

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 options⁶¹. 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 group⁶², 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 **significant**⁶³ **economic, environmental, or social impacts**⁶⁴ 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 **small**⁶⁵;
- when **impacts cannot be clearly identified** ex ante;

⁶¹ 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.

⁶² See Tool #8 (*What steps should be followed for an impact assessment*).

⁶³ 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.

⁶⁴ 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.

⁶⁵ 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)⁶⁶. 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'⁶⁷ 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 Vice-President in charge of 'better regulation'. The Vice-President 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.

⁶⁶ 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.

⁶⁷ See Tool #51 (*Consulting stakeholders*)

A. Initiatives for which the need for an impact assessment should be assessed⁶⁸
New legal acts
Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts ⁶⁹
Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law ⁷⁰
Recommendations for the negotiation of international agreements
Social partner agreements pursuant to Articles 154-155 TFEU ⁷¹
Financial programmes (i.e. all basic acts for spending programmes and financial instruments) ⁷²

B. Initiatives for which no impact assessment is required a priori:	
Type⁷³	Reason
Administrative decisions ⁷⁴	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

⁶⁸ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁶⁹ 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).

⁷⁰ A key determining factor will be whether the Commission has any policy discretion over the content of its transposing measures.

⁷¹ See Tool #10 (*Treaty-based social partner consultations and initiatives*)

⁷² See Tool #9 (*Spending programmes, financial instruments and budgetary guarantee*)

⁷³ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁷⁴ 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 impacts⁷⁵. 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

⁷⁵ 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 governance⁷⁶
 - 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 agencies⁷⁷. 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 assessment⁷⁸.
- 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

⁷⁶ https://europa.eu/european-union/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

⁷⁷ 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).

⁷⁸ 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 do⁷⁹. 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.

⁷⁹ 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 time⁸⁰, unless a ‘back-to-back’ evaluation and impact assessment⁸¹ 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 proposal⁸² 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 group (ISG)

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

(3) ‘Call for evidence’

After political validation of the initiative, the lead DG should prepare a ‘call for evidence’⁸³ together with the Secretariat-General. It is recommended to share the ‘call for evidence’ with and consult the ISG members. The consultation of the ISG 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 activities⁸⁴.

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

⁸⁰ 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*).

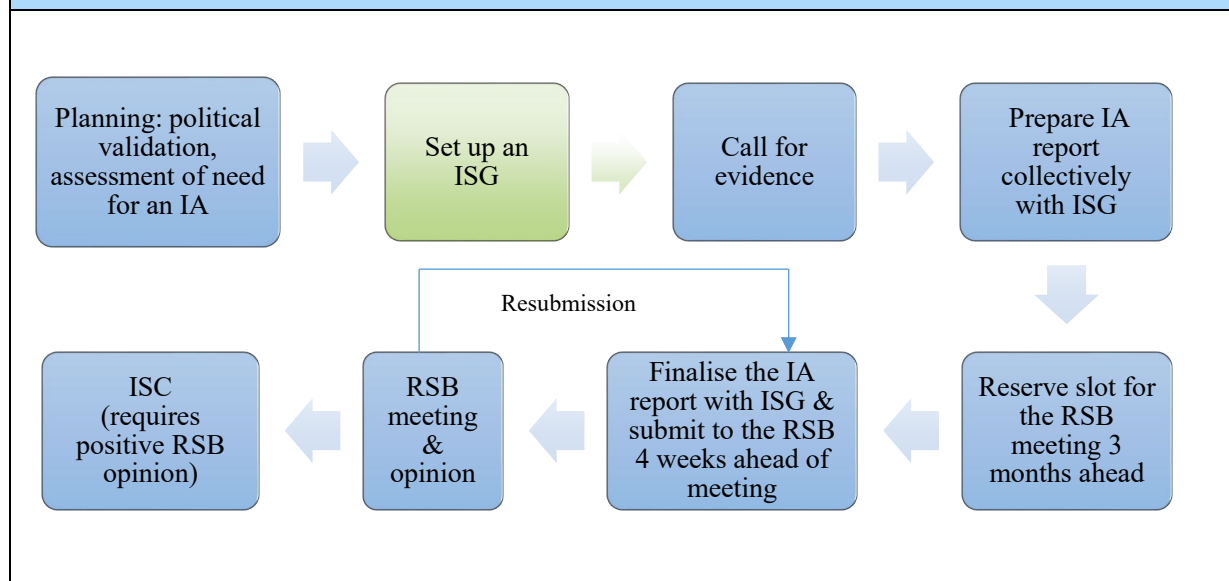
⁸¹ See Tool #50 (*‘Back-to-back’ evaluation and impact assessment*)

⁸² See Tool #7 (*What is an impact assessment and when it is necessary*)

⁸³ See Tool #51 (*Consulting stakeholders*)

⁸⁴ 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 ISG.

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 date⁸⁵. 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 ISG⁸⁶.

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 ISG) will have to submit a revised draft report to the Board, which will issue a second opinion, usually in written procedure.

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).

⁸⁵ To book a slot, the lead DG should contact the RSB secretariat at REGULATORY-SCRUTINY-BOARD@ec.europa.eu

⁸⁶ 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.

(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 Vice-President 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 group contributing to an impact assessment (ISG)	
The ISG 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 ISG) 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 Service⁸⁷.</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 ISG 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 ISG. It should support those in charge of the initiative to prepare the IA report, throughout the whole process.</p>
	The Secretary-General (where the SG chairs the ISG) or the Director-General of the lead DG should send an invitation (note) to the relevant DGs asking to nominate a representative.
	Where possible, existing ISGs should be used to steer the IA work, particularly where an ISG 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.
	Consultants and agencies ⁸⁸ are not regular members of the ISG, 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 ISG members. The lead DG should make

⁸⁷ 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.

⁸⁸ This applies to any EU agency.

	<p>sure the confidential nature of internal ISG 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, ISG 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, ISG 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 ISG is established as soon as the initiative has been politically validated⁸⁹.</p> <p>The ISG 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 ISG should help identify the most significant impacts. The ISG 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 ISG 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 ISG 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 ISG <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 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</p>

⁸⁹ See Tool #6 (*Planning and validation of initiatives*)

	and also use written consultations.
How?	<p>Meetings should be well prepared with invitations and documents being circulated at least one week in advance. Similarly, ISG 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 ISG members. The minutes of the last ISG 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 documents⁹⁰.

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 instrument⁹¹. 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 memorandum⁹². 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 Law⁹³. The explanatory memorandum of the initiative has to refer to main elements of the attached subsidiarity assessment grid⁹⁴.

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.

⁹⁰ See [GoPro](#) for more details on interservice consultations.

⁹¹ See Tool #11 (*Format of the impact assessment report*)

⁹² See Tool #40 (*Drafting the explanatory memorandum*)

⁹³ See Tool #19 (*Sustainable development goals*) and #36 (*Environmental impacts*)

⁹⁴ Template for the subsidiarity assessment grid is available in [GoPro](#)

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)⁹⁵. 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.

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.

⁹⁵ These also include the tables from Annex 3 of the impact assessment.

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 guarantee⁹⁶.

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 required⁹⁷ 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 programmes⁹⁸:

- 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.

⁹⁶ 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.

⁹⁷ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁹⁸ 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 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**⁹⁹. 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 used¹⁰⁰. 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

⁹⁹ See Tool #8 (*What steps should be followed for an impact assessment*)

¹⁰⁰ 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)¹⁰¹ and in the tool relating to the five criteria used for evaluation of EU interventions (which includes EU added value)¹⁰².

- (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 used¹⁰³.
- (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

¹⁰¹ See Tool #5 (*Legal basis, subsidiarity and proportionality*)

¹⁰² See Tool #47 (*Evaluation criteria and questions*).

¹⁰³ 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 act¹⁰⁴.

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 Statement¹⁰⁵.

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:

¹⁰⁴ See Tool #43 (*Monitoring arrangements and indicators*) and Tool #44 (*Legal provisions on monitoring and evaluation*)

¹⁰⁵ 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 programme¹⁰⁶.
- 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)¹⁰⁷.

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;

¹⁰⁶ See Tool #16 (*How to identify policy options*)

¹⁰⁷ 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) TFEU¹⁰⁸; 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 countries¹⁰⁹;
- 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 indicators¹¹⁰, 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 proposal¹¹¹ 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.).

¹⁰⁸ DG COMP can assist in this assessment

¹⁰⁹ DG TRADE can assist in this assessment

¹¹⁰ See Tool #43 (*Monitoring arrangements and indicators*) and Tool #44 (*Legal provisions on monitoring and evaluation*)

¹¹¹ 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 objectives¹¹²;
- 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.

¹¹² 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 partners¹¹³, 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 consultation¹¹⁴.
- 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).

¹¹³ 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.

¹¹⁴ 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 Communication¹¹⁵.

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' consultation¹¹⁶.

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. 155¹¹⁷

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

¹¹⁵ Communication from the Commission strengthening social dialogue in the European Union, [COM/2023/40 final](#)

¹¹⁶ 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 DGT standard pages¹¹⁸. 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 format¹¹⁹ and plain language¹²⁰ 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 annexes¹²¹;

¹¹⁸ A standard DGT page is defined as 1500 characters excluding spaces.

¹¹⁹ <https://webgate.ec.europa.eu/connected/groups/data-visualisation>

¹²⁰ [Get your document edited \(europa.eu\)](#)

¹²¹ 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

- The impact assessment report should use the template provided in GoPro, but must have a standard cover page created in Legiswrite¹²²;
- 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 principles¹²³ 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 partners¹²⁴ 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 assessments¹²⁵, 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 reports¹²⁶:

describing the outstanding options for decision and their likely impacts, while the problem and subsidiarity sections would be relatively limited, mainly summarising/referring back to relevant analysis of the impact assessment of the basic act.

¹²² [Legiswrite template CP-026 – SWD linked](#)

¹²³ <https://webgate.ec.europa.eu/connected/groups/data-visualisation>

¹²⁴ See Tool #10 (*Treaty-based social partner consultations and initiatives*)

¹²⁵ See '[Better regulation' guidelines](#)

¹²⁶ 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-offs¹²⁷ 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.

¹²⁷ 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 level¹²⁸. 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 REFIT¹²⁹. 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.

¹²⁸ 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.

¹²⁹ 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 test¹³⁰. 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 steering group, considering the suggestions from the [SME filter](#), carried out with the support of the SME Envoy Network. The detailed results of the SME test for ‘relevant’ and ‘highly relevant’ initiatives can be included in an additional non-compulsory annex, for which a standard template is available. 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 (for further guidance, see the Appendix – *Competitiveness check*) and summarised in the compulsory Annex 5 (see section below on annexes) presenting a synthetic assessment of the different competitiveness dimensions. The assessment of impacts on competitiveness should, as far as possible, include quantitative estimates.
- **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.

¹³⁰ 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.
- All revisions of existing legislation are REFIT initiatives. For these, the REFIT aspects should be addressed in a separate sub-section in Section 8. 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. The REFIT section concerns only the simplification parts of the initiative, not the overall impacts.
- For proposals with significant costs implications a section on application of the 'one in, one out' approach needs to be added¹³¹.
- 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.

¹³¹ 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 schedule¹³² 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 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

¹³² In both terms of having data already available and the right moment in the Strategic Planning and Programming cycle.

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;

- 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'.

Also significant impacts relating to the UN sustainable development goals should be highlighted here and presented in Table III (see below)¹³³.

Impacts of the preferred option on fundamental rights have to 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 OIOO calculator¹³⁴.

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

¹³³ Except for very technical initiatives where the relation to SDGs would at best be indirect.

¹³⁴ [One In One Out Calculator](#)

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.

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

(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. Application of the 'one in, one out' approach – Preferred option(s)			
[M€]	One-off (annualised total net present value over the relevant period)	Recurrent (nominal values per year)	Total
Businesses			
New administrative burdens (INs)			
Removed administrative burdens (OUTs)			
Net administrative burdens*			
Adjustment costs**			
Citizens			
New administrative burdens (INs)			
Removed administrative burdens (OUTs)			
Net administrative burdens*			
Adjustment costs**			
Total administrative burdens***			

(*) *Net administrative burdens = INs – OUTs;*

(**) *Adjustment costs falling under the scope of the OIOO approach are the same as reported in Table 2 above. Non-annualised values;*

(***) *Total administrative burdens = Net administrative burdens for businesses + net administrative burdens for citizens.*

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 uncertainty¹³⁵ 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

¹³⁵ See Tool #65 (*Uncertainty and sensitivity analysis*)

- 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

The annex should be limited to one single page. It consists of a standardised table and a synthetic assessment explaining the table. The annex should summarise the analysis presented in the main report and provide an overview of the impacts of the preferred option on competitiveness.

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

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. It should draw on the analysis provided in the main report and 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, the Appendix to the 'better regulation' toolbox lists the relevant tools that provide specific guidance for executing the competitiveness check. These include the 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). The Appendix also provides further guidance for the analysis of the different competitiveness dimensions.

Optional Annexes

Helpful tools: #4 –evidence-informed policymaking; #49 – the evaluation report, #50 – 'back-to-back' evaluations and impact assessments

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**¹³⁶ 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 group (ISG)**, 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 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 meetings¹³⁷.

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.

¹³⁶ 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’).

¹³⁷ 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 actor¹³⁸.

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

¹³⁸ See Tool #17 (The choice of policy instruments)

Separate guidance has been prepared in respect of expenditure programmes and financial instruments¹³⁹ and initiatives in the social policy field pursuant Articles 154-155 TFEU¹⁴⁰.

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.

¹³⁹ See Tool #9 (Spending programmes, financial instruments, and budgetary guarantee)

¹⁴⁰ 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 need¹⁴¹. 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 persist¹⁴². 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

¹⁴¹ 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.

¹⁴² 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 ¹⁴³ . 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 ¹⁴⁴ .

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.

¹⁴³ See Chapter 8 on methods for details.

¹⁴⁴ 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 ¹⁴⁵ .
	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).

¹⁴⁵ 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.)¹⁴⁶. 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.

¹⁴⁶ 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*)¹⁴⁷.

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 ¹⁴⁸	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

¹⁴⁷ See also https://knowledge4policy.ec.europa.eu/behavioural-insights_en

¹⁴⁸ 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 ¹⁴⁹ .
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>

¹⁴⁹ 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>
<p>Examples</p>	<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>
<p>Possible policies</p>	<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 growth¹⁵⁰.

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**¹⁵¹.

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.

¹⁵⁰ 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.

¹⁵¹ 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 initiatives¹⁵².

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

¹⁵² 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 risks¹⁵³ 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 Commission¹⁵⁴ including implementing risk management approaches determined in the basic legislation¹⁵⁵. 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 change¹⁵⁶, 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 required¹⁵⁷. An IA may also be required for those decisions that invoke the precautionary principle, where these three conditions are met¹⁵⁸. 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

¹⁵³ 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*).

¹⁵⁴ Note that the European Union Aviation Safety Agency, in short EASA, can also take risk management decisions.

¹⁵⁵ In areas such as food/feed safety, animal health, plant health, animal welfare, medicinal products, medical devices, cosmetics, biocides, chemicals.

¹⁵⁶ Climate change is a critical component of the European Green Deal and receives here particular attention.

¹⁵⁷ Emergency measures (to prevent contagion/spread of a disease etc.) would generally be exempt.

¹⁵⁸ 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 *Artégodon* 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)¹⁵⁹. 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)¹⁶⁰.
- *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 hazard¹⁶¹. 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

¹⁵⁹ 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.

¹⁶⁰ https://www.ipcc.ch/site/assets/uploads/2018/03/SREX-Chap2_FINAL-1.pdf

¹⁶¹ 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)¹⁶². 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, EASA¹⁶³);
- scientific committees set up by the Commission¹⁶⁴ (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);

¹⁶² 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.

¹⁶³ European Environment Agency, European Food Safety Authority, European Chemicals Agency, European Medicines Agency, European Centre for Disease Prevention and Control, European Aviation Safety Agency.

¹⁶⁴ 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 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^{165, 166}.
- (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 them¹⁶⁷.

Uncertainty is inherent in every stage of risk assessment. Irrespective of the different definitions and classifications of uncertainty¹⁶⁸, the key is to understand how important such uncertainty is and, on that basis, understand the reliability of the risk assessment. To do so,

¹⁶⁵ 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.

¹⁶⁶ This component (at least in public health/food safety) is usually integrated in the risk characterisation step.

¹⁶⁷ See Tool #57 (*Methods to assess costs and benefits*) (including non-market impacts) and Tool #32 (*Health impacts*).

¹⁶⁸ 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)¹⁶⁹.

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 conclude¹⁷⁰). 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 protection¹⁷¹. Proportionate

¹⁶⁹ Guidance on Communication of Uncertainty in Scientific Assessments; <https://www.efsa.europa.eu/en/efsajournal/pub/5520>

¹⁷⁰ See Tool #61 (*Simulation models*)

¹⁷¹ 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 review¹⁷².

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)¹⁷³.

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);

¹⁷² 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](#).

¹⁷³ 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 principle¹⁷⁴ 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

¹⁷⁴ 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 assessment¹⁷⁵

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.

Risk assessment		IA process	Main actor(s)
1.	Identify potentially significant risk(s)	Identify problem	Lead DG together with ISG (with input

¹⁷⁵ In areas where the risk assessment process is not specifically described in legislation.

	Identify how and by whom the risk assessment will be carried out		from risk assessors where relevant)
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 ISG (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 policy¹⁷⁶.

2. HOW TO SET OBJECTIVES

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

<i>Box 1. General, specific, and operational objectives</i>	
<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 ¹⁷⁷ 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').

¹⁷⁶ See Tool #43 (*Monitoring arrangements and indicators*); and Tool #44 (*Legal provisions on monitoring and evaluation*).

¹⁷⁷ 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**¹⁷⁸. For major policy initiatives, the objectives should also consider the challenges and opportunities identified through strategic foresight¹⁷⁹.

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**¹⁸⁰.

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)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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.

¹⁷⁸ [See in particular the political guidelines of the Commission.](#)

¹⁷⁹ See Tool #20 (*Strategic foresight for impact assessments and evaluations*).

¹⁸⁰ 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>).

II. Consider a wide variety of policy options in addition to the baseline (no policy change) to look at content, tools, and instruments.

Why?	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 ¹⁸¹ . 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

¹⁸¹ See Tool #17 (*The choice of policy instruments*)

	<p>recent developments in relevant academic fields, like behavioural economics and social psychology¹⁸².</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 solutions¹⁸³. 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 solutions¹⁸⁴.</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 policy¹⁸⁵. For example, consider whether the use of digital technologies could contribute to reducing administrative burdens (and where relevant

¹⁸² https://knowledge4policy.ec.europa.eu/behavioural-insights_en

¹⁸³ See Chapter IV of the 'better regulation' guidelines and the Tool #28 (*Digital-ready policymaking*).

¹⁸⁴ See Tool #17 (*The choice of policy instruments*).

¹⁸⁵ 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?	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).
	The key <u>criteria for screening</u> the viability of your options are:
	<i>Legal feasibility</i>
	Options should respect the principle of conferral ¹⁸⁶ . 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.

¹⁸⁶ 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)¹⁸⁷. 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. 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.

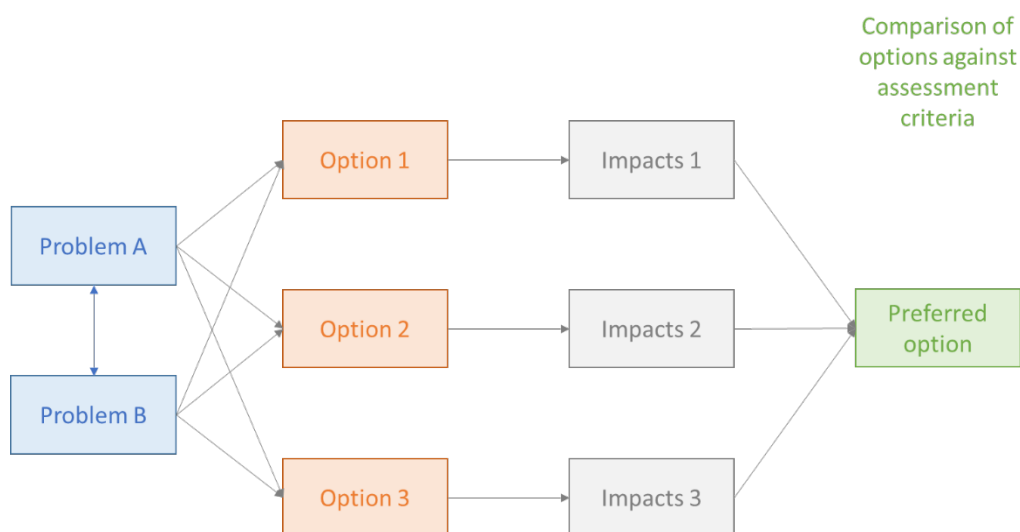
When selecting the policy options, it is necessary to choose the level of aggregation of the policy options: broad alternative options, alternative packages of measures, individual sets of measures targeting specific issues to be bundled together at the end of the analysis or a mix of high-level options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

¹⁸⁷ 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?

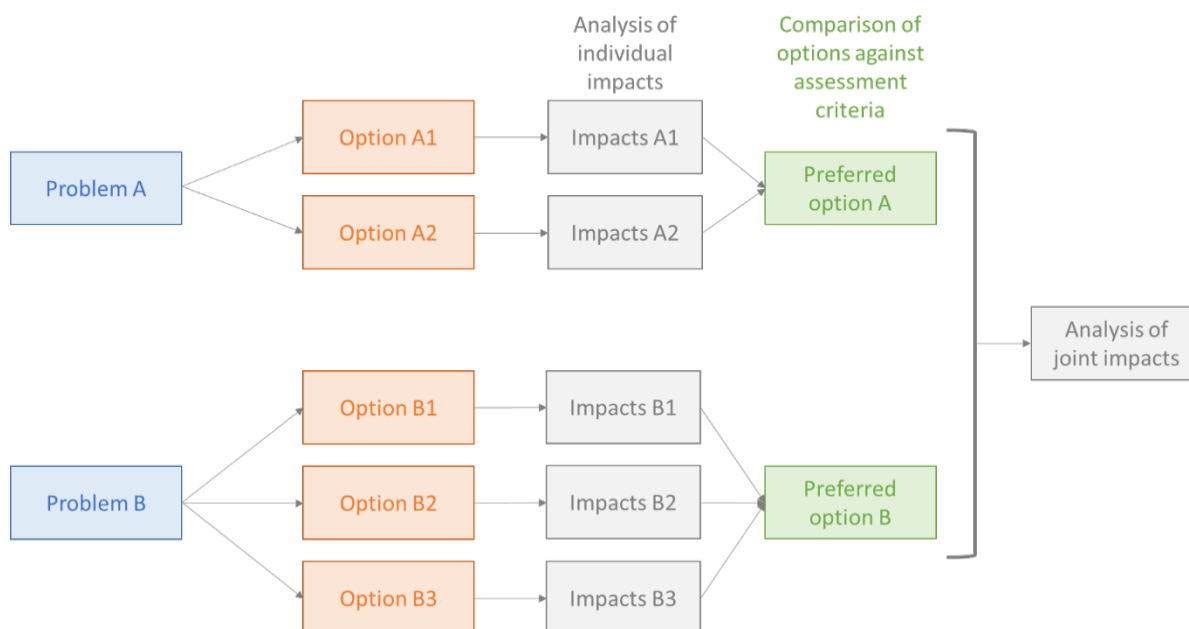


Source: RSB Annual Report 2020

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 carefully¹⁸⁸:

- 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](#));

¹⁸⁸ 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 particular¹⁸⁹. 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

¹⁸⁹ 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 monitoring¹⁹⁰. 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%)

¹⁹⁰ 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 recognised¹⁹¹ 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 ISO¹⁹²/IEC¹⁹³ 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](#):

¹⁹¹ Annex I of Regulation (EU) No 1025/2012 on European standardisation

¹⁹² ISO - International Organization for Standardization; www.iso.org

¹⁹³ 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 citizens¹⁹⁴. 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).

¹⁹⁴ 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*”¹⁹⁵. 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

¹⁹⁵ 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 content¹⁹⁶.

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 insights¹⁹⁷.

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.

¹⁹⁶ [Revision of the Energy Taxation Directive](#)

¹⁹⁷ 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.

