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Better Regulation Guidelines

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Chapter I

Better Regulation in the Commission

1. INTRODUCTION

European policies and legislation impact the lives of the Union's 500 million inhabitants and its millions of companies. A substantial body of legislation now exists and this legislation must continue to keep pace with evolving political, societal and technological developments. The European Commission has a key role in this regard given its right to initiate new legislation and its responsibility to ensure the correct application of Union law. EU action must lead to a simple, clear, stable and predictable regulatory framework for businesses, workers and citizens that continue to add value as problems evolve, new solutions emerge and political priorities change.

The European Commission is determined, therefore, to ensure that its proposals meet policy goals at minimum cost and deliver maximum benefits to citizens, businesses and workers while avoiding all unnecessary regulatory burdens. This is key to support growth and job creation – allowing the EU to ensure its competitiveness in the global economy - while maintaining social and environmental sustainability.

Determining when and how EU action should be undertaken, reviewed or repealed is ultimately a political choice. The quality of these choices, however, can be improved if "better regulation" principles and practices are followed when preparing, implementing and evaluating policies and measures.

Box 1. How to apply these guidelines

- The guidelines and associated Better Regulation "Toolbox" should be applied in a proportionate manner using common sense bearing in mind that the aim is not to respect procedural requirements per se but to ensure that the Commission is equipped with relevant information on which to base its decisions in a timely manner. Similarly, the depth of analysis should also reflect the significance of the impacts or effects of the initiative or intervention.
- The main guidelines set out the mandatory requirements and obligations for each step in the policy cycle while the Toolbox provides additional guidance and advice which is not binding unless expressly stated to be so.
- There may be cases where it may not be possible or most appropriate to follow each step in the guidelines. 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. In other case, there may be a political imperative to move ahead quickly, an emergency that requires a rapid response or a need to abide to specific timeframes set in legislation which cannot be simply respected on the basis of proper planning. In such well justified cases it may, for instance, be necessary to combine evaluation and impact assessment, adopt ad hoc consultation strategies etc. Such cases (and the related approach) should be discussed as early as possible in the planning phase with the Secretariat General and, whenever relevant, spelled out in the draft Roadmap which informs the political validation of each initiative. Whenever needed, the agreed approach should be externally communicated together with a justification and an explanation of the efforts made to respect the spirit of the guidelines (typically through the final roadmap).

- To avoid undue delays and to maximize the quality of outputs, the efficient application of these guidelines requires a constructive and timely collaboration between the lead service, the Secretariat General and those services included in interservice groups.
- The Secretariat General will attentively monitor the impact of the introduction of new procedural requirements. It will review their implementation and propose, if needed, how to eliminate any source of administrative burden or undue procedural delay thus identified by 2017. Any such review will not endanger the respect of the better regulation principles identified in these guidelines and in the Commission Communication 'Better regulation for better results – An EU agenda'.¹

These guidelines explain what Better Regulation is and how it should be applied in the day to day practices of Commission officials preparing new initiatives and proposals or managing existing policies and legislation. The guidelines should be read by all officials involved in Better Regulation activities and managers who are responsible for quality control and the allocation of resources within Commission departments. Better Regulation cannot be implemented without dedicated financial and human resources and DGs must ensure that appropriate centres of expertise (or functions) and training are available to support the various aspects of Better Regulation.

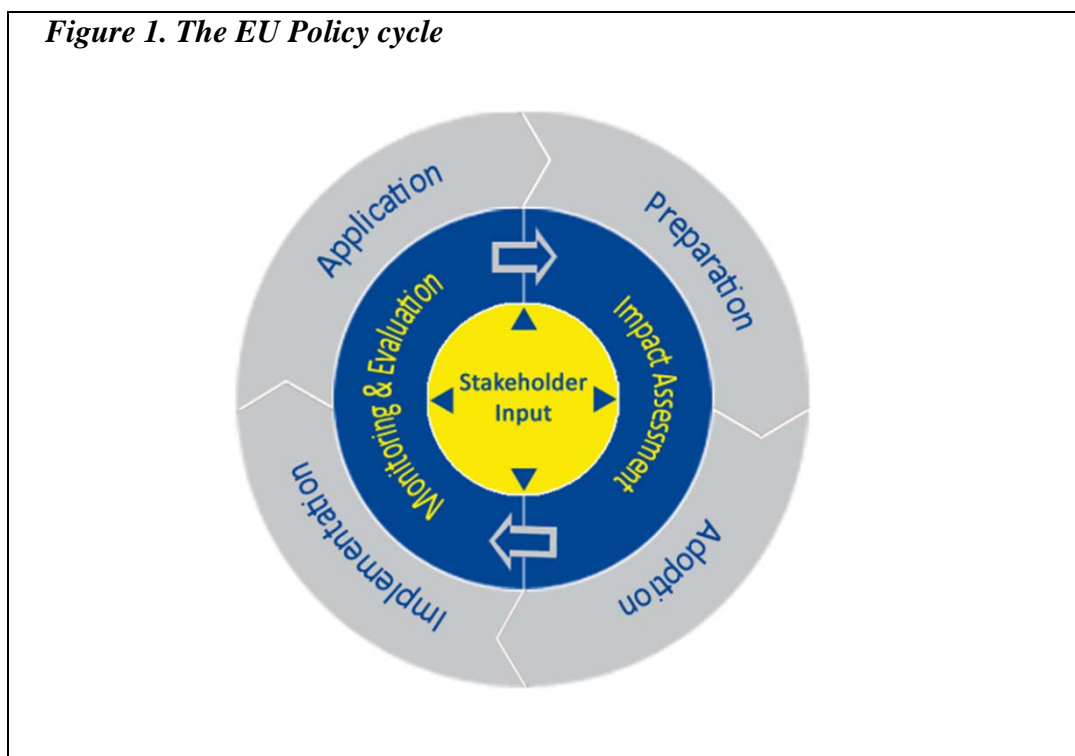
2. WHAT IS BETTER REGULATION?

"Better Regulation" means designing EU policies and laws so that they achieve their objectives at minimum cost. Better Regulation is not about regulating or deregulating. It is a way of working to ensure that political decisions are prepared in an open, transparent manner, informed by the best available evidence and backed by the comprehensive involvement of stakeholders. This is necessary to ensure that the Union's interventions respect the overarching principles of subsidiarity and proportionality i.e. acting only where necessary and in a way that does not go beyond what is needed to resolve the problem.

Better Regulation covers the whole policy cycle – policy design and preparation, adoption; implementation (transposition, complementary non-regulatory actions), application (including enforcement), evaluation and revision. For each phase of the policy cycle, there are a number of Better Regulation principles, objectives, tools and procedures to make sure that the EU has the best regulation possible. These relate to planning, impact assessment, stakeholder consultation, implementation and evaluation.

¹ COM(2015)215

Figure 1. The EU Policy cycle



The different phases are closely interrelated and to recognise better the connections and to ensure greater coherence the previously separate guidance documents have been brought together into a single streamlined and integrated Better Regulation guide. These guidelines replace the previous standalone guidelines which addressed separately impact assessment, evaluation, implementation and also include new guidance on planning and stakeholder consultation².

3. HOW TO REGULATE BETTER? - THE ESSENTIALS

3.1. Forward planning and political validation

Good regulation starts with good planning. Work should focus on the Commission's priorities as reflected in the President's political guidelines³ and the Commission's annual work programmes⁴. Good planning covers the initial consideration of an initiative within the Commission and the organisation of the supporting processes – the evaluation of policies already in place, the assessment of problems and alternative solutions and the active engagement with stakeholders. These take time and require resources to deliver timely results.

² These guidelines confirm and further define the general rules on how Commission services should consult set out in the 2002 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, complemented by COM(2012) 746 and accompanying SWD(2012) 422 and by COM(2014) 368.

³ http://ec.europa.eu/priorities/docs/pg_en.pdf

⁴ http://ec.europa.eu/atwork/key-documents/index_en.htm

The first step in the planning process is to define the scope of the planned initiative and seek political validation to develop the idea further. The main planning tools used in this process are Agenda Planning⁵ and Roadmaps. The details on which initiatives must be uploaded in Agenda Planning are provided in the instructions of the Secretary General⁶ which complement the Working Methods of the European Commission 2014-2019⁷ and outlined in detail in Chapter II on Planning.

Box 2. Scoping, political validation and interservice work

- **Major initiatives** must be accompanied by a **Roadmap** and entered into Agenda Planning as soon as preparatory work starts - at least 12 months prior to adoption by the College. They must be validated by the lead Commissioner, relevant Vice-President and the First Vice-President before being accepted to be included into the Commissions' planning. The political validation must be understood as giving the green light to proceed with further preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudices the outcome of any impact assessment process, stakeholder consultation or later political discussion in the College.
- **Roadmaps** explain what the Commission is considering. A Roadmap describes the problem to be tackled and the objectives to be achieved. It sets out why EU action may be needed and its value added. The policy options being considered are outlined. The Roadmap also justifies the absence of an impact assessment. It also announces the details of the stakeholder consultation strategy (see later chapter). A (different) Roadmap is also prepared for each evaluation and Fitness Check. This specifies the scope of the evaluation and presents the evaluation questions to be answered.
- An **Inception Impact Assessment** is a Roadmap for initiatives subject to an IA that sets out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.
- All Roadmaps and Inception Impact Assessments are published by the Secretariat-General on the Commission's website⁸ so that stakeholders are informed and can provide initial feedback (including data and information they may possess) on all aspects of the intended initiative and impact assessment.
- Evaluations, impact assessments, stakeholder consultations, policy proposals and implementation plans must be prepared collectively by the services⁹ within an **interservice group**. It is important that all services with an interest participate actively in the interservice work from the outset, particularly those DGs with specific expertise (e.g. competitiveness, SME impacts, social impacts, environmental impacts

⁵ Agenda Planning is the Commission's IT platform for managing the preparation of initiatives.

⁶ <https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx>

⁷ C(2014)9004; <http://ec.europa.eu/transparency/regdoc/rep/3/2014/EN/3-2014-9004-EN-F1-1.Pdf>

⁸ http://ec.europa.eu/atwork/planning-and-preparing/work-programme/index_en.htm

⁹ See also art 23 of the Rules of Procedures of the Commission 'Cooperation and coordination between departments':
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1427880050708&uri=URISERV:o10004>

and scientific/analytical).

3.2. Stakeholder consultation

Stakeholder consultation is an essential element of policy preparation and review. Good policy development is built on openness. Stakeholder inputs provide feedback and evidence for all types of evaluation, impact assessments and political decisions. Planning stakeholder consultation is good practice, and should be reflected in a simple, concise consultation strategy that identifies and targets relevant stakeholders in order to collect all relevant evidence (comprising data/information) and views.

It is important to consult as early and as widely as possible in order to maximise the usefulness of the consultation and to promote an inclusive approach where all interested parties have the opportunity to contribute to the timely development of effective policies. At the same time, consultation is an ongoing process and consulting stakeholders throughout the whole policy cycle remains key. Consultation should allow for reasonable time limits to stimulate informed and effective feedback from all relevant stakeholder groups, and should ensure that feedback is given to respondents about how their information and views were used. Open public consultation is essential for impact assessments, evaluations and Fitness Checks.

3.3. Evaluation/Fitness Checks

Policy preparation should be supported by both retrospective performance evaluations and forward looking impact assessments. Both look at how a problem is, or should be, addressed (and its underlying causes) to achieve the desired objectives taking account of costs and benefits. Both are based on an integrated approach that addresses impacts across the environmental, social and economic pillars of sustainable development and so contribute to the mainstreaming of sustainability in policy making at the Union level.

Evaluations gather evidence to assess how well a specific intervention has performed (or is working), taking account of earlier predictions made in the context of an impact assessment and whether there were unintended/unexpected effects which were not anticipated by the impact assessment or the act agreed by the Legislator. An evaluation also draws conclusions on whether the EU intervention continues to be justified or should be modified to improve its effectiveness, relevance and coherence or to eliminate excessive burdens or inconsistencies or simply be repealed.

A Fitness Check is a comprehensive evaluation of a policy area that usually addresses how several related legislative acts have contributed (or otherwise) to the attainment of policy objectives. Fitness Checks are particularly well-suited to identify overlaps, inconsistencies synergies and the cumulative impacts of regulation.

Box 2. Regulatory Fitness Programme (REFIT)

Given their focus, evaluations and Fitness Checks are particularly important in the context of the tools that are used to implement the Regulatory Fitness and Performance programme (REFIT): a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose', that regulatory burdens are minimised and that all simplification options are identified and applied. Evaluations and Fitness Checks always consider efficiency and effectiveness and identify any overly burdensome and complex aspects of EU legislation and its implementation in the Member States as well as any subsequent implementing or

delegated legislation adopted by the Commission.

It is important to monitor the impacts flowing from the implementation and application of the legislation in order to allow both Member States and the Commission to undertake a meaningful evaluation of the intervention at a future point in time. If there is no useful monitoring information, it will be difficult to evaluate the intervention appropriately and to rectify any problems or improve the delivery of desired results.

3.4. Impact assessment

Impact assessments collect evidence (including results from evaluations) to assess if future legislative or non-legislative EU action is justified and how such action can best be designed to achieve desired policy objectives. An impact assessment must identify and describe the problem to be tackled, establish objectives, formulate policy options and assess the impacts of these options. 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 policy making.

3.5. Quality control

Staff working documents are required to present the results of all impact assessments and evaluations/Fitness Checks.

The quality of these staff working documents is checked by the Regulatory Scrutiny Board (RSB) who will assess all impact assessments and all major¹⁰ evaluations and Fitness Checks. The Board issues opinions based on the requirements of these guidelines. DGs are expected to modify their reports to reflect the Board's opinion. In the case of impact assessments, and according to the Commission Working Methods, a positive opinion from the Board is necessary before a formal interservice consultation can be launched. The formal interservice consultation should check how the Board's comments have been integrated and should also check the quality of the drafting of the initiative/legal proposal (see Chapter IV).

3.6. Implementation support and monitoring

The full benefits of an EU intervention will only be delivered if the policy is implemented and applied appropriately. Similarly, burdens for business may be increased beyond what is foreseen by the legislation if the Member States impose unjustified additional obligations (so-called "gold-plating") or implement the legislation inefficiently. That is why it is essential to take into account implementation and enforcement issues when designing an EU intervention including the impact assessment process and associated stakeholder consultation. It is also important to identify ways to assist Member States in the transposition phase (aligning national legislation with EU legislation) by preparing so-called 'implementation plans' (in the form of SWD) which should also be subject to interservice consultation together with the impact assessment and the proposed intervention. Checks on transposition and assessments of compliance are also key tools used to monitor the correct application of EU legislation.

¹⁰ Major evaluations capture REFIT evaluations, Fitness Checks; major MFF programme evaluations and any other evaluations which the RSB may scrutinise based on the DGs rolling evaluation plan.

4. THE STRUCTURE OF THE GUIDELINES

The Better Regulation guidelines are structured into separate chapters which cover

- Chapter II: Planning
- Chapter III: Impact Assessment;
- Chapter IV: Implementation;
- Chapter V: Monitoring;
- Chapter VI: Evaluation and Fitness Checks;
- Chapter VII: Stakeholder consultation; and
- Chapter VIII: A description of the web-based Toolbox which contains more detailed guidance on:
 - Principles of Better Regulation;
 - How to carry out an impact assessment;
 - How to carry out an evaluation/Fitness Checks;
 - How to consult;
 - How to assess sectorial impacts; and
 - Methods, models and costs and benefits.

The Secretariat-General is responsible for the preparation of the Better regulation guidelines. Questions about their interpretation or application can be obtained from the following units in the SG using the associated functional mailboxes.

- SG-C1: Evaluation, Fitness Checks: [SG EVALUATION AND SIMPLIFICATION](#)
- SG-C2: Impact Assessment: [SG IMPACT ASSESSMENT GUIDELINES](#)
- SG-C3: Implementation: [SG IMPLEMENTATION PLANS](#); [SG INFRACTIONS](#)
- SG-C4: Planning & stakeholder consultation: [SG PLANNING](#); [SG STAKEHOLDER CONSULTATION](#)

Individual DGs and services with particular expertise in the field of Better Regulation may also make additional materials available to those preparing evaluations, Fitness Checks, Impact Assessments and stakeholder consultations via their respective web sites.

Chapter II

Guidelines on Planning

Key requirements

- Work may only start and the necessary resources attributed if an initiative has received political validation at the appropriate level and a valid entry exists in Agenda Planning, where applicable (cf. point 3 below).
- "Major" new initiatives have to be accompanied by a Roadmap or Inception IA and require political validation from the lead Commissioner, Vice-President and First Vice President.
- A valid agenda planning entry is needed in order to launch an interservice consultation.

1. WHEN CAN POLICY PREPARATION BEGIN?

The identification and delivery of the political priorities of the Commission are carried out in the context of the Strategic Planning and Programming cycle¹¹ and on the basis of the political priorities¹² of the Commission President and the Commission Work Programme (CWP)¹³.

Effective and quality EU action starts with good and timely planning. New initiatives including evaluation work must receive political validation *before* concrete work can start and resources are allocated. Policy planning and implementation are always steered by the political level. **The political validation must be understood as giving the green light to proceed with further preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudices the outcome of any impact assessment process or later political discussion in the College.**

For each initiative or evaluation/Fitness Check you need to

- Categorize the future initiative; and
- Identify the level of political validation required (see point 3).

To obtain validation you should, via the Agenda Planning entry and, if applicable, via the Roadmap/ Inception IA:

- Explain why you consider it necessary to work on a particular initiative (e.g. an identified policy problem, a legal obligation, implementation concerns, evaluation recommendations, political commitment, request by other institutions, citizens' initiative etc.);
- Explain why action may be needed at EU level;

¹¹ <https://myintracomm.ec.europa.eu/corp/sg/en/spp/Pages/cycle.aspx>

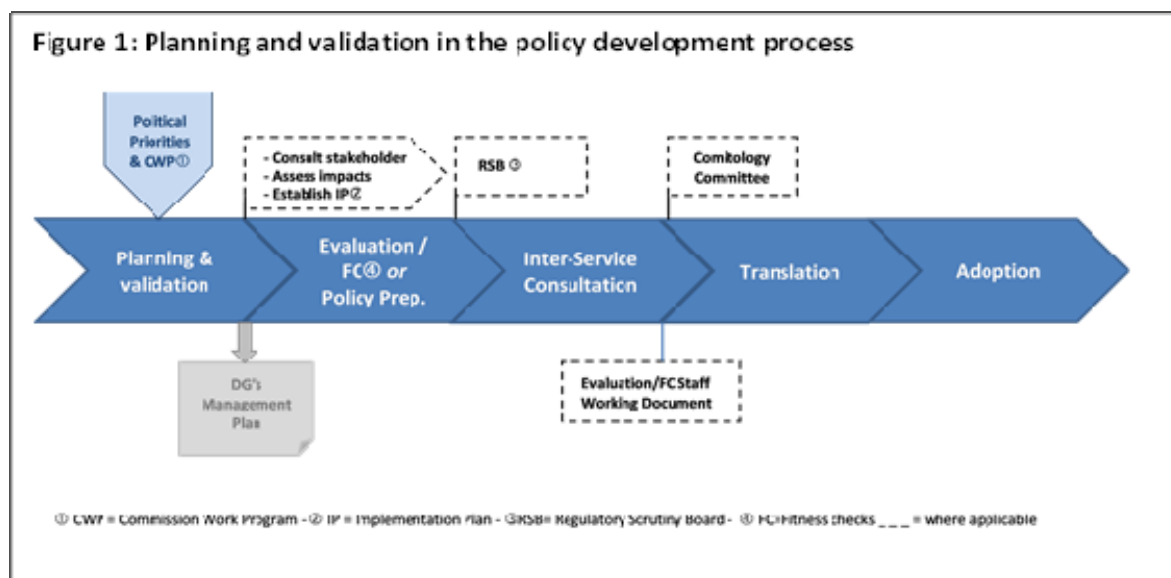
¹² http://ec.europa.eu/priorities/docs/pg_en.pdf

¹³ http://ec.europa.eu/atwork/key-documents/index_en.htm

- Describe how the initiative would contribute to established political priorities.

The scope and format of evaluation roadmaps are further explained in the toolbox.

Work may start and the necessary resources may be attributed only if political validation has been obtained from the appropriate level.



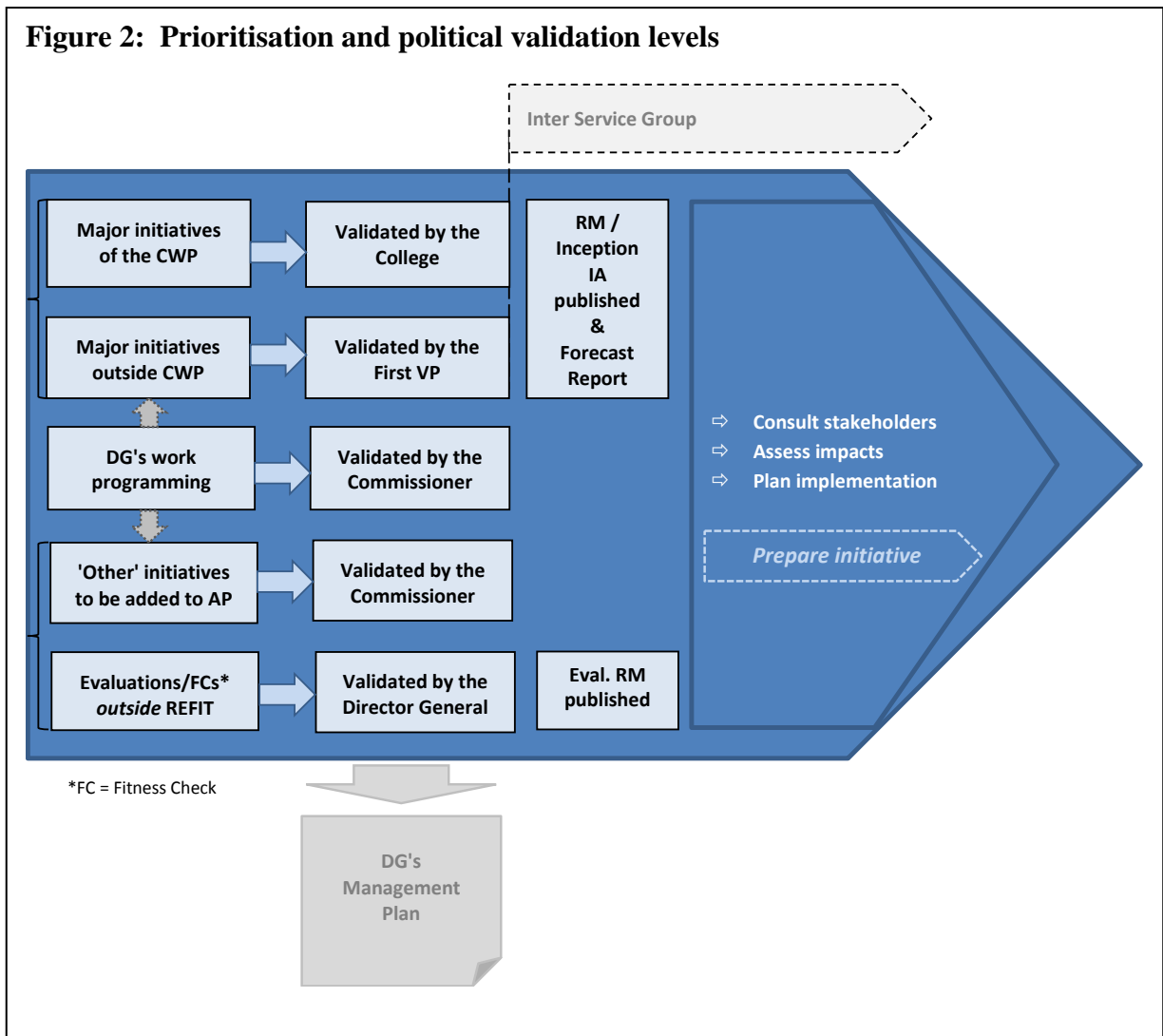
Good planning also implies taking into account from the very beginning the various procedural requirement and their duration, including translations. Once validation obtained, translations should be factored in as soon as possible, so as to ensure the highest possible quality of documents translated.

2. WHO IS INVOLVED IN THE VALIDATION PROCESS?

The lead DG encodes new initiatives in Agenda Planning and seeks the necessary political validation by the responsible Commissioner(s) and (if major) Vice-President(s). New initiatives can be encoded and validated throughout the year.

The Secretariat-General coordinates a comprehensive screening process for all initiatives that have received political validation and is responsible for seeking the political validation for major items from the First Vice-President, who acts in close cooperation with the President's Cabinet. The Secretariat-General is also in charge of publishing approved Roadmaps/Inception IA on the Commission website and compiling and publishing regular reports to other institutions about planned initiatives.

Figure 2: Prioritisation and political validation levels



3. WHAT NEEDS TO BE VALIDATED?

The instructions implementing the working methods of the Commission¹⁴ focus on the use of the Agenda Planning¹⁵ application, which is designed to help the Commission screen and manage the flow of initiatives in line with the Political Guidelines. The Agenda Planning entry and the accompanying Roadmap, where applicable, provide a first outline of the initiative and are essential for the political validation.

All 'major initiatives' need to be entered into Agenda Planning at the latest 12 months before their planned adoption date and be accompanied by a Roadmap¹⁶ or an Inception IA. The implementing instructions identify certain types of acts as being *per definition* 'major'. However, any other Commission initiative that is sensitive or important should also be considered as 'major'. It is the responsibility of each DG to consider carefully aspects such as the political importance and sensitivity, the magnitude of the expected impacts; importance for other policy areas and prior knowledge about divergent or sensitive stakeholder views.

¹⁴ <https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx>

¹⁵ <https://webgate.ec.europa.eu/agendap/agenda/protected/agendaItems/list.agenda>

¹⁶ Where Impact Assessments will follow-on directly from evaluations, DGs may, on a case by case basis and after discussion with the Secretariat General, consolidate the roadmap exercise into one.

Different initiatives and validation requirements				
	Major initiatives	'Other' initiatives		DG internal work plan
Which acts?	<ul style="list-style-type: none"> • Initiatives included in the CWP • REFIT items • New legislative proposals • Recommendations for the negotiation of international agreements and proposals for their conclusion • Policy communications • Delegated and implementing acts having significant impacts • Financing decisions having significant impacts • Other Commission initiatives that are sensitive or important 	<ul style="list-style-type: none"> • Delegated and implementing acts not having significant impacts • Commission reports except for Evaluations or Fitness Checks 	Non-major evaluations and Fitness Checks	<ul style="list-style-type: none"> • Commission decisions of administrative and routine nature • Intermediate legislative acts • Implementing decisions under International Treaties • Financing decision of a routine nature • Information notes for the Commission • Decisions granting delegated powers (empowerment and delegations) • Infringement, competition and state aid cases, trade defence cases, enforcement action under international trade rules • Emergency procedures (duly justified) • Any other initiative
AP entry?	Mandatory	Mandatory	Mandatory	Not required
Roadmap/ Inception IA needed?	Mandatory, signed off by the Commissioner(s). For initiatives that will undergo impact assessment, the Roadmap should be presented in the form of an Inception IA.	Not required	Mandatory, signed off by the Director General	Not required
Political validation by	Commissioner(s), VP(s) and the First VP, in close cooperation with President's Cabinet	Commissioner	Director General through the Management Plan endorsement	Commissioner
ISG required	Yes (Important/sensitive cases chaired by SG)	No	Yes	No
Conditions to launch ISC	<ul style="list-style-type: none"> • Only if complete AP entry exists • If impact assessment: positive opinion of the RSB • Validation by the Commissioner(s), VP(s) and the First VP 	<ul style="list-style-type: none"> • Only if complete AP entry exists • Validation by Commissioner(s), VP(s) and the First VP 		<ul style="list-style-type: none"> • Validation by the Commissioner

If preparatory work for a possibly important or sensitive initiative is carried out only at internal DG level and outside of Agenda Planning, the launch of the ISC may not be validated at political level, or the initiative may be blocked by any DG at the ISC stage, due to the lack of transparency and non-compliance with the implementing instructions.

Methodological advice regarding the selection of the appropriate type of act can be asked via SG HELPDESK PROCEDURES and concerning the inclusion of an initiative in Agenda Planning, either as "major" or "other" initiative, via SG PLANNING. GoPro and the Agenda Planning website also provide useful information in this regard¹⁷.

¹⁷

<https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

Chapter III

Guidelines on Impact Assessment

Key requirements

- IAs must set out the logical reasoning that links the problem (including subsidiarity issues), its underlying drivers, the objectives and a range of policy options to tackle the problem. They must present the likely impacts of the options, who will be affected by them and how.
- Stakeholders must be able to provide feedback on the basis of an Inception Impact Assessment which describes the problem, subsidiarity related issues, objectives, policy options and an initial consideration of relevant impacts of these policy options.
- A 12-week internet-based public consultation covering all of the main elements of the IA as part of a broader consultation strategy to target relevant stakeholders and evidence.
- IAs must compare the policy options on the basis of their economic, social and environmental impacts (quantified as far as possible) and present these in the IA Report.
- Certain elements must be included in the final IA Report. These include: (i) a description of the environmental, social and economic impacts and an explicit statement if any of these are not considered significant; (ii) a clear description of who will be affected by the initiative and how; (iii) impacts on SMEs; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.
- The draft IA Report must be presented to the Regulatory Scrutiny Board for its scrutiny. A positive opinion of the Board is necessary before an interservice consultation can proceed.
- The IA report must be complemented by a 2-page executive summary sheet available in all languages.

1. INTRODUCTION

Who Should Read These Guidelines?

All officials involved in the preparation of an impact assessment (IA) should read these guidelines including officials and managers who are responsible for ensuring the quality of impact assessments in the lead DG.

More detailed guidance is also available in a separate "tool box" which accompanies this guide. This is aimed at those directly involved in preparing the various elements of an IA. These "tools" contain important guidance on specific issues such as when an IA is necessary, on the identification of the various social, environmental and economic impacts, including on SMEs and competitiveness, and many other aspects regarding methodological or other aspects in the preparation of an impact assessment.

What is Impact Assessment and when is it required?

Impact assessment is about gathering and analysing evidence to support policy making. In this process, it verifies the existence of a problem, identifies its underlying

causes, assesses whether EU action is needed, and analyses the advantages and disadvantages of available solutions.

IA promotes more informed decision-making and contributes to Better Regulation which delivers the full benefits of policies at minimum cost while respecting the principles of subsidiarity and proportionality. **However, IA is only an aid to policy-making/decision-making and not a substitute for it.**

An IA is required for Commission initiatives that are likely to have significant economic, environmental or social impacts.

Provided that the above conditions are fulfilled, impact assessments should be carried out for both legislative and non-legislative initiatives as well as delegated acts and implementing measures, **taking into account the principle of proportionate analysis.** When the above conditions are not met, no impact assessment is needed regardless of the nature of the initiative¹⁸.

What are the procedural steps?

The IA work is led by the Directorate-General(s) responsible for the relevant policy initiative. DGs should establish as early as possible in the policy planning/political validation process **whether an IA is required on the basis of the associated Roadmap. If it is established that an IA will be carried out, the Roadmap should be developed and presented as an Inception IA.**

The Inception IA provides a first description of the problem and possible policy options along with an overview of the different planned stages in the development of the initiative, including foreseen impact assessment work and consultation of stakeholders. If an impact assessment will not be carried out, this should equally be explained in the regular Roadmap.

The subsequent preparation of an IA involves the following main steps:

- (1) The creation of an interservice group (ISG) which will steer the IA process and collectively prepare the IA report. For those initiatives in the Commission's work programme (or other important/sensitive initiatives), the ISG will be established and chaired by the Secretariat-General;
- (2) Finalisation of the Inception IA by the ISG and publication on the Commission's website, allowing stakeholders to be informed and to provide feedback and evidence in relation to the problem, possible policy options and their likely impacts and subsidiarity considerations;
- (3) The preparation of a consultation strategy by the ISG including a mandatory 12-week internet-based open public consultation¹⁹. The consultation strategy should ensure that stakeholders' views are sought on all key impact assessment questions;

¹⁸ See tool on when an impact assessment is necessary for more detail and cases when no IA is necessary such as when the Commission has no discretion over the policy content etc.

¹⁹ Where the evaluation and IA are done "back to back" it is possible to conduct only one open public consultation as long as relevant stakeholders are consulted on all the main elements of the IA.

- (4) The collection and analysis of all relevant evidence, including data, scientific advice, other expert views, stakeholder input, etc;
- (5) Drafting of the IA Report;
- (6) Submission of the draft IA report to the Regulatory Scrutiny Board for quality review, followed by revision to take account of its recommendations for improvement;
- (7) Subject to a positive opinion by the Board, submission of the IA report to inter-service consultation together with the accompanying policy initiative.

The IA **should begin as early as possible during the process of policy-development subject to the political validation requirements**. The time needed to prepare an IA will vary from case to case. It should also be remembered that there is close link with ex-post evaluations or Fitness Checks of existing policy frameworks and programmes, whose results should be ready in time to feed meaningfully into the IA of a new proposal. The timing of the two processes may need to be carefully planned therefore.

An Impact Assessment Report presents the final results of the IA process and accompanies the draft proposal through the Commission decision-making process. The Commission's **Regulatory Scrutiny Board (RSB)** scrutinises the quality of all draft IAs and issues an opinion on the draft IA Report. A positive opinion by the RSB is required before an initiative can proceed.

Following adoption, the final IA Report is published and transmitted to the co-legislators together with a 2-page executive summary sheet and the adopted initiative.

2. THE KEY QUESTIONS AND PRINCIPLES OF IMPACT ASSESSMENT

IA is a tool to help structure reflection and conduct analyses informing policy design. It is not a list of tasks to tick off. There is no recipe for the perfect IA. Given the widely differing nature of Commission initiatives, the best way to carry out an IA 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. An impact assessment should be comprehensive, proportionate, evidence-based, open to stakeholders' views, unbiased, prepared collectively with relevant Commission services, embedded in the policy cycle, transparent and of a high quality²⁰.

The Questions An Impact Assessment Should Answer	
1.	<i>What is the problem and why is it a problem?</i>
2.	<i>Why should the EU act?</i>
3.	<i>What should be achieved?</i>

²⁰ See details in tool on Better Regulation principles.

The Questions An Impact Assessment Should Answer	
4.	<i>What are the various options to achieve the objectives?</i>
5.	<i>What are their economic, social and environmental impacts and who will be affected?</i>
6.	<i>How do the different options compare in terms of their effectiveness and efficiency (benefits and costs)?</i>
7.	<i>How will monitoring and subsequent retrospective evaluation be organised?</i>

The process of finding answers to these questions is necessarily iterative. The IA process should start from broad definitions of the problem, the objectives and the possible solutions and then narrow them down to what is most relevant. The questions are also interrelated. Compliance with subsidiarity and proportionality, for example, can only be fully verified once objectives are set and the impacts of alternative options assessed. The following should guide the IA process:

- (1) When making choices about the focus and depth of the analysis, the IA should concentrate on what is relevant to inform decision-making, leaving out what is not.
- (2) The results of any relevant evaluations of the existing policy framework should be used as the starting point for the IA. The expertise of other services in the Commission should also feed into the IA in order to consider and properly assess all relevant issues.
- (3) The most appropriate methods should be identified to collect data and analyse impacts. Where necessary, external studies may be contracted out to provide input on specific elements.
- (4) A consultation strategy should be designed, keeping in mind the need to consult on all key IA issues. The IA Report should corroborate the conclusions of the analysis with stakeholder views and justify any significant differences. The synopsis report summarising the results of stakeholder consultation should be integrated into the IA Report as a mandatory annex.
- (5) Throughout the IA Report, conclusions should be substantiated with evidence (e.g. data, estimations, scientific findings) together with appropriate citations and, if this is not possible, it should be explained why. Stakeholder views should also be referred to.

2.1. Question 1: What is the problem and why is it a problem?

An IA starts by verifying the existence of a problem, identifying who is affected, estimating the problem's scale, analysing its causes and consequences, and assessing its likelihood to persist in the absence of (further) EU policy intervention.

The answer to this question should give policy-makers the information needed to decide whether there is a problem for which a policy response may be warranted.

Better regulation is about regulating only when necessary and in a proportionate manner. High quality policy proposals are built on a clear problem definition and understanding of the underlying factors and behaviours (so-called “problem drivers”). The first step of an IA, therefore, is to (i) verify the existence of a problem and identify who is affected; (ii) estimate the problem's scale and analyse its underlying causes and consequences; and (iii) identify the EU-dimension and assess the likelihood that the problem will persist. A key input to this assessment should be relevant evaluations or Fitness Checks of existing policy frameworks as well as stakeholder feed-back.

A problem can be caused by several factors, such as the existence of market failures, behavioural biases, regulatory inefficiencies or the need to ensure respect of fundamental rights. It may already have negative consequences or simply present a risk of negative occurrences. Developing a clear understanding of these underlying factors is important, using relevant internal and external expertise including scientific advice.

It is equally important to make clear in the analysis how individuals, enterprises or other actors are affected by the problem:

- How much does the "problem" affect their daily life?
- Whose behaviour would have to change for the situation to improve?

Addressing these questions will ensure that the analysis stays concrete, focused, close to stakeholders' concerns and mindful of the practical implications of any initiative. This will facilitate the subsequent identification of proportionate policy alternatives and analysis of impacts.

The problem description **in the IA Report** should be clear and specific. It should focus on the issues to be addressed by the initiative under consideration, avoiding lengthy presentations of general issues and/or Commission objectives in the relevant policy area.

2.2. Question 2: Why should the EU act?

Having established the existence of a problem, its scale and the causes, the IA analysis should verify whether Member States alone could resolve it sufficiently and whether the EU has the competence to act (i.e. a legal basis), and would be best placed to do so.

The answer to this question should give policy-makers the information needed to decide whether a policy response at the EU level is needed.

The fact that the Union has the competence to address a problem (i.e. that there is a legal basis for it) does not automatically mean the EU is best placed to solve it. In areas that fall outside its exclusive competence, the Union must act in accordance with the principle of subsidiarity²¹, i.e. act only where Union action would be more effective than action taken by the Member States at central, regional or local level.

The IA should verify whether EU action in areas outside its exclusive competence is compatible with the principle of subsidiarity. This is not to be taken for granted and it is important to remember that, pursuant to the Treaty of Lisbon, the respect of the principle

²¹ See Article 5 of the Treaty on European Union.

of subsidiarity is closely scrutinised by the other EU institutions and by national Parliaments and that Union acts can be annulled by the Court for non-respect of the principle²².

When assessing whether or not the subsidiarity principle is respected the following key questions should be reviewed: whether the problem addressed has transnational aspects which cannot be adequately addressed by action by Member States and whether action at EU level would produce greater benefits compared with action at the level of Member States due to its scale or effectiveness.

This assessment is likely to be an iterative process. Preliminary analyses in the Inception IA and early in the IA process should clarify the legal basis and indicate whether advancing further at EU level would make sense. A final verification of compliance with the subsidiarity principle will only be possible once all relevant information is collected and the analysis of impacts is completed. In addition, the assessment of whether an initiative is proportionate 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.

Assessing subsidiarity necessarily involves elements of political judgement, particularly when evidence is inconclusive and/or stakeholder views diverge. All elements should, therefore, be presented objectively **in the IA Report**, providing the basis for a political appreciation by the College. General statements and circular reasoning should be avoided in favour of concrete arguments, specific to the issues being analysed and substantiated with qualitative, and where possible, quantitative evidence.

2.3. *Question 3: What should be achieved?*

The IA should set out what EU policy should achieve.
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The objectives of policy action should be clearly identified, including the level of policy ambition and the criteria against which alternative policy options would be compared and the success of any initiative assessed.
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For reasons of transparency and accountability, any EU policy intervention should have clear objectives. These should help in:

- Establishing the logical chain between the identified problems and the solutions considered;
- Clarifying the relationship between an initiative's specific goals and any horizontal EU objectives and any other agreed political goals in the area;
- Highlighting any trade-off between policy goals;
- Setting out the criteria for comparing the different policy options;
- Defining indicators to measure performance and progress towards the declared objectives;

²² http://ec.europa.eu/dgs/secretariat_general/rerelations/rerelations_other/npo/

- Establishing the operational monitoring and evaluation framework for the implemented policy measure.

Objectives should be as S.M.A.R.T.²³ as possible. Providing general objectives is important to put the proposed initiative into the overall context of the Union's policies and to assess later if and how the initiative has contributed. However, **the IA Report** should focus on the presentation of the more specific and operational objectives (for the preferred option) the proposed initiative aims to achieve. For non-legislative policy initiatives, it may be sufficient to set out the general and specific objectives, leaving the definition of more detailed operational objectives to the relevant follow-up initiatives.

2.4. *Question 4:* **What are the various options to achieve the objectives?**

There are different ways to achieve policy objectives. The IA should allow for an informed decision about which one to pursue. To do so, available options should be identified and screened with a view to selecting the most relevant ones for further analysis and comparison.

At the end of this process, the most relevant alternative policy options should have been identified for further examination in the impact analysis stage.

It is important to consult widely about alternatives, think outside the box and give due consideration to all different options. This is one of the key functions of an impact assessment process. When well done, this is perhaps the impact assessment component most appreciated by external stakeholders. When badly done, it tends to be the most criticised and significantly undermines the credibility of the whole exercise and its usefulness for political decision making. Keeping an open mind is important even if, in many cases, the IA analysis may start from an idea, stakeholder view or political statement, about what a policy proposal may look like. Often there is already an existing policy framework in place in the area under analysis and this affects the breadth of choices realistically available but initial ideas should be comprehensively tested in the IA process.

However, existing policies may have fallen short of their objectives, proved too costly or no longer be fit for purpose. Also, views on the best policy typically differ (among stakeholders, Member States, policy-makers, Commission services and experts). In addition, a solid justification should be given for any relevant option that is discarded early on.

This should be done through an iterative process:

- (1) **Start by considering the widest range of policy alternatives both in terms of content and instruments.** Consider regulatory and non-regulatory means, less or more prescriptive measures, actions at national, EU and international level.

When identifying options, the guiding principle should be whether and how a certain measure could influence the drivers of the problem and change the relevant behaviours in a way that would lead towards the desired objectives. The IA Report will need to show

²³ Specific, Measurable, Achievable, Relevant and Time-bound.

that there is a clear logic between the problems, objectives and policy interventions under consideration.

When designing the policy options, always consider:

- The option of changing nothing (also known as the "baseline"): The “baseline scenario” should always be developed and used as the benchmark against which the alternative options should be compared. As such, it should take account of both national and EU policies in place and reflect possible developments of these in the absence of new EU-level action. It should also try to anticipate important technological or societal developments such as the pervasive role of the internet and other ICTs;
- The option of improving implementation and enforcement of existing legislation; or doing less / simplifying existing legislation;
- Options that take account of new technological developments. All new initiatives should be "digital and internet ready" and operate effectively both in the digital and the physical worlds²⁴;
- Alternative policy approaches: e.g. different policy content / approaches to reach the objective;
- Alternative policy instruments: e.g. non-regulatory alternatives; self- or co-regulation²⁵; market-based solutions, regulatory alternatives; international standards²⁶, and their mix;
- Alternative scope: for instance, is the "think small first" principle taken into account; are micro-enterprises excluded from the scope of any proposed legislation²⁷.

Consider options which have been proposed by stakeholders²⁸ and/or are likely to be proposed during the legislative process but do not discard *a priori* options with little support or facing strong opposition²⁹.

²⁴ Adaptive Governance and Internet inclusive Legislation

²⁵ See the principles for better self- and co-regulation at <https://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>

²⁶ The IA Report will need to recall the reasons for any divergence from international standards – where they exists – as well as from regulation with similar ambition in major jurisdictions whenever regulatory divergence may have a significant negative impact on trade and investment flows. Possible inconsistencies with obligations undertaken at the WTO or in international agreements should also be explained.

²⁷ Where micro-enterprises must be covered by legislative proposals for public policy reasons recourse to adapted solutions and lighter regimes will be sought concerning all forms of regulatory burden including, in particular regarding administrative requirements – see COM(2011) 803 final 'Adapting EU regulation to the needs of micro-enterprises'.

²⁸ For example, from stakeholders, experts, Member States, other EU institutions and third country partners.

- (2) **Screen the previously identified policy alternatives.** In many cases, little analysis will be needed to justify discarding some alternatives (e.g. those not technically feasible, not legally viable, difficult to implement, disrespecting fundamental rights or with other unacceptable or disproportionate impacts). Options that clearly restrict the scope for national decision making over what is needed to achieve the objectives satisfactorily should also be abandoned early on (as they would fail to respect the principle of proportionality).
- (3) Having screened the options, the most relevant ones **should be retained, together with the baseline, for further detailed examination.**
- "Straw man" options (i.e. clearly more costly or less effective alternatives retained only to highlight the benefits of the preferred option) should be avoided. They do not strengthen the argument for any preferred option but rather undermine the credibility of the IA;
 - If it is difficult to identify at least two credible alternatives on top of the baseline, make an extra effort to think 'outside of the box' (e.g. have all choices been considered?). If there are no other alternatives, the focus of the subsequent analysis should be on determining the detailed design of the retained option, for example, by considering alternative "sub-options" for some of the individual elements of the proposal or different implementation modes;
 - After a first assessment of impacts, it may be necessary to go back to the drawing board and experiment with modifications to the original alternatives to further improve them. This will typically be the case when options fail to meet the objectives in a satisfactory way or when they are likely to lead to disproportionate negative effects (of any type, for instance, on fundamental rights, SMEs, competitiveness, trade partners, regions, developing countries, etc.). An option should not be judged inferior before having reviewed possible improvements and/or mitigating measures to reduce its negative impacts.

The IA Report does not need to describe this process in detail. It should, however, demonstrate that all relevant options have been considered, taking into account stakeholders' views and justifying why some options were discarded without a full assessment of their impacts. A sufficiently detailed description of the alternatives retained should be provided.

A particularly strong justification should be provided when, exceptionally, only one option is retained for full assessment against the baseline.

2.5. Question 5: What are the impacts of the different policy options and who will be affected?

Once a set of policy options is selected, a robust assessment should be carried out of their economic, social and environmental impacts and of who will be affected.

At the end of this process, policy-makers should know to what extent different policy

²⁹ If such options are exceptionally excluded early on, this should be clearly spelled out alongside a solid justification.

options would meet their objectives, with what benefits, at what cost, with what implications for different stakeholders, and at what risk of unintended consequences.

To support policy decisions that deliver the best balance between benefits and costs, the IA analysis must assess all the relevant advantages and disadvantages of the retained policy alternatives ("the options") against the reference of the baseline. Once again, it is best to do this through an iterative process that starts with a wide reach and then focusses, and deepens, the analysis on the most relevant impacts, being ready to go back and improve the retained options before finalizing.

Using internal and external expertise along with stakeholders' knowledge is particularly helpful when analysing impacts. The consultation strategy, any external studies and the ISG work should be organised in a manner which allows views to be collected and results tested with regard to all elements of the impact analysis.

2.5.1. Identify all potential impacts of the options.

For all retained options, the impact assessment should specify how they would tackle the identified problems and meet the policy objectives.

To do this, there is a need first to identify the changes that a proposal would imply for those affected, notably those who would have to comply with any new legislative requirement, those who would have to implement and enforce it and those who are expected to be the final beneficiaries:

- What actions and measures would affected parties need to take (to comply or to enforce compliance)?;
- Would these realistically be taken (balance between compliance costs and costs for public authorities involved in ensuring compliance)?;
- Would this allow the objectives to be reached?

Answering these questions at the very beginning of the analysis is important to ensure that the technical assessment of the impacts remains concrete and closely related to the practical implications of the various policy options.

Answering such questions will also highlight how different options can trigger different changes and thus have different types of impacts. A wide range of possible impacts should be reviewed across the economic, social and environmental policy areas, going beyond the most obvious consequences of the proposed policy. All potentially important impacts should be identified regardless of whether or not it will be possible to assess them precisely. It is important not to "miss" a significant impact as this may affect the overall comparison of options or weaken the case for the Commission's proposal later on. The impact assessments should, in particular, examine the impact of the different options on fundamental rights, when such an assessment is relevant and address the potential exposure to fraud in the context of spending programmes.

Potentially important indirect impacts should also be considered, i.e. positive or negative consequences that are incidental to the main purpose of the initiative (such as those stemming from an increase in the accumulated costs borne by a party, evasive behaviour by those who need to comply, or positive spill-overs from one affected sector to another).

Both positive impacts (i.e. the benefits) as well as negative impacts (i.e. the costs or adverse environmental and social impacts) should be identified. A positive impact for one party can be negative for another. It is therefore important to identify who would be specifically affected by each impact.

It is also likely that a policy option will require some sort of IT system or network to automate business processes, publish/exchange information, deliver online services via web-based Portals, etc. It means that the impact related to the implementation of new or the adaptation of existing ICT solutions should be assessed. The possibility of re-using what exists already and not "reinvent the wheel" should not be overlooked. A "digital screening" and possible further ICT impact analysis may be needed (see the tool on ICT impacts in the BR toolbox). "

At the end of this analysis, all potential impacts– positive or negative - should be mapped out according to their expected magnitude and likelihood and to the specific parties that would be affected. The following classifications can be used when describing identified impacts:

- Broad nature: economic, social and environmental.
- Specific nature, for instance: increases (or decreases) in compliance costs, i.e. those costs incurred by the relevant parties (businesses, citizens etc.) to comply with any new legislative requirement, their sub-components (administrative burdens, labour costs; equipment costs etc.) and the administration and enforcement costs incurred by the responsible authorities; gains (or falls) in market efficiency, competitiveness, innovation; impacts on health, quality of the environment, combating climate change, levels of education and training, fundamental rights, employment and skills, social inclusion, poverty etc.;
- Relation with the underlying initiative: direct impacts are those directly generated by a policy measure. Indirect (or second-round) impacts arise as a result of the behavioural changes prompted by the direct impacts and often affect third parties and can be just as significant as direct impacts.
- Affected parties, groups or regions: businesses of different sizes (SMEs or not), citizens, workers, learners, consumers, public administrations, third country actors, developing countries, different territories and regions (less developed or prosperous regions, cities, rural areas, border regions, overseas territories etc.);
- Frequency and certainty: long/short term, one-off, recurrent; certain or likely (risks).

While all of the above classifications are useful in principle, each analysis should use the categories that are most appropriate for the initiative at hand. Importantly, the IA Report should always be transparent about the methodological choices made to assess impacts, the underlying reasons particularly where non-standard approaches are deployed).

2.5.2. *Select the significant impacts.*

The choice of impacts to be retained for deeper assessment should be clearly justified, taking account of their:

- Expected overall magnitude;

- Relevance for specific stakeholders (enterprises and in particular SMEs, trading partners, economic sectors, consumers, learners, workers, public administrations, regions, developing countries etc.);
- Importance for Commission horizontal objectives and policies.

The expected significance of impacts should be assessed in terms of changes relative to the baseline. In making the selection, the principle of proportionate analysis should be applied. However, it is important not to leave out anything that is of relevance for political decision-making. The choice should take account of stakeholders' views and relevant expertise, including within the Interservice Group.

2.5.3. *Assess the most significant impacts.*

All relevant impacts should be assessed quantitatively, if possible³⁰, as well as qualitatively. Similarly, impacts should be monetized whenever possible.

When quantifying, spurious precision should be avoided and ranges provided, complemented by qualitative comments. In many cases, quantification will rely on a given set of assumptions. These should be clearly presented. Whenever an assumption is particularly important or uncertain, sensitivity analysis should be used to check whether changing it would lead to significantly different results³¹.

There are several methods to quantify impacts, both in terms of overall methodological approach³² and specific techniques for individual types of impacts. For each case, the most appropriate method should be used. The choice of method should be clearly justified and explained in the IA Report.

There is no best method which would apply to all possible Commission initiatives. There is, however, an obligation to make the most sensible methodological choice given the specificities of the case at hand, the availability of data and the requirement to carry out a proportionate analysis. In all cases, methodological complexity is not an excuse for not presenting the practical implications of different options for affected parties. Similarly, the fact that it may not be possible to monetize, or quantify, some impacts does not mean they should not be taken into due account. All significant impacts should be analysed regardless of the nature of the available methodology to do so.

When quantitative analysis is not possible or proportionate, impacts should be assessed qualitatively. Also the qualitative analysis should be rigorous and thorough, focussing on the practical implications for affected parties. As for quantitative assessments, important underlying assumptions will have to be stated. The conclusions should rely on available theory and evidence³³, including on illustrative examples, while also referring to stakeholder views. They should acknowledge limits and clearly distinguish between

³⁰ I.e. if they are susceptible of being quantitatively estimated through a sound methodology and if the required data exists and can be collected at a proportionate cost.

³¹ Ranges of outcomes or confidence interval should then be provided rather than precise results.

³² For instance, general vs. partial equilibrium approaches, bottom up vs. top down methods.

³³ For instance regarding a subset of the targeted sector / Member States for which data and reliable analyses are available.

facts, expert opinions and stakeholder views. If a broad order of magnitudes cannot be given, a qualitative reasoning should be provided of why one option is considered likely to have larger (or smaller) impacts than another.

In the case of both quantitative and qualitative analysis, it is important to remember that:

- Changes should be assessed relative to the baseline scenario. Normally, this will evolve overtime (for instance as a result of on-going policies). Therefore, changes should not simply be determined relative to the current situation but to how the latter would evolve in the absence of a new planned initiative;
- 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 monetized estimates as appropriate when these are available;
- Impacts should be assessed from the point of view of society as a whole although distributional effects and cumulative burdens on individual parties should also be proportionately assessed and considered. Whenever impacts are aggregated, you should make sure you avoid any double-counting (for instance, businesses transferring increased compliance costs on consumer prices, public authorities imposing fees to cover for the costs of enforcing a regulation).

Assessing impacts can be particularly challenging at the EU level. First, data across the EU may not be available or comparable. Secondly, final impacts will often depend on Member States' choices at the implementation stage (or on future delegated and implementing acts). It is often difficult, therefore, to provide accurate estimates, at the Commission proposal stage, even of direct impacts such as compliance or implementation costs. Nevertheless, "known unknowns" should not be cast aside in the analysis. On the contrary, they should be readily acknowledged. In case of lack of data or uncertainties, the qualitative assessment needs to be strengthened (e.g. based on theoretical approaches), while being transparent about the impact that such uncertainties may have on the comparison of options.

At the end of this analysis, there should be a solid understanding of the extent to which each option achieves the objectives, with what benefits and at what costs at the aggregate level and for affected parties. Potentially disproportionate impacts (e.g. on fundamental rights, SMEs, competitiveness, specific communities, workers' health and safety, employment, poverty, regions or Member States, developing countries etc.) should have been identified along with any significant risk of unintended consequences. This will help compare the options in terms of their coherence with horizontal EU objectives as well as to identify potential mitigating measures for any preferred option.

The IA Report should summarize the results of the impact analysis in an accessible manner. It should be clear and transparent about any limitations (e.g. data, methodological) and risks of unintended consequences. While the more technical aspects of the assessment are important, the final concrete impacts for individuals, enterprises or public administrations, and where possible the societal or geographical distribution of such impacts, should be kept at the forefront of the analysis and the IA Report. Aggregated costs and benefits should be clearly distinguished from distributional impacts and transfers. The choices made in the selection of relevant impacts and in the analytical methods should be clearly justified in the annexes. Data sources should be provided and underlying assumptions illustrated in relation to any quantification.

2.6. *Question 6:* **How do the options compare?**

Based on the assessment of the various impacts and their distribution across affected stakeholders, the IA should compare the different options with regard to their effectiveness, efficiency and coherence, as well as their compliance with the proportionality principle.

At the end of this process, the IA should present the relevant information for policy-makers to make a choice and, where appropriate, suggest a preferred option.

Having assessed the likely economic, social and environmental impacts, as well as their distribution across stakeholders, the IA analysis should bring together the results in a clear comparison of the options. This should facilitate the identification of the preferred option.

Cost-benefit analysis, cost-effectiveness analysis, compliance cost analysis and multi-criteria analysis are the most commonly used methods to do this. Choosing one (or a mix of them) depends on several factors including the number and nature of impacts and objectives, the extent to which benefits and costs can be monetized (or quantified) and the relevance of distributional concerns.

The IA does not need to identify a preferred option, but it should attempt objectively to compare the options against common criteria, in particular:

- The extent to which different options would achieve the objectives (effectiveness);
- The benefits versus the costs (efficiency),³⁴
- The coherence of each option with the overarching objectives of EU policies (coherence).

The compliance of the options with the proportionality principle, and in particular of any preferred option, should also be considered by answering additional questions such as:

- Whether the option goes beyond what is necessary to achieve the objectives satisfactorily?;
- Whether the scope of the option is limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?;
- Whether costs for the Union, national governments, regional or local authorities, economic operators or citizens, are minimised in relation to the objective to be achieved?;
- Whether the form of action (choice of instrument) is as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?

³⁴ Alternatively the extent to which objectives can be achieved for a given cost, a.k.a. cost effectiveness.

When comparing the options, the underlying analysis and hypotheses should be kept in mind: the robustness of the comparison should be verified, sensitivities and limitations of the analysis highlighted, trade-offs between objectives flagged and uncertainties that could significantly affect the result of the comparison referred to.

The IA Report should present the results of this comparison in an accessible manner, for example in a summary table, clearly flowing from the previous analysis. When no preferred option is indicated, this should be clearly stated. In case the IA leads to the conclusion that no proposal is warranted, this should be communicated in the IA Report that should still be published.

2.7. Question 7: How would actual impacts be monitored and evaluated?

Having the entire policy cycle in mind, the IA should identify monitoring and ex-post evaluation arrangements to track whether the policy measure actually delivers the intended results and to inform any future revisions of the policy.

At the end of this process, policy-makers should know how the policy will be monitored and evaluated, allowing for future policy-adjustments whenever needed.

Policy makers and stakeholders need to be able to check if policy implementation is ‘on track’, and the extent to which it is achieving its objectives, at what costs and with what benefits. To do so, one should start from a clear idea of how the situation should look like in the future if the initiative is successful. What will be different and for whom after a few years of implementation? How can this be verified?

Actual results are likely to differ from those estimated or desired, regardless of the quality of the IA and the proposed initiative. However, when a policy is not achieving its objectives, or the costs and negative impacts are more significant than expected, it is important to know if this is the result of unexpected exogenous factors, problems with the design of the policy, amendments introduced during the legislative process (if relevant) or poor implementation.

Monitoring and evaluation arrangements (including the definition of a set of indicators), provide valuable information in this regard. The IA should outline, therefore, what these arrangements will be. Core indicators should be defined for the main policy objectives in relation to the preferred option where one is stated. Where no preferred option is presented in the IA Report, monitoring and indicators should refer to the specific objectives of the initiative.

Indicators must allow measuring to what extent the objectives of the policy have been achieved (and on potential negative impacts). Indicators on transposition, implementation and enforcement in Member States might also be useful.

Underlying data should be easily available and the cost of data collection, proportionate. If lack of data was a significant concern for the IA, the IA Report should sketch out how this issue will be addressed for the future policy evaluation.

According to the Commission's evaluation rules, all its activities have to be evaluated on a regular basis. For spending programmes evaluation is compulsory (including anti-fraud measures) and many other policy instruments also contain a review clause. Where, such a review is requested it should be based on an evaluation of the existing policy framework. Evaluations should be announced and described in advance, with a clear indication of the

timing, the main focus and purpose, who will be responsible for carrying them out, and to whom the results will be addressed.

The IA Report should sketch out core indicators relating to the operational objectives and the main monitoring and evaluation provisions of the preferred option (including any relevant data collection aspects).

3. SUMMING IT ALL UP: THE IMPACT ASSESSMENT REPORT

The Impact Assessment Report should summarise and present the final results of the IA analysis. Annexes should be used for the more detailed / technical parts of the analysis. The Report should be presented as a Staff Working Document.

As the previous pages have made clear, the IA Report is not the IA. The IA is an iterative process supporting the design of a policy proposal. The IA Report is a document through which you communicate the results of this process to policy makers to inform their decision and to stakeholders, to show the evidence basis on which a Commission has taken a decision.

The IA Report should be transparent, objective and balanced.

While IA analysis can be complex, the IA Report should be written with non-expert readers in mind. In most cases, a main report of some 30-40 pages of text, accompanied by annexes for the more detailed technical parts of the analysis, should be sufficient.

A reader should easily be able to understand what the problem being addressed is, why EU level action is appropriate, what the pros and cons of different courses of action are and who would be affected. Stakeholder views and how these have been considered should be transparently referred to throughout the IA Report. All external material used (studies, reports, scientific findings etc.) should also be systematically referenced.

Certain elements must be included in the final IA Report. These include (i) a description of the environmental, social and economic impacts and an explicit statement if any of these are not considered significant; (ii) a clear description of who will be affected by the initiative and how; (iii) impacts on SMEs; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.

To allow for an easily accessible overview of the main findings of the IA, an executive summary sheet of a maximum of 2 pages should also be prepared. It should be presented as a separate Staff Working Document and be translated into all EU languages.

4. FROM IMPACT ASSESSMENT TO POLICY-MAKING

The IA process should have allowed for the identification of one (or more) preferred options. When developing the proposal, it is useful to double-check a number of key questions to ensure that the final proposal linked to the IA is fit for purpose and in line with better regulation principles.

Policy-makers should cross-check that the final proposal would contribute positively to regulatory fitness in the EU.

It is useful to test the preferred option for its regulatory fitness at the end of the process. This is not necessary when the impact assessment indicates no (further) EU policy

response is needed. However, it should always be done when a legislative option has been chosen.

Verifying regulatory fitness for a proposal requires checking issues some of which will have already been touched upon during the impact assessment process:

- Does the draft (legal) text fully comply with subsidiarity?;
- Is the proposal proportionate?;
- Is it in line with the Charter of Fundamental Rights?;
- Are the draft legal provisions as simple and clear as possible? Do they avoid unnecessary deviations from international standards? Can they be made easier to implement?;
- Has the "Think Small First" principle been applied? Could microenterprises be exempted from the scope of the initiative, and if not, why?;
- Do the draft legal provisions take into account the challenges and opportunities offered by developments in ICTs (e.g. simplified monitoring and information reporting)?;
- Without affecting the overall achievement of the objectives, is there scope to modify some of the legal provisions so as to reduce:
 - Expected compliance costs for SMEs and any other relevant stakeholder;
 - Any negative impact on sectoral EU competitiveness;
 - Any potential negative impacts on international trade, developing countries etc.;
 - Impact on human rights in the partner country in relation to its obligations arising from international treaties (for proposals with an external dimension);
 - Any other impact (including social, environment, or those on specific groups, territorial areas, Member States, innovation, etc.).
- Without affecting the overall cost of the proposal, are there still ways to modify some of the proposed legal provision so as to increase the effectiveness and coherence of the proposed text?

For legislative initiatives, the Commission's political appreciation of its final proposal is set out in the **Explanatory Memorandum**, which describes how the proposal conforms to the subsidiarity, proportionality and better regulation principles. After Commission adoption of the concerned policy initiative, the IA is transmitted to the European Parliament and to the Council who are likely to discuss its content and quality. The European Parliament and the Council have made commitments to provide additional analyses to support any substantive amendments they propose.

Chapter IV

Guidelines on preparing proposals, implementation, and transposition

Key requirements

- Implementation Plans (SWD) must accompany proposals for major Directives and should describe implementation challenges and relevant support actions to be taken by the Commission.
- Use available guidance to prepare high quality legal text and explanatory memorandum. The need for Explanatory Documents relating to major Directives must be justified in the proposal.
- A compliance assessment of EU Directives must be carried out in two stages: (1) timely and systematic check whether Member States have transposed Union law; (2) a timely and systematic conformity check of national transposing measures against the relevant Union legislation.

1. INTRODUCTION

Who Should Read these Guidelines?

All officials involved in the preparation of an initiative and its subsequent implementation/application should read these guidelines.

Why is good implementation important?

Effective application of EU law is essential if the European Union is to meet its policy objectives. While Member States are responsible for the timely and accurate transposition of directives as well as the correct application of the entire *acquis*³⁵, the Commission has to monitor the Member States' efforts and ensure that their legislation complies with Union law. The Commission has three important roles:

First, during the preparation of a new initiative where issues and problems related to implementation and application should be anticipated and taken into account. Second, the Commission should prepare well-drafted, high quality legal texts that are easy to understand and implement. Third, the Commission needs to have thorough and consistent information on implementation/application in the Member States. It needs rigorously to examine national implementing measures to ensure that the laws of the Member States are fully compliant with the Union *acquis*.

The following aims to assist services to take implementation aspects better into account when preparing new initiatives and to help them in identifying ways to check the implementation of EU law. This chapter complements the subsequent chapter which deals with how to monitor the application/effects of Union policies.

³⁵ Article 291 (1) TFEU.

2. ANTICIPATE IMPLEMENTATION PROBLEMS AND FACILITATE TRANSPOSITION: IMPLEMENTATION PLANS³⁶

Good implementation starts with a good impact assessment and stakeholder consultation. For each policy option, the analysis should explicitly address any clearly identifiable problems or issues which are likely to be encountered with its implementation and application by the Member States or other local or regional authorities or enforcement agencies. A key issue will be to assess the balance between the efforts of those who will be directly regulated or obliged to comply with a new initiative and the efforts of public authorities who will be responsible for enforcement in terms of costs and other resource implications. The analysis should also build on any relevant evaluation that may have identified implementation problems associated with existing legislation.

Box 1. Regulatory costs versus Enforcement costs for public authorities

- Legal rules have to be monitored and enforced to be effective. Depending on the policy option chosen, enforcement may be very cheap or costly for public authorities.
- Abolishing business reporting obligations on health and safety measures does not remove the desirability of monitoring health and safety at the workplace. This will likely lead to more monitoring and inspection by public authorities;
- Speed limits enforced via police officers will be more costly than by using centralised speed cameras (entailing one-off capital costs and recurring maintenance costs and centralised administration issuance of fines);
- Enabling private actions for antitrust damages creates greater demand (and backlogs) and costs for the use of the legal system which falls on public authorities.

In parallel, the consultation strategy should ensure that it targets the views of those public authorities who will ultimately be responsible for the effective application of the initiative and associated enforcement activities. This will ensure that relevant implementation experience and expertise is collected and built into the initiative.

The Commission should also support Member States in their transposition and implementation efforts by preparing implementation plans (IPs) for certain directives and regulations. The preparation of an IP aims at facilitating the timely and effective application of law, fully recognising the responsibility for the latter rests with the Member States³⁷.

When is an implementation plan needed?

An IP should be prepared when the implementation of the legal act concerned, because of its nature or complexity, could benefit or be facilitated by supportive measures.

IPs would normally be required for framework directives; directives with a large scope containing a large number of legal obligations; directives aimed at the full harmonisation of a policy area, and directives having a significant impact on or amending various branches of the national legal order. In contrast, IPs would normally not be required for

³⁶ This guidance replaces the guidance provided by the Annexe II of the Note dated 7/01/2013 (Ares(2013) 12012).

³⁷ Article 288 TFEU

directives with a limited or very technical scope or which do not require transposition measures³⁸, directives containing only one or a very limited number of legal obligations and directives amending only one or a very limited number of legal obligations of an existing directive.

Concerning regulations, an IP would be recommended in case the implementation requirements are similar to those of a directive and supporting measures to facilitate the application by Member States would be beneficial. The DGs are responsible for identifying where an IP for regulations concerning their particular sectors would be necessary.

Inter-service Consultation on the implementation plan

The preparation of an IP should be flagged in agenda planning before launching an ISC. If no IP is planned, this should be justified in Agenda Planning. The SG will verify and if necessary discuss justifications. The IP should be prepared as a staff working document and accompany the proposal in inter-service consultation and as background to the discussions in the institutions. If the proposal evolves significantly in the legislative process, the IP will need to be updated. More guidance is provided in the Toolbox.

What should an implementation plan contain?

The preparation of the Implementation Plan should start with an assessment of the challenges which the Member States will face in applying the legislation. On the basis of the assessment, The IP should set out the various types of support which the Commission services will provide to the Member States to assist them in their implementation of the legislation. It should also set out the monitoring arrangements designed to ensure the availability of strong data and other evidence to track progress and report on the performance of the measure. A template for such an implementation is provided in the tool box.

3. BETTER DRAFTING OF LEGAL ACTS

Union legislation should be well drafted in order to ensure it adequately reflects the intention of the legislator and can achieve its regulatory aim. Respect for the requirements of legislative drafting plays an important role in achieving the goal of legal certainty. If legislation is clear it can be implemented effectively, citizens and economic actors can know their rights and obligations and the courts can enforce them.

Where can legislative drafting rules be found?

The importance of good legislative drafting has been recognised for many years in the different institutions. The Interinstitutional Agreements on the quality of drafting of legislation³⁹ and on the use of codification⁴⁰ and recast⁴¹ techniques have established a common approach.

³⁸ For example, Directives updating provisions related to (inter-) institutional issues such as comitology.

³⁹ Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ C 73, 17.3.1999, p.1).

⁴⁰ Interinstitutional Agreement of 20 December 1994 on an accelerated working method for official codification of legislative texts (OJ C102, 4.4.1996, p.2).

The Joint Practical Guide for persons involved in the drafting of European Union legislation⁴² builds upon the agreed principles. In addition, the Quality of Legislation team in the Legal Service has developed the Drafters' Assistance Package (DAP)⁴³ which offers guidance, step by step, on how to draft legal acts and is based on the Joint Practical Guide. It even provides useful links and suggested wording. In practice, if your draft is of high quality it is less likely to be altered later in the legislative procedure.

DAP only covers the legal act itself and does not deal with other related documents, such as the impact assessment or the explanatory memorandum. DAP is integrated into the Legiswrite models but can also be accessed as a stand-alone wiki.

Box 1. How to prepare a good quality legal act – some important steps

- Use the correct LegisWrite model whenever you draft a legal act;
- Follow the rules in the Joint Practical Guide and check in DAP whenever you have questions as to how a provision should be drafted;
- Bear in mind that your text may need to be translated into other languages;
- Check that references are accurate.

What is the Recast technique?

Recast is a tool for the simplification of Union legislation. It is a technique which makes it possible to amend an earlier act (which itself may have already been amended) while immediately codifying the new amendments with the existing provisions of the earlier act. It results in a new legal act which incorporates both the amendments and the unchanged provisions. The new legal act replaces the earlier one which is repealed.

The recast of legislative acts is governed by specific rules laid down in the Interinstitutional Agreement on a more structured use of the recasting technique for legal acts. The Agreement sets the "*rules of the game*" necessary for preserving both the right of initiative of the Commission and the right of the legislator to make amendments to the Commission's proposal in a recast exercise.

Advice should always be sought from the Legal Service when determining whether recast is appropriate in a given case. In particular, the Quality of Legislation Team can offer guidance and practical assistance⁴⁴ and should be contacted at an early stage. More information is also available in DAP.

What is Codification?

⁴¹ Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts (OJ C77, 28.3.2001, p.1).

⁴² Joint Practical Guide of the European Parliament, the Council and the Commission for persons involved in the drafting of European Union legislation
<http://www.cc.cec/wikis/display/dap/Legislative+drafting+resources>

⁴³ <http://www.cc.cec/wikis/display/dap/Home>

⁴⁴ SJ.juristes-reviseurs@ec.europa.eu

Codification brings together all of the provisions of an existing legal act and all of its amendments in a new legal act replacing the earlier one, which is repealed.

It is governed by the Interinstitutional Agreement on an accelerated working method for official codification of legislative texts.

Codification – which passes through the full legislative process - should not be confused with the unofficial consolidation carried out by the Publications Office which results in texts which are not legally binding.

Codification is carried out on the basis of initiatives undertaken in cooperation between the Legal Service and the operational DGs, with the Legal Service acting as lead DG. The Legal Service is therefore responsible for the preparation of the proposal for a codification and for following up the procedure leading to the adoption of the new, codified act. The distinctive feature of codification is that, in contrast to recast, no substantive changes may be made to the earlier act.

Other issues to consider when preparing proposals for legislation

The Commission is committed to the use of **common commencement dates** for EU regulations and decisions affecting businesses generally. Proposed Decisions, Regulations and delegated regulations should, where possible, stipulate a commencement date of 1 January or 1 July in a given year to help simplify the actions of affected parties.

Sunset clauses may be used to prevent obsolete legal provisions from remaining in force. They terminate or repeal some or all provisions of a legal text after a specific date unless further legislative action is taken to extend them. As such, they can be used to direct an assessment of the continuing need for legislation and may be particularly relevant where "emergency" legislation is adopted, for example, in response to a particular crisis or unexpected issue etc.

Box 2. Example of a sunset clauses

- The EU Agency on Network and Information security was initially established with a time limited mandate.

Legislative proposals should also foresee when, how and on what basis ***legislation will be evaluated in the future***. The next chapter describes how monitoring arrangements should be conceived at the design stage of a new initiative in order to support such evaluations.

*The explanatory memorandum*⁴⁵

The purpose of the explanatory memorandum is to explain the Commission's proposal. It is required for all legislative proposals non-legislative proposals for adoption by the Council or by the EP and the Council⁴⁶. It is transmitted to the other Institutions together with the accompanying proposal and is available to the public. The explanatory

⁴⁵ See tool on how to draft an explanatory memorandum for more detail.

⁴⁶ A simpler explanatory memorandum also exists for delegated acts which are not directly covered by this guideline although elements of the guide and tool may still be relevant.

memorandum is, however, not published in the Official Journal and will not become part of the act to be adopted.

The explanatory memorandum should be used to communicate the following issues which are important for the Commission's Better Regulation Agenda:

- **Legal basis:** Explain the legal basis of the proposal. Where several feasible options exist, justify the choice on the basis of objective criteria.
- **Subsidiarity (for non-exclusive competence):** Explain the Union dimension of the problem. Describe why the objectives of the proposal cannot be adequately achieved by the Member States (necessity test). Explain why action at EU level, by reason of its scale or effects, would produce clear benefits as opposed to action at Member State level (effectiveness test).
- **Proportionality:** Explain the scope of the proposal and why it is considered proportionate (i.e. not going beyond what is necessary to achieve the objectives). Explain the choice of instrument and why it is considered the most suitable act for achieving the objective.
- Summarise results of any **ex-post evaluations/Fitness Checks** and clarify the link to the identified problem(s) addressed by the proposal.
- Describe the results of the **stakeholder consultations** undertaken including the views of respondents and how these were taken into account in the proposal.
- A short summary on the **external expertise** on which the Commission has relied upon (approach, range, advice received and used, public available information).
- **Impact assessment:**
 - Where the initiative is not supported by an impact assessment, explain the reasons why with reference to the associated Roadmap and toolbox⁴⁷.
 - In addition, a justification must be given where the impact assessment is not supported by a positive opinion from the Regulatory Scrutiny Board.
 - Explain which policy alternatives were examined, how they compare and why the final proposal was considered to be the preferred policy choice.
 - Describe the main economic, social and environmental impacts of the preferred option, who would be affected and how;
 - Where the final policy proposal deviates from the options assessed in the IA, clarify the likely impacts of such a change.
- **Regulatory fitness and simplification:**

⁴⁷ See tool on when an IA is necessary.

- Mention, with quantified estimates wherever possible, the extent to which the proposal will reduce regulatory burden or simplify the existing legal framework.
 - Outline whether and how the proposal exempts micro-enterprises (and reasons if no exemption is proposed) or provides a lighter regulatory regime for SMEs generally including how it minimizes compliance costs for SMEs.
 - The possible negative impacts on sectoral EU competitiveness or international trade should also be specified;
 - Explain how the initiative is "digital and internet ready" so that initiatives are appropriate for both the digital and physical worlds (see the tool on ICT impacts in the BR toolbox).
- **Implementation plans, monitoring, evaluation and reporting arrangements:** Refer to the implementation planning associated with the measure, including to the monitoring, evaluation and reporting framework to be applied to assist with its implementation and application and to report on its performance.
 - **Explanatory documents (for directives):** Explain if the proposal requires Explanatory Documents on the transposition and why (see later section).

4. THE LINK BETWEEN EU LAW AND MEMBER STATE TRANSPOSING MEASURES: EXPLANATORY DOCUMENTS⁴⁸

Why is it important to make the link between EU law and national transposition measures?

The Commission is the guardian of the Treaties. That means that it has to monitor the application of EU law and should be able to identify clearly how Member State measures link with EU legislation⁴⁹.

The European institutions have agreed on a set of joint political declarations, which indicate how the Commission can be provided with this information on the transposition of directives. The Member States undertake to accompany the notification of transposition measures with one or more so-called 'explanatory documents', which can take the form of correlation tables or other documents serving the same purpose. The Commission must first justify the need for, and the proportionality of, providing such documents on a case by case basis, when presenting its proposals.

When is it justified to ask for explanatory documents?

The Commission lead service should justify the request for explanatory documents. The key question to be answered is whether the document is necessary for the Commission to carry out its task of overseeing the transposition of directives.

The Commission should weigh up the following:

⁴⁸ This guidance replaces the guidance provided in the Note dated 20/12/2011 (Ares(2011) 1386838).

⁴⁹ The policy is contained in a (1) joint political declaration between the Commission and the Member State (OJ 2011/C 369/02); and (2) a joint declaration between the EP, Council and Commission (OJ 2011/C 369/03).

- The complexity of the directive concerned – the more complex, the more likely an explanatory document is needed;
- The complexity of the area concerned in view of its transposition into the legal order of the member States;
- Possible additional administrative burden – is the request proportionate to the legislative initiative being prepared?

The Commission must be sure that the document is essential in order for it to carry out its task of overseeing the application of Union law. To facilitate this assessment, the Commission services should consider the following.

Explanatory documents would normally not be required if the notification of individual transposition measures itself is largely self-explanatory. This usually applies to:

- Directives containing only one or a very limited number of legal obligations;
- Directives amending only one or a very limited number of legal obligations of an existing Directive;
- Directives concerning well delimited and not heavily regulated domains at national level.

By contrast, explanatory documents are usually needed for:

- Framework directives;
- Directives with a large scope containing a large number of legal obligations;
- Directives aimed at full harmonisation of a policy area;
- Directives having a significant impact or amending various branches of the national legal order.

It should be noted that the Commission has also committed itself vis-à-vis the European Parliament to justify also all cases in which it will not request explanatory documents (in addition to the scenario of positive requests as contained in the political declarations). Although such justification may be shorter than those requiring explanatory documents, they should also be based on the considerations as mentioned above.

Justification for Explanatory Documents in Commission Proposals

For all new proposals for Directives, including delegated acts, a justification should be prepared as part of the explanatory memorandum.

In cases where the services propose to request explanatory documents, a standard recital should directly be included in the proposed directive:

"In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the

components of a directive and the corresponding parts of national transposition instruments."

For all directives to be adopted through comitology, the justification for explanatory documents should be provided orally to the Member States during committee discussions (this can then be reflected in the summary record of the committee meeting).

5. MONITORING IMPLEMENTATION

*Compliance assessment*⁵⁰

The Commission is committed to more systematic monitoring of the implementation of directives.⁵¹ This is done, inter alia, by conducting compliance assessments of both transposition and conformity. Compliance assessment is two-staged:

First, the services carry out a **transposition check**, assessing the status of the transposition of the directive concerned. If directives are not completely transposed, services propose to launch an infringement procedure under Article 258 or, where a legislative Directive is concerned, in conjunction with Article 260(3) TFEU⁵².

Once the transposition check is finalised and once possible ensuing infringement procedures for failure to communicate transposition measures have been closed, services should immediately start the second stage of the compliance assessment, the **conformity check** without excluding the possibility of launching conformity checks on parts of the Directive that have already been transposed completely. This check aims at getting a meaningful picture of the conformity of the legislation of the Member State with the Directive.

Monitoring application

Good implementation also involves the monitoring of the application of legislation on the ground. This is to ensure that the intervention performs as intended and to provide information so that corrective action can be taken if it is not performing or if there have been unintended consequences etc.

The Commission may decide that a "soft" policy instrument is preferable to a pure legislative approach (although these may be combined). This may include voluntary agreements or other forms of self-co-regulatory action which are described more fully in the tool on policy instruments. In such cases, there will also be a need to monitor the performance of such approaches against the policy/legislative principles underpinning them²⁵, the commitments made by the parties and the objectives of the initiative.

The next chapter deals in more detail with monitoring the effects over time associated with a given intervention.

⁵⁰ This term covers transposition and conformity check

⁵¹ [COM \(2012\) 746 final](#).

⁵² See [Commission Communication, Implementation of Article 260\(3\) of the Treaty](#), OJ C12/02 of 15 Jan. 2011, para. 7.

Chapter V

Guidelines on monitoring

Key requirements

- Make sure it will be possible to assess the performance of an initiative while avoiding unnecessary or duplicative requests for data and information.
- Impact assessment to set out the future monitoring and evaluation arrangements which should identify data needs and data.
- Establish monitoring arrangements and indicators that will generate the necessary information for subsequent evaluation of the performance of the intervention while minimising data collection costs.
- Ensure that monitoring arrangements initially sketched out in the impact assessment are updated to reflect the actual proposal presented by the Commission and what is finally agreed by the Legislator.

1. INTRODUCTION

Who Should Read These Guidelines?

All officials involved in the preparation of an impact assessment (IA) and related Commission proposals and Implementing Plans should read these guidelines including officials and managers who are responsible for ensuring the quality of monitoring systems in place in the lead DG. The guidelines are recommended also to those involved in the Strategic Planning and Programming cycle, in particular those who prepare Management Plans, and those involved in subsequent evaluations to allow them to understand how a monitoring system is set up.

This chapter concentrates on monitoring during the application of the intervention on the ground.⁵³ More detailed guidance is also available in the separate "toolbox" which accompanies this guide.

What is monitoring and when is it required?

Monitoring generates evidence on an intervention's activities and impacts over time in a continuous and systematic way. A monitoring system is a necessary and integral part of Better Regulation helping to:

- Identify whether a policy is being applied on the ground as expected;
- Addressing any implementation problems of an intervention; and/or
- Identifying whether further action is required to ensure that it can achieve its intended objectives.

⁵³ Clearly, issues such as the timely and correct transposition of Union legislation into national rules and their appropriate enforcement will also influence the observed performance of the intervention. These aspects are dealt with in the preceding chapter.

Good monitoring generates factual data to improve the quality of future evaluation and impact assessment. It provides time series data that, under normal circumstances, will be more reliable in explaining behavior than one-off data collection exercises.

The monitoring (and evaluation) arrangements should first be outlined in the impact assessment and revised, if necessary, following adoption of the intervention by the Co-legislator. This will allow more efficient evidence gathering to be integrated into the intervention and permit the maximum exploitation of existing sources thereby minimising costs for those involved in providing, collecting, storing and disseminating evidence.

In principle, part of the evaluation should assess the adequacy of the monitoring system in place.

2. THE KEY QUESTIONS AND PRINCIPLES OF MONITORING

Monitoring needs to consider the objectives of the intervention and what evidence need to be collected to track its progress and performance. This is linked to understanding both the logic of the intervention and how the evidence collected will be used. Consideration needs to be given to the frequency and method of collection, different sources of evidence taking into account what is already available and cost for different parties involved. This leads to a series of questions.

The key questions a monitoring system must address	
1	<i>What evidence needs to be collected?</i>
2	<i>When and how should evidence be collected?</i>
3	<i>Who will collect the evidence and from whom?</i>

In answering these questions several governing principles need to be followed.

Governing principles

Comprehensive: the monitoring system put in place must cover the objectives of the intervention. Whilst high level monitoring of key indicators linked to general objectives is likely to exist already, new monitoring arrangements may need to be identified for specific or operational objectives. Although monitoring systems generally collect objective (e.g. factual, quantitative) evidence, it is also possible to put in place monitoring of subjective (e.g. opinion based, qualitative) evidence such as periodic opinion polls or surveys.

Proportionate: the system put in place needs to reflect the importance placed on different aspects of the intervention. Collection of evidence comes at a cost and care should be taken to challenge the necessity of each (new) monitoring requirement being considered.

Minimise overlap: The EU, Member States, Agencies, international organisations collect a lot of evidence. It is important to know what we have already and when and how it is collected. This should help to avoid duplication and the creation of unnecessary data collection burdens by concentrating only on the gaps which need to be filled.

Timeliness: Whilst the monitoring system should be set up as soon as possible after the intervention is agreed, this does not mean that all evidence needs to be collected from that point onwards. Not all evidence needs to be collected at the same time – sometimes it is better to collect evidence as it happens, other times it can be done later. Consideration also needs to be given to when the evidence will be used – different legal requirements may play a role not just in deciding what is needed, but also the when it is collected.

Accessibility: in principle, all evidence gathered should be made available to the general public. Unless data includes confidential elements, it is recommended that it is made available via the EU Open Data Portal⁵⁴ which provides a single point of access to a growing range of data produced by the institutions and other bodies of the European Union. Such information has a significant potential not just to increase transparency but also, through its re-use, to create new products and services and efficiency gains in administrations. Facilitating access to public data will also foster the participation of citizens in policy making processes.

As mentioned above, monitoring plays a key role in providing part of the evidence base. Good monitoring is in particular important for evaluation, which cannot be undertaken satisfactorily without relevant information/evidence to assess the performance of the intervention⁵⁵.

Early planning of data needs

Considering the evidence required early at the impact assessment stage (or policy design stage) brings a number of advantages:

- The optimal evidence requirements can be identified more readily which increases the chances it will be available throughout the policy lifecycle;
- Requirements can be designed into the intervention so that evidence is delivered routinely so that the costs/impacts for providers and handlers can be clearly assessed;
- Baselines and counterfactual data can be collected.

However, the final arrangements can only be established once the content of the intervention is clear i.e. following adoption by the Legislator.

2.1. Question 1: What evidence needs to be collected?

Consideration should be given to what evidence need to be gathered to give reliable and consistent measurement against the objectives of a given intervention.

⁵⁴ For more information see: <http://open-data.europa.eu/en/data/>

⁵⁵ 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 Annual Activity Report gives an account of progress made towards key policy objectives and core activities of a DG taking into account the corresponding resources used each year. To enhance performance reporting on both spending and non-spending activities, DGs now include output, result and impact indicators for all activities which need to be accompanied by good monitoring arrangements to assess the impact of EU policies on society.

A good monitoring system will cover all parts of the implementation and application of an intervention.

The first step in defining a monitoring system is to carefully consider the **objectives** of the intervention and the **reporting requirements** that have been set. Different reports contain different kinds of evidence, serving different purposes, particularly depending on the time they are written in the policy cycle.

In relation to an evaluation, evidence can be collected and help to assess:

- Whether the intervention logic underpinning the original initiative at the impact assessment stage remains valid;
- Whether the foreseen steps/milestones necessary for delivering the policy objectives have been completed successfully or progress against specified targets is on track;
- The numbers and characteristics of those who might be affected by a given intervention – such information being useful in future stakeholder consultation strategies;
- The costs and benefits to society. This could cover a wide range, from individual stakeholders to particular interest groups such as public authorities, businesses by sector, NGOs etc.;
- The wider impacts of the intervention.

Box 1. Implementation reports and evaluation

Implementation reports are generally focussed on the Member States' implementation measures. They often have a wider scope than pure legal compliance reports but nonetheless build on existing conformity/compliance checking. They do not constitute a full evaluation as they do not look into how and why the intervention has performed. They describe the state of play based on limited monitoring data and provide information on progress against agreed timetables or objectives.

In some cases, the requirement to prepare implementation reports may be repeated (typically 3-5 years). However, consideration should be given to the advantages of undertaking a full evaluation of the measure, rather than preparing a further (and limited) report on implementation.

2.2. Question 2: When and how should evidence be collected?

Once it is clear what evidence is needed, careful consideration needs to be given to the timing and process of its collection.

To set up a good monitoring system a clear link needs to be established between objectives and indicators bearing in mind the arrangements needed to collect the necessary new evidence in time to meet reporting requirements.

It is important to know what and when is already being collected to avoid asking for the same data several times or creating new burden by asking for extra data when existing data cover broadly the same ground.

Monitoring/reporting requirements can create administrative burdens which should be kept to what is absolutely necessary. Smart use of technology can reduce costs – electronic data capture at the point of origin is cheaper than periodic interviews or

surveys. Over the longer term, systematic monitoring systems can be more efficient than one-off exercises and provide information on trends.

For every initiative checks on existing tools, systems, practices, standards etc. should be made to identify what can be reused – to avoid reinventing the wheel or developing new systems for every policy area. As much as possible all these systems and solutions should be "open", i.e. favouring the use of open standards and of open data.

Timing of the evidence gathering needs to be considered vis-à-vis progress of intervention's implementation and reporting requirements. The desired outcome of a policy intervention may not materialise for many years and this should be reflected in the monitoring arrangements. Where it takes too long to capture the final policy outcome or where it will not be possible the outcome it may be necessary to monitor against intermediate or proxy outcomes. Again, these should be identified early in the design of the initiative.

Careful planning for future data collection is also important to ensure that possible ethical/privacy issues are identified and fully addressed, that the costs of data provision are transparently presented and that arrangements to ensure data quality assurance, storage and transmission are planned for.

Indicators

A good monitoring system links objectives with their relevant indicators.

- **Output indicators:** These relate to the specific deliverables of the intervention such as a new database for collecting monitoring results or a new CEN standard etc.).
- **Outcome/Result indicators:** These match the immediate effects of the intervention with particular reference to the direct addressees.
- **Impact indicators:** These relate to the intended outcome of the intervention in terms of impact on the wider economy/society beyond those directly affected by the intervention.

The Common tool on monitoring and indicators sets out in more detail how to define objectives and indicators which link the impact assessment and evaluation phases of the policy cycle.

Each **indicator** should be clearly **defined**. Even slight differences in definition can have important implications both in terms of accuracy/reliability and data collection costs. A clear definition, including **the unit of measurement**, is particularly important as data need to be aggregated at the EU level. Aggregation of data can also become problematic if the definition is not provided or if indicators are not calculated on a consistent basis.

The frequency of measurements has implications for the overall costs of data collection. As regards **sources of data** – it is always advisable to exploit existing data sources as much as possible in order to reduce costs.

The baseline allows for assessment of the progress made. If we don't know where we started, we can't say how much progress has been made. **Targets** are not always set for initiatives, but if they are, they should have a deadline for attainment and a numerical value.

Table 1: Indicators⁵⁶

Indicator	Definition	Unit of measurement	Source of data	Frequency of measurement	Baseline	Target

2.3. Question 3: Who will collect the evidence and from whom?

Consideration should be given to who will have responsibility for gathering data and who will be responsible for providing it.

Evidence should be gathered at appropriate level with consideration to cumulative burden it could trigger.

There should be a clear understanding of what evidence needs to be collected and what existing data and data collection paths already exist. In the EU context, this requires an understanding of the different systems in the Member States'. In principle, evidence should be collected centrally, at a Member State level or through a national or EU coordinating body.

Evidence providers will vary according to the intervention and the indicator. Sometimes evidence is needed from individual stakeholder (e.g. businesses or citizens); sometimes it can come from a collective body (e.g. business or consumer organisation, local/regional/national level). Every effort should be made not to impose excessive burdens on the stakeholder in terms of monitoring requirements.

⁵⁶ Indicators should be presented by their level, e.g input, result and impact indicators.

Chapter VI

Guidelines on evaluation and Fitness Checks

Key requirements

- Evaluations must be followed by an Interservice Steering Group (ISG) composed of a minimum of three members, including a representative from the lead DG's evaluation function. For Fitness Checks a representative from the Secretariat General must be included in the ISG.
- An evaluation roadmap summarising the design, purpose and scope of the upcoming evaluation must be published for all evaluations and Fitness Checks and stakeholders must be able to provide feedback on it.
- All evaluations must follow a clearly defined, robust methodology intended to produce objective findings. As a minimum, evaluations must assess effectiveness, efficiency, relevance, coherence and EU added value or explain why this is not done in the evaluation roadmap.
- Evaluations and Fitness Checks must assess all significant economic, social and environmental impacts of EU interventions (with particular emphasis on those identified in a previous IA).
- As part of a broader consultation strategy to target relevant stakeholders and collect evidence, a 12-week internet-based public consultation should generally be conducted, covering all of the main elements of the evaluation.
- A SWD must be prepared for all evaluations. This SWD must contain information and annexes as indicated in the toolbox and be complemented by a 2 page executive summary available in FR, DE and EN.
- The following files related to the evaluation must be published centrally:
 - (1) The evaluation roadmap;
 - (2) (if applicable) Terms of Reference, final contractors' report and associated Quality Assessment;
 - (3) The Staff Working Document and its executive summary (in FR, DE and EN);
 - (4) (if applicable) The Regulatory Scrutiny Board opinion.
- At the end of an evaluation, appropriate follow up actions must be identified and fed into the decision making cycle.
- Evaluation findings must pinpoint areas where there is potential to reduce inefficiencies, including regulatory burden and simplify the intervention.

1. INTRODUCTION

Who Should Read these Guidelines?

All officials involved in the preparation of an evaluation or a Fitness Check should read these guidelines⁵⁷ including officials and managers in the evaluation function of the lead DG.

These guidelines apply to evaluations (i.e. Fitness Checks, final, ex-post and interim evaluations) of EU policies and interventions governed by legal instruments, including the Financial Regulation and its Implementing Rules.

It may not be necessary to apply them fully when evaluating:

- Individual intervention projects, groups of projects or sub-activities where their findings will feed into an overarching evaluation. This is particularly relevant for external programmes where findings coming from evaluations of country programmes, specific delivery methods/tools or elements of certain themes feed into major evaluations including legal instruments;
- The internal administrative policies of the Commission (Translation, Interpretation, Human Resources and Security, the Publications Office and certain areas of Eurostat). For these a more proportionate approach should be applied.

Such evaluations should nonetheless follow the definition, concepts and principles of evaluation presented here. Where a Directorate General has doubts about the degree of application, they should agree the approach with the Secretariat General, preferably during the annual discussions establishing the evaluation plan.

What is evaluation?

Evaluation is defined as an **evidence-based judgement** of the extent to which an intervention has:

- Been **effective and efficient**,
- Been **relevant** given the needs and its objectives,
- Been **coherent** both internally and with other EU policy interventions and
- Achieved **EU added-value**.

Evaluation is a tool to help the Commission assess the actual performance of EU interventions compared to initial expectations. By evaluating, the Commission takes a critical look at whether EU activities are fit for purpose and deliver, at minimum cost, the desired changes to European businesses and citizens and contribute to the EU's global role. Evaluation also provides a key opportunity to engage stakeholders and the general public, encouraging feedback on how EU interventions are perceived.

Evaluation is not an assessment of *what* has happened; it also **considers *why*** something has occurred (the role of the EU intervention) **and, if possible, *how much has changed as a consequence***. It should look at the wider perspective and provide an independent and objective judgement of the situation based on the evidence available.

⁵⁷ The guidelines set out the key requirements and obligations for evaluation and replace the previous (2004) guidelines and (2007) standards.

Evaluation *looks for evidence of causality* – i.e. did the intervention bring about the expected changes or were there other unintended or unexpected changes. Beyond listing outputs and describing changes, evaluations should seek to link changes in a situation to the EU intervention. To be most effective, such evaluation should be carried out once the intervention has been implemented and sufficient time has passed to allow for changes to be identified and/or measured.

An evaluation should also assess the strength of the evidence obtained, and the implications for the robustness of the conclusions reached. Although there are many useful activities which may cover some of these elements (e.g. reports particularly implementing reports, monitoring exercises, audit, studies including cumulative cost assessments) it is unlikely that any of these sources will contain sufficient information to qualify as an evaluation.

What is a Fitness Check?

Traditionally, Commission evaluations have been conducted on *individual* interventions, but the increased focus on the performance has led to the creation of a new type of evaluation - *the Fitness Check*⁵⁸.

A *Fitness Check* is like an evaluation of an individual intervention except that it covers a group of measures which have some relationship with each other which justifies their being evaluated together (normally a common set of objectives).

A Fitness Check assesses whether the framework⁵⁹ for a given sector is fit for purpose by assessing the performance of the relevant framework with respect to its policy objectives. A Fitness Check should pay particular attention to identifying any synergies (e.g. improved performance, simplification, lower costs, reduced burdens) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures) within the group of measures which may have appeared over time, and help to identify the cumulative impact of the interventions covered, covering both costs and benefits.

The evaluation of individual interventions and Fitness Checks of policy areas are complementary and mutually reinforcing tools. While evaluations of individual initiatives provide more details on particular elements, they do not always show the full picture and a more strategic and global view is often required. Fitness checks can group together into one exercise evaluations that would otherwise have been undertaken separately, and potentially less coherently. Fitness Checks can provide economies of scale and place a greater focus on overall objectives and performance. Their particular strength is in addressing the cumulative effects of the applicable framework - these are not addressed via evaluations of individual initiatives and the cumulative effects do not necessarily correspond to the sum of effects identified through evaluations of individual measures.

⁵⁸ The concept of a Fitness Check was introduced in COM (2010) 543 final – Smart Regulation in the European Union

⁵⁹ Such a framework may be purely regulatory, but is often a mix of regulatory and non-regulatory actions and in some instances it can be wholly non-regulatory e.g. consisting of EU level strategies, guidance documents etc.

Why do we evaluate?

Evaluation at the Commission serves several purposes. Although the importance may differ, most evaluation results will contribute to:

- **Timely and relevant advice to decision-making and input to political priority-setting:** Evaluation supports decision-making, contributing to strategic planning and to the design of future interventions. The Commission applies the "**Evaluate First**" principle to make sure any policy decisions take into due account the lessons from past EU Action. Thus for instance, lessons learned from evaluation should be available and feed into IA work from the very beginning.
- **Organisational learning:** The results of an evaluation can be used to improve the quality of an on-going intervention. Evaluations should identify not just areas for improvement but also encourage the sharing of (good and bad) 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.
- **Efficient resource allocation:** Evaluation results contribute to a more efficient allocation of resources between interventions, between the separate elements of a specific programme or activity, or between activities.

What are the requirements to evaluate?

Evaluations are an essential step to manage and revise the existing body of EU legislation and policy and should precede impact assessment⁶⁰.

The Commission is committed to evaluate in a proportionate way all EU spending and non-spending activities intended to have an impact on society or the economy⁶¹. A commitment to evaluation is included in Article 318 of the Treaty on the Functioning of the European Union (TFEU). Further sector-specific evaluation requirements are also explicitly included in the EU Treaties in the area of justice, freedom and security; common security and defence policy; research, technological development and space; industry; employment; social policy and public health. More specific requirements are often written into individual legal acts.

These commitments are all brought together under the Commission's Internal Control Standard 14⁶².

Evaluation is required where:

⁶⁰ See section "Applying Smart Regulation instruments", Instructions of the Secretary General implementing the European Commission 2014-2019 Working Methods available at: <https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx>.

⁶¹ SEC (2007)213 Responding to Strategic Needs: Reinforcing the use of evaluation

⁶² The internal control standards are available at: http://ec.europa.eu/budget/biblio/documents/control/control_en.cfm#ci_risk.

- The legal basis of the relevant intervention so requires (e.g. a "review" clause where sufficient operational/implementation experience has accumulated to permit evaluation and/or specific evaluation requirements);
- Indicated by the Financial Regulation and Rules of Application (i.e. for all programmes and activities entailing significant overall spending (over €5 million));
- Indicated by Council Regulation (EU) 2015/323 on the financial regulation applicable to the 11th European Development Fund.

Where a DG has doubts about the degree of application, they should contact the Secretariat General.

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 according to these guidelines and, where necessary, the Commission can report to the European Parliament and Council by the date set in the legal base. Where an evaluation is linked to a (review) clause that also provides an opportunity to present new proposals by a certain date, care must be taken to ensure that the planning allocates appropriate time for any subsequent impact assessment.

The key steps in an evaluation are⁶³:

1. Establish an **inter-service steering group (ISG)** to steer the evaluation, finalise the roadmap, help establish the Terms of Reference and complete the Quality Assessment on the final report by any contractors. The ISG must be involved in all the key steps of the evaluation and be composed of a minimum of three members, including a representative from the lead DG's evaluation function. For Fitness Checks it must include a member representing the Secretariat General.
2. Draft the **evaluation roadmap** which summarises the evaluation design, including clear statements on the subject, purpose and scope of the evaluation, the issues to be addressed and the evidence that will be gathered. Publication of the roadmap will provide greater transparency and enable stakeholders to provide their feedback.
3. Prepare a **consultation strategy with the ISG**, complying with the requirements set out in Chapter VII, **including a 12 week internet based public open consultation**⁶⁴.

⁶³ Further more detailed information on each individual step is provided in the toolbox Chapter "Evaluation and Fitness Checks".

⁶⁴ Without prejudice to the cases identified in box 1 and the general rules set out in COM(2002) 704, the consultation strategy should include a 12 week internet-based open public consultation at some point over the lifetime of the evaluation. Where the evaluation and IA are done "back to back" it is possible to conduct only one open public consultation as long as relevant stakeholders are consulted on all the main elements of the IA. Where the evaluation is of an activity conducted outside the EU or where the internet is not a practical support tool, including for duly justified confidentiality reasons, this mandatory open public consultation may be waived as long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. Before applying derogations, the DG must contact the Secretariat General.

4. Prepare the **Staff Working Document** and a short **executive summary** presenting the findings of the evaluation process. Depending on the approach followed this will either draw completely on the work of a contractor or bring together the work of the Commission Services and contractors. For "**major**"⁶⁵ **evaluations**, the draft evaluation SWD must be submitted to the **RSB** and its comments must be incorporated;
5. Launch the **Inter Service Consultation** for the SWD;
6. **Publish** the Staff Working Document and any supporting contractors' report centrally and, **where required by legal article**, transmit these to the Parliament and the Council in a short report;
7. **Disseminate** the **evaluation findings** and encourage active discussion and debate on the findings with stakeholders;
8. Identify any **appropriate follow-up actions** to put into practice the lessons learned and feed the evaluation findings into the next step of the decision making cycle. Some of this information may already be included in the report to the co-legislators.

2. KEY PRINCIPLES AND CONCEPTS

What are the principles?

All evaluations should be of high quality and respect certain principles:

Comprehensive: The definition of evaluation deliberately targets five criteria – effectiveness, efficiency, relevance, coherence and EU added value⁶⁶. Other criteria may also be added as appropriate.

Proportionate: The scope and analysis conducted must be tailored to the particular intervention, its maturity and the data available⁶⁷. For some criteria new data will need to be collected, analysed and compared with other findings; for others, a short summary can be presented based on existing reports and information or providing a standard explanation (e.g. in areas where the EU has exclusive competence).

Independent and Objective: Robust and reliable results can be delivered only by independent and objective evaluations. An evaluation can be considered as independent when evaluators: (i) carry out their tasks without influence or pressure from the organisation; (ii) are given full access to all relevant information required; and (iii) have full autonomy in conducting and reporting their findings.

⁶⁵ Major evaluations capture REFIT evaluations, Fitness Checks; major MFF programme evaluations and any other evaluations which the RSB may scrutinise based on the DGs rolling evaluation plan.

⁶⁶ See Tool "Identifying the evaluation criteria and questions" of the toolbox.

⁶⁷ In general it is recommended to evaluate only once sufficient time has elapsed from the implementation of the intervention to allow at least 3 years of reasonably full data to be collected.

Transparent Judgement⁶⁸: Evaluators must make judgements based on the evidence (good or bad) and analysis available. These judgements should be as specific as possible and judgement criteria for each evaluation question (success factors, related indicators, required evidence and information) should be clearly identified during the design of the evaluation.

Evidence-based: Evaluations are based on the best available evidence (factual, opinion based etc.), which should be drawn from a diverse and appropriate range of methods and sources (**triangulation**). Not all sources of evidence are equally robust and consideration must be given as to when and how the evidence was collected and whether there is any bias or uncertainty in it. Where possible, sensitivity and/or scenario analysis should be conducted to help test robustness of the analysis⁶⁹. Any limitations to the evidence used and the methodology applied, particularly in terms of their ability to support the conclusions, must be clearly explained.

What are the concepts?

Deciding when and how to evaluate requires careful consideration. There is no "one size fits all" rule, reflecting the Commission's decision to decentralise evaluation and the different intervention life-cycles that exist. All interventions follow their own cycle and timeline for the desired results to manifest themselves. Often trade-offs need to be made between when and how to conduct the evaluation (in order to feed further decision making process) and the amount of reliable data which is available.

The starting point for an evaluation is to consider the intervention logic of the policy/programme under review.

Evaluations look back at the performance of the (completed or on-going) intervention and critically compare what has actually happened to the earlier estimates and assumptions of what was expected to happen.

The evaluation design must thus be informed by any previous relevant impact assessment covering the intervention being evaluated. Where the impact assessment has paid particular attention to certain stakeholder groups, or categories of impacts, the subsequent evaluation must perform the corresponding complementary retrospective analysis or explain why this has not been possible⁷⁰.

Evaluations thus need to deconstruct the expected chain of events by using a simplified model of causality – showing how an intervention was triggered by a certain set of needs or problems occurring within a certain context and how it was designed, with the intention of producing the desired changes.

⁶⁸ The requirement to provide judgements can be a critical factor distinguishing an evaluation from a study.

⁶⁹ See tool "Useful analytical methods to compare options or assess performance" of the toolbox.

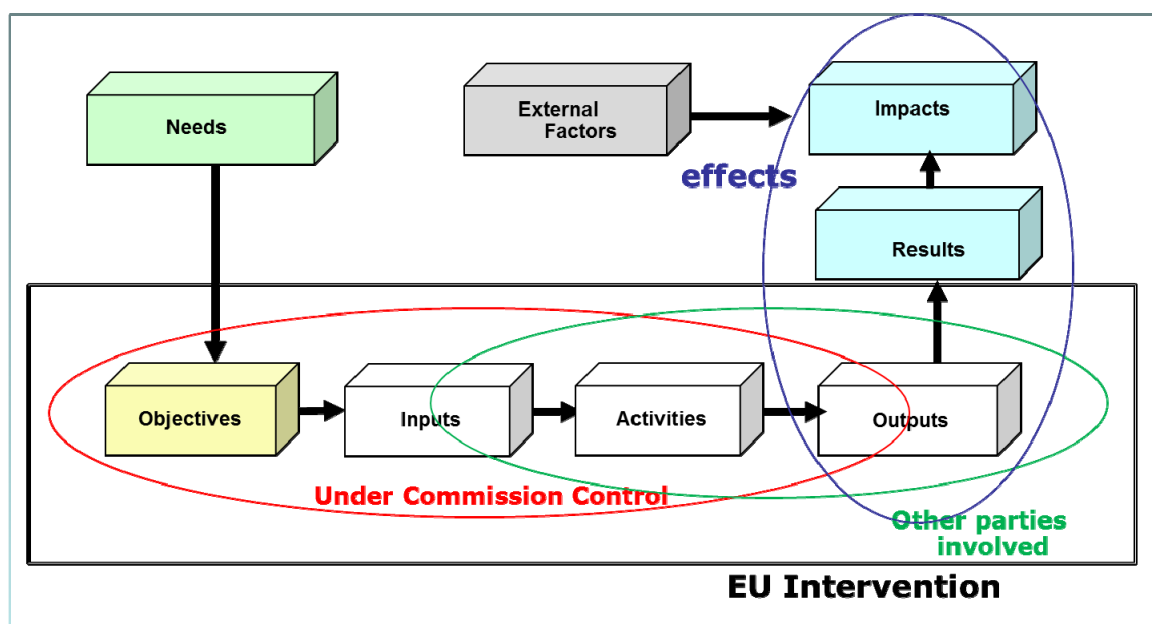
⁷⁰ Care needs to be taken to consider how expected impacts may have altered as a result of changes to the proposal introduced during the adoption process, which may have been assessed in impact assessment work conducted by the co-legislators.

Such "cause and effect" relationships are challenging to prove, particularly when evaluating EU policies which operate in a complex environment influenced by a wide range of factors falling both within and outside the scope of the EU intervention.

When evaluating EU legislation, it is particularly difficult to identify a robust counterfactual situation (i.e. what the situation would be if EU laws had not been adopted), making absolute quantitative analysis problematic. Often, EU evaluations have to rely on qualitative, reasoned arguments (backed by the appropriate evidence) about the likely contribution of an EU intervention to the changes observed.

Figure 1 illustrates how the different components of evaluation are linked together to present the expected intervention logic⁷¹.

Figure 1: The different components of the "intervention logic"



3. KEY QUESTIONS AN EVALUATION MUST ANSWER

The questions an evaluation must answer	
1.	<i>What is the current situation?</i>
2.	<i>How effective has the EU intervention been?</i>
3.	<i>How efficient has the EU intervention been?</i>
4.	<i>How relevant is the EU intervention?</i>
5.	<i>How coherent is the EU intervention internally and with other (EU) actions?</i>

⁷¹ Further guidance on how to create an intervention logic is provided in the Tool "Designing the Evaluation".

The questions an evaluation must answer

6. *What is the EU added value of the intervention?*

All evaluations must answer the above listed questions⁷², following a process which complies with the principles identified in the previous section. Depending on the subject being evaluated, further evaluation criteria may be added e.g., sustainability, utility etc.⁷³

3.1. *Question 1: What is the current situation?*

An evaluation starts by finding out how the situation has evolved since the intervention began, how the intervention has been implemented and/or applied, what has happened/is happening to different stakeholders.

The answer to this question should give all readers an overview of the current situation and explain key issues or external factors that may be referred to later when answering the remaining questions.

The first step of an evaluation is to understand the background, context and current situation of an intervention. Developing a clear understanding of the current situation and its underlying factors involves answering the following set of questions:

- What is the origin of the intervention and what were its objectives?
- Where things are – what progress has been made over time?
- What is the current situation for different stakeholders and how are they affected by the intervention? This should include consideration of how different elements of the intervention or different options have worked in practice.

Addressing these questions will ensure that the evaluation stays concrete and focussed, remaining close to stakeholders' concerns.

3.2. *Question 2: How effective has the EU intervention been?*

The evaluation should analyse the progress made towards achieving the objectives of the intervention, looking for evidence of **why**, **whether** or **how** these changes are linked to the EU intervention.

The answer to this question should go further than showing if the intervention is on track. It should seek to identify the factors driving or hindering progress and how they

⁷² The evaluation of a single intervention may on an exceptional basis omit one or two of the five evaluation criteria. Clear justification for such omission must then be provided in the evaluation roadmap and repeated in the final evaluation report. Fitness Checks always consider the five criteria.

⁷³ Further information is provided in Tool "Identifying the evaluation criteria and questions" of the toolbox.

are linked (or not) to the EU intervention.

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives. The evaluation should form an opinion on the progress made to date and the role of the EU action in delivering the observed changes. If the objectives (general, specific, operational) have not been achieved or things are not on track, an assessment should be made of the *extent* to which progress has fallen short of the target and what factors have influenced *why* something was successful or *why* it has not yet been achieved. Consideration should also be given to whether the objectives can still be achieved on time or with what delay. The analysis should also try to identify if any *unexpected* or *unintended* effects have occurred.

Typical examples of effectiveness questions

- *To what extent have the objectives been achieved?*
- *What have been the (quantitative and qualitative) effects of the intervention?*
- *To what extent do the observed effects correspond to the objectives?*
- *To what extent can these changes/effects be credited to the intervention?*
- *What factors influenced the achievements observed?*
- *To what extent did different factors influence the achievements observed?*
- *For spending programmes, did anti-fraud measures allow for the prevention and timely detection of fraud?*

3.3. Question 3: How efficient has the EU intervention been?

The evaluation should always look closely at both the costs and benefits of the EU intervention as they accrue to different stakeholders, identifying what factors are driving these costs/benefits and how these factors relate to the EU intervention.

The answer to this question should provide evidence on the actual costs and benefits, making it clear what can be linked to the EU intervention and what cannot. Efficiency analysis is a key input to policy making, helping both policy makers and stakeholders to draw conclusions on whether the costs of the EU intervention are proportionate to the benefits.

Efficiency considers the relationship between the resources used by an intervention and the changes generated by the intervention (which may be positive or negative). Differences in the way an intervention is approached and conducted can have a significant influence on the effects, making it interesting to consider whether other choices (e.g. as demonstrated via different MS) achieved the same benefits at less cost (or greater benefits at the same cost).

Efficiency analysis can differ depending on the type of intervention being evaluated. Typical efficiency analysis will include an examination of administrative and regulatory burden⁷⁴ and look at aspects of simplification – these are important for ALL evaluations, but particularly those identified under the REFIT programme. **Where appropriate,**

⁷⁴ For definition of regulatory burden please refer to the Tool "What key impacts must be considered" of the toolbox.

evaluation findings should pin-point areas where there is potential to reduce inefficiencies particularly regulatory burden and simplify the intervention.

The full efforts to support and perform an intervention can be broken into different categories such as: staff, purchases made, time and/or money spent, fixed costs, running costs, etc.⁷⁵ These costs can be associated to different aspects of an intervention and judged against the benefits achieved.

Good evaluations should make strong efforts to go beyond a qualitative description of the different costs and benefits of the EU intervention and seek to quantify them. While assessing costs and benefits may be (methodologically) easier for spending programmes, such assessment in policy areas may be a challenge since obtaining robust, good quality data is difficult, particularly across 28 Member States which may have implemented legislation in a variety of different manners.

Typical examples of efficiency questions

- *To what extent has the intervention been cost effective?*
- *To what extent are the costs involved justified, given the changes/effects which have been achieved?*
- *To what extent are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?*
- *What factors influenced the efficiency with which the achievements observed was attained?*
- *How affordable were the costs borne by different stakeholder groups, given the benefits they received?*
- *If there are significant differences in costs (or benefits) between Member States, what is causing them?*

3.4. Question 4: How relevant is the EU intervention?

The evaluation must look at the objectives of the EU intervention being evaluated and see how well they (still) match the (current) needs and problems.

The answer to this question should identify if there is any mismatch between the objectives of the intervention and the (current) needs or problems. This is key information that will assist policy makers in deciding whether to continue, change or stop an intervention.

Relevance looks at the relationship between the needs and problems in society and the objectives of the intervention. Things change over time - certain objectives may be met or superseded; needs and problems change, new ones arise. Relevance analysis is very important – because if an intervention does not help to address present needs or problems then it does not matter how effective, efficient or coherent it is – it is no longer appropriate. This is why there is a strong link between relevance analysis and the criteria

⁷⁵ Further information is provided in Tool "Typology of costs and benefits" of the toolbox.

of EU added value – which assesses whether action continues to be justified at the EU level.

Typical examples of relevance questions

- *To what extent is the intervention still relevant?*
- *To what extent have the (original) objectives proven to have been appropriate for the intervention in question?*
- *How well do the (original) objectives (still) correspond to the needs within the EU?*
- *How well adapted is the intervention to subsequent technological or scientific advances? (N.B. Could include issues related to the specify policy here e.g. social, environmental)*
- *How relevant is the EU intervention to EU citizens?*

3.5. Question 5: How coherent is the EU intervention internally and with other (EU) actions?

The evaluation should look at how well the intervention works: i) internally and ii) with other EU interventions.

The answer to this question should provide evidence of where and how EU interventions are working well together (e.g. to achieve common objectives or as complementary actions) or point to areas where there are tensions (e.g. objectives which are potentially contradictory, or approaches which are causing inefficiencies).

No policy exists in a vacuum. There are many different actors involved in many different interventions, both inside and outside the EU. Even small changes in how one intervention is designed or implemented can trigger improvements or inconsistencies with other on-going actions. The evaluation of coherence involves looking at how well or not different actions work together.

Checking internal coherence means looking at how the various internal components of an EU intervention operate together to achieve its objectives. Similar issues can arise externally at different levels: for example, between interventions within the same policy field (e.g. a specific intervention on drinking water and wider EU water policy) or in areas which may have to work together (e.g. water policy and chemicals policy, or chemicals and health and safety). At its widest, external coherence can look at compliance with international agreements/declarations (for example EU labour market initiatives might be looking into coherence with ILO conventions).

The focus on coherence may vary depending on the type of evaluation and is particularly important in Fitness Checks, where coherence analysis will look for evidence of synergies or inconsistencies between actions in a related field which are expected to work together. Even when evaluating an individual intervention, it can be important to check coherence with (a limited number of) other interventions.

Typical examples of coherence questions

- *To what extent is this intervention coherent with other interventions which have similar objectives?*

- *To what extent is the intervention coherent internally?*
- *To what extent is the intervention coherent with wider EU policy?*
- *To what extent is the intervention coherent with international obligations?*

3.6. Question 6: What is the EU added value of the intervention?

The evaluation should consider arguments about the value resulting from EU interventions that is additional to the value that would have resulted from interventions initiated at regional or national levels by both public authorities and the private sector.

The answer to this question should, where applicable, respond to the subsidiarity analysis conducted in any related IA. For spending programmes, EU added value may result from different factors e.g. co-ordination gains, improved legal certainty, greater effectiveness or complementarity. The analysis of EU added value is often limited to the qualitative, given the stated difficulties to identify a counter-factual.

EU-added value⁷⁶ looks for changes which it can reasonably be argued are due to EU intervention, rather than any other factors. In many ways, the evaluation of EU added value brings together the findings of the other criteria, presenting the arguments on causality and drawing conclusions, based on the evidence to hand, about the performance of the EU intervention and whether it is still justified.

The sources and nature of this additional value vary from intervention to intervention. It is, in particular, useful to distinguish the European added value of an EU policy measure in general (like an EU regulation to foster the single market) and that of an EU spending programme per se. In both cases, European added value may be the results of different factors: coordination gains, legal certainty, greater effectiveness, complementarities etc. In all cases, measurement is a challenge and the final judgement on whether expected added value would justify an EU intervention is ultimately the result of a political process.

In areas where the EU has exclusive competence, the appropriate answer to the question of EU added value may simply involve re-stating the reasons why the EU has exclusive competence or may already be answered by the efficiency and effectiveness analysis. Sometimes it may be necessary to question if the assumption of exclusive competence still holds or whether the needs have changed (see also common tool on subsidiarity/EU added value). In such instances, the evaluation may focus more strongly on consideration of the relevance and efficiency of the intervention.

Where there is little evidence of the EU added value of an intervention, consideration should be given to its repeal.

Typical examples of EU added value questions

- *What is the additional value resulting from the EU intervention(s), compared to what could be achieved by Member States at national and/or regional levels?*

⁷⁶ For further information see SEC(2011) 867 final "The added value of the EU budget".

- *To what extent do the issues addressed by the intervention continue to require action at EU level?*
- *What would be the most likely consequences of stopping or withdrawing the existing EU intervention?*

4. SUMMING IT ALL UP: THE EVALUATION STAFF WORKING DOCUMENT

The evaluation Staff Working Document (SWD) summarises and presents the final results of the evaluation process. It draws on work conducted:

- Exclusively by external contractors (via one or more reports)
- And/or the Commission Services.

The lead DG must take a position on the robustness of the process and findings, stating if necessary, where there are any disagreements and why.

The mandatory format for the evaluation SWD is provided in the Toolbox⁷⁷.

The evaluation SWD will communicate the results and conclusions of the evaluation: (i) to policy makers, helping to inform their decision making and (ii) to stakeholders, showing the method, evidence base and analysis used for the evaluation. It will draw together all the different steps of the evaluation process – answering the commitments made in the evaluation roadmap or explaining why this has not been possible, summarising and critiquing the method applied, the evidence collected and the analysis conducted, drawn from a wide range of sources. The evaluation SWD should be transparent, objective and balanced. Non-expert readers should be able to follow the arguments.

The process followed for the evaluation will influence the length of the evaluation SWD. Where the full body of work described in the evaluation roadmap has been outsourced to contractors, who have written up their process and findings as a separate report, the evaluation SWD should be no more than 15-20 pages excluding annexes. For all Fitness Checks and those evaluations which have had either limited or no support from contractors the main document is likely to be longer (50 pages maximum) as it will have to present the process, evidence and analysis in more detail.

In all instances, stakeholder views and how these have been considered should be transparently referred to throughout the evaluation SWD (and any supporting contractor's report) as well as summarised in an Annex. All external material used (reports, scientific findings etc.) should also be systematically referenced. To allow for an easily accessible overview of the headline findings from the evaluation, a short executive summary (recommended length three pages) must also be prepared and translated into EN, FR and DE.

For major evaluations, the Regulatory Scrutiny Board (RSB) will review the draft evaluation SWD and the related inter-service consultation cannot start before the RSB has issued its opinion. The package to be sent to the RSB will include the draft

⁷⁷ For further information see Tool "Staff Working Document for evaluation".

evaluation SWD and associated executive summary, the minutes of the last ISG meeting and where applicable the relevant contractors' report and associated Quality Assessment by the ISG.

5. USING THE EVALUATION RESULTS

Evaluation results should be assessed and, where relevant, be complemented by follow up actions to ensure maximum use of the results. Active discussion and debate on these findings should be encouraged.

5.1. Disseminating the evaluation findings

Evaluation is an opportunity to assess the performance of an EU intervention and feed any lessons learned into the next round of decision making in a timely manner. By conducting evaluations in a transparent manner the Commission is providing an account of its actions to all interested stakeholders and EU citizens. To maximise transparency and ease access:

- Any related contractors report must be published in the EU bookshop
- The final evaluation Staff Working Document, alongside the final evaluation roadmap, consultation strategy and related consultation documents, Terms of Reference and associated final contractors report (if applicable) and the opinion of the Regulatory Scrutiny Board (if applicable) must be published centrally

Further dissemination activities tailored to the needs of the different audiences who may wish to know about the evaluation and what it has concluded should also be considered⁷⁸.

5.2. Identifying the follow-up actions

Evaluation is not the end of the process. Completing the evaluation Staff Working Document and disseminating the evaluation findings should stimulate discussion and lead to the identification of appropriate follow-up actions to put into practice the lessons learned and feed the evaluation findings into the next cycle of decision making. The evaluation results must feed into the Annual Activity Reports and related follow up actions must be identified in the Annual Management Plans of the Commission Services.

Follow-up can take many forms, such as impact assessment or improving guidance or further monitoring. Identifying and sharing planned follow-up actions is part of accepting responsibility and accountability for EU actions and ensures transparency. It should also mean that evaluation findings are used and not simply filed on a shelf.

In many instances the immediate dissemination/follow-up to an evaluation is identified in the legal base of the intervention and takes the form of a Commission Report to Council and the European Parliament on the findings of the evaluation. In this instance, the Commission Report should be a short document, presenting the headline findings of the evaluation and presenting next steps (in varying detail depending on what is appropriate). The executive summary for the evaluation Staff Working Document could be the starting point for this report.

⁷⁸ Further information on dissemination can be found in Tool "Disseminating the evaluation findings".

Chapter VII

Guidelines on Stakeholder Consultation

Key requirements

- A simple consultation strategy identifying and targeting relevant stakeholders and evidence must be developed for each initiative, evaluation or Fitness Check and Green Paper.
- The consultation strategy and consultation documents must be discussed and agreed by the Inter Service Group (ISG) or, if no ISG is established, by the Secretariat General and any other associated service.
- Without prejudice to the exceptional circumstances outlined in box 1, a 12-week internet-based public consultation must be part of the consultation strategy for initiatives subject to impact assessments, evaluation and Fitness Checks as well as for Green Papers.
- Key elements of the consultation strategy should be outlined in the Roadmap/Inception IA.
- Stakeholders must be able to provide feedback on each Roadmap (including for evaluations) or Inception Impact Assessment, on legislative and policy proposals adopted by the College and for draft implementing and delegated acts⁷⁹.
- Any consultation activity (but not the provision of feedback opportunities) must fulfil the Commission's minimum standards for consultation, as outlined in these guidelines.
- A report outlining the overall results of the consultation work and providing feedback (synopsis report) must be published on the consultation website and, where applicable, added as an annex to the impact assessment/evaluation report. Such a report would also provide an occasion to summarise relevant feedbacks received in parallel.

1. INTRODUCTION

Who should read these guidelines?

All officials involved in the preparation of legislative or policy proposals or in their evaluation should read these guidelines including officials and managers who are responsible for ensuring the quality of stakeholder consultation in the lead DG.

More detailed guidance is also available in a separate "tool box" which accompanies this guide. This is aimed at those directly involved in preparing the various steps of stakeholder consultation.

Why does the Commission consult stakeholders?

The initial design, evaluation and revision of policy interventions benefits from considering the input and views provided by stakeholders, including those who will be directly impacted by the policy but also those who are involved in ensuring its correct application. Stakeholder consultation can also improve the evidence-base underpinning a

⁷⁹ For delegated and implementing acts certain exceptions apply, see section 4.1.

given policy initiative. Early consultation can avoid problems later and promote greater acceptance of the policy initiative/ intervention.

In addition, the Commission has a duty to identify and promote in its policy proposals the general public interest of the Union as opposed to special interests of particular Member States or groups or parts of society – hence the need to consult widely.

Box 1. Treaty provisions

- According to Article 11 of the Treaty on European Union⁸⁰, ‘the European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union’s actions are coherent and transparent’.
- Protocol No. 2 on the application of the principles of subsidiarity and proportionality annexed to the Treaty stipulates that ‘before proposing legislative acts, the Commission shall consult widely’.

2. SCOPE AND DEFINITION OF STAKEHOLDER CONSULTATION

Consultation is a formal process by which the Commission collects input and views from stakeholders about its policies.

Consultation is a continuous process and formal stakeholder consultations complement the Commission's broader interaction with stakeholders (e.g. meetings or exchanges or through existing permanent platforms for dialogue⁸¹).

The term 'stakeholder consultation' applies to all consultations with stakeholders in the process of preparation of a policy initiative or the implementation of an existing intervention.

It does not apply to:

- Inter-institutional consultations (e.g. reports from the EP, opinions from national parliaments etc.),
- Specific frameworks for consultation provided for in the Treaties or in primary legislation, such as
 - the consultation of the consultative committees in the context of the legislative process (Articles 304 and 307 TEU),
 - the consultation of social partners (Articles 154-155 TFEU)⁸²,
 - consultations in the area of environment (Regulation (EC) N° 1367/2006).
- Opinions provided by Committees under Comitology,
- Opinions provided by expert groups involved in the preparation of Delegated Acts,

⁸⁰ http://europa.eu/about-eu/basic-information/decision-making/treaties/index_en.htm

⁸¹ E.g. [Action Platform on Diet, Physical Activity and Health](#) (DG SANTE), Technical Platform for Cooperation on the Environment (DG ENV).

⁸² However, if after a social partner consultation, which did not lead to an agreement, a Commission proposal is foreseen, the stakeholder consultation guidelines apply. More details can be found in the 'Better Regulation Toolbox'.

- Stakeholder consultation preceding the submission of draft Delegated and Implementing Acts prepared by any EU agency or body to the Commission,
- Input from citizens in the context of the 'European Citizen Initiative' (Article 11 [4] of the TEU).

3. GENERAL PRINCIPLES AND MINIMUM STANDARDS FOR STAKEHOLDER CONSULTATION

Stakeholder consultation is governed by four principles and five minimum standards taking proportionality into account.⁸³ They are complemented and further defined by these guidelines.

Box 2: General principles and minimum standards for consultation

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

- (1) Participation:** Adopt an inclusive approach by consulting as widely as possible;
- (2) Openness and Accountability:** Make the consultation process and how it has affected policy making transparent to those involved and to the general public;
- (3) Effectiveness:** Consult at a time where stakeholder views can still make a difference, respect proportionality and specific restraints;
- (4) Coherence:** Ensure consistency of consultation processes across all services as well as evaluation, review and quality control.

These principles are complemented by **five Minimum Standards** that all consultations have to respect:

- A. Clear content of the consultation process ('Clarity'):** All communication and the consultation document itself should be clear, concise and include all necessary information to facilitate responses;
- B. Consultation of target groups ('Targeting'):** When defining the target group(s) in a consultation process, the Commission should ensure that all relevant parties have an opportunity to express their opinions;
- C. Publication:** The Commission should ensure adequate awareness-raising publicity and adapt its communication channels to meet the needs of all target audiences. Without excluding other communication tools, (open public) consultations should be published on the internet and announced at the "single access point"⁸⁴;
- D. Time limits for participation ('Consultation period'):** The Commission should provide sufficient time for planning and responses to invitations and written contributions;
- E. Acknowledgement of feedback ('Feedback'):** Receipt of contributions should be acknowledged and contributions published. Publication of contributions on the "single access point" replaces a separate acknowledgment if published within 15 working days. Results of (open public) consultations should be published and displayed on websites

⁸³ These general rules on how Commission services should consult are set out in the 2002 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, complemented by COM(2012) 746 and accompanying SWD(2012) 422 and by COM(2014) 368.

⁸⁴ "Your Voice in Europe": <http://ec.europa.eu/yourvoice/>.

linked to the "single access point" on the internet and adequate feedback given on how the results of the consultation have been taken into account.

4. WHEN IS STAKEHOLDER CONSULTATION REQUIRED?

Stakeholders should always be consulted when preparing a Commission legislative or policy initiative or when performing an evaluation or Fitness Check.

According to the working methods of the Commission 2014-2019⁸⁵ and accompanying instructions to the services, stakeholder consultations can in principle take place **throughout the whole policy cycle**. However, stakeholder consultations can only be launched for initiatives which have received political validation by the appropriate political level (cf. Chapter II on Planning).

As part of promoting greater transparency, stakeholders should be consulted or be able to provide feedback on the following⁸⁶.

Box 3: Mandatory consultation and feedback requirements

Mandatory open, internet-based public consultation (minimum 12 weeks)⁸⁷:

- Initiatives with impact assessments. Consultation is on the basis of consultation documents including questionnaires, background information, the Inception IA etc.;
- Evaluations. Consultation is on the basis of consultation documents including questionnaires and background information, the Roadmap, etc.;
- Fitness Checks. Consultation is on the basis of consultation documents, including questionnaires, background information, Roadmaps, etc.;
- Green Papers.

Stakeholders must be able to give feedback on:

- Roadmaps for Evaluations and Fitness Checks roadmaps (4 weeks), and Roadmap and Inception Impact Assessments (suggested timeline for feedback to be provided on a case by case basis taking in to account the expected timing of any subsequent consultation);
- Draft Delegated Acts and Implementing Acts (4 weeks)⁸⁸;
- Legislative or policy proposals adopted by the College and, where applicable, the accompanying impact assessments (8 weeks).

⁸⁵ C(2014)9004.

⁸⁶ For more details see "Summary of documents on which stakeholders are consulted or can provide feedback" in the Better Regulation toolbox. 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 particular document which will be considered in the further elaboration of the document or initiative.

⁸⁷ Without prejudice to the exceptional cases referred to in box 1 and in full respect of the general rules set out in COM(2002) 704. Accordingly, where several consultation steps are mandated as part of a process to elaborate an initiative, it is not necessary to conduct multiple 12-week consultations each time.

⁸⁸ Certain exceptions apply, see section 4.1.

4.1. Delegated Acts and Implementing Acts

The opportunity to provide feedback on delegated acts will apply with a limited number of exceptions. For implementing acts, the opportunity to provide feedback must be considered for acts adopted under committee control. However, several categories of exemptions apply and due to the varied nature of implementing acts the final decision should be made on a case-by-case basis. Delegated and implementing acts are now, as a general rule, included in Agenda Planning. When introducing the Agenda Planning entry, an indication should be given whether the opportunity for stakeholders to comment on the draft text is foreseen. This is in order to facilitate the preparation of a forward planning to inform stakeholders of the Commission's future intentions to seek feedback on particular delegated acts and implementing acts.

In certain cases, the Commission will not consult on draft delegated and implementing acts. These cases and the reasons are summarised in the table below:

Exceptions to the 4-week public consultation on Delegated/Implementing Acts⁸⁹:

Type	Reason	Examples
No (or limited) margin of discretion	Lack of policy alternatives	Acts implementing an international standards into EU law without any (or limited) discretion. Corrigenda
Drafts have been prepared by an EU agency or body and have been subject to full public consultation before being submitted to the Commission and for which the Commission does not have the intention to significantly modify them	Extensive consultation on the draft text has already taken place in a dedicated framework	Acts based on regulatory technical standards submitted by the European Banking Authority or by European Securities and Markets Authority
Urgency / emergency measures	Time limitations do not allow additional consultation period	Acts under the urgency procedure or other urgent acts, e.g. temporary exceptional support measures in the agricultural field, urgent/emergency measures addressing threats to public, animal or plant health.
Budgetary procedures and	Lack of policy	Decisions on work

⁸⁹ The table refers to delegated and implementing acts. This does not prejudice in any way the choice of instrument; certain types of acts such as those linked to budgetary procedures and programme management or individual authorisation decisions, can, by their nature, only be implementing acts.

Type	Reason	Examples
measures, programme management decisions	alternatives / implementation of agreements already decided on	programmes and selection and award decisions
Individual authorisation decisions / acts / decisions based on the assessment of compliance with legal requirements	Lack of significant impact, routine acts	Marketing authorisations in the pharmaceutical field or comparable authorisations, inclusions, amendments in the PDO&PGI register, (de) classification of control bodies
Temporary risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors	Temporary food safety measures
Based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency findings	Extensive consultation on the substance has already taken place in a dedicated framework	Areas in which agencies such as EFSA have given a scientific advise
Other duly justified reasons, eg.: <ul style="list-style-type: none"> • Involving business secrets or security threats • Influence on markets 	Public consultation not possible or not appropriate, eg. due to legal restrictions or practical constraints.	<p>Acts with confidential content (such as in the aviation safety or space area, Galileo)</p> <p>Acts relating to the common organisation of the markets in agricultural products, measures relating to aid to certain Member States</p> <p>Authorisations to Member States relating to own resource calculations</p>

5. WHO IN THE COMMISSION SERVICES IS RESPONSIBLE TO SET UP CONSULTATION ACTIVITIES?

The responsibility for running stakeholder consultations is decentralised to the Commission service responsible for the respective initiative. Commission services choose consultation tools and methods on the basis of consultation objectives, target groups and available resources, taking into account the key mandatory requirements set out in these guidelines.

Consultation strategies and consultation documents must be discussed and agreed by the **inter-service group (ISG)** established for the policy initiative⁹⁰. The inter-service group ensures that the consultation strategy and the various consultation activities are in line with the relevant requirements and monitors the quality of consultation activities, including where parts of them are outsourced. If no ISG is set up for a given initiative, the responsible Directorate General must consult and seek approval from the Secretariat General. The Secretariat General is responsible for launching all public consultations on the 'Your voice in Europe' website⁹¹.

In some cases, external consultants can support or even conduct the consultation work, but the lead service remains accountable for setting the scope and objectives of the consultation, its process, outcome as well as compliance with the Minimum Standards and requirements⁹².

6. HOW TO PREPARE AND CONDUCT A CONSULTATION - THREE INTERACTING PHASES

The consultation process can be structured into three interacting phases:

- (1) Establishing the consultation strategy;
- (2) Conducting consultation work;
- (3) Informing policy making.

Each phase consists of several consecutive steps which provide the framework for a high quality, transparent stakeholder consultation.

6.1. Phase 1 - Establishing a consultation strategy

Effective and useful consultation starts with a good planning of all consultation work that is to be conducted in the course of preparing an initiative (consultation strategy).

Consultation is not a one-off event, but a dynamic, on-going process that may vary in terms of objectives, target groups, methods and tools used and timing. It is important, therefore, to plan carefully and design a consultation strategy which:

- Covers all consultation activities that will be carried out;
- identifies the most appropriate consultation methods, tools and communication methods to announce the consultation;
- provides all relevant and interested stakeholder groups with the opportunity to express their views;
- endeavours to receive relevant input of highest possible quality;

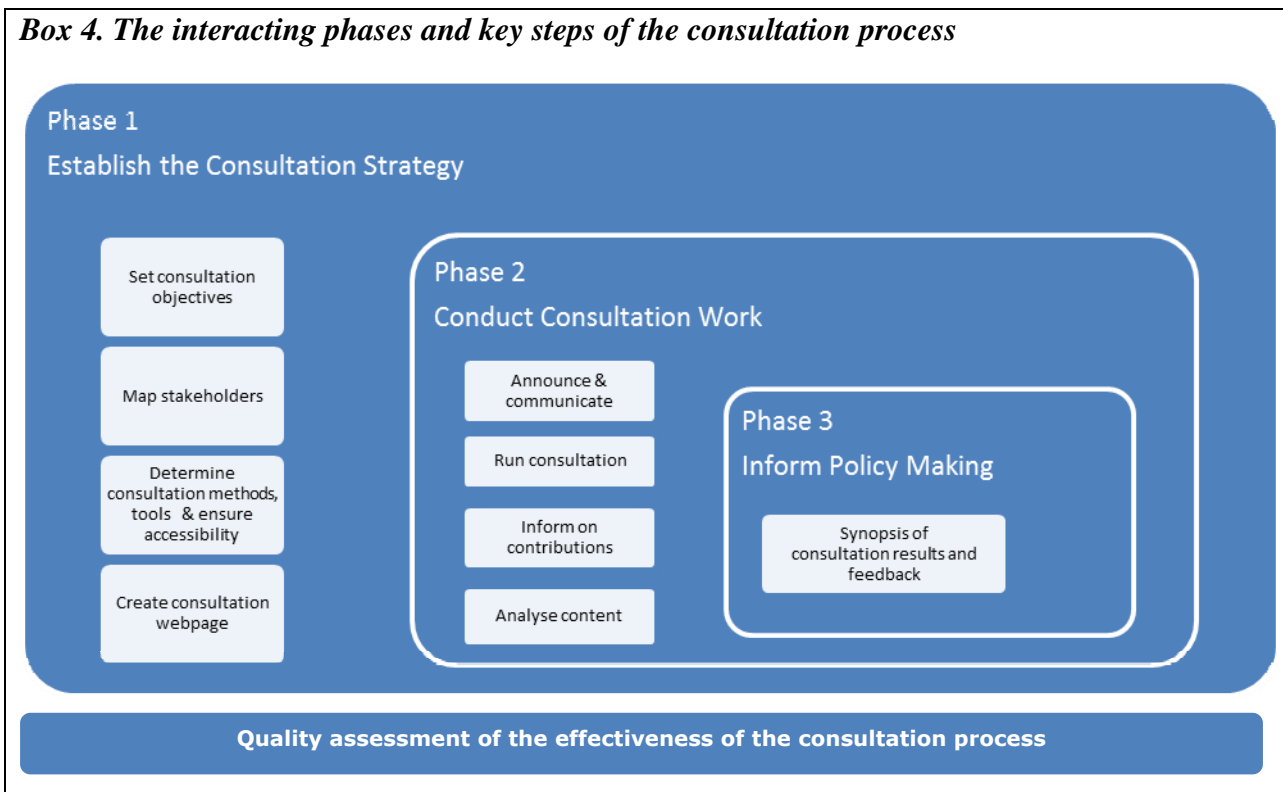
⁹⁰ See figure 2 in chapter II (Planning) for which initiatives an ISG should always be set up.

⁹¹ See the Better Regulation toolbox for more detail on the procedure for approval of consultation documents and for the launch of public consultations.

⁹² The Secretariat General organises training sessions on stakeholder consultation under the 'Ariane' training programme, which are highly recommended to staff involved in consultation activities.

- defines the required time and resources to carry out the different consultation activities;
- remains proportionate to the expected scope and impact of the initiative it supports and to the consultation objectives.

Box 4. The interacting phases and key steps of the consultation process



A consultation strategy is always case-specific and should be defined early in the planning process of the initiative, impact assessment, evaluation or Fitness Check. The consultation strategy may need to be adjusted throughout the policy preparation phase, in order to take into account policy developments or conclusions drawn from the application of other better regulation tools.

The consultation strategy should be outlined in the Roadmap, Inception IA or Evaluation Roadmap to provide advanced information to stakeholders on upcoming consultation activities, allowing them to prepare well or select consultations they want to participate in. The consultation strategy must, therefore, be discussed and endorsed by the ISG or associated services (cf. point 5 of this chapter) when finalising the Roadmap or Inception IA.

The consultation strategy⁹³ should cover the following elements:

- Step 1: Set consultation objectives;
- Step 2: Identify or "map" stakeholders;
- Step 3: Determine consultation methods, tools and ensure accessibility;
- Step 4: Create a consultation webpage.

⁹³ For details see tool on stakeholder consultation in the Better Regulation toolbox.

6.1.1. Step 1: Set consultation objectives

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

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

Based on the stage in the policy development process, the consultation objectives can be, for example, to gather new ideas⁹⁴, collect views and opinions⁹⁵, gather factual information, data and knowledge⁹⁶; and test existing ideas and analysis⁹⁷.

Issues to consider when defining consultation objectives
<ul style="list-style-type: none"> • The <i>context, scope and expected impacts of the initiative</i> and the <i>stage in the policy development process</i>.
<ul style="list-style-type: none"> • The <i>consultation background</i> of the initiative under preparation: <ul style="list-style-type: none"> • consultations that have already taken place; • future consultations that will take place after the current one and their respective objectives. <p>This should help identifying the information already available and the additional elements sought from the stakeholder consultation.</p>
<ul style="list-style-type: none"> • The <i>scope of the consultation</i>: <ul style="list-style-type: none"> • What items or aspects are the focus of a consultation at a particular stage of the procedure? • Where is it still possible to influence the outcome of the policy preparation, what items or aspects have already been decided?
<ul style="list-style-type: none"> • The difference between collecting views or opinions (subjective) and collecting data or facts (objective). <p>Clear <i>communication of the objectives</i> on the consultation web page and in the relevant consultation documents: transparency about the objectives of each consultation activity allows stakeholders to identify quickly and at minimum effort if the content of a consultation affects them or not, and its expected outcome will avoid mismatched expectations from the responding target groups and obtain the input that is being sought.</p>

⁹⁴ For example, identifying issues at stake, additional policy options, and possible (indirect) impacts.

⁹⁵ For example, opinions of respondents on a given topic, on the suggested EU level involvement in a given policy area, or views on the implementation arrangements for selected policy options.

⁹⁶ For example, examples/evidence/data/experience that would help to estimate or indicate the magnitude and scale of identified problems and their potential effects on the performance of existing policy

⁹⁷ For example, clarify whether the identified issues are perceived in the same way by relevant stakeholders/whether they are considered as priority for them, clarify possible impacts of a proposal, verify assumptions/hypothesis, validate existing information or analysis, as a form of external quality control; receive critical feedback on analysis or on suggested ways forward.

The scope of consultation will differ depending on the nature of the initiative, the timing and the context. For initiatives accompanied by Impact Assessments as well as for Evaluations and Fitness Checks, the scope must at least cover the following aspects:

Mandatory scope of consultations on Impact Assessments, Evaluations and Fitness Checks⁹⁸
<p>Initiatives accompanied by Impact Assessments⁹⁹:</p> <p>Stakeholders must be consulted on all IA elements in the IA process. The key issues which must be addressed are therefore:</p> <ul style="list-style-type: none"> • The problem to be tackled; • The issue of subsidiarity and the EU dimension to the problem, • The available policy options; and • The impacts of the policy options.
<p>Evaluations and Fitness Checks¹⁰⁰:</p> <p>It is essential to consult on the mandatory evaluation criteria, which are:</p> <ul style="list-style-type: none"> • Effectiveness of the intervention; • Efficiency of the intervention in relation to resources used; • The relevance of the intervention in relation to the identified needs/problem it aims to address; • Coherence of the intervention with other interventions which share common objective; and • The EU added value resulting from the intervention compared to what could be achieved by Member State action only.

6.1.2. Step 2: Map Stakeholders

An important element of any consultation strategy is to identify or map the stakeholder groups that should be consulted. This will help determine the most appropriate consultation methods and tools. Where available and useful, modern ICT tools to help catalogue, identify and reach stakeholder groups in a comprehensive manner.

⁹⁸ Where the evaluation and IA are done "back to back" it is possible to conduct only one open public consultation as long as relevant stakeholders are consulted on all the main elements of the IA. Where the evaluation is of an activity conducted outside the EU or where the internet is not a practical support tool, this mandatory open public consultation may be waived as long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. Before applying derogations, the DG must contact the Secretariat General.

⁹⁹ For details, see chapter III on Impact Assessments.

¹⁰⁰ For details, see chapter VI on Evaluations and Fitness Checks.

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

A successful stakeholder mapping involves¹⁰¹:
<ol style="list-style-type: none"> 1. Identification of stakeholder categories relevant for or interested in the concerned policy area(s), 2. Sorting stakeholder categories according to the level of interest in or influence on the concrete initiative that is to be consulted upon.

Identification of stakeholder categories relevant for or interested in the policy area

The key issue is to identify which stakeholder categories are relevant for the concerned policy area(s).

Services should build up knowledge on who has an interest in the policy area. They should also identify the persons and groups with expertise or technical knowledge in a given field and keep track of inputs made in earlier consultation exercises or less formal contacts and exchanges. Member States could also be invited to provide a list of interest groups for the concerned policy area within their countries.

Existing contacts (e.g. in mailing or distribution lists), subscriptions in the 'Commission at work notifications' and the 'Transparency register' or the track record of participants in previous consultations could be used as a starting point. Also advisory or expert groups or standing groups of stakeholders, established by Directorates General around a specific policy area could be considered, in particular for targeted consultations. Interservice Group members could also suggest new contacts. Due attention should be paid to data protection issues¹⁰².

Stakeholders categories (non-exhaustive list):	
Citizen/individual	
Industry/business/workers' organisations	<ul style="list-style-type: none"> • Multi-national/global • National • Small and Medium-sized Enterprises • Business organisation • Trade Union • Chamber of commerce
EU platform, network, or association	<ul style="list-style-type: none"> • Representing for-profit interests • Representing not-for-profit interests • Representing professions/crafts
Organisation/association	<ul style="list-style-type: none"> • National organisation representing for-profit interests • National organisation representing not-for-profit

¹⁰¹ See the tool on stakeholder consultations for guidance on stakeholder mapping.

¹⁰² For information on data protection rules see the Better Regulation toolbox.

	interests, <ul style="list-style-type: none"> • National organisation representing professions/crafts • International/ Inter-governmental organisation
Public authority	<ul style="list-style-type: none"> • EU institution • National government • National Parliament • Regional/ local/municipal authority • National competent authorities/agencies
Consultancy	<ul style="list-style-type: none"> • Think-tank • Professional consultancy • Law firm
Research/academia	<ul style="list-style-type: none"> • University • School & education establishment • Research institute
Other	

Sorting stakeholder categories according to the level of interest in or influence on the concrete initiative

Understanding the stakeholder type to which stakeholders belong helps identifying their potential level of interest or influence on the concrete initiative which is to be consulted upon. In turn, this supports the selection of the most appropriate consultation methods and tools.

Box 5: Stakeholder types

The Minimum Standards define three stakeholder types, those:

- Affected by the policy;
- Who will have to implement it;
- Who have a stated interest in the policy.

It is useful to distinguish between stakeholder categories, which the concrete initiative may affect (both directly and indirectly) in a significantly different way, e.g. consumers versus industry; those who will benefit versus those who will have to pay/to change their actions/behaviour etc..

Differentiation within a specific stakeholder category should also be examined. For example, businesses can be affected by the concrete initiative differently, depending on their size (e.g. micro, small or medium-sized business), location (including those in third countries), type of activity, whether they are public or private, incumbent operators or new entrants.

For a successful stakeholder mapping, the following aspects should be considered:

- **Identify target groups that run the risk of being excluded:** There might be differences between stakeholder groups regarding their access to consultations or availability of resources they can dedicate to participation in consultations. For

example, for rural areas with limited internet access, using different tools than an internet-based consultation can ensure wider participation.

- Seek **balance and comprehensive coverage**: social, economic and environmental bodies; large and small organisations or companies; wider constituencies (e.g. religious communities) and specific target groups (e.g. women, the elderly, the unemployed, ethnic minorities), organisations in the EU and those in non-member countries (e.g. candidate, associated or developing countries or major trading partners of the EU). It should also be recognised that similar stakeholder groups in different Member States may operate under different conditions, (such as for instance the local business environment and market or regulatory conditions) and may not always have similar interests.
- Identify if you have the need:
 - **For specific experience**, expertise or technical knowledge; or
 - **To involve non-organised interests**, as opposed to organised interested parties at European or Member States level.
- **Avoid 'regulatory capture'**: The same businesses/representative organisations should not always be exclusively consulted, as this increases the risk of listening to a narrow range of interests.
- **Use clear and transparent criteria for selection of participants**: For targeted consultations like meetings, conferences or other types of stakeholder events with limited capacity, a pre-selection of participants in the consultation event may be necessary.

6.1.3. Step 3: Determine consultation methods, tools & ensure accessibility

The most appropriate consultation methods and tools¹⁰³ depend on the objectives of the consultation, the identified stakeholders, the nature of the initiative as well as required time and resources.

A consultation strategy can foresee several consultation activities, using different consultation methods and tools, serving different purposes at different stages of the policy development process and **targeting different stakeholder categories**. Not all stakeholders must be addressed in every consultation activity.

Anticipate how contributions will be analysed in relation to the choice of the consultation method and designing the consultation tools;

The **overall result of the consultation will be the sum of various inputs received**, at various moments, through different methods and tools and from all participating stakeholders, all of which will inform the ultimate decision.

¹⁰³ See the Better Regulation toolbox' for an overview of possible consultation methods and tools.

Consultation methods

There is a general choice between open public or targeted consultations, depending on the consultation objectives and target group(s) identified through the stakeholder mapping:

- **Open public consultation** reaches a wide spectrum of respondents without, however, ensuring full representativeness. The relevance of opinions collected needs, therefore, to be thoroughly assessed¹⁰⁴. Open public consultations can foster transparency and accountability and ensure broadest public validation and support for an initiative.
- **Targeted consultations** allow more focused interactions or dialogue and may tap expertise more efficiently, in particular when dealing with a very specific or technical subject. Privileged access for some stakeholders should be avoided.

Consultation tools

The choice of the consultation method will determine the consultation tools. The consultation tools most commonly used are written consultations via consultation documents or questionnaires as well as direct interactions with stakeholders via meetings, conferences, hearings or other events¹⁰⁵.

The selection of the most appropriate consultation tool should take into account

- Proportionality;
- The degree of interactivity needed (e.g. written consultation versus stakeholder events/ online discussion fora/ other internet based tools);
- Accessibility considerations (language regime, disability etc.)¹⁰⁶; and
- Timing requirements.

In practice, effective consultation often requires a combination of written consultation tools (used for both open public and targeted consultations) and more direct interactions with stakeholders.

If the consultation should provide statistically representative results, then particular tools should be foreseen, such as surveys (e.g. Eurobarometer).

¹⁰⁴ Average response rates have been rather low in the past which requires efforts to raise stakeholders' awareness about the public consultation.

¹⁰⁵ Specific tools exist to reach particular groups, such as SMEs: the Small Business Act Follow-Up meetings with stakeholders or SME Panel Consultations run by DG GROW, or, platforms of the Committee of the Regions and the Economic and Social Committee etc.

¹⁰⁶ See tool on stakeholder consultation for more detail.

Mandatory timeframes for consultation and feedback		
<i>Mandatory open, internet-based public consultation:</i>	<i>How long?</i>	<i>When?</i>
<ul style="list-style-type: none"> • Initiatives with impact assessments • Evaluations • Fitness Checks 	Minimum 12 weeks ¹⁰⁷	Decision on case-by-case basis
<ul style="list-style-type: none"> • Green Papers 		After adoption by the Commission
<i>Stakeholders must be enabled to give feedback on:</i>	<i>How long?</i>	<i>When?</i>
<ul style="list-style-type: none"> • Roadmaps for Evaluations and Fitness checks 	4 weeks	After publication
<ul style="list-style-type: none"> • Roadmaps, Inception Impact Assessments 	Indication to be provided	After publication
<ul style="list-style-type: none"> • Draft Delegated Acts¹⁰⁸ 	4 weeks	After conclusion of the Inter-Service-Consultation in parallel with Member State experts.
<ul style="list-style-type: none"> • Draft Implementing Acts¹⁰⁹ 	4 weeks	After conclusion of the Inter-Service-Consultation and before the vote in the Comitology Committee
<ul style="list-style-type: none"> • Legislative or policy proposals adopted by the College and, where applicable, the accompanying impact assessments 	8 weeks	After adoption by the Commission

6.1.4. Step 4 - Create a consultation webpage

Establish a consultation webpage on the DG's websites for the policy initiative under preparation and publish the consultation strategy, including the planned dates of the various consultation activities, as soon as known. Dates for consultations will also be included in the Commissions' Consultation Planning Calendar, compiled by the SG based on information received from the DGs and to be published on 'Your Voice in Europe'.

Add and up-date all information about the various consultation activities linked to a given initiative. Communication relating to a consultation should be clear and concise.

Specific sub-pages for the various consultation work should be created (e.g. open public consultation, stakeholder conference etc.).

¹⁰⁷ Without prejudice to the exceptional cases referred to in box 1 and the general rules set out in COM(2002) 704.

¹⁰⁸ Certain exceptions apply, see section 4.1.

¹⁰⁹ Certain exceptions apply, see section 4.1.

The link to an **open public** consultation webpage will be posted on the 'Your voice in Europe' website which is available in all official EU languages.

In order to ensure consistency and user-friendly access to information, the standard consultation page template should be used¹¹⁰. A vade mecum with explanatory notes on how to prepare the standard consultation page is available on the internal Commission website¹¹¹.

6.2. Phase 2 – Conduct the consultation work

Once the consultation strategy has been endorsed by the ISG (Phase 1), the various consultation activities can be launched. For each consultation activity, the following steps should be followed:

- Step 5: Announce and communicate;
- Step 6: Run consultation;
- Step 7: Inform on contributions;
- Step 8: Analyse content.

6.2.1. Step 5 – Announce and communicate

Announce the launch of a planned consultation activity on the dedicated website and ensure that the advertisement chosen is adapted to all target audiences. Services should use those communication channels which are most appropriate to reach the relevant target groups.

The consultation target group(s) should be clearly specified in the consultation document and on the consultation web page.

¹¹⁰ For further information, please see the Better Regulation toolbox.

¹¹¹ <https://myintracomm.ec.europa.eu/corp/sg/en/stakeholder/Pages/template.aspx> .

Box 6. Ways to publicise the consultation

- Press conference, including issuing a press release and/or the possibility of a more in-depth briefing for journalists;
- Mid-day express and newsletters;
- Speeches delivered during relevant events;
- Placing announcements in relevant publications; adding links on web sites and proposing articles for either general and/or more specialized media;
- Commission's blogs and social media;
- Commission Representation in the Member States could also be a distribution point, as well as DG COMM which can provide useful input and resources;
- Other 'intermediaries' through which information can be spread are the Permanent Representations to the EU and the Member States' expert groups; invite Member States to publicise on national/regional/local websites;
- If an open public consultation is launched, certain stakeholders will be automatically alerted via their registration with the Transparency Register or the Notifications system of the Commission¹¹².
- Contacting interested parties or organizations¹¹³

6.2.2. Step 6 – Run the consultation and provide acknowledgment

The practical organisation and facilitation of the consultation needs full attention. There should be sufficient staff foreseen to reply to questions, solve technical problems and process the contributions.

Consultation documents

All consultation documents need to be endorsed by the ISG or, for open public consultations for initiatives for which no ISG exists, by the Secretariat-General.

The quality of consultation documents determines the quality of contributions and thus the quality of input to policy making.

It is good practice to **test consultation documents** (e.g. presentations, surveys or questionnaires) with some test persons who were not involved in the drafting. These should be as closely as possible resembling the actual target audience of the consultation or sub-groups of this target-audience.

The purpose of this testing is to find out whether the target group will find the consultation documents easy to understand and practical to use. Test persons can for instance be colleagues in other units, other DGs or stakeholder groups who can give their

¹¹² <https://webgate.ec.europa.eu/notifications/homePage.do?locale=en>

¹¹³ Organisations representing the interest of SMEs can be alerted also through the Small Business Act Follow-Up meetings managed by DG GROW.

personal critical feedback on how to improve the documents further, e.g. the European Enterprise Network if the consultation targets also individual SMEs.

Stakeholder identification and Transparency Register

It is important to mention clearly in the consultation notice that the identity of stakeholders and their interests should be mentioned in order to ensure consideration of the contribution¹¹⁴. You should make sure that the personal and background information requested by respondents before they can reply will allow you analysing replies by any of the stakeholder categories you target (e.g. if individual SMEs cannot identify themselves as such in their reply, you will not be able to analyse their replies separately).

Organisations, networks, platforms or self-employed individuals engaged in activities aiming at influencing the EU decision making process are expected to register in the Transparency Register. During the analysis of replies to a consultation, contributions from respondents who choose not to register will be treated as individual contributions (unless the contributors are recognized as representative stakeholders through Treaty provisions¹¹⁵).

Acknowledgement of receipt

Written contributions can be provided under different forms such as (e-)mail, web tools or social media. Whenever stakeholders provide written contributions to any type of consultation, it is best practise to send an acknowledgement of receipt and provide information as to when the contributions are likely to be published. If contributions are sent by e-mail or using social media platforms, these same channels can be used to acknowledge receipt. To minimize work, individual or collective acknowledgments of receipt could be automatically generated at the entry point.

In case contributions are published within 15 days after closure of the consultation activity, the publication will replace a separate acknowledgment of receipt. If the 15-days' limit cannot be respected, reasons for the delay should be explained on the website and a new deadline should be indicated.

6.2.3. Step 7 – Inform about contributions

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

Publication of contributions on the webpage

After a consultation has ended, the contributions made by stakeholders should be published. Contributions should be published in the languages in which they were submitted and/or the language used for the consultation activity.

Written contributions should be made public on the dedicated consultation webpage. In the case of stakeholder consultation events (meetings, hearings, conferences, etc.), summary minutes and speeches or presentations provided during the event should be made public on the consultation webpage.

¹¹⁴ See also box 5 under step 4, bullet on Transparency Register

¹¹⁵ European Social Dialogue, Art. 154-155 TFEU

According to the relevant data protection rules¹¹⁶, respondents have the following options:

- Publication of the contribution with personal information;
- Anonymised publication of the contribution (without the name/ name of the organization);
- No publication but use of the contribution for statistical and analytical purposes.

Inform on key issues of the contributions

It is good practice to prepare and publish on the consultation website a short document summarising the key issues raised in each of the separate stakeholder consultations foreseen in the consultation strategy (e.g. informal report, minutes of a stakeholder meeting, list or table of contributions). This is particularly useful where consultation activities are spread out over a longer period of time and will facilitate the preparation of the final synopsis report which should summarise the results of all consultation activities undertaken.

The summary documents of consultation activities help increase transparency and provide the basis for further analysis and feedback to stakeholders on how the consultation has informed policy making.

Summarise contributions	
Give a concise and balanced overview of contributions received during a specific consultation activity	
Give factual information on input received	<ul style="list-style-type: none"> • Who contributed? • Whom are they representing? • What aspects are addressed? • What are their views and concerns? • Which communication channels were used for contributions?
Stay neutral	<ul style="list-style-type: none"> • Document the input as received: Avoid qualifying it, taking position or giving feedback
Aggregate at an appropriate level	<ul style="list-style-type: none"> • Cluster information
Inform on the process	<ul style="list-style-type: none"> • Inform on what was done so far in terms of consultation activities and on the next steps
Add Disclaimer	<ul style="list-style-type: none"> • Emphasise that the contributions received cannot be regarded as the official position of the Commission and its services and thus does not bind the Commission.

¹¹⁶ See Better Regulation toolbox.

6.2.4. Step 8 - Analyse content

Once consultation work is completed, the input received for each consultation needs to be thoroughly analysed.

Keep in mind that responses to consultations are generally not statistically representative of the target population: Ratios can generate a false perception of representativeness and can thus lead to wrong conclusions. If you need statistically representative input, use an appropriate consultation method (e.g. surveys).

The way of presenting results should be objective and unbiased.

A brief descriptive overview of contributions should be complemented by a qualitative assessment.

Brief descriptive overview of the profile of respondents

Based on simple descriptive data, an overview of the profiles of respondents can, for example, provide information on:

- The distribution of respondents across Member States and/or third countries;
- The distribution of respondents by stakeholder category;
- The distribution across any other dimension (e.g. clustering by sector) that might be relevant for the specific consultation or where similar trends in replies or particular concerns can be observed.

Analysis based on substance/content of responses (qualitative)

Examine content of contributions:

- Do the contributions respond to the questions/expectations?
 - Compare the input with the objectives of the consultation, as defined in the consultation strategy and identify replies unrelated to the consultation topic.
 - Distinguish between information (data/facts) and subjective opinions and views provided by respondents. Where possible, the source and reliability of data/facts needs to be verified.
- Are there views that strongly diverge from the mainstream view?
- Do the contributors match up with the list of stakeholder target groups? If not, is additional consultation necessary?

Provide a qualitative appreciation of the responses and the respondents:

- Respondents' involvement and interest in the policy,
- the way they benefit or are impacted by the policy
- if they reply on their behalf or if they represent some specific interests,

- to which extent and how their contribution has been consolidated (i.e. stakeholder organisations should as a good practice describe how they organised their internal consultation and come up with a consolidated reply).

Presentation of the analysis

(i) Analysis on the basis of the different stakeholder categories

This approach would be appropriate when consulting many different stakeholder groups with differing and potentially conflicting views on a few issues:

- Distinguish the main stakeholder categories – the brief descriptive overview builds already the basis for this.
- Distinguish within the main stakeholder categories e.g. if similar response profiles can be identified (geographical-Member State group 1 and Member State group 2; citizens–students and citizens–retired; or industry-producer, intermediary, distributor etc.)
- Once broken down by stakeholder category, identify the nature of the responses, e.g.:
 - Do they support/oppose/suggest modifications to a certain policy measure?
 - Do they provide new ideas? Do they suggest an alternative approach?
 - Do they provide further information/facts of the impact of a policy measure?
 - Can the information/facts be considered objective? How reliable is the provided information/facts (identify source and reliability)

The relative importance of this analysis should result from the consultation objectives in the consultation strategy (Phase 1).

(ii) Analysis on the basis of the different consultation topics

This approach would be suitable when many issues are discussed and fewer stakeholders with potentially less differing or conflicting views consulted.

- Identify the main issues that stem from the replies to the consultation
- Distinguish between the views of main stakeholder categories, for each of these issues and identify the nature of responses (e.g. facts vs opinions). The questions could be structured as indicated under (i).

6.3. Phase 3 – Inform policy making and provide feedback

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

6.3.1. Step 9 – Synopsis of entire consultation results

Adequate feedback should be provided to stakeholders. It is critical for those participating in stakeholder consultations to know how, and to what extent, their input has been taken into account and to understand why certain suggestions could not be taken up in the policy formulation. Providing effective feedback will contribute to the overall transparency of the Commission's policy-making, enhance the Commission's accountability and credibility, and potentially solicit better responses to future consultations.

Synopsis report

At the end of the consultation work, an overall synopsis report should be drawn up covering the results of the different consultation activities that took place.

The synopsis report must consist of the following elements:

- Documentation of each consultation activity undertaken on the same initiative including, if applicable, reasoning as to how and why the consultation strategy outlined in the Roadmap / Inception IA has been altered,
- Information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached,
- Description of the results of each consultation activity, if different consultation activities have been undertaken on the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions,
- For ad hoc contributions received outside the formal consultation context, a description of the origin of the contributions received including identification of the type of stakeholder and their represented interests,
- Feedback on how the results of the consultation have fed into policy making.

The synopsis report should not exceed 10 pages and be made available in all languages in which the consultation was published on the consultation website.

The synopsis report should accompany the initiative through Inter Service Consultation to adoption of the initiative by the Commission. If the consultation has taken place in the context of an Impact Assessment or Evaluation, the synopsis report is also annexed to the IA or Evaluation report.

Explanatory memorandum

For legislative proposals, the explanatory memorandum should reflect how far the main contributions have been taken into account in the draft policy initiative and if not, substantiated why not.

Give the reasons for the options chosen:

- Report why certain options were discarded (especially when those were widely supported by the respondents);
- Highlight the link between respondents'/participants' input, impact assessment or any other factor that justifies the options the Commission proposes.

7. QUALITY CONTROL

Internal quality assessment of the consultation process

With the view to improve future consultations, it is good practice to carry out a proportionate internal quality assessment of the consultation process. The conclusions should be shared with the services involved in the inter service group or, in case no ISG has been established, with the services associated for the initiative, including the SG.

Assessment of the effectiveness of the consultation strategy

An end-of-process survey addressed to all consulted parties could help gauge the depth of stakeholder satisfaction with the process, as well as with the final outputs and outcomes. This could also help to identify best practices, learn from past experiences and to reap the benefits of a well-organised consultation process. A summary of the outcome of this survey should be published on the consultation webpage established for the initiative.

The assessment of the consultation strategy should help answer three questions:

- (1) Did the consultation strategy work? (E.g. did it reach its target groups, did it meet its objectives, how effective and efficient were the different tools, and how relevant were the responses collected and what was their impact?)
- (2) Did the process work? (E.g. what worked well and less well, how satisfied were stakeholders participating in the consultation, which are the lessons to be drawn for the future?)
- (3) What impact did the process have? (E.g. on participants, on the outcome, on policy makers?)

Chapter VIII

The content of the Better Regulation Toolbox

The different chapters in this Better Regulation guideline are complemented by the following tools¹¹⁷ which provide more detailed information.

General principles of Better Regulation	
1	Principles of Better regulation
2	Evidence gathering
3	Subsidiarity and proportionality
How to carry out an impact assessment	
4	When is an impact necessary?
5	What steps should I follow for an IA?
6	IA for spending programmes and financial instruments
7	IA requirements for social partner agreements
8	Format of the IA report
9	How to undertake a proportionate IA?
10	Stakeholder consultation in the context of an IA
11	How to analyse problems
12	Risk assessment and management
13	How to set objectives
14	How to identify policy options
15	The choice of policy instrument
How to identify impacts in Impact Assessments, evaluations and Fitness Checks	
16	Identification/Screening of Impacts
17	Impacts on sectoral competitiveness
18	Impacts on Research and Innovation
19	The SME test
20	Impacts on Competition
21	Impacts on the Internal market
22	Impacts on external trade and investment
23	Impacts on ICT, the digital economy and society
24	Fundamental Rights & Human Rights

¹¹⁷ http://ec.europa.eu/smart-regulation/index_en.htm

25	Impacts on Employment, working conditions, income distribution and inequality
26	Impacts on education, culture and youth
27	Impacts on health
28	Impacts on consumers
29	Territorial impacts
30	Impacts on developing countries
31	Impacts on resource efficiency
Implementation, transposition and preparing proposals	
32	The Implementation Plan
33	Transposition checks
34	Drafting the explanatory memorandum
Monitoring implementation	
35	Monitoring arrangements and indicators
Evaluations and Fitness Checks	
36	What is an evaluation and when is it required?
37	Preparing for an evaluation
38	Planning: The (5 year) rolling evaluation plan
39	Setting up an inter-service steering group
40	Establishing an evaluation roadmap
41	Designing the Evaluation
42	Identifying the evaluation criteria and questions
43	What key impacts must be considered?
44	Stakeholder consultation in the context of Evaluation
45	Conducting the evaluation
46	Completing the Quality Assessment
47	The Evaluation Staff Working Document
48	Disseminating the evaluation findings
49	Follow up action plans
Stakeholder consultation	
50	Stakeholder consultation tools
Methods, models and costs and benefits	
51	Typology of costs and benefits
52	Methods to assess costs and benefits
53	The Standard Cost Model for estimating administrative costs
54	The use discount rates

55	Useful analytical methods to compare policy options or assess performance of existing interventions
56	The use of analytical models in IA or evaluation
57	Multi-criteria analysis
58	Life Cycle analysis
59	Use of visual aids

Glossary

<i>Term</i>	<i>Meaning</i>
<i>Agenda Planning</i>	Agenda planning (AP) is the Commission's tool for managing and tracking the most important initiatives which proceed to adoption by the College. AP entries provide information about timing and content, adoption procedure, a link to Roadmaps (where applicable) and indicate whether an Impact assessment (IA) and/or Implementation Plan (IP) is being prepared.
<i>Application</i>	Application means actually putting the requirements of legislation into daily practice after it has entered into force. EU Regulations apply directly from their date of entry into force, the rules laid down in EU Directives will apply only from the date of entry into force of the national legislation which has transposed the EU Directive into national law. Application covers transposition and implementation.
<i>Consultation</i>	Consultation describes a process of gathering feedback, comments, evidence or other input on a particular intervention from other entities either from within the Commission (interservice consultation) or from outside the Commission (stakeholder consultation).
<i>Consultation Strategy</i>	A Consultation strategy sets out one or more approaches to ascertain the views of stakeholders about a given issue. The strategy identifies relevant stakeholders for a new initiative under preparation by the Commission and defines the appropriate methods, tools and timing of consultation activities. For example, web-based public consultation may be complemented by approaches such as workshops, meetings, letters etc. The Roadmap informs about the Consultation strategy.
<i>Evaluation / Evaluation report</i>	Evaluation is an assessment of the effectiveness, efficiency, coherence, relevance and EU added-value of one single EU intervention. The Roadmap informs about evaluation work and timing. An evaluation report (SWD) is prepared by the lead service and presents the findings and conclusions about the evaluation. The quality of <i>major</i> evaluation reports is checked by the Regulatory Scrutiny Board against the requirements of the relevant guidelines prior to publication and/or transmission to the Legislator as part of a formal report from the Commission.
<i>Fitness check / Fitness check report</i>	A Fitness check is an evaluation of the effectiveness, efficiency, coherence, relevance and EU added-value of a number of related EU interventions in a policy area/business sector. It identifies excessive burdens, inconsistencies and obsolete or ineffective measures and helps to identify the cumulative impact of legislation. A Fitness check report (SWD) is prepared by the lead service which presents the findings of the Fitness check. The quality of <i>major</i> Fitness check reports is checked by the Regulatory Scrutiny Board against the requirements of the relevant guidelines prior to publication and/or transmission to the Legislator as part of a formal report from the Commission.
<i>Gold-plating</i>	Gold-plating describes a process by which a Member State which has to transpose EU Directives into its national law, or has to implement EU legislation, uses the opportunity to impose additional requirements, obligations or standards on the addressees of its national law that go beyond the requirements or standards foreseen in the transposed EU legislation.
<i>Impact</i>	In an impact assessment process, the term impact describes all the changes which are expected to happen due to the implementation and application of a given policy option/intervention. Such impacts may occur over different timescales, affect different actors and be relevant

	at different scales (local, regional, national and EU). In an evaluation context, impact refers to the changes associated with a particular intervention which occur over the longer term.
<i>Impact Assessment / Impact Assessment report</i>	Impact Assessment is an integrated process to assess and to compare the merits of a range of policy options designed to address a well-defined problem. It is an aid to political decision making not a substitute for it. The Roadmap informs whether an impact assessment is planned or justifies why no impact assessment is carried out. An impact assessment report is a SWD prepared by the lead service which presents the findings of the impact assessment process. It supports decision making inside of the Commission and is transmitted to the Legislator following adoption by the College of the relevant initiative. The quality of each IA report is checked by the Regulatory Scrutiny Board against the requirements of the relevant guidelines.
<i>Implementation</i>	Implementation describes the process of making sure that the provisions of EU legislation can fully enter into application. For EU Directives, this is done via transposition of its requirements into national law, for other EU interventions such as Regulations or Decisions other measures may be necessary (e.g. in the case of Regulations, aligning other legislation that is not directly touched upon but affected indirectly by the Regulation with the definitions and requirement of the Regulation). Whilst EU legislation must be transposed correctly it must also be applied appropriately to deliver the desired policy objectives.
<i>Implementation Plan</i>	An implementation plan is a SWD that is prepared to support the implementation by the Commission and the Member States of certain new Directives and Regulations. It accompanies any impact assessment and the proposal itself. It identifies implementation needs and actions required of different entities to ensure a timely, effective and consistent implementation. The Roadmap informs if an Implementation plan is established.
<i>Inception Impact Assessment</i>	The inception Impact Assessment is the initial description of the problem, its underlying drivers, the policy objectives, policy options and the economic, social, environmental impacts of those policy options. It provides a comprehensive basis for stakeholders to provide feedback, information and opinions.
<i>Interservice (steering) group</i>	An interservice group is a group of Commission representatives from more than one DG or service who discusses priority cross-cutting issues and steers and monitors elements of the policy making process that require the interaction of more than one DG or other Commission service. Interservice steering groups are required for the preparation of major initiatives, entailing impact assessments, stakeholder consultations, evaluations and Fitness Checks.
<i>Initiative</i>	An initiative is a policy instrument prepared at EU level to address a specific problem or societal need. An impact assessment will assess options to inform the policy content of the initiative.
<i>Intervention</i>	Intervention is used as umbrella terms to describe a wide range of EU activities including: expenditure and non-expenditure measures, legislation, action plans, networks and agencies.
<i>Intervention logic</i>	The intervention logic is the logical link between the problem that needs to be tackled (or the objective that needs to be pursued), the underlying drivers of the problem, and the available policy options (or the EU actions actually taken) to address the problem or achieve the

	objective. This intervention logic is used in both prospective Impact Assessments and retrospective evaluations.
<i>Monitoring</i>	Monitoring describes the process of tracking the implementation and application of EU legislation by the Commission or the progress of spending programmes.
<i>REFIT</i>	REFIT is the European Commission's Regulatory Fitness and Performance programme launched in December 2012. Under REFIT, action is taken to make EU law simpler, lighter, more efficient and less costly, thus contributing to a clear, stable, least burdensome and most predictable regulatory framework supporting growth and jobs.
<i>Regulatory Scrutiny Board</i>	A body inside the Commission which scrutinises draft impact assessment reports and major retrospective evaluations and issues opinions with a view to improving their quality or providing guidance for the future.
<i>Roadmap</i>	A roadmap is a tool to substantiate the political validation of an initiative the Commission is preparing and, to inform stakeholders about planned consultation work, impact assessments, evaluations, Fitness Checks. It is published at an early stage by the Secretariat General on the Commission's web site and helps stakeholders prepare timely and effective inputs to the policy making process.
<i>SME</i>	SME is the abbreviation for micro, small and medium-sized enterprises (SMEs). SMEs are defined in Commission Recommendation 2003/361 as enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.
<i>Stakeholder</i>	Stakeholder is any individual or entity impacted, addressed or otherwise concerned by an EU intervention.
<i>Transposition</i>	Transposition describes the process of incorporating the rights and obligations set out in an EU Directive into national legislation, thereby giving legal force to the provisions of the Directive. The Commission may take action if a Member State fails to transpose EU legislation and /or to communicate to the Commission what measures it has taken. In case of no or partial transposition, the Commission can open formal infringement proceedings and eventually refer the Member State to the European Court of Justice.