Chapter 1 – General principles of 'better regulation'

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 recommendations[1] 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'	
Embedded in the planning and policy cycle	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.
Of high quality	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.
Evidence-based	'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 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 initiative[3] 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 Vice-President responsible for 'better regulation' will then explicitly cover the intended exception.

- If an exception is required after validation[5], DGs must seek approval from the Director responsible for 'better regulation' in the Secretariat-General in consultation with the Cabinet of the Vice-President 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 efforts[6] on simplification and burden reduction.

The concept has evolved over time. REFIT now requires all evaluations[7] 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 practices[8].

Concretely this means REFIT has to be considered:

- during planning[9];
- by the interservice groups that are set up to contribute to evaluations and impact assessments[10];
- in the consultation of citizens and stakeholders;
- in evaluation reports[11];
- in impact assessments[12];
- in the assessment by the Regulatory Scrutiny Board;
- in explanatory memoranda accompanying legislative proposals[13].

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

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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; therfore Commission services can consider involving DIGIT in the interservice steering groups.

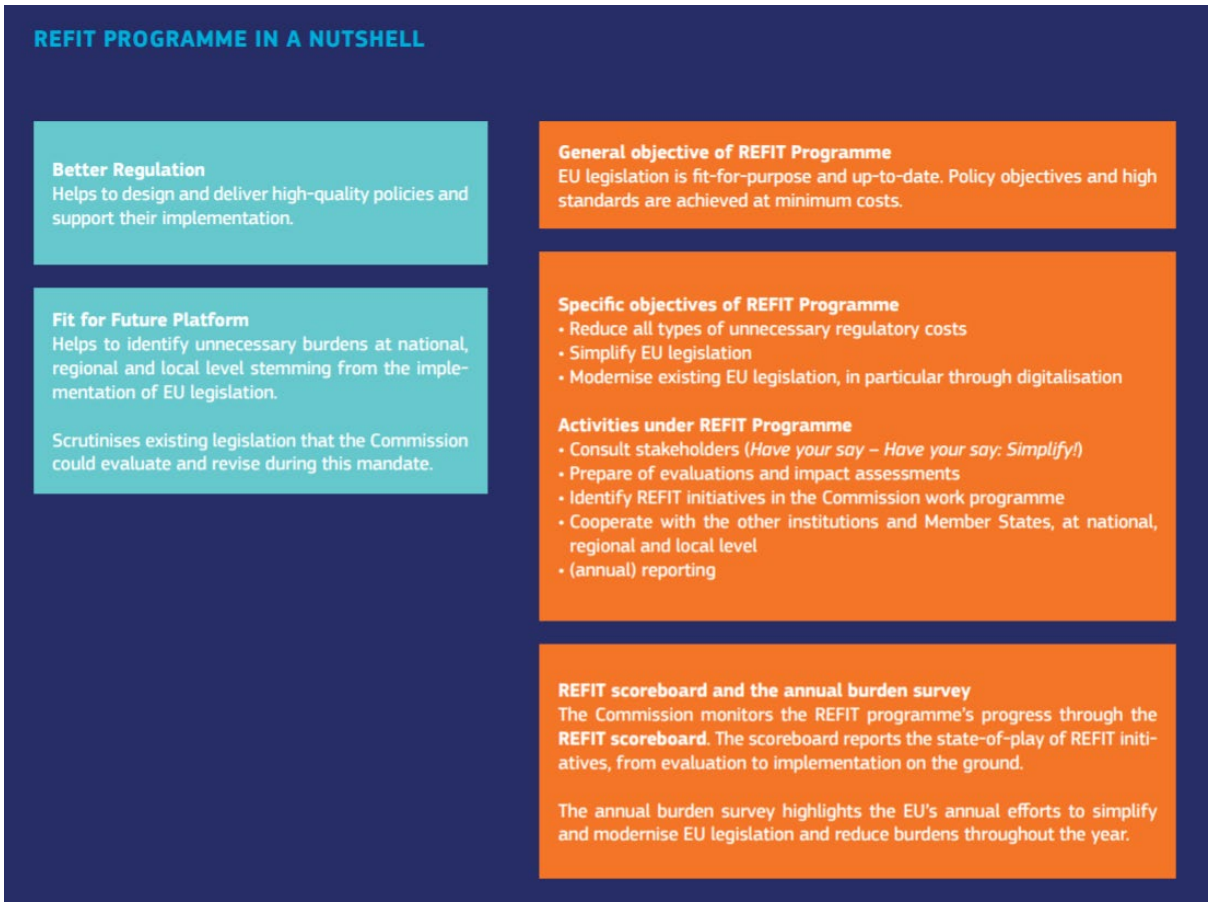
11 See template for the evaluation report and in particular the section on efficiency and relevant REFIT information.

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' approach[14].



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)2977[16] 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 circumstances[17]. 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 year[18]. 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 opinions[19].

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

Impact Assessments	
What?	• 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 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?	• The lead DG should reserve a slot[20] 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?	• 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.
Resubmissions	
	• 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 ISG (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.
Follow-up	
	• 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 group. • A second negative opinion does not allow the lead DG to start the interservice consultation without a derogation granted by the Vice-President responsible for 'better regulation'.

Fitness checks and evaluations selected for scrutiny by the RSB	
What?	• 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 applicable[21]. • Minutes of the last meeting of the interservice 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?	• 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.

	• 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?	• 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.
Follow-up	
	• 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 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[22] 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.

[22] The checklist templates are available on the relevant 'better regulation' GoPro pages.

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 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 opinion[23] and the way in which an impact assessment

[23] 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

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.

- ***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 prejudge or bind the Board in its subsequent opinion on the concerned cases.

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).

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**[24], 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 planning[25] 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 data[26];
- clarifying the method used to collect, interpret, process data and transform it into information;

[24] See Tool #67 (*Data identification for evaluations & impact assessments*).

[25] 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*).

[26] 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).

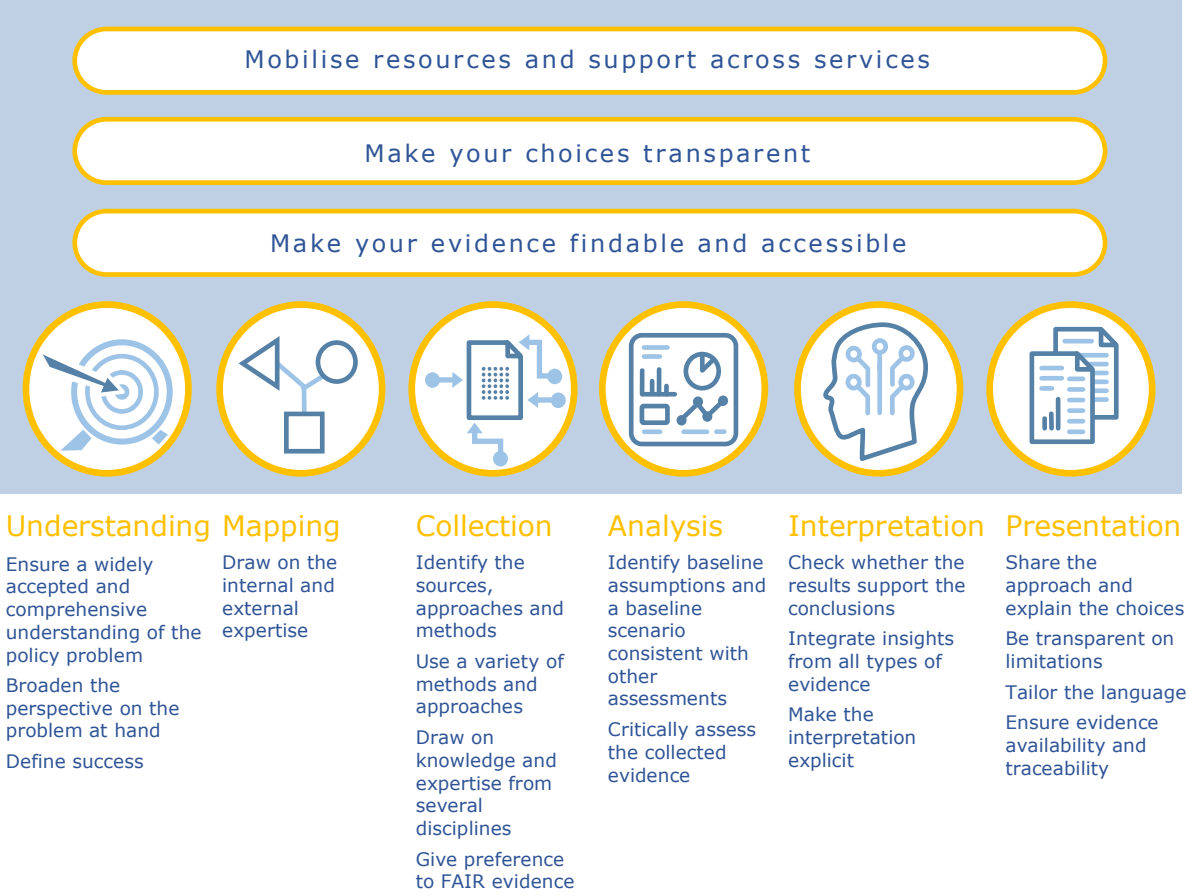


Figure 1. Gathering and communicating best available and transparent evidence for policy

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 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 costs[27]. 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.

[27] 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' [28] 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'[29] 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

[28] See Tool #50 ('*Back-to-back' evaluations and impact assessments*)
[29] 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 identifiers[30]. The key evidence should be cited by providing all relevant details to allow its findability, including persistent identifiers and/or permalinks to ensure functioning hyperlinks[31].

Supporting evidence – including underlying data if it is open[32] – 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 transparently[33]. 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."[34]

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.

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

31 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.

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

33 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/

34 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 agreements[35].
- The Commission **Data Advisory Service**[36] 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**.

[35] 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.

[36] 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 Members 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 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)[37]. 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.

[37] 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**[38] 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 Treaties[39]. 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 courts[40]. 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 proportionality[41]. 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 competence[42] of the Commission[43].

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 basis[44] (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 competition[45].

38 Article 5(1) of the Treaty on European Union.
39 Article 5(4) of the Treaty on European Union.
40 Protocol No 2 of the TFEU on the application of the principles of subsidiarity and proportionality.
41 COM (2018) 703 final, "The principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking".
42 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).
43 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.
44 EU Court of Justice; case-law on choosing the right legal basis – issues of single or multiple, etc.
45 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 competence[46]. 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 necessary[47] 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 document[48]. 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.

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[46] 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.

[47] 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.

[48] 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 evidence[49].

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.

[49] 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	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: • 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	Illustrate the specific limits of Member States' action, their underlying drivers, and why they would/have not be(en) "sufficient". Move to next step.
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	• 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?[50]
If yes	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. The principle of subsidiarity is complied with.
If no	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.
Examples	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.

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…

[50] 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.

EU action is/has been needed due to the strong diversity of policies/practices across Member States.	The negative consequences resulting from diverse/non-harmonised policies/practices lead to significant market entry obstacles, such as higher establishment costs amounting up to…..

Box 3. Illustrative examples of qualitative subsidiarity analyses

- 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."[51] 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 report[52]. 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 proportionality[53]:

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?

[51] Article 5(4) of the Treaty on European Union
[52] In the context of IA for example, proportionality is a key criterion to consider in the comparison of the policy options.
[53] 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 acts[54] to be adopted by oral, written, empowerment or delegation procedure as well as 'stand-alone' staff working documents need an individual Decide Planning entry[55]. 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 validated[56]. 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 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' requirements[57]. 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[58].

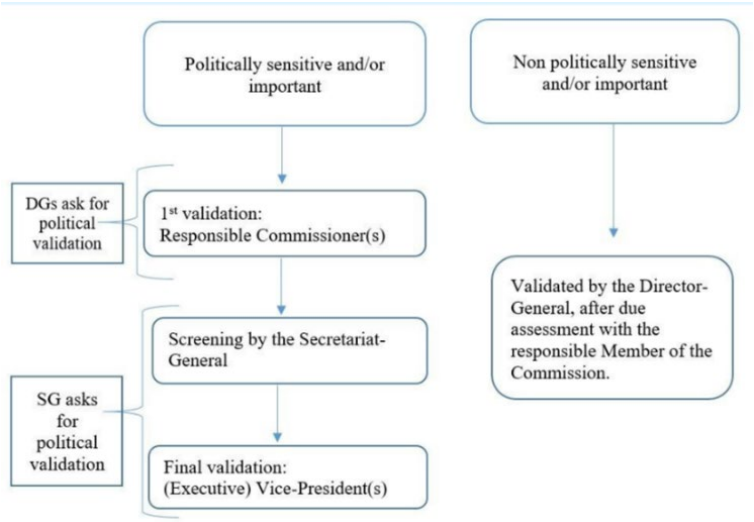
[54] This does not apply to acts concerning the management of litigation, corrigenda or in the exceptional cases where there would be no planning entry because of urgency reasons. In such cases, with the exception of decisions taken by empowerment or delegation, the Secretariat-General and/or the President's 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.

[55] 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)

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

[57] Any derogation requests with the corresponding justification should as a rule be included in the Decide Planning entry.

[58] 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'[59]. 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**

• 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:
  ○ the European Parliament (Art 225 TFEU)
  ○ the Council (Art 241 TFEU)
  ○ an European Citizens' initiative (Art 11 TEU; Art 24 TFEU)
	• 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
		• 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

[59] 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 entry[60].

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.

[60] See also Tool #1 (*Principles, procedures and exceptions*)