



# *Better Regulation* **GUIDELINES**

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**Better Regulation Guidelines**

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# Introduction

‘Better regulation’ is about creating legislation that achieves its objectives while being targeted, effective, easy to comply with and with the least burden possible. To do this, the Commission uses various regulatory instruments:

- comprehensive **evaluations** and **fitness checks** involve thorough analysis of how existing legislation and spending programmes have been performing, to check that they are efficient, effective, relevant and coherent, and that EU-level intervention is actually adding value;
- **impact assessments** look at the problems to be tackled, the objectives to be achieved, the trade-offs to consider, options for action and their potential impacts;
- **input from stakeholders** supports this work throughout the policy cycle, to provide policymakers with the best possible evidence base; and
- **compliance promotion tools** help Member States transpose, implement and apply EU law in a timely and correct manner.

The recently adopted ‘better regulation’ Communication<sup>1</sup> reiterates the call for evidence-informed policymaking, a stronger approach to stakeholder consultation, burden reduction and the analysis of key impacts, and the integration of strategic foresight. All this is based on the results of a 2019 stocktaking of the Commission’s ‘better regulation’ policy<sup>2</sup>.

These guidelines build on the key aspects of the ‘better regulation’ Communication. They explain what ‘better regulation’ is and how it applies to the day-to-day practices of Commission officials preparing new initiatives and proposals, or managing existing policies and legislation. The ‘better regulation’ toolbox, in turn, provides operational and detailed guidance on specific aspects.

These guidelines are internal instructions for the Commission staff<sup>3</sup> in order to deliver the objectives of ‘better regulation’; in so far as they formulate ‘requirements’ and/or ‘mandatory’ instructions, they cannot be construed as legally binding rules or legal commitments towards outside actors and stakeholders. The guidelines should be read and applied by all Commission officials involved in regulatory activities and managers responsible for quality control and for the allocation of resources. ‘Better regulation’ cannot be implemented without dedicated financial and human resources. Central services and Directorates-General (DGs) must therefore ensure that appropriate centres of expertise (or functions) and training are available to support the proper implementation of the various aspects of ‘better regulation’ according to the principles outlined in these guidelines.

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<sup>1</sup> Better regulation: joining forces to make better laws ([COM\(2021\) 219 final](#)).

<sup>2</sup> Commission Communication, Better regulation: taking stock and sustaining our commitment, [COM\(2019\)178 final](#)

<sup>3</sup> Therefore, some of the included references to complementary tools, further instructions or websites are only accessible internally to Commission staff.

# Chapter I

## ‘Better regulation’ in the Commission

### **Box 1. How to apply these guidelines**

- The guidelines set out requirements for the key steps in the policy cycle, while the ‘better regulation’ toolbox provides practical, hands-on guidance and operational details<sup>4</sup>;
- The guidelines and the toolbox should be applied in a proportionate manner using common sense. The aim is not to meet procedural requirements *per se* but to ensure that the Commission has relevant and timely information on which to base its decisions. Similarly, the depth of analysis should reflect the significance of the impacts or effects that a given initiative or intervention may have within and outside the EU;
- In some cases, it may not be possible or appropriate to follow each step in the guidelines<sup>5</sup>. For instance, there may be a political imperative to move ahead quickly, an emergency that requires a rapid response, a need to meet specific deadlines in legislation that cannot be met based on normal planning, or a need to protect security-related or confidential information;
- Exemption from the guidelines can be requested at the point of political validation (via the planning module of Decide<sup>6</sup>) or, for cases arising after validation, requests for exemption should be sent to the ‘better regulation’ unit in the Secretariat-General. The following functional mailbox should be used for such requests: [SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu](mailto:SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu);
- The approach retained for the application of the ‘better regulation’ instruments should be communicated externally, together with a justification (typically through the ‘call for evidence’<sup>7</sup>);
- To avoid undue delays and to maximise the quality of outputs, the application of these guidelines requires constructive and timely cooperation between the lead service, the Secretariat-General, the ‘better regulation’ support units and the services represented in interservice groups<sup>8</sup>;
- While the ‘better regulation’ support functions within the DGs should serve as the first point of contact, questions of interpretation or application can be put to the responsible units in the Secretariat-General using the functional mailboxes below:

Aspects of ‘better regulation’	Functional mailbox
Planning	<a href="mailto:SG-PLANNING@ec.europa.eu">SG-PLANNING@ec.europa.eu</a>
Impact assessment, evaluation & fitness checks, feedback mechanisms	<a href="mailto:SG-BETTER-REGULATIONS@ec.europa.eu">SG-BETTER-REGULATIONS@ec.europa.eu</a>

<sup>4</sup> The new instructions have also been inserted in the respective chapters of [GoPro](#), the Guide to Procedures of the Commission.

<sup>5</sup> For example, a special regime applies to the Commission’s proposals for a Council decision to implement social partners’ agreements under Article 155 TFEU due to the role and autonomy entrusted by the Treaty to the social partners.

<sup>6</sup> Decide is a tool designed to help the Commission screen and manage the flow of initiatives in line with the President’s political guidelines.

<sup>7</sup> See Chapter III.

<sup>8</sup> Established in line with the Commission’s working methods.

- The Secretariat-General will monitor the impact of the guidelines on an ongoing basis and, if necessary, in consultation with the ‘better regulation’ network<sup>9</sup>, propose ways to eliminate any source of administrative burden or undue procedural delay. Any such review will uphold the principles set out in the Commission communications on ‘better regulation’ and in these guidelines.

## 1. KEY CONCEPTS AND PRINCIPLES OF ‘BETTER REGULATION’

‘Better regulation’ refers to the Commission’s regulatory policy, whereby it seeks to design and prepare EU policies and laws in such a way that they achieve their objectives in the most efficient way. ‘Better regulation’ is not about regulating or deregulating. It is a way of working that allows political decisions to be prepared in an open and transparent manner, informed by the best available evidence<sup>10</sup>, including via the comprehensive involvement of stakeholders. This is to ensure that the EU acts in line with the overarching principles of subsidiarity and proportionality, i.e. only where necessary and in a way that does not go beyond what is needed to address the problem at hand.

‘Better regulation’ is also a means of guaranteeing that EU legislation has the broad support of EU citizens and remains fit for purpose, future-proof and open to innovative solutions in a context of ever more rapid technological, societal and environmental change.

‘Better regulation’ in the Commission relies on a number of key concepts and principles that comply with and complement those in the Treaties<sup>11</sup> and the EU Charter of Fundamental Rights:

- ✓ a **comprehensive** approach — just as EU laws and regulation affect many aspects of everyday life, business operations and the environment, ‘better regulation’ considerations should cover all relevant economic, social and environmental impacts, all interested parties and every phase in the policy cycle (see section 3 below). In particular, any significant impacts on gender equality, territorial and rural issues<sup>12</sup>, and the geopolitical context must be transparently assessed and presented. The same applies to the external implications of internal policies and their significant impacts on third countries. Also, impacts on competitiveness and small and medium-sized enterprises (SMEs) must be screened and assessed systematically;
- ✓ a **coherent** approach — EU laws and regulation cannot be adopted in isolation. The ‘better regulation’ framework is helpful in checking consistency with high-level and long-term policy objectives, e.g. by applying the ‘do no significant harm’<sup>13</sup> and ‘digital by default’<sup>14</sup> principles, implementation of the European

<sup>9</sup> The ‘better regulation’ network is a network of representatives of the ‘better regulation’ functional units of all relevant Directorates-General.

<sup>10</sup> ‘Evidence’ refers to multiple sources of data, information, and knowledge, including quantitative data such as statistics and measurements, qualitative data such as opinions, stakeholder input, conclusions of evaluations, as well as scientific and expert advice. The official portal for European data: [data.europa.eu](https://data.europa.eu) is an important source of open data. Further operational guidelines related to evidence are presented in Tool #4 (*Evidence-informed policymaking*).

<sup>11</sup> The principles of conferral, subsidiarity and proportionality (see Article 5 TEU).

<sup>12</sup> Including urban/rural areas, cross-border areas and outermost regions.

<sup>13</sup> As defined by Article 17 of the Taxonomy Regulation ([Regulation \(EU\) 2020/852](https://eur-lex.europa.eu/eli/reg/2020/852))

Climate Law<sup>15</sup>, by advancing the digital transition through digital-ready policymaking, and by incorporating the United Nations sustainable development goals (SDGs)<sup>16</sup> and strategic foresight;

- ✓ a **proportionate** approach — while comprehensive, the approach should also be proportionate to the expected impacts and analysis should focus on areas where it matters most;
- ✓ a **participative** approach — all interested parties, be they experts or individuals or groups affected by EU laws and regulation, should be able to contribute to policymaking by expressing their views and providing relevant data;
- ✓ an **evidence-based** approach — policy decisions need to be informed by the best available evidence (including scientific evidence, where available);
- ✓ **transparency** — preparing laws and regulation in a transparent way (i.e. openly documenting the process, making available the evidence underpinning political decisions and explaining the underlying rationale) improves the legitimacy and accountability of EU action; and
- ✓ **learning from experience** — laws and regulation can always be improved, partly because the world is in constant flux, but also due to the EU’s inherent diversity (which EU policies have to capture and to which they have to adapt). Policymakers need to learn from the experience of implementing and applying EU rules on the ground. This is why the ‘evaluate first’ principle should apply whenever legislation is revised.

## 2. ‘BETTER REGULATION’ IN PRACTICE

EU laws and regulation are proposed where the benefits are likely to outweigh the associated costs<sup>17</sup>. By applying the ‘better regulation’ principles, the Commission can identify solutions that are likely to maximise the former, while minimising the latter.

To make sure that EU legislation remains fit for purpose, the Commission’s rolling **regulatory fitness and performance programme (REFIT)**<sup>18</sup> identifies opportunities to simplify laws, streamline procedures and eliminate unnecessary burdens without undermining the objectives and benefits of the policy in question, e.g. by means of looking for digital solutions. All evaluations and impact assessments accompanying proposals for legislative revision have to analyse the potential for simplification and burden reduction.

REFIT is complemented by the ‘**one in, one out**’ approach, whereby the Commission offsets new burdens imposed on individuals or businesses as a result of its proposals.

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<sup>14</sup> As defined by the Commission Communication EU eGovernment Action Plan 2016-2020: Accelerating the digital transformation of government ([COM\(2016\) 0179](#) )

<sup>15</sup> [Regulation \(EU\) 2021/1119](#)

<sup>16</sup> <https://sdgs.un.org/goals>

<sup>17</sup> Irrespective of whether costs and benefits are qualitatively assessed or quantified.

<sup>18</sup> [https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof\\_en](https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en)

## **Box 2. Overview of implementing guidelines for ‘one in, one out’**

**Scope:** Initiatives<sup>19</sup> that are accompanied by an impact assessment (or by an analytical report - staff working document) in cases where the Commission was unable to produce an impact assessment where one should have been prepared) and have significant cost implications for businesses or citizens, starting with (but not limited to) those in the Commission’s work programme.

**Input:** Analysis and quantification (estimates) should be produced for all compliance costs<sup>20</sup> where this is feasible and proportionate. Administrative burdens are subject to offsetting. Adjustment costs will be transparently and systematically presented in impact assessments to the extent this is feasible and proportionate. Other measures will be taken with a view to compensating adjustment costs to the greatest extent possible.

**Justification, transparency and reporting of estimates:** Impact assessments should set out and present estimates of adjustment and administrative costs. If the Commission is unable to produce an impact assessment where one should have been prepared<sup>21</sup>, it should present justified estimates of costs and benefits in analytical reports alongside the proposal or within 3 months, explaining clearly how they have been calculated.

**Offsetting:** Annual administrative burdens must be reported in the dedicated online administrative burden calculator and offset within:

- the remit of the Directorate-General in question; or, if this is not possible
- the REFIT area<sup>22</sup> directly affected by the proposal; or, if this is not possible (e.g. in the case of a cross-sectoral initiative or where the Directorate-General does not produce sufficient legislation or the existing legislation in the policy domain is recent);
- the broader policy area, i.e. the headline ambition in the Commission’s work programme<sup>23</sup>.

**Flexibility:** Three types of flexibility apply:

- flexibility within the reporting period;
- ‘trading’ across policy areas; and
- exemptions in certain exceptional circumstances.

**Annual overview report:** Based on reporting in the online calculator, the Secretariat-General will produce an overview of the annual application of ‘one in, one out’ in the Annual Burden Survey.

*More operational guidelines can be found in Tool #59 (Cost estimates and the ‘one in, one out’ approach).*

To facilitate assessment of the Commission’s proposals, the ‘better regulation’ policy relies (where feasible and proportionate) on the **quantification of impacts, including costs and benefits**. Given the diversity of policy areas in which the Commission operates, it is not possible to quantify and monetise the costs and benefits of all its legislative proposals. However, the Commission should do so wherever feasible, relevant and proportionate.

<sup>19</sup> Including delegated and implementing acts.

<sup>20</sup> See Tool #56 (*Typology of costs and benefits*) for definitions.

<sup>21</sup> See Chapter IV, section 1.

<sup>22</sup> I.e. agriculture and rural development; climate action; communication networks, content and technology; competition; employment, social affairs, inclusion and education; energy; environment; financial stability, financial services and capital markets union; health and food safety; internal market, industry, entrepreneurship, SMEs and statistics; justice, consumers and gender equality; maritime and fisheries policy; migration and home affairs; mobility and transport; regional and urban policy; research and innovation; taxation, customs union and anti-fraud; or trade and external action.

<sup>23</sup> I.e. ‘a European Green Deal’, ‘fit for the digital age’, ‘an economy that works for people’, ‘a stronger Europe in the world’, ‘promoting our European way of life’ or ‘a new push for European democracy’.

### 3. KEY INSTRUMENTS OF ‘BETTER REGULATION’

‘Better regulation’ covers the whole **policy cycle** (see Figure 1), from policy design and preparation, through adoption, implementation (including monitoring and enforcement) and application to evaluation and revision. For each phase, there are relevant ‘better regulation’ principles, objectives, tools and procedures to make sure that the EU develops sound, evidence-informed policies. The following sections cover the main instruments of ‘better regulation’.

*Figure 1. The EU policymaking cycle*



#### 3.1. Forward planning and political validation

Sound policymaking starts with **good planning**, focusing on the priorities reflected in the President’s political guidelines<sup>24</sup> and the Commission’s work programme<sup>25</sup>. Planning consists of the initial consideration of an initiative and the organisation of supporting processes:

- evaluation of existing policies;
- assessment of problems and alternative solutions;
- active engagement with stakeholders; and
- the preparation of initiatives.

Good planning also involves allowing time to reflect on the initiative and to meet the various procedural requirements, including scrutiny by the Regulatory Scrutiny Board

<sup>24</sup> [https://ec.europa.eu/info/files/political-guidelines-new-commission\\_en](https://ec.europa.eu/info/files/political-guidelines-new-commission_en)

<sup>25</sup> [http://ec.europa.eu/atwork/key-documents/index\\_en.htm](http://ec.europa.eu/atwork/key-documents/index_en.htm)

(RSB), political validation to launch the interservice consultation, conducting the interservice consultation and translation<sup>26</sup>.

**Political validation** at the appropriate level<sup>27</sup> is required before substantive work<sup>28</sup> on an initiative can start and stakeholders can be consulted. This requires a valid entry in Decide. No public consultation or interservice work should be launched on an initiative or course of action before it has been politically validated. Political validation represents a green light to start substantive preparatory work – it should not be interpreted as a decision that prejudices the outcome of any impact assessment or later political discussion in the College.

### 3.2. Stakeholder consultation

Stakeholder consultation is an essential element of policy preparation and review. Good policy development is built on openness and participation. Stakeholders provide contributions to support evaluations, impact assessments, and the preparation of initiatives and political decisions.

It is good practice to plan consultations using a simple, concise strategy that identifies relevant stakeholders and targets them with a range of activities, in order to gather all relevant evidence (data, other information and views)<sup>29</sup>. For maximum usefulness and inclusivity, it is important to consult as widely as possible (while avoiding ‘consultation fatigue’), giving all interested parties the opportunity to contribute to the timely evaluation or development of effective policies. All relevant stakeholders should have a reasonable period, in which to make informed and effective contributions<sup>30</sup>. Subsequently, the respondents should receive feedback on how their contributions have been used.

Public consultation is an essential element of impact assessments; it can also be useful for many evaluations and fitness checks. Chapter II provides further details on stakeholder consultations.

### 3.3. Evaluation and fitness checks

Policy preparation should be supported by evaluations and impact assessments, which look at the underlying causes of the problem at hand and how it has been or is to be addressed to achieve the desired objectives, taking account of costs and benefits.

**Evaluations** gather evidence to assess how a specific intervention has performed (or is working), taking account of earlier expectations in the context of an impact assessment and/or ensuing from the adopted legislation and whether there were unintended or unexpected effects that were not anticipated and taken into account in the impact

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<sup>26</sup> Communication (2016) 2000 describes the role of translation in the Commission’s decision-making process, including the limits on document length, language regimes and translation deadlines.

<sup>27</sup> The toolbox (Tool #6 (*Planning and validation of initiatives*)) and [GoPro](#) provide more detailed information on the classification of initiatives and the planning and political validation processes.

<sup>28</sup> I.e. launching the ‘call for evidence’, stakeholder consultation, quality control by the RSB, or launching interservice consultation.

<sup>29</sup> Including from different territories: urban, rural, cross-border, etc. and from the EU outermost regions, where relevant.

<sup>30</sup> In line with the Commission Strategy for the Rights of Persons with Disabilities (Commission Communication, Union of Equality: Strategy for the Rights of Persons with Disabilities 2021-2030, [COM\(2021\) 101 final](#)), consultations should become progressively accessible to persons with disabilities.

assessment or the adopted act. They also draw conclusions as to whether the EU intervention:

- remains fit for its purpose;
- should be adjusted for greater effectiveness, relevance and coherence, and/or to eliminate unnecessary burdens or inconsistencies; or
- should simply be repealed.

A **fitness check** is a comprehensive evaluation of a policy area that usually addresses how a set of related legislative acts have contributed to the attainment of policy objectives. Fitness checks can also be conducted for horizontal issues, focusing on specific matters across many different legislative acts (e.g. reporting obligations). Fitness checks are particularly well suited to identifying regulatory overlaps, inconsistencies, synergies, digitalisation potential and cumulative impacts.

It is important to **monitor** systematically the effects of the implementation and application of legislation, in order to enable the Member States and the Commission to carry out a meaningful evaluation of the intervention at some point in the future. In the absence of such information, it will be difficult to evaluate the intervention appropriately and to rectify problems or improve delivery of the desired results. Chapter III provides further details on evaluations/fitness checks and while Chapter V elaborates on monitoring.

### 3.4. Impact assessment

Impact assessments collect evidence (including evaluation results) to assess whether future legislative or non-legislative EU action is justified and, if so, how it can best be designed to achieve relevant policy objectives. They must:

- identify and describe the problem to be tackled;
- establish objectives for the EU action;
- formulate policy options, assess their potential impacts and, where appropriate, identify a preferred option; and
- set out how the expected results will be monitored and evaluated.

The Commission's impact assessment system follows an integrated approach that assesses the environmental, social and economic impacts of a range of policy options thereby mainstreaming sustainability into Union policymaking and the implementation of the UN sustainable development goals. Chapter IV provides further details on impact assessments.

### 3.5. Quality control

Quality control of the 'better regulation' processes starts in the DGs that have the responsibility to carry out evaluations, impact assessments and stakeholder consultations. 'Better regulation' support functions have an important role to play in these processes. Centrally, the Secretariat-General provides methodological guidance and is responsible for developing the 'better regulation' policy in the Commission. Interservice groups contribute to this process with specific knowledge or expertise.

Responsible DGs must present the results of all impact assessments, evaluations and fitness checks in staff working documents (SWDs). To ensure that these SWDs are of the

best possible quality to support policy decisions, the Commission has set up the Regulatory Scrutiny Board (RSB) as an independent quality control body. The RSB assesses all impact assessments, all fitness checks, and some selected evaluations

The RSB issues opinions based on the requirements of these guidelines, as follows:

- for *impact assessments*, there are three types of opinion – positive, positive with reservations and negative. Where the opinion is positive, the DG can proceed with the initiative, but has to **take into account** the RSB’s recommendations for improvement. Where the opinion is positive with reservations, the DG can also proceed with the initiative, but **must revise** the impact assessment report accordingly. Where the opinion is negative, the DG has to submit an amended impact assessment to the Board<sup>31</sup>; and
- for *evaluations and fitness checks*, only positive and negative opinions apply. Where the opinion is negative, the DG has the option to resubmit an amended report to the Board.

The opinions of the RSB are published in the [Register of Commission Documents](#) once the Commission adopts the relevant legislative proposal. For initiatives supported by impact assessments, the Commission’s working methods stipulate that a positive RSB opinion is needed before an interservice consultation can be launched. In the interservice consultation, the Secretariat-General will verify if and how the Board’s comments have been reflected in the revised reports and the drafting of the initiative/legal proposal.

### 3.6. Compliance support and implementation

EU intervention will deliver its full benefits only if the policy is implemented and applied appropriately. Moreover, excessive burdens may be placed on businesses as a result of Member States imposing obligations that go beyond what is envisaged in the legislation (‘gold-plating’)<sup>32</sup> or implementing the legislation inefficiently. It is therefore essential to take account of implementation and enforcement issues in the design of all aspects of an EU intervention, including the impact assessment process and stakeholder consultation.

It is also important to identify ways to assist Member States in transposing directives (aligning national legislation with EU legislation) by preparing an **implementation strategy**, which should be subject to interservice consultation together with the impact assessment and the proposed intervention.

Checks on transposition and assessments of compliance are key tools for monitoring the correct application of EU legislation. Chapter V provides further details on compliance support tools and enforcement.

## 4. INTERINSTITUTIONAL CONTEXT

‘Better regulation’ is a shared commitment of all EU institutions. The Interinstitutional Agreement on Better Law-Making<sup>33</sup> covers annual and multi-annual programming and

<sup>31</sup> See also Chapter IV, section 1.

<sup>32</sup> For example, directives in the social policy field adopted on the basis of Article 153 TFEU set minimum requirements, so it is envisaged in the Treaty that Member States may establish higher standards when transposing such directives.

<sup>33</sup> OJ L 123, 12.5.2016, p.1 (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC>); The Agreement (signed by the European Parliament, the Council and the Commission) replaced the previous (2003) agreement and the 2005 interinstitutional accord on impact assessment.

all aspects of the policy cycle. It also sets out the institutions' various commitments to deliver high-quality EU legislation that is efficient, effective, simple and clear, and that avoids overregulation and unnecessary burdens for individuals, public authorities and businesses, especially SMEs. More detailed guidance has been prepared for its implementation in the Commission<sup>34</sup>.

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<sup>34</sup> [https://myintracomm.ec.europa.eu/sg/better\\_regulation/Pages/IIABL.aspx](https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/IIABL.aspx)

# Chapter II

## Stakeholder consultation

### 1. INTRODUCTION

Under Article 11 of the Treaty on European Union (TEU)<sup>35</sup>, the Commission has a duty to carry out broad consultations with interested parties in order to ensure that EU action is coherent and transparent. Consulting stakeholders is an important means of collecting evidence to support policymaking. Taking account of their views, practical experience and data will improve our understanding of the issues at stake and lead to better quality and credibility (and therefore acceptance and trust among EU citizens) of policy initiatives.

The consultation system is based on the ‘**call for evidence**’ - the entry point for public consultation and feedback.

The ‘**call for evidence**’ is a streamlined, inclusive and simple system which combines two elements:

- Feedback to the ‘**call for evidence**’ **documents** (for impact assessments, evaluations of broad public interest and fitness checks<sup>36</sup>). The ‘call for evidence’ document is translated into all EU’s official languages;
- And, when required, a **public consultation**.

It is published on the ‘*Have Your Say*’ web portal<sup>37</sup>, the entry point for all contributions to the Commission’s legislative proposals, evaluations/fitness checks, communications, etc.

### 2. SCOPE AND DEFINITION

Stakeholder consultation is a formal process, by which the Commission collects information and views from stakeholders about its policies. It explicitly includes environmental and digital aspects where this is relevant.

In these guidelines, stakeholder consultation covers all consultations (public consultations or targeted consultations) with stakeholders in the process of preparing a policy initiative or evaluating an existing intervention, where relevant. However, some parts concern only public consultations, as further specified.

It does not cover:

- interinstitutional consultations (e.g. reports from the European Parliament, opinions from national parliaments, etc.);

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<sup>35</sup> [Treaty on European Union](#)

<sup>36</sup> See box 4 below.

<sup>37</sup> ‘*Have Your Say*’ is the web portal through which stakeholders, including members of the public, scientific and technical experts, can contribute to initiatives as they take shape before and after adoption by the Commission.

- opinions from expert groups involved in the preparation of delegated acts or in the context of well-established consultation procedures<sup>38</sup>;
- stakeholder consultations prepared and conducted by any EU agency or Commission body prior to the Commission’s finalisation of draft delegated and implementing acts<sup>39</sup>; or
- European citizens’ initiatives under Article 11 (4) TEU.

Neither does it replace specific frameworks for consultation provided for in the Treaties or in primary legislation, such as:

- the consultation of consultative committees in the context of the legislative process (Articles 304 and 307 TFEU); and
- the consultation of social partners (Articles 154-155 of the Treaty on the Functioning of the European Union (TFEU))<sup>40</sup>;
- other regular or *sporadic* public engagement activities (e.g. citizens’ dialogues).

For consultations on environmental matters, these guidelines apply without prejudice to the requirements of Regulation (EC) No 1367/2006<sup>41</sup>.

### 3. GENERAL PRINCIPLES AND MINIMUM STANDARDS

Stakeholder consultation is governed by the following principles and minimum standards<sup>42</sup>:

#### ***Box 3. General principles and minimum standards for consultation***

Relations with stakeholders are governed by **four general principles**:

- *participation* – take an inclusive approach by consulting as widely as possible;
- *openness and accountability* – make the consultation process and how it has affected policymaking transparent to those involved and to the general public, including to persons with disabilities;
- *effectiveness* – consult at a time when stakeholder views can still make a difference, taking account of proportionality and specific restraints; and
- *coherence* – ensure the consistency (across all services) of consultation processes, analysis, review and quality control.

<sup>38</sup> As an example, such procedures are well established in the area of occupational safety and health, where the Advisory Committee for Safety and Health at Work (ACSH) issues opinions that support legislative initiatives in the context of the ordinary legislative procedure.

<sup>39</sup> These consultations are nevertheless expected to respect the same standards indicated in these guidelines and further detailed in the toolbox.

<sup>40</sup> For more details, see Tool #10 (*Treaty-based social partner consultations and initiatives*).

<sup>41</sup> Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

<sup>42</sup> Commission Communication, Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission, [COM\(2002\)704 final](#).

These principles are complemented by **five minimum standards** that apply to all consultations:

- ✓ *clarity* – all consultation documents should be clear and concise<sup>43</sup>, and include all necessary information to facilitate responses. It is advised that questionnaires that are very technical in nature include a set of more general questions for non-specialists;
- ✓ *targeting* – ensure that the consultation strategy targets all interested parties so that they have an opportunity to express their opinions;
- ✓ *outreach* – ensure adequate awareness-raising and publicity, and adapt communication channels to the needs of all target audiences. Without excluding other communication tools, public consultations should be published on the ‘Have Your Say’ web portal (the ‘single entry point’)<sup>44</sup>;
- ✓ *sufficient time for participation* – allow sufficient time for planning and responses to invitations and written contributions. As a rule, ‘calls for evidence’, which include public consultations, are published for 12 weeks; and
- ✓ *publication of contributions and results* – of public consultations on the ‘Have Your Say’ web portal and, if possible, on DGs’ websites (with an appropriate link to ‘Have Your Say’)<sup>45</sup>.

#### 4. WHEN IS STAKEHOLDER CONSULTATION REQUIRED?

Stakeholders should normally be consulted when preparing an initiative accompanied by an impact assessment. For evaluations of policies and programmes of broad public interest and for fitness checks, a public consultation is highly recommended. Where ‘back-to-back’ impact assessments and evaluations are carried out (see Chapter III), the mandatory public consultation should cover both the backward- and forward-looking elements, to provide input for the evaluation and the impact assessment.

For very technical initiatives of limited interest for the general public, a targeted consultation of stakeholders is a more suitable means of collecting the necessary evidence.

To promote transparency, one should consult stakeholders or request feedback on the following<sup>46</sup>:

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<sup>43</sup> In this context, authors should consider using the editing service offered by the Directorate-General for Translation (DGT-Edit);

[https://myintracomm.ec.europa.eu/serv/en/dgt/making\\_request/edit/Pages/index.aspx](https://myintracomm.ec.europa.eu/serv/en/dgt/making_request/edit/Pages/index.aspx)

<sup>44</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say_en)

<sup>45</sup> See Tool #54 (*Analysing data and informing policymaking*) for more details about publishing the contributions and results.

<sup>46</sup> For more details, see Tool #51 (*Consulting stakeholders*). Consultation involves a more structured engagement with stakeholders where the consultation principles and standards apply, whereas the feedback process allows stakeholders to provide comments on a document, to be considered in further work on the document or initiative.

#### **Box 4. Public consultation and feedback requirements<sup>47</sup>**

##### **Mandatory internet-based public consultation (minimum 12 weeks)<sup>48</sup>**

- *initiatives with impact assessments<sup>49</sup>* – consultations are based on documents, including questionnaires, background information, the ‘call for evidence’ document, etc.;
- *evaluations conducted alongside impact assessments (‘back-to-back’)* – the public consultation covers both backward-looking and the forward-looking aspects;
- *Commission communications with the explicit purpose of launching a consultation process (consultative communications)* – the consultation is based on the communication itself, as adopted by the Commission;
- *green papers.*

##### **Recommended internet-based public consultation (minimum 12 weeks)<sup>50</sup>**

- *evaluations of broad public interest and fitness checks* – consultations are based on documents, including the ‘call for evidence’ document, questionnaires and background information, etc.

##### **Stakeholders must be able to give feedback on:**

- ‘call for evidence’ documents for impact assessments, evaluations of broad public interest and fitness checks (for a period of 12 weeks) – when published together with the launch of the public consultation<sup>51</sup>;
- ‘call for evidence’ documents for initiatives not accompanied by a public consultation (for a period of 4 weeks);
- draft delegated acts and implementing acts of general application and draft measures following the regulatory procedure with scrutiny (for a period of 4 weeks) – there are limited exceptions to this requirement<sup>52</sup>, e.g. where there is a need for urgent action or where the feedback would bring little added value;
- legislative proposals adopted by the College and, where applicable, the accompanying final impact assessments (for a period of 8 weeks); and
- how to improve existing legislation (at any time via the ‘[Have Your Say: Simplify!](#)’ website).

<sup>47</sup> The ‘Have Your Say’ web portal provides access to all consultation and feedback mechanisms; [https://ec.europa.eu/info/law/better-regulation/have-your-say\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say_en).

<sup>48</sup> Without prejudice to the exceptional cases referred to in Box 1 and in full respect of the general rules set out in the Commission Communication *Towards a reinforced culture of consultation and dialogue – general principles and minimum standards for consultation of interested parties by the Commission* (COM(2002) 704). Accordingly, where several consultation steps are required in developing an initiative, it is not necessary to conduct a 12-week consultation each time.

<sup>49</sup> For very technical initiatives, a targeted consultation is a better means of collecting the necessary evidence.

<sup>50</sup> Without prejudice to the exceptional cases referred to in Box 1 and in full respect of the general rules set out in the Commission Communication *Towards a reinforced culture of consultation and dialogue – general principles and minimum standards for consultation of interested parties by the Commission* (COM(2002) 704). Accordingly, where several consultation steps are required in developing an initiative, it is not necessary to conduct a 12-week consultation each time.

<sup>51</sup> If the ‘call for evidence’ document is not published at the same time as the launch of the public consultation, the period for feedback is normally 4 weeks. The subsequent public consultation is open for contributions for 12 weeks.

<sup>52</sup> See Tool #51 (*Consulting stakeholders*). Delegated and implementing acts are included in Decide, where an indication should be provided about posting the draft act for stakeholders to provide feedback.

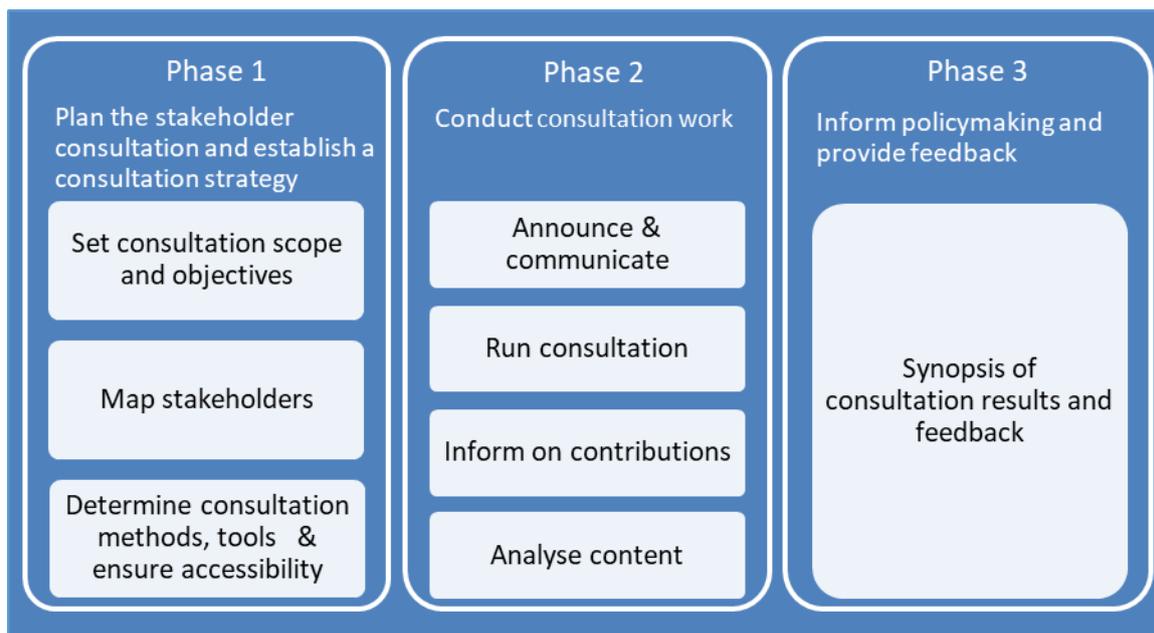
## 5. PLANNING AND CONDUCTING STAKEHOLDER CONSULTATION AND INFORMING POLICYMAKING

The consultation process can be broken down into three interacting phases:

- (1) planning the stakeholder consultation and establishing the consultation strategy;
- (2) conducting the consultation work; and
- (3) informing policymaking.

Each phase consists of a series of steps that provide a framework for a high-quality, transparent stakeholder consultation.

**Figure 2. The interacting phases and key steps of the consultation process**



### 5.1. Phase 1 — Planning the stakeholder consultation and establishing a consultation strategy

The lead DG must start preparing a consultation strategy in the early stages of planning a policy initiative. For politically important/sensitive initiatives, a first reflection on the consultation strategy is required at the time of requesting political validation. After validation, the strategy and all relevant consultation documents, should be finalised and shared with the **interservice group** established for the initiative.

The key elements of the consultation strategy (see Box 5) must be included in the ‘call for evidence’ documents on which stakeholders can provide feedback. The ‘call for evidence’ document is translated into all EU’s official languages.

The Secretariat-General is responsible for launching all public internet-based consultations on the ‘*Have Your Say*’ web portal<sup>53</sup>.

It is important to plan carefully and design a consultation strategy that:

<sup>53</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say_en)

- sets out clearly the scope of the consultation and its objectives;
- identifies all relevant stakeholders that may have an interest in the policy issue(s); and
- identifies the most appropriate consultation activities, methods and tools, ensures accessibility<sup>54</sup> and considers appropriate ways of promoting the consultation.

### 5.1.1. *Setting the consultation scope and objectives*

The first step in designing the consultation strategy is to determine the consultation objectives:

- what is the aim of conducting the consultation?
- what proposal or initiative, or what aspects of it, are to be consulted on?

Depending on the stage of the policy development process, the consultation objectives could be, for example, to gather new ideas, to collect the widest spectrum of views and opinions, to gather scientific evidence, data and knowledge, or to test existing ideas and analysis.

The type and scope of consultation activities will depend on the type and scope of the initiative, the timing and the context. For initiatives accompanied by impact assessments, and for evaluations of broad public interest and fitness checks, the scope must cover at least the elements listed in Box 5.

#### ***Box 5. Mandatory scope of consultations in impact assessments, fitness checks and evaluations (if accompanied by consultation activities)***<sup>55, 56</sup>

##### **Initiatives accompanied by impact assessments**<sup>57</sup>

Together, the activities outlined in the consultation strategy must cover all elements of the impact assessment process<sup>58</sup>. The key issues to be addressed in the consultation strategy are therefore:

- the problem to be tackled;
- the issue of subsidiarity and the EU dimension to the problem;
- the available policy options and their potential impacts; and
- when modifying existing interventions, the scope for efficiency improvements (reducing regulatory costs) and simplification measures that do not affect the achievement of objectives.

##### **Fitness checks and evaluations of broad public interest**<sup>59</sup>

Together, the activities outlined in the consultation strategy must cover the five mandatory evaluation criteria: relevance, effectiveness, efficiency, coherence, and EU added value. Individual activities, including the public consultation, may focus on some of the criteria only, as appropriate.

<sup>54</sup> Including accessibility for persons with disabilities.

<sup>55</sup> Where the evaluation and impact assessments are conducted ‘back-to-back’, only one public consultation has to be conducted, as long as relevant stakeholders are consulted on all the main elements of the impact assessment.

<sup>56</sup> Stakeholder consultations explicitly cover social, environmental and digital aspects where relevant.

<sup>57</sup> For details, see Chapter IV (Impact assessment).

<sup>58</sup> The assessment of the preferred option in impact assessments will be expanded to cover the analysis of the ‘do no significant harm’ and ‘digital by default’ principles.

<sup>59</sup> See Chapter III (Evaluation (including fitness checks)).

### 5.1.2. Mapping stakeholders

An important element of any consultation strategy is to identify and map the stakeholder groups that should be consulted. This will help determine the most appropriate consultation methods and tools.

The basic rule is to **consult broadly and transparently** among stakeholders, who might be concerned by the initiative, seeking a whole spectrum of views in order to avoid bias or skewed conclusions promoted by specific constituencies ('regulatory capture').

Successful stakeholder mapping involves:

- *identifying* stakeholder categories relevant for or interested in the policy area(s) in question; and
- *prioritising* stakeholder categories to engage with according to their level of interest in, expertise about, or influence on the initiative, bearing in mind:
  - whom it will affect;
  - who will have to implement it; and
  - who has a stated interest in the policy.

One important category of stakeholders is the research community, that can provide evidence based on rigorous scientific methods and peer review processes, and that might need to be specifically targeted.

#### *Consultation methods*

Consultations may be public or targeted:

- **public consultations** can foster transparency and accountability, and ensure the broadest public validation and support for an initiative. However, the respondents are self-selecting and therefore not representative. One should assess the relevance of responses thoroughly, particularly where response rates are low or there are signs of significant campaigns to coordinate responses;
- **targeted consultations** allow more focused interaction or dialogue and may tap expertise more efficiently, in particular when dealing with a very specific or technical subject. One should avoid granting privileged access to some stakeholders.

The selected method should reflect the consultation objectives and the target group(s) identified through the stakeholder mapping. For some initiatives, a public consultation is mandatory (see Box 4).

#### *Consultation tools*

The choice of consultation method will determine the tools to use. The most commonly used tools are consultation documents, questionnaires (for written consultations), and direct interactions with stakeholders via interviews, meetings, conferences, hearings or other events.

<b>Box 6. Timeframes for consultation and feedback</b>		
<b>Internet-based public consultation</b>	<b>How long?</b>	<b>When?</b>
Initiatives with impact assessment Evaluations and fitness checks, where relevant	minimum 12 weeks <sup>60</sup>	Decided case by case
Consultative communications Green papers		After adoption by Commission
<b>Stakeholders must be enabled to give feedback on:</b>	<b>How long?</b>	<b>When?</b>
‘Calls for evidence’ for impact assessments, fitness checks and evaluations (where relevant)	12 weeks <sup>61</sup>	After publication
‘Call for evidence’ documents for initiatives, non-accompanied by a public consultation	4 weeks	After publication
Draft delegated acts <sup>62</sup>	4 weeks	After interservice consultation
Draft implementing acts	4 weeks	After interservice consultation and before Comitology Committee vote
Legislative proposals adopted by the College and, where applicable, the accompanying impact assessments	8 weeks	After adoption by Commission and publication of all language versions of the document

## 5.2. Phase 2 — Conducting the consultation work

Once the consultation strategy has been finalised and shared with the interservice group, together with the relevant documents, the various consultation activities can be launched. For each activity, follow the steps below:

- announcing and communicating;
- running the consultation;
- informing about contributions received; and
- analysing the responses.

### 5.2.1. *Announcing and communicating*

The launch of a consultation activity should be announced on a dedicated website in a form that takes account of all target audiences. The communication channels that are most appropriate for reaching the relevant target groups should be used.

<sup>60</sup> Without prejudice to the exceptional cases referred to in Box 1 and the general rules set out in the Commission Communication *Towards a reinforced culture of consultation and dialogue – general principles and minimum standards for consultation of interested parties by the Commission* (COM(2002) 704).

<sup>61</sup> If the public consultation is not launched at the same time, the feedback period for the ‘call for evidence’ documents is 4 weeks.

<sup>62</sup> For exact scope, see Tool #51 (*Consulting stakeholder*).

### 5.2.2. *Running the consultation and acknowledging contributions*

The practical organisation and facilitation of any consultation activity will require sufficient resources for replying to questions, solving technical problems and processing the contributions (including moderating them).

#### *Consultation documents*

The quality of the consultation documents will determine the quality of contributions received and thus the quality of input to policymaking.

It is good practice to **test consultation documents** (e.g. presentations, surveys or questionnaires) with groups of people who were not involved in drafting them. These should resemble as closely as possible the actual target audience or subgroups thereof.

### 5.2.3. *Informing about contributions*

The careful and transparent treatment of contributions received in the course of a consultation is crucial and establishes a good basis for future constructive cooperation and fruitful relations with stakeholders.

#### *Publication of contributions*

Contributions to a consultation must be published. They should be published in the language in which they were submitted. Written contributions should be made public on the dedicated consultation webpage. For consultation events (meetings, hearings, conferences, etc.), summary minutes and speeches or presentations should be made public on the DG's consultation webpage<sup>63</sup>.

Respondents should be given the following options as regards the publication of their contributions:

- publication with personal information; or
- anonymised publication.

Procedures for the collection, handling and publication of personal data should respect the relevant data protection rules<sup>64</sup> and be set out in a privacy statement published on the consultation page.

#### *Informing about the contributions – factual summary report*

Within 8 weeks of the closure of the public consultation<sup>65</sup>, it is mandatory to publish on the consultation website a short **factual summary** of the key issues raised in the public consultation. It is also a good practice to publish on the consultation website a short factual summary on the key issues raised in each of the targeted consultation activities

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<sup>63</sup> In cases where the publication of targeted consultation activities contributions would lead to disproportionate workload, the DG responsible for conducting consultations should contact SG.A2.

<sup>64</sup> See Tools #53 (*Conducting consultation activities*) and #54 (*Analysing data and informing policymaking*).

<sup>65</sup> This applies to public consultations only. The 8-week timeframe is indicative for public consultations with a large number of responses. Respondents' feedback on legislative proposals is published online at the time of submission on 'Have Your Say'.

envisaged in the consultation strategy (e.g. an informal report, minutes of a stakeholder meeting, and/or a list or table of contributions).

#### *5.2.4. Analysing content*

The input received in each consultation needs to be thoroughly analysed.

Responses to consultations are in most cases not statistically representative of the target population. Where statistically representative input is needed, a different consultation method should be used (e.g. Eurobarometer<sup>66</sup>).

The results of the consultation should be presented in an objective, unbiased way, briefly describing respondents' profiles and recording all views, including dissenting ones.

### **5.3. Phase 3 — Informing policymaking and providing feedback**

The contributions received through the various consultations carried out in the context of the consultation strategy feed into further work on the policy initiative. It is up to the lead DG to provide information on the outcome of the overall consultation work, possible conclusions and any other related issues.

#### *5.3.1. Synopsis of consultation results*

Beyond the factual summary, stakeholders should receive adequate and thorough feedback through a synopsis report, prepared at the end of the consultation activities. It is critical for respondents to know how, and to what extent, their input has been taken into account and to understand why certain suggestions have not been taken up. Providing effective feedback will contribute to the overall transparency of the Commission's policymaking, enhance its accountability and credibility, and potentially lead to better responses to future consultations.

The synopsis report is attached to the impact assessment or the evaluation report as an annex and accompanies the initiative through interservice consultation to the Commission's adoption. In other cases, the synopsis report should be published as a dedicated linked SWD or integrated in a linked SWD (other than an impact assessment or evaluation report) accompanying the initiative.

For legislative proposals, the explanatory memorandum should contain a reference to the outcome of the stakeholder consultation.

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<sup>66</sup> <https://europa.eu/eurobarometer/>

# Chapter III

## Evaluation (including fitness checks)

### 1. INTRODUCTION

#### *What is an evaluation and when is it required?*

**Evaluation** is an evidence-based assessment of the extent to which an intervention:

- is *effective* in fulfilling expectations and meeting its objectives;
- is *efficient* in terms of cost-effectiveness and proportionality of actual costs to benefits;
- is *relevant* to current and emerging needs;
- is *coherent* (internally and externally with other EU interventions or international agreements); and
- has *EU added value* — i.e. produces results beyond what would have been achieved by Member States acting alone.

Evaluations aim to help the Commission learn about the functioning of EU interventions and assessing their performance against initial expectations. By evaluating, the Commission takes a critical look at whether EU legislation and spending programmes are fit for purpose and deliver their intended objectives at minimum cost (i.e. avoiding unnecessary costs or burdens). Evaluation also provides a key opportunity to engage with stakeholders and the public.

An evaluation goes beyond an assessment of *what* has happened; it also considers *why* it has happened (the role of the EU intervention) and, if possible, *how much* has changed. It should look at the wider perspective and provide an independent and objective judgment of the situation on the basis of the available evidence<sup>67</sup>.

A **fitness check** is a comprehensive evaluation of two or more interventions usually in the same policy area that are related in some way (normally by sharing the same objectives or specific procedures, e.g. reporting), thus justifying a joint analysis<sup>68</sup>.

A fitness check assesses whether a set of interventions is fit for purpose by assessing its performance against its policy objectives. In particular, it should determine the coherence of the various measures and seek to quantify any synergies (e.g. improved performance, simplification, lower costs, reduced burdens) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies, implementation problems, and/or obsolete measures) over time. This will help identify the cumulative impact of the interventions, in terms of costs and benefits.

<sup>67</sup> See Tool #4 (*Evidence-informed policymaking*) for guidance on collecting and processing evidence.

<sup>68</sup> The concept of a fitness check was introduced in *Smart Regulation in the European Union* ([COM\(2010\) 543 final](#)).

As part of the REFIT programme<sup>69</sup>, all evaluations should specifically look at **simplification and burden reduction potential** as part of the efficiency analysis. In the context of the ‘one in, one out’ approach, evaluations and fitness checks will be useful in identifying possibilities for simplification and burden reduction without jeopardising benefits. Every revision of legislation should, in principle, be preceded by an evaluation.

**Evaluations** support decision-making and contribute to strategic planning and the design of future interventions. The Commission applies the ‘**evaluate first**’ principle to make sure any policy decisions takes due account of lessons from past EU action.

The Commission’s evaluations serve several purposes. Most evaluation results will contribute (to a greater or lesser extent) to:

- ✓ *timely and relevant input for decision-making and political priority-setting* – lessons learned from evaluation should be available and feed into impact assessment work from the outset;
- ✓ *organisational learning* – evaluation results can be used to improve the quality of an ongoing intervention. Evaluations should identify not just areas for improvement but also encourage the sharing of practices and achievements. Evaluation also provides the opportunity to look for the unintended and/or unexpected effects of EU action;
- ✓ *transparency and accountability* – all stakeholders and the general public have a right to know what the EU has done and achieved; and
- ✓ *efficient resource allocation* – evaluation results contribute to more efficient allocation of resources between interventions and different activities.

The Commission is committed to evaluating in a proportionate way all EU spending and non-spending activities intended to have an impact on society or the economy<sup>70</sup>. An obligation to evaluate spending activities is included in Article 318 TFEU and the EU Treaties contain further sector-specific evaluation requirements. Specific requirements are often written into individual legal acts.

#### **Evaluation is required:**

- on the basis of the ‘evaluate first’ principle, i.e. before revisions of EU legislation;
- where demanded by the legal basis of the relevant intervention (e.g. an evaluation clause<sup>71</sup>); and
- as indicated in the Financial Regulation, i.e. for all programmes and activities entailing significant overall spending<sup>72</sup>.

#### *What are the procedural steps?*

The time needed to prepare an evaluation will vary from case to case. **Sufficient time needs to be allocated** to ensure that the evaluation can be conducted in accordance with

<sup>69</sup> See Tool #2 (*Regulatory fitness programme (REFIT) and the Fit for Future Platform*).

<sup>70</sup> Responding to strategic needs: reinforcing the use of evaluation (SEC(2007) 213).

<sup>71</sup> See Tool #44 (*Legal provisions on monitoring and evaluation*).

<sup>72</sup> Indicatively over EUR 5 million.

these guidelines and, where necessary, that the Commission can report to the European Parliament and Council by the date set in the legal basis. Where an evaluation is linked to a review clause that invites the Commission to present new proposals by a certain date, take care to ensure that planning allows sufficient time for the evaluation.

Normally, evaluations and impact assessments are conducted one after the other, so that the results of the former can be fully used in the latter. However, where necessary, they may be launched at the same time and carried out ('back-to-back') as a single process<sup>73</sup>. The intention to conduct a 'back-to-back' evaluation/impact assessment must be clearly signalled when the initiative is presented for political validation<sup>74</sup>.

The evaluation work is led by the DG(s) responsible for the relevant EU legislation. Generally, evaluations are included in the annual management plan and encoded in the interinstitutional study database. Each individual evaluation is introduced and **validated** in Decide.

Following validation, an interservice group should be set up that includes representatives from:

- ✓ the 'better regulation' support unit in the lead DG(s);
- ✓ other interested DGs; and
- ✓ the Secretariat-General.

The interservice group must be involved in all key steps of the evaluation work following validation, up to the launch of the interservice consultation and if applicable, the associated report/communication to the European Parliament and the Council. If a public consultation is conducted (as recommended for evaluations of broad public interest and fitness checks), the interservice group should be involved in preparing the questionnaire.

The lead DG(s) prepares an **evaluation report** (a staff working document) presenting the analysis and answering the evaluation questions detailed below. For evaluations selected for scrutiny by the RSB, the draft report must be submitted to the RSB.

The RSB will scrutinise the draft reports of the evaluations it selects and all fitness checks, and the interservice consultation cannot be launched before it has issued its opinion. If the opinion is negative, the lead DG(s) may, but is (are) not obliged to, submit a revised draft to the RSB for a second opinion before proceeding with the interservice consultation.

To maximise transparency and public access, the final evaluation report alongside the 'call for evidence', related consultation documents and, if applicable, the contractor's final study and the RSB opinion must be published centrally<sup>75</sup>.

DGs must feed the evaluation results into their annual activity reports and identify follow-up actions in their annual management plans. Identifying and sharing the planned

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<sup>73</sup> See Tool #50 ('Back-to-back' evaluations and impact assessments).

<sup>74</sup> See Tool #6 (Planning and political validation of initiatives).

<sup>75</sup> The evaluation report, the 'call for evidence', related consultation documents and, if applicable, the RSB opinion must be published on the 'Have Your Say' web portal. The contractor's study is published on the DG's website.

follow-up actions is part of accepting responsibility and accountability for EU actions, and ensures transparency.

Where required by the basic legal act, the lead DG(s) should transmit a **report** summarising the results of the evaluation to the European Parliament and the Council together with the evaluation report. In such cases, a separate executive summary is not required.

## 2. KEY PRINCIPLES AND QUESTIONS

### *What are the principles?*

All evaluations should be of high quality and respect the following principles:

- ✓ *comprehensiveness* – evaluations should cover at least the following criteria<sup>76</sup>:
  - effectiveness;
  - efficiency;
  - relevance;
  - coherence; and
  - EU added value.

Other criteria may be added as appropriate:

- ✓ *proportionality* – the scope of the evaluation must be tailored to the particular intervention, the time since its implementation and the available data<sup>77</sup>. For some criteria, new data will need to be collected, analysed and compared with other findings. For others, it is acceptable to produce a short summary on the basis of existing reports and information, or to provide a standard explanation (e.g. in areas where the EU has exclusive competence);
- ✓ *independence and objectivity* – only independent and objective evaluations can deliver robust and reliable results. The analysis in an evaluation can be considered independent and objective (even if it is based on the findings of a study by a contractor), provided that it is based on all relevant information, it is conducted without influence or pressure by third parties and reports transparently on the positive and negative elements of the analysis;
- ✓ *evidence-based approach* – evaluations should be based on the best available evidence drawn from a diverse and appropriate range of methods and sources (triangulation). Not all sources are equally robust and one should consider when and how the evidence was collected and whether it is subject to bias or uncertainty<sup>78</sup>. Where necessary, sensitivity and/or scenario analysis should be

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<sup>76</sup> See Tool #47 (*Evaluation criteria and questions*).

<sup>77</sup> In general, it is recommended that you do not conduct an evaluation until you have been able to collect at least 3 years' of reasonably full data on the implementation of the intervention; see Tool #46 (*Designing the evaluation*).

<sup>78</sup> See the Group of Chief Scientific Advisors guidelines for good scientific advice under conditions of complexity and uncertainty: [https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors/scientific-advice-european-policy-complex-world\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors/scientific-advice-european-policy-complex-world_en).

conducted to test the robustness of the evidence<sup>79</sup>. Any limitations related to the evidence and the methodology, particularly in terms of their ability to support the conclusions, must be clearly explained.

- ✓ *transparent judgment* – evaluations must make judgments on the basis of the available evidence and analysis. The judgments should be as specific as possible and the judgment criteria should be clearly identified in the design of the evaluation.

### *What are the questions?*

<b>Box 7. The questions an evaluation should answer<sup>80</sup></b>	
<b>1.</b>	<p><b><i>What was the expected outcome of the intervention?</i></b></p> <p>The evaluation starts by explaining the rationale for the intervention at the time it was prepared/adopted, i.e. the problem or the needs the EU was trying to address and its underlying causes, what it expected to achieve and how that achievement was to be assessed (the intervention logic). It should draw to the extent possible on the impact assessment report (if available), the explanatory memorandum and the preamble of the final legal text. It should also include the points of comparison against which the intervention will be assessed. Wherever possible, it should include a reference to the UN sustainable development goals (SDGs) that the intervention aimed to address.</p>
<b>2.</b>	<p><b><i>How has the situation evolved over the evaluation period?</i></b></p> <p>The evaluation gives a factual presentation of progress to date in implementing the intervention (both legally and on the ground).</p>
<b><i>Evaluation findings (analytical part<sup>81</sup>)</i></b>	
<b>3.</b>	<p><b><i>To what extent was the intervention successful and why? [criteria to be assessed: effectiveness, efficiency, coherence]</i></b></p> <p>The evaluation compares the expected situation (<i>What did we expect to achieve?</i>) with the actual situation (<i>How have things changed over the evaluation period?</i>).</p> <p>‘Success’ is assessed in terms of the extent to which an intervention achieves its objectives<sup>82</sup>:</p> <ul style="list-style-type: none"> <li>– effectively;</li> <li>– efficiently; and</li> <li>– in a coherent way.</li> </ul> <p>The evidence gathered to answer the questions addressing these three evaluation criteria<sup>83</sup> should feed into the narrative here. Arguments supporting the narrative should be clearly presented and their association to any of the three evaluation criteria clearly</p>

<sup>79</sup> See Tool #57 (*Methods to assess costs and benefits*).

<sup>80</sup> See Tool #49 (*Format of the evaluation report*).

<sup>81</sup> The ‘evaluation findings’ part should be analytical and the narrative should clearly encompass the five evaluation criteria. The evidence gathered on the targeted questions addressing each of the five evaluation criteria (see Tool #47 (*Evaluation criteria and questions*)) should feed into this part in order to substantiate the discussion with the necessary evidence base. Detailed analysis could be provided in Annex III to the evaluation report (‘Evaluation matrix and answers to the evaluation questions (by evaluation criterion)’).

<sup>82</sup> As outlined in the intervention’s legal act and/or any prior impact assessment. In the latter case, if co-legislators amendments affect the initial objectives as presented in the impact assessment, the initial objectives should be updated accordingly.

<sup>83</sup> See Tool #47 (*Evaluation questions and criteria*).

	<p>referenced.</p> <p>More detailed analysis can be documented in Annex III (<i>Evaluation matrix and answers to the evaluation questions (by evaluation criterion)</i>) to the evaluation report.</p> <p>Under the effectiveness and efficiency discussion, efforts should be made to address in quantitative terms benefits and costs arising from the intervention.</p> <p>The analysis of efficiency should cover administrative and adjustment costs, and aspects of simplification— these are important for all evaluations. Where appropriate, evaluation findings should pinpoint areas where there is potential to reduce inefficiencies (particularly unnecessary costs) and simplify the intervention by considering e.g. the use of digital solutions.</p> <p>The proportionality of costs and benefits should be assessed. Actual costs and benefits should be outlined in Annex IV, in the ‘Overview of benefits and costs’ table and, where relevant, the separate table on ‘Simplification and burden reduction’.</p>
4.	<p><b><i>How did the EU intervention make a difference?</i></b> [criterion to be assessed: EU added value]</p> <p>The evaluation should give an assessment of the intervention’s EU added value for individuals and businesses in the EU. This should go beyond restating the legal reasons/objectives of the intervention to present an <i>ex post</i> evidence-based assessment.</p> <p>The narrative should explain clearly to whom the EU intervention made a difference. Where relevant it should provide an assessment of the EU added value in different territories (rural, urban, cross-border, outermost regions).</p>
5.	<p><b><i>Is the intervention still relevant?</i></b> [criterion to be assessed: relevance]</p> <p>The evaluation should look at the objectives of the intervention and see how well they reflected and most importantly, they still reflect current and future needs (continuing relevance). This is key information that will help policymakers decide whether to maintain, adjust or terminate the intervention.</p> <p>The narrative here should highlight any mismatch between the original objectives and current and future needs and problems (considering also elements of strategic foresight) and the reasons for it.</p>
6.	<p><b><i>What are the conclusions and lessons learned?</i></b></p> <p>Evaluations enable the organisation to learn and to raise critical policy issues for attention at political level. Information reported in the previous sections will feed into conclusions as to the results of the evaluation; as a minimum, these should include:</p> <ul style="list-style-type: none"> <li>• an account of which elements of the intervention are (not) working and why (not);</li> <li>• a summary of specific benefits from the intervention that could not have been achieved without EU involvement; and</li> <li>• a presentation of credible evidence-based lessons and, where possible, areas for improvement<sup>84</sup>.</li> </ul> <p>As all evaluations should investigate the potential to simplify and reduce unnecessary costs, clear reference should be made to lessons learned relating to REFIT issues, such as regulatory or unnecessary burden, simplicity/complexity, efficiencies/inefficiencies and the achievement of objectives at low/high (appropriate/reasonable) cost.</p>

<sup>84</sup> To support the digital and green transition, the evaluation, where relevant, should explore whether environmental impacts could be further minimised and whether more could be done for a successful digital transformation.

### 3. EVALUATION REPORT

The evaluation report summarises and presents the final results of the evaluation process in the form of a staff working document. It draws on work conducted by:

- external contractors (via one or more study reports), where applicable; and
- Commission services.

All evaluation reports must answer the questions set out in the previous section, following a process in line with the principles set out in that section<sup>85</sup>.

The evaluation report will explain the method, evidence base and analysis used for the evaluation and communicate the results and conclusions to:

- policymakers (thus helping to inform their decision-making); and
- stakeholders.

The report will draw together all the steps of the evaluation process summarising and assessing the method applied, the evidence collected and the analysis conducted, on the basis of a wide range of sources. A template for the format of the report can be found on GoPro<sup>86</sup>.

**The report should be a transparent, objective and balanced presentation of the evaluation process, evidence and analysis.** In addition, it should be:

- ✓ *concise* – the evaluation report should **not be longer than 50 pages** of text accompanied by annexes as appropriate;
- ✓ *non-technical* – i.e. accessible to non-expert readers; and
- ✓ *self-standing* – it must provide sufficient detail to enable the reader to follow the evidence and logic, and to understand the conclusions without having to read any supporting material (e.g. a study prepared by contractors).

Stakeholder views and how these have been considered should be the subject of transparent references throughout the report and summarised in the synopsis report<sup>87</sup> (to be added as an annex to the staff working document). All external material used (reports, scientific findings, etc.) should also be systematically referenced.

Where there is no requirement to submit a report to the European Parliament and Council (see section 1 above), prepare a **short executive summary** (max. 4-5 DGT pages) giving an accessible overview of the headline findings and lessons learned from the evaluation, and make it available as a stand-alone staff working document in English, French, and German.

Evaluation is not the end of the process. The findings should stimulate discussion, inform follow-up action (to put into practice the lessons learned) and feed into the next cycle of decision-making. Follow-up can take many forms, such as an impact assessment, improved guidance or further monitoring.

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<sup>85</sup> For further information, see Tool #49 (*Format of the evaluation report*).

<sup>86</sup> [GoPro evaluation templates](#).

<sup>87</sup> See Chapter II.

# Chapter IV

## Impact assessment

### 1. INTRODUCTION

#### *What is an impact assessment and when is it required?*

Impact assessment is about **gathering and analysing evidence** to support policymaking. It involves verifying the existence of a problem, identifying its underlying causes, assessing whether EU action is needed, and analysing the advantages and disadvantages of available solutions.

Impact assessment promotes informed decision-making and contributes to ‘better regulation’ that delivers the full benefits of policies at minimum cost, while upholding the principles of subsidiarity and proportionality. However, **it is only an aid to policy-making and decision-making and not a substitute for it.**

All spending programmes, financial instruments and budgetary guarantees that entail significant expenditure<sup>88</sup> should be accompanied by an *ex ante* evaluation (also referred to as ex-ante financial statement), as required by the Financial Regulation. Major programmes under the multiannual financial framework will generally be accompanied by impact assessments that fulfil this requirement, but also entail stakeholder consultation and scrutiny by the RSB.

**An impact assessment is required for Commission initiatives that are likely to have significant economic, environmental or social impacts or which entail significant spending, and where the Commission has a choice of policy options.**

Where the above conditions are fulfilled<sup>89</sup>, an impact assessment is required for legislative and non-legislative initiatives and for delegated acts and implementing measures (taking into account the principle of proportionate analysis, in particular for the latter two categories). Where an impact assessment is required in principle, but this is not possible and a derogation is granted, an analytical document in the form of a staff working document presenting the evidence behind the proposal and cost estimates should be prepared within three months of the initiative’s adoption.

#### *What are the procedural steps?*

The impact assessment work is led by the Directorate(s)-General responsible for the policy initiative. DGs should establish as early as possible in the policy planning process whether an impact assessment is required and seek confirmation through the political validation process.

<sup>88</sup> Indicatively in excess of EUR 5 million.

<sup>89</sup> Where the above conditions are not met, no impact assessment is needed, regardless of the nature of the initiative. See Tool #7 (*What is an impact assessment and when it is necessary*) for more details.

Following validation, an interservice group should be set up to steer the impact assessment process and contribute to the preparation of the ‘call for evidence’ and the draft impact assessment report. In particular, the interservice group should help identify the relevant and significant impacts, with a view to collecting appropriate evidence.

The lead DG(s) should allow **sufficient time** to collect and analyse all the relevant evidence (including data, scientific advice, other expert views, stakeholder input, etc.) and present the outcome of the impact assessment process in a report. The report benefits from other DGs’ and services’ contributions through interservice work.

The RSB reviews the quality of the impact assessment report and issues one or more opinions on it and recommendations for improvement. **A positive RSB opinion on the draft impact assessment report is required before an initiative can proceed to interservice consultation.** Where the RSB issues two negative opinions, only the vice-president responsible for ‘better regulation’ can give the green light for the adoption of the initiative. The RSB opinion(s) accompany the legislative proposal in the decision-making process.

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 (see section 3 below);
- the subsidiarity grid<sup>90</sup>;
- the adopted initiative; and
- the RSB opinion(s)<sup>91</sup>.

## 2. KEY PRINCIPLES AND QUESTIONS OF IMPACT ASSESSMENT

Impact assessment is a tool to help structure reflection and conduct analyses to inform policy design. Given the wide range of Commission initiatives, the best way to carry out an impact assessment and present its results will vary from case to case.

However, all impact assessments must answer a set of key questions and respect a number of principles. They should be comprehensive (considering all types of impact), proportionate (in the detail of the analysis and focusing on the relevant impacts), evidence-based, open to stakeholders’ views, unbiased, prepared collectively with relevant Commission services, embedded in the policy cycle, transparent and of a high quality<sup>92</sup>.

### ***Box 8. The questions that an impact assessment should answer***

<b>1.</b>	<p><b><i>What is the problem and why is it a problem?</i></b></p> <p>An impact assessment starts by verifying the existence of a problem, identifying who is affected, estimating the scale of the problem, analysing its causes and consequences, and assessing how likely it is to persist in the absence of (further) EU policy intervention and in view of possible long-term developments, trends and challenges (using foresight</p>
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<sup>90</sup> ‘Subsidiarity grid’ [template on GoPro](#).

<sup>91</sup> These also include the tables from Annex 3 (*Who is affected and how*) of the impact assessment.

<sup>92</sup> For more details, see Tool #1 (*Principles, procedures and exceptions*).

	<p>elements and scientific advice, where appropriate). For a revision, the answer should draw on the conclusions of the evaluation, if one was prepared.</p> <p>The answer to these questions should give policymakers the information they need to decide whether a policy response is required.</p>
2.	<p><b><i>Why should the EU act?</i></b></p> <p>The analysis should then assess whether Member States alone could resolve the issue satisfactorily, whether the EU has the right to act (i.e. a legal basis) and whether it is best placed to do so.</p> <p>The answer to these questions should give policymakers the information they need to decide whether an <i>EU-level</i> policy response is required.</p>
3.	<p><b><i>What should be achieved?</i></b></p> <p>The impact assessment should set out what the EU policy should achieve.</p> <p>It should clearly identify the objectives of policy action, including the level of policy ambition, potential trade-offs between them, and the criteria against which policy options will be compared and the success of any initiative assessed. These should take account of the key long-term challenges and corresponding EU policy ambitions.</p>
4.	<p><b><i>What are the options for achieving the objectives?</i></b></p> <p>There are different ways to achieve policy objectives. The impact assessment should allow for an informed decision about which to pursue. It should therefore identify and screen available options with a view to selecting the most relevant ones for analysis and comparison, again in the light (<i>inter alia</i>) of the key long-term challenges and corresponding EU policy ambitions.</p> <p>At the end of this process, the most relevant policy options should have been identified for further examination in the impact analysis stage.</p>
5.	<p><b><i>What are their economic, social and environmental impacts and who will be affected?</i></b></p> <p>Once a set of policy options is selected, carry out a robust assessment of their economic, social and environmental impacts and of who will be affected and to what degree.</p> <p>This assessment should inform policymakers of the extent to which different options would meet their objectives, with what benefits, at what cost, with what implications for different stakeholders, and at what risk of unintended consequences.</p> <p>The analysis will also involve identifying relevant sustainable development goals and – if feasible – how the initiative contributes to their implementation, impacts on SMEs and, where relevant, on gender equality, fundamental rights, territories (e.g. urban, rural, cross-border, outermost areas) and regions, non-EU countries, and on essential security interests of the EU (including resilience against hybrid threats), and checking for conformity with the ‘do no significant harm’ and ‘digital by default’ principles<sup>93</sup>.</p>
6.	<p><b><i>How do the options compare (effectiveness, efficiency and coherence)?</i></b></p> <p>Based on the above assessment, compare the options with regard to their effectiveness, efficiency and coherence, compliance with the proportionality principle and how future-proof they are, given the long-term challenges, including the coherence with the European Climate Law<sup>94</sup>.</p> <p>At the end of this process, present the relevant information to support decision-making and, where appropriate, suggest a preferred option.</p>
7.	<p><b><i>How will monitoring and subsequent evaluation be organised?</i></b></p> <p>Having the entire policy cycle in mind, set out arrangements for monitoring and <i>ex post</i></p>

<sup>93</sup> See Chapter III of the ‘better regulation’ toolbox for more specific guidance on these elements.

<sup>94</sup> [Regulation \(EU\) 2021/1119](#).

<p>evaluation to track whether the policy measure actually delivers the intended results and to inform any future revisions of the policy.</p> <p>At the end of this process, policymakers should know how the policy will be monitored and evaluated, allowing for future policy adjustments as needed.</p>
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The process of finding answers to these questions is necessarily **iterative**. It should start from broad definitions of the problem, objectives and possible solutions, and then narrow them down to what is most relevant. The questions are also interrelated.

The following should guide the impact assessment process:

- When deciding on the *focus and depth* of the analysis, concentrate on what is relevant for decision-making, leaving out what is not. Insights from strategic foresight should inform the analytical process for major policy initiatives;
- Use the results of any relevant evaluations and fitness checks of the existing policy framework as the starting point for *defining the problem*. Other DGs'/services' expertise should feed into the impact assessment in order to consider and properly assess all relevant issues. Independent scientific advice<sup>95</sup> can also play an important role in defining the problem and identifying courses of action;
- Identify the most appropriate methods for *collecting and interpreting data and for analysing impacts*. Where necessary, commission external studies and/or consider scientific advice to gather input on specific elements;
- Assess all relevant impacts *qualitatively and quantitatively* where possible. It will not be possible to quantify impacts in all cases, but it is expected (in the context of the 'one in, one out' approach and for REFIT initiatives) that systematic efforts will be made to do so, to the extent that this is proportionate<sup>96</sup>;
- Assess the expected significance of impacts in terms of *changes relative to a dynamic baseline* (i.e. one that evolves over time due to other policies or expected events). In this context, apply the principle of proportionate analysis, while keeping in mind that it is important not to leave out anything that is of relevance for political decision-making;
- Analyse the identified relevant impacts<sup>97</sup>, with a particular attention to those that always have to be reported in the impact assessment (see section 3 below):
  - Economic (including SMEs and competitiveness<sup>98</sup>), social and environmental;
  - fundamental rights; and

<sup>95</sup> For example from the Commission's Scientific Advice Mechanism [https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors\\_en](https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en).

<sup>96</sup> Relevant analytical methodologies for impact assessment are described in Chapter 8 of the toolbox. When simulation models are used, these should be included in MIDAS, the Commission's repository of models (<https://web.jrc.ec.europa.eu/policy-model-inventory/>).

<sup>97</sup> See Chapter III of the toolbox and in particular Tool #18 (*Identification of impacts*) for further specific guidance.

<sup>98</sup> Where significant impacts on companies are expected.

check conformity with the ‘do no significant harm’ and ‘digital by default’ principles; and identify the relevant sustainable development goals;

- Analyse when relevant the specific impacts at least on gender equality, regions and (types of) territories (urban/rural areas, cross-border areas and outermost regions), digital aspects (including interoperability) and external aspects of internal EU policies;
- *Different impacts are likely to occur at different times* (with costs often being incurred early on and benefits emerging only later). This should be reflected in the assessment, discounting monetised estimates as appropriate, where these are available;
- Assess impacts from the point of view of *society as a whole*. However, relevant distributional effects and cumulative burdens on particular individuals or groups should also be assessed and considered;
- Refer to *stakeholder views* systematically throughout the report, taking into account any minority and dissenting views. The analysis of views should inform the impact assessment. Explain/justify any significant differences between stakeholder views and the conclusions of the impact assessment report. The *synopsis report* summarising the results of stakeholder consultations must be attached as an annex to the impact assessment report;
- Include *evidence* (e.g. data, estimates, scientific findings) to substantiate the conclusions of the analysis or, where this is not possible, explain why not (e.g. if substantial knowledge gaps and uncertainties exist). Limitations to the analysis should be signalled clearly and transparently;
- The impact assessment should outline *monitoring and evaluation arrangements* (including a set of indicators and any relevant aspects of data collection) to track progress in implementing the legislation and assess its ultimate impacts on the ground;
- Explain the *necessity and added value of EU action* guided by the questions included in the ‘subsidiarity grid’<sup>99</sup> that must be presented as a linked staff working document with each politically sensitive and important initiative accompanied by an impact assessment.

### 3. IMPACT ASSESSMENT REPORT

The impact assessment report summarises and presents the results of the impact assessment analysis in the form of a linked staff working document. It should be transparent, objective and balanced, as it provides the evidence base for the Commission’s decision-making. Annexes should be used for the more detailed and technical parts of the analysis. A template for the impact assessment report can be found on the relevant pages of GoPro (impact assessment).

While the analysis can be complex, the report should be written with non-expert readers in mind. **The main report should be limited to 40 pages of text**, accompanied by annexes as appropriate. It is important to strike the right balance between the information

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<sup>99</sup> ‘Subsidiarity grid’ [template on GoPro](#).

in the report and that in the (more technical) annexes, keeping in mind the need for a focused, self-standing report.

The reader should be able to understand easily:

- the nature of the problem being addressed;
- why EU-level action is appropriate;
- the pros and cons of different courses of action; and
- who would be affected.

The report should consider future trends and challenges to ensure that it will remain valid and relevant. It should refer transparently throughout to stakeholder views and how these have been taken into account. Relevant external material used (studies, reports, scientific findings, etc.) should be systematically referenced.

**The final report must contain at least:**

- ✓ a description of the *social, economic and environmental impacts* and an explicit statement if any of these are not considered significant;
- ✓ a clear indication of *who will be affected* by the initiative and how, with special attention to the quantification of costs and benefits (in particular, in the light of the ‘one in, one out’ approach);
- ✓ impacts on *SMEs and competitiveness*;
- ✓ impacts on *fundamental rights*;
- ✓ consideration of the ‘*do no significant harm*’ and ‘*digital by default*’ principles;
- ✓ consistency with the objectives set out in the European Climate Law;
- ✓ assessment of the impacts on the relevant *sustainable development goals*; and
- ✓ a detailed description of the consultation strategy and the results obtained from it (i.e. the synopsis report).

It is not possible to make a final verification of compliance with the subsidiarity principle until all relevant information is collected and the analysis of impacts is completed. The assessment of proportionality is clearly linked to the assessment of subsidiarity and the need to match the nature and intensity of a given measure to the identified problem. The analysis of the subsidiarity and proportionality of the preferred option(s) in the impact assessment report will help fill in the subsidiarity grid that has to be attached to the legislative proposal.

To give an accessible overview of the main findings of the impact assessment, an **executive summary** should be prepared (4-5 DGT pages). This should be presented as a separate linked staff working document and be translated into all EU’s official languages.

#### 4. FROM IMPACT ASSESSMENT TO POLICYMAKING

For legislative proposals and non-legislative proposals for adoption by the Council or by the European Parliament and the Council<sup>100</sup>, the Commission's political appreciation of its final proposal is set out in the **explanatory memorandum**<sup>101</sup>.

The impact assessment informs collegiate decision-making. It is complete before the Commission decides. It is entirely possible that the College takes a different approach than the one presented in the preferred policy option in the impact assessment report. The explanatory memorandum accompanying the proposal should be used to explain such situations.

The explanatory memorandum is transmitted to the other institutions together with the proposal, and is made available to the public. However, it is not published in the *Official Journal* and will not form part of the act to be adopted.

The explanatory memorandum should cover the following points, which are important for the Commission's 'better regulation' policy:

- the legal basis;
- subsidiarity (for non-exclusive competence);
- proportionality;
- the results of any evaluations and fitness checks;
- the results of stakeholder consultations;
- a short summary of input from external experts;
- a summary of the impact assessment process (or explanation as to why none was conducted) including:
  - the consultation of the RSB;
  - regulatory fitness and simplification;
  - conformity with the EU Charter of Fundamental Rights;
  - description of the main impact categories;
  - conformity with the 'do no significant harm' and 'digital by default' principles;
  - an assessment of the contribution to progress towards relevant sustainable development goals;
  - a description of the monitoring, evaluation and reporting arrangements.

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<sup>100</sup> A simpler explanatory memorandum exists for delegated acts that are not directly covered by these guidelines (although elements of the guidelines and tools may still be relevant). In addition, there are templates for initiatives pursuant to Article 218 TFEU (see GoPro and MyIntracomm).

<sup>101</sup> See Tool #40 (*Drafting the explanatory memorandum*).

# Chapter V

## Implementation, transposition and application of EU law

### 1. INTRODUCTION

Working in partnership with the Member States on the implementation of EU law is one of the main components of the Commission's enforcement policy. While the Commission should seek to prepare well-drafted, high-quality legal texts that are easy to understand, implement and apply, it should also support Member States in their subsequent efforts to implement them. The Commission needs thorough and consistent information on the implementation and application of EU legislation in the Member States. It should examine national implementing measures carefully to ensure full compliance and initiate remedial action where necessary.

Responsibility for the effective application of legislation rests with the Member States<sup>102</sup>, but the Commission and Member States should agree on the best way to monitor implementation.

### 2. ANTICIPATING IMPLEMENTATION PROBLEMS: SETTING UP AN IMPLEMENTATION STRATEGY

#### *When is an implementation strategy needed?*<sup>103</sup>

The relevant sectoral DGs are responsible for deciding where a strategy is needed for the implementation of a regulation or directive. To this end, they should assess potential difficulties affecting implementation and application by the Member States, national courts or other local or regional authorities or enforcement agencies.

An implementation strategy helps with the tracking of progress in the implementation and application of legislation, and the subsequent collection and use of data for reporting. Implementation strategies should be prepared for all major directives and regulations, but are normally *not* required for regulations or directives that:

- already include provisions for tracking implementation<sup>104</sup>;
- have a limited or very technical scope or do not require transposition or implementation measures<sup>105</sup>;
- impose only one or very few legal obligations; or
- amend only one or very few existing legal obligations.

#### *What should an implementation strategy contain?*

The implementation strategy should include all major steps that the Commission should take when monitoring compliance of national laws with EU legislation; in particular, it should:

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<sup>102</sup> Article 288 TFEU.

<sup>103</sup> This guidance replaces the guidance in Annex II to the note dated 7 January 2013 (Ares(2013) 12012).

<sup>104</sup> E.g. as in this case of spending programmes implemented under shared management.

<sup>105</sup> E.g. directives updating provisions on (inter)institutional issues such as [comitology](#).

- identify the various *types of support* (see section 3 below) that the Commission services will provide to assist Member States in the transposition and implementation of the legislation; and
- set out the *arrangements for monitoring* implementation, including a timeline for the Commission’s compliance assessments, possible enforcement action and implementation reports.

When transposing directives, Member States should refrain from unjustified ‘gold-plating’<sup>106</sup> (i.e. adopting transposition measures that go beyond the requirements of the directive) and ensure a level playing field<sup>107</sup>. Under the Interinstitutional Agreement on Better Law-Making<sup>108</sup>, the European Parliament, the Council and the Commission have committed themselves to promoting greater transparency on gold-plating. Member States must provide the Commission with a precise account of how national provisions transpose the corresponding obligations in directives<sup>109</sup>. In their notifications, they may also indicate which national measures go beyond the requirements of EU directives. The Commission will report annually on its monitoring of the application of EU law and on instances of gold-plating. It should also encourage Member States to make the original text of national transposition measures available on Eur-Lex.

### 3. COMPLIANCE PROMOTION TOOLS<sup>110</sup>

The Commission has developed compliance promotion tools to help Member States transpose, implement and apply EU law in a timely and correct manner. These include guidance documents, expert groups, explanatory documents, training and workshops, and ‘package meetings’<sup>111</sup>. Preventing national measures that run counter to EU law will help ensure a level playing field for individuals and businesses in the single market and avoid lengthy infringement proceedings.

#### *When are compliance promotion tools needed?*

One should use the compliance promotion tools on a regular basis to prevent or, in parallel with infringement procedures, to correct breaches of EU law and to avoid referring cases to the Court of Justice.

Use a combination of tools to address problems and promote compliance with EU law. The choice of tools will vary across policy areas, depending on the Commission’s competences, the type of EU legal instrument, the specificities of national legal systems and available resources. One should take due account of the potential burden on Member States.

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<sup>106</sup> Note, however, that directives in some policy areas (e.g. social or environmental policy) set minimum requirements, so it is envisaged in the Treaty that Member States may establish higher standards when transposing such directives.

<sup>107</sup> Long-term action plan for better implementation and enforcement of single market rules (COM(2020) 94).

<sup>108</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC>

<sup>109</sup> Judgment of the Court of Justice in Case C-543/17 *Commission v Belgium*.

<sup>110</sup> See Tool #38 (*Compliance promotion and verification tools*).

<sup>111</sup> I.e. targeted meetings to address various non-compliance issues with a given Member State.

#### 4. MONITORING IMPLEMENTATION

The Commission is committed to more systematic monitoring of implementation. It uses **verification tools**<sup>112</sup>, which include enforcement actions and complement compliance promotion tools, to check the compliance of Member States' transposition measures; this is a two-stage process:

- first, a **transposition (completeness) check** is carried out to assess the degree to which the Member State has transposed the provisions of a directive. If it has failed to (completely) transpose the directive, propose the launch of an infringement procedure under:
  - Article 258 TFEU; or
  - (in the case of a legislative directive), Article 258 in conjunction with Article 260(3) TFEU<sup>113</sup>; and
- second, once the transposition check is finalised and any infringement procedures for failure to communicate transposition measures have been closed<sup>114</sup>, start the **conformity check**<sup>115</sup>.

#### *Explanatory documents*

Member States have to draw up and notify to the Commission documents explaining how their national instruments transpose the provisions of the directive in question. These are essential for the compliance checks and Member States must submit them when notifying their transposition measures<sup>116</sup>. The documents may consist of correspondence tables, but other forms are acceptable, provided they match the legal obligations stemming from a Directive with a corresponding legal obligation in the national legislation.

Where a Member State fails to submit a (satisfactory) explanatory document, the Commission may launch or take the next step in an infringement procedure, on the basis that it has not received the information required.

#### 5. KEY PRINCIPLES AND QUESTIONS OF MONITORING THE PERFORMANCE OF LEGISLATION

Monitoring involves the **continuous and systematic generation of evidence** on an intervention's application and effects over time. A monitoring system is a necessary and integral part of 'better regulation', helping us to:

- better understand how interventions are achieving their objectives in an effective and efficient way;
- communicate with stakeholders;

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<sup>112</sup> See *EU law: better results through better application* (C(2016) 8600; OJ C 18, 19.1.2017, p 10) and Commission Communication, *EU regulatory fitness* (COM(2012) 746).

<sup>113</sup> [Commission Communication, Implementation of Article 260\(3\) of the Treaty](#) (OJ C 12, 15.1.2011, p. 2; para. 7).

<sup>114</sup> The Commission may launch conformity checks immediately on parts of the directive that have already been transposed completely.

<sup>115</sup> See Tool #39 (*Compliance assessment: explanatory documents, transposition and conformity checks*).

<sup>116</sup> In its judgment of 8 July 2019 in Case C-543/17 *Commission v Belgium*, the Court clarified that Member States must provide sufficiently clear and precise information and state, for each provision of the directive, the national provision(s) ensuring its transposition.

- meet external requirements for compliance and control; and/or
- identify whether further action is required to ensure that an intervention achieves its intended objectives.

A well-designed monitoring system should be governed by the following principles:

- ✓ *comprehensiveness* – i.e. covering all objectives of the intervention;
- ✓ *proportionality* – i.e. reflecting the costs of collecting information and the importance placed on different aspects of the intervention;
- ✓ *minimal overlap* – i.e. avoiding duplication and unnecessary data collection burdens by concentrating only on data gaps; these should be identified through a preliminary analysis of existing data collection (including by other DGs);
- ✓ *timeliness* – not all evidence has to be collected at the same time but should be ready by the time of a planned evaluation; and
- ✓ *accessibility* – in principle, all evidence should be made available to the public with clear information on their specificities and limitations, subject to confidentiality arrangements and rules on data protection.

The monitoring arrangements should reflect the objectives of the intervention and what evidence is needed to track its progress and performance. This involves understanding the logic of the intervention and how the evidence will be used. Consideration should be given to the frequency and method of collection, and different sources of evidence, taking account of what is already available and the costs for the various parties involved.

This leads to a series of questions:

<b>Box 9. The key questions that a monitoring system must address</b>	
<b>1.</b>	<p><b><i>What evidence should be collected?</i></b></p> <p>Consider what evidence is needed to track systematically the progress of a given intervention against its objectives and generate information for future evaluation and impact assessments.</p> <p>A good monitoring system will cover the intervention throughout the period of implementation and be complemented by data prior to the intervention, if possible.</p>
<b>2.</b>	<p><b><i>When and how should evidence be collected?</i></b></p> <p>Once it is clear what evidence is needed, give careful consideration to timing, the collection process, existing data and monitoring systems, and data quality.</p> <p>Establish a clear link between objectives and indicators, bearing in mind the costs and arrangements needed to collect the necessary new evidence in time to meet reporting requirements.</p>
<b>3.</b>	<p><b><i>Who will collect the evidence and from whom?</i></b></p> <p>Consider who will be responsible for gathering data and who will be responsible for providing it.</p> <p>Evidence should be gathered at appropriate levels, bearing in mind cumulative burdens that this may trigger.</p>

Monitoring plays a key role in providing part of the evidence base for decision-making. Good monitoring is particularly important for evaluations and impact assessments, which rely on relevant evidence to assess the performance of an intervention<sup>117</sup>.

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<sup>117</sup> Monitoring information is also relevant for a DG's management plan and the Commission's strategic planning and programming cycle. It provides an overview of all inputs that contribute to EU policies and the results and impacts of those policies. It also presents the elements of the performance framework to which the work of the DG contributes. The DG's annual activity report gives an account of its core activities and progress towards its key policy objectives, taking account of the resources used.