justification for excluding e.g. certain articles, covering only a shorter period or not all EU Member States). The 'call for evidence' should not detail all possible EU interventions that could be covered under coherence but should identify key policy areas which will be looked at.

In case of the 'call for evidence for an evaluation and an impact assessment run in parallel'⁷⁴² approach (see sub section 2.4 below) the 'call for evidence' should cover to the extent possible the five evaluation criteria and the four key elements of an IA.

For **initiatives** not supported by an IA nor related to an evaluation or fitness check, the 'call for evidence' can focus on any element/issue identified in the consultation strategy on which stakeholders should be consulted.

'Better regulation' requirements

The 'call for evidence' document should be explicit about the 'better regulation' steps of the initiative. The reasons why an impact assessment will not be prepared, or why an evaluation is not necessary, should be clearly explained in the 'call for evidence'. Where no additional consultation activities are planned, a justification should be provided.

2.4. Evaluations and impact assessments run in parallel

Political urgencies or timing constraints may arise so that there is some degree of overlap between the evaluation and the impact assessment while carried out in a 'back-to-back' manner.

The intention to conduct an evaluation and an impact assessment run in parallel should be clearly specified when the initiative is presented for political validation. This should also indicate the expected degree of overlap of the two processes which will define the subsequent steps to be followed. In this case, a combined 'call for evidence' should be published. The appropriate template is available from the [GoPro](#) page.

See Tools #52 (*Consultation strategy*) and #53 (*Conducting consultation activities*) for further guidance on drafting and preparing a public consultation.

⁷⁴² See Tool #50 (*'Back-to-back' evaluation and impact assessments*)

2.5. Workflow overview

Workflow for the 'call for evidence'

- **Politically sensitive and/or important', 'Non-politically sensitive and/or important' and 'Evaluations/Fitness Checks' must be encoded in Decide planning.**
- When encoding the description of the 'call for evidence' to be published on the '[Have your say](#)' web portal in Decide planning, it is important to use the correct 'call for evidence' template.
- **The 'call for evidence' templates are:**
 - 'call for evidence' for an initiative (without an impact assessment)
 - 'call for evidence' for an impact assessment
 - 'call for evidence' for an evaluation/fitness check
 - 'call for evidence' for an evaluation and an impact assessment run in parallel
- A 'call for evidence' should be finalised by the lead DG together with the Secretariat-General. It is recommended to share the 'call for evidence' with and consult the ISCG members (if an ISCG is established).
- **All documents in a 'call for evidence' should be written in plain language – short and simple sentences with no EU jargon.**
- **By default, a 'call for evidence' also launches the related public consultation. The 'call for evidence' document is published on '[Have your say](#)' for 12 weeks⁷⁴³ in all EU languages.** It is possible however to publish the public consultation at a later stage. In this case, the 'call for evidence' document is published for feedback for 4 weeks. Then, a public consultation is published after the related 'call for evidence' document, for 12 weeks.
- **For evaluations of policies and programmes of broad public interest and for fitness checks, a public consultation is highly recommended.**
- For very technical initiatives of little interest for the general public, a targeted consultation of stakeholders is a more suitable means of collecting the necessary evidence.
- The public and stakeholders can provide feedback on the description of the 'call for evidence' and share their views in the related public consultation directly on the '[Have your say](#)' web portal.
- **All feedback on the 'call for evidence' document is published real-time on the '[Have your say](#)' web portal. Contributions to the public consultation questionnaire are published within 8 weeks of the closure of the public consultations on the '[Have your say](#)' web portal.**
- No formal translation of the feedback is required and no specific replies are expected from the Commission in response to individual feedback/contributions.
- Feedback comments and contributions to the 'call for evidence' which contradict the

⁷⁴³ During the summer holidays, this period is usually extended to 14 weeks.

- [rules in place for providing suitable content](#) must be removed.
- A **'factual summary report'** summarising the key elements of the public consultation associated with the 'call for evidence' must be published within 8 weeks of the closure of the public consultation⁷⁴⁴, along with the contributions to the public consultation on the '[Have your say](#)' web portal.
 - Feedback and contributions to all consultation activities (public or targeted) should be summarised and referred to in the **'synopsis report'**.

3. FEEDBACK ON LEGISLATIVE PROPOSALS

3.1. Introduction

After a legislative proposal is adopted by the College, the public and stakeholders can provide feedback on the proposal and, where relevant, on the accompanying IA.

Feedback can be provided for a period of **eight weeks**, in parallel with the period during which national parliaments have the opportunity to provide reasoned opinions on subsidiarity grounds.

According to the Inter-institutional Agreement on Better Law-making *“the three Institutions will keep each other regularly informed throughout the legislative process about their work, about on-going negotiations among them and about any stakeholder feed-back they may receive, via appropriate procedures, including dialogue between them”*. Following this agreement, the post-adoption feedback mechanism is a means for the Commission to transparently inform on the views of different stakeholders on its final proposal (and impact assessment).

Therefore, the collected feedback will be summarised by the Commission and presented to the European Parliament and Council, with the aim to feed these views into the legislative debate.

3.2. Workflow overview

- Workflow for feedback on legislative proposals and accompanying impact assessments**
- After adoption by the College, the legislative proposal and, where relevant, the accompanying impact assessment is published automatically on the '[Have your say](#)' web portal.
 - Feedback can be provided **up to 8 weeks after the last language version is published**.
 - All feedback is published on the '[Have your say](#)' web portal. Respondents have the possibility to opt for publication of their contribution with their personal information or anonymous publication of their contribution.
 - No formal translation of the feedback is required, and no specific replies are expected

⁷⁴⁴ See Tool #54 (*Analysing data and informing policymaking*) and Tool #55 (*Horizontal matters – publication of responses, data protection, access to documents and transparency register*)

from the Commission in response to individual feedback.

- The **responses must be summarised and sent to the European Parliament and the Council by means of a letter from the Director-General** of the Directorate-General in charge of the file. This letter should be sent as soon as possible after closure of the feedback period to inform the work of the respective Committees and Working Groups in Parliament and Council. **A copy of the letters must be sent to the office of the Secretary-General.** In case no feedback has been received, no letter should be sent to the European Parliament and Council.
- For the **European Parliament**, the letter should be addressed to the **chair(s) of the Committee(s) to which the proposal is attributed**. Normally, by the time the feedback mechanism is closed, the corresponding proposal should have been attributed to one or more Committees. If it is not yet attributed to a lead committee, the letter should be sent to the Chair of the Conference of Committee Chairs.
- For the **Council**, the letter should be addressed to the **Ambassador of the Presidency with copy to the Council Secretariat and the chair of the Council Working Group** in charge of the file. If the file is not yet attributed the letter should only be addressed to the Ambassador of the Presidency, with the Council Secretariat in copy.
- The letter should provide **a factual summary of the feedback received**, without any further qualitative assessment or reference to the Commission’s viewpoint on provided views. The letter should also include **a reference to the ‘Have Your Say’ web portal where all feedback responses are published**. No formal interservice consultation is required, however, where relevant, **associated DGs should be consulted on the draft**.

4. FEEDBACK MECHANISM FOR DRAFT DELEGATED AND IMPLEMENTING ACTS AND DRAFT MEASURES SUBJECT TO REGULATORY PROCEDURE WITH SCRUTINY (RPS/PRAC MEASURES)

4.1. Introduction

Delegated act empowerments allow the Commission to adopt legal acts of general application to supplement or amend certain non-essential elements of a legislative act. Implementing act empowerments are used where uniform conditions for implementing legally binding acts are needed⁷⁴⁵.

Stakeholders have the possibility to provide feedback on the draft texts of delegated and implementing acts and regulatory procedure with scrutiny (RPS) measures, with exceptions (see below). This feedback period lasts for four weeks.

In practice, this means that DGs need to consider, already at the planning stage, whether an upcoming act qualifies for the feedback mechanism and flag this in the Decide planning module. The list of upcoming delegated and implementing acts and RPS measures that will be published for feedback is made available at regular intervals on the ‘[Have Your Say](#)’ webpage on Commission Europa, in order to allow stakeholders to plan ahead and prepare. Also, DGs need to factor in the additional time needed for feedback and for analysis of the

⁷⁴⁵ See Tool #42 (*Delegated acts and implementing acts*) for more information

feedback received. For delegated acts, information on stakeholder input in general, including feedback, should in addition be referred to in the explanatory memorandum⁷⁴⁶.

4.2. Workflow overview for draft delegated acts

Workflow for feedback on draft delegated acts

- All delegated acts need to be **included in the Decide planning module**, those that will be subject to feedback need to be flagged (Feedback Yes/No).
- The planning of upcoming delegated acts subject to feedback is published at regular intervals on the '[Have Your Say](#)' web portal of the Commission.
- The draft delegated act can only be published **after the interservice consultation** has taken place. When launching the interservice consultation DGs need to indicate whether the feedback is planned and if not, which exception applies.
- **Publication** can be done **only once per draft act and is irreversible**. It is therefore compulsory, before triggering the publication, that the **appropriate hierarchical validation** is given; the required hierarchical level for validation is decided by the Director-General of the responsible DG.
- Feedback can be provided **for a period of 4 weeks** after publication.
- All feedback is published on the '[Have Your Say](#)' web portal. Respondents have the possibility to opt for publication of their contribution with their personal information or anonymous publication of their contribution.
- No formal translation of the feedback is required, and no specific replies are expected from the Commission in response to individual feedback.
- Following the 4 weeks, the lead DG assesses the feedback received and explains how it took it into account in the explanatory memorandum accompanying the delegated act.
- Discussions in the expert group⁷⁴⁷ can precede, run in parallel or come after the feedback period, depending on the nature of the act and the amount of technical expertise required for its preparation. In any case, **Member State experts shall be given the opportunity to see the last version of the draft** (i.e. the one incorporating the feedback), prior to the launch of the adoption procedure by the College

4.3. Workflow overview for draft implementing acts and measures subject to regulatory procedure with scrutiny

Workflow for feedback on implementing acts and regulatory procedure with scrutiny measures

- All **implementing acts** with committee control that are due to be adopted via oral or written procedure need to be **included in the Decide planning tool**; out of those, the ones that will be subject to feedback need to be flagged (Feedback Yes/No).
- All Regulatory procedure with scrutiny (**RPS**) measures need to be **included in**

⁷⁴⁶ See also Tool #40 (*Drafting the explanatory memorandum*)

⁷⁴⁷ C(2016) 3301 <http://ec.europa.eu/transparency/regexpert/index.cfm>

- planning tool**; out of those, the ones that will be subject to the 4-week feedback period need to be flagged (Feedback Yes/No).
- The planning of upcoming implementing acts and RPS measures that will be subject to the feedback period is published at regular intervals on the '[Have Your Say](#)' web portal.
 - **Publication** can be done **only once per draft act and is irreversible**. It is therefore compulsory, before triggering the publication, that the **appropriate hierarchical validation** is given; the required hierarchical level for validation is decided by the Director-General of the responsible DG.
 - When launching the interservice consultation, DGs need to indicate in the cover note whether the feedback is foreseen and, if not, which exception applies.
 - Feedback can be provided **for a period of 4 weeks** after publication.
 - **All feedback is published** on '[Have Your Say](#)' web portal. Respondents have the possibility to opt for publication of their contribution with their personal information or anonymous publication of their contribution.
 - No formal translation of the feedback is required, and no specific replies are expected from the Commission in response to individual feedback.
 - Following the 4 weeks, the lead DG assesses the feedback received and explains in the committee meeting how it took it into account. This explanation is included in the **summary record of the meeting**, that is then made public in the [Comitology Register](#).
 - The publication for public feedback is done before the vote on the draft implementing acts or RPS measure in the committee.

4.4. Scope of the feedback

Publication of draft acts for stakeholder feedback is a measure aimed at improving transparency of the Commission's work. **The feedback mechanism should aim to capture all such acts.** However, there will be situations where publication of the draft act would bring little added value, duplicate previous consultations or would not be possible. The reasons for not publishing are explained in the table below and these must be interpreted restrictively.

The DG makes a first assessment, at the planning and at the interservice consultation stage. This is then scrutinised during the interservice consultation. In case of doubt whether to subject a draft act to feedback, the Secretariat-General is ready to provide guidance (SG COMITOLOGIE). It is, however, the responsibility of the DGs to apply the rules on publication so as not to undermine the objective of improving transparency.

	Type	Reason	Examples
1	No (or limited) margin of discretion	Lack of policy alternatives	Acts implementing international standards into EU law without any (or limited) discretion. Corrigenda
2	Drafts have been prepared by an EU agency or other EU body and have been subject to	Extensive consultation on the draft text has already taken place in a	Acts based on regulatory technical standards submitted by the European Banking Authority (EBA) or by European Securities

	full public consultation before being submitted to the Commission and for which the Commission does not have the intention to significantly modify them	dedicated framework	and Markets Authority (ESMA)
3	Urgency / emergency measures	Time limitations do not allow additional consultation period	Acts under the urgency procedure or other urgent acts, e.g. temporary exceptional support measures in the agricultural field, urgent/emergency measures addressing threats to public, animal or plant health.
4	Budgetary procedures and measures, programme management decisions	Lack of policy alternatives / implementation of agreements already decided on	Decisions on work programmes, selection and award decisions
5	Individual authorisation decisions / acts / decisions based on the assessment of compliance with legal requirements	Lack of significant impact, routine acts	Marketing authorisations in the pharmaceutical field or comparable authorisations, inclusions
6	Temporary risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors	Temporary food safety measures
7	Based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency/scientific committee findings	Extensive consultation on the substance has already taken place in a dedicated framework	Areas in which EU decentralised agencies such as the European Food Safety Agency (EFSA) have given a scientific advice
8	Other duly justified reasons, e.g.: <ul style="list-style-type: none"> • Involving business secrets or security threats • Influence on markets 	Public consultation not possible or not appropriate, e.g. due to legal restrictions or practical constraints.	Acts with confidential content (such as in the aviation safety or space area, Galileo) Acts relating to the common organisation of the markets in agricultural products, measures relating to aid to certain Member

			States Authorisations to Member States relating to own resource calculations
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4.5. General principles governing publication of draft acts for feedback

- **Feedback is the default approach**

The default is that draft delegated and implementing acts and RPS measures are published for the 4-week feedback. Exceptions to this rule must be applied in a restrictive manner.

- **Targeted or public stakeholder consultation does not replace the feedback**

Many DGs carry out extensive targeted stakeholder consultations in the preparatory phase, both for implementing and delegated acts. Such early targeted consultations do not replace the feedback, which gives the public at large the possibility to react to and comment on the actual draft act. In some cases, e.g. when an impact assessment is required, a public consultation is carried out in the preparatory stages, which, similarly to targeted consultations, does not replace the feedback mechanisms (given that the purpose of the latter is to allow stakeholders to comment on the actual draft text).

- **Urgency cannot be the result of insufficient planning**

Urgency is justified in those cases in which strict deadlines are provided for in the legal basis. It cannot be used to make good for insufficient planning in the earlier stages but may be used in truly exceptional circumstances of political urgency.

- **Feedback also applies to very technical acts**

The majority of delegated and implementing acts are very technical and may in reality only trigger comments from a specialised group of stakeholders. The feedback applies nevertheless and gives the public at large the possibility to react on the actual draft act.

- **Feedback can also be sought if exceptions would apply**

DGs may still decide to use the feedback mechanism even though it may be justified not to publish the draft act.

- **Limited margin to act**

This is meant to cover cases in which the Commission's margin is limited due to prior commitments, notably in the context of international agreements or existing legislation. Obviously, discretion in relation to delegated and implementing acts is always circumscribed and limited by the empowerment itself but this is not enough to justify relying on the exception.

- **Procedures with set deadlines**

In some cases, the basic act includes a specific procedure for the Commission with set deadlines. Here it may not be possible to add a four-week public feedback period.

- **Technical Barriers to Trade (TBT) notification**

The TBT notification does not replace the need for feedback. In practice, the two processes can go in parallel, with the 4-week feedback running together with the 60-to-90-day TBT notification.

- **Risk management measures**

Depending on the legal framework risk management measures can be **individual measures** (e.g. a decision addressed to a company allowing it to place a specific substance on the market, as is the case for example for medicinal products and GMOs) or **general measures** (e.g. an amendment of an annex or a list allowing for the use of a substance up to a certain concentration limit, e.g. cosmetics). **All individual authorisation decisions are exempted** from the feedback mechanism.

Risk management **measures of general application can also be exempted from the feedback** under exception 7, provided that they are:

- (1) based on a scientific opinion from an agency or scientific committee (not a consultant);
- (2) subject to a prior public consultation that has taken place on the scientific opinion, (not on the draft measure) and the recommendations concerning the risk management are clearly spelled out); and
- (3) drafted following the agency / scientific committee findings (i.e. the recommendation is essentially translated into legal text and all that is added is the entry into force / applicability / transitional measures for products on the market, without adding new elements).

5. PROVIDING INPUT ON SIMPLIFICATION THROUGH '*HAVE YOUR SAY: SIMPLIFY!*'

The Commission has set up the Fit for Future Platform (F4F)⁷⁴⁸ to support the work on simplification of EU laws and reducing unnecessary costs. F4F also examines whether EU laws are future-proof.

F4F will gather evidence on topics identified in an [annual work programme](#). This includes seeking input from stakeholders and citizens on simplification possibilities through '[Have Your Say: Simplify!](#)'

The input received and any accompanying document are published on the '[Have Your Say: Simplify!](#)' webpage as well as the Fit for Future Platform's website.

The Platform will consider this input and may use it when preparing opinions to the Commissions with suggestions on how to simplify and reduce costs linked to EU laws.

If a suggestion is not considered (for instance, because it does not concern simplification and unnecessary costs reduction, or because it has to do with national legislation rather than EU laws), an explanation will be sent to the person or organisation who submitted it.

⁷⁴⁸ See Tool #2 (*The regulatory fitness programme (REFIT) and the Fit for Future Platform*)

The EU helpdesk Europe Direct provides an explanation to anyone who has submitted a suggestion that falls outside the mandate of the Platform.

6. FREQUENTLY ASKED QUESTIONS

The list of FAQ is regularly updated and published on [GoPro](#).

7. FURTHER READING AND REFERENCES

- [GoPro pages](#);
- Updated [Guidelines on Delegated](#) and [Implementing Acts](#).

TOOL #52. CONSULTATION STRATEGY

Consulting stakeholders is an important means to collect information for evidence-based policymaking. Their views based on insights from practical experience as well as quantitative data at their disposal can help deliver higher quality and more credible policy initiatives, by feeding into impact assessments, evaluations, and fitness checks. Stakeholder consultation also ensures transparency and legitimacy of the policy development process and contributes to a more successful policy implementation.

For all Commission initiatives, whether or not a public consultation is carried out⁷⁴⁹, a consultation strategy is necessary, and the ‘better regulation’ procedural and methodological requirements apply.

Stand-alone public consultations, i.e. those that are not linked to the preparation of an initiative, an impact assessment, an evaluation or a fitness check, are not covered by this tool. However, if they are published on the ‘[Have Your Say](#)’ web portal, they need to follow all the relevant procedural steps covered in this tool.

Box 1. The consultation strategy – key elements

- A consultation strategy is a key requirement for Commission initiatives that involve consulting stakeholders, including those accompanied by an impact assessment (IA), a major evaluation and fitness check, and should build on the overall mapping of available evidence and identified gaps.
- The consultation strategy should cover the following key elements: consultation scope and objectives, identification of stakeholders, envisaged consultation activities, their timing, language regime, and the communication plan to promote the consultation (communication actions in function of the identified consultation objectives, targeted stakeholders and consultation activities, e.g. on social media, web, face-to-face, press, publications).
- The consultation strategy should be finalised and discussed by the interservice coordination group (ISCG). If no interservice coordination group is established, the consultation strategy should be endorsed by the Secretariat-General and, where relevant, associated DGs.
- The consultation strategy should be outlined in the ‘call for evidence’⁷⁵⁰, in particular in the section on ‘better regulation instruments – consultation strategy’, to inform all stakeholders and to invite them to provide their feedback.
- In the case of a ‘back-to-back’⁷⁵¹ approach, a single consultation strategy is sufficient.

1. INTRODUCTION

The purpose of the consultation strategy is to design an effective and efficient consultation approach. It should build on the overall mapping of *available* and *needed* information⁷⁵² for a

⁷⁴⁹ See Tool #51 (*Consulting stakeholders*) for the specific cases when a public consultation needs to be carried out.

⁷⁵⁰ See Tool #51 (*Consulting stakeholders*).

⁷⁵¹ See Tool #50 (*‘Back-to-back’ evaluation and impact assessment*).

⁷⁵² This information includes views, practical experience, and data.

specific initiative, major evaluation or fitness check and be fed by a thorough and structured desk review of relevant sources⁷⁵³. The consultation strategy should aim to ensure that all relevant evidence and expertise is collected, including data about costs, societal impacts, and the potential benefits of the initiative. It should explicitly cover environmental impacts (see Tool #36) and digital aspects (see Tool #28), when relevant. Evidence and expertise collected from stakeholders should complement evidence obtained from other sources (e.g. from the work of the external contractors/consultants).

Designing a consultation strategy is a key requirement for each initiative accompanied by an impact assessment, and by a major evaluation and fitness check. When requesting political validation⁷⁵⁴, the political level should be informed of which ‘better regulation’ instruments are intended to be used, including planned data collection and consultation activities.

The key elements to cover in the consultation strategy are: the consultation scope and objectives; the stakeholder groups; the envisaged consultation activities and their timing, as well as the languages in which the consultation activities will be published (language regime). The DG and SG ‘better regulation’ and communication units are available to support DGs in the drafting of the consultation strategy and outreach plans.

2. SETTING THE CONSULTATION SCOPE AND OBJECTIVES

Box 2. Consultation scope and objectives – key elements⁷⁵⁵

- Be clear from the outset what is ‘in-scope’ and ‘off-scope’ due to legal or political limits.
- Map the available sources and information in a concrete and topic-related way. This also includes a check of past, but still valid stakeholder consultation work.
- Identify information gaps that can be filled in via consultation activities and the type of information needed for each topic: quantitative data or qualitative data.
- The consultation strategy should also include a phase where the received consultation results are assessed for their completeness. If needed, other tools can then be used to fill any remaining gaps.
- Define the concrete and topic-related scope of stakeholder involvement.
- Include sensitive, controversial, or highly uncertain issues.
- Be aware of potential blind spots that consultation work should detect.
- Specify which of the consultation activities (public consultation, consultations with social partners, experts, EU decentralised agencies and other EU bodies, lobbyists, Eurobarometer surveys, focus groups, randomly selected samples of citizens, public hearings, ‘citizen dialogues’, or others) will be used and how the selected activities will complement each other.
- Be clear on the specific purpose of public consultations, their intended use and the official EU languages into which the questionnaires and other consultation documents (e.g. background information, the ‘call for evidence’ document, reports with the results) will be

⁷⁵³ See Tool #4 (*Evidence-informed policymaking*)

⁷⁵⁴ See Tool #6 (*Planning and validation of initiatives*)

⁷⁵⁵ Practical examples for systematic scoping is available on [GoPro](#).

translated.

There is no single approach to consultation. In practice, a consultation strategy will include a combination of consultation methods (i.e. public/targeted) and tools (i.e. the 'call for evidence', questionnaire, document, meeting, hearing, interview, workshop).

Below are considerations to keep in mind when defining the consultation scope for major evaluations and fitness checks as well as impact assessments and other policy initiatives.

Evaluations and fitness checks

Consultation activities in the context of evaluations or fitness checks should contribute to the subsequent analysis of the five evaluation criteria: effectiveness, efficiency, EU added value, relevance, and coherence. These consultation activities are usually based on consultation documents which may include background information and existing evidence related to the evaluation criteria and a questionnaire aiming to collect views, expertise, and information of stakeholders or to test/validate already existing analysis. This does not mean that each consultation activity needs to address all evaluation criteria; always consider the right scope of planned consultation activities keeping in mind stakeholders that they target. The stakeholder contributions feed into the evaluation report.

As indicated in the Tool #51 (*Consulting stakeholders*), for evaluations of policies and programmes of broad public interest and for fitness checks, a public consultation is highly recommended. Upon decision of the lead DG, the ISCG should be consulted whether a public consultation is needed to support an evaluation. Targeted or specialised consultations of specific stakeholder groups or experts can be more relevant to gather specific technical input in relation to the questions on the evaluation criteria.

Initiatives accompanied by impact assessments

Consultation activities in the context of an impact assessment (including public consultation) should cover its key elements to be addressed: the problem definition, the subsidiarity and the EU dimension to the problem, possible policy options and their likely impacts. Like for evaluations and fitness checks, this does not mean that each consultation activity needs to address all these aspects; always consider the right scope of planned consultation activities keeping in mind stakeholders that they target. When modifying existing interventions, the scope for efficiency improvement (regulatory cost reduction) and simplification measures not affecting the achievement of objectives should also be covered.

The consultation is usually based on consultation documents rather than the draft legal text, which comes only later in the policy preparation process. These consultation documents may include background information, existing evidence and ideas related to the key elements to be addressed in the impact assessment and a questionnaire aiming to collect views, expertise, and information of stakeholders on these key elements or to test/validate already existing analysis. The stakeholder contributions feed into the impact assessment and help shape the draft legal text.

Given the variety of Commission initiatives accompanied by an impact assessment, there is no one-size-fits-all solution on how to consult. The consultation strategy must envisage a

public consultation included in the 'call for evidence'⁷⁵⁶ published on '[Have Your Say](#)' web portal. The public consultation should be complemented with more targeted or specialised consultations of specific stakeholder groups, experts or EU decentralised agencies and other EU bodies, which can be more relevant to gather specific technical input and expertise in relation to the impact assessment questions.

Political and/or sensitive initiatives not accompanied by an impact assessment

A public consultation is not always necessary for political and/or sensitive initiatives not accompanied by an impact assessment. In these cases, it is at the discretion of a DG whether a public consultation is needed. For such initiatives, the 'call for evidence' can be complemented with targeted or specialised consultations of specific stakeholder groups, experts or EU decentralised agencies and other EU bodies, which can be more relevant to gather specific technical input.

3. STAKEHOLDER MAPPING

Box 3. Stakeholder mapping – key elements

- Identify all stakeholder categories relevant for or interested in the policy area concerned.
- Sort stakeholder groups according to the level of interest, influence, and expertise on the initiative to which the consultation refers.
- Identify if there is a sectoral social dialogue or other sectoral committee that would be relevant to consult regarding the scope of the policy area concerned.
- Do not limit mapping to the 'obvious' stakeholders, identify target groups that run the risk of being excluded – underserved groups. ISCG members should contribute to identify these target groups.
- Keep in mind data protection considerations when making use of existing stakeholder lists gathered during previous consultations or in the context of networks, expert groups or stakeholders listed in the Transparency Register – stakeholders should have previously indicated that they wish to be contacted again concerning a consultation with the same purpose.

3.1. Identification of stakeholder groups

The identification of the concrete stakeholders to be consulted can be done in an unstructured and/or structured way⁷⁵⁷. The table in box 4 gives an overview of the main stakeholder categories identified by the Commission services.

Box 4. Stakeholder categories⁷⁵⁸ (non-exhaustive list):

⁷⁵⁶ In some cases, DGs might opt for publishing first the 'call for evidence' and launch the public consultation later. See Tool #51 (*Consulting stakeholders*) for further details.

⁷⁵⁷ The [JRC Policy LAB](#) can provide support

⁷⁵⁸ Organisations and businesses eligible to register in the Transparency Register that choose not to register should be considered as a separate category 'non-registered organisations/businesses' unless they are recognised as representative stakeholders via relevant Treaty provisions.

Citizens	<ul style="list-style-type: none"> • The general public: individual non-expert citizens • Individual expert citizens responding on their own behalf
Businesses⁷⁵⁹	<ul style="list-style-type: none"> • Large-sized enterprises • SMEs • Microenterprises • Self-employed
Social partners and representatives of professions and crafts	<ul style="list-style-type: none"> • Chambers of commerce • Employers' organisations • Business organisations • Trade union organisations • Representatives of professions or crafts
Non-governmental organisations	<ul style="list-style-type: none"> • Non-governmental organisations • Platforms • Networks • Similar associations
Consultancy	<ul style="list-style-type: none"> • Professional consultancies • Law firms • Self-employed consultants
Research and academia	<ul style="list-style-type: none"> • Think-tanks • Research institutions • Academic institutions
Organisations representing regional, local, and municipal authorities, other public or mixed sub-national entities	<ul style="list-style-type: none"> • Regional, local, or municipal structures • Other sub-national public authorities • Transnational associations and networks of public sub-national authorities • Other public or mixed entities, created by law whose purpose is to act in the public interest
National public authorities, EU decentralised agencies and other bodies (EU agencies) and international public authorities.	<ul style="list-style-type: none"> • National and regional/local governments • National and regional/local Parliaments • National and regional/local public authorities or agencies • EU institutions, EU decentralised agencies and other bodies (EU agencies) • Intergovernmental organisations

It might be useful to start with a brainstorming: just list those people, businesses or organizations, social partners, representatives of professions and crafts who may be affected by the policy, who have influence on or an interest in its conclusion or revision. Discuss who has relevant information and expertise and who is responsible for implementation or application of a policy.

⁷⁵⁹ For the identification of the business size please consult the [User guide to SME identification](#).

3.2. The 'six tests for stakeholder identification'

This stakeholder identification tool consists of six questions with a set of sub-questions, which can be used for a structured approach to identify stakeholders (see box 5).

It helps to list those that are impacted, needed for implementation, and having expertise and/or interest in the subject.

<i>Box 5. The six tests for stakeholder identification⁷⁶⁰</i>
<i>Test 1. Who is directly impacted?</i>
<ul style="list-style-type: none"> • Whose daily/weekly lives will change because of this policy? • Who cannot easily take steps to avoid being affected by this policy? • Who will have to change their behaviour because of this policy?
<i>Test 2. Who is indirectly impacted?</i>
<ul style="list-style-type: none"> • Whose daily lives will change because others have been directly impacted by the policy? • Who will gain or lose because of changes resulting from this policy?
<i>Test 3. Who is potentially impacted?</i>
<ul style="list-style-type: none"> • In particular circumstances, who will have a different experience as a result of this decision? • Are there individuals or groups who will have to adjust their behaviour if specific conditions apply?
<i>Test 4. Whose help is needed to make it work?</i>
<ul style="list-style-type: none"> • Are there vital individuals or groups in the delivery chain? • Who will have the ability to obstruct implementation unless co-operating? • Who understands the likely impact of this decision on other stakeholders?
<i>Test 5. Who thinks they know about the subject?</i>
<ul style="list-style-type: none"> • Who has studied the subject and published views on it? • Who has detailed know-how and expertise that those implementing the policy should also understand? • Are there individuals or groups that will be perceived as knowledgeable on the subject?
<i>Test 6. Who will show an interest in the subject?</i>
<ul style="list-style-type: none"> • Are there organisations, authorities, bodies, or individuals who think they have an interest? • Has anyone been campaigning about the issue? • Is there anyone publishing or broadcasting views on this subject?

4. DETERMINING THE APPROPRIATE CONSULTATION METHOD AND TOOLS

<i>Box 6. Consultation method and tools – key elements</i>
<ul style="list-style-type: none"> • The most appropriate consultation activities depend on the nature of the initiative, the

⁷⁶⁰ Source: The Consultation Institute, London (Bedfordshire)

scope of the consultation, the identified stakeholders, as well as on time and resources required and available.

- If you prepare an impact assessment, it is mandatory to include a 12-week internet-based public consultation in your consultation strategy as it ensures transparency and accountability and gives any stakeholder the possibility to contribute. For evaluations of policies and programmes of broad public interest and for fitness checks, a public consultation is highly recommended. The ISCG, upon decision of the lead DG, should be consulted whether a public consultation needs to be conducted.
- The public consultation should be complemented, where appropriate, by other consultation activities to engage all relevant stakeholders and to target potential information gaps.
- In case of a 'back-to-back'⁷⁶¹ approach to evaluation and impact assessment, a single 12-week internet based public consultation is sufficient. It should be complemented by other targeted consultation activities.
- Plan early and consider the timing and sequencing of the proposed consultation work and operational arrangements (i.e. internal and external resources, translations⁷⁶²).
- All consultation work, including any activity outsourced to contractors, should follow the Commission's 'better regulation' guidelines.
- Ensure that persons with disabilities can participate in consultations on an equal basis.

Based on the scoping and stakeholder mapping for the concrete policy initiative, evaluation or fitness check the most appropriate consultation activities should be identified.

There is no one-size-fits-all solution regarding the type of consultation activities. In addition, not all identified stakeholders need to be addressed in every consultation activity, but all stakeholders should have the opportunity to contribute somehow.

However, following the scoping and stakeholder mapping steps, information should be available which allows identifying the most appropriate:

- mix of public and targeted consultations,
- sequence of consultation activities,
- degree of interactivity for the various stakeholder groups,
- level of effort needed to stimulate contribution of stakeholders; this includes considerations like language regime and accessibility participation of persons with disabilities.

If an external service provider or a facilitator⁷⁶³ (who should comply with the minimum standards for stakeholder consultation and follow the 'better regulation' guidelines) is considered for certain consultation work, it should be ensured that the contractors involved have no interest in the policy area which is subject to consultation and can operate in an independent way on behalf of the Commission.

⁷⁶¹ See Tool #50 on ('Back-to-back' evaluation and impact assessment)

⁷⁶² DGT should be contacted as early as possible so that language needs of the target audience(s), length of documents, timing and available translation resources can be properly assessed and considered.

⁷⁶³ The JRC.I.2 Policy lab and the 'Community of participatory management' is available to facilitate participatory stakeholder consultation activities like workshops, conferences, policy labs.

The 'call for evidence'⁷⁶⁴ and the section on 'better regulation instruments – consultation strategy' in particular, will summarise all the consultation activities to be carried out.

4.1. Overview of key consultation methods – public, targeted, and exploratory consultations

The key elements of public, targeted, and exploratory consultations are described below:

- **Public consultations:** A public consultation allows the public as well as stakeholders to contribute freely. The objective is to gather input and views from a broad range of stakeholders. The most common tool used is a web-based consultation (questionnaire) published on the '[Have your say](#)' web portal⁷⁶⁵. Respondents can contribute by logging into the EU Survey questionnaire using their EU or social media login.
- **Targeted consultation:** A targeted consultation activity addresses specific well-defined stakeholder groups and invites them to participate. In a restricted targeted consultation activity, stakeholders are pre-selected and only the explicitly invited stakeholder groups or individuals can participate in the consultation activity (e.g. focus group, workshop, targeted survey). In the case of a restricted targeted consultation, the criteria used to select the stakeholders as well as information on who has been selected and to what stakeholder group they belong should be indicated on the consultation page. A DG takes full responsibility for the preparation, organisation, and follow-up of the consultation activity. This includes its announcement on the policy website, the publication of contributions or a narrative of them, and information on the way forward and next steps. Wherever applicable, targeted consultation of social partners should be defined in the consultation strategy. These consultations may take various forms such as:
 - Dedicated hearings on initiatives with significant social or employment implications
 - Consultation in the relevant Sectoral Social Dialogue Committees on specific initiatives with social and employment implications
- **Exploratory consultations:** Exploratory consultations are preliminary in nature, do not yet address the broad public, but are targeted to those that 'have the information'. They may provide insights to determine if any problem exists and could be addressed by EU action or sketch the potential scope of a genuinely new policy. It thus may contribute to the agenda setting of the Commission. They can help identifying how far the Commission should invest in further studies and consultation work on a specific topic and are carried out before validation for a concrete new initiative is sought and before stakeholder consultation linked to a concrete initiative takes place – e.g. they may feed the design of a green paper.

Exploratory consultations need to be part of the DG work plan and validated at DG level. As with a targeted consultation, a DG takes full responsibility for the preparation, organisation, and follow-up of the consultation activity. This includes its announcement on the policy website, the publication of contributions or a narrative on them, and information on the next steps. Where relevant, associated DGs should be informed or

⁷⁶⁴ See Tool #51 (*Consulting stakeholders*)

⁷⁶⁵ For detailed information, see Tool #51 (*Consulting stakeholders*)

consulted on consultation documents (background papers, questionnaires, etc.) and be kept informed on the outcome of the consultation.

Exploratory consultations do not waive formal consultation requirements in case they trigger the preparation of a concrete Commission initiative. Information on the exploratory consultation should be incorporated in the scoping part of the consultation strategy of the new initiative.

4.2. Other, frequently used consultation methods

Table 1 presents other frequently used consultation methods and their use.

Table 1: Use of consultation methods (in alphabetical order)

Method	Used for
Conferences, public hearings & events	Gathering input from a larger number of targeted stakeholders through direct interaction.
Eurobarometer surveys	Gathering views of European citizens through representative samples of targeted populations. Can also target professional stakeholders (e.g. in-depth studies).
Expert groups of the Commission	Gathering inputs and advice from experts on a well-defined mandate.
EU decentralised agencies and other EU bodies	Gathering inputs and expertise in relation with their mandates
Focus groups	Gathering information through group discussion of citizens/stakeholders with similar features.
Interviews	Collecting information via in-depth, more or less structured conversations with individuals.
Public consultations	Gathering inputs from a broad range of stakeholders through different instruments. Mandatory for impact assessments, major evaluations, fitness checks, Commission Communications launching a consultation process and green papers.
Consultations targeting SMEs – the SME panel	Gathering information directly from SMEs via the Enterprise Europe Network, managed by DG GROW (see Tool #23).
Social partners' consultations	For social policies and labour markets, gathering joint positions by employers and workers organisations at cross-industry or sectoral level; or individual contributions by the relevant organisations (see Tool #10).
Workshops, meetings, and seminars	Collecting specific information from targeted stakeholders through direct interaction.

TOOL #53. CONDUCTING CONSULTATION ACTIVITIES

Box 1. Conducting and analysing consultation activities – key elements

- Consultation activities should be conducted in line with the stakeholder consultation strategy. The latter should be described in the ‘call for evidence’⁷⁶⁶.
- Ensure that consultation documents are explicit, clear, and understandable, including for non-experts. Avoid the use of technical and/or EU jargon.
- Questions in consultation questionnaires should be relevant, short and simple, and be designed in a neutral manner. The right balance between open and closed questions should be struck.
- Contributions to consultations, both public and targeted, must be published, either with personal information or anonymously, according to the option chosen by the respondent.
- Reflect well on the questionnaire design: it determines the type of analysis that can be performed on contributions.
- Proper reference needs to be made to data protection rules⁷⁶⁷.
- Organisations should be urged to register in the Transparency Register. Contributions received from organisations that choose not to register will be processed as a separate category ‘non-registered organisations/businesses’⁷⁶⁸ unless they are recognised as representative stakeholders via relevant Treaty provisions⁷⁶⁹.
- Consider the target audience when deciding on type of graphs and output resulting from the analysis.
- A basic analysis should go beyond the collective results (for example, “78% of all respondents agreed that (...)”) and should consider the responses by stakeholder group, country, area of activity etc.
- A factual summary report must be published within 8 weeks after closing the public consultation. This report should remain factual and neutral and therefore not contain a qualitative interpretative assessment of contributions, which should be done in the synopsis report later in the process⁷⁷⁰.
- Consider sufficient resources for analysing the contributions received.

1. ANNOUNCING CONSULTATION ACTIVITIES

Consultation activities should be prepared as early as possible, and the public – especially the targeted stakeholders – should be adequately informed about the planned launch of a consultation activity:

⁷⁶⁶ See Tool #51 (*Consulting stakeholders*)

⁷⁶⁷ See Tool #55 (*Horizontal matters – publication of responses, data protection, access to documents and transparency register*)

⁷⁶⁸ See section on stakeholder categories in Tool #52 (*Consultation strategy*)

⁷⁶⁹ European Social Dialogue, Articles 154-155 TFEU.

⁷⁷⁰ For further information on the factual summary and the synopsis report, see Tool #54 (*Analysing data and informing policymaking*)

- Update the information on the specific upcoming consultation activity on the policy consultation website⁷⁷¹. Add concrete dates, agenda, and other relevant information.
- In case of a targeted consultation activity, ensure balanced stakeholder participation, use clear and transparent criteria for selecting participants and provide information about these criteria on the policy website.
- Reach out to and invite relevant stakeholder groups to participate in the most effective way. Announce the upcoming event through various communication channels (e.g. press releases, social media⁷⁷²), and use networks and other multipliers⁷⁷³.
- For both feedback mechanisms launched on the '[Have your say](#)' web portal and public consultations using EU Survey and launched on the '[Have your say](#)' web portal, a privacy statement is published on '[Have your say](#)'. However, for targeted consultation activities, a distinct privacy statement will be needed.

2. RUNNING A CONSULTATION ACTIVITY

When consulting stakeholders, it is essential to ensure that the documents and questionnaires used in the consultation activities are of the highest quality. They should be written in plain language – short and simple sentences with no EU jargon. Acronyms should be spelled out and explained.

There are different conceptual approaches to consulting stakeholders:

- using a **clearly defined and structured list of questions**. This can for example take the form of an (online) questionnaire or questions to be asked in person / over the phone.
- using a **more generic approaches**, either by simply requesting general views on a topic or by having stakeholders comment on a specific document such as a Commission Communication launching a consultation process or a green paper.
- **combining both approaches**, e.g. a generic green paper open for general input including embedded structured questions.

While more generic approaches most often use open questions, structured approaches (from now on 'questionnaires') should feature an appropriate mix of both open and closed questions.

2.1. Methodological and practical guidance on questionnaires

There is no 'right' answer on how to design a questionnaire. Whether a questionnaire is suitable – meaning likely to deliver the information needed – depends on a range of factors. After having decided to use a questionnaire, this implies choosing an appropriate structure for

⁷⁷¹ See Tool #52 (*Consultation strategy*). The '[Have your say](#)' web portal features a timeline for each initiative which announces all next steps in the policymaking cycle. In parallel, DG's websites should be updated with further information on upcoming consultation activities.

⁷⁷² Advert e.g. on Twitter or Facebook account of the DG; teaser question to wake interest and link directly to a consultation activity.

⁷⁷³ Contact e.g. the 500 Europe Direct Centres in the Member States, Representations of the EU in Member States, umbrella organisations of stakeholder groups, SME-Panel or Network of local SMEs.

it, designing the questions as clearly and simply as possible, and finding the most appropriate means to run the questionnaire.

Developing a good questionnaire takes time and preparations should therefore start as early as possible. A good questionnaire increases the quality of answers and, in turn, leads to more impactful input to policymaking.

For questionnaires for public consultations, the 'better regulation' coordination desks in the Directorates-General as well as in the Secretariat-General provide methodological support and procedural information. Questionnaires are discussed and reviewed by the interservice coordination groups set up to follow the work on new initiatives and/or evaluations / fitness checks.

2.1.1. When to use a questionnaire?

Given the many consultation activities they can be used for, questionnaires can almost always be helpful when consulting stakeholders. Much depends on *how* they are used: if little prior knowledge is available, a questionnaire consisting of mostly open questions can help to get a better understanding of the issue. If the existing body of knowledge is substantial, closed questions can be used to rank potential solutions and open questions can be used to collect good practices or detailed information. Furthermore, the use of a clearly structured questionnaire often makes it easier to subsequently analyse the answers received.

Box 2. Strengths and limitations of questionnaires	
Strengths	<ul style="list-style-type: none"> • Allow collecting information in a structured manner. • Facilitate the analysis of responses (e. g. descriptive statistics provided by EU Survey tool). • May be perceived as less time consuming for respondents, resulting in a high(er) number of contributions. • Allow for a broad outreach to stakeholders.
Limitations	<ul style="list-style-type: none"> • Do not allow for more detailed input from respondents, as replies to most of the questions are pre-defined. • Risk of bias in the way questions are drafted and various options are presented; • For open questions – the number of open questions and the length of free text for replies is usually limited. • Depending on the design of the questionnaire, response choices are limited, and some answers might be excluded in the first place (especially if limited range of responses is offered). • While the results from consultations are not statistically representative, there is a risk that they are perceived as such.

2.1.2. Questionnaire design

When designing a questionnaire, start with the **scope** of the questionnaire, as identified in the consultation strategy⁷⁷⁴. What is it that you really need to know from the public and/or the

⁷⁷⁴ For further information, see Tool #52 (*Consultation strategy*)

stakeholders? Only ask those questions that are likely to provide you with the necessary information. Otherwise, try to reformulate or remove the question.

Consider how to meaningfully structure the questionnaire. Only use **sections** that are clear from the perspective of the public and/or the stakeholders. For example, a division into sub-themes is much more meaningful than a division into questions for an evaluation and questions for an impact assessment (in the case of a back-to-back consultation). Such a themed section could, for example, consist of several closed questions and an associated text box for further thoughts and explanations.

As both expert and non-expert stakeholders are targeted, it is recommended that the questionnaire is divided in two parts:

- the first part would consist of general questions that can be answered by a non-specialist public,
- whereas the second, more detailed part would be addressed predominantly to experts. However, even if parts of the questionnaire or specific questions are particularly relevant for certain stakeholder groups, other stakeholders might have relevant input. All questions in public consultations should be open to all stakeholders – also for transparency reasons.

In case an initiative is targeted particularly at national, regional, and local authorities, or has a strong impact in certain areas, some questions can directly target these authorities.

Every questionnaire should contain an **introduction** which explains – in simple terms – the background and context: What is the initiative about? What is the aim of the initiative? What is the aim and scope of this consultation? In addition, consider beginning each section with a brief explanatory paragraph, especially when the questionnaire is addressed to non-experts.

As the Commission does not accept anonymous contributions, all questionnaires need to include a **stakeholder identification section**. This section asks for relevant information about the respondent (e.g. which stakeholder category he or she belongs to; contact details for follow-up questions). As many of these questions are used invariably for all public consultation questionnaires, the Secretariat-General has prepared a template (Better Regulation Portal-BRP Public Consultation) that can be accessed directly in [EU Survey](#).

A questionnaire is usually a **combination of closed questions** (with pre-defined answers from which the respondent must choose) **and open-ended questions** (leaving the possibility to the respondent to formulate his/her own answer). A right balance between closed and open questions should be struck. This depends also on the aim of the respective questionnaire.

Closed questions are easier to answer and analyse. They should be mainly used to gather quantitative data. When used to collect opinions, the questions and range of answers should be carefully reflected upon to avoid bias.

Open questions should mainly be used to gather qualitative data. They offer stakeholders the possibility to explain their views, to add individual information/concerns, and to refer to issues not yet addressed in the questionnaire. Open questions thus help to get a broader and potentially deeper picture, to refine the substantiation of responses. They will improve the qualitative assessment of the contributions. A good compromise could consist of using open

questions when particularly interested in the views of stakeholders on a particular issue and to cap the length of replies (character limit).

Box 3. Closed versus open questions		
	Strengths	Limitations
Closed questions	<ul style="list-style-type: none"> • Suitable to collect quantitative data • Quick to answer & analyse • Data can be reported statistically, and answers to various questions cross-tabulated 	<ul style="list-style-type: none"> • Force respondents to choose pre-set answer options (usually tick/circle answers) → can exclude useful points
Open Questions	<ul style="list-style-type: none"> • Suitable to collect qualitative data • Allow respondents to give the answers they want in the way they want (open space). • Useful for obtaining insights into the reasons behind the responses to closed questions 	<ul style="list-style-type: none"> • Less suitable to collect quantitative data • Difficult to carry out statistical analysis. • Can be time consuming to code and interpret, particularly if there are many responses in numerous languages.

It is usually **recommended to start a questionnaire with simpler, more general questions, aimed at a non-specialist public**. These often take the form of closed questions. They can then be followed up with more detailed or complex questions that often take the form of open questions or tables containing a series of closed questions.

It is recommended to **always offer respondents the possibility to submit separate documents** (position papers, background documents) to accompany the responses to the questionnaire or to add free text to some more complex questions. The EU Survey Better Regulation Portal (BRP) template for public consultations, includes as standard the possibility for respondents to submit additional documents.

It is also recommended to provide **an indication of the estimated time required to fill in the questionnaire**. It may also be useful to measure the actual time it takes to reply to the questionnaire. The longer it takes, the less likely are contributions from non-experts. In that case, try to reduce the number of questions, simplify the questionnaire or reserve one part of the questionnaire for experts.

It is equally recommended to **pilot** draft questionnaires, i.e. 'test' them with selected respondents. For example, asking a few colleagues to reply to the draft questionnaire and to identify problems – either technical or methodological – can help improving the quality and thus usefulness of the questionnaire.

2.1.3. Question design

In addition to focusing on the design of the overall questionnaire, it is important to ensure that its building blocks – the individual questions – are equally well chosen and designed.

Questions and their answer options should be **relevant, non-biased, short, and simple**. Note that short questions and answer options will also make it easier to present the results in tables and figures in the subsequent analysis.

The **language used should be adequate and adapted** to the stakeholders:

- abbreviations should not be used, and jargon should be avoided or, at least, explained
- ambiguous words or questions (e.g. double negatives) should be avoided
- language should be consistent throughout the questionnaire⁷⁷⁵.

Questions need to be designed in a neutral manner, meaning that they should not 'push' respondents to answer in any way. This includes using a balanced answer scale, such as a five-point scale with two positive answer options, two negative answer options and a neutral option.

Answer scales need not only to be balanced, but they also need to reply to the question at hand and need to ensure that respondents can always appropriately answer the question. The latter point is particularly important for mandatory questions as it might otherwise result in a misleading answer. If not all possible answer choices can be envisaged, it is recommended that respondents be given the possibility to select 'other'. In addition, it is also recommended to allow for an 'I do not know' and/or 'Not applicable' option as well as providing respondents the possibility to add further comments or explain their answers in a text box.

2.1.4. *Online questionnaire tools*

While questionnaires can be used for a variety of consultation activities, many are used for public consultations. The Commission has therefore developed a free, open source and easy-to-use tool, [EU Survey](#). The functionalities of this tool are constantly being improved and an up-to-date overview is available [online](#).

EU Survey has been developed with the needs of the Commission in mind (e.g. its interface is available in all official EU languages; it fulfils high standards of data protection; it complies with European accessibility requirements⁷⁷⁶ and standards). Given its technical compatibility with the europa.eu portal, Commission services must use this tool for all public consultations to be published to '[Have Your Say](#)' web portal. A specific template for the public consultations launched by the Commission has been developed to this purpose. The EU Survey team can be [contacted](#) to prevent or solve any technical problems related to the questionnaire.

2.2. **Methodological and practical guidance on generic consultation approaches**

2.2.1. *When to use generic approaches?*

In some situations, relying on questionnaires might not produce the necessary results. More general approaches can – sometimes in combination with a short list of guiding questions – be useful alternatives. Requesting general comments from stakeholders or having

⁷⁷⁵ For example, if several questions relate to 'the period 2016-2018', all questions should use the same formulation. Deviating from this formulation by referring to 'the last four years' would, at best, unnecessarily confuse the respondents and might even have a different meaning, thus resulting in different answers.

⁷⁷⁶ See annex I of Directive 2019/882

stakeholders comment on a policy document such as a green paper or a communication launching a consultation process might help to avoid the bias inherent in questionnaires. They can also be useful for starting a comprehensive debate in a policy area.

2.2.2. *Green papers*

Green papers are documents published by the European Commission to stimulate discussion on given topics at European level. They invite all stakeholders to participate in a consultation process and debate based on the ideas and suggestions they put forward. They are published on the '[Have Your Say](#)' web portal and open for stakeholder input for at least 12 weeks. [Example: Demographic change in Europe: green paper on ageing](#)⁷⁷⁷.

2.2.3. *Commission communications launching a consultation process*

A communication launching a consultation process is a consultation document in the form of a communication adopted by the College. The same rules apply as to green papers. When they are published on the '[Have Your Say](#)' web portal, **these consultative communications should follow the process and rules in place applicable to public consultations.**

Examples of such communications include the [Communication from the Commission to the EP and Council concerning a consultation on fishing opportunities for 2016 under the Common Fisheries Policy](#) or the [Commission Communication to the Council, EP, CoR and EESC launching a public consultation on the EU Urban Agenda](#).

⁷⁷⁷ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12722-Demographic-change-in-Europe-green-paper-on-ageing/public-consultation_en

TOOL #54. ANALYSING DATA AND INFORMING POLICYMAKING

At the end of the consultation process, it is essential to analyse all the input received from stakeholders and the public and present an overview and the conclusions of the consultation work carried out in the context of a policy initiative under preparation, an evaluation, or a fitness check.

Within 8 weeks from the closure of the public consultation, a short **factual summary report** must be published. Section 2.1 of this tool provides further guidance on this.

Furthermore, the outcome of all consultation activities must be presented in a more thorough analysis either in an annex to the impact assessment report, the evaluation report, or the fitness check, or in a self-standing **synopsis report** where none of these is prepared. Section 2.2 of this tool provides further guidance on this.

Consultation activities should also be reported in the explanatory memorandum of Commission proposals and delegated acts, where relevant.

1. ANALYSIS OF CONTRIBUTIONS TO CONSULTATION QUESTIONNAIRES

1.1. Overview⁷⁷⁸

There is no ‘right’ answer to the question how to best analyse data input for questionnaires, which often consists of a mix between ‘open’ and ‘closed’ questions⁷⁷⁹. Rather, there is a wide range of factors to consider in order to ensure that a reasonably robust analysis can be performed within the constraints of available time and resources, and considering that the number of responses may be higher than expected.

An efficient method is to structure the data associated to the replies in a data-analysis exploitable way (e.g. involve transferring the data to a ‘master’ Excel spreadsheet containing responses to both ‘closed’ and ‘open’ text questions). With this in mind, it becomes obvious that a consultation which allows for broad ranging submissions (including position papers in different formats like Word and pdf) requires a structured process of the information received via different sources.

There are primarily two levels of consultation data/results analysis:

- **Basic analysis**, which can be undertaken by those with a reasonably proficient data literacy.
- **Advanced analysis**, which can be undertaken by those with specific skills to use specialised software aimed at assisting with the analysis of data (e.g. campaign detection⁷⁸⁰, entity recognition, computer-aided analysis of open text responses, correlations, cluster analysis etc).

In certain cases, in particular where a large number of contributions have been received, it may be desirable to outsource the analysis and reporting to a professional contractor (polling or market research company).

⁷⁷⁸ For further detail see also Commission study ‘[Consultation Support and Development of Advice](#)’

⁷⁷⁹ See section on ‘Methodological and practical guidance on questionnaires’ of the Tool #53 (*Conducting consultation activities*)

⁷⁸⁰ Commission’s data analytics tool [CODA](#) can be used to identify potential campaigns.

Note that when reporting on the outcome of the consultation, the methodologies and tools should be explained for transparency reasons.

Contributions received represent the views of those that responded. Respondents to public consultations are self-selecting and are not a statistical sample of the EU population⁷⁸¹.

However, in some cases, the respondents may represent a very high percentage of the population of specific stakeholder groups that are directly impacted by the subject of the consultation. For example, potential changes affecting particular industry groups may trigger responses from all the relevant manufacturers.

1.2. Data preparation in view of the analysis

There are three main considerations in the analysis of contributions:

- time and resources for analysis of **closed questions** depend less on the number of responses but more on the complexity of questions and possible replies;
- time and resources for analysis of **open questions** depend significantly on the number of responses and, to a lesser extent, to the diversity of languages in which they were submitted;
- time and resources to complement the analysis of the responses with other information associated to the consultation (e.g. geographical identification, personal information collected, distribution in time of responses).

1.2.1. Data cleansing

The collected data in contributions to the questionnaires may be incomplete, contain duplicates or errors. The need for data cleansing will arise from problems in the way that data is entered and stored.

Data cleansing is the process of preventing, identifying, addressing and, eventually, correcting these errors. Common tasks include record matching, identifying inaccuracy of data, overall quality of existing data, deduplication, and column segmentation. Such data problems can also be identified through a variety of analytical techniques. For example, with financial information, the totals for specific variables may be compared against separately published numbers believed to be reliable. Unusual amounts above or below pre-determined thresholds may also be reviewed. Quantitative data methods for, e.g. outlier detection can be used to identify and possibly get rid of likely incorrectly entered data. Textual data spellcheckers can be used to lessen the number of mistyped words, but it is harder to tell if the words themselves are correct.

The first step of the data analysis is to simply check the admissibility/eligibility of the data/contributions. For example, contributions received before the consultation started should be deleted – as these will most likely be associated with final testing and checking of the questionnaire. Contributions received a few hours after the formal closure time must be subject to a validation screening and could be accepted if there may have been valid reasons for the delay. Contributions received long after the closure of the consultation, should be subject to an assessment by the lead DG on whether they can be considered in the public consultation results (depending on the reasons of the delay), discarded or considered

⁷⁸¹ See also section 1.3 on analysis of data.

separately in the synopsis report. Contributions received outside the dedicated timing or tool (EU Survey) subject to the assessment of the lead DG can still be taken into account and should be reported as such in the synopsis report.

Mischievous (or mistaken) entries can be checked and validated if considered necessary (for example, individuals claiming to represent a national government).

Duplicates are identical entries across all the questions (including, or not, name and location). Such entries may be entered deliberately or accidentally. The first step is to identify duplicates and assess their numerical relevance.

In case Excel is used, the 'remove duplicates' data tool should be used. CODA tool developed by and available to Commission services can also do this 'cleaning'.

A more advanced approach is to use statistical software (for example [STATA](#)) to readily group the duplicates allowing the user to determine quickly whether duplicate entries may be a range of common names or whether it is an obvious deliberate multiple entry.

Box 1. Summary procedure for considering duplicates

- Identify the level of duplicate responses (anything over 1% is probably indicative of duplicates).
- Assess if the duplicates are genuine input (for example related to a campaign promoted by an organisation) and take a business decision on how to handle duplicates (e.g. remove them, consider them as appropriate input).
- Assess the overall impact of duplicates on the outcomes of the consultation (e.g. if the duplicates count for 90% of the responses, removing them will have consequences on the interpretation of the results).
- Remove 'obvious' duplicates.
- Review and possibly remove remaining duplicates.
- If in doubt, leave duplicate entries in place (as their overall impact on the results will be low).

1.2.2. Campaigns

Overview

Where respondents have responded to a public consultation with the same answers this may be a coincidence, or it may be part of a co-ordinated campaign. **Campaigns are very effective to generate interest amongst stakeholders and to highlight key messages for policy makers. At the same time, they present a challenge for those analysing the responses to a public consultation.** It is therefore essential to identify campaigns, analyse them separately and present results adequately.

Presence of campaigns

Once a public consultation is launched, it should be continuously monitored. As such, occasional searches on the internet and social media may reveal the presence of organised

campaigns which are suggesting answers to the questionnaire.

Once the consultation has finished, identifying campaigns through this method will become less effective as the information is changed/removed or simply overtaken by new events.

Identifying campaigns – basic analysis

Where there is a limited number of responses (e.g. 100 or less) to a public consultation, it is possible to 'manually' assess them and check whether these are the **same across all closed questions or the same or almost the same across open questions**. This suggests a campaign – particularly if the respondents represent a particular sub-group of stakeholders (by activity and/or interest and/or location).

As a rule of thumb, the minimum threshold should be 10 or more identical responses (across all the closed questions) to count as a 'campaign'. On the other hand, if there were 10 identical responses from very diverse groups of respondents to a short questionnaire with a total of 10 000 responses, this would rather be a coincidence.

Identifying campaigns – advanced analysis for closed questions

Although common data tools such as Excel can be used to assist with the manual identification of campaigns, it is more efficient to use professional statistical software as offered by the Commission (advanced analytics) or available on the market (e.g. [STATA](#)⁷⁸²). Some tools are quite intuitive and may efficiently serve the campaign detection purposes for services. Professional software is more complex, compared to common data analytical tools as offered, by example, by Excel, and may require someone with training or prior knowledge of the programme in order to use it.

Identifying campaigns – advanced analysis for open questions

While some campaigns suggest a series of responses to closed questions, other campaigns may recommend that their supporters should adopt some standard text in their open text responses. As such, the responses may not be exactly the same, but some key messages will be repeated.

The most efficient way to identify the presence of campaigns in responses to open questions is to use software designed for qualitative data analysis such as the Commission tool 'CODA' or the commercial tool [NVivo](#), but there are also other [similar tools available](#).

Identifying campaigns – advanced analysis for all questions

Although professional software may be used to look for duplicates across all fields, this may not be efficient. For instance, analysis across closed questions may yield a campaign supported by a particular stakeholder. However, the wording used in the supporting comment boxes may vary slightly due to differences in use of capital letters, mistyping, etc. As such, if the search for campaigns would extend across both closed and open questions, many campaign responses may be missed.

⁷⁸² There are various other well-known statistical packages which can provide additional functionality beyond that provided by Excel, including: R, MiniTab, SAS, SPSS, etc.

Segregating campaigns and reporting

It is recommended to look for campaigns in both 'closed' and 'open' questions. Once campaigns have been identified, the associated responses should be segregated and analysed separately from the non-campaign responses.

If campaigns are identified, they should be referred to in the factual summary report as well as in the synopsis report. Reporting on campaigns should include the number of respondents supporting the campaign as well as a summary of their points of view – either in text or tabular form.

1.2.3. Data moderation

Feedback comments and suggestions which contradict the [rules in place for providing suitable content](#) to Commission's consultation must be removed. Feedback or suggestions containing abusive, obscene, vulgar, slanderous, hateful, and xenophobic, off-topic language, unrelated to the proposed legislation, or could be linked to illegal or pirated software etc. are considered unsuitable content and must be removed from the '[Have Your Say](#)' web portal.

In case such feedback or contribution is accompanied by a position paper, DGs could also discard the latter as being related to a contribution not observing the rules for feedback and suggestions. However, it is ultimately at the discretion of the lead DG to assess if the uploaded document is to be taken into consideration.

The lead DG must keep a detailed track of such feedback comments and suggestions as well as of the reasons based on which they were discarded. For transparency reasons, DGs must also mention the number of the responses they discarded in the factual summary report as well as in the synopsis report.

1.3. Analysis of data

1.3.1. Analysis of closed questions

Basic analysis

Basic analysis of closed questions generates information such as: '67% of respondents considered that the legislative framework was delivering benefits.' Such information is not so helpful to policy makers unless qualified by the perspective of the stakeholder, for example: 'Although 74% of industry respondents considered that the legislative framework was delivering benefits, only 32% of citizens agreed with this view.'; or 'Less than 30% of Danish respondents considered that the legislative framework was delivering benefits, while 67% of Estonian respondents agreed with this view.' Even this information is of limited value if there were only 6 respondents from Estonia while there were 240 from Denmark. For an accurate analysis of contributions, the number of respondents should always be mentioned when putting forward the percentages, which used individually could be misleading.

Basic statistical terms include:

- mean: the total of a distribution of values divided by the number of values;
- median: the mid-point in a distribution of values;
- mode: the value that occurs most frequently in a distribution;

- standard deviation: a measure of dispersion around the mean;
- percentages: a rate, number, or amount in each hundred to express any proportion or share in relation to a whole:
 - when to report percentages – when values are high enough for them to mean something. It is generally bad practice to report percentages if the total number of values is lower than 100, as a percentage point bigger than > 1;
 - when reporting changes over time, the difference between percent and percentage points (p.p.):
 - *percent* is used for a measure of changes in values;
 - *percentage point* is used for a measure of change in percentages;
 - e.g.:
 - Last year, in a workforce of 300, 30 people (10%) were smokers.
 - This year, in the same workforce of 300, 15 people (5%) are smokers.
 - The number of smokers has fallen by 50% or the percentage of smokers has fallen by 5 percentage points;
 - It is **good practice to calculate and report percentages and valid percentages** (percentages of those who answered the question) so that readers can see response rate on questions.
 - **Avoid using only percentages in the presentation of results**, make always the link with the amount of responses they correspond to.
 - Example: Q: Do you receive a disability benefit of any kind? Yes: 83
No : 256; => out of a total of 460 who returned a questionnaire (=N)

(N=460)	N	%	Valid
Yes	83	18.04	24.50
No	256	55.65	75.50
Not answered	121	26.31	-

More advanced analysis

Respondents to a **public consultation** are self-selected, which means that **the responses are not drawn from a representative sample**. While it is accepted that advanced statistical analysis has an important role for some types of analysis, such statistics provide limited added value to results from a self-selecting (i.e. non-randomly selected) sample and can potentially be misleading. In other words, statistics provide little additional information (of use to the policy maker) beyond that obtained by the analysis presented here.

However, this should not suggest that further analysis beyond the 'basic' analysis cannot be undertaken.

Interpretation of data – weighting and representativeness of respondents and replies

There is a fundamental difference between a survey, such as Eurobarometer⁷⁸³, and public consultation (see the previous paragraph).

Data gathered through public consultation does not provide a representative view of the EU population.

Weighting of data is a statistical technique of making answers count for more or less to ensure they are representative of the population. You can only use this technique if you have a good understanding of the demographic make-up of the population and returns.

It is generally very difficult to get this understanding and therefore **it is not recommended** to apply weighting techniques **for the analysis of data from public consultations**. If you need to have representative views, other tools, such as Eurobarometer, should be considered.

Note that when reporting back on the outcome of the consultation the methodologies and tools should be explained for transparency reasons, including if weighting techniques have been applied.

Box 2. Interpretation of data – key aspects

Consultations aim to gather evidence, which is used as input for policy preparation and contributes to informed decision-making. It is therefore **essential to provide the right context of the consultation when presenting the outcome**, including information on who participated and whom respondents represent:

- when analysing⁷⁸⁴ and presenting the results, **distinction should be made between the different stakeholder categories** that contributed to the consultation. A short description should be provided about the different stakeholders (background, whom they represent, etc.);
- do, preferably, the ‘**stakeholder credibility test**’ and consider its outcome in the analysis:
 - *longevity*: Has the stakeholder organisation been established long enough to acquire the wisdom in the policy field?
 - *expertise*: How well does it know the subject matter?
 - *representativeness*: Who exactly does it represent and how well does it do so?
 - *track record*: How useful/credible has its contribution been in the past?
 - *reputation*: How seriously do other people take this organisation?
- contributions from **citizens** should be analysed as a separate stakeholder category;
- **campaigns should be identified** and the relevant responses should be segregated, analysed and presented separately from the non-campaign responses (see para 1.2.2);
- **avoid using only percentages** when presenting results; they should be linked to the corresponding amount of responses (see para 1.3.1).

⁷⁸³ <http://ec.europa.eu/COMMFrontOffice/publicopinion/index.cfm>

⁷⁸⁴ See also ‘better regulation’ guidelines, chapter II

1.3.2. Analysis of open questions

Overview

Textual input to open questions is considered as qualitative data, which is, compared to quantitative data, richer and more complex and therefore it cannot be treated statistically. However, this does not mean that systematic and rigorous analysis techniques cannot be applied. Qualitative data, more than quantitative, is extremely prone to bias, and systematic analysis helps prevent this. Under the approach to basic analysis, responses would most commonly be grouped into broad stakeholder groups (typically citizens/NGOs, international, national, local and/or regional authorities, industry, others). Under the simplest approach, responses from a particular group for a particular question could then be quickly read to get an overview of the two or three most recurrent points being made.

2. INFORMING POLICYMAKING

2.1. Factual summary report

For each consultation activity, it is good practice to publish factual information on the input received from stakeholders to ensure transparency. Apart from the publication of consultation documents and any written contribution, this also includes a factual summary report on the issues raised.

Following the closure of a public consultation published on the '[Have Your Say](#)' web portal, it is mandatory to publish a factual summary report within 8 weeks⁷⁸⁵. The factual summary report should not go beyond 5 DGT pages. It is published on the '[Have Your Say](#)' web portal.

The factual summary report should not be confused with the synopsis report, to be drafted at the end of *all* consultation activities (see section 2.2 below).

The purpose of factual summary report on the stakeholders' input is to give a first, succinct overview on 'what has been said'. It should be neutral, as it precedes the in-depth analysis and interpretation of consultation results. As these factual summaries may contain views and positions from stakeholders not necessarily shared by the Commission or may refer to issues on which a decision has not yet been taken, an appropriate disclaimer⁷⁸⁶ should be added. Basic statistics on the number of the participants to the consultation activities, their country of origin, their stakeholder type and other relevant basic figures should be provided. The Commission services can draw the necessary statistical information from the '[Have Your Say](#)' internal interface. When referring to percentages in the presentation of results, the link with the number of responses they correspond to, out of the total of the replies, should always be made (i.e. 75% of the respondents – 150 out of 200).

⁷⁸⁵ The 8-week timeframe is indicative for public consultations with a large number of responses.

⁷⁸⁶ Disclaimer: "This document should be regarded solely as a summary of the contributions made by stakeholders [add consultation activity] on the [add title of policy initiative or evaluation or fitness check]. It cannot in any circumstances be regarded as the official position of the Commission or its services. Responses to the consultation activities cannot be considered as a representative sample of the views of the EU population."

The factual summary following a public consultation should contain the following main elements:

Box 3. Factual summary report (max. 5 pages)	
Give a concise and balanced overview of contributions received during a specific consultation activity	
Give factual information on input received	<ul style="list-style-type: none"> • Who contributed? • Whom are they representing? Reference should be made to EU decentralised agencies and other bodies (EU agencies), to the national Parliaments as well as to national, local and regional authorities (national, regional or local) having contributed, if any, and to the issues they put forward. • What aspects are addressed? • What are their views and concerns? • Which communication channels were used for contributions?
Stay neutral	<ul style="list-style-type: none"> • Document the input as received • Avoid qualifying it, taking position or giving feedback
Aggregate at an appropriate level	<ul style="list-style-type: none"> • Cluster information
Inform on the process	<ul style="list-style-type: none"> • Inform on what was done so far in terms of consultation activities and on the next steps
Inform on results/data processing and security	<ul style="list-style-type: none"> • Systematically check whether the contributions submitted are unique and not artificially created and report on such checks • Information on the number of discarded responses, if any, for not observing the rules for feedback and suggestions⁷⁸⁷ • Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses)
Add disclaimer	<ul style="list-style-type: none"> • Emphasise that the contributions received cannot be regarded as the official position of the Commission and its services and thus does not bind the Commission. Contributions to public consultations cannot be considered as a

⁷⁸⁷ <https://ec.europa.eu/info/law/better-regulation/rules-feedback-and-suggestions>

	representative sample of the views of the EU population.
Publish on ' Have Your Say '	<ul style="list-style-type: none"> • The factual summary should be published on the 'Have Your Say' web portal, within 8 weeks after the closure of the public consultation. • The factual summary report should not exceed 5 DGT pages.

2.2. Synopsis report

The synopsis report covers *all* consultation activities (the 'call for evidence', the public and targeted consultations, conferences, workshops or focus groups, etc.), ad hoc contributions directly linked to the preparation of the policy, evaluation or fitness check and information on the input received through the 'call for evidence'⁷⁸⁸.

The synopsis report is usually annexed to the impact assessment report, evaluation report, fitness check, or can be self-standing. It is published in English on the '[Have Your Say](#)' web portal once the proposal is adopted by the College or the evaluation / fitness check is finalised.

It summarises the results of all consultation activities in relation to a particular initiative and gives both a qualitative and a quantitative analytical overview of these results. Its aim is twofold:

- to inform policymaking on the outcome of all consultation activities (public, targeted, exploratory consultations, workshops, focus groups, interviews etc.), while differentiating the views of the different categories of stakeholders.
- to inform stakeholders on how their input has been considered and to explain why certain suggestions could not be taken up.

The synopsis report should be prepared as soon as possible after the last consultation activity has taken place and be discussed and endorsed by the interservice coordination group (ISCG) or if an ISCG is not established, with the Secretariat-General. The report⁷⁸⁹ accompanies the initiative through interservice consultation up until adoption and is published on the consultation webpage of the initiative once this has been adopted by the College or the evaluation / fitness check has been finalised.

2.2.1. Content of the synopsis report

Whether in a self-standing report or integrated into the impact assessment, evaluation, or fitness check, the synopsis must comprise the following general elements:

- a key outline of the consultation strategy, referring to the consultation objectives as defined therein, identified stakeholders and selected consultation methods and tools;

⁷⁸⁸ See Tool #51 (*Consulting stakeholders*)

⁷⁸⁹ See paragraph 2.2.2 'Format of the synopsis report'

- documentation of each consultation activity;
- information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached;
- reference to quantitative data on the number of the participants to the consultation activities, their country of origin, their stakeholder type, the potential number of moderated contributions (not in accordance with the feedback rules⁷⁹⁰), should also be made, using some visual aids like tables and graphs;
- when referring to percentages in the presentation of results, a link with the number of responses they correspond to, out of the total of the replies, should always be made (e.g. 75% of the respondents (150 out of 200));
- short description of the methodology and tools used to process the data;
- description of the results of each consultation activity, including qualitative and interpretative analysis; if different consultation activities have been undertaken in the context of the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions in relation to contributions and main stakeholder categories;
- information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses). The information should include the share of contributions and their viewpoint in a separate paragraph. Commission services should systematically check whether the contributions submitted are unique and not artificially created and report on such checks;
- for ad hoc contributions received outside the formal consultation context, a separate paragraph should be added describing the origin of the contributions received including identification of the type of stakeholder and their represented interests;
- a paragraph summarising the feedback⁷⁹¹ received on the 'call for evidence' document describing the initiative should be included;
- explanation on how the input gathered in the context of the consultation work, including feedback received on the 'call for evidence' document has been considered in the further work on the initiative, evaluation, or fitness check. Where relevant, this should include explanation on why certain widely supported views were not or not entirely considered. Information on the number of discarded feedback comments/responses to the 'call for evidence', if any, in line with the rules for feedback and suggestions⁷⁹²;
- if EU decentralised agencies and other bodies (EU agencies) have contributed, it is mandatory to inform in a separate section which EU agencies or bodies contributed and what are the main issues they addressed. Particular reference should be made to whether the points raised by these EU agencies and bodies were taken on board; alternatively, the synopsis should explain why these views could not be integrated in the initiative;

⁷⁹⁰ <https://ec.europa.eu/info/law/better-regulation/rules-feedback-and-suggestions>

⁷⁹¹ See Tool #51 (Consulting stakeholders)

⁷⁹² <https://ec.europa.eu/info/law/better-regulation/rules-feedback-and-suggestions>

- If national Parliaments, local and regional authorities have contributed, it is also mandatory to inform in a separate section which national Parliaments and authorities contributed (Member State, chamber, level of local and regional authorities, agencies) and what are the main issues they addressed. Particular reference should be made to whether the points raised by the national Parliaments and the local and regional authorities were taken on board; alternatively, the synopsis should explain why these views could not be integrated in the initiative.

The presentation of the stakeholder views in all consultation activities (whether public and/or targeted) should be clear, complete, neutral, unbiased, and balanced across all groups. For public consultation, it should be reminded that views are not statistically representative.

2.2.2. *Format of the synopsis report*

The synopsis report should take the **form of a staff working document (SWD)**.

In case the report refers to an initiative accompanied by an impact assessment, an evaluation or fitness check, the report should be part of the annex of the impact assessment or evaluation report. Note that the synopsis report as part of the annex of an impact assessment or evaluation report should contain the elements set out in the former paragraph. The main part of the impact assessment or evaluation report should make extensive reference to the conclusions of the synopsis where relevant. In other cases, the synopsis report should be published as a linked SWD or integrated in a SWD (other than an impact assessment or evaluation report) accompanying the initiative.

The synopsis report should not exceed ten to fifteen pages.

Box 4. Synopsis report (max. 10-15 pages)

Give a qualitative and quantitative analytical overview of the results of *all* consultation activities: 'call for evidence', public consultation, targeted consultations and other consultation activities.

Give brief and concise information on input received

- Who contributed?
- Whom are they representing? Reference should be made to the EU decentralised agencies and other bodies (EU agencies) as well as to national Parliaments and to national, local and regional authorities (national, regional or local) having contributed, if any, and to the issues they put forward.
- What aspects are addressed?
- What are their views and concerns?
- Which communication channels were used for contributions?

<p>Discuss the results</p>	<ul style="list-style-type: none"> • Give an in-depth analysis and interpretation of the results of all consultation results (public, targeted, exploratory consultations, workshops, focus groups, interviews, 'call for evidence', feedback, etc.).
<p>Aggregate at an appropriate level</p>	<ul style="list-style-type: none"> • Cluster information.
<p>Inform on the process</p>	<ul style="list-style-type: none"> • Inform on what was done in terms of consultation activities (public, targeted, exploratory consultations, workshops, focus groups, interviews, 'call for evidence', feedback, etc.).
<p>Inform on data processing and security</p>	<ul style="list-style-type: none"> • Systematically check whether the contributions submitted are unique and not artificially created and report on such checks. • Information on the number of discarded responses, if any, for not observing the rules for feedback and suggestions⁷⁹³. • Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses).
<p>Add disclaimer</p>	<ul style="list-style-type: none"> • Emphasise that the contributions received in the context of the public consultation published on the 'Have Your Say' web portal cannot be regarded as the official position of the Commission and its services and thus does not bind the Commission nor that the contributions can be considered as a representative sample of the EU population.
<p>Publish on 'Have Your Say' web portal</p>	<ul style="list-style-type: none"> • The synopsis report should not exceed 10 to 15 pages. • It should be endorsed by the ISCG (where applicable) and published on the 'Have Your Say', once the initiative is adopted by the College or once the evaluation / fitness check is finalised. It can be published as an annex to the impact assessment or to the evaluation report. If self-standing, the synopsis report takes the form of a staff working document. • The synopsis report is published only in English.

⁷⁹³ <https://ec.europa.eu/info/law/better-regulation/rules-feedback-and-suggestions>

3. EXPLANATORY MEMORANDUM

For legislative proposals, the explanatory memorandum should explain how far the main contributions have been considered in the draft policy initiative, or why they could not (all) be taken into account.

- Explain the overall consultation strategy and add reference to the factual summary and synopsis report (if relevant).
- Highlight the link between respondents'/participants' input and the impact assessment or any other element that justifies and explains the options proposed by the Commission.
- Report why certain options were discarded (in particular when those were widely supported by respondents) and be transparent about minority and dissenting views.

TOOL #55. HORIZONTAL MATTERS – PUBLICATION OF RESPONSES, DATA PROTECTION, ACCESS TO DOCUMENTS AND TRANSPARENCY REGISTER

1. INTRODUCTION

Several cross-cutting elements are fundamental to consulting with stakeholders in a careful and transparent manner. These horizontal matters, including the publication of responses, data protection, access to documents and transparency register, are described in further detail below.

2. PUBLICATION OF RESPONSES

The Commission is committed to being open and transparent throughout the policy cycle, including in the way it consults with its stakeholders. Therefore, stakeholders' input⁷⁹⁴ submitted in the context of the various consultation and feedback mechanisms must be published on the relevant webpage of the '[Have Your Say](#)' web portal⁷⁹⁵.

Respondents are informed in the [privacy statement](#) published on the '[Have Your Say](#)' web portal that:

- Responses to and contributions received for a consultation and/or feedback mechanism will be published on the internet. For transparency, the type of respondent, country of origin, organisation name and size, and its transparency register number, are also always published. The publication of further information depends on the respondent's privacy choice;
- Documents submitted in the context of a consultation or feedback mechanism, such as position papers or background documents, will be published as received. If a respondent chooses anonymous publication, they should not include personal data within their response to a public consultation or contribution to a feedback mechanism, including within documents that they may submit, as they will be published as received;
- Regardless of whether a respondent chooses to have their personal data published or not, to avoid misuse they are required to identify themselves and, if applicable the organisation on whose behalf they are responding. Anonymous contributions to consultations and feedback mechanisms are not accepted. However, it is at the discretion of a DG whether a contribution made by dubious respondents, is accepted or not.

In the framework of a 'call for evidence', feedback is published immediately on the webpage of the initiative on the '[Have Your Say](#)' web portal⁷⁹⁶.

As long as the feedback period is open, a respondent may delete their feedback by logging in to the feedback mechanism on the '[Have Your Say](#)' portal. Once the feedback period is closed, it is not possible to remove contributions. However, a respondent may choose to have their personal details removed and their published contribution made anonymous by logging

⁷⁹⁴ Contributions include responses to questionnaires, position papers, background material, etc.

⁷⁹⁵ See Tool #52 (*Consultation strategy*).

⁷⁹⁶ See Tool #54 (*Analysing data and informing policymaking*), section 1.2.1 on Data cleansing and section 1.2.4 on Data moderation

in to the feedback mechanism on the '[Have Your Say](#)' portal and amending their selected privacy settings. By selecting to remain anonymous, it means that the respondent withdraws their consent to the publication of their personal data as indicated in the privacy option that they originally selected. The withdrawal of the respondent's consent does not affect the lawfulness of the processing carried out before they withdrew their consent.

Contributions to the public consultation are published collectively and only after the consultation has closed. They are published on the webpage of the initiative within the '[Have Your Say](#)' web portal. While a public consultation is still open a respondent may contact the 'operational controller'⁷⁹⁷ to request the deletion of their contribution.

Contributions to a public consultation are published by the pertinent DG through the internal tool known as '[the BRP backend](#)'.

3. DATA PROTECTION

The internal data protection [Regulation \(EU\) 2018/1725](#) governs the protection of personal data collected when the Commission gathers feedback on its initiatives or launches a public consultation. Personal data can only be gathered under strict conditions and for a legitimate purpose. People or organisations, including EU institutions, which collect and process personal data must protect them from misuse, ensure the security of processing, and must respect certain rights of the data subjects, guaranteed by EU law.

3.1. Harmonised approach to data protection

To limit the administrative burden of Commission services having to provide individual records of processing and/or privacy notice for each feedback opportunity and consultation, the Data Protection Officer of the Commission agreed with a harmonised approach for the following stakeholder engagement tools:

- feedback opportunities on 'call for evidence' documents, delegated and implementing acts, and legislative proposals on the '[Have Your Say](#)' web portal;
- public consultations launched using EU Survey on the '[Have Your Say](#)' web portal.

A corporate centralised data protection record and privacy statement for all public consultations and feedback mechanisms, which is published on the '[Have Your Say](#)' web portal, were approved by the [Commission Data Protection officer \(DPO\)](#) in August 2020. The corporate privacy statement is published on the '[Have Your Say](#)' web portal. The related data protection record is published in the Register of the Data Protection Officer (DPO). Therefore, DGs do not need to draft a specific privacy statement for a public consultation published on the '[Have Your Say](#)' web portal as long as their processing observes the provisions of the record of processing and privacy statement and the questionnaire of the consultation provides, in a clear and transparent manner, the contact of the organisational entity responsible for the specific consultation or feedback mechanism.

The unit responsible for 'evaluation and impact assessment' in the Commission's Secretariat-General, as well as the Directorate-General / unit launching the feedback mechanism or public consultation are considered respectively as '*horizontal controller*' and '*operational*

⁷⁹⁷ See 3a below for further details

controller' on behalf of the European Commission in the [data protection record for feedback mechanisms and public consultations](#). Operational controllers are responsible and accountable for the processing of personal data conducted.

Operational (or de facto) controller

The DG/unit launching a feedback mechanism or public consultation, acting as 'operational (or de facto) controller', is responsible for:

- ensuring that their public consultation respects the rules and conditions set out in the record of processing and of Regulation 2018/1725;
- ensuring that their entity and e-mail contact are visible on the consultation webpage on '[Have Your Say](#)'. This allows respondents to contact the unit directly in case of queries or data subject requests.
- handling requests from data subjects (inform the 'horizontal controller');
- managing personal data breaches, including mitigating measures, risk assessment, documentation of breach, and, if necessary, EDPS notification and communication with data subjects (inform the 'horizontal controller' of the incident and consult the 'horizontal controller' on the risk assessment).

The 'operational controller' may decide to involve an external company to manage the feedback mechanism and/or public consultation as well as treat and analyse the contributions received. In case that external company conducts any processing of personal data for the purpose of public consultation or other feedback mechanism it is a 'processor' pursuant to Article 3(12) of Regulation 2018/1725. Therefore, it is the responsibility of the DG/unit launching the feedback mechanism or public consultation to ensure compliance with Article 29 of Regulation 2018/1725, including to ensure that appropriate data protection clauses are in place.

Horizontal controller

The unit responsible for 'evaluation and impact assessment' in the Commission's Secretariat-General, acting on behalf of the Secretariat-General as 'horizontal controller' is responsible to:

- provide a data protection record of processing operations on personal data and a corporate privacy statement;
- provide corporate oversight of data protection. The 'horizontal controller' needs to be consulted on risk assessments and informed of data subject requests. The 'horizontal controller' can ask the 'operational controller' to seek the opinion of the DPO;
- manage the 'SG consultation data controller' functional mailbox and forward any incoming data subject requests to the operational controller concerned;
- provide data protection training and guidance to the 'better regulation' network.

Further information and guidance concerning the role and responsibilities of the unit launching a feedback mechanism or public consultation are included in [GoPro](#).

Targeted consultations

Targeted consultation activities – including surveys, interviews and focus groups – seek the views of (well-defined) stakeholders and individuals concerned by the specific consultation subject. For targeted consultations and/or exploratory consultations – not linked to any initiative or evaluation – a data processing 'record' must be drafted by each unit/DG, according to their requirements.

The responsibility for the processing of personal data collected in the context of a targeted consultation remains exclusively with the unit that conducts the targeted consultation. This unit oversees the targeted consultation; the SG has no corporate role under this processing operation. The unit carrying out the targeted consultation acts on behalf of their Directorate-General or service that is ultimately responsible and accountable for the processing of personal data conducted (the so-called 'delegated controller' as defined in the Commission's [data protection implementing rules](#)).

The unit carrying out the targeted consultation:

- assumes all obligations of a data controller of Regulation 2018/1725 (with the exception of record keeping) (on behalf of their Directorate-General or service);
- conducts a risk assessment before starting the collection of personal data (go ahead if no high risks for the data subjects are identified or conduct a DPIA if necessary) and [documents the risk assessment](#);
- ensures that special categories of personal data can only be processed (Art. 10(1)) if one of the conditions of Art. 10(2) is met; (see point b below);
- drafts a specific privacy statement and informs data subjects thereof at the outset of the processing of their data;
- is responsible for lawfully using and recording consent as a legal basis / condition for engaging a processor (Art. 29), for handling requests from data subjects, for managing personal data breaches, liaising with the DPO, etc.

A targeted consultation privacy statement template has been approved by the DPO and is available from the DG data protection coordinator and on GoPro.

3.2. Special categories of personal data

The corporate privacy statement published on '[Have Your Say](#)' does not cover 'special categories of personal data'. These categories are:

- racial or ethnic origin;
- political opinions;
- religious or philosophical beliefs;
- trade union membership;
- genetic data;
- biometric data for the purpose of uniquely identifying a natural person;
- data concerning health or data concerning a natural person's sex life or sexual orientation.

If a public consultation questionnaire includes questions on these special categories and the responses to these questions will refer to (the life of) an identified (for example, the respondent) or identifiable individual, the questions must not be included in the

questionnaire. Instead, neutral questions whose answers will not lead to the identification of an individual, or a targeted consultation based on a specific risk assessment should be used.

Contact your DG data protection coordinator if you plan to ask questions related to special categories of personal data.

3.3. Data retention and archiving

Personal data, received in the context of a public consultation and/or feedback mechanism, is kept only for the time necessary to fulfil the purpose of collection or further processing of the information, namely 5 years after the closure of the administrative file to which the consultation or feedback mechanism relates. A file is closed at the latest once there has been a final outcome in relation to the initiative to which the consultation or feedback mechanism contributed.

In accordance with the common Commission-level retention list, after the administrative retention period mentioned above, files (and the personal data contained in them) will be transferred to the Historical Archives of the Commission for historical and archiving purposes⁷⁹⁸.

The common Commission-level retention list is a regulatory document in the form of a retention schedule that establishes the retention periods and transfers to the Historical Archives for different types of Commission files. That list was notified to the European Data Protection Supervisor.

For further information on data retention see GoPro.

4. ACCESS TO PERSONAL DATA

Respondents to a public consultation or feedback mechanism have the right to request access to or edit the personal data they submitted by emailing the [functional mailbox](#) managed by unit SG.A.2. Respondents can equally contact the unit responsible for the public consultation or feedback mechanism who shall liaise with the horizontal controller, if necessary, for the handling of the request.

5. ACCESS TO DOCUMENTS

Contributions, including personal data provided, may be subject to a request for access to documents under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents ('[Regulation 1049/2001](#)'). Regulation 1049/2001 provides any EU citizen and any natural or legal person residing or having its registered office in a Member State the right of access to documents of the EU institutions, subject to principles, conditions and limits defined in the Regulation. If access is requested, the request is subject to a case-by-case analysis based on Regulation 1049/2001 in order to assess the applicability of the exceptions defined in its Article 4, considering the legitimate interests and the justifications of non-disclosure in case provided by the author of the contribution. Where disclosure of the contribution, or parts thereof, would undermine the

⁷⁹⁸ For further information regarding the processing operation concerning the Historical Archives, please see record of processing 'Management and long-term preservation of the European Commission's Archives', registered under reference number [DPR-EC-00837](#).

protection of commercial interests of a natural or legal person, the institutions shall refuse access in accordance with Article 4(2), first indent of Regulation 1049/2001.

6. TRANSPARENCY REGISTER

Organisations and self-employed consultants⁷⁹⁹ that wish to participate in consultation activities are asked to provide the Commission and the public at large with information about which interests they represent when seeking to influence EU legislation and policy-making (representativeness is not a factor for all interlocutors, e.g. consultancies, companies, academic institutions), by joining the [Transparency Register](#). Contributions from interlocutors that choose not to register will be treated as a separate category 'non-registered organisations' unless they are recognised as representative stakeholders via relevant Treaty provisions⁸⁰⁰.

Publishing a public consultation on the '[Have Your Say](#)' web portal or a 'call for evidence' document on the [dedicated webpage](#) will trigger an e-mail alert to registered organisations.

7. ACCESSIBILITY OF CONSULTATIONS AND THE LANGUAGE REGIME

Consultations should be planned and conducted in such a way that all stakeholder groups can participate easily and effectively. A key aspect for accessibility relates to the language regime of consultation activities. **It is essential to ensure adequate language coverage of the consultation activity.** The table below provides information on linguistic accessibility, accessibility of activities and consultation channels, and timing and consultation periods.

Box 1. Accessibility of consultations	
1. Linguistic accessibility	
Language regime	<ul style="list-style-type: none"> • In general, ensure that consultation documents are translated into as many languages as feasible and appropriate in accordance with the scope and outreach of a consultation. While highly technical consultations could be conducted in English or a few languages only, consultations reaching out to non-expert stakeholders or citizens in general should be translated into all EU languages. Equally, ensure that consultation events are interpreted, whenever necessary. • The 'call for evidence' document is published in all EU languages. • The language regime for consultation activities should be explained and justified in the 'call for evidence', to be endorsed by the interservice coordination group (ISCG) or Secretariat-General (SG) and interested DGs in case no ISCG is established. The language regime should be referred to in the consultation section of the 'call for evidence'. Whenever the lead DG deems the topic of the initiative might raise a high public interest, the questionnaire of the consultation should be translated into all EU official languages. • Consultation documents related to public consultations for

⁷⁹⁹ For the purposes of the Transparency Register 'businesses' are organisations broadly speaking, whereas self-employed individuals are mentioned separately.

⁸⁰⁰ For example, European Social Dialogue, Art. 154-155 TFEU

	<p>initiatives included in the Commission Work Programme – Annex I need to be translated into all official EU languages⁸⁰¹. The consultation web page on the 'Have Your Say' web portal is translated into all official EU languages.</p> <ul style="list-style-type: none"> • The questionnaires and any accompanying documents of all other public consultations need to be made available in at least English, French, and German. Whenever the lead DG deems the topic of the initiative might raise a high public interest, the questionnaire of the consultation should be made available in all EU languages. • Exceptions to language requirements, to be duly justified, should be requested to the Secretariat-General⁸⁰². • All language versions of the consultation documents should be available at the launch of the consultation. If that is <u>exceptionally</u> not possible, stakeholders should be informed when the missing translations will be made available. • The Secretariat-General can help in identifying the appropriate language coverage. The Commission translation service (DGT) can advise on timelines for translation of consultation documents. Please contact DGT as early as possible when planning a consultation so that length of documents, timing and available translation resources can be properly assessed and taken into account⁸⁰³. • Stakeholders should be informed that they can always reply to a consultation in any official EU language regardless of the translation of the consultation documents.
<p>Stakeholder-friendly language</p>	<ul style="list-style-type: none"> • Communicate in a manner that is easily understood by diverse audiences including persons of limited linguistic proficiency. • Ensure that consultation documents ('call for evidence', questionnaire, background documents) are explicit, clear, and understandable. It is recommended to have them proof-read by non-experts. • Avoid bureaucratic or too technical language. Abbreviations should be avoided too. Necessary specialist terms should be explained. • Make use of plain language guidance when drafting consultation documents. The Commission has issued a guide called 'How to write clearly',⁸⁰⁴ available in all official EU languages, and also offers trainings on clear writing. The European Court of Auditors' list of 'Misused English words and Expressions in EU publications' can also

⁸⁰¹ Until the capacity to translate into Irish has been fully built up, translation of public consultations into Irish should be assessed on a case-by-case basis.

⁸⁰² In accordance with the procedure for exceptions set out in Tool #1 (*Principles, procedures & exceptions*)

⁸⁰³ DGT can provide translations of consultation documents of up to 10 pages into all requested EU official languages. Details and information about other services offered by DGT in the context of translations of consultations is provided in the internal note Ares (2013)2752242. More info is available on [GoPro](#).

⁸⁰⁴ DGT-EDIT can help to transform technical language to plain and accessible language.

	<p>help improve clarity.</p> <ul style="list-style-type: none"> • Involve your DG's communication units in the questionnaire creation design process to ensure readability and accessibility. • Consider modular structure, opened for contributors with different level of expertise.
<p>Participation of persons with disabilities</p>	<ul style="list-style-type: none"> • Ensure that persons with disabilities can participate in 'calls for evidence' on an equal basis with others and in line with the UN Convention on the Rights of Persons with Disabilities and the European Disability Strategy 2010-2020. • Use a variety of communication means and accessible formats. The Commission has, for example, already used a sign-language video for a consultation and made simplified, easy-to-read questionnaires available. • Ensure that the consultation page complies with the international Web content accessibility guidelines (WCAG) (version 2.0), level AA. This means that texts, images, forms, sounds, etc. should be accessible and understandable by as many people as possible without discrimination. • As of May 2016, the EU Survey tool allows respondents to switch to a WCAG-compliant view. It is not anymore necessary to manually activate this option when designing the questionnaire. Contact the EU Survey team should there be any problems with the tool. • Keep the language of the 'calls for evidence' as simple as possible, using simple question types like free text, single/multiple-choice, and matrixes. Try to avoid tables and file uploads. For questionnaires, try to avoid 'visual' elements and try not to use formulations like 'in the question below' or 'in the next section'. Refer to the name of the section or question instead. When adding images to your questionnaire make sure to provide a meaningful descriptive text.
<p>2. Ensuring participation to consultation activities</p>	
<p>Selection of activities and communication channels</p>	<ul style="list-style-type: none"> • Include a comprehensive communication plan that will raise awareness about your consultation activities in a timely way and will encourage all identified stakeholders to participate. Involve your DG's communication units in the development of this plan. • Ensure that relevant target groups are reached and invited to participate in the most effective way. Usually, a combination of different communication channels (e.g. press release, networks, multipliers, events, social media, Commission delegations and representations in Member States) works best. Public consultations should also be included in the planning calendar well in advance. • Target groups in remote and rural areas with more difficult access to internet may need to be addressed by other consultation tools and communication channels than target groups in more densely

	<p>populated areas with higher access rates to internet. EC Representations and Europe Direct centres could be engaged in identifying appropriate tools and channels. The Committee of the Regions and the Economic and Social Committee channels can be mobilised to reach out.</p>
<p>3. Timing and consultation period</p>	
<p>Timely consultation</p>	<ul style="list-style-type: none"> • Identify the stages of policy preparation where stakeholder input will be needed and define the appropriate moment for each consultation activity as well as their sequence accordingly. • Spread information early and widely.
<p>Timeframe for contributions</p>	<ul style="list-style-type: none"> • Allow sufficient time for replying to consultations to increase participation. • The consultation period should strike a reasonable balance between the need for adequate input and the need for swift decision-making. • The minimum period for replies to the 'call for evidence' without an associated public consultation is 4 weeks. In case the 'call for evidence' is accompanied by a public consultation, the period for replies is 12 weeks. It is strongly recommended to prolong this period by 2 weeks if it overlaps with holiday periods. • For meetings, hearings, conferences or other consultation events, relevant documents should be disseminated 20-working-days ahead of the meeting⁸⁰⁵.

⁸⁰⁵ See the [2002 General principles and minimum standards for consultation of interested parties by the Commission](#).

Chapter 8 – Methodologies for analysing impacts in impact assessments, evaluations, and fitness checks

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Chapter 8 presents a **non-exhaustive list of relevant methodologies for policy analysis** in impact assessments and evaluations⁸⁰⁶. According to the 'better regulation' guidelines, significant impacts should be assessed quantitatively if possible as well as qualitatively. The analytical methods in Chapter 8 cover a wide spectrum of approaches and contribute to ensure effectiveness, consistency, and transparency of the policy process.

Every **impact assessment** aims to provide answers to two fundamental questions (see questions 5 and 6 in the 'better regulation' guidelines Chapter IV), namely:

- What are the impacts of the different policy options and who will be affected?
- How do the options compare?

Correspondingly, **evaluations and fitness checks** (see question 3 in the 'better regulation' guidelines Chapter III) aim to reply to:

- To what extent was the intervention successful?

The methods comprise both forward-looking and backward-looking approaches, although several tools are relevant for both. Furthermore, ensuring coherence across the policy cycle implies considering the links that connect the various phases. If the intervention logic and the planning of data are well done in the ex-ante phase, the later evaluation will be easier to conduct. Conversely, a good evaluation can and should feed into an impact assessment.

The choice of which impacts to analyse and methods to use should be guided by the principle of proportionate analysis (see Tool #12 (*How to apply proportionality to impact assessments*)). This means that the scope and depth of the analysis should be proportionate and consistent with the importance and type of initiative as well as with the nature and magnitude of the expected impacts. The effort invested in data collection, the depth of analysis, the extent of quantification and thereby choice of analytical method(s) should correspond to the likely magnitude of impacts.

A preliminary screening of potential impacts across the social, economic, and environmental dimensions should identify those that are likely to be most significant or critical for political decision-making for each specific initiative.

Guiding questions outlining the criteria for choosing the most appropriate analytical approach

1. **What are the most significant effects and impacts? Which method can be applied?**
Not every method is equally suited to analyse the specific effects or impacts of a measure. Often a single measure needs various (inter-linked) methods (e.g. to analyse economic, social and environmental impacts)
2. **Which type of problem structuring is required?**
Which are the steps to implement the method for a real-world measure?
3. **What is the time horizon of the expected effects of the intervention?**
The method should cover the full time horizon with significant effects.

⁸⁰⁶ See Tool #51 for an overview of methods to consult stakeholders, both in open and targeted manner – such as interviews, focus groups, seminars, Eurobarometer surveys and others.

4. **What kind of data/information (quantitative, qualitative ...) are required to analyse the problem?**
Is the required data available and accessible? How sensitive is the method for (partially) missing data?
5. **How big is the amount of information/data required by the method? Which technical tools (software, databases etc.) are necessary to apply the method?**
Are the necessary technical tools, knowledge, and hardware available to handle the required amount of data? If not, can they be acquired?
6. **What kind of knowledge/expertise is required on the part of the analyst?**
Is the required knowledge/expertise available and if not, can it be acquired?
7. **How many resources does the method need?**
Is the investment in a method proportional to the size of the problem? Can the results or methods be used (again) for other (future) problems (including in other DG's)?
8. **How long does it take to apply the method?**
What is the estimated timeframe of the analysis and does it correspond with the objectives or deadlines of the political process? What are the strategies if there is a lack of time?
9. **Has the method been used in previous IAs/evaluations/fitness checks/studies?**
Who might have experience in using the method and can provide advice?

The **Joint Research Centre** provides operational guidance and assistance on methodologies.

- The **Commission Competence Centre on Modelling (CC-MOD)** provides advice on model use for policymaking; its Modelling Inventory and Knowledge Management System (MIDAS); uncertainty and sensitivity; transparency and policy coherence with baseline scenarios; social multi-criteria evaluation of policy options; and peer-reviews by external experts.
Contacts: EC-CCMOD@ec.europa.eu
https://ec.europa.eu/knowledge4policy/modelling_en
- The JRC supports DGs with their **Life Cycle Assessments** studies at product and meso/macro scale (Tool #66). **Contacts:** JRC-ENVIRONMENTAL-FOOTPRINT@ec.europa.eu
- The **Commission Competence Centre on Microeconomic Evaluation (CC-ME)** provides advice and support for ex-post evaluation for policymaking (Tools #67, #68).
Contacts: EC-CC-ME@ec.europa.eu
https://ec.europa.eu/knowledge4policy/microeconomic-evaluation_en
<https://microeconomicevaluation.jrc.ec.europa.eu/> (tools)
- The **Commission Competence Centre on Foresight (CC-FUTUR)** provides advice on the use of foresight and knowledge bases, such as EC Megatrends Hub, Horizon Scanning (Tool #20).
Contacts: JRC-FORESIGHT@ec.europa.eu
EU Policy Lab: <https://blogs.ec.europa.eu/eupolicylab/>
EC Megatrends Hub: https://ec.europa.eu/knowledge4policy/foresight_en
Megatrends Workshop: https://ec.europa.eu/knowledge4policy/foresight/megatrends-engagement-tools_en
JRC Horizon Scanning Network: <https://webgate.ec.europa.eu/connected/groups/horizon->

scanning

- The Commission **Competence Centre on Behavioural Insights** (CC-BI) combines insights from different disciplines to support EU policymaking by identifying behavioural elements in policies and proposing behavioural levers to increase their effectiveness. (Tool #69).

Contacts: JRC-CCBI@ec.europa.eu

<https://ec.europa.eu/jrc/en/research/crosscutting-activities/behavioural-insights>

- The Commission **Competence Centre on Text Mining and Analysis** (CC-TMA) uses text mining and analysis tools to extract information from online data, including traditional or social media, or from large public or proprietary document sets.

Contacts: JRC-TMA-CC@ec.europa.eu

https://knowledge4policy.ec.europa.eu/text-mining/about_en

TOOL #56. TYPOLOGY OF COSTS AND BENEFITS

1. INTRODUCTION

To assess the impacts of a policy option – both ex ante in impact assessments and ex post in evaluations / fitness checks – one needs to look to as many benefits and costs as possible, in a proportionate manner. Depending on the nature of the impacts, these costs and benefits can be direct or indirect. This tool describes the different types of costs and benefits, and Table 1 lists them⁸⁰⁷.

Costs related to an initiative/intervention, often are concentrated on a specific group of stakeholders. Benefits, on the other hand, tend to emerge over a longer period and may be more society-wide.

At times, what is a cost to one party may be a benefit to another and these symmetrical changes in private welfare will normally cancel out at the societal level. In addition, investments, which are needed to comply with legislation, generate at the same time economic activity and income while (possibly) enabling cost savings later. It is therefore very important to distinguish between costs and benefits that represent net additions or reductions of total welfare for the society, as opposed to costs and benefits that arise for specific categories of stakeholders as a result of a transfer of resources. It is equally important to report both on the net societal effect and the distributional effects on individual groups in the society as this may determine the type of measures considered in the initiative.

Costs and benefits can be aggregated and compared more easily when expressed in the same units. Economists tend to favour monetary terms, using ‘market prices’. However, many (equally important) impacts are not easily expressed in monetary terms (e.g. what is the monetary value of fundamental rights or biodiversity?). In some cases, methods can help to convert these into impacts in monetary terms (see Tool #57 (*Methods to assess costs and benefits*)).

2. CATEGORIES OF COSTS AND BENEFITS

For the application in the ‘better regulation’ policy⁸⁰⁸, three main categories of costs and benefits can be distinguished:

- **Direct and indirect**
Direct costs/benefits can be clearly linked to the intervention as they result from the respective legal provisions.
Indirect costs/benefits are observed in related upstream or downstream markets or experienced by consumers, government or other stakeholders (e.g. third countries) that are not directly targeted by the initiative/regulation.
- **Private and societal**
 Costs and benefits can be analysed from the perspective of citizens, consumers, businesses, or public administrations. Impact assessments look at all of these together

⁸⁰⁷ [Assessing the Costs and Benefits of Regulation; CEPS \(2013\)](#) a study prepared for the European Commission; Chapter 1.

⁸⁰⁸ In other domains, the considered categories of costs will differ depending on the purpose. For instance, in finances or accounting one can distinguish between e.g. fixed, variable, operational, marginal, sunk, and (un)controllable costs.

to provide an analysis from the point of view of society as a whole, whilst identifying the winners and losers.

- **One-off and recurrent**

Depending on the point in time in which costs have to be borne or benefits occur, all the costs and benefits can be either 'one-off' or 'recurrent'.

One-off costs/benefits often appear shortly after an initiative is implemented (including the grace periods where relevant).

Recurrent costs/benefits appear more or less regularly over a certain period of time (or indefinitely) and they should be discounted to take into account the time preference (see Tool #64 (*Discount factors*)).

Figure 1. A map of regulatory costs and benefits

		Costs	Benefits
Direct	Direct compliance costs	Adjustment costs Administrative costs Charges	Improved welfare Health Safety Environment Direct economic benefits
	Enforcement costs	Information and monitoring Complaint handling Inspections Adjudication/litigation	Cost savings Improved market efficiency Improved information
	Hassle costs		Wider range of products/services
Indirect	Indirect compliance costs		Indirect compliance benefits
	Other indirect costs	Substitution effects Transaction costs Opportunity costs Negative effects on market functioning	Wider economic benefits Other, non-monetary benefits
Aggregate impacts			

3. DIFFERENT TYPES OF COSTS

Next to observing the occurrence of costs in time, the most useful distinction from the regulatory perspective is to look at direct and indirect costs of a given initiative; taken together, they represent the total cost of intervention:

(1) *Direct costs of regulation*

- *Direct compliance costs* are the costs that need to be borne to comply with the provisions of the regulation. They are composed of:
 - *Adjustment costs*, which encompass those investments and expenses that businesses, citizens, or public authorities have to bear in order to adjust their activity to the requirements contained in a legal rule;
 - *Administrative costs* are those costs borne by businesses, citizens, civil society organisations and public authorities as a result of administrative activities performed to comply with administrative obligations included in legal rules;
 - *Regulatory charges*, which include fees, levies, taxes, etc.
- *Enforcement costs* are associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation.
- *Hassle costs* are often interpreted as ‘regulatory annoyance’ resulting from unnecessary waiting time, delays, redundant legal provisions, corruption, etc. They can apply equally to businesses, consumers, and citizens. As this category of costs is not well-defined, in most cases it is not analysed in impact assessments, evaluations and fitness checks.

(2) *Indirect costs of regulation* – incurred in related markets or experienced by consumers, government agencies or other stakeholders that are not directly targeted by the initiative/regulation.

Indirect costs are usually transmitted through changes in the prices and/or availability and /or quality of the goods or services produced in the regulated sector. Changes in these prices then ripple through the rest of the economy changing prices in other sectors and ultimately affecting the purchasing power of consumers and activities of economic sectors. The category includes:

- *indirect compliance costs* – cost related to the fact that other stakeholders have to comply with legislation;
- *offsetting/substitution costs* – for example costs related to reliance on alternative sources of supply;
- *transaction costs* – costs of renegotiating contracts;
- *opportunity costs* – the costs of foregone alternative investments; and
- *negative impacts on market functioning* such as reduced competition or market access, reduced innovation or investment.

Different policy instruments (see Tool #17) usually imply the existence (and therefore analysis) of different cost categories (Table 2).

Table 1: Policy types and associated recurrent costs

Type of regulatory alternative	Recurrent costs
Self-regulation	Monitoring costs Transaction costs Direct compliance cost
Co-regulation	Monitoring costs Enforcement costs Transaction costs Direct compliance cost
Market-based instruments	Transaction costs Charges Direct compliance costs Indirect compliance costs
Performance-based standards	Monitoring costs Direct compliance costs Indirect compliance costs
Command and control	Charges Administrative burdens Direct compliance costs Indirect compliance costs Monitoring costs Enforcement costs Adjudication

4. IMPACT OF REGULATORY COSTS ON DIFFERENT STAKEHOLDERS

Table 2 categorise costs in terms of major stakeholders i.e. business, citizens and consumers and public administrations. For individual initiatives this classification may vary somewhat.

Table 2: Impact of regulatory costs on different stakeholders					
Type of cost		Citizens	Consumers	Business	Administrations
Direct costs					
Direct compliance costs	Adjustment costs	•		•	•
	Administrative costs	•		•	•
	Charges		•	•	
Enforcement costs	Information & monitoring	•		•	•
	Inspections and sanctions			•	•

	Complaint handling	•		•	•
	Adjudication/litigation	•		•	•
Hassle costs		•		•	•
Indirect costs					
Indirect compliance costs			•	•	
Other indirect costs	Offsetting/substitution effects		•	•	
	Transaction costs		•	•	
	Opportunity costs		•	•	
	Reduced competition		•	•	
	Reduced market access		•	•	
	Reduced investment/innovation		•	•	

Citizens: means citizens and society as a whole and refers to impacts that are widespread and do not affect a particular sub-group in a specific way;

Consumers refers to a specific product or service. Consumers do not necessarily overlap with citizens but may be a sub-group e.g. a group of citizens targeted by a given regulation;

Business includes all types of businesses including SMEs;

Public administrations are EU, national, regional or local administrations.

5. DIFFERENT TYPES OF BENEFITS

Benefits are often the objective of the initiative. They can be more difficult to classify as sometimes the beneficiaries can be a society-wide and more diffuse group than the stakeholders that bear the costs (see Table 1):

- (1) **Direct regulatory benefits** – these are usually expressed as objectives of the intervention and can be broadly divided into two categories:
 - The general *increase in welfare* of individuals and society by means of improvements in health, environment, and safety (also known as *non-market benefits*); and
 - *Market efficiency improvements*, which include higher economic productivity, improved allocation of resources, removal of regulatory or market failures or cost savings but also information availability and enhanced product and service variety and quality for end consumers.
- (2) **Indirect regulatory benefits** – similarly to indirect costs, indirect benefits occur as secondary impacts to the intended achievements of the intervention, i.e. they are not

explicitly formulated as objectives. They are often referred to as co-benefits (or ancillary benefits). They can be in general classified in to the following:

- *Spill-over effects* related to third-party compliance with legal rules (so-called '*indirect compliance benefits*'). These are benefits which accrue to individuals or business that are not the direct addressees of the initiative but who enjoy positive effects due to the compliance of others who are directly addressed (e.g. lower societal healthcare costs due to strategies to reduce obesity or tobacco smoking; suppliers of environmental technologies);
- *Wider macroeconomic benefits*, including higher GDP, productivity enhancements, greater employment rates, improved job quality etc.; and
- *Other non-monetary benefits*, such as protection of fundamental rights, social cohesion, reduced gender discrimination, international and national stability, etc.

The 'aggregate impacts' of a policy intervention: - All regulations usually aim, as an ultimate impact, to achieve some advancement in social welfare, which can be described in terms of efficiency or in other terms. These ultimate impacts encompass welfare, environmental quality, and more economic goals such as GDP growth and employment.

TOOL #57. METHODS TO ASSESS COSTS AND BENEFITS

Different methodological approaches can be used to estimate costs and benefits ex ante (impact assessment) or ex post (retrospective evaluation/fitness check). The most appropriate choice will depend on various factors such as the nature of the initiative, proportionality, and data availability. Box 1 considers a few important general issues:

Box 1. Important issues with respect to assessing costs and benefits

When assessing costs or benefits it is important to:

- distinguish between private or social, direct or indirect, and one-off or recurrent costs / benefits;
- avoid double-counting costs and benefits of regulation by recognising that the gains of one category and the losses of another may be two sides of the same coin⁸⁰⁹;
- all costs (and benefits) generated by a new legal provision are by definition incremental costs, i.e. they are additional to the existing costs and benefits in absence of a new policy measure ('business as usual', BAU).

Costs

1. HOW TO ASSESS COMPLIANCE COSTS

Direct costs are those costs linked to the needs to divert resources to implement or abide by the requirements of a regulatory option⁸¹⁰. **An important category of direct costs are the so-called compliance costs**, i.e. those costs incurred by businesses and other parties in undertaking the actions necessary to comply with the new regulatory requirements⁸¹¹.

Compliance costs are often the aggregate of all direct costs generated by legislation: over time, they have become the subject of specific assessment methods in various countries. It is often useful to analyse (and estimate) compliance costs based on their individual components. Box 2 gives an overview of different compliance cost components.

It is important to distinguish the costs borne only once, usually upfront ('one-off' costs) from the costs that occur several times (recurrent costs) throughout the period in which the legislation/intervention remains in place. For the latter, it is necessary to identify the frequency with which the costs have to be borne (e.g. (bi)annually, quarterly, monthly) and – in case of applying quantitative methods – to discount them to express them in the present value of money (see Tool #63 (*Cost-benefit analysis*) and Tool #64 (*Discount factors*)).

Direct costs linked to a regulatory initiative, will not only change the actions of the upstream and downstream businesses or other parties that are affected; but due to the economic

⁸⁰⁹ For example, [Economic impacts of EU clean air policies assessed in a CGE framework](#) discuss an example for the European Clean Air Package. Table 4 illustrates that the direct abatement costs can be larger than the economy-wide costs (GDP), as the costs imposed to the polluting industries lead to increased production and employment in the sectors providing the green technologies.

⁸¹⁰ [Assessing the Costs and Benefits of Regulation; CEPS \(2013\)](#) a study prepared for the European Commission.

⁸¹¹ [OECD \(2014\). OECD Regulatory Compliance Cost Assessment Guidance](#). See page 62 for a list of regulatory compliance activities.

integration may lead to (sometimes significant) indirect costs or benefits to other parties. These indirect effects are, typically, measured by models such as general equilibrium models (see Tool #61 (*Simulation models*)).

Box 2. Compliance cost components	
Regulatory charges	
Regulation often affects businesses and consumers by imposing the payment of fees, levies, or taxes on certain stakeholders. These costs are often easy to calculate, as their extent is known. It is more difficult to assess who will bear those costs, as this might depend on the extent to which these costs are passed on to entities other than those targeted by the legal rule ⁸¹² . For example, copyright levies might be passed on downstream on end consumers in the form of higher prices for certain hardware devices.	
Administrative costs	
These are the costs of complying with administrative requirements imposed by regulation. For details, see Tool #58 (<i>EU Standard Cost Model</i>).	
Adjustment costs	
These are the incremental (i.e. non-business as usual) costs of complying with new regulation other than charges and administrative costs. They can be <i>broken down into</i> ⁸¹³ :	
<i>Implementation costs</i>	The costs regulated entities incur in familiarising themselves with new or amended regulatory compliance obligations, developing compliance strategies, and allocating responsibilities for completing compliance-related tasks. In large part, therefore, they are short-term one-off costs.
<i>Direct labour costs</i>	The costs of staff time devoted to completing the activities required to achieve regulatory compliance. Only the costs of staff directly involved in undertaking these activities should be included: the costs of staff supervision/management are included in the overhead cost category (see below). Direct labour costs include two main elements: the cost of wages paid and non-wage labour costs.
<i>Overheads</i>	The costs of rent, office equipment, utilities and other inputs used by staff engaged in regulatory compliance activities, as well as corporate overheads, such as management inputs, that are attributable to compliance activities.
<i>Equipment costs</i>	Those costs incurred by businesses whenever they need to purchase items of capital equipment to comply with a regulation. This can include both machinery (e.g. equipment to treat the emissions from a production facility to conform to new emissions standards) and software (e.g. programs required to undertake real-time monitoring of actual emissions).
<i>Material costs</i>	The incremental costs incurred in changing (or substituting) some of the material inputs used in the production process to ensure regulatory compliance (thus, they are sometimes called 'input costs'). They are therefore recurrent costs.

⁸¹² In economic theory, this ability to pass on part of the costs is defined by the elasticity of demand.

⁸¹³ The categorization proposed in the OECD Regulatory Compliance Cost Assessment Guidance.

<i>Cost of external services</i>	<p>The cash cost of payments made to external suppliers providing assistance in achieving regulatory compliance.</p> <p>For example, faced with more stringent emissions controls, a firm may hire consulting engineers to advise on the available means of reaching compliance and their relative costs and benefits.</p>
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The extent to which different types of compliance costs are assessed can be guided by different principles. All have their limits and elements to consider are:

- The expected magnitude of compliance costs: the higher the expected cost, the more resources should be invested in estimating compliance costs;
- The distributional impact: the more heterogeneous the affected actors are or the more disproportionate the impacts are, the higher the need for a thorough the analysis;
- The availability of data: the greater the availability of data, the more comprehensive compliance costs should be quantitatively estimated;
- The nature of the initiative: when compliance can be broken down into a relative precise set of activities, total compliance costs can more easily be estimated by adding up the various costs of these activities for a typical business/citizen/public authority. Conversely, a top-down approach may be more appropriate in the case of complex policy proposals, where the range of starting positions across regulated entities is wide and/or where there are different ways to achieve compliance.

Making methodological choices, but also applying the principle of proportionate analysis, include seeking compromises by focussing on major cost drivers and relying on simplified assumptions (e.g. extrapolating data from some economic actors or member states to others). All key methodological choices and limitations need to be justified. When appropriate, a sensitivity analysis may be considered (See Tool #65 (*Uncertainty and sensitivity analysis*)). Box 3 gives an overview of various methods to estimate compliance cost components.

<i>Box 3. Methods to estimate compliance cost components</i>
Methods to assess compliance costs build up on the standard cost model ⁸¹⁴ , which is used specifically to estimate administrative costs. The following provides a short summary.
<i>Regulatory charges</i>
Charges = Targeted population x Frequency x Cost
For example, if 2 500 enterprises pay a licence fee of €500 twice a year, the total on a yearly basis will be (2 500 x 500 x 2) = €2.5 million.
<i>Administrative costs</i>
Administrative costs are the costs incurred by enterprises, the voluntary sector, public authorities, and citizens in meeting administrative obligations towards public authorities or private parties. Administrative obligations in a broad sense include labelling, reporting,

⁸¹⁴ See CEPS (2013) and OECD (2014) for references to existing methods which extend the standard cost model from administrative cost to compliance costs more generally.

registration, monitoring, and assessment needed to provide the information. In some cases, the information must be transferred to public authorities or private parties. In others, it only must be available for inspection or supply on request.

Whenever a measure is likely to impose significant administrative costs on business, citizens or public authorities, the EU Standard Cost Model presented in Tool #58 should be applied.

In the context of the reporting requirements linked to the 'one in, one out' approach, new and/or removed administrative costs for businesses should be encoded in an online OIOO calculator⁸¹⁵ established specifically for this purpose.

Adjustment costs

(1) Identify substantive requirements

These are all the activities necessary to comply with, except for those linked to administrative obligations and charges. Here one should distinguish between one-off and recurrent requirements.

(2) Estimate the population of stakeholders that must comply with each substantive requirement for each of the alternative options.

(3) Estimate the time needed for a 'normally efficient business', an 'ordinary citizen' or a 'normally efficient administration' to comply with each substantive requirement.

This stage is required to assess the cost of labour needed to comply with the substantive requirements. The concept of 'normal efficiency' is needed in order not to factor into the analysis the inefficiency of some of the targeted entities. This implies the assumption that regulated entities handle their substantive tasks neither better nor worse than may be reasonably expected. Information on the time it takes for normally efficient entity is usually gathered via surveys, interviews or drawing parallels with similar tasks for which the average time is already known.

(4) Estimate the 'BAU factor' for each substantive requirement and each of the alternatives, based on direct assessment or empirical data.

Estimation of the business-as-usual (BAU) factor is needed to estimate the incremental costs of regulation. It is often obtained by consulting targeted stakeholders or experts: BAU estimates involve the exercise of identifying costs that would normally exist regardless of new policy interventions. In some cases, the BAU factor can be estimated directly by looking at the share of costs associated with a substantive requirement that are borne by similar entities that are not targeted by specific legislative provisions.

(5) Consider segmenting the population by creating case groups differentiated according to size (micro, small, medium, large enterprises) or other dimensions (level of government for public administrations, availability of Internet connection for citizens, etc.).

This step will potentially identify any distributional impacts of costs imposed by the considered options and allow for designing mitigation measures if necessary.

(6) Estimate the adjustment cost associated with each substantive requirement for each segment and each alternative.

⁸¹⁵ [The online OIOO calculator](#)

The costs of each of the adjustment cost components (see Box 2 above) need to be estimated and summed up considering potential differences between segments. The calculation has to reflect that some of the costs will be one-off and some recurrent (e.g. cost of materials). For the latter, if they are monetised, discounting them is necessary to calculate their net present value (see Tool #64 (*Discount factors*))⁸¹⁶.

(7) *Assess whether adjustment costs are likely to change over the life of the proposed legislation.*

One should assess whether, because of entry/exit of businesses, technological innovation, 'learning by doing' or any other relevant factor, the impact of the costs identified is likely to change over time. This should be considered in a prospective analysis on regulatory costs, and – if possible – coupled with sensitivity analysis on the assumptions behind the evolution of costs over time.

(8) *Calculate all incremental adjustment costs and extrapolate them to reach a total estimate for each of the alternative options considered.*

The incremental adjustment cost is equal to the calculated adjustment cost minus the business-as-usual cost. The incremental adjustment costs should then be extrapolated to the whole population of affected entities per identified segment.

The accuracy of these methods depends significantly on the extent to which resources are devoted to data collection and prospective analysis. **Without reliable data and/or robust assumptions on future evolutions, results of an assessment of costs and benefits can only be considered as indicative of the relative magnitude of compliance costs across different alternative options.**

2. HOW TO ASSESS ENFORCEMENT COSTS

Enforcement costs are those costs direct borne by public authorities in implementing, administering, and enforcing regulatory requirements.

They can include the cost of publicising new requirements, establishing licencing or permit systems, dealing with queries and applications, handling complaints, implementing inspections and audits to verify compliance and sanctioning non-compliance⁸¹⁷.

In principle, enforcement costs can be estimated following a similar bottom-up approach to the one described in for adjustment costs: first defining the activities required to implement and enforce legislation, then estimating their frequency and their cost taking into consideration the BAU factor and possibly distinguishing between different case groups as appropriate. Enforcement authorities may be in a position to provide good unit cost estimates for different types of activities.

In reality, however, estimating these costs ex ante at the stage of Commission proposal may be complex. First, data are rarely available. Second, implementation and enforcement activities often cannot be defined (and thus costed) since they are to be decided and implemented by Member States at a later stage. However, Member States may be in a position to provide estimates of costs for similar activities performed by them in the context of a similar enforcement area. In this case, one could complement the estimate with a

⁸¹⁶ Further useful guidance on this can be found in chapter 3 of the OECD (2014).

⁸¹⁷ For a list of possible implementation and enforcement activities, see p. 63 in OECD (2013).

qualitative assessment in order to consider any trade-offs and synergies between business (or citizens) adjustment costs and enforcement costs⁸¹⁸.

3. HOW TO ASSESS CUMULATIVE COSTS

Every new policy proposal should be assessed on its own merits. For this reason, impacts are assessed against a baseline, meaning that only the incremental costs and benefits of the new initiative need to be estimated. It is the sign and the magnitude of the net change in costs and benefits that matter most for the proposal of new policy initiatives.

Cumulative cost assessments (CCA), however, look at the aggregate (or cumulative) costs of all different regulations from the point of view of a single economic sector. The exercise is of backward-looking nature and can be used as an input to define the baseline scenario. **It is a partial approach, which by definition does not look at benefits.**

A prominent tool for making CCAs is the Dutch Compliance Cost Assessment tool ('CAR model') which was conceived essentially for retrospective analyses of existing legislation⁸¹⁹.

Not all regulatory proposals lead to direct cost increases. At times, the very aim of a regulatory proposal is to reduce existing, cumulative regulatory costs either by simplifying existing EU legislation or by harmonising regulations across Member States and thus generally reducing compliance costs for businesses operating across the single market. In case of reducing administrative costs, they should be recorded in a dedicated online calculator supporting the application of the 'one in, one out' approach (see Tool #58 (*EU Standard Cost Model*)). **It is recommended that all revisions of legislative acts (i.e. REFIT initiatives) have simplification as one of its specific objectives where this is relevant.** Please see Tool #2 (*The regulatory fitness programme (REFIT) and the Fit for Future Platform*) and Tool #15 (*How to set objectives*) for further details.

It is advisable to consider cumulative impacts to the extent that this may be possible and proportionate. Some reflections in this regard can be found in Box 4.

Box 4. Assessing cumulative impacts	
Why?	Because it helps avoiding redundant requirements (for instance, reporting ones) and/or highlights opportunities to simplify legislation. Cumulative assessments can also help in defining better the baseline scenario.
	Because a good assessment of indirect impacts may depend upon a good understanding of cumulative impacts.
	For instance, the impacts on sectoral competitiveness of an increase in regulatory costs depend upon the overall aggregated cost structure (incl. cumulative

⁸¹⁸ Thus, an option that provides greater flexibility in the ways in which business can comply with the regulatory requirements may minimise costs to firms, but may increase the costs of administering the regulation, since verifying compliance will be more complex and involve a higher degree of professional judgement. Total direct costs may well be higher than under a less flexible regulatory option. Total costs would of course also depend on indirect impacts such as impacts on business competitiveness, innovation, the ultimate goal of the regulation, etc.

⁸¹⁹ The Study on Assessing the costs and benefits of Regulation prepared by the Centre for European Policy Studies (December 2013); pp 70 for description of the model and its strengths and weaknesses in relation to impact assessments and evaluations.

	regulatory costs) of the sector vis-à-vis international competitors.
How and when?	<u>During public consultations</u> when stakeholders discuss interactions between a proposed initiative and the existing body of legislation.
	<u>When conducting fitness checks</u> as part of the input to assess efficiency of (all or part of) the legislation affecting a specific sector.
	<u>When designing policy options</u> , the lead service and the ISCG should cross check the proposal with the existing body of legislation (across the sector and policy areas) for possible redundant requirements, overlaps etc. In doing so, the results of the ex-post evaluation(s) may provide useful information.
	<u>When assessing impacts</u> and, notably <u>indirect impacts and impacts on micro and small enterprises</u> ⁸²⁰ . No generally recognised standard methodology exists for the consideration of cumulative impacts. However, a growing number of studies are generating data by sector and firm type. The methodologies can also inform quantitative models.

Benefits

4. HOW TO ASSESS COST SAVINGS

Box 5 gives an overview of different methods to estimate cost savings.

<i>Box 5. Methods to estimate direct cost savings</i>
Whenever a policy option leads to a reduction in regulatory charges , one could follow the same approach as suggested in Box 3 to estimate the value of the reduction.
Whenever a policy option leads to a reduction in adjustment and administrative costs , the same approach is applicable as in Box 3 of this tool and in Tool #58 (<i>EU Standard Cost Model</i>) on administrative costs to estimate the value of the reduction.
Whenever a policy option leads to a reduction in enforcement costs , to estimate the value of the reduction (or at least assess its relevance qualitatively), instructions given in section 2 of this tool are valid.

All the usual caveats applying to bottom-up estimation approaches apply to the above. In particular, it is very important to complement any such estimation with an assessment of indirect costs and of direct and indirect benefits. This guarantees that cost savings do not reduce regulatory benefits (or at least do not reduce them in a manner that worsens both the effectiveness and the efficiency of an existing policy). It is also necessary to consider possible trade-offs among different categories of costs. Box 6 lists such trade-offs using administrative obligations as an example.

⁸²⁰ See Tool #23 (*The 'SME test'*)

Box 6. Verifying the effective nature of cost savings

A proposal may reduce administrative costs, but at the same time increase other compliance costs for the same targeted businesses.

Administrative costs (ACs) constitute only a subset of costs imposed on businesses by legislative acts. For example, the implementation of an e-government or any other IT-enabled solution can reduce the amount of time related to compliance with the information obligation. At the same time, however, it may require a degree of investment in upgraded IT equipment and training of employees, which would not be considered as ACs, but fall generally in the category of adjustment costs. Similarly, a proposal that reduces ACs may increase public expenditure in monitoring and enforcement (see below): these costs may be recovered by the government through higher tax burdens, thus increasing direct charges. Finally, a proposal may reduce administrative obligations by requiring structural changes in the production process, which would guarantee a certain level of product safety without any need for burdensome certifications: in this case too, ACs are reduced, but adjustment costs may increase.

A proposal may reduce administrative costs, but at the same time increase administrative costs of a different origin.

With multi-level governance, the reduction of ACs achieved by eliminating some information obligations at e.g. the EU level may require the introduction of new information obligations at e.g. the national or regional levels.

A proposal may reduce administrative costs, but at the same time increase costs for other private actors (businesses and/or citizens, workers).

For example, reducing labelling obligations for products may increase information costs borne by consumers, who would need to collect their information from other sources in order to make an informed choice of what products are most likely to fit their preferences.

A proposal may reduce administrative costs, but at the same time increase monitoring and enforcement costs for public authorities.

This is often the case whenever the eliminated information obligations involve the keeping and reporting of information available to businesses, but not to public authorities. For example, the reporting on respecting the hygiene standards or on the large exposures by banks are typical instances of highly burdensome activities for businesses. These information obligations are vital for public authorities. Without them, public authorities would have to deploy more resources to obtain the information, which is likely to lead to more inspections and enforcement costs – in the two examples, more hygiene inspections and more investigations into the riskiness of banks' exposure *vis à vis* certain clients.

A specific case of savings can occur whenever there are options that have an impact on the **Single Market**, especially when such options entail the harmonisation of national legislation. Box 7 presents the specificities of such a category of cost savings.

Box 7. Single market cost savings

Savings might emerge whenever EU legislation harmonises fragmented and inconsistent national legislation. When legislation is fragmented across Member States, companies wishing to engage in cross-border trade have to incur ‘adaptation costs’, such as:

- ***Having to change contracts or other practices to comply with differing national legislation.*** Monetising these costs is normally possible. One way of doing it is to collect data directly from companies and validate them with experts.
- ***Having to modify standards or equipment, or train personnel to deal with differing national legislative requirements.*** These costs are easily monetised by referring to market prices, and (in the case of equipment) depreciating these assets over time.
- ***Incur additional administrative costs because national legislation contains different information obligations,*** which have to be complied with and which would not be incurred if the company refrained from entering the national market. In this case, one has to estimate the time that would be spent complying with the additional information obligations and convert this into a monetary value by using data on labour costs for the job profile of the person that would perform the relevant administrative activities.

A number of *caveats* should be kept in mind when performing these calculations. First, adaptation costs might not be incurred by companies if they keep internal compliance programs that apply to one or more countries: for example, if a company adopts an internal antitrust compliance program that is tailored to the most restrictive country, this will automatically mean that the company also complies with legislation in less strict countries. Also, the magnitude of administrative burdens should be gauged against the ‘BAU factor’, *i.e.* the extent to which the activities performed to comply with national legislation would be performed anyway, even when not required by EU law.

Finally, cost savings are only one category of benefits one has to deal with when looking at harmonisation of legislation. Indirect benefits may emerge due to market efficiency impacts. Estimating these benefits is normally not prohibitively difficult but for accurate monetisation, one needs data on demand and supply elasticities⁸²¹. Expert guidance for this type of estimation⁸²² may be helpful (See Tool #25 on impacts in the internal market).

5. NON-MARKET BENEFITS

Assessing quantifiable direct or indirect benefits does not substantially differ from assessing the corresponding costs and may use the similar methods. Wider economic benefits, like GDP growth, employment increase, or productivity growth, can be assessed, among others, with modelling (Tool #61 (*Simulation models*)). Social cost/benefit analysis assesses the net value of a policy or project to society. Many non-market benefits (e.g. health, quality of the environment) are often expressed in physical units. Monetisation of non-market benefits is easier when the values can be linked to market prices. E.g. air pollution might reduce crop yields, thus allowing for relatively straightforward monetisation. Other non-monetary

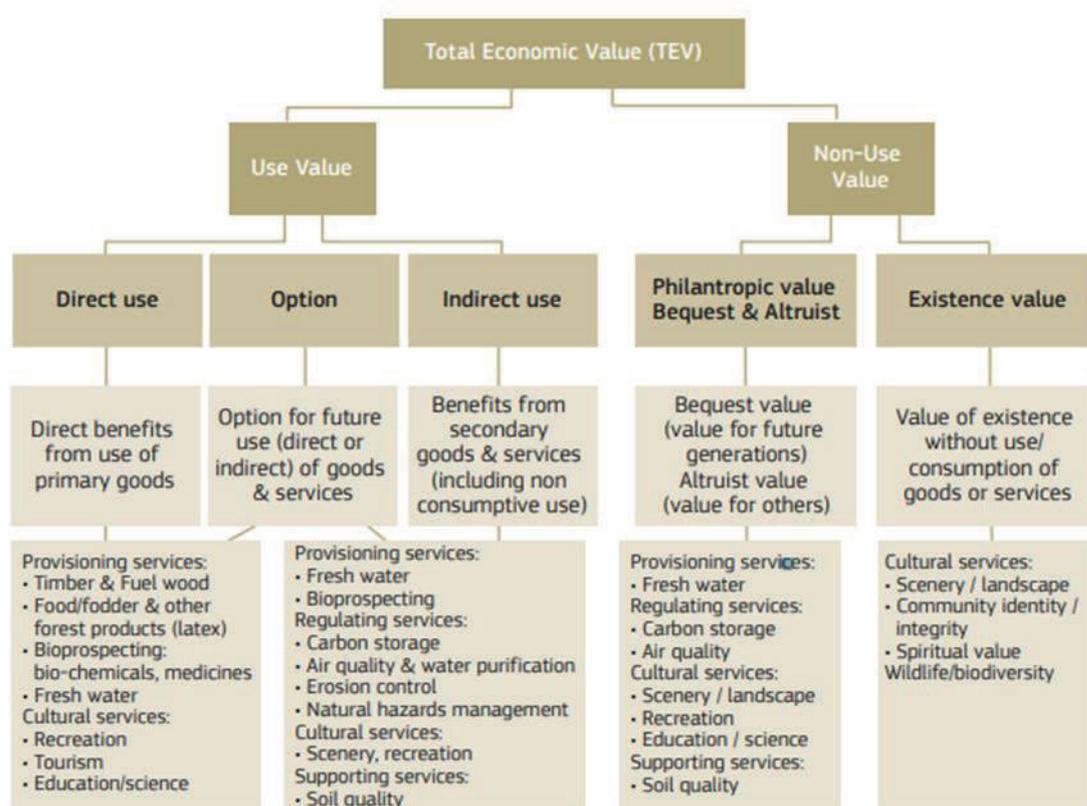
⁸²¹ In the US, dedicated databases make it easier to estimate the response of supply and demand to a change in price or in the quality of products (e.g. [here](#), in particular the section on commodities and food elasticities). In the economic literature, several estimates of elasticity are available, which could be collected into a single dataset. See for example in relation to [air transport](#).

⁸²² For a general presentation see CEPS (2013), p. 178-182.

benefits, such as improvements in protection of fundamental rights, social cohesion, or international stability, are less straightforward to measure and are assessed by surveys or proxy indicators (e.g. counting LGBTQ laws). However, the full value of many goods (benefits) such as health, environment, or education cannot be easily deducted from the market price. However, these important social impacts cannot be ignored in policymaking. The valuation of non-market impacts is challenging but could be undertaken wherever possible. Complementary tools exist to compare the merits of policy options where monetary information may be limited (e.g. multi-criteria decision analysis, Tool #62). Box 8 looks at dedicated methods attempt to assign market values and monetary units to these benefits.

Box 8. Market based approaches: Stated preference and Revealed preference

Valuation techniques allow for estimation of the total economic value (TEV), which refers to the value derived by people from a natural resource even if the services that it provides are not fully reflected in market prices. It is an aggregation of the (main function based) values provided by a given ecosystem⁸²³.



Market based approaches estimate the change in utility by simulating a market. The willingness to pay (WTP) is the maximum amount of money an individual is willing to give up in order to receive a good. The willingness to accept (WTA) is the minimum amount of money they would need to forego or give up a good. The willingness to pay/accept depends on their income level so valuations are usually obtained by averaging across income groups. The approaches can be used to estimate the value of improved health outcomes^{824, 825} (such as

⁸²³ [Economic Benefits of Natura 2000 report](#)

⁸²⁴ See Tool #32 (Health impacts)

from reduced air pollution), reduced road congestion, reduced road fatalities and injuries, disamenity (e.g. from waste disposal and quarrying) and recreational amenity (e.g. forests).

'Revealed preference' vs 'stated preferences' vs 'experiments'⁸²⁶

- Revealed preference techniques involve inferring the implicit price placed on a good by consumers by examining their behaviour in a similar or related market. For example, the value of house prices and its relationship to ambient noise or the travel costs incurred by individuals who wish to enjoy a forest or other recreational site.
- Stated preference techniques use specially constructed questionnaires to describe a hypothetical choice within a hypothetical market in order to elicit estimates of the willingness to pay or willingness to accept. When using stated preferences, the main choice is between contingent valuation and choice modelling. The former elicits WTP or WTA via direct questions on the amounts they would be prepared to pay to receive a particular good while the latter present respondents with a series of alternatives and asking for their preference.
- Experiments are different to revealed or stated preference surveys, as subjects in experiments make incentivised choices, and may accrue benefits and incur losses. In revealed and stated preference surveys, these types of incentives are not present. (see Tool #69 (*Emerging methods and policy instruments*))

While revealed preference methods are perceived to be more reliable, these techniques cannot be used for new assets or new users. Here, stated preference techniques can be an alternative. It may be difficult to judge the reliability of estimates emerging from a single study using a single method. In any event, a range of values could indicate the sensitivity.

In the absence of an existing reliable and accurate monetary valuation of an impact, a decision could be made whether to commission a study, and if so, how much resource to allocate to the project in line with the principle of proportionate analysis. Factors to consider include (i) whether further research is likely to yield a robust valuation; (ii) whether the results will be useful for future IAs; (iii) how accurate the valuations need to be; (iv) the political importance/magnitude of the policy initiative and the expected impacts.

The technique of 'benefits transfer' (or 'cost transfer') can also be used to estimate values of impacts that do not have market prices. To save time and resources, values obtained in one study are transferred to a different study. For example, estimates of the costs of preventing a motorway accident in one Member State might be used to estimate the costs in other Member States. Using this technique increases the uncertainty of the estimated values but can be helpful to give an order of magnitude of likely impacts, even with time or money constraints. A good example of benefits transfer is the DG MOVE Handbook on the **external costs of transport** (Version 2019)⁸²⁷ that provides information on how to generate state-of-the-art

⁸²⁵ For example, the OECD has done a study to explain the variation in the estimates of Value of Statistical Life (VSL) estimates according to the characteristics of risk (type and size of risk, baseline risks, latency, etc.), and socio-economic characteristics (age, income, gender, health status, etc.). Their [meta-analysis](#) suggests a VSL of around 3.5 million euro. In the [chemicals context, standard values](#) are also found for different health end points.

⁸²⁶ See overview in Table 29 of the CEPS 2013 study on Assessing the Costs and Benefits of Regulation, pp. 185. http://ec.europa.eu/smartregulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

⁸²⁷ <https://ec.europa.eu/transport/sites/transport/files/studies/internalisation-handbook-isbn-978-92-79-96917-1.pdf>

estimates for all main external costs of transport. The European Environment Agency has made accessible some unit values for the valuation of **industrial activity**. It is also difficult to carry out benefits transfer for biodiversity and water pollution or scarcity. Some environmental issues are highly location specific (e.g. biodiversity, water pollution), and, hence, benefit transfer may be difficult. The environmental valuation reference inventory (EVRI) database⁸²⁸ may help with case studies.

When valuing impacts, the proportionality principle applies, as in all parts of impact assessment: it may not be worth applying these techniques for very small impacts. Further, there may be significant impacts that cannot sensibly be monetised, and these should be presented in non-monetary units (e.g. air pollutant concentrations) or in more qualitative terms⁸²⁹. Where costs cannot be valued in monetary terms, they should still be reflected in the impact assessment.

6. OTHER METHODS USED FOR ESTIMATING COSTS AND BENEFITS

Simulation models (economic or physical), such as partial or general equilibrium models, are commonly used in the preparation of impact assessments. The JRC has established a Competence centre on modelling (CC-MOD) which can provide information about the available models and help and assistance in using such models (see Tool #61 (*Simulation models*)).

The tools on cost-benefit analysis and multi-criteria decision analysis discuss how the costs compare to benefits. Box 9 gives an overview of other analytical methods that do this comparison.

Box 9. Other analytical methods

A **SWOT analysis** is used to identify the Strengths, Weaknesses, Opportunities and Threats in relation to a project/organisation and how such an assessment will change over time.

In the context of an evaluation, this method can be used for assessing the services provided by a project/programme. SWOT can take past weaknesses and transform them into a constructive learning process. SWOT is not an analytical tool by itself; instead it is a way to synthesise preceding analyses and use them for developing a strategy.

Least cost analysis is primarily used in the impact assessment context. It only looks at costs, in order to select the alternative option that entails the lowest net cost. You should choose this method whenever benefits are fixed, and you only need to choose how to achieve them. Costs do not need to be precisely monetised or even quantified but their relative magnitude across options should be determined.

Cost-effectiveness analysis (CEA) entails that you quantify (not monetise) the benefits that would be generated by one euro of costs imposed on society. While CEA is closely related to CBA, instead of monetised benefits it uses other measures, such as increased life expectancy, educational attainment, abated emissions. A typical method to compare options for an impacts assessment is the so-called **benefit-cost ratio**, which means dividing the benefits by

⁸²⁸ <https://evri.ca/en/content/about-evri>

⁸²⁹ <https://www.oecd.org/env/tools-evaluation/CBA-brochure-web.pdf>

costs. This method can be used for expenditure programs, as it helps to identifying the 'value for money'. In the evaluation context, the cost-effectiveness analysis can compare the evaluated intervention against best practice or similar interventions. It can also be used to assess effectiveness of the implementation process where different implementation approaches have been pursued. CEA is less easily applicable to interventions with more than one main objective. If the intervention aims to achieve a number of objectives (e.g. job creation and environmental protection), or have indirect impacts, the results of CEA may be misleading or irrelevant.

A **counterfactual analysis** is a statistical method devoted to quantifying the size of the effect of a given intervention (see Tool #46 (*Designing the evaluation*))

7. FURTHER INFORMATION

- Study prepared by the Centre of European Policy Studies on [the assessing the costs and benefits of regulation \(2013\)](#).
- [OECD Regulatory Compliance Cost Assessment Guidance \(2014\)](#).

TOOL #58. EU STANDARD COST MODEL

1. ADMINISTRATIVE COSTS AND THE 'STANDARD COST MODEL'

Administrative costs are a specific type of compliance costs incurred by enterprises, public authorities, and citizens **in meeting administrative obligations**. This captures a broad range of administrative activities including labelling, reporting, registration, provision of data, as well as monitoring and assessments needed to generate the information. In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supplied on request.

Box 1. Example of administrative costs vs. adjustment costs

- A regulation on air quality sets an obligation to keep a register of pollutant emissions and an obligation to meet an air quality threshold.
- Keeping a register of pollutant emissions is an administrative cost, while action taken to meet an air quality threshold is not. That type of compliance cost is referred to as 'adjustment cost' because the obligation affects the core industrial or economic activity.
- Keeping a register does not entail in itself any obligation to change the production process, the nature of the end-products or the treatment of emissions. Meeting the pollution threshold will require a substantive change to the industrial activity (for instance the installation of new filters).

Whenever a measure is likely to impose significant administrative costs on business, citizens or public authorities, the **EU Standard Cost Model** should be applied to the extent that the underlying data is available. The main aim of the model is to assess the **net cost of administrative obligations** imposed by EU legislation⁸³⁰. The results of this analysis should be presented in **Annex 3** ('who is affected and how') of the impact assessment or for evaluations or fitness checks in **Annex IV** ('overview of benefits and costs'). In case an initiative imposes new or eliminates existing burdens on businesses or citizens, these should be measured with a dedicated online calculator⁸³¹, supporting the implementation of the 'one in, one out' approach (see Tool #59 (*Cost estimates and the 'one in, one out' approach*)).

2. OUTLINE OF THE MODEL

2.1. Definition of administrative costs and administrative burden

Both **recurring administrative costs** and, where significant, **one-off administrative costs** have to be considered.

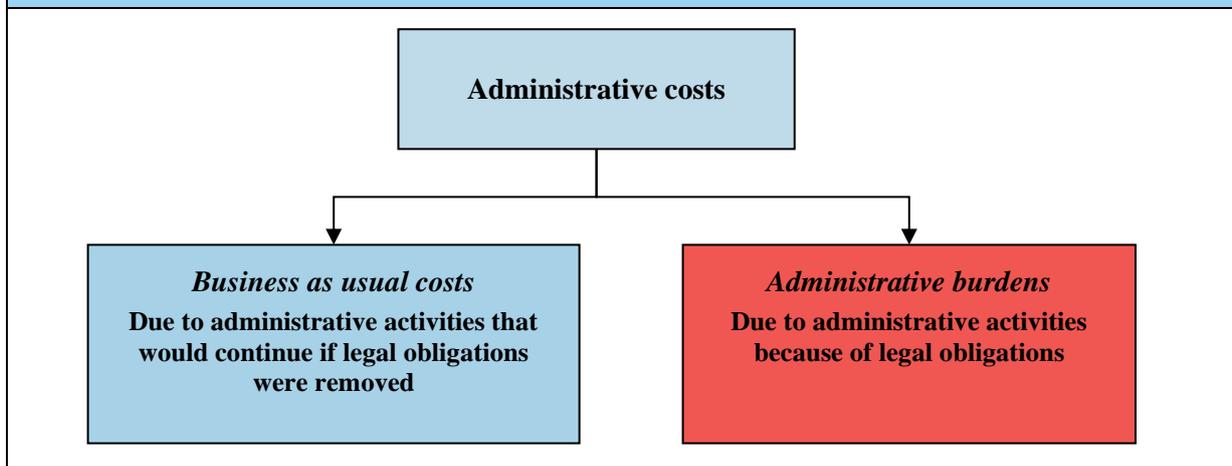
The administrative costs consist of two different cost components: the **business-as-usual costs** and **administrative burdens**. While the business-as-usual costs correspond to the costs resulting from collecting and processing information that would even be done in the absence

⁸³⁰ Net costs = costs introduced by a proposal if adopted, minus the costs it eliminates at EU and/or (sub)national level.

⁸³¹ [The online OIOO calculator](#)

of any legislation, **administrative burdens stem from the part of the process which is done solely because of a legal obligation**⁸³².

Box 2. Components of administrative costs



2.2. Core equation of the cost model

Administrative net costs are assessed by multiplying the **average cost of the required administrative activity** (Price) with the **total number of activities performed per year** (Quantity) and by subtracting the cost of administrative activities removed (at EU/national level).

The average cost per activity can be estimated by multiplying a tariff (based on average labour cost per hour including pro-rated overheads) and the time required per action. Where appropriate, other types of costs such as outsourcing, equipment or supplies' costs should be considered⁸³³. The quantity will be calculated as the frequency of required actions multiplied by the number of entities concerned. In case of multiple relevant administrative activities per information obligation these need to be summed up to calculate the administrative cost per information obligation. The core equation of the EU Standard Cost Model is as follows:

Box 3. Core equation of the EU Standard Cost Model

$$\text{Administrative cost} = \sum P_N \times Q_N - \sum P_R \times Q_R$$

where **P** (for Price) = Tariff x Time; **Q** (for Quantity) = Number of businesses x Frequency; and **N** – new obligations, **R** – removed obligations at EU/national level

⁸³² Most businesses would for instance have an accounting system, even in the absence of legal bookkeeping, but would not necessarily provide caloric value information for all their products.

⁸³³ Many small businesses, for instance, use services by external accountants, chambers of commerce, and professional associations to fulfil certain information obligations set by Company Law.

2.3. Scope of application of the model and expected level of accuracy

The effort of assessment should remain proportionate to the scale of the administrative costs imposed by the legislation and should be determined according to the principle of proportionate analysis (see Tool #12 (*How to apply proportionality to impact assessments*)). Therefore, there is no need to assess the administrative costs when these are **bound to be insignificant**, for instance, when **little equipment** is required, **if the amount of time per action is small** and **the frequency low**. Such decisions (i.e. no costing) should be taken on a case-by-case basis and should be justified. In order to keep assessment of costs at a reasonable level and ensure comparability of results, **estimates will be based on standard assumptions** simplifying the complex reality of the EU. These assumptions are presented together with **step-specific guidelines below**.

3. STEP-BY-STEP GUIDE

The assessment of positive or negative effects on administrative burden on businesses, citizens or public administrations resulting from EU legislation should begin with a **full mapping of introducing new or eliminating existing administrative obligations** for each of the options under review. Such a comparative table will usually indicate the type of administrative obligation, its specific requirements, the target group, and the frequency of that obligation.

In the first phase, the mapping should clearly show how policy options differ in terms of administrative obligations, and, in particular, identify those obligations that are likely to impose **significant administrative burdens**. The significance (high – medium – low) is determined by a qualitative assessment of the likely number of entities concerned as well as the frequency and complexity of the required data.

Significant burdens will then be quantified (monetary estimates) on the basis of the **EU Standard Cost Model** (see Box 3).

A greater level of detail is expected for the monetary assessment of administrative burdens stemming from the preferred option. This detailed application can be divided in a number of steps. The entire workflow is summarised in Table 1, followed by a description of each step.

Table 1: Step by step application of the model

Phase I: Preparatory analysis	
Step 1	Identification and classification of additional administrative obligations and obligations eliminated at EU/national level (e.g. labelling of products) and its specific requirements (e.g. the label must provide the date of production and composition of the product)
Step 2	Identification of required complementary actions (e.g. training members and employees about the information obligations, filling forms)
Step 3	Identification of target group(s), also called segmentation (e.g. large enterprises that have to fulfil obligation 'A' and small enterprises that have to fulfil obligation 'B', the size of the enterprise being defined by its

	turnover)
Step 4	Identification of the frequency of required actions (e.g. enterprises have to fill a form once a year)
Step 5	Identification of relevant cost parameters (e.g. particular relevance of external costs – using accounting firms – and equipment) Qualitative assessment of significant burdens (i.e. applying a threshold test to determine which information obligations need to be quantified)
Step 6	Choice of data sources and, if necessary, development of data capture tool(s) (e.g. deciding that the number of entities concerned will be extrapolated on the basis of data available on Eurostat, but that the number of hours each need to perform required actions will be based on the results of interviews of enterprises; for the latter task, preparation of an interview guide and selection of a representative sample of entities including organisations representing citizens)
Phase II: Data capture and standardisation	
Step 7	Assessment of the number of entities concerned (e.g. 100 000 SMEs) (For businesses, this step requires the knowledge of the market structure in the regulated sector.)
Step 8	Assessment of the performance of a ‘normally efficient entity’ in each target group (e.g. enterprises spend once a year, on average, 25 hours of work by an engineer to gather information and 5 hours of work by a clerk to fill the annual form)
Phase III: Calculation and reporting	
Step 10	Assessment of the ‘business as usual’ costs, extrapolation of data to EU level (assessment of the proportion of the costs that would have been borne even if there was not obligation at the EU level, e.g. a company would have to present financial reports even if there were no EU rules on that and the cost of such reports could be similar)
Step 11	a) Reporting in an impact assessment and – for business costs – in the ‘one in, one out’ online calculator. b) If no impact assessment is conducted due to political urgencies but should have been, then reporting is done in post-adoption document published within three months after the adoption.

Step 1: Identification and classification of administrative obligations

To facilitate the assessment of administrative costs and to improve data analysis (identification and comparison of the most burdensome types of obligation across various

sectors), services are asked to use the following typology of the administrative obligations (Box 4) when inserting relevant information obligations in the dedicated online OIOO calculator for the reporting of administrative costs.

Box 4. Types of administrative obligations

- Notification of (specific) activities or events (e.g. for transportation of dangerous cargos; when an accident affects the environment)
- Submission of (recurring) reports (e.g. annual accounts)
- Information labelling for third parties (e.g. energy labelling of domestic appliances; price labelling)
- Non labelling information for third parties (e.g. financial prospectus)
- Application for individual authorisation or exemption i.e. obligation to fulfil each time a particular task has to be carried out (e.g. building permits; road transporters applying to be exempted from Sunday driving ban)
- Application for general authorisation or exemption (e.g. license granting permission to engage in an activity such as banking or liquor selling)
- Registration (e.g. entry in a business register or a professional list)
- Certification of products or processes, i.e. obligation to deliver a certificate (e.g. treatment facilities having to issue a certificate of destruction of a vehicle) or to get a certificate (e.g. aeronautical products and organisations involved in their design, production and maintenance must get the certification of the European Aviation Safety Agency – EASA)
- *Inspection on behalf of public authorities (e.g. businesses having to monitor working and other conditions for employees, such as those related to occupational health and safety)**
- *Cooperation with audits & inspection by public authorities or their appointees (e.g. obligation to cooperate with workplace inspection), including maintenance of appropriate records (e.g. obligation for treatment facilities to keep records about waste electronic equipment entering and leaving the treatment facility; obligation for hotels to keep a visitor log; these records must be presented during the inspection)**
- *Application for subsidy or grant (e.g. to structural or cohesion funds)**
- Other

* This type of administrative cost is not subject to offsetting in the context of the 'one in, one out' approach (see also Tool #59 (*Cost estimates and the 'one in, one out' approach*))

Distinguishing an administrative obligation from other regulatory obligations is normally straightforward. There could however be a number of **borderline cases** where it is difficult to decide whether an obligation falls within the scope of the model or not. Ideally, such borderline cases are assessed to ensure consistency with respect to the decisions taken in other similar areas.

Box 5. Examples of borderline administrative obligations

- Costs induced by exercising a right to complain. These costs are not considered as an administrative cost by Member States quantifying administrative costs using the Standard Cost Model because there is no ‘obligation’ to complain.
- Costs induced by inspection. The usual purpose of an inspection is to collect the information needed to verify compliance with legal obligations (review of corporate books, etc.). Ensuing costs are clearly administrative costs. However, inspections are sometimes used to collect information unrelated to legal obligations (level of satisfaction of businesses, etc.). Submitting to such inspection is by definition voluntary and ensuing costs therefore fall outside the definition of administrative costs imposed by legislation.
- Costs induced by policy assessment. Some EU programmes require Member States to draw up national reform programmes. Designing a reform programme is quite different from an obligation to provide information. However, designing monitoring schemes, collecting data on the implementation of the policy, filling tables and submitting them to the Commission are clearly linked to information obligations. So policy design should not be considered as administrative cost, but the design of policy assessment should.
- Costs induced by the obligation of drawing safety plans. Some EU acts require businesses to design staged evacuation strategies, conduct exercises to verify that everyone knows what to do and when, etc. (e.g. plans for so-called Seveso establishments, airports, etc.). This is of course quite different from an obligation to provide information; resulting costs should therefore not be considered as administrative burden. The only eligible costs here basically are those linked to the obligation to collect information about impending risks (safety plans must often be based on a risk assessment) and the obligation to file and/or send the safety plan.
- Testing costs. When business have to submit their products & processes to a test in order to get an authorisation or a certificate, these testing costs are not considered as administrative costs.
- Some EU legislative acts and proposals also mention the possibility for Member States to ask for additional information (i.e. ‘...*Member States may ... require the inclusion of other statements in the annual accounts in addition to the documents referred to in the first subparagraph ...*’). Such possibilities are not to be included as EU administrative obligations, insofar as Member States are not obliged to ask that information. Nevertheless, such possibilities should be documented as they often pave the way for Member States’ additions (‘gold-plating’).

Step 2. Identification of required complementary action

The services are asked to use the following typology on the type of required action.

Box 6. Types of required complementary action

- Familiarising with the information obligation
- Training members and employees about the information obligations
- Retrieving relevant information from existing data
- Adjusting existing data and producing new data
- Designing information material (e.g. leaflet conception)
- Filling forms and tables (including recordkeeping)
- Holding meetings (internal/external with an auditor, lawyer etc.)
- Inspecting and checking (including assistance to inspection by public authorities)
- Copying (reproducing reports, producing labels or leaflets)
- Submitting the information to the relevant authority (e.g. sending it to the relevant authority)
- Filing the information
- Buying (IT) equipment & supplies (e.g. labelling machines) to specifically used to fulfil information obligations
- Other

Step 3. Classification by regulatory origin

In order to enhance transparency on who is responsible for what, the **regulatory origin of administrative obligations** needs to be identified. In the context of the impact assessment, services are only requested to determine costs originating from the EU level, not those that may originate at national or lower levels. When the Commission assesses a possible measure, there is no point guessing what level of 'gold-plating' transposing authorities in each Member State might introduce. The Commission only has to account for proposals transposing international obligations in the EU and those resulting from its own initiative.

Two simple rules should be used for this:

- If the obligation arises entirely from an EU Regulation, i.e. needs implementation into the national legislative frameworks without any changes, 100% of costs induced by the obligation should be assessed.
- If the obligation is set in EU Directive, i.e. requires transposition by Member States and they do not limit themselves to what is needed to meet the obligation (by 'gold-plating'), attribute only the percentage of costs resulting from the obligation set in the EU legislation. 'Gold-plating' in the case of administrative obligations refers, among other things, to increasing the reporting frequency, to add 'data requirements' or to

widen the target groups. Naturally, only evaluations, not impact assessments, can assess the size of 'gold-plating'.

Step 4. Identification of target groups

As for the target groups, it may be useful to distinguish between groups on the basis of their size, type or location. Size may be particularly pertinent for enterprises. It is indeed often the case that an obligation is more burdensome for small enterprises than for large ones benefitting from economies of scale. Regulation often adjusts the type of administrative obligations according to a number of objective criteria (number of employees, turnover level, financial capacity of the citizens, etc.). A more in-depth knowledge of the market structure in the regulated sector is required to be able to properly identify the affected groups if they are not specifically targeted by the initiative.

Step 5. Identification of the frequency of required actions

The frequency indicates how many times per year an action is required⁸³⁴.

In some cases, the frequency may vary in time. For instance, in a number of statistics regulations such as Intrastat⁸³⁵, enterprises have to report if their dispatches are above a set threshold. Their level of intra-EU sales will therefore determine if they have to report or not. Here again, the advice is to keep things simple and proportional. If such fluctuations concern a limited number of enterprises, they should not be considered.

Step 6. Identification of relevant cost parameters

The relevant cost parameters are determined by the core equation of the standard cost model (see Box 3). It is assumed that the main costs induced by administrative obligations are **labour costs**. Where appropriate, **equipment or costs of supplies** per action should be considered or used as the basis for analysis (rather than taking time as the basis unit).

The cost parameters for the *price per action* (administrative action carried by the targeted entity itself) are the (i) **number of minutes spent on a specific action**, (ii) the **hourly pay** of those performing the action. This hourly pay should correspond to the gross salary plus overheads costs (25% by default)⁸³⁶.

The cost parameters for *equipment & supplies* (i.e. acquired by the targeted entity to comply with the information obligation and solely used for that purpose) are the **acquisition price** and the **depreciation period** (service life of 'x' years)⁸³⁷.

The cost parameters for the *outsourcing costs* (administrative action contracted out) are what the service provider charges on average per administrative obligation, per entity and per year.

⁸³⁴ By definition, that notion does not apply to one-off costs such as 'familiarising with the information obligation'.

⁸³⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l11011a>

⁸³⁶ The current tariffs are available in the dedicated online OIOO calculator for the reporting of administrative costs.

⁸³⁷ For instance, barcode printer and scanner.

Step 7. Choice of data sources and, if necessary, development of data capture tool(s)

Data collection methods can differ for individual cases and include focus groups, consultation of stakeholders, field trials, consultancy studies, and expert assessment. Irrespective of the source and mode of collection, the collected data needs verification and interpretation.

In standard cases, it will be sufficient to produce overall estimates based on the method above as well as on available EU statistics;

In exceptional cases, field work limited to a sample of Member States and/or questionnaires sent to a standard sample of the business community or organisations representing individuals (for example, consumers), and simulation may have to be used.

Step 8. Assessment of the number of entities concerned

In order to ensure comparability of estimates made by different DGs, the assessment of administrative costs should be based on the basis of an **assumption of full compliance by all entities concerned**. All the assumptions concerning population size (e.g. SMEs), in particular for proposals with long time horizon, should be clearly explained.

Step 9. Assessment of the performance of a 'normally efficient entity'

In order to keep assessment of costs at a reasonable level and ensure comparability, the **assessment will be based on representative types** (typical firms, typical public service, etc.).

The assessment begins with a critical review of available data, identification and removal of obvious outliers (entities whose performance is clearly atypical, i.e. greatly below or above the other performances). In many cases, calculating the median or the average of remaining data might be sufficient.

In addition to the **number of minutes**, the 'normal' level of qualification required by the main actions linked to information obligations and the **'normal' labour cost per hour** including prorated overheads (expenses for premises, telephone, heating, electricity, IT equipment, etc.) will have to be determined.

Step 10. Assessment of the 'business as usual' costs and extrapolation of validated data to EU level

As the aim of the EU standard cost model is to assess the additional burdens originating from EU legislation, one should assess what **part of the costs of administrative obligations would have been borne even in the absence of EU legislation**. For instance, if a company is obliged under an EU Regulation to report on greenhouse gas emissions but would have been obliged to report under national rules on CO₂ emissions only, the burden stemming from EU legislation relates only to reporting on additional greenhouse gases and the 'business as usual' factor amounts to, e.g. 60%.

There is **no need to provide specific estimates for each Member State** or administrative body concerned, unless to do so would be proportionate. In most cases, EU costs will be

estimated by extrapolating available data at national or EU level by considering the number of affected entities across the EU.

Step 11. Report

Estimates of administrative burdens **need to be reported in an impact assessment at least for the preferred option in the obligatory Annex 3 ('who is affected and how')**. If the initiative is likely to generate significant administrative burdens by its nature or such costs are a significant distinguishing factor among the considered options, they should be reported for all the options.

For any initiatives introducing new or removing existing recurring administrative burdens, such costs should also be reported by means of a dedicated online OIOO calculator⁸³⁸ that supports reporting on the application of the 'one in, one out' approach.

⁸³⁸ [The online OIOO calculator](#)

TOOL #59. COST ESTIMATES AND THE ‘ONE IN, ONE OUT’ APPROACH

1. INTRODUCTION

The Commission has committed to the ‘one in, one out’ (OIOO) approach⁸³⁹. This means **offsetting new burdens⁸⁴⁰ resulting from the Commission’s proposals⁸⁴¹ by reducing existing burdens in the same policy area**. The ‘better regulation’ Communication of 29 April 2021, COM(2021) 219 final, sets out the main principles of the approach. Burdens shall be identified through cost estimation methods. The present tool gives practical guidance on how to estimate costs and report them for the purpose of OIOO. The tool links closely to tools #56 (*Typology of costs and benefits*), #57 (*Methods to assess costs and benefits*) and #58 (*EU Standard Cost Model*).

2. SCOPE OF COST ESTIMATES

OIOO is based on cost estimates for how proposals affect businesses and citizens. Hence, **impact assessments accompanying proposals will need to consider whether these would have significant⁸⁴² cost implications for businesses and citizens⁸⁴³**. This will need to be done already at the planning stage to identify necessary data collection and analytical work to be undertaken for the impact assessment.

In the Decide entry, services should specify if the case is likely to have significant costs implications (add or remove compliance costs, i.e. administrative and/or adjustment costs). The REFIT box must be checked, if the file is a revision of existing legislation, as all revisions must seek burden reduction and simplification, or justify if this is not the case. For relevant cases, necessary data collection and analytical work will have to be planned and carried out.

For most proposals with significant cost impacts on businesses and citizens, an impact assessment will be produced. This is because significant cost implications would tend to overlap with the ‘significant impact’ criterion for impact assessments⁸⁴⁴. In these cases, the impact assessment will be the basis for the calculation and presentation of the cost estimates. In cases where the Commission was unable to produce an impact assessment where one should have been prepared, cost estimates will be presented in an analytical SWD, which shall present and justify the cost estimates made⁸⁴⁵.

⁸³⁹ See Political Guidelines of President von der Leyen, ‘better regulation’ Communication COM(2021) 219).

⁸⁴⁰ As defined in Tool #58 (*EU Standard Cost Model*)

⁸⁴¹ Legislative proposals and delegated and implementing acts.

⁸⁴² In line with proportionality, cost estimates are prioritised for cases with significant costs. This means that OIOO does not cover proposals, which entail negligible administrative costs for businesses and citizens. Costs may be negligible either because the proposal does not involve businesses or citizens very much or because ins and outs in a proposal offset each other. ‘Significant costs’ relates to the overall magnitude of a burden as stemming from the substance of the requirements, the number of affected business/citizens (i.e. the impact on a large number of business, relevance for SMEs and micro businesses, etc.). If in doubt, consult the ‘better regulation’ functional mailbox.

⁸⁴³ Consequently, OIOO does not concern cost implications for Member States, national and regional authorities or public administrations. Furthermore, OIOO only concern businesses in the EU and EU citizens.

⁸⁴⁴ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁸⁴⁵ Where an impact assessment should have been prepared, but it wasn’t, estimates of costs and benefits should be presented in analytical reports alongside the proposal or within 3 months, explaining clearly how they have been calculated.

Commission services must identify relevant cases with significant costs implications – starting with the **Commission work programme** and make sure that the required work is undertaken to produce all relevant estimates. The Secretariat-General will help ensure that relevant cases are identified and that the OIOO procedures are followed.

3. THE NATURE OF COMMISSION COST CALCULATIONS

The Commission will not be able to anticipate how Member States intend to transpose, implement, and enforce its proposals, after they have been amended and adopted in the legislative process. For this reason, cost calculations at the level of the Commission legislative proposal do not account for the specific implementation, enforcement modes and efficiency of public authorities in 27 different Member States. Instead, Commission cost calculations are based on working assumptions simplifying the complex reality of the Union and are meant to convey magnitudes of the costs involved to policy makers. For this reason, describing assumptions and uncertainty is important.

Costs can be estimated based on a variety of sources. These may include:

- data obtained from Member States, public authorities, agencies, etc.;
- data from public or targeted consultations, stakeholder workshops, surveys or similar;
- evidence provided by social partners and representatives of economic and professional interests;
- results of SME panels;
- evaluations;
- reports and studies from consultants and academics.

4. APPLICATION OF THE 'ONE IN, ONE OUT' APPROACH

4.1. Compliance costs

Compliance costs are all costs directly linked to the compliance with a law. These consist broadly of adjustment and administrative costs. The OIOO mechanism rests on these two legs.

- **Adjustment costs** refer to incremental costs for investments, equipment, etc. relating to adjusting to the substantive legal requirements of proposals. See Tool #56 (*Typology of costs and benefits*) for a precise definition.
- **Administrative costs** are costs that result of administrative activities performed to comply with administrative obligations included in legal rules. They concern costs for providing information, such as notification of activities, submission of reports, information labelling and certification of products or processes. See Tool #58 (*EU Standard Cost Model*) for precise definitions.

All relevant compliance costs or savings should be estimated, be it adjustment or administrative costs, one-off or recurrent costs, direct or indirect costs, to the extent that this is feasible. Tools #57 (*Methods to assess costs and benefits*) and #58 (*EU Standard Cost Model*) provide all the steps to follow for cost estimations. If it is not possible to provide a quantitative estimate, a qualitative estimate should be made. The Regulatory Scrutiny Board will review costs estimates as part of the regular scrutiny of impact assessments.

Adjustment costs and administrative costs will be treated in a different way within the OIOO approach, as follows.

4.2. Adjustment costs

DGs shall estimate adjustment costs for business and citizens in impact assessments, to the extent that this is feasible and proportionate.

Adjustment cost are the incremental costs – other than fees and administrative costs – to the target group. They cover elements such as direct labor costs, overheads, equipment costs, material costs, cost of external services and implementation costs⁸⁴⁶.

Box 1: Steps for estimating adjustment costs

- 1) Identify substantive requirements that legislation (in line with the preferred option) will impose on citizens and/or business⁸⁴⁷;
- 2) Estimate the number of businesses and citizens who will be affected by the proposal.
- 3) Estimate the adjustment net costs for a 'normally efficient business' or citizen;
- 4) Estimate the 'business as usual' factor⁸⁴⁸;
- 5) Consider special groups (SMEs, micro businesses, etc.);
- 6) Estimate adjustment costs for every substantive requirement;
- 7) Estimate whether adjustment costs are likely to change over time (i.e. correct for digitalisation);
- 8) Sum up and extrapolate⁸⁴⁹, if necessary.

Adjustment costs shall be presented transparently and systematically in impact assessments when discussing the preferred option. A specific section will illustrate the application of the OIOO approach for all relevant initiatives in the following way:

- adjustment cost estimates for business and citizens will be illustrated for each category, where possible;
- benefits will be quantified to the extent possible, as an order of their magnitude (or at least with a solid qualitative analysis);
- sources of estimates will be referenced, and data limitations shown transparently;
- if models are applied, they will be referenced in [MIDAS](#);
- where possible, existing or included compensatory measures⁸⁵⁰ for business will be identified.

⁸⁴⁶ See Tool #56 (*Typology of costs and benefits*) for more details.

⁸⁴⁷ If the impact assessment has no preferred option, the cost estimates will reflect the choice of the actual proposal. In this case, cost estimates can be presented in the explanatory memorandum.

⁸⁴⁸ 'Business as usual' costs are those that the business would have incurred even in the absence of the proposal. For instance, a proposal may lead to changes, which have already been introduced in national legislation in some Member States or it may already be a business practice in certain sectors. Certain costs may turn into 'business as usual' costs over time as they are integrated in standard business practices.

⁸⁴⁹ In some cases, individual company data or data from a few Member States will need to be extrapolated to the EU level.

Adjustment costs and benefits will be specified in the obligatory summary table of the Annex 3. Under the preferred option, relevant initiatives will summarise:

- adjustment costs estimates (as explained in box 1) and benefits of the proposed option⁸⁵¹;
- administrative costs that will be offset.

Adjustment costs in the short term can lead to business opportunities in the longer term. For example, the twin transition might entail short-term costs and financing that, in the medium term, will make Europe more resilient to the benefit of the wellbeing of citizens and firms, by allowing business to have first-mover advantages, acquire new markets and introduce more efficient business models. Some of these advantages cannot be monetised and go beyond GDP⁸⁵², to increase the overall resilience of the system.

Adjustment costs will be **compensated** to the greatest possible extent to cushion the short-term effects of these measures and allow businesses to overcome any adjustment and other costs in the short term. An example of such broad compensations are initiatives such as the Next Generation EU⁸⁵³.

Companies may also benefit generally from the support provided to other sectors, for instance, education and research, infrastructure, etc. including that directed to Member States, public entities, etc.

These compensatory measures will help mitigate the costs of adjustment. They will provide broad or targeted relief, which will support business facing these costs. These compensatory measures, where the case, will be presented in the relevant impact assessments to the extent possible. Any further follow up compensatory measures will be presented in the Annual Burden Survey.

4.3. Administrative costs

Administrative costs, when significant, will be **offset**⁸⁵⁴. To do so, they need to be identified, estimated, reported, and made comparable (monetised) so that they can be aggregated. While the standard cost model is useful (see Tool # 58 (*EU Standard Cost Model*)), and services should strive to apply it as much as possible, it is not obligatory to apply all its dimensions, given that the information required for it may not be available (such as estimated time used, or the number of businesses affected).

⁸⁵⁰ Impact assessments shall present mitigation measures taken in context of the proposal and/or refer to compensatory measures already in place.

⁸⁵¹ Compensatory measures, where the case, will be presented in the relevant impact assessments to the extent possible.

⁸⁵² This is in line with the Commission's ambition, stated in COM(2020) 493 final, to find new metrics to measure progress beyond GDP, whereby resilience dashboards are being developed.

⁸⁵³ [Recovery plan for Europe | European Commission \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/pages/press-room.aspx?pid=14737)

⁸⁵⁴ In many cases businesses would have to bear costs even if there was no obligation at the EU level in a given policy area (the 'business as usual' costs). The offsetting is applied only to the remaining administrative burden defined as administrative costs minus 'business as usual' costs, see Tool #58 (*The EU Standard Cost Model*). The OIOO calculator will help services calculate the right estimate based on information about administrative costs, etc.

Both administrative costs for citizens and business will be reported. Cost for citizens will be treated on a par with costs for business.

Several issues should be considered when undertaking estimates for administrative costs:

- **Consideration of costs in European Commission proposals only:** OIOO only applies to cost implications originating from Commission proposals. Hence, costs imposed by other parties – for instance added by co-legislators or by Member States and local, regional authorities – are not included⁸⁵⁵.
- **‘Business as usual’ costs are excluded**⁸⁵⁶: Cost estimates should only cover the impact of new regulatory requirements. For instance, for some Member States, a certain administrative requirement may already be in place. Hence, to the extent that new elements overlap with existing processes, the ‘business as usual’ costs should be subtracted in cost estimates for OIOO. This goes also for revisions, where cost estimates should only account for new costs added or subtracted, not costs incurred by existing legislation. Information available as ‘business as usual’ information may however vary from one Member State to the other and between sectors as well. This should be accounted for to the extent possible. See Tool #58 (*EU Standard Cost Model*) for more precise methods to account for ‘business as usual’ costs. When introducing a new requirement, administrative cost may be significant, but, over time, requirements may become normalised in the business context – integrated in the standard business processes and accounted for in the general framework. Thus, costs from new requirements may become ‘business as usual’ costs over time.
- **Account for single market simplification:** In cases, which involve a certain harmonisation of requirements across EU Member States, the resulting simplification of the regulatory framework in the single market should be considered. For instance, when one common EU standard replaces 27 different standards, businesses active cross border in the internal market will experience a simplification in the regulatory environment that needs to be considered. Plausible assumptions may have to be made, for instance based on existing performance of Member States or lessons learned in evaluations. See dedicated tool on the internal market (Tool #25).
- **Cost implications in evaluations and fitness checks:** Cost implications (in particular the ‘outs’) are not always linked to important new proposals. They may occur, for example, when digitalisation projects streamline existing reporting and monitoring processes; or when initiatives bring important legal clarity to a policy area, where practices have previously been diverging and uncertainly prevailed. Evaluations and fitness checks can also lead to corrections in previous cost estimates by providing real evidence of how requirements are handled in reality. This may lead to adjustments. Such cost implications may be documented in evaluations or fitness checks⁸⁵⁷.

4.4. Reporting administrative costs

For administrative costs, the online Administrative Burden Calculator should be used. The Commission has developed a dedicated calculator for reporting administrative costs for

⁸⁵⁵ Costs imposed through proposals transposing international agreements already endorsed by Member States are also exempt from OIOO. Legal proposals reflecting European Citizens’ Initiatives are exempt.

⁸⁵⁶ See Tool #58 (*EU Standard Cost Model*) for further info about ‘business as usual’ costs.

⁸⁵⁷ Such cost implications will have to be linked to Commission initiatives. There will obviously be a certain time lag in the recording of such estimates.

the purpose of OIOO and administrative burden reduction targets. The calculator is based on the EU standard costs model but allows aggregation by policy area and greater flexibility in reporting data. Nonetheless, it will remain important to be transparent in the impact assessment report about how the estimates have been produced and on which basis they rely.

Services shall make sure that every proposal with significant administrative cost implications is recorded in [the online Administrative Burden Calculator](#)⁸⁵⁸. Impact assessments are the standard basis for this recording.

The calculator provides a flexible module for recording cost estimates (ins and outs) for offsetting under OIOO. Cost estimates shall be recorded in the tool at the latest at the time of adoption of the Commission proposal⁸⁵⁹, although it is recommended to do this at the time of submission of the documents to the Regulatory Scrutiny Board.

If you have practical difficulties in applying it, please contact SG-BETTER-REGULATIONS@ec.europa.eu. If you have IT related questions to the calculator, please contact the IT helpdesk.

Box 3: Requirements for reporting OIOO administrative costs

Cost estimates for OIOO to be reported in the calculator will have to be calculated as follows:

1. Entries in the calculator shall result in one single administrative burden (administrative costs minus business-as-usual costs) estimate per entry (impact assessment/proposal/initiative). This can be positive (ins) or negative (outs). One single amount per act⁸⁶⁰ or per initiative per year (in EUR). While there can be different underlying elements (ins and outs), these will have to be summed up to provide one single number per initiative.
2. Cost estimates shall be specified in absolute amounts (EUR). Thus, it is not possible to specify costs per procedure, per unit or as a share of turnover or investments or similar.
3. Costs can be estimated and reported in the impact assessment and elsewhere as a range with a minimum and maximum, reflecting the level of uncertainty of the estimate. However, for the purpose of OIOO, a single value (for example the average/median value) will have to be reported. The level of uncertainty can be indicated in the comments field.
4. Costs reported from proposals with joint DG responsibility can be assigned to the DGs proportionately.

⁸⁵⁸ Access to the tool is restricted to the ‘better regulation’ functions in the DGs. For receiving access to the tool, please contact SG BETTER REGULATIONS.

⁸⁵⁹ In cases where an impact assessment was not carried out due to urgency, a SWD will be published maximum three months after adoption (see COM (2021) 219). In such cases, the deadline for recording cost estimates in the online OIOO calculator will naturally follow the SWD.

⁸⁶⁰ For cases where the impact assessment results in more than one legislative initiative, the administrative costs should be introduced in the impact assessment, i.e. per initiative, not per each legislative proposal. These may include directives/regulations as well as delegated and implementing acts.

4.5. Offsetting of administrative burdens

The offsetting of administrative burdens will take place through an **offsetting hierarchy**:

- 1) First, burdens will have to be offset within the remit of each DG.
- 2) If this is not possible, burdens will be offset within the REFIT area⁸⁶¹ directly affected by the proposal.
- 3) If this is not possible (e.g. in the case of a cross-sectoral initiatives or where the Directorate-General does not produce sufficient legislation or the existing legislation in the policy domain is recent), the costs will be offset within the broader policy areas, i.e. the Commission work program's headline ambitions. The six headline ambitions of the European Commission define the policy areas:
 - A European green deal;
 - A Europe fit for the digital age;
 - An economy that works for people;
 - A stronger Europe in the world;
 - Promoting our European way of life;
 - A new push for European democracy.
- 4) If the proposed legislation is deemed to be necessary, but it is not possible to find an 'out' in the same area, the Commission can, in exceptional cases, decide to take the 'out' from a different policy area, thus 'trading' can take place **between policy areas**.
- 5) If an 'out' cannot be identified in the same year, costs will be reported to the next year. Hence, OIOO accounts will not balance every year, but should balance **over time**.

Furthermore, the Commission can – in exceptional cases – decide to exempt an initiative from OIOO and from offsetting. This may apply to regulations in emerging areas, where it is necessary to fill a regulatory gap. Services should signal the request for exempting an initiative from OIOO and explain the reasons. The exemption is granted by the College following a presentation by the Commissioner responsible for 'better regulation', and the explanation will be provided in the explanatory memorandum of the proposal.

Services who wish to exempt a proposal from the 'one in, one out' approach should send a reasoned request to the functional mailbox: SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu.

⁸⁶¹ i.e. agriculture and rural development; climate action; communication networks, content and technology; competition; employment, social affairs, inclusion and education; energy; environment; financial stability, financial services and capital markets union; health and food safety; internal market, industry, entrepreneurship, SMEs and statistics; justice, consumers and gender equality; maritime and fisheries policy; migration and home affairs; mobility and transport; regional and urban policy; research and innovation; taxation, customs union and anti-fraud; trade and external action.

5. FINAL COMMENTS

While DGs shall prepare the cost estimates and enter them in the dedicated online Administrative Burden Calculator, Secretariat-General will aggregate estimates in view of offsetting and reporting for the Annual Overview Report. Specific impact assessment, SWDs and explanatory memoranda shall refer to offsetting measures only when these are inherent to the proposal. The offsetting will be reported in the Annual Overview Report, based on the offsetting hierarchy indicated above.

6. REFERENCES

- 'Better regulation' Communication ([COM\(2021\) 219 final](#))
- Dedicated [online Administrative Burden Calculator](#)
- 'Better regulation' toolbox, notably Tools # 56 (*Typology of costs and benefits*), #57 (*Methods to assess costs and benefits*) and #58 (*EU Standard Cost Model*).
- OECD: One-In, X-Out: regulatory offsetting in selected OECD countries (OECD regulatory policy working paper). <https://doi.org/10.1787/67d71764-en>
- OECD (2014), OECD Regulatory Compliance Cost Assessment Guidance, OECD Publishing. <http://dx.doi.org/10.1787/9789264209657-e>
- [European-Commission-Admin-Burdens-Cost-Model-Manual-2006.pdf \(regulatoryreform.com\)](#)

TOOL #60. BASELINES

1. WHAT ARE BASELINES?

The ‘better regulation’ guidelines state that the design of possible policy options should always consider the option of changing nothing and use this as the **benchmark against which the policy option(s) should be compared**. This benchmark is usually referred to as baseline⁸⁶² (scenario).

As described in Tool #11 (*Format of the impact assessment report*), a baseline is a ‘no-policy-change’ scenario which **includes all relevant national, EU-level and global policies and measures which are assumed to continue to be in force**. In addition, (relevant) Commission proposals even if not yet adopted by the co-legislator can also be included⁸⁶³.

In general, one should define the baseline such that it allows to assess the environmental, economic and social effects of the policy initiative. For the sake of coherence, where two or more initiatives are being developed simultaneously, or presented together (e.g. as a ‘package’) each impact assessment report should use the same baseline. It may be useful to consider alternative baselines to demonstrate the impacts of other related initiative(s) or proposals.

Baselines are not only relevant in impact assessments (as defined in Tool #11), but also in evaluations (Tool #46 (*Designing the evaluation*)). Due to the different nature of the evaluations, their baselines can be different from the general approach for impact assessments. The evaluation will assess the intervention against this baseline (or point of comparison). This can be for example the situation before the intervention started (T0), the dynamic no-change scenario in the impact assessment (baseline), or the situation expected to be achieved at that point in time (preferred option). Different points of comparison may help to assess different evaluation criteria and the evaluation should clearly explain the choices made.

Both for evaluations and for impact assessments, the baseline should develop an appropriate time horizon to allow for the expected impacts to be realised. It will also be relevant to include expected socio-economic developments (aging, GDP growth, etc.) as well as important technological/societal developments, including foresight elements such as megatrends (Tool #20 (*Strategic foresight for impact assessments and evaluations*)). Baselines should be quantified as far as possible, although in many cases baselines of impact assessments and evaluations are of qualitative nature.

Much of the remainder of this tool will focus on the quantification of baselines, alternated with recommendations that are valid for both quantified and qualitative baselines.

2. QUANTIFICATION OF BASELINES

In the European Commission, the reference scenarios for [Energy, Transport and Green House Gas Emissions](#) or the [Agricultural Outlook](#) are examples of detailed, quantified and

⁸⁶² Alternatively, the term ‘reference scenario’ is used instead of ‘baseline scenario’, but the two notions usually carry the same meaning.

⁸⁶³ Where it is clear that a subsequent legislative procedure will deliver a substantially different outcome to the Commission’s original proposal, this outcome should also be reflected in the baseline.

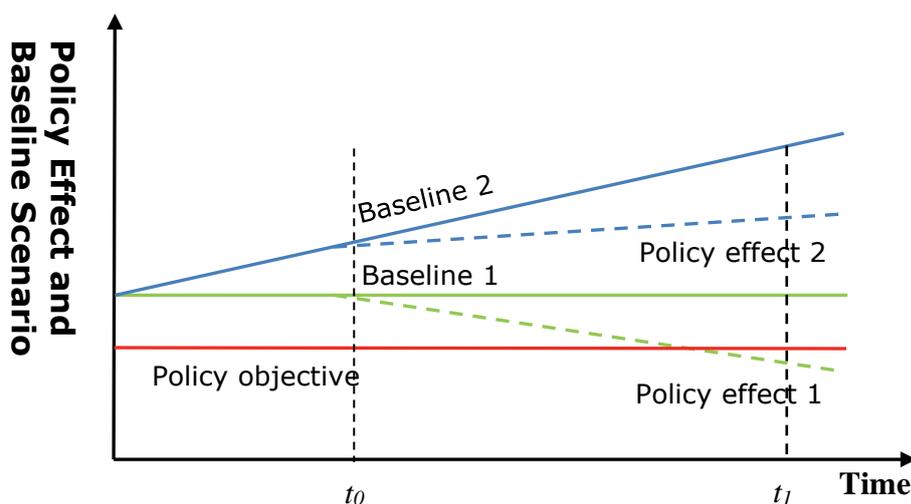
comprehensive scenarios, which are produced regularly and involve a large number of variables and assumptions.

A baseline scenario is a projection based on a number of baseline assumptions and status quo policies as input(s). Broadly speaking, baseline assumptions are all (implicit and explicit) assumptions underlying a baseline scenario. These baseline assumptions could come from different methodologies such as a forecasting model; or alternatively be based on expert judgement. The values of these baseline assumptions may (or may not) change over the time horizon of the assessment. Relevant assumptions for most baselines include expected socio-economic developments (aging, GDP growth, etc.), technological/societal developments or megatrends. As such, baselines can be one of the channels to bring foresight (Tool #20) into the 'better regulation' framework.

2.1. Why do baseline assumptions matter?

The impact of a policy option typically is compared with a clearly defined baseline. If the baseline is ill-defined or poorly specified, then so will be the estimated effects of the policy.

Figure 1: Baselines and policy effects



Figure

1 illustrates the importance of a well-defined baseline. Consider a policy action that seeks to curb CO₂ emissions from road transport in absolute terms – the policy objective – by fostering the fuel efficiency of cars through restrictions on fleet consumption⁸⁶⁴. If the analyst assumes (in Baseline 1) that the total mileage (number of vehicles times kilometres driven) of cars remains largely constant, then a 10% improvement of fuel efficiency should reduce emissions by approximately 10% in the course of time as more efficient cars are put into service. If, on the other hand, total mileage is assumed to increase by 20% over time (in Baseline 2), say because there are more vehicles on the road, then a 10% efficiency improvement will not reduce emissions as required and additional measures may be needed.

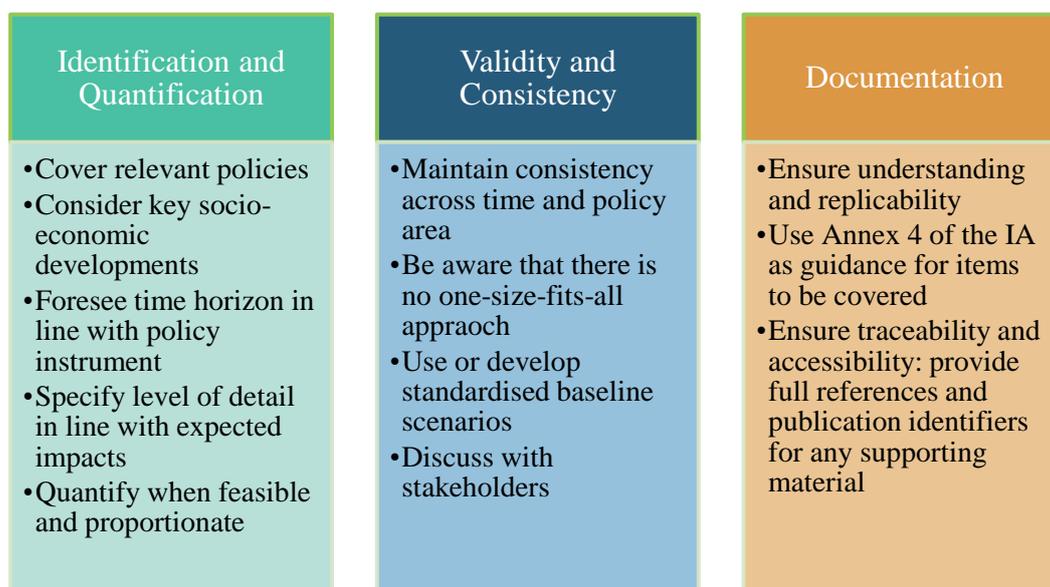
Since baseline assumptions are likely to evolve over time (for instance because of other ongoing policies or other exogenous changes), the policy effects in t_1 should ideally not be compared with the current situation (i.e. the situation in year t_0 or the *status quo*), but with the baseline in time horizon t_1 .

⁸⁶⁴ The example provided is illustrative and only serves to exemplify a complex situation.

Practical implementation steps

The identification of baseline assumptions and, subsequently, of a baseline scenario requires three key steps: Identification and quantification, Validity and Consistency checks, and Documentation (Figure 2).

Figure 2: Steps to be taken



2.2. Identification: what is to be considered?

Baseline assumptions should **include all relevant national, EU-level and global policies and measures**, which are assumed to be in force or to be implemented by the time the new policy proposal will take effect. In the above example in Figure 1, relevant policies include all policies other than the one to be assessed, which have an impact on the future mileage of cars. These may be closely related policies, such as excise taxes on fuel, but also policies in more remote fields such as investment in transport infrastructure. Where it is clear that a subsequent legislative procedure will deliver a substantially different outcome to the Commission’s original proposal, this outcome should also be reflected in the baseline.

Where the impact assessment concerns regulatory initiatives based on a legal obligation for the Commission to act (e.g. through delegated or implementing acts), **the baseline should be construed as a ‘no action’ reference scenario** which, serves primarily as a benchmark for comparing options.

Expected socio-economic developments and trends (aging, GDP growth, etc.) as well as **important technological/societal developments** inside and outside the EU, such as the pervasive nature of the internet, social media, and emerging technologies should be considered, provided they are deemed relevant for the policy field of the impact assessment, the baseline scenario, and the expected effects of the policy. Using again the above example, both growing GDP and shrinking household size may lead to an increase in the number of cars and thus change the baseline while increasing fuel prices may reduce the use of cars.

A complicating factor is that **the policy or legislation itself might envisage already an end date ('sunset clause')** and that a positive decision of the Commission and Legislator will be necessary to put in place a new policy regime. In such cases, it can be difficult to decide on the appropriate baseline. Two options are possible:

- Option 1: include the 'sunset clause' in the baseline if a comprehensive evaluation concludes that the policy is ineffective. Policy options would then include establishing a new action and the impacts would be measured against a no-policy baseline. This approach should, however, be avoided if there are clear political commitments to continue the policy in some form or another for reasons other than its effectiveness.
- Option 2: include a continuation of the current policy approach in the baseline even if it formally comes to an end, where, for example, a comprehensive evaluation concludes that the policy is effective. Given that the College or Legislator could (theoretically) decide not to propose or enact legislation, this approach should usually be accompanied by a policy option, which would explicitly repeal the current policy and would demonstrate the cost of the Union not acting ('the cost of non-Europe').

The most appropriate option has to be decided on a case-by-case basis considering the degree of political commitment to a continuation of the current policy and the results of evaluations and fitness checks.

Baseline assumptions should be determined for an **appropriate time horizon**. Its length depends on the likely lifetime of any individual option and on the expected timespan for impacts to be realised (which may occur long after the policy has ended).

Also the **level of detail and precision** should be chosen with care in order to avoid information overload while capturing the effects that are to be examined. In model-based impact assessments, the baseline assumptions of the impact assessment correspond in principle to those of the underlying model(s) and should therefore cover all relevant assumptions underpinning the model itself, its application and implementation.

Baseline assumptions and the resulting scenario(s) should, whenever and wherever possible, **be quantified**. In doing so, analysts should draw upon the best available evidence, expert judgement and scientific knowledge, and being aware of plausible surprise events or other kinds of discontinuities. Such events, for instance a political conflict leading to a sharp increase in fuel prices, may have a significant impact on the environment, in which the policy measure is to be implemented, but do not result from a projection of past trends and may therefore be difficult to quantify. A false degree of precision should be avoided, meaning that it is important to be transparent with the limitations and error margins of the quantification values.

2.3. Consistency of baseline assumptions and scenarios

A set of baseline assumptions is consistent (with another set) if there are no logical and factual contradictions including significant differences within or between both sets. However, a baseline is also context-dependent and there may be differences across baselines for various reasons:

- **Same model – different policy areas:** when a model is used for assessing different policy fields, different (ideally, non-contradicting) baselines can be used.

- **Same area of analysis – similar models:** if similar models are used in the same policy field(s), their baseline may differ somewhat due to the different model structure and implementation of the (same) baseline assumptions (e.g. E3ME⁸⁶⁵ vs. JRC-GEM-E3⁸⁶⁶).
- **Same impact assessment – different models with shared assumptions:** if the impact assessment makes use of various models whose underlying assumptions overlap to some extent, i.e. which share some of the variables of the other models used in this impact assessment (e.g. GEM-E3 vs. POLES⁸⁶⁷).
- **Different impact assessment with different models with overlapping assumptions:** when impact assessments for different policy fields use different models with nevertheless significantly overlapping assumptions and variables such as data on GDP or population trends.
- **Same model – different points in time:** if the same model is used repeatedly over time in order to analyse similar policy actions, each time with a different set of assumptions.

Standardised baseline scenarios

Contradictions between baseline assumptions can undermine the credibility of impact assessments, and if they occur, should be explicitly recognised and fully justified. A comprehensive set of assumptions in a numerical context (e.g. the EU Reference Scenarios) help identify possible inconsistencies.

While avoiding contradictions can be regarded as a general principle of good governance, one should strive for consistency to facilitate comparability of impact assessments across time, policy area, or institution. From this, it follows that wherever possible, standardised baseline scenarios could be developed and used for various related policy fields.

The [EU Reference Scenario for energy, transport and climate policies](#) is a prime example. It is updated regularly and built upon a modelling framework in which simulation models across various policy fields consistently interact with each other. While the Reference Scenario has been developed for specific policy fields, it is also used in others. Consider therefore whether (parts of) the Reference Scenario is suitable for the impact assessment under preparation.

The yearly [EU Agricultural Outlook](#) is another example, based on a consistent set of assumptions regarding macroeconomic conditions, the agricultural and trade policy environment and market developments.

A third example are the [EU and Global macroeconomic baselines](#) which integrate macroeconomic projections and sectoral information in a consistent Input-Output framework.

Sharing baseline scenarios ensure consistency, transparency, and reduce the costs of carrying out impact assessments. At the same time, models can interact with each other through shared scenarios and assumptions whenever that is required for a specific impact assessment.

⁸⁶⁵ <https://www.e3me.com/>

⁸⁶⁶ <https://ec.europa.eu/jrc/en/gem-e3>

⁸⁶⁷ <https://ec.europa.eu/jrc/en/poles>

The preparation of reference scenarios requires close cooperation between modellers and policymakers as well as other relevant stakeholders such as national experts, market experts, and experts from private companies and international organisations.

Justified differences between baselines

The above arguments imply by way of inversion that baseline assumptions can be different in **some situations**. The most obvious case concerns impact assessments which are carried out at different points in time as this may imply that:

- data take on (a) different value(s) at different points in time,
- new evidence becomes available and/or previous evidence becomes obsolete,
- data collection or sampling methods (including measurement methods) are newly developed that allow a modified parametrisation of the model.

Other reasons for justified differences include:

- different sectoral, temporal or spatial granularities of data, e.g. because more data are collected allowing for further differentiation among sampled entities,
- different data requirements for the models used along the above dimensions of granularity, e.g. because some models allow for greater detail than others.

Before reusing a baseline scenario, analysts should therefore check whether the underlying assumptions are still fully justified or whether an update is warranted.

2.4. Documentation

All assumptions that have been made in the course of the analysis should be **documented in Annex 4** to the impact assessment (see Tool #11 (*Format of the impact assessment report*))⁸⁶⁸. This applies in particular to all numerical assumptions and chosen model parameters, if applicable, and other relevant numerical values. Where the analysis makes use of models or methodologies developed by third parties, only the idiosyncratic assumptions should be identified and documented. For all other assumptions, it is sufficient to provide references to manuals or other guidance that allow third parties to obtain information on these assumptions, as long as these references reflect the assumptions at the time of the impact assessment⁸⁶⁹.

3. ADDITIONAL INFORMATION

- [EU Reference Scenarios for energy, transport and climate policies](#)
- [EU Agricultural Outlook](#)
- [EU and Global macroeconomic baselines for policy assessments](#)

⁸⁶⁸ If your assumptions are equal to those used in a past impact assessment, please document them in Annex 4 anyway, to ensure maximum transparency. This is particularly true if the assumptions are based on those of a past impact assessment or reference scenario but have been partially updated to match the evolving policy landscape.

⁸⁶⁹ Note that especially manuals have the tendency to evolve over time. To ensure that all relevant information to understand the impact assessment remains traceable also considerable time after the impact assessment has been carried out, the references to manuals should include versioning information, and each version must remain traceable over time.

TOOL #61. SIMULATION MODELS

1. MAIN FEATURES

This tool gives an introduction to some practical considerations, if one chooses to use models for a policy analysis. **Models** are stylized representations of the real world that are used to make projections or to assess the behaviour of a system under specific (policy) assumptions. Models can provide support to policy makers throughout the policy cycle and across a wide range of policy areas. While all models are simplifications of reality, good models can provide useful insights and understanding if appropriately used. A good model selection and use is crucial to deliver high quality, policy relevant results. Simulation models can assess a wide array of **economic, social and environmental impacts**. A detailed description of all model types is well beyond the scope of this tool; some examples of commonly used model types for Commission impact assessments are listed in Box 1.

Box 1. Models used in impact assessment

Economic models used in impact assessments include *general equilibrium models*, that allow for consistent comparative analysis by ensuring that the economic system and individual markets remain in equilibrium in the long term; *econometric models*, estimated using historical time-series data, to capture medium/long-term effects from shocks and for forecasting; *partial equilibrium models*, used in the detailed analysis of one or more specific economic sectors over the short/medium/long term; and *micro-simulation models*, typically used for analyses at a detailed disaggregated level over the short term focusing on individuals, households or firms.

Environmental models can represent dynamics and impacts on resources such as water, air, land and on biological processes or assets. **Energy models** simulate energy systems and markets, while **transport models** allow the analysis of transport activities, related energy consumption and air emissions. Models are also used in a variety of other fields, such as to simulate **land use and population dynamics**.

By combining several models together, **integrated modelling approaches** allow assessing impacts in several policy areas. Ensuring coherence is of major importance when developing and building linkages between the models.

Ex-ante policy analysis and impact assessments can look at sustainable development through the overarching **sustainable development goals (SDGs)** framework, and models are a fundamental tool to understand the complexity of sustainability and development challenges, which often lie in multidisciplinary domains. Furthermore, achieving sustainable development requires a good understanding of the interlinkages (synergies and trade-offs) among the goals, and modelling can provide a concrete contribution to this. The JRC SDG Platform⁸⁷⁰ maps models with the SDGs framework at goal and target level, and links them with the EUROSTAT and UN SDGs indicators. This is a useful tool to support policymakers in identifying the appropriate model(s) for the assessment of their specific policy options.

In **impact assessments (IA)**, models are extensively used to assess the environmental, economic, and social impacts of policies. They are used for the problem definition, to contribute to the construction of baselines, and for the evaluation of existing policies. 16% of

⁸⁷⁰ <https://knowsdgs.jrc.ec.europa.eu/>. See also Tool #19 (*Sustainable development goals*).

all IAs carried out by the European Commission in the years 2003-2018 are supported by models, growing to 25-30% of IAs from 2015 onwards. Around 120 models have been used to this end (Acs et al., 2019). Policy areas characterised by frequent use of models in support of policy making in the EU include climate and environment, economics, transport, energy, trade, agriculture, and the complex interaction between sustainability and development (see Box 1).

Models can be used alone or in **combination**. Complementarities between different models should also be explored, as model types could offer a more accurate representation of some impacts in respect to others. Models can consistently interact with each other through shared scenarios and assumptions. For example, the development of EU Reference Scenarios combines models for the assessment of the impacts on economy, energy, transport, land use, agriculture, forestry and air quality⁸⁷¹. Figure 1 presents models used to inform the European Commission's 'A Clean Planet for all' (COM (2018) 773).

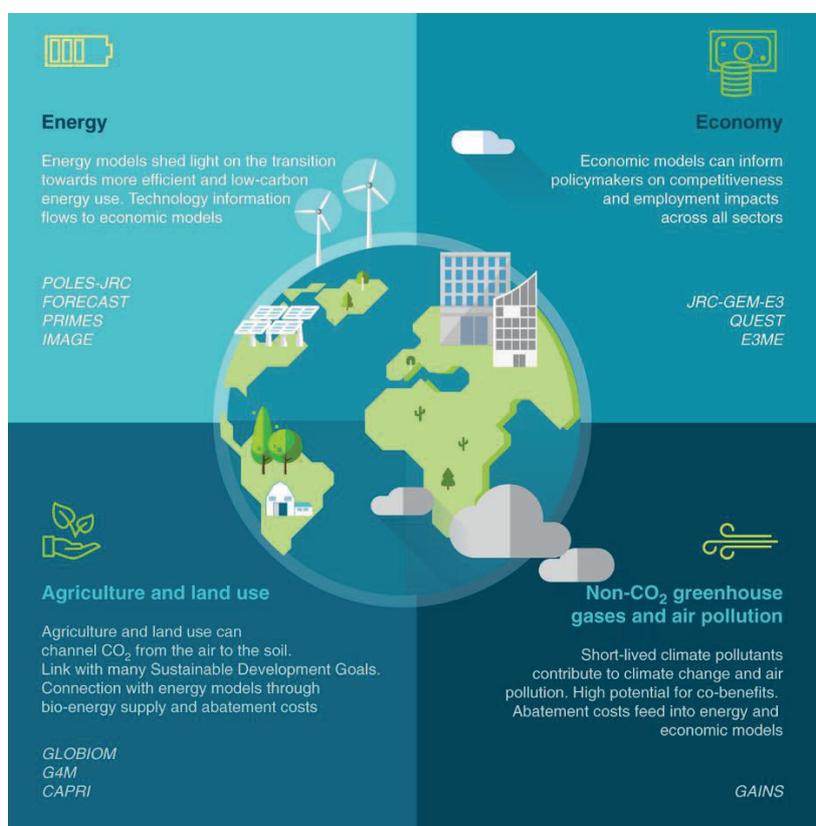


Figure 1: The modelling toolbox (model names are at the bottom of each box) to inform the European Commission's 'A Clean Planet for all - A European strategic long-term vision for a prosperous, modern, competitive and climate neutral economy' [COM (2018) 773]⁸⁷²

Modelling is a complex and technical activity for which **specific expertise** is needed. Models can have different spatial coverage and detail, and can represent short-, medium- or long-term effects. Input data requirements usually are demanding, and data quality is fundamental for the quality of model output. Specific software is needed for handling the input data, running model simulations, and interpreting and presenting the results.

⁸⁷¹ <https://ec.europa.eu/energy/data-analysis/energy-modelling/eu-reference-scenario-2016>.

⁸⁷² Weitzel, M., Vandyck, T., Keramidas, K. et al. Model-based assessments for long-term climate strategies. Nature Climate Change 9, 345–347 (2019).

Models are developed and run **within the Commission** (JRC and policy DGs), as well as by **external organisations** on behalf of the Commission, such as research institutes, universities, and private consultancies. In general, the development of a new model is a complex, resource- and time-intensive process. Sufficient and long-term resources are needed to ensure model maintenance over time. Developing a model and preparing scenarios in light of a new policy initiative therefore needs to be anticipated well in advance. JRC has multi-annual administrative arrangements with many DGs, many of which include modelling.

Model development and use entail **close collaboration over time between modellers and policymakers**. On the one hand, models should be developed, managed and maintained by appropriately skilled and experienced staff. On the other, decision makers should understand the general model functioning, limitations, risks, major assumptions and outputs. This can be ensured by close communication with modellers on how a model works and the strengths and limitations of a specific approach. This mutual interaction is key to build trust and ensure a high-quality outcome. Trust in the models in use by the European Commission can be further strengthened through transparency and by engaging Member States' experts in the validation of the data, the modelling results and the baseline scenarios.

2. TRANSPARENCY AND QUALITY ASSURANCE

Models used for policy support should be sound from a scientific point of view and transparent from the perspective of stakeholders. The higher the **quality** and thus reputation of a model, the more convincing the modelling results for policy support. The process to achieve these requires time and resources, typically covering various impact assessment cycles, and is the result of a number of actions. These should be proportionate to the impact and complexity of the model and be an integral part of the work both when models are run by Commission services and by external contractors, through appropriate terms of reference.

Transparency of the model and its use includes the documentation and sharing of model assumptions, architecture, code, data and results (see Tool #4 (*Evidence-informed policymaking*)). It enables scrutiny and replication of results by fellow scientists, reuse of the model over time, as well as better understanding, trust, and acceptance by a wider audience. Documenting models and their use helps policymakers to choose an adequate model when preparing a new impact assessment; the co-legislators to better interpret modelling results; and the general public to get a better picture of the evidence that underpins policymaking. The Modelling Inventory and Knowledge Management System **MIDAS** (see section 3 below), details transparency requirements for model use in impact assessments.

Model **quality assurance** typically includes testing and checking consistency before a new model version is released; if applicable, validation that a model can reproduce historical/statistical data; critical assessment of the model assumptions, in collaboration with the relevant experts and stakeholders, to determine whether they are realistic and relevant to the problem at hand. In addition, as for all impact assessment methods, communicating and understanding **uncertainty in model outputs** is vital. To the extent possible, uncertainty should be quantified and accounted for. This is particularly relevant in an impact assessment as this could change the ranking and conclusions about the policy options (see Tool #62 (*Multi-criteria decision analysis*)). Regular **internal and external review** and discussion in the scientific community (in particular, peer-reviewed publications) are key for the trust in the process and acceptance of the results. **Coherence** could be ensured through a shared baseline, the reference scenario that provides a base for comparison (see Tool #60 (*Baselines*), and Figure 1).

- **Practical steps**

Using models for impact assessment requires close collaboration between modellers and policy officers. As the modelling exercise might require up to several months, it is important to plan well and to perform all preliminary steps in due time to ensure that high quality results can be included in the impact assessment report. Box 2 lists a number of steps that can help informing the impact assessment process with evidence from the modelling exercises.

Box 2: Steps of model use for impact assessment

1 - Assess whether modelling is relevant for your case

- A. Look at available evidence, including whether related impact assessments, evaluations, or studies by your or other DGs make use of models
- B. Consult the MIDAS modeling inventory
- C. Identify which model(s) can simulate the relevant policy impacts

2 - Select which model(s) to use

- A. Carefully consider, also by consulting experts and stakeholders:
 - i. relevance and appropriateness of model assumptions for your specific case
 - ii. model quality
 - iii. model transparency
- B. Assess if models are available within the Commission or resort to external contractors
- C. In case you consider developing a new model, a long-term vision is necessary. Carefully assess time and resource implications.

3 - Design and plan the modelling exercise

- A. Define relevant model assumptions
- B. Define the baseline consistently with existing reference scenarios (Tool #60 (*Baselines*))
- C. Define the policy options scenarios
- D. Define and plan over time all steps of the modelling exercise (e.g. data collection and update, model developments, model calibration, model simulation, results' validation)
- E. Ensure coordination if more than one model are to be used
- F. Check how to document models and their use (see section 3 further below on the Modelling Inventory MIDAS)

4 – Run the model and validate model output

- A. Run the model (by Commission Services or external contractors)
- B. Account for uncertainty in model results (Tool #65 (*Uncertainty and sensitivity analysis*))
- C. Analyze and discuss model results
- D. Validate results together with relevant experts and stakeholders

5 - Communicate model results

- A. Present results, clearly explaining assumptions and limitations
- B. Considering publishing a specific report describing the modelling exercise, to be referenced in the IA report
- C. Encourage the experts to publish (at the adequate point in time) a peer-reviewed

article on the modelling exercise
 D. Ensure permanent traceability of documentation for citing the modelling exercise

- **The Modelling Inventory of the European Commission ([MIDAS](#))**

Coherently documenting these models and their use is a fundamental step for transparent and evidence-based policymaking. All models that make a substantial contribution to the assessment of policy options in an impact assessment have to be described in the **Modelling Inventory and Knowledge Management System of the European Commission (MIDAS)**. MIDAS contains the descriptions of models in use by the Commission in support of the policy cycle and is open to the public. This gives access to the descriptions of the models and related contributions to Commission impact assessments. The information available in MIDAS can conveniently be used to complete Annex 4 of the impact assessment reports (see Tool #11 (*Format of the impact assessment report*)). Therefore **inserting information in MIDAS at an early stage of the IA is highly recommended.**

Box 3. Practical actions to document models used for the policy process

Planning & validation phase

You can check in [MIDAS](#) if and how modelling was used in previous impact assessments in your field. This can help to assess if the use of models is relevant for your case.

Getting in touch at an early stage of the IA process with the MIDAS team would allow publishing the information in MIDAS timely, to effectively support the audiences of the IA report. In exceptional cases (such as legal barriers), you can decide who can access the information (Commission only, European Parliament and Council, public).

Policy preparation

If you intend to use models in IAs **for the assessment of policy options**, then the models and their contribution **should be described in MIDAS**. In all other cases (support to problem definition, baselines, evaluation of an existing policy), their insertion in MIDAS can be considered wherever relevant and feasible⁸⁷³.

The **policy DG** leading the IAs is **responsible for the content** to be shared in the public version of MIDAS. By **informing the MIDAS support team at an early stage about intended model use** (see Tool #8 (*What steps should be followed for an impact assessment*)), **you can also get specific support throughout the IA process**: to help you describing the model or to formulate call for tenders or contracts, which ensure that your contractor provides the required information and agrees to its publication in MIDAS under EU copyright.

Concretely, MIDAS describes three different main elements:

1. The Model

The model description includes, according to a predefined structure: **general information** about the model; **details on model structure**; information on **model quality and**

⁸⁷³ This is the case in particular when models are used for the construction of a consolidated baseline (like in case of the EU Reference Scenario for Energy, transport and GHG emissions Trends to 2050, doi: 10.2833/001137)

transparency and related documentation.

2. The Model contribution to the impact assessment

This refers to how model results contributed to the IA. Concretely, for the assessment of policy options you need to indicate the specific impacts the model helped to assess.

3. Additional information on the full modelling exercise

The modelling exercise refers to comprehensive information on the specific model configuration, any input data and sources, other models involved, as well as information on quality assurance measures. This information is usually either described in a separate annex of the IA report, and/or in a separate study or article referenced in the IA. In MIDAS, **you only need to state who ran the model** for the IA and provide the **reference** to the modelling exercise.

Contact of the MIDAS support team : EU-MIDAS@ec.europa.eu

https://ec.europa.eu/knowledge4policy/modelling/topic/corporate-modelling-inventory-knowledge-management_en

3. ADDITIONAL INFORMATION

- Acs, S., Ostlaender, N., Listorti, G., Hradec, J., Hardy, M., Smits, P., Hordijk, L., *Modelling for EU Policy support: Impact Assessments*, EUR 29832 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-09671-9, doi:10.2760/748720, JRC117250.
- Ostlaender, N., Acs, S., Listorti, G., Hardy, M., Ghirimoldi, G., Hradec, J. and Smits, P., *Modelling Inventory and Knowledge Management System of the European Commission (MIDAS)*, EUR 29729 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-02852-9, doi:10.2760/900056, JRC116242.

TOOL #62. MULTI-CRITERIA DECISION ANALYSIS

1. MAIN FEATURES

After having assessed their likely economic, social and environmental impacts, as well as distribution across stakeholders, **the impact assessment analysis compares the different options** with regard to their effectiveness, efficiency and coherence, as well as their compliance with the proportionality principle. As a consequence, here there is a need for a systematic, transparent and rigorous **integrative framework**.

In welfare economics and decision theory literature, the most traditional and widespread approaches for comparing options are **cost-benefit analysis (CBA)** and **multi-criteria decision analysis (MCDA)**. **Cost-benefit analysis is characterised by the attempt of measuring all effects of a policy option in monetary units.** CBA is grounded on market mechanisms; this implies that the analysis is based on the behaviour of individuals as consumers on the market. **Its main aim is thus to assess efficiency**⁸⁷⁴. Obviously, issues connected with actions outside of markets and behaviour of people different from the class of consumers cannot be considered⁸⁷⁵. To use only one measurement unit for incorporating a plurality of dimensions, objectives and values, implies a high risk of reductionism. **Multi-criteria decision analysis allows considering a wide range of assessment criteria, all of them shown in their original units of measurement;** there is no need to transform them in monetary terms as required by CBA. **MCDA** is particularly useful in case of complex interventions with diverse quantified impacts measured in different units and/or qualitative. This high degree of comprehensiveness and transparency is the most important success factor of multi-criteria methods.

MCDA is thus more comprehensive than CBA. CBA and MCDA can be considered as competitive methods *only* if **all** consequences of a policy decision can be correctly transformed into monetary values and efficiency is the only relevant policy objective. When a plurality of policy objectives exists, CBA can be used as one component of a MCDA framework dealing with the objective of efficiency in a consistent way.

Social multi-criteria evaluation (SMCE), which has been explicitly designed for public policy, also allows the capture of distributional consequences (e.g. in terms of stakeholder types, EU regions/countries or time) and trade-offs between dimensions (such as between some economic, social or environmental impacts, or between some families of criteria).

The **multi-criteria impact matrix** presents in a structured way the information on the various ‘criterion scores’, i.e. each element of the matrix represents the performance of a certain policy option according to each criterion (see Table 1). The various criterion scores can assess impacts by using both **quantitative** (e.g. as result of simulation models) and

⁸⁷⁴ Alternatively, the extent to which objectives can be achieved for a given cost (cost effectiveness).

⁸⁷⁵ “... there is such a long tradition in parts of economics and political philosophy of treating one allegedly homogeneous feature (such as income or utility) as the sole ‘good thing’ that could be effortlessly maximized (the more the merrier), that there is some nervousness in facing a problem of valuation involving heterogeneous objects, ...And yet any serious problem of social judgement can hardly escape accommodating pluralities of values, ...We cannot reduce all the things we have reason to value into one homogeneous magnitude.” (A. Sen, *The Idea of justice*, The Belknap Press of Harvard University Press, Cambridge, Massachusetts, 2009, p. 239).

qualitative (e.g. results of participatory techniques) **information**. Some examples of criteria that can be all present simultaneously in a multi-criteria impact matrix include:

- “implementation cost for a Member State”, “EU added value” (measured in euro), “administrative burden”, “complementarity with other EU instruments”, “avoidance of social exclusion” (measured in qualitative terms, e.g. very good, very bad or ++, --, ...),
- “impact on labour force”, “additional leukaemia risk” (measured by using probability distributions),
- “emissions reduction commitments” (measured in avoided CO2 emissions),
- “share of renewable energies” (measured in megawatt-hours of installed capacity),

		Options			
Criteria	Units	a1	a2	a3	a4
g1		g1(a1)	g1(a2)	.	g1(a4)
g2	
g3	
g4	
g5	
g6		g6(a1)	g6(a2)	.	g6(a4)

Table 1. Example of a multi-criteria impact matrix

The current practice for comparing policy options in Commission IAs very often builds such a matrix⁸⁷⁶, thus the **use of standard definitions** from decision theory literature is recommendable (see Figure 1).

- **Dimension** is the highest hierarchical level of analysis. For example, in IA studies, this refers to the general categories of economic, social and environmental impacts.
- **Objective** indicates the desired direction of a policy change. For example, within the economic dimension, economic growth has to be incentivised; within the environmental dimension, the contribution to the EU's climate change commitments in the context of COP 21 has to be maximised; in the social dimension, the fairness should be maximised.
- **Criterion** is an empirical indicator that associates each policy option with a variable indicating its desirability according to its expected real-world consequences. Any objective may imply a number of different criteria. A classic example in the economic dimension might be GDP, saving rate and inflation rate inside the objective “growth maximisation”.
- **Criterion score** is an assessment of the impact according to a given criterion with reference to each single policy option. Criterion scores can be both qualitative and quantitative; uncertainty can also be included. These assessments are the ones presented in the elements of the impact matrix (as in Table 1 above).

⁸⁷⁶ Examples in published IA studies can be found in Munda (2017).

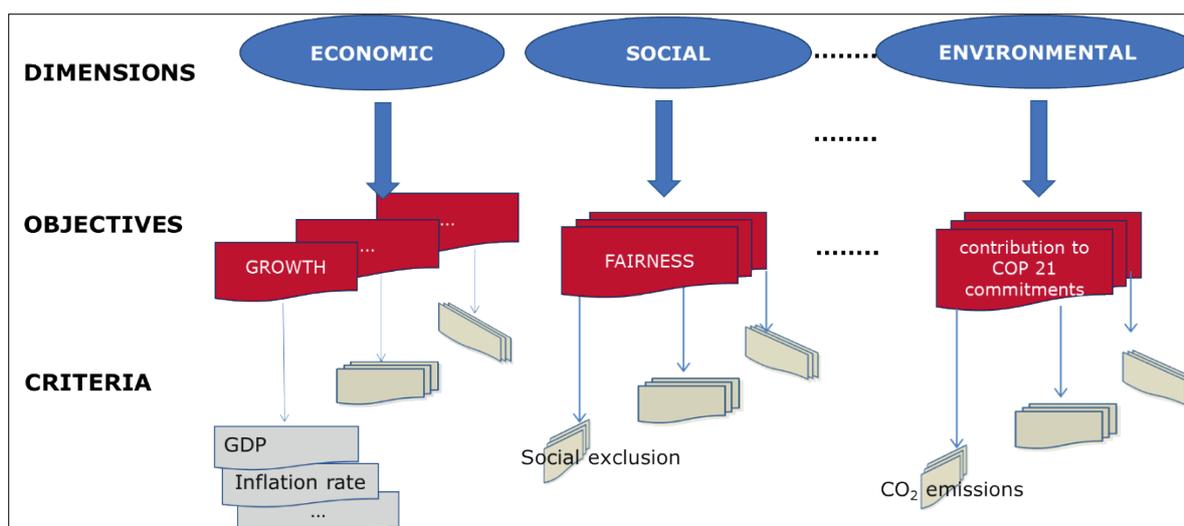


Figure 1: Example of the hierarchical structure for the application of SMCE to each option.

2. PRACTICAL IMPLEMENTATION STEPS

The application of SMCE is **not particularly time consuming**, since it **formalises in a consistent and efficient way a process that often is already done in the current practice of IA**. Many IA studies present the results in a form of an impact matrix.

Box 1. The main steps to implement a Social Multi-Criteria Evaluation framework

1. Selection of the relevant social actors for the problem at hand.
2. Definition of **social actors' values, desires, and preferences**. Stakeholder consultation methods described in Chapter 7 can be used to deal with both steps 1 and 2.
3. Generation of **evaluation criteria** to represent social actors' needs, preferences, and desires.
4. Construction of **the multi-criteria impact matrix** synthesising the performance of each option according to each criterion. In practice, this implies the integration in a coherent and integrative framework the results of the various sectorial models computing the various impacts (e.g., on economy, environment, health, energy, etc.).
5. Construction of an **equity impact matrix**, identifying all the distributional consequences of each single option in terms of stakeholder types, EU regions/countries or time (e.g. by considering consequences on future generations explicitly).
6. Application of a **mathematical procedure** to rank all the policy options in a consistent way. Multi-criteria mathematics solves the standard objection that the aggregation of apples and oranges is impossible in a definitive way. This makes the overall IA study much more defensible in comparison with the use of simple qualitative reasoning to isolate the most preferred option.
7. **Sensitivity and robustness analysis** checks if the ranking of policy options is stable and determines which of the input parameters influence more the output. Local sensitivity analysis looks at a) the exclusion/inclusion of different criteria and dimensions and b) changes of the weight of dimensions, criteria, or social actors; these are changed one per time. Global sensitivity analysis focuses on all the possible combinations of criterion

weights; all parameters are changed simultaneously (see also Tool #65 (*Uncertainty and sensitivity analysis*)).

In operational terms, two points deserve particular attention:

1) The **use of weights** can be a very sensitive issue. A reasonable practice can be to start by giving the same weight to each dimension and then splitting each weight among the objectives and criteria of any dimension proportionally. Of course, one could assume that some dimensions are more important than other ones, and thus their weight should be higher, but this should be justified based on strong and transparent ethical, scientific, institutional or legal arguments. Stakeholder processes can inform the weights attributed. **Sensitivity or robustness analyses** have to check the consequences for the final ranking of these arguments; they are thus a way to improve transparency on the assumptions introduced in an IA study.

From an operational point of view, the support of a **software tool makes all required computations very quick**. For example **SOCRATES**, developed by the [JRC Competence Centre on Modelling of the JRC](#), is explicitly designed for IA problems. SOCRATES helps in structuring IA problems in the hierarchy dimensions, objectives, criteria and makes the weighting relations transparent, by also allowing for sensitivity and robustness analysis. SOCRATES also allows to analyse all the distributional consequences of each option.

3. ADDITIONAL INFORMATION

- Arrow, K.J., Raynaud, H. (1986) Social choice and multicriterion decision making. M.I.T. Press, Cambridge.
- Figueira, J., Greco, S. and Ehrgott, M. (eds.) (2016) Multiple-criteria decision analysis. State of the art surveys. Springer International Series in Operations Research and Management Science, New York.
- Munda G. (2017) A social multi-criteria framework for ex-ante impact assessment, EUR 28752 EN, doi 10.2760/909528
- Munda, G. (2008), Social Multi-Criteria Evaluation for a Sustainable Economy, Springer, Heidelberg, 2008 – also available from the Commission libraries.

TOOL #63. COST-BENEFIT ANALYSIS

1. MAIN FEATURES

Social investment has positive consequences for economic growth and societal well-being in general. However, as in any category of economic decisions, social investments have to consider their opportunity cost and try to answer difficult questions such as: how much of the national budget has to be devoted to environmental protection or education? Is it better to invest in pre-schooling or in universities? Is it better to invest in renewable energy or in pollution control? Economists try to answer these questions by considering the costs and benefits linked to each option; **cost-benefit analysis (CBA) is characterised by the attempt of measuring all effects of a policy option in monetary units**; it focuses on the selection of the option that exhibits the highest net benefit, which is considered as the most efficient one.

CBA assumes that all impacts of a policy can be monetised, and efficiency is the only relevant policy objective. Instead, **Multi-criteria decision analysis (MCDA) allows considering a wide range of assessment criteria**, which can be included in their original units of measurement (see Tool #62 for the relation between CBA and MCDA).

The **time and resources** needed for the development of a cost-benefit analysis depends a lot on the procedures used to monetise costs and benefits. This choice should be proportionate, and it depends on the extent of the impacts and available data. If the analysis affects several markets, directly or indirectly, one could opt for a general equilibrium approach (see Tool #61 (*Simulation models*)), but this needs more preparation and specialist expertise. On the contrary, a CBA does not need specialist software for the sequence of straightforward manipulations. However, monetisation can be very complex.

In practice, most impact assessments compare the costs and benefits of different policy options, using a mixture of data: monetary units; or quantified in a non-monetary way (e.g. ton of emissions/year); or qualitative, non-quantifiable data. This reflects the difficulties of monetising or quantifying all the relevant economic, social, and environmental impacts. What is important is that policymakers consider as solid an evidence base as is possible in a proportionate way. As such, most impact assessments are a blend of CBA and MCDA.

2. PRACTICAL IMPLEMENTATION STEPS

The **application** of cost-benefit analysis requires the following **main steps**:

1) *Identification and monetisation of costs and benefits*

An overview of the typologies of costs and benefits is presented in Tool #56. In CBA, the main effort consists in trying to apply the right valuation techniques to transform everything into money terms. Different techniques exist, and it is not always clear which one is most appropriate for a certain real-world problem. The principal ones are: contingent valuation, the travel cost method, hedonic pricing, and the shadow project approach. Among these only **contingent valuation** is universally applicable. The aim of contingent valuation is to elicit valuations (or 'bids') which are close to those that would be revealed if an actual market existed. Respondents say what they would be willing to pay or willing to accept if a market existed for the good in question. To determine the value of intangible goods and services, economists try to identify how much people would be willing to pay (willingness to pay, or

WTP) for these goods in artificial markets. Alternatively, the respondents could be asked to express their willingness to accept (WTA) compensation.

2) *Selection of the relevant time horizon and social discount rate*

Most new policies or projects result in **costs and benefits** that arise **at different times**. Typically, while costs tend to be concentrated earlier in the implementation, benefits tend to occur later in time (for example, building a new railway line has an immediate cost but provides benefits for many years in the future). The social discount rate is used to compare costs and benefits that occur in different time periods from the point of view of society (see Tool #64 (*Discount factors*)). **CBA results may vary a lot according to the discount rate chosen** (see Box 1). High discount factors tend to give a low value to future costs and benefits, thus prioritising close benefits and shifting costs to future generations. Here a sensitivity analysis is very useful tool to guarantee transparency.

3) *Choice of a mathematical aggregation rule*

In *empirical applications*, the most common mathematical aggregation rules are **net present value (NPV)** and the **benefit-cost ratio (BCR)**. The NPV is:

$$NPV = \sum_{i=0}^{i=n} \frac{B_i}{(1+r)^i} - \sum_{i=0}^{i=n} \frac{C_i}{(1+r)^i}$$

Where C_i and B_i are respectively the Costs and Benefits in a given year i over the policy/project lifetime of n years (starting in year 0), and r is the discount factor. For economic acceptability, **NPV** must be positive; the higher the NPV the more desirable the option.

In the case of **BCR**, the ratio between benefits and costs is used, instead of their difference. In this case, for economic acceptability BCR must be higher than one; the higher the BCR the more desirable the option.

To **choose only one option** among a set of competitive alternatives, the decision can be made on the grounds of the highest NPV. Instead, for a **complete ranking**, the choice of the right aggregation method to use is more complex, since NPV and BCR provide different results to the ranking problem. In fact, while NPV is an indicator of the attractiveness of an option in absolute terms (thus the larger the difference between benefits and costs, the better), in BCR the attractiveness is independent from the scale of options considered. Finally, one should also note that both NPV and BCR are very sensitive to the discount rate chosen, which could also change the ranking of the policy options (see Box 1 for an illustrative example).

4) *Presentation of the impacts and formulating the judgement on the performance of existing public intervention or the comparison of the policy options*

The different types of costs and benefits which have been monetised should be presented together with qualitative information on non-monetised costs and benefits. They should be compared in terms of the various cost/benefit categories, net benefits and net present value, as well as distributional impacts on stakeholders.

5) *Checking the robustness of the results*

It is important to highlight that **no 'objective value free' approach exists**; results provided by CBA depend on a number of assumptions. Full **transparency on the assumptions** introduced in any specific application should always be assured. In the case of CBA, it should be noted that all monetary valuation attempts suffer technical uncertainties such as: Which monetary valuation technique has to be used? Which time horizon has to be considered? Which social discount rate? Which mathematical aggregation rule?

Box 1. Example: effect of the choice of the discount rate on the ranking between policy options

Time	Option A	Option B	Option C
1	-100	-100	-100
2	10	30	50
3	20	30	60
4	30	40	50
5	40	40	50
6	50	40	20
7	60	40	20
8	70	40	20
Discount rate	NPV		
1%	165 (1)	148 (3)	160 (2)
5%	114 (2)	107 (3)	125 (1)
10%	69 (3)	70 (2)	92 (1)

Let us consider three options A, B, and C. They present costs only at time 1 and then cash flows are all positive. Option A present high positive inflows at more distant time periods than option B and C. As one can see, this characteristic creates a rank reversal of A with B and C when the discount rate becomes higher (in the table above, the ranks are indicated in parenthesis).

6) *Accounting for distributional and cumulative impacts*

Distributional (e.g. Member States, richer and poorer groups, SMEs) and cumulative impacts (e.g. future generation) should also be considered in a proportionate way. It is crucial be aware of disproportionate impacts in the cost benefit analysis and consider segmenting the population in smaller groups to identify and illustrate distributional impacts where relevant.

3. **ADDITIONAL INFORMATION**

- Study prepared by the Centre of European Policy Studies on assessing the costs and benefits of regulation, available at http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf
- Pearce D.W., Nash C.A. (1989) The social appraisal of projects, MacMillan, London.

- Newnan, D.G., Eschenbach, T.G., Lavelle, J.P. (2019) - *Engineering Economic Analysis*, 14th Ed., Oxford University Press, Oxford.
- Luenberger D. G. (2012) – *Investment science*, Oxford University Press, Oxford

TOOL #64. DISCOUNT FACTORS

1. INTRODUCTION

Individuals have time preferences, i.e., the availability of EUR 1 now is worth more than EUR 1 in the future. This can be explained as money can be invested today to generate a higher value tomorrow, there is inflation, or one will be dead in some future.

To capture this phenomenon one can use a discount factor. If an individual invests EUR 1 now to have some revenues in 5 years and wants to be compensated for the fact that this individual is not buying any good or service today with this EUR 1. This compensation is measured by a discount factor. A **discount factor** is a numerical factor used to **convert monetary values in the future to 'present values'**, so that money flows can be compared over time. It measures the present value of one euro received in year t . It relates to the complementary concepts of interest rate, rate of return, opportunity cost of a project, or cost of capital. In practice, discounting is using an appropriate interest rate back-to-front.

Most new policies or projects result in **monetary flows or/and net social effects (social benefits minus costs) that arise at different times**. Usually, costs have to be incurred in the present, so that benefits may be obtained in the future. The process of discounting is used to compare these monetary flows or net social effects at a given point in time, usually when the decisions about future private investments or public policies have to be made.

Discounting requires an important choice regarding the appropriate discount factor or discount rate as small differences in the discount factor can result in large changes of the net present value and thus can influence the evaluation of the proposal. The higher the discount factor used in an evaluation, the more difficult is the approval of the investment or the policy proposal (as the future benefits are smaller when converted into the present time).

One can distinguish between the **market discount factors** which usually are to be used when comparing private sector investment projects and the **social discount factors** which usually are used when evaluating future cost and benefits with societal value that are related to public policies. If the flows are to be compared from the point of view of the society, one should apply the **social discount factor**. If discounting is done from the perspective of an individual project, or the private sector, the discount factor applied will be different (usually higher) than a social discount factor as capital business projects are typically riskier than the projects related to public projects⁸⁷⁷.

The choice of an appropriate social discount factor for public policy is highly debated in the economic literature. The most important theories are **the social rate of time preference rate (SRTP)**⁸⁷⁸ and the **social opportunity cost of capital (SOC)**⁸⁷⁹. Each approach has its advantages and disadvantages.

⁸⁷⁷ Opportunity cost of capital is the rate of return that capital could be expected to earn in the best alternative investment of equivalent risk. It is usually calculated by examining the returns of different projects available measured in net present value.

⁸⁷⁸ The social rate of time preference consists of three components ($SRTP = p + e * g$), where p is the pure time preference, e is the elasticity of the marginal utility of consumption, i.e. the percentage change in individuals' marginal utility corresponding to each percentage change in consumption; g is the expected growth rate of per capita consumption. The positive pure time preference is about preferring the present over the future (as discussed before).

2. SOCIAL DISCOUNT FACTOR FOR EU POLICIES

As EU policies and projects funded by the EU budget are public policies with societal value, the social discount factor⁸⁸⁰ can be used to assess them. Both investment projects funded by the EU budget as well as evaluations of EU policies call for a longer-term rate to be used, as such policies or projects typically need time to roll out and become effective. A social discount factor should be as transparent, factual, and predictable as possible. For practical reason this tool proposes a single central rate for all projects.

The social discount factor recommended for EU policy analysis is 3% in real terms⁸⁸¹. This value follows the recommendation of the DG REGIO Economic Appraisal Vademecum^{882,883} for EU-funded projects in the period 2021-2027.

However, for discounting health impacts or environmental projects, it is a common practice in many countries to choose a lower rate⁸⁸⁴. A similar argument is made to choose a lower rate for long-term impacts or projects. Section 6 stresses the need for **sensitivity** and to use alternative lower and higher discount factors than the central 3% value, in order to assess the robustness of the analysis.

If you are dealing with costs and benefits expressed in nominal prices one needs to adjust for the inflation: e.g. with an inflation of 2% per annum, a 5% **nominal social discount factor** (3% real rate plus 2% to account for inflation) would be used.

A certain stability over time is recommended. That should be balanced against possible changes due to evolving economic and social conditions. Societal projects are intended to deliver (direct and indirect) positive externalities. Therefore, social discount factors could be different than strictly financial discount factors.

3. FINANCIAL DISCOUNT FACTOR

The financial discount rate is used to determine the present value of future cash flows in a discounted cash flow analysis. This helps determine if the future cash flows from a project or investment will be worth more than the capital outlay needed to finance the public project or investment in the present. The cost of capital is the minimum rate needed to justify the cost of a new project or investment; and the discount factor is the number that needs to meet or exceed the cost of capital. This financial discount factor merely looks to the financial transactions directly related to the project or investment. It does not consider whether the

⁸⁷⁹ The social opportunity cost of capital (SOC) argues that resources are scarce in any economy. This implies that the public and private sectors compete for the same funds. As a consequence, public investments should guarantee at least the same net social benefit as the private ones; otherwise an improvement can be obtained by reallocating resources to the private sector.

⁸⁸⁰ A number of methods can determine the investment rates and the social discount factor for EU policy analysis such as Market-based determination, Judgemental determination, Model-based estimation, and Sharpe-Lintner CAPM.

⁸⁸¹ Historically governments across the world have been using social discount rates ranging from 2% up to 15%, depending on the long-term average risk-free rate. Rates tend to have declined over time. Therefore, the recommended social discount factor for EU policies is lower than the 4% in the 2017 version of the ‘better regulation’ toolbox.

⁸⁸² https://ec.europa.eu/regional_policy/en/information/publications/guides/2021/economic-appraisal-vademecum-2021-2027-general-principles-and-sector-applications

⁸⁸³ Catalano, G. *et al.* (2021, forthcoming). The social cost of capital: Recent estimates for selected countries. CSIL working paper

⁸⁸⁴ E.g. DE, DK, FR, NL, NO, and UK uses 1.5% for health and.

project or investment generate any benefits elsewhere in the economy (e.g. environment, or increased productivity in economic sectors).

The financial discount factor recommended for EU analysis is 0.5%⁸⁸⁵ in real terms. As the financial discount factor is used for financial cash flows and based on long-term bonds, the value will change in function of the financial markets.

4. COSTS FROM THE PERSPECTIVE OF PRIVATE CAPITAL

There is widespread consensus that the social discount factor is usually lower than the discount factor that should be used for individual companies or households, who are unable to diversify risk as effectively as the society as a whole. The social discount factor is only used, therefore, when looking at issues from the societal point of view. For example, a higher discount factor should be used when trying to assess the behaviour of a company in respect of an investment decision. This would essentially be the internal rate of return required to trigger an investment. For a business, a good proxy is the **Capital Asset Pricing Method**, which takes account of both the costs of capital and the riskiness of the investment.

In some cases, the **Weighted Average Cost of Capital (WACC)** could also be used⁸⁸⁶ when it is important to ensure that the future benefits are sufficient to compensate the required investment as well as the costs of funding. This approach may also be used for instance to evaluate projects that are only partially funded by the EU budget and the public resources are used to attract private investments.

Higher discount factors may also apply for households when deciding on whether to make an investment due to a range of factors: such as finance costs and other behavioural constraints like split incentives (e.g. landlord/tenant), short time horizons, risk averseness, information asymmetries or other obstacles or barriers. Similarly, there are proposals to use a higher discount factor for poorer actors as they have a higher necessity to satisfy today's needs compared to richer peers⁸⁸⁷.

The discount rate used when deciding whether to invest may be different to the actual cost of financing as it includes other factors, barriers, or risks. E.g. for a firm, the cost of financing would be the weighted average cost of capital. However, hassle or transaction costs are a valid cost category and can be added to the total discount factor.

In a single analysis, different discount factors can be used. The policy measure itself can from a social point of view use a lower social discount factor; private actors may face higher discount factors; and a distinction may be made for income groups. However, while conceptually different discount factors can be justified, it is not straightforward to determine by how much these discount factor can differ. Therefore, all discount factors used should be transparent, and, if relevant, alternative discount factor values need to be explored to increase the robustness of conclusions.

⁸⁸⁵ The figure of 0.5% is calculated in June 2021, using a 3 year moving average on the [Euro area government bonds with 10-year maturity](#)

⁸⁸⁶ The Weighted Average Cost of Capital consists broadly of a risk-free rate plus the Beta for the sector times the equity risk premium. Its value is not affected by a firm's choice between chosen equity and debt funding to fund investment.

⁸⁸⁷ <https://www.oxera.com/insights/agenda/articles/social-discount-rates-inequality-and-the-long-term/>

5. THE MECHANICS OF DISCOUNTING: NET PRESENT VALUES (NPV)

Calculating the present value of the *difference* between the benefits *and* the costs provides the **Net Present Value (NPV)** of a policy option.

Box 1. Formula for the determination of Net Present Value

$$NPV = \sum_{i=0}^{i=n} \frac{B_i}{(1+r)^i} - \sum_{i=0}^{i=n} \frac{C_i}{(1+r)^i}$$

Where the Costs and Benefits in a given year i are C_i and B_i respectively over the policy/project lifetime of n years (starting in year 0), while r is the chosen discounting rate.

Box 2. Determination of present values using a social discount factor of 2.5% (and 4% for comparison)

The factor to discount present values is given by the formula below, where r is the discount factor and n is a future year:

$$\text{Discount factor in a future year } n = \frac{1}{(1+r)^n}$$

As an example, the present value of €1000 to be obtained in the future 5 years is shown below:

	Year					
	0	1	2	3	4	5
<i>Present Value with 2.5%</i>	€1000	€976	€952	€929	€906	€884
<i>Present Value with 4%</i>	€1000	€962	€925	€889	€855	€822

Box 3. The calculation of NPV for two competing policy options with 3%

Alternative projects A and B are both expected to improve the functioning of an organisation.

Option A: requires €10 million in capital costs initially in order to realise benefits of €2.5 million per annum in the following 4 years.

Option B: requires €5 million in capital costs initially to realise benefits of €1.5 million per annum in the following 4 years.

Year	0	1	2	3	4	NPV
Discount factor	1.0000	0.9709	0.9426	0.9151	0.8885	
Option A						
<i>Costs (€ m)</i>	10	0	0	0	0	
<i>Benefits (€ m)</i>	0	2.5	2.5	2.5	2.5	
<i>Benefits less costs (€ m)</i>	-10	2.5	2.5	2.5	2.5	
<i>Present value (€ m)</i>	-10.00	2.43	2.36	2.29	2.22	-0.71

Option B						
<i>Costs (€ m)</i>	5	0	0	0	0	
<i>Benefits (€ m)</i>	0	1.5	1.5	1.5	1.5	
<i>Benefits less costs (€ m)</i>	-5	1.5	1.5	1.5	1.5	
<i>Present value (€ m)</i>	-5.00	1.46	1.41	1.37	1.33	0.58

Project B realises a positive NPV of €0.58 million whereas Option A has a negative NPV of - €0.71 million. Therefore, Project B is preferable.

The net present value can be used to distinguish between two competing policy options. If the NPV is negative, this means that the future benefits are not sufficient to compensate the costs incurred given the selected discount factor (or required rate of return). The project with the higher NPV is to be selected. Boxes 3 and 4 compare the calculation of the NPV for 2.5% and 4%, respectively. While the order of the options does not change in these two examples, it can be observed that a lower discount rate leads to a higher NPV, and, hence, favours long-term investments.

Box 4. The calculation of NPV for two competing policy options with 4%

Alternative projects A and B are both expected to improve the functioning of an organisation.

Option A: requires €10 million in capital costs initially in order to realise benefits of €2.5 million per annum in the following 4 years.

Option B: requires €5 million in capital costs initially to realise benefits of €1.5 million per annum in the following 4 years.

Year	0	1	2	3	4	NPV
Discount factor	1.0000	0.9615	0.9246	0.8890	0.8548	
Option A						
<i>Costs (€ m)</i>	10	0	0	0	0	
<i>Benefits (€ m)</i>	0	2.5	2.5	2.5	2.5	
<i>Benefits less costs (€ m)</i>	-10	2.5	2.5	2.5	2.5	
<i>Present value (€ m)</i>	-10.00	2.40	2.31	2.22	2.14	-0.93
Option B						
<i>Costs (€ m)</i>	5	0	0	0	0	
<i>Benefits (€ m)</i>	0	1.5	1.5	1.5	1.5	
<i>Benefits less costs (€ m)</i>	-5	1.5	1.5	1.5	1.5	
<i>Present value (€ m)</i>	-5.00	1.44	1.39	1.33	1.28	0.44

Project B realises a positive NPV of €0.44 million whereas Option A has a negative NPV of - €0.93 million. Therefore, Project B is preferable.

6. SENSITIVITY ANALYSIS

To use one constant social discount factor across impact assessments and evaluation is important to ensure **coherence and comparability**; however, one should remember that

discounting at even modest rates reduces the value of monetary flows almost to zero over long time periods. This can be criticised because it excludes future generations from consideration in today's decisions. For example, let us consider a policy option with a non-discounted difference between benefits and costs of EUR 1 000 000. The higher the discount factor is, the quicker the net present value (NPV) becomes very low; for example, at 10% it is close to zero in 50 years, while at 1% or 2%, it is still positive after 150 years.

Discounting is a concept developed with the objective of being able to compare different cash flows between different time periods. The selection of the discount factor should be clearly motivated. **Sensitivity analysis of the effects of the applied discount factor (whether social or private) is highly desirable for assuring transparency.** Therefore it is recommended to have alternative calculations with sufficiently higher and lower values (up to +/- 1% at least).

7. CORRECTING FOR INFLATION

To consistently compare prices or macroeconomic variables (e.g. GDP) over time it is necessary to adjust observed prices for inflation over time (or to deflate). The nominal value are the current prices that are observed at a time. The constant prices are in real value, i.e. they have been adjusted for inflation with a price index. A price index reflects the inflation over time in comparison with a reference year.

$$\frac{\text{Current Price}}{\text{Price Index (decimal form)}} = \text{Constant Price}$$

8. ADDITIONAL INFORMATION

- Frederick S., Loewenstein G., O'Donoghue T. (2002) - Time Discounting and Time Preference: A Critical Review, [Journal of Economic Literature](#), Volume 40, Number 2, 1 June , pp. 351-401(51).
- Harrison, M. (2010). [Valuing the Future: the social discount rate in cost-benefit analysis](#), Visiting Researcher Paper, Productivity Commission, Canberra.
- HM Treasury (2018). "[The Green Book, Central Government Guidance On Appraisal and Evaluation](#)".
- Mohanram and Gode (2013). [Removing predictable analyst forecast errors to improve implied cost of equity estimates.](#)
- OECD (2018), [Cost-Benefit Analysis and the Environment: Further Developments and Policy Use](#), OECD Publishing, Paris.
- Stern, N. (2014). [The Economics of Climate Change. The Stern Review](#), Cambridge University Press.

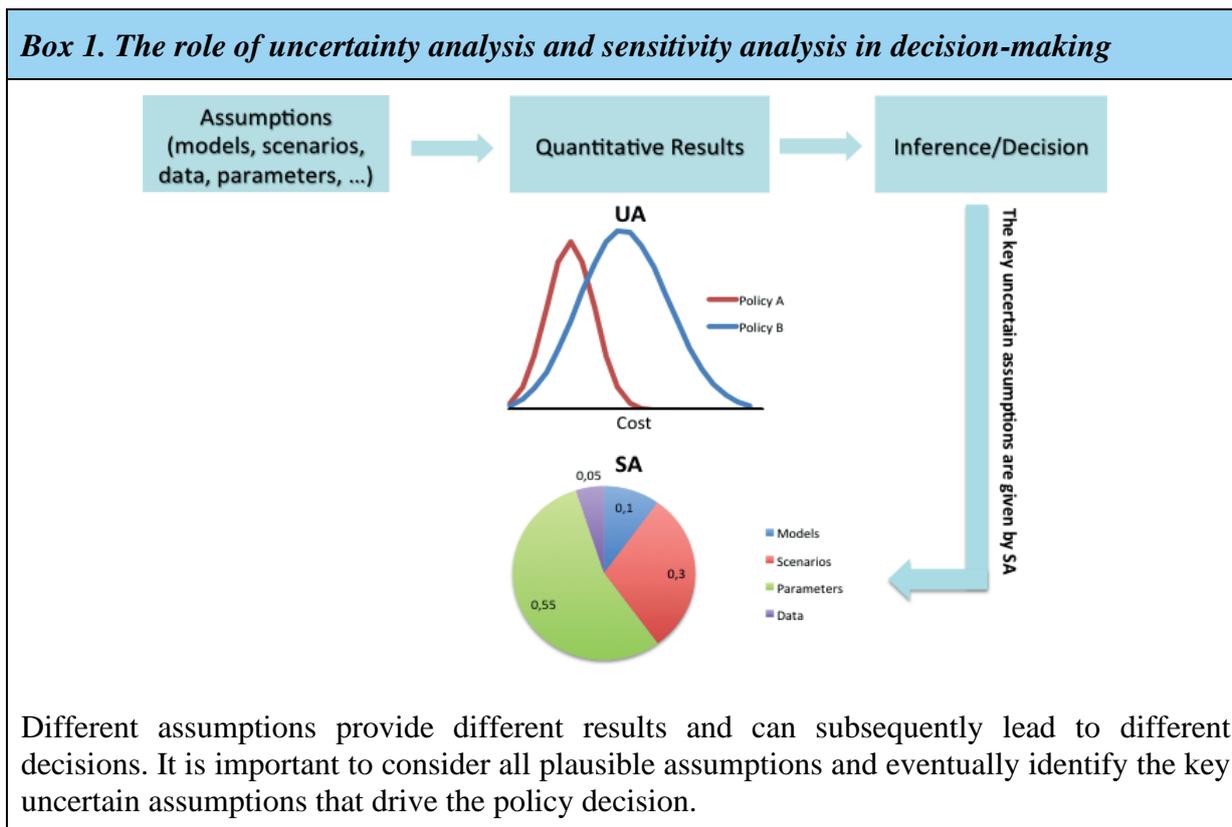
TOOL #65. UNCERTAINTY AND SENSITIVITY ANALYSIS

1. MAIN FEATURES

What	Uncertainty analysis aims at quantifying uncertainties in model results provided to the decision-makers due to uncertain assumptions/inputs. Sensitivity analysis allows identifying the uncertain assumptions mostly responsible for uncertainty in model results.
Why	A transparent and high-quality impact assessment should acknowledge and, to the extent relevant or possible, attempt to quantify the uncertainty in results as it could change the ranking and conclusions about the policy options.
How	Assessing the uncertainties in model results by propagating model input uncertainties through the model and inferring a posteriori the relevant uncertain inputs by subsequent statistical analysis.

Simulation models are extensively used for impact assessments (see Tool #61). When preparing and running these models, the current state of knowledge and all available data should be considered. Good and transparent practice in providing evidence for policy support requires that uncertainty be quantified and considered as much as possible (uncertainty analysis).

Box 1. The role of uncertainty analysis and sensitivity analysis in decision-making



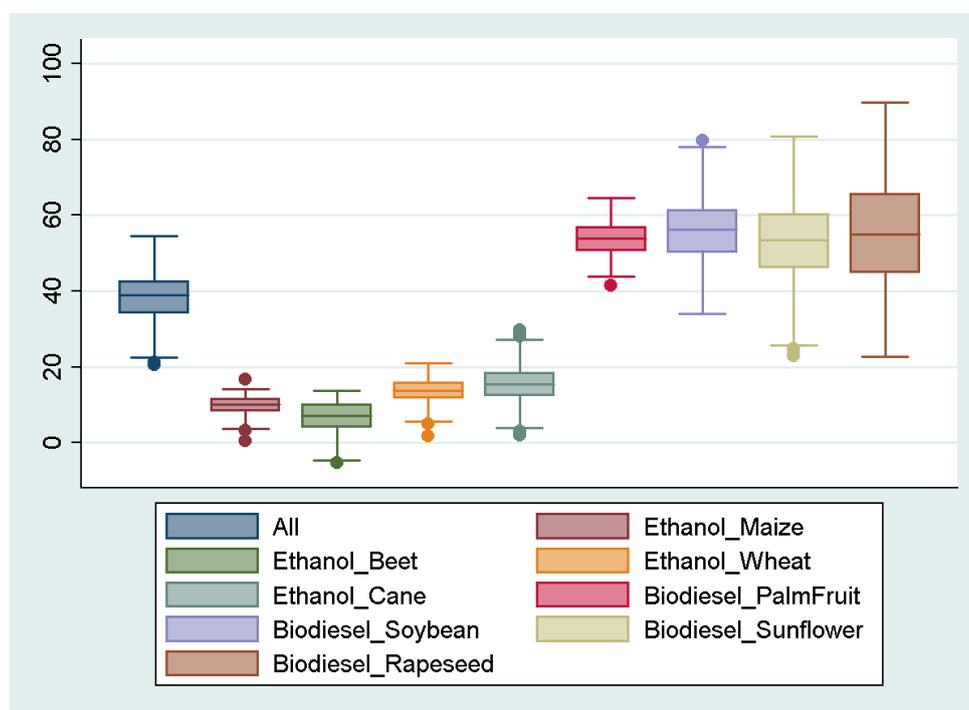
Different assumptions provide different results and can subsequently lead to different decisions. It is important to consider all plausible assumptions and eventually identify the key uncertain assumptions that drive the policy decision.

Uncertainty analysis aims at quantifying uncertainty in a model output using the propagation of uncertainty in the input variables. **Sensitivity analysis** is about understanding how the uncertainty in model results can be attributed to the different sources of uncertainty in the model inputs.

Uncertainty analysis can either i) point to a clear positive impact of a policy option compared with the others, or ii) fail at providing a clear decision because the uncertainties are too large. The first case leads to a robust decision because it means that, despite the uncertainties, the impact of the preferred policy option is consistently the better choice. In both cases, performing sensitivity analysis will allow to highlight which key uncertain variables (related to data and/or knowledge) are responsible for the uncertainty in policies' impact.

Box 2. Monte Carlo analysis to illustrate the range of uncertainty of ILUC GHG factors (IA on biofuels and indirect land use change (SEC(2012) 343)).

The IFPRI-MIRAGE-BioF model was used to model the consumption of biofuels used in the EU and to estimate the emissions of greenhouse gases associated with indirect land-use change for a range of biofuel feedstocks.



Results of the Monte-Carlo analysis: estimated indirect land-use change emissions (gCO₂/MJ)-under scenario of current trade policy. The bars indicate 1st and 99th percentile, while the boxes are 25th and 75th percentiles.

On the one hand, sensitivity analysis identifies which variables must be known more precisely to reduce the uncertainty in the results. Analysts can then try to refine their knowledge about the key variables (by expert judgments, data collection, measurement errors, etc.). On the other hand, sensitivity analysis informs the decision-makers about the key assumptions that drive the results and subsequently their decision (see Box 1).

Uncertainty analysis and sensitivity analysis are very informative ingredients of modelling for impact assessment and reporting the results in terms of range of values rather than a single value enriches the analysis and impact assessment (Box 2). Otherwise, one would give a spurious impression of accuracy. Furthermore, model results could also be accompanied with charts or indicators representing the importance of the key variables for each quantitative outcome.

It is important to stress that uncertainty analysis and sensitivity analysis are intended to be **problem-oriented** and not model-oriented. This means that uncertainty and sensitivity analyses may provide different results for different impact assessments even though the same models are employed. This is because the assumptions and data might differ from one study to another.

Undertaking uncertainty analysis and sensitivity analysis is likely to require extra computational, human or financial resources to be deployed during the impact assessment. These resources may not be routinely available for particularly complex models. Nonetheless, those undertaking modelling studies should attempt to identify the key drivers of their results. The use of emulators (or meta-models) could reduce the computational burden associated with sensitivity analysis.

There are different ways to quantify uncertainty. 'Local' uncertainty analysis and sensitivity analysis examine the variation in the model output by changing one input variable at a time, usually to the minimum and maximum plausible values. This **'one-at-a-time' (OAT) approach** is commonly used as it requires less resources, but it can be inaccurate or insufficient.

A **'global' approach allows for the simultaneous exploration of all sources** of known uncertainty and can capture nonlinearities and interactions between model inputs. In global uncertainty and sensitivity analysis (GSA), probability distributions are assigned to uncertain model inputs. This uncertainty is then propagated through the model by running it repeatedly with different input values, which provides probability distributions of the model output of interest.

2. PRACTICAL IMPLEMENTATION STEPS

Uncertainty and sensitivity analyses imply a carefully planning during the model design and execution for impact assessment (see Tool #4 (*Evidence-informed policymaking*) and the introduction to Chapter 8). A timely evaluation of the cost and feasibility of these analyses is primordial.

Box 3. The basic steps to performing global uncertainty and sensitivity analysis

1. **Define the variables of interest for the analysis.** These variables should include the most relevant outputs for the impact assessment.
2. **Identify all model variables that are affected by uncertainty** in consultation with experts and stakeholders as appropriate. Inputs can be of various nature, i.e. scalar variables, time series or spatially distributed maps.
3. **Characterise the uncertainty for each selected input** by assigning a probability distribution using all available information such as experiments, estimations, physical bounds considerations and expert opinion. Extended peer-review should be considered. This crucial step may require significant resources.
4. **Generate a sample** from the previously defined probability distributions. The sample is a matrix which specifies the input values to use for each model run. The sample is generated so as to explore the full extent of uncertainty and is based on the input distributions specified in the previous step. Software packages are available for this.
5. The model is run many times using the sampled input variables for each model run as

identified in the previous step. **For each run, the value of the output variables of interest is recorded.**

6. The results of the model runs are then used to **estimate sensitivity indices, as well as uncertainty** in the model output.

Sensitivity analysis can be complicated, impractical or infeasible. E.g. large models require sufficient computing power and may take a long time to run. There may also be large numbers of uncertain model inputs, and correlations between input variables.

Box 4. A simple example of sensitivity analysis

A model is built to estimate the potential economic cost of a chemical accident at a proposed plant in a European region, including trans-boundary effects. It examines the number of people and businesses living within a certain radius and estimates the total value of lost property and life corresponding to different classes of explosion or fire.

Applying sensitivity analysis, the output variable of interest is the total cost of the damage. Uncertain inputs include medical costs per individual, total population within the impact radius, the size of the impact radius, and the assumed proportion of people and businesses affected, among others. Using expert opinion and available statistics, probability distributions are assigned to each variable, and a sample is constructed consisting of some thousand runs of the accident model. The sample is used to run the model, and the resulting output vector is used to estimate sensitivity.

It is found that, with 95% confidence, the estimated cost is within €2Bn to €20Bn. Furthermore, the most influential input variable is the stock of flammable material, causing 38% of the variance in the cost, followed by engineering variables accounting for 15% of the variance, with a set of meteorological parameters (wind speed and direction) accounting for most of the remaining variance.

It should be noted that sensitivity analysis addresses uncertainties that can be quantified (Box 3). In some cases, i.e. when a deeper assessment of the framing of the analysis is needed, or where there is a major disagreement among stakeholders about the nature of the problem, the analysis can be extended to **sensitivity auditing**.

Sensitivity auditing is a wider consideration of the effect of all types of uncertainty, including structural assumptions embedded in the model, and subjective decisions taken in the framing of the problem. In general, sensitivity auditing stresses the idea of clearly communicating the extent to which particular models can be used to support policy decisions and their results can be trusted, considering as much as possible all forms of potential uncertainty, and to anticipate criticism by third parties. In particular, one should avoid giving the impression of false confidence by 'quantification at all costs'. In some cases there is simply not enough data, or the process is too complex, to give a meaningful quantitative prediction.

3. ADDITIONAL INFORMATION

The JRC (Competence Centre on Modelling) has developed an online tool for uncertainty analysis and sensitivity analysis, available to Staff of the European Commission at <https://web.jrc.ec.europa.eu/rapps/sensitivity/>

- Azzini, I., Listorti, G., Mara, T. and Rosati, R., Uncertainty and Sensitivity Analysis for policy decision making, EUR 30432 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-24752-4, doi:10.2760/922129, JRC122132.
- Saltelli, M. Ratto, T. Andres, F. Campolongo, J. Cariboni, D. Gatelli, M. Saisana and S. Tarantola, *Global Sensitivity Analysis. The Primer*, Chichester: Probability and Statistics, John Wiley and Sons, 2008.
- Saltelli, A., Guimarães Pereira, Â., Van der Sluijs, J.P. and Funtowicz, S., 2013, What do I make of your latinorum? Sensitivity auditing of mathematical modelling, *Int. J. Foresight and Innovation Policy*, 9, 2/3/4, 213–234

TOOL #66. LIFE CYCLE ASSESSMENT

Sustainability dimensions (environmental, social and economic) should be considered in an integrated and holistic manner. By adopting life cycle thinking, impacts can be assessed:

- embracing all steps of value chains, namely of production and consumption systems (e.g. from extraction of raw materials to end of life/waste management);
- fostering comprehensiveness, e.g. entailing different kind of impacts;
- unveiling trade-offs and avoiding shift of burdens from one life cycle stage to another (e.g. from extraction to processing or processing to consumption phase); or across impact categories (e.g. improving on climate change while worsening in water use); or in terms of spatial and temporal resolution (e.g. shifting impacts from within the EU to other world regions or from current generations to future ones).

1. MAIN FEATURES

Life-cycle thinking is a broad concept that facilitates an integrated assessment of the benefits and the burdens in terms of environmental, social, and economic aspects, and can be applied at different scales, from products to regions and complex systems. The application of life-cycle thinking requires specific methods for impact quantification, such as Life Cycle Assessment (LCA) to assess environmental impacts, social LCA to evaluate social impacts, and Life Cycle Costing to assess direct and indirect economic impacts. The combination of these assessments methods provides a complete and comprehensive Life Cycle Sustainability Assessment. This tool focuses on LCA, i.e., on the environmental dimension; while many of the principles are analogous for the other sustainability dimensions. Similarly, this method can also be applied to the social dimension.

LCA is a holistic approach, which supports the integration of environmental sustainability into design, innovation and evaluation of goods and services (products). Being developed since the 1970, LCA is now a mature environmental assessment methodology, internationally standardised (ISO14040/44, 2006). LCA is mentioned as leading principle in many EU^{888,889,890,891} and international^{892,893} policies since the 90's⁸⁹⁴. Moreover, LCA is now central in several European Green Deal policy initiatives and beyond^{895,896,897,898,899,900,901}.

⁸⁸⁸ Integrated Product Policy - Building on Environmental Life-Cycle Thinking. Communication from the Commission; [COM\(2003\) 302](#)

⁸⁸⁹ Thematic Strategy on the Prevention and Recycling of Waste. Communication from the Commission; [COM\(2005\) 666](#).

⁸⁹⁰ A Sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment. [COM\(2018\) 673 final](#).

⁸⁹¹ Building the Single Market for Green Products. Communication from the Commission; [COM \(2013\) 196 final](#)

⁸⁹² UNEP, 2004. Why take a life cycle approach? Paris, p 28

⁸⁹³ UNEP-SETAC life cycle initiative; <http://www.lifecycleinitiative.org/>

⁸⁹⁴ For an overview of the use of LCA in: Sala et al. (2021). The evolution of life cycle assessment in European policies over three decades. The International Journal of Life Cycle Assessment, 1-20.

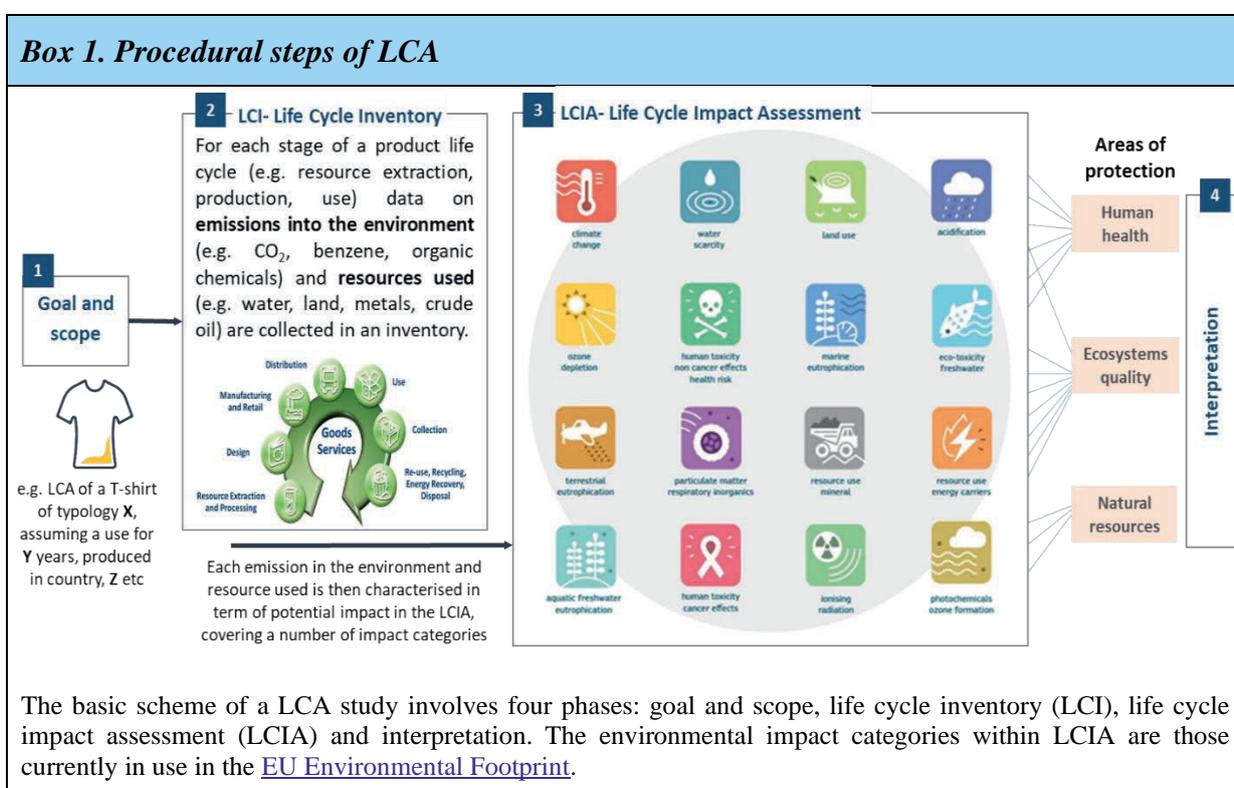
⁸⁹⁵ A new Circular Economy Action Plan For a cleaner and more competitive Europe; [COM\(2020\) 98 final](#).

⁸⁹⁶ A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system; [COM\(2020\) 381 final](#).

LCA aims at an integrated environmental assessment of products (goods and services) and organisations along their supply chain, covering a wide variety of pressures and impacts associated with human health, ecosystem quality, and resources consumption. The method enables the comparison of the environmental impact of products by quantifying all inputs and outputs of energy and material flows in each stage along the entire life cycle. By applying a life-cycle approach, priorities and trade-offs can be identified more transparently thereby potentially resulting in more effective policies.

In an LCA, the natural resources (raw material, water, land) consumed and the emissions into air, water and soil are quantified in an inventory. The potential burdens associated to that inventory are then quantified using specific assessment models for each category of impacts, resulting in a number of impact indicators addressing different impact categories, e.g. climate change, eutrophication, ecotoxicity, land use-related impacts etc.

According to the ISO standard (ISO 14040), LCA consists of four phases (*Box 1*):



- **Goal and scope (1) definition phase:** definition of the aim(s) of the LCA study and description of the central assumptions and system characteristics (e.g. system boundaries, scenarios) in the assessment are described; the environmental impacts refer to a functional unit (e.g. the function provided by a car, a litre of milk) set as a reference quantity for the study, reflecting a specific product/service and its function, based on the defined goal and scope);

⁸⁹⁷ Pathway to a Healthy Planet for All EU Action Plan: ‘Towards Zero Pollution for Air, Water and Soil’. [COM\(2021\) 400 final](#).

⁸⁹⁸ Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. [COM\(2020\) 667 final](#).

⁸⁹⁹ EU Biodiversity Strategy for 2030 Bringing nature back into our lives. [COM\(2020\) 380 final](#).

Box 2. Examples of LCA results

The comparison of two products is presented by highlighting the relative performance in each Environmental Footprint category. For example, in the figure below the environmental impacts of two products A and B are shown, with the highest impact value set to 100% and the other option as relative to that. The analysis can be done also for assessing hotspots of impacts. The example highlights the relevance of each life cycle stage per each impact category for product A.

Impact categories	Product A	Product B	Product A life cycle				
			Raw material extraction	Manufacturing	Distribution	Use stage	End of Life
Climate change	100%	90%	Very relevant impact	Very relevant impact	Slightly relevant	Slightly relevant	
Ozone depletion	29%	100%	Very relevant impact				
Particulate matter	87%	100%		Very relevant impact	Slightly relevant		
Ionising radiation	70%	100%	Relevant impact			Slightly relevant	
Photochemical ozone formation	25%	100%	Relevant impact			Slightly relevant	Very relevant impact
Acidification	91%	100%		Slightly relevant			
Eutrophication, terrestrial	86%	100%		Very relevant impact			Relevant impact
Eutrophication, marine	100%	96%		Very relevant impact			Relevant impact
Eutrophication, freshwater	100%	85%	Relevant impact				Very relevant impact
Ecotoxicity, freshwater	100%	92%		Very relevant impact			
Human toxicity, non-cancer	51%	100%	Slightly relevant			Very relevant impact	
Human toxicity, cancer	100%	88%	Slightly relevant			Very relevant impact	
Land use	100%	95%	Very relevant impact				
Water use	100%	89%	Very relevant impact				
Resource use, fossil	100%	87%	Very relevant impact	Very relevant impact	Slightly relevant		
Resource use, minerals and metals	100%	60%	Very relevant impact	Very relevant impact			

	Very relevant impact
	Relevant impact
	Slightly relevant
	Not relevant

- **Life Cycle Inventory (LCI) (2):** data collection of resource use and emissions related to the chosen products/services for each process in each life cycle stage, from extraction of raw material to end of life;
- **Life Cycle Impact Assessment (LCIA) (3):** resource use and emissions data collected in the LCI phase are translated into indicators that reflect impacts associated with human health, ecosystem quality, and resources consumption, covering different impact categories. This calculation is based on specific impact assessment models and characterisation factors, which represent the potential environmental impact per unit emission or resource consumption. The impact on different impact categories may then, be associated with three protection areas: human health, biodiversity (ecosystem quality), and natural resources. The EU Environmental Footprint method identified 16 impact categories and indicated the use specific models for assessing those impacts⁹⁰².
- **Interpretation (4):** the outcome of the LCA calculation is interpreted in accordance with the aim defined in the goal and scope of the study. This step (illustrated in Box 2) is frequently performed in a decision-making context that requires political choices.

⁹⁰² EU recommended impact categories, models and factors are available at <https://eplca.jrc.ec.europa.eu/EnvironmentalFootprint.html>

LCA is a bottom-up methodology developed to capture in a systematic manner complex systems and supply chains. The more representative the data, the more robust is the LCA analysis. Methodological developments are aiming at improving over time LCA effectiveness in addressing cause-effect relationships in dynamic and rapidly evolving production and consumption systems. Some supply chains are well characterised (e.g., EU production), while others need further improvement (e.g., emerging products and global markets, like food and feed production in developing countries). EU and international efforts are ongoing to ensure that the large amount of data originating from different sources are reaching the best possible quality (in terms of accuracy, technological, temporal and geographic representativeness). Sensitivity and uncertainty analyses can be conducted to improve the robustness of the results.

Box 3. European Platform on Life Cycle Assessment (EPLCA)

The European Commission has acknowledged the potential of LCA as a decision-support method and has further refined LCA to a policy-decision context, considering the methodological and data-related challenges. The European Commission’s JRC established the [European Platform on Life Cycle Assessment](#), which represents the reference point for data and methods recommended at EU level to implement life cycle-based approaches. Complementary to the Platform, the [Life Cycle Data Network](#), aims to provide an international basis for inter-operable, quality assured life cycle inventory data. It also provides a series of tools, guidelines, reference packages and format specifications to facilitate and harmonise the development of those data.

The Platform launched the [International Reference Life Cycle Data System \(ILCD\)](#) handbook. As LCA results could differ for a multitude of reasons including input data used, differences in approach, system boundaries, reference systems and different methods of allocation of the impacts between different products and co-products, this handbook provides a series of operational guidance documents for different types of LCA applications to support robust, replicable and transparent assessment.

The handbook constituted the basis for the development of the [Product Environmental Footprint \(PEF\)](#) and [Organisation Environmental Footprint \(OEF\)](#) methods. The two methods are annexes to the [Commission Recommendation \(2013/179/EU\)](#) on the use of common methods for measuring and communicating the life cycle environmental performance of products and organisations. These methods provide harmonised approach for multi-criteria environmental LCAs and build on international guidelines and ISO standards (e.g. ISO 14040, 14044, 14067, 14072). The two methods provide practical and prescriptive guidance for performing a more robust, consistent, reproducible and verifiable environmental assessment of products and organisations.

PEF and OEF can be used to substantiate green claims in line with the new Circular Economy Action Plan⁹⁰³. To enable comparisons within product groups and sectors, [Product Environmental Footprint Category Rules](#) (PEFCRs) and [Organisation Environmental Footprint Sector Rules](#) (OEF SRs) are developed, which provide more specific rules for performing the environmental assessment of product groups and economic sectors based on sector-specific organizations representing the EU and global markets. These rules (e.g. the choice of the functional unit) avoid methodological choices and increase the comparability and robustness of the results.

⁹⁰³ A new Circular Economy Action Plan For a cleaner and more competitive Europe; [COM\(2020\) 98 final](#).

2. PRACTICAL IMPLEMENTATION

LCA has been used in different applications related to policies, such as:

- **Support of EU policy development:** LCA is central in several EU policies, including the European Green Deal related initiatives⁹⁰⁴. LCA is mentioned across various policy domains, such as environmental product policy, renewable energy and waste policy. Some examples of LCA use in EU policy development are here reported:
 - Definition of emerging problems related to products and product supply chains, and new technologies, such as to evaluating the environmental performance of economic activities included in the EU Taxonomy⁹⁰⁵.
 - Identification of policy options: e.g. the impact assessment of plastic bags directive has been based on a number of different LCA’s.
 - Development of voluntary environmental product policy instruments, such as the definition of minimum environmental criteria (e.g. EU Ecolabel Regulation, Green Public Procurement).
 - Development of mandatory requirements for product (e.g. communication of carbon footprint for new batteries put into the market, according to the recent proposal for Regulation on Batteries⁹⁰⁶).
- **Enable comparisons within product groups and sectors:** In 2019, 19 [Product Environmental Footprint Category Rules](#) were finalised covering different products (such as batteries and accumulators, several food products – e.g. dairy, beer, packed water, household detergents, IT equipment) and 2 [Organisation Environmental Footprint Sector Rules](#) (copper production and retail).
- **Baselines of environmental impacts to test policy options:** The LCA-based Consumption Footprint and Consumer Footprint indicators⁹⁰⁷ assess the environmental impacts of consumption at Member State and at individual (citizen) level respectively. These indicators can be used as baselines to assess the environmental benefits of policies (see e.g. the role for the monitoring of the circular economy⁹⁰⁸) and to monitor in a holistic manner the evolution of impacts in relation to consumption patterns. Moreover, impacts could be compared against planetary boundaries to assess the extent to which EU production and consumption are surpassing sustainability thresholds.
- **Supporting implementation of UN SDGs at product/service level** with LCA (e.g. in support to the achievement of the SDG 12 on responsible consumption and production; and assessing transboundary impacts of EU production and consumption on other world regions).

⁹⁰⁴ Sala et al. (2021). The evolution of life cycle assessment in European policies over three decades. The International Journal of Life Cycle Assessment, 1-20.

⁹⁰⁵ [Regulation \(EU\) 2020/852](#) of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088. EU(2020) 852.

⁹⁰⁶ Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020; [COM \(2020\) 798 final](#).

⁹⁰⁷ <https://eplca.jrc.ec.europa.eu/sustainableConsumption.html>

⁹⁰⁸ A new Circular Economy Action Plan For a cleaner and more competitive Europe. [COM\(2020\) 98 final](#).

3. ADDITIONAL INFORMATION FEATURES

- European Platform on Life Cycle Assessment <https://eplca.jrc.ec.europa.eu/>
- Sala et al. (2016). Life cycle assessment for the impact assessment of policies. Luxembourg. Publications Office of the European Union: ISBN 97892-79-64813-7
- Sala et al. (2019) Indicators and Assessment of the environmental impact of EU consumption. Consumption and Consumer Footprint for assessing and monitoring EU policies with Life Cycle Assessment, Luxembourg: Publications Office of the European Union, ISBN 978-92-79-99672-6
- Sala S. (2020) Life cycle assessment and evaluation of solutions towards sustainable development goals. In: Filho W. L. (Eds). Encyclopedia of the UN Sustainable Development Goals, Springer, ISSN: 2523-7403
- Sala, S., Amadei, A. M., Beylot, A., & Ardente, F. (2021). The evolution of life cycle assessment in European policies over three decades. The International Journal of Life Cycle Assessment, 1-20.

TOOL #67. DATA IDENTIFICATION FOR EVALUATION AND IMPACT ASSESSMENT

This tool gives an overview on the data collection required to produce evidence on policy impacts.

1. INTRODUCTION – THE NEED FOR EVIDENCE

Impact assessments aim to collect ex-ante evidence to assess the environmental, social, and economic impacts an intervention is expected to have. Evaluations aim to collect ex-post evidence to assess an intervention against the five evaluation criteria of (i) effectiveness, (ii) efficiency, (iii) coherence, (iv) relevance and (v) EU added value. The assessment is applied both to the intervention itself, as well as to related policies such as delegated and implementing acts. The ultimate aim of the impact assessment is to explore the best possible future action, while the ultimate aim of evaluations is to learn what worked from experience and to improve the policy. The present tool classifies data and asks relevant questions on 'what data to collect' for impact assessments and evaluations. Moreover, it provides guidance on how to design data collection at an early stage.

2. DATA ACROSS THE POLICY CYCLE

The following 11 questions recap some of the main data considerations, focusing on the obvious and less obvious links related to data among the three main simplified phases of the policy cycle, namely the ex-ante, the implementation and the ex-post phases. It is important to reflect on these questions throughout *all phases* of the policy cycle.

- 1. What are the objectives and issues addressed by the policy?** What does the current intervention aim to change, i.e. what are its objectives? What are the main issues that the policy aims to tackle? What are their drivers and which ones is the policy going to intervene on?
- 2. Why should it work?** All policy initiatives benefit from designing upfront the 'intervention logic', where for instance the rationale of the policy intervention, policy context, expected chain of effects on the intervention, and expected outcomes of the intervention (both intended ones and side-effects) are explicitly listed and discussed usually in an impact assessment. The use of such an intervention logic has the advantage to consistently guide actors through different phases of the policy cycle i.e. from design phase to implementation and evaluation with some learning/adaptation of the intervention logic allowed along the way.
- 3. What will the success look like?** Given the intervention logic, one should choose appropriate indicators that would help measuring whether the intervention was successful or not. To the extent possible, the selected indicators should cover both intended effects and side-effects. This can feed into a plan on how to access data on these outcomes, the 'data plan'. The number of indicators of success should be limited to a manageable handful.
- 4. Who is affected?** EU legislations affect individuals/firms/regions to a different extent. Answering this question can lead to a plan on how to obtain data on relevant individuals/firms/regions.

5. **What data plan is needed?** An early 'data plan' (see 3.3) is the biggest facilitator for any future evaluation. If done upfront, it efficiently guides a fit-for purpose ex-ante phase, informs the implementation phase and carries the blueprint for the evaluation phase.
6. **What type of impacts need to be considered?** Depending on the intervention to be evaluated all relevant impacts in addition to social and/or economic and/or environmental ones, need to be considered. In addition, for economic impacts, special consideration is required on compliance costs and in particular administrative costs for which the 'one in, one out' approach applies (see Tool #59 (*Cost estimates and the 'one in, one out' approach*)).
7. **What types of data need to be considered?** Stakeholder consultations provide data on *opinions*. Data from markets, balance-sheets of firms, registries (health, social security, unemployment) etc. are *observational data*. Observational data can be micro (having records for every single individual or firms, etc.) or macro (as in national accounts aggregating data over a specific group). Data on opinions complement observational data. These two types of data are complementary but not substitutes.
8. **What are the interactions, the trade-offs, the synergies?** What interactions are there between the policy initiative and other initiatives? Are these trade-offs, synergies or other interactions? What does this imply for the data plan, i.e. can one address data collection jointly with other parts of the package?
9. **Where should data come from? What is its quality?** Monitoring and evaluation clauses could mandate the (re)use of data that is already collected by local and national government (registry data, market data) or data from EU institutions. This way to access data is the most cost-effective. However, if new data is needed for evaluation purposes, monitoring and evaluation clauses should appropriately mandate their collection and sharing (see Chapter 5 on monitoring).
10. **Are ex-ante and ex-post impact indicators the same?** There needs to be consistency across phases of the policy cycle. Outcomes/impacts considered in the ex-ante and ex-post phases need to be measured by the same indicators. These outcomes should also be included in the monitoring phase and serve as a basis for the 'evaluate first' principle.
11. **Can one use monitoring data for evaluation?** There are synergies between monitoring and evaluation. Monitoring should aim to collect data on the impacts, which are usually identified in the ex-ante and gathered in the ex-post phases. If monitoring data is collected or accessed for individual/firms/regions with different treatment level or status this will allow having better monitoring information, where differences between groups will signal success of the intervention in a more robust way.

3. WHICH DATA TO COLLECT?

Not 'any data' can serve as evidence for an intervention. Data needs to be relevant in respect to: (a) the impact assessment and evaluation criteria (b) the specific intervention logic. Therefore, using 'the data that we have', however tempting it is in a situation where evidence is limited, should be assessed in view of its usefulness.

The best data for an impact assessments and evaluation is linked to the policy objectives and intervention logic. If choice exists, it is preferable to collect more granular data, as this facilitates the use of causal methods (see section 1).

3.1. From the intervention logic to measuring impacts

A simplified intervention logic for an evaluation is outlined in Tool #46 (*Designing the evaluation*), and the use of an intervention logic / problem tree for impact assessments is highlighted in Tool #11 (*Format of the impact assessment report*).

Based on the intervention logic, one should be able to identify data for:

- i. *Policy inputs*; these are the means to achieve the EU policy objectives of a given intervention. In spending programmes, it is important to record how much financial resources were given to any single recipient of the funds. Often policy input indicators are collected by managing authorities or by the Commission. It is hence important to record and make accessible this type of data;
- ii. *Outputs*; this is what is expected to be generated directly by the policy intervention;
- iii. *Results/impacts*; these are what the given intervention expects to achieve in the medium to long term.
- iv. *External/contextual factors*; these are factors that can influence the results/impacts of the intervention in addition to policy inputs; external/contextual factors are important. For example, to measure the impact of most social policies one needs to account for the macroeconomic conditions related to the business cycle (external/contextual factors).
- v. *Other overlapping policies*; the coherence with other policies can affect the comparison point and degree of analysis possible.

In order to frame the question 'what data to collect?' one needs to consider the intervention's expected results/impacts, since they dictate the next steps on data identification and collection.

A complementary way to approach the question 'what data needs to be collected' is to focus on the main actors that the policy is targeting. For instance, if a policy initiative is trying to guide citizens to favour sustainable products by regulating labelling of goods, one could consider as relevant indicators the level of sales of sustainable goods on the side of consumers, and possibly the level of costs incurred by firms to label the goods. This may imply the need to collect data on sales and on firms' costs, probably from different sources.

One consequence of this observation is that, while *all* EU policies aim at improving the welfare of citizens, evaluations need to stay *close to the specific aims* of the given policy, starting from providing evidence on behaviour of the main actors that the policy aimed to influence.

3.2. Unintended effects

When answering the question 'what data to collect' unintended or side-effects of a policy intervention need also to be considered. Using the labelling example above, the requirement for new labelling of goods may induce higher production costs, which may (at the extreme) force some companies to reduce their manpower. This is an example of unintended effects or side-effects of a policy intervention.

3.3. Data availability and data plans

If some of the needed data is not already available, what can be done? A lot can be and should be planned in advance, for instance using a carefully constructed stakeholder consultation strategy. Early action is often the cure to many of the data limitations encountered later in the EU policy cycle.

The first principle is to start planning a clear monitoring structure from the impact assessment / design phase (see Tool #43 (*Monitoring arrangements and indicators*)). If it is recognised that the right data is not currently available, then the design of the legal text may envisage ways how to make it available next time an evaluation is to be carried out. One way to do this is to insert specific monitoring and evaluation provisions. In addition, when there is a lack of data make sure to explore all of the Commission resources available. That includes, but is not limited to, checking internally for data from previous evaluation and studies, data from the work of other DGs such as Eurostat or EU decentralised agencies and other EU bodies, as well as engaging with data platforms such as RegHub, Fit4Future or EESC in the quest for data.

Is some data better than no data? Yes, but not any data. If the available data at hand is related to the evaluated policy in the sense of being linked to the intervention logic, then it should be used. However, even large amounts of data that are only remotely linked or not informative about the given policy are useless. So it is important to think ahead and plan collecting data from the beginning of the policy cycle.

3.4. Data triangulation

If the data plan is well done, one may find different sources of data that try to measure the same phenomenon. Data triangulation is a way to validate the quality of different sources of data. For instance, one may cross-check the opinions collected in consultations with statistical data on the same issue. Should they not match, further investigation is required on the possible reasons.

3.5. Impacts ex ante and ex post

The outcome variables (impacts) of an evaluation should be the same as the ones considered in the impact assessment, and the outcome variables in an impact assessment should in the best-case scenario build on a previous evaluation, when available. The different evidence base gathering processes of the policy cycle should help improve each other and is another reason for a careful and thoughtful design of the monitoring of an intervention.

If something cannot be measured in the evaluation, maybe it should not have been included as impact in the impact assessment or the relevant monitor indicator was missing. This consideration may limit the number of impacts considered in the subsequent revision of the legislation or inspire looking for alternative indicators that can be measured in the next policy cycle.

While the types of impacts considered in impact assessments and evaluations should be the same, the way to measure those impacts (i.e. the methods) should be different. When preparing policies, ex-ante impacts can be estimated with a model. These estimates should be

later compared with real (not estimated) data collected in the evaluation. In other words, re-running the same model in the policy preparation and policy evaluation phase using the same input data would not give evidence on the realisation of impacts.

3.6. Different types of data

The overall strength of evidence comes from the quality of data gathered in previous parts of the policy cycle, from the appropriateness of the methodology applied, and from the concurrence of different parts of the evidence (see Tool #4 (*Evidence-informed policymaking*)).

Scientific evidence on the quality and impact of public interventions, policies and programmes is based on the application of the scientific method to data coming from either:

- observational data, i.e. data collected by passive observation of individuals, firms, communities potentially affected by the policy;
- opinion data;
- randomised control trials (RCT), i.e. data from a controlled experiment.

Assume a new market regulation is introduced, and this is the policy of interest for an evaluation. Data is generated by the functioning of the market to which the new regulation is applied. The data generated by the market is an example of **observational data**, which is typically collected by appropriate reporting provisions in the legal act.

The new market regulation may have affected consumers and firms; both of them are stakeholders, and they may be asked to state their perceptions on the effects of the policy. The data collected on the opinions or perceptions of stakeholders is **opinion data**. Data on stakeholders’ opinions is typically gathered through stakeholder consultations (see Chapter 7).

Remark on data types: data on opinions and observational data are *complementary sources* of information. They can be used to provide different types of evidence for the evaluation. **Hence, both types of data need to be collected.**

Observational data can be recorded for single citizens (individuals), products, firms, or geographical areas like regions. For instance, one may wish to record the price increase of a certain type of product sold in a given market, like the price of 1 kg of a certain cheese, protected by Geographical Indication (GI). These types of data are called **microdata** because they are disaggregated (micro), and it would not make sense to record data at a lower level of aggregation (i.e. at a higher level of granularity).

It is possible to aggregate microdata at different levels. For instance, the price of a category of goods can be aggregated; one may wish to record the price of 1 kg for all types of cheese in a given market. Prices can be aggregated across categories of goods and services, and/or at sector level, at national level and so on. These types of data are called **macrodata**. A typical example of an aggregate would be households’ consumption of dairy products.

When evaluating policies, it is preferable to use microdata, as it is usually simpler and more convincing to link them to the policy effects. If microdata are not available or accessible, macrodata can also be used, albeit the attribution of the effects to the policy at hand might be more difficult or less direct than when using microdata. For the GI cheese, one may be

interested to observe the time evolution of the GI-protected cheese (the ‘treated’ group) and to compare this with the time evolution of non-GI-protected cheese (the ‘control group’). The time evolution of the aggregate price of cheese may conceal these differences, hence making it difficult to attribute price changes to the GI scheme.

Other data can also be acquired or accessed from market surveillance organisms and regulators, government administrations and other public institutions; this type of data is called registry data or **administrative data**. Administrative data needs to be accessed with due personal privacy safeguards, compliant with the GDPR⁹⁰⁹. Using administrative data is very cost-effective, as the data has already been collected for other purposes (so the acquisition cost is marginal), with large number of individual records and good representativeness (see below for definition).

Government authorities may be unwilling to share data, unless specific provisions to collect and share data exist in the legislation. It is therefore important to mandate their collection and sharing when defining monitoring and evaluation provisions in the policy development stage (see also Section 4). EU decentralised agencies and other EU bodies, managing and regulatory authorities in Member States usually collect data on products, services, individuals, firms that are influenced or affected by EU policy. They are another potential source of data to consider when defining monitoring and evaluation provisions.

Other observational data can be collected via surveys. Survey data may inform both about opinions and perceptions of respondents, as well as on objective data, such as personal income. Self-reporting of such variables in surveys may be, however, prone to various biases and requires triangulation (see section 3.4 above). Overall, the cost of data from surveys is usually higher than the one of administrative data. Moreover, the level of non-response in surveys can be very high.

Remark on the cost of data: administrative data (including data from government authorities and regulatory national authorities) is quite inexpensive as it has already been collected for other purposes when compared to survey data. Moreover, administrative data usually covers the whole population, and hence the sample size is much larger than what can typically be covered by surveys. Conversely, some information can only be collected with especially designed surveys. Hence, **the best approach is to integrate administrative and survey data**, foreseeing which data to link from various sources.

Remark on available secondary sources: The gathering and identification of suitable data often comes down to a meticulous literature review and thorough desk research. The [Find-eR search tool](#) gives access to the Commission library collection of e-journals, eBooks, portals and database.

3.7. Data linkage

Different sources of data can be linked together. For instance, the tax records may contain the turnover of a firm and the social security files may contain the number of employees of the

⁹⁰⁹ The General Data Protection Regulation (GDPR) from 2018 provides the legal rules to be obliged to in the European Union. See also Tool #55 (*Horizontal matters – publication of responses, data protection, access to documents and transparency register*) on i.a. data protection.

same firm. In order to merge or *link* the two sources of information, the same identifier of the firm needs to appear in both data sets. This process of merging data is called 'data linkage'⁹¹⁰.

Some EU Member States have special agencies whose task is to link data for policy evaluation research. These agencies are usually public and may charge a relatively small fee to perform data linkage.

Remark on data linkage: data from different sources (including government authorities, Regulatory National Authorities etc.) can be linked using unique **identifiers**. For instance, data from different sources can be linked via geographical reference, such as when data refers to the same NUTS3 region. Data on firms can be linked via their name and address or national TAX code, etc. If needed, data can subsequently be anonymized in order shield sensitive information from analysts.

3.8. How should data be collected?

Appropriate methodology needs to be applied to analyse different types of data, to extract evidence on the policy intervention. The correct method is the one that fits the right data, and the process with which this data was collected, as discussed above.

There are methods that are more robust in capturing the causal links between policies and their effects. These methods are called *causal*, and they described in Tool #68 (*Methods for evaluating causal effects*). The ultimate choice of the method will depend on the available data.

Remark on the sequence of questions to ask: One could start with the question: what is the best data-and-method combination for this policy intervention and the evaluation of it?

One can start from listing data, and next, given each dataset, define which method can be best used to produce evidence. Some other times e.g. in structural modelling one can proceed in the reverse order, selecting methods first and data next.

Both opinion data and observational data need to be collected. In both cases, one may need a **sampling design**, i.e. a plan about how to sample from the given population to produce representative samples. Sometimes this plan has already been collected by someone else, for instance by some other agency or institution; in this case one needs to give account of this and to consider this sampling design. Some other times, one needs to directly collect data, and hence one needs to clarify the sampling design.

In business research, companies must often generate samples of customers, clients, employees, and so forth to gather their opinions. Sample design is also a critical component of marketing research and employee research for many organizations. During sample design, the officers responsible for the design must answer questions such as:

- What is the relevant population, sampling frame, and sampling unit?
- What is the appropriate margin of error that should be achieved?
- How should sampling error and non-sampling error be assessed and balanced?

⁹¹⁰ See e.g. Chapter 6 in Crato & Paruolo (2019).

These issues require very careful consideration. Some introduction and reference are given next; these considerations apply both to stakeholder survey as well as to other surveys used to collect observational data.

A few of the above suggestions are summarised in the following box:

Suggestions:

- a) Focus on a few outcomes of interest that are close to the objectives in the intervention logic.
- b) If impacts cannot be measured ex post it is often not useful to consider them ex ante.
- c) Make an ex-ante plan on how to collect data for the ex post evaluation.
- d) Try to access data that has already been collected (administrative data, data from government authorities and national regulatory authorities).
- e) If you have data in-house (like the ones on inputs), share it with all of the Commission.
- f) If you outsource an impact assessment or evaluation to contractors, ask them to hand in the data that they collect.
- g) Where possible, survey data should be representative for the population (collected randomly).
- h) Report survey data by subpopulations.
- i) Report uncertainty estimates from surveys.

4. ADDITIONAL INFORMATION

- An introductory 2 minute video on administrative data is available [here](#).
- An introductory 2 minute video on data for evaluation is available [here](#)
- A tutorial (25 minutes) on pros and cons of different types of data, data collection, data access and data merging in relation to causal methods is available [here](#).

Relevant publications:

- Cochran W. (1977) Sampling Techniques, Third Edition
- Groves et al (2009) [Survey Methodology](#) Wiley

TOOL #68. METHODS FOR EVALUATING CAUSAL EFFECTS

This tool introduces the principles of ex-post quantification of impacts in evaluations, especially relevant for (i) efficiency (ii) effectiveness (iii) EU value added. **Quantitative analysis** complements **qualitative analysis**: both are essential to build the narrative of the evaluation and to explain the analysis of impacts.

1. CAUSAL EFFECTS

Evaluations aims to answer questions such as: “What were the effects of the policy? Who was affected? What change did it make?” These questions are summarised as “What worked and for whom?” in the following.

The **causal effect** of a policy or intervention is **the consequence (i.e. the effect) attributable to it**. Causal analysis aims to identify the effect of the intervention (called ‘*x*’) on the **outcomes** of interest (both intended and unintended – called ‘*y*’), considering (or controlling for) other causes of the phenomenon generating the outcomes, including other policy interventions (**contextual indicators**, called ‘*z*’).

Evaluation aims to **draw conclusions about the causal effects of** an intervention, using but going beyond the description of *what* happened, and looking for reasons *why* it happened (the mechanism through which the causes act on it), i.e., it aims to attribute observed changes to the intervention. In other terms it would like to conclude that “*x* causes *y* controlling for *z*”. (i.e. taking ‘*z*’ into account)

As an example, one may observe neutral or negative changes in the outcome of interest; one should not (only on the basis of this) conclude that the intervention was ineffective or detrimental. This is because “what would have happened without the policy” called the **counterfactual**, could have been worse. Of course, the same applies to positive changes. Isolating the observed changes and attributing them to the intervention is a challenging exercise but one should **strive to identify causal effects**, if possible (in terms of data and methods).

2. CORRELATION AND CAUSALITY

A simple concept in quantification is the one of correlation. Assuming for a moment that there are no contextual indicators ‘*z*’ to consider, one could wish to measure the correlation between outcome ‘*y*’ and the intervention ‘*x*’, indicated here as $\text{corr}(x,y)$. For the purpose of this section, also assume that “*x* does not cause *y*” (or vice versa) is translated into “*x* and *y* are independent.”

This section illustrates that correlation and causality are different, but related concepts. Correlation is a measure of linear association between *x* and *y* and does not have any ‘direction’ (unlike in cause-and-effect statements)⁹¹¹. As it is well known, $\text{corr}(x,y)$ can be positive, zero or negative, and takes values between -1 and +1. $\text{corr}(x,y) = 0$ corresponds to lack of linear association between *x* and *y*.

What is the relation between correlation and causality? Some variables may be correlated because of an underlying common cause. For instance, there could be a positive correlation

⁹¹¹ $\text{corr}(x,y) = \text{corr}(y,x)$

between ice-creams sold and number of shark attacks, but they do not cause each other. A more plausible causal explanation is warm weather causing people to go to the beach and increasing the likelihood of both ice creams sold and shark attacks. It is important not to draw causal conclusions on correlation, and whenever possible go beyond correlations to cause-and-effect relation. Correlation is not causation, but what is causation? To use another example, a headache pill can positively correlate with relieved headache, however, causal inference tries to identify the extent to which the relief is attributed to the pill.

Full causality analysis is not always possible, in these instances correlation (regression) analysis is better than nothing, as long as appropriate limitations are accounted for and explained. Of course, if possible, the aim should be to analyse causal effects, for which appropriate methods are detailed in what follows.

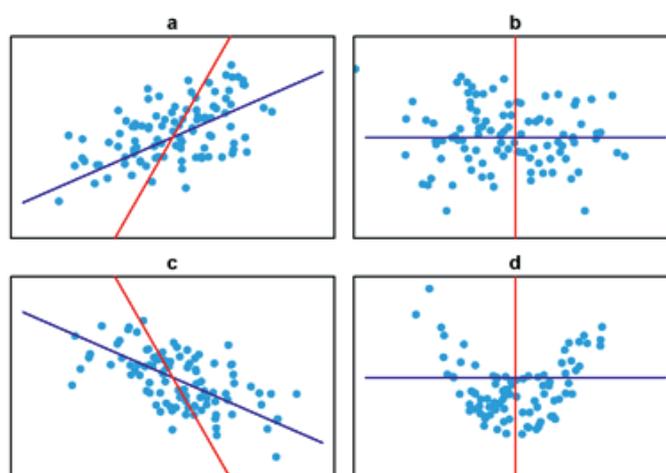


Fig.1. Examples of types of correlations between x (on the horizontal axis) and y (on the vertical axis). The plots contain dots that represent sample values of (x,y) together with regression line of y on x (blue line) and regression of x on y (red line). ¹¹

- a: positive correlation, $\text{corr}(x,y) = 0.7$ (x,y dependent);
- b: zero correlation with independence, $\text{corr}(x,y) = 0$ (x, y independent);
- c: negative correlation $\text{corr}(x,y) = -0.7$ (x,y dependent);
- d: zero correlation with dependence, $\text{corr}(x,y) = 0$ (x, y dependent).

¹¹ a,b,c: (x,y) jointly normal. d: y generated as $y = 0.25x^2 - 1 + u$, with x normal with mean 0 and variance 4 and u uniform between -1 and 1 and independent from x .

3. COMPARISON GROUP

3.1. A comparison group may help

As explained in Tool #46 (*Designing the evaluation*), one would like to compare policy outcomes with a situation that could have been expected in the absence of a new policy intervention, a ‘no-policy-change’ scenario⁹¹². The identification of behaviour in the ‘no-policy-change’ scenario may use a reliable group of untreated units, called **control group**.

⁹¹² This situation is often called generically ‘the counterfactual’, which relates to or expresses what has not happened and what could have been.

A **control group** is made of units that are as similar as possible to the treated ones except from the fact of not being affected by the policy. This control group may be used to estimate the counterfactual scenario of no EU policy.

One needs also to consider the context in which the EU intervention took place, including for instance, national policies with similar objectives (**contextual indicators**) described in Tool #67 (*Data identification for evaluation and impact assessment*). This may allow to 'control' for these national policies when evaluating the EU intervention. The main idea would be to compare the treated group with the control group controlling for contextual indicators.

Lastly, it may not be possible for all EU policies to define a treatment and control group in the strict sense, and several factors and biases should be considered before conducting a causal analysis. Many of them are highlighted below.

3.2. Selection bias, measuring bias and spurious relationships.

In every causal analysis it is important to consider factors that could weaken the causal claim. Some of the more frequent biases that might arise in both observational studies and randomised experiments are selection bias, measurement bias and confounders. These factors should be considered in order to present a robust analysis of causal effects. **The selection bias problem occurs when** the assignment to the treated and the control group was not done at random but out of a selection process related to the outcomes; in this case the population from which the control group was sampled is substantially different from the one of the treated group and comparing them directly would be misleading. For example, if unemployed people self-select into a training programme (the policy intervention), their (hopefully) higher chances to find a job after training may reflect either the benefits of training (i.e. an effect of the policy intervention) or the fact that they may come from the sub-population of unemployed with better motivation and entrepreneurial skills with respect to the ones that did not apply for the training. In the latter case the higher chances to find a job are not an effect of the policy intervention.

This selection bias problem hence complicates the issue of finding a proper control group. Many causal methods solve this issue in various ways. Box 1 provides an example on how to avoid selection bias in student mobility.

Another important factor to consider is whether the causal effect is misgiving or weakened due to the data collection process, **the measurement error bias**. In fact y , x , z could all be measured with an error. Continuing on the example above, training x could be measured with error (for instance some people could have been registered as participants but never showed up at training), their years of work experience z could be measured with error (for instance some years of self-employment may have been not recorded) and their working status 6 months after training y may contain reporting errors (for example people were interviewed 12 months after the end of the training, and some forgot to properly recall their employment status 6 months before). Measurement error (especially in x , z) may induce substantial bias in the estimates of impacts.

A third aspect is related to **the importance of considering contextual indicators**. Contextual indicators refer to variables z that are associated with both the treatment (independent variable x) and the outcome (dependent variable y). When the contextual indicators are not accounted for, one could find a relationship between the independent

variable x and the dependent variable y when no relation exists. In such a case this could be termed a **spurious relationship**, namely, an observed correlation (or association) without a causal link. For example, the relationship between the beneficial effects of a training programme (dependent variable y) and the training program itself (independent variable x) does often not exist 'in a vacuum'. Other variables such as the participant's education, income or age could also have a significant causal effect on the outcome. Therefore, contextual indicators z are a major threat to the validity of inferences made about cause and effect, when not considered.

Box 1. An example on how to avoid selection bias: student mobility

What is the effect of student mobility (e.g. participation in Erasmus programme) on future employment status?

Mobile students are generally more motivated, have better language skills and hence better labour market outcomes than the average non-mobile students, even before their mobility experience. Hence, **taking any non-mobile students as control group would lead to selection bias.**

Like with many evaluations, different methods can be used for constructing a control group. A good control group would consist of non-mobile students as similar as possible to mobile students in their characteristics.

One possibility would be to create a control group with students who did want to take part in mobility but *just* missed a specific threshold of university qualifications (e.g. a threshold of 50 of a score ranging from 0 to 100) that is necessary to obtain for being eligible for the mobility grant; see e.g. Granato et al. (2020) Comparing these non-mobile students close to the threshold for eligibility (i.e. grades 45 to 49) with those mobile who just made it (i.e. grades 50 to 54) is likely to lead to very similar control and comparison groups, since the **allocation to the comparison and control group around the threshold is likely to be random.** The causal evaluation model adopted in this framework is called **Regression Discontinuity Design** (see below).

Another possibility for constructing a control group is to compare only those non-mobile students with mobile students, who are similar in a large set of characteristics (i.e. upper secondary school mark, motivation etc.) linked to the outcome variable of interest (i.e. being in employment; see Schnepf and d'Hombres 2019). This method of counterfactual impact evaluation is called **Propensity Score Matching**, see (see below).

3.3. Everyone is treated

For regulatory policy, it is often the case that the same rule applies to all citizens or to all firms, so that everyone is treated and there is a lack of a control group. Even in such cases the variation of the treatment could allow for an analysis of causal effects for instance, some methods estimate a **dose-response model**. Namely, those more exposed to the policy intervention are expected to respond more than those less exposed.

3.4. Only aggregate data is available

In case data at the appropriate level of granularity cannot be accessed, but data at aggregate level exists, what can be done? First, one could plan to insert appropriate clauses in the next

policy design phase (ex-ante) so that data at the appropriate level of granularity will be accessible in the future. Secondly, one may work with the **aggregate data** that is available (see Tool #67 for a more detailed discussion on types of data). One approach is to compare estimated models for different periods of time under different policy regimes and compare the structural parameters across periods; this is sometimes called **models for structural change**. Here attribution of the difference to a single policy change is assumed, and this need to be substantiated by appropriate qualitative evidence.

3.5. Can the same policy have different effects at different scales?

The effects of some policies may be different at different scales. Consider for instance some labour market intervention like training, aimed at supporting the long-term unemployed. This intervention may generate higher exit rates from long-term unemployment on a micro scale, i.e. the long-term unemployed subject to the policy intervention may re-enter employment more often or more quickly than the ones not taking training.

At the more aggregate general unemployment rate, this policy may have no effect, as the trained long-term unemployed may have found jobs that have displaced other individuals, with a zero aggregate effect. These more aggregate effects are sometimes called **(general) equilibrium effects**. A consequence of this is that an evaluation needs to decide at what level(s) of granularity it needs to be applied. Different levels may lead to different answers.

3.6. Specific contribution in a policy package

Often, one policy intervention is part of a policy package with general objectives. This is a central aspect for **fitness checks** but applies more generally to most evaluations. For instance, labelling of sustainable products may be part of the European Green Deal, and possibly contributing to other policy priorities. This implies that each evaluation should consider how to address the following problems:

- (i) What is the contribution of the single policy intervention to the overall objectives and outcomes of the policy package?
- (ii) What is the specific effect of the single policy intervention within the overall policy package, i.e., what is the effect of the single policy intervention that could not have been achieved by the rest of the package?
- (iii) Were there trade-offs or synergies with other parts of the policy package?
- (iv) Were there trade-offs or synergies with other policy priorities?

Answering these questions requires advance joint planning from the Commission services working on the different related initiatives.

Box 2. Specificities, trade-offs and synergies in product labelling

Consider for instance a regulation overseeing labelling of sustainable products in a market, with the objective to increase sustainability of the economy and to contribute to the overall climate policies of the EU. The specific effects of this regulation may be best measured in the product market where this labelling takes place: possible indicators capturing the specific contribution could hence be the volume and price of goods traded with this label, relative to other unlabelled products with similar characteristics.

A possible trade-off for this labelling regulation could be associated to excessive regulatory burden: if the cost for firms to label their product as sustainable was disproportionately high, this could make the products too expensive relative to competing products, and the overall effect could fail to increase sustainability of the economy overall.

Possible synergies in this area could come from certification of the firm as being sustainable or ‘green’ overall via related regulation (such as the Green Taxonomy): the effects of the labelling of a product and the certification of the producing firm as ‘green’ could reinforce each other.

As the example in Box 2 shows, one would need to combine data from product markets and certification of firms to see the effects of these two pieces of legislation in action on their own or in combination.

Causal evaluation methods that address these questions require to have data on inputs and outcomes of different interventions of the policy package and of other policy priorities, hopefully for granular level of data. Moreover, it requires to have contextual information on other national policies that are present in the same policy domain.

4. METHODS

The benchmark for scientific quantitative methods is **randomised control trials**, where units are assigned to treatment or to the control group at random. This solves the selection bias issue. When **randomised control trials** are not possible, one can resort to **quasi-experimental** methods that mimic the experimental design to solve the selection bias, under appropriate assumptions. Other methods can also be used, that are not delivering causal analysis. Conducting causal methods requires knowledge on statistical methods and the JRC is available to offer advice on when and how to use the methods. However, it is important to know the advantages and disadvantages for applying the variety of methods outlined below.

4.1. Randomised control trial (RCT) or experimental approach

Units of the same population are assigned to treatment and control groups at random – e.g. using a lottery; this is called **randomisation**. Randomisation could be used e.g. in the case of over-subscription, when there are more applicants than available slots for a specific programme. When assignment into treatment is random, the average treatment effect is estimated by comparing the average outcome for the treated and the controls; this is very simple and in ideal situations does not require to use data of contextual indicators.

It could also be used in the case of phase-in interventions, i.e. interventions implemented in several phases, due, for example, to limited capacity to serve all the units at the same time: eventually every unit will be treated, but the time of treatment is randomised. A comparison between the unit treated first and the not-yet treated can show the effect of the policy in the short term, as this is equivalent to random assignment.

Key requirements for randomised control trials: random assignment of individuals/firms to the policy intervention.

4.2. Matching methods

Matching methods select a control group by matching each treated unit with at least one untreated unit that is as similar as possible to the treated one, based on a wide range of

characteristics (such as contextual indicators) covered in the data set available (so-called **observable characteristics**). Therefore, the quality of the control group hinges on the richness of the data available and a large sample size.

The most famous of these methods is the **Propensity Score Matching (PSM)**. In this method the matching is performed on an index, the Propensity Score, which is defined as the probability of self-selecting into the intervention, for given different individual observed characteristics.

Box 3. Example on propensity score matching: the evaluation of a European Social Fund (ESF) funded intervention in Flanders (Belgium), 2015-2018 (Canzian et al 2020)

The “Work Experience for Young Persons” (WIJ) programme is targeted at low-qualified young unemployed with the aim of facilitating their entry to the labour market, through an intensive guiding and counselling activity. Individuals registered at the public employment service were selected and assigned to the treated group using criteria based on age, level of education and previous work experience. However, given financial restrictions not all young individuals registered at employment services were assigned to the intervention, and many of them remained untreated.

The analysis aimed at evaluating the impact of WIJ in terms of probability of being employed or re-entering education for young unemployed, some months after the counselling activity was finished. The evaluation of this intervention was done using PSM since the key data requirements were met. First of all, information was available for a good number of observable characteristics, including relevant demographic variables (gender, nationality, date of birth), level of education and previous work history (including months spent in unemployment, employment or inactivity since graduation, number and type of contracts). Second, conditional on these observable characteristics available, it was possible to estimate well individuals’ participation in the programme. Finally, a huge number of untreated units were available, sharing similar characteristics with the treated, so that it was possible to select several control units for each treated.

Key requirements for matching methods:

- availability of information on the observable characteristics influencing the selection into the treatment and influencing the outcomes, for both treated and untreated units;
- observable characteristics should be measured before the assignment into the treatment;
- relatively large sample sizes for treated and – in particular – untreated group.

4.3. Regression Discontinuity Design (RDD)

This approach can be adopted when participation in the intervention is determined by a rule or a **threshold** on the value of a **continuous** variable, called the **forcing** variable or the **running variable**. Examples of forcing variables are income, age, or a test score. Many spending programmes have assignment rules based on thresholds: social benefits based on income, scholarships based on grades, employment programmes based on age, etc.

It is common to distinguish between the case when the assignment rule to treated and untreated is applied with no exceptions, called **sharp RDD**, from the case when exceptions to this strict rule can happen; this latter case is called **fuzzy RDD**. Fuzzy RDD is technically linked to Instrumental variables (IV), see below.

Box 4. Example of RDD: the impact of longer unemployment benefits on time in unemployment (Lalive, 2008)

Austria implemented in the late 1980s and early 1990s a programme that extended the maximum duration of unemployment benefits from 30 weeks to 209 weeks of unemployed benefit duration to individuals aged 50 years or older who have been living in certain parts of Austria. Given that the programme was strictly targeted with respect to age and region, a sharp RDD on age and distance to regional boarder is a natural choice to evaluate this policy.

Sharp discontinuities in treatment assignment at age 50 and at the border between eligible regions and control regions identify the effect of extended benefits on unemployment duration.

Key requirements for RDD:

- The probability of participation in the intervention needs to jump at a threshold value of a continuous score (i.e. age, income etc.).
- Enough units (i.e. individuals) should be observed on both side of the threshold (treated and untreated).

4.4. Differences in Differences (DiD)

The method 'differences in differences' compares the changes in the outcome variable over time between treated and untreated units. Provided that (i) in the pre-intervention period, the outcome variables in the treated and control groups follow similar trends (the '**parallel trends' assumption**), and that (ii) the factors explaining differences in outcomes between the two groups **are constant over time**, differences in the trajectory of the outcome variable between the two groups can be attributed to the participation in the programme only.

This approach requires repeated observations over time on both groups (so-called longitudinal data or repeated cross sections).

Box 5. Example of DiD: the Airport Charges Directive (Conti et al 2019)

The Airport Charges Directive (ACD, Directive 2009/12/EC) was approved in 2009 and converted into national legislation between 2011 and 2014, with most Member States transposing in 2011 and 2012. The Directive is meant to be applied only to airports with more than 5 million passengers (or to the country's largest airport if no airports pass this threshold) and involves only a subset of airport charges (i.e. *in scope* charges). The primary objective is to increase the bargaining power of airlines vis-à-vis airports.

One approach to define the treated/control group is to use the population of airports with more/less than 5 million passengers. In this case there are too few airports on each side of the threshold, so RDD could not be used. Hence, this regulatory framework lends itself to a DiD

approach, exploiting the magnitude of the changes in the average level of *in-scope charges* (outcome variable) in treated and non-treated airports before and after the adoption of the directive.

Key requirements for DiD:

- The policy, targeting only a group of units (the treated), should become effective at a certain point in time; this point in time should be known.
- Data for the outcomes of interest should be available both before and after the policy adoption, for both the treated and control group.
- In the pre-treatment period, trends of the outcome variable in the treated group and in the control group should be parallel. This may be checked if a longer time series of the outcome variable before the policy is implemented is available.

4.5. Instrumental Variables (IV)

This method uses an observable variable (called the instrument) which influences the treatment assignment of units but that it is otherwise unrelated to the outcome of interest; this latter requirement is known as the **exclusion restriction**. For example, if a policy offers an unemployment programme at a specific service provider, the distance from each individuals' home to the place where the programme takes place is likely to impact on the participation in the programme but is generally unlikely to be associated with the outcome of the programme.

Box 6. Example of an instrumental variable approach: the Covenant of Mayors (Martelli et al 2018)

The Covenant of Mayors (CoM) was the mainstream European movement for local authorities voluntarily committing to meet and exceed the EU's 20% Green House Gas (GHG) emission reduction target by 2020. In Italian municipalities, the CoM is the best known and recognised action primarily targeting the reduction of GHG emissions.

Martelli et al (2018) want to answer the question "Does the CoM increase the approval of a candidate?" and hence choose as outcome variable the percentage of votes a Mayor receives in re-elections. Treatment status is participation in the CoM, which is not random, and may be associated with positive additional characteristics of the candidate.

The instrument used here is the presence of a so-called 'Covenant Territorial Coordinator,' which provides technical support for drawing up a sustainability plan necessary to join the CoM. This instrument is assumed to affect the probability of treatment (i.e. joining the CoM), but to be unrelated to the political outcome otherwise (exclusion restriction).

Key requirements for instrumental variable approach:

- An instrumental variable is available; an instrumental variable is a variable that affects the outcome of interest only via its influence on the probability to be treated.
- Data on the instrument should be available for both treated and non-treated units.

4.6. What if everyone is treated? DiD with staggered implementation

When every unit is treated, one could use the following scheme. Sometimes units, e.g. individuals, firms, or Member States, adopt the policy or treatment of interest at a particular point in time, and then remain exposed to this treatment at all times afterwards; this situation is called 'staggered implementation'. All units are eventually treated, but not all and every unit is treated at each point of time.

One approach to exploit this situation is to use a DiD approach. The idea is to compare the changes in the outcome of interest for the treated and the control groups. At each point of time, there are units that have already started to be treated, which form the treated group, and other that are waiting to be treated, and they form the control group.

Box 7: Evaluation of the late payment directive (Conti et al. 2018)

Consider the introduction of a directive such as the Late Payment Directive (LPD) aimed at reducing the payment duration between the Public Administration (PA) and the private sector. Assume that the time of implementation varies across Member States, that is a given industry can be treated in a given Member States, but not treated yet in another one. Hence, the impact of the Directive is estimated by comparing changes in the outcome variable (i.e., firms' exit rate, employment rate, investment rate) in the industries in adopting countries to changes in the same outcome variable in the same industries in non-adopting countries, before and after the specific country's enactment of the directive.

Key requirements for staggered implementation with DiD:

- Staggered time of implementation/adoption of the intervention.
- Same requirements as for DiD.

4.7. DiD with intensity of treatment

There are situations where all units comply with the policy intervention (regulatory change), but they differ in the extent to which they are exposed to the intervention. This creates different treatment **intensities**, which can be exploited to identify the effect of the intervention. This approach compares the changes in the outcome variable over time between units more exposed as compared to less exposed ones, using a DiD comparison before and after the intervention.

Box 8: Evaluation of the late payment directive (continued)

Consider again the introduction of the Late Payment Directive (LPD) aiming to reduce the payment duration between the Public Administration (PA) and the private sector. While all industries are subject to the Directive, they may differ in the level of treatment intensity, that is the industries' exposure to the Directive is defined on the basis of the degree of economic dependence of an industry on the Public Administration (PA).

The more an industry sells to the PA (as a fraction of its total sales), the more that industry is exposed to the LPD and hence the higher the expected impact on the firms in that sector. Therefore, the average change over time of the probability to exit the market for a group of

industries more dependent on the PA is compared to the average change of the same variable for a group of industries whose business activity is less and/or not connected to the PA, before and after the adoption of the Directive. Again, see Conti et al. (2018).

Key requirements for DiD with interaction with intensity:

- The possibility to define a degree of exposure to the change in all units of the analysis. The degree of exposure calls for a definition of 'more' treated units as compared to 'less' treated ones.
- Same requirements as for DiD.

4.8. Generalised propensity score (GPS)

The propensity score matching (PSM) method described above matches treated units with similar units that are not treated. The Generalised Propensity Score methods (GPSM) extend this principle, for example, to cases where: (i) different units may be subject to distinct types of treatment; (ii) the units may be subject to the same treatment but with distinct levels or intensities (as in the example above). Under similar requirements as the PSM, the relevant treatment effect compares the impact of different treatments, or the impact of different treatment intensities.

Box 9. Regional growth (Becker et al 2012)

One example of this in the context of the evaluation of regional policies can be found in Becker et al (2012), using data at the NUTS3 level from the last two EU budgetary periods (1994–1999 and 2000–2006) and generalised propensity score estimation to analyse to which extent the goal of fostering growth in the target regions was achieved with the funds provided and whether or not more transfers generated stronger growth effects.

Key requirements for GPSM:

- Availability of information on the observable characteristics influencing the selection into the different treatments or distinct levels of treatment, and the outcome, for all the considered groups.
- These observable characteristics should be measured before the assignment into the various treatments or level of treatment.

4.9. Synthetic controls

The synthetic control method differs from other counterfactual methods because it can be used to evaluate the effect of policies at an aggregate level. For example, a whole country is affected by some specific policy or condition, and one wishes to measure its effect. Assume only one unit is treated, and a few are untreated units. The control group is built as a weighted average of the available set of untreated units, which is called the 'synthetic control' or 'artificial control group' and serves as the counterfactual for the treated unit.

This technique has two main assumptions: first, the selected predictors of the outcome should include variables that approximate the evolution of the treated units without anticipating the effects of the intervention. Second, untreated units used to generate the synthetic control should not be affected by the programme.

Box 10. Example of a synthetic control method (Campos et al. 2019)

Campos et al. (2019) is a recent example of synthetic controls. It aims to estimate the economic benefits of European integration. The key economic and policy question is “What would have been the levels of per capita GDP or productivity in a given country if it had not become a full member of the European Union?” Using synthetic control methods, the authors estimated how GDP per capita and labour productivity would have behaved for the countries that joined the European Union (EU) in the 1973, 1980s, 1995 and 2004 enlargements, if those countries had not joined the EU.

Key requirements for synthetic controls:

- Data on outcome of interest and other controls on one treated and several untreated units over time, before and after the policy.
- Data must be available for several periods before the intervention/policy in the treated unit and the pool untreated units.

4.10. Structural-change time series models

If aggregate data exists on the outcomes of interest and its determinants, one could adopt a ‘structural-change’ approach for time series models. The idea is to estimate a (set of) relationship(s) in a time series model before and after the policy intervention, and then to compare the changes in parameters associated with these two different periods. This would signal evidence of changes in the relationship associated with the policy change. The attribution of these effects to the single policy intervention is the part of this approach that is most difficult to establish.

This approach is common in monetary economics for international real interest rates and inflation, for the equity premium, global house prices, CO₂ emissions, etc.

Box 11. The effects of the euro on national Phillips curves (Girardi and Paruolo 2013)

An example of application to the effects of the euro on the Phillips curves in the EU is Girardi and Paruolo (2013), who investigate possible structural changes induced by the euro on the macroeconomic relations among wages, prices and unemployment for the five major European economies. The dynamic adjustment and the level relations are found to be different across subperiods as well as across countries; for an interpretation of results see the original paper.

Key requirements for structural-change time series models:

- Data on outcome of interests and their determinants across time, before and after the policy.
- Enough data should be available for both periods to allow separate estimation.

4.11. Correlation (or regression) models

If none of the above methods can be applied, it is usually possible to run regression (or correlation) analysis among the outcome variables of interest and other determinants. A large degree of covariance between the treatment and the outcome, controlling for all contextual indicators, is suggestive of the presence of causality, although it may not necessarily prove it.

Many of the causal methods reported above are based on some form of regression; what makes these causal methods attractive is that they state explicitly under what conditions the obtained estimates have a causal interpretation. Whenever possible, it is advisable to provide the list of assumptions that would make the estimates causal and discuss why it is expected (or not expected) that they are satisfied in the specific application.

4.12. Mixed methods for evaluation

Quantitative methods, like the ones presented in the present tool, answer the question “Was there a causal effect of the program or regulation, when did it occur and what is its size?” Once the effects have been estimated, qualitative methods can provide useful information to understand the mechanisms at work behind the estimated impact, also especially when the effects are estimated to be null. This mixture of qualitative and quantitative methods is called the **mixed method approach**.

Qualitative methods include, for example, focus groups or in-depth interviews with selected beneficiaries; these can provide the context and help explain the obtained quantitative results, getting insight on the mechanisms underlying the estimated effect of the intervention. They can also provide information on the implementation process, which can be different from how the intervention was initially planned.

Any lack of success of the policy intervention could be due either to design failure, when the proposed policy design was not appropriate to achieve the intended objectives in the particular context or implementation failure, when the project was not implemented as originally planned. These considerations are important to guide re-design of future policies.

Mixed methods incorporate qualitative contextual analysis examining the influence of external factors (via the use of participant interviews or focus groups) with process analysis (via similar qualitative techniques applied to the programs’ organisational processes) to assess the process of project implementation and how this affected program outcomes and the estimated impact.

Some of these methods can offer insights while the intervention is still ongoing, i.e. during the monitoring phase, and they may help to re-target the intervention or to improve some of its features, even before impacts are estimated using quantitative methods.

Qualitative techniques at the beginning of the intervention plan can help to target specific groups of the population, which are not registered in official administrative data and may

therefore be not easily reachable through regular surveys’ techniques. For example, some marginalised social groups, such as the homeless or irregular migrants cannot be found in registry data, do not appear in official statistics; they can probably be only reached via in-depth field interviews. Similarly, information about some sensitive topics (for example, domestic violence) could be obtained more easily with this kind of interviews, rather than with standard survey data or data from official registries.

Qualitative data and methods have been used extensively to complement quantitative analysis of the effect of interventions in developing countries, Bamberger et al. (2010).

Box 12. Qualitative methods as complements ESF evaluation for Flanders (Belgium) (Canzian et al 2020),

This intervention was evaluated using matching techniques, which compared treated individuals to similar non-treated ones. The results show that people participating in this intervention did not show higher employment probabilities than similar people not participating. However, very little was known about the selection process (how case-workers decided which individuals would be assigned to the intervention, once the age and education requirements were met) and on the real contents of the interventions.

Qualitative interviews with the case workers can help shed more lights on the selection process. In addition, focus groups or interviews with some of the participants, or qualitative interviews with some of the NGOs in charge of providing the support could provide insights on why the intervention did not bring the expected results. However, qualitative data alone would not have answered the question “Has this intervention worked?”

5. ADDITIONAL INFORMATION

- A tutorial (25 minutes) on how to choose the right causal evaluation method, given policy’s features is available [here](#).
- An introductory 5-minute video on RCT and Matching is available [here](#).
- An introductory 2-minute video on RDD is available [here](#).
- An introductory 2-minute video on DiD is available [here](#).
- An introductory 2-minute video on IV is available [here](#).

TOOL #69. EMERGING METHODS AND POLICY INSTRUMENTS

This tool discusses the regulatory sandboxes and behavioural insights, two emerging approaches that may get a bigger role in the policy assessment in the future.

1. REGULATORY SANDBOXES

1.1. What is a regulatory sandbox and why is it relevant for policymaking?

Regulatory sandboxes are a relatively new policy instrument. They are part of efforts by regulators across the globe to tackle regulatory challenges generated by technological transformation, and the emergence of new products, services and business models⁹¹³. Although no commonly agreed definition exists, **regulatory sandboxes can be broadly described as schemes that enable firms to test innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority**⁹¹⁴. They are usually organised on a case-by-case basis, include a temporary loosening of applicable rules, and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection. Two approaches are theoretically possible to set up a sandbox: one where the request (and identification of a regulatory barrier) is initiated by innovators⁹¹⁵, and another, where the regulator identifies legislative provisions for testing and calls for applications by interested organisations⁹¹⁶. Additional approaches or a combination of the above may emerge with time.

Their novelty limits the comparability of existing experience; however, current regulatory sandboxes tend to share the following characteristics:

- **Genuine innovation:** the products / services / business models admitted to a sandbox should represent a genuine innovation, not currently available in the market. A new use of an existing technology can also qualify;
- **Societal and/or consumer benefit:** these innovations are expected to deliver consumer and/or wider societal benefits, for instance by addressing unmet social needs or by contributing to policy objectives on e.g. environmental protection, financial stability, competitiveness, and so on;
- **Readiness for testing:** an innovation is advanced enough to be tested in a controlled environment/market and the relevant legislative barrier is identified; theoretical links between an innovative idea and existing rules are not sufficient to set up a sandbox;
- **Defined scope and time:** the boundaries of a regulatory sandbox may be grounded in law (e.g. an experimentation clause)⁹¹⁷. In any event, boundaries are established ex ante and usually clarify the legislation and sector(s) covered by the test, its duration and exit conditions. This approach ensures legal predictability and facilitates measuring and evaluating sandbox outcomes;

⁹¹³ For an overview, see Attrey et al. (2020) and Leshner (2020).

⁹¹⁴ See e.g. [Report](#) from the European Supervisory Authorities (ESAs) Joint Committee (2019); Federal Ministry for Economic Affairs and Energy - BMWi (2019), [Making Space for Innovation: The Handbook for Regulatory Sandboxes](#); Office for Gas and Electricity Markets (2018), [What is a regulatory sandbox?](#).

⁹¹⁵ Some examples are available in [ESAs Joint Committee \(2019: 22-24\)](#).

⁹¹⁶ See for instance the German experience as described in [BMW \(2019\)](#).

⁹¹⁷ On this point see Tool #22 (*Research and innovation*) and [the Council conclusions of 16 November 2020](#).

- **Safeguards:** the purpose of a sandbox is not deregulation. Hence, even in a controlled setting, appropriate safeguards to preserve policy objectives and legal requirements apply (e.g. safety when testing self-driving vehicles).

Box 1: recent examples of regulatory sandboxes in the EU

- **EU-level: Artificial Intelligence Act**

Article 53 of the Commission’s proposal provides the general framework for the formal establishment and operation of artificial intelligence (AI) regulatory sandboxes by one or more Member States competent authorities or the European Data Protection Supervisor. The proposal states (Recital 71) that “*competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service*”. This approach is meant to ensure compliance with the requirements of the AI Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox. Article 54 also provides a special legal basis for the processing of personal data lawfully collected for other purposes that can be re-used for the development – in the sandbox – of certain AI systems in the public interest, subject to additional safeguards and conditions.

- **EU-level: Pilot Regime for Distributed Ledger Technology (DLT) market infrastructures**

The proposed Regulation on DLT market infrastructures aims to enable market participants to operate a DLT market infrastructure (either a DLT multilateral trading facility or a DLT securities settlement system) under certain conditions. It establishes requirements for acquiring a permission to operate a DLT market infrastructure, sets limitations on the transferable securities that can be admitted to trading, and frames the cooperation between the DLT market infrastructure, competent authorities and the European Securities and Markets Authority (ESMA). The proposed regime concerns a limited set of assets and transactions. The overall objective is to remove regulatory hurdles to the issuance, trading and post-trading of financial instruments in crypto-asset form and for regulators to gain experience on the application of DLT in market infrastructures. The Regulation mandates ESMA to carry out a review on the application of the pilot regime three years after its entry into force. It proposes safeguards to ensure consumer protection, market integrity and financial stability. All participants will also have to provide a clear exit strategy, to ensure smooth transitions once the pilot period is over.

- **Germany: transport of medical samples by drone**

The regulatory sandbox Medifly Hamburg allows for the transportation of sample tissue between hospitals located in the same urban area. The sandbox is backed by the Hamburg Authority for Economy, Transport and Innovation, and involves Hamburg’s aviation authority and the relevant air traffic control office. The participating consortium, led by the Centre of Applied Aeronautical Research, includes a research institution, software companies, and a drone operator. The sandbox is based on an experimentation clause in Section 21b subsection 3 of the Rules of the Air Regulations. Six test flights were successfully carried out in February 2020.

- **France: facilitating innovative projects for collective self-consumption of electricity**

A derogation to articles L. 315-2 and L. 315-3 of the Energy Code aims to facilitate the development of innovative projects in the area of collective self-consumption of electricity. The derogation widens the boundaries of collective self-consumption so that local facilities, larger than those originally permitted under the Energy Code, can fall under the self-consumption definition. The experiment may also remove the 100 kW threshold (article L. 315-3 of the Energy Code) linked to the applicable tariff for the use of public electricity networks. The sandbox runs for five years and is operated under France Experimentation, an initiative by the French Ministry of Economy and Finance.

- **Pan-European blockchain regulatory sandbox**

The EU Member States, Norway and Liechtenstein signed a Declaration creating the European Blockchain Partnership to establish a European Blockchain Services Infrastructure (EBSI) and support the delivery of cross-border digital public services, with the highest standards of security and privacy. In cooperation with the European Commission, the European Blockchain Partnership is now planning a pan-European regulatory sandbox to become operational in 2021/2022. Use cases covered by the sandbox may include data portability, B2B data spaces, smart contracts, and digital identity (Self-Sovereign Identity) in the health, environment, mobility, energy and other key sectors.

Regulatory sandboxes present both advantages and difficulties for all parties involved. Provided the concerned firm(s) can meet the requirements to take part in a sandbox, advantages include the possibility to test own innovations in a real-life setting, and gaining a better understanding of applicable rules, particularly when these fall in the remit of different regulators. Participation in a sandbox may also facilitate access to finance and reduce time-to-market for the innovator.

From a regulator’s perspective, sandboxes allow some degree of flexibility without giving up regulatory standards; they facilitate learning, keeping up with developments in the sector, and highlight the implications of existing rules on cross-sectoral innovation and on innovation happening at the ‘periphery’ of the regulator’s competence. They strengthen ties between regulators from different policy fields. Overall, these features can contribute to resilient and relevant legislation. On the downside, regulatory sandboxes may alter the level-playing field in the market; and can increase risks of market fragmentation and ‘regulatory arbitrage’ if sandboxes for the same rules/innovation lead to different results across the EU. They also require significant resources and time, as well as dedicated skills, that are also needed for ‘core’ regulatory functions.

Sandboxes are one of the most recent tools of adaptive regulation⁹¹⁸. Other forms of experimentation are available and may be more appropriate for a specific case, for instance when a clarification of how existing legislation applies to an innovation can be provided through interpretive guidelines and without additional testing⁹¹⁹. In fact, sandboxes may be the follow-up to other, looser forms of experimentation, if these did not yield the desired clarity on the link between an innovation and the existing regulatory framework.

⁹¹⁸ For further details on anticipating change and ensuring that policies and legislation are future proof, see Tool #20 (*Strategic foresight for impact assessments and evaluations*)

⁹¹⁹ See Tool #22 (*Research and innovation*) for other forms of experimentation. For additional examples, see [ESAs Joint Committee \(2019\)](#) on innovation hubs in fintech.

1.2. Elements to consider before setting up a regulatory sandbox

As with other 'better regulation' tools, the principle of proportionate analysis applies when considering whether to set up a regulatory sandbox. A valuable starting point would be to draw a list of existing experimentation tools in the policy field under consideration, including examples at the national level. Such a stocktaking exercise can already shed light on potential frictions between legislation and selected innovations. It may well be that guidelines would already reduce regulatory uncertainty, without the need for temporary exemptions or testing. At EU level, another potentially relevant source of evidence are innovation deals⁹²⁰, if any have been concluded in the policy field concerned. Similar initiatives also occur at national level, for instance through innovation hubs.

For further guidance, Table 1 includes a set of questions to consider before deciding whether to establish a regulatory sandbox. The list is divided per focus area and draws on key elements that turned out to be relevant in the limited experience with sandbox implementation. The list is not exhaustive, and practice will complement it in the future.

Note also that existing regulatory sandboxes are limited to specific policy areas (e.g. financial services, energy, digital technologies) and usually implemented locally, as this is where the regulator can more easily control the parameters of the sandbox experiment. One of the main difficulties of a regulatory sandbox is to scale-up the results observed in the testing environment to the wider market. At EU level, an additional challenge is worth mentioning: the impact on the Single Market and the risk of fragmentation if sandboxes for the same innovation are implemented in an uncoordinated manner in different member states. This risk is already known to regulators and various approaches are being considered to mitigate it.

Table 1: Questions for the set-up of a regulatory sandbox

Focus areas	Possible questions	Remarks
Innovation and the market	<ul style="list-style-type: none"> – Which features of the product/service/business model qualify it as a genuine innovation? – What alternatives to the innovation exist on the market? To what extent are they comparable? – What are the main competitors of the firms concerned? How can fairness be ensured for the firms that do not take part in the sandbox? – Which criteria will be used to establish that an innovation is beneficial? 	<ul style="list-style-type: none"> – This focus area is at risk of subjective judgment and thus open to contestation during e.g. a standstill period before the final list of firms admitted to a sandbox is made public. It is important to ensure transparency on how the relevant criteria are established and applied, and do so early in the process.
Applicable rules and flexibility	<ul style="list-style-type: none"> – Which body of legislation is relevant for the regulatory sandbox (e.g. banking regulation, data protection, liability for automotive vehicles, etc.)? – Is this a cross-sectoral sandbox, involving different government departments? – Is the regulatory barrier for testing precisely identified? – Who establishes which regulatory requirements/barriers will be covered by the sandbox? Are these chosen by the regulator or 	<ul style="list-style-type: none"> – Existing rules can be customised/made flexible in various ways: e.g. by relaxing or suspending applicable requirements for a limited time and for selected innovations; by waiving enforcement against usually non-permitted behaviour. Another option could be to introduce a limited (in time and scope) but blanket exemption from existing rules: this approach would cover more than one

⁹²⁰ See Tool #22 (*Research and innovation*).

	<p>identified exclusively by the applicant?</p> <ul style="list-style-type: none"> - What are the objectives of the relevant legislation that need to be safeguarded during implementation? - What is the scope for making regulatory requirements more flexible? Which form should this flexibility take? - Are there risks of fragmentation for the EU Single Market? 	<p>type of innovation thus levelling the playing field.</p> <ul style="list-style-type: none"> - In case of cross-cutting policy issues, are there different learning/testing objectives for each area of legislation? - Important to clarify that the purpose of the sandbox is not to deregulate.
Access to the sandbox	<ul style="list-style-type: none"> - How will the selection criteria be outlined in an unambiguous way in the application form? - How is fairness in access ensured for all applicants? What mechanisms are needed to ensure that selection criteria are applied consistently? - Is there a standstill period for unsuccessful applicants to contest the decision leading to their non-admission to the sandbox? - Is there any form of support (e.g. guidance, funding, mentoring) envisaged for applicants? 	<ul style="list-style-type: none"> - Consider the objectives of the sandbox and available resources when preparing the application process: are applications welcome at fixed dates or all the time? Do you have enough resources to react in each case? - Clarify that the sandbox is not an endorsement of the innovation being tested (risk of affecting competition in the market, uneven playing field).
Design and implementation	<ul style="list-style-type: none"> - What are the goals of the regulatory sandbox? What are its limitations? What indicators will be used to monitor progress and to correct course if needed? - How many companies/innovations can be meaningfully observed in the sandbox? What happens if a company exits the sandbox before the end? - What criteria will be used to close/exit the sandbox? What could be possible consequences on the market, e.g. if a product is discontinued as a consequence of the sandbox? 	<ul style="list-style-type: none"> - How will you clarify what this sandbox is not about?
Evaluation and learning	<ul style="list-style-type: none"> - What will success look like? - How will you establish if the results of the sandbox can be scaled up, beyond the controlled environment? What risks could materialise when scaling up and how can they be mitigated? 	<ul style="list-style-type: none"> - Ideally, the main evaluation criteria should be established ex ante. If new elements emerge during implementation, they should be integrated into the evaluation strategy in a fair and transparent manner.
Time and resources needed	<ul style="list-style-type: none"> - Is there any experience at national level, in or outside the EU with a sandbox in this area? If so, can the findings be used as a starting point? - Are sufficient resources available to set-up, run and exit the sandbox? Is there a need to coordinate with other DGs, member states, sectoral regulators and other competent authorities? What are the resources implications of coordination? Are all the parties involved equally equipped to sustain the necessary effort over time? 	

1.3. Regulatory sandboxes in 'better regulation'

If available at the early stages of policy preparation, the findings of a regulatory sandbox can be used – together with other sources of evidence – to inform impact assessments and in particular the problem definition and the baseline scenario. Insofar as they provide indications on how a given innovation interacts with applicable legislation, the results of a sandbox may also be used to estimate the impacts of policy options affecting the regulatory environment (e.g. relaxing certain licensing requirements). When doing so, it is important to always consider whether the indications provided by the sandbox remain true when scaling-up. If potential new risks and positive/negative impacts are likely to derive from scaling-up or from an EU-wide application, these should be factored in the analysis.

Regulatory sandboxes may also be useful for an evaluation or fitness check, when specific regulatory barriers to innovation have been signalled during public consultation, through the Fit-for-Future Platform and other channels (e.g. innovation deals). In this case, the regulatory sandbox can inform possible future approaches to tackle these barriers and make the corresponding rules more adaptive and future-proof.

1.4. References and additional sources

- Attrey, A. M. Leshner and C. Lomax (2020), [The role of sandboxes in promoting flexibility and innovation in the digital age](#), OECD Going Digital Toolkit Policy Note N. 2.
- European Supervisory Authorities Joint Committee (2019), [FinTech: Regulatory sandboxes and innovation hubs](#), Report.
- Leshner M. (2020), [Bringing new digitally enabled products and services to market: Sandboxes and the role of policy experimentation](#), Vox EU.
- Parenti R. (2020), [Regulatory Sandboxes and Innovation Hubs for Fintech](#), Study for the committee on Economic and Monetary Affairs, European Parliament.

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2. BEHAVIOURAL INSIGHTS

2.1. Main features

Behavioural insights (BI) are **evidence-based conclusions about human behaviour**. They provide a better understanding of how people think, act and feel. Behavioural sciences arrive at these insights through systematic observation and analysis.

Behavioural insights show that human beings are often not rational. They do not always base their decisions on an analysis of all possible courses of actions. **Policy initiatives may fail if they expect rational behaviour by the public**. By understanding how people really behave, we can make policies more effective.

Behavioural insights **can contribute to the EU impact assessment process**. They are not restricted to any particular policy area. Rather, they are relevant when the effectiveness of a policy depends on human behaviour. This will be the case when the policy seeks to change behaviour. But it also applies when the public's reaction to the policy is key to its success.

BI can contribute to the IA process when defining the **problem** or the **policy options**.

- If a policy problem has a behavioural element to it, BI can help identify the source of the problem. E.g., BI can explain why farmers do not adopt greener technologies (even if it is in their interest).
- BI can also help identify policy options. E.g., behavioural experiments tested energy labels for electrical appliances. They found that an 'A-to-G' energy label worked best. EU energy regulation has now incorporated this finding.

The impact assessment process often requires a **quantification of the impact** of a given policy option. Depending on the method used, behavioural insights may or may not be able to provide this. For instance, laboratory experiments can test how a policy option may impact behaviour and establish the direction of the impact. Calculating its size, however, may imply testing in real life conditions.

A good behavioural study **needs time**. In particular, experiments and randomised control trials (RCTs)⁹²¹ need at least 5-6 months. First of all, a thorough literature review is needed to gather relevant evidence and develop a sound protocol design. Then, programming, recruitment of subjects, data collection and analysis are additional time-consuming tasks.

For this reason, the potential future needs should be well anticipated, and behavioural insight studies should initiate well before any concrete impact assessment work starts (e.g. in the context of evaluations or as general policy development work for policies which depend crucially on human behaviour). Moreover, behavioural insight studies may well go beyond the policy options that are usually covered in impact assessments, such as detailed issues in the legal drafting.

2.2. Practical implementation steps

The acronym **DO IT** (define, observe, identify, test) helps to remember the practical steps for applying behavioural insights (see Figure 1).

- **Define** the behavioural element.

This first step is very important and will determine whether a behavioural insights approach is relevant and can add value. It implies defining the relevant behaviour and establishing how it relates to the policy problem. For example, do we need to change behaviour or understand it better? In the case of energy labels for household appliances, the Commission was concerned that consumers did not clearly understand the energy efficiency labels. A behavioural study then showed that alphabetic scales worked better than numeric scales, and that an 'A to G' scale worked better than the existing 'A+++ to D' scale. The EU regulation on energy efficiency labelling incorporated this insight accordingly⁹²². Another issue to consider is *whose* behaviour is relevant. Behavioural insights usually focus on an individual's behaviour. However, policymakers might also want to understand or change organisations' behaviour. This may imply a different approach of behavioural insights.

⁹²¹ See Tool #68 (*Methods for evaluating causal effects*)

⁹²² https://ec.europa.eu/energy/sites/ener/files/documents/1_EN_ACT_part1_v6.pdf

- **Observe** the behaviour and try to understand it.

Before targeting a behaviour, we need to observe it and try to understand what lies behind it (i.e. what motivates it). For this, we should rely on a literature review or preliminary empirical analysis. How do people think, act and feel in relation to the policy problem? Is there some ‘ideal’ behaviour that people are not showing in the first place? Why would this be? Do they exhibit some kind of bias? Are other stakeholders exploiting these biases for their own interest? For example, the Commission observed that, in online transactions, pre-checked boxes were leading consumers to make choices that were not in their best interest. A literature review confirmed that these boxes were capitalising on the ‘status quo bias’, which makes people stick with the default option. The result was a ban on pre-checked boxes, made explicit in art. 22 of the Consumer Rights Directive (2011)⁹²³.

- **Identify** policy options to address this behaviour.

Behavioural insights can help identify policy options to tackle the behaviour that lies at the core of the policy problem. These options can include ‘hard’ regulation (see energy labelling and pre-checked boxes examples above) or ‘soft’ behavioural interventions, like *nudges*. Nudges are changes to the environment in which a person makes a decision, aiming to help them make the best decision for themselves. However, they preserve the individual’s freedom to choose. For example, a behavioural study tested possible nudges to curb problematic online gambling behaviour. Some of those implemented *in-gamble*, which effectively interrupted human-machine interaction, were effective. Those implemented *pre-gamble*, like self-commitment strategies, were not. This evidence on potential policy remedies was incorporated in the EU Recommendation on online gambling services⁹²⁴.

- **Test** the effectiveness of these options.

Applying behavioural insights to policymaking is more than bringing a better understanding of behaviour. It is also about testing policy options empirically. These tests are commonly experiments, conducted in a controlled environment, which determine which policy options could be effective. A policy that fails to meet its objectives is an expensive policy. Spending some time and resources testing it before implementing it makes sense. Testing, with whatever method of research, might have some limitations. Yet it is far better to proceed based on some evidence than based on none. For example, the revision of the Tobacco Products Directive put forth a set of pictures and warning messages to be included in tobacco packages to dissuade people from smoking⁹²⁵. These were not picked out of a hat, but rather were the result of a series of behavioural experiments that tested the effectiveness of different pictures and messages.

There is no single best method for observing and testing behaviour (for the **O** and the **T** described above). A number of different methodological options are available:

- *Literature reviews* will teach us a great deal about the behaviour in question. Only if this process leaves questions unanswered should we conduct empirical work.

⁹²³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0083&from=EN>

⁹²⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014H0478&from=EN>

⁹²⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=EN>

- *Qualitative research* includes in-depth interviews, focus groups and participant observation, among others. They can describe the meaning people associate with their actions. This is key to understanding why they behave the way they do.
- *Surveys* measure how people *talk* about behaviour (i.e. what they did or what they intend to do). Results are generalisable but they are not as reliable as measures of actual behaviour.
- *Experiments* observe actual behaviour in a controlled environment. They compare the behaviour of a treatment group, which receives an intervention, and a control group, which does not. If there is a difference, it will be due to the intervention (i.e. experiments can establish causality).
- *Randomised controlled trials (RCTs)* are similar to experiments, but in real-life settings. They do not rely on small samples, but on large sectors of the population. Findings can be quite persuasive but may not be transferable to other contexts.

2.3. Additional information

- [Seven Points to Remember when Conducting Behavioural Studies in Support of EU Policy-making](#) (JRC report, 2015)
- [Qualitative methodology in behavioural studies for EU policymaking](#) (JRC report, 2016)
- [Behavioural Insights Applied to Policymaking](#) (JRC report, 2016)
- [Applying Behavioural Science to EU Policy-Making](#) (JRC report, 2013)

Figure 1: Behavioural Insights applied to a policy process

