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COMMISSION STAFF WORKING DOCUMENT

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Determining when and how EU action should be undertaken, reviewed or repealed is ultimately a political choice.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, measures and financial programmes.

Box 1. How to apply these Guidelines

- The Guidelines and associated better regulation "Toolbox" should be applied in a proportionate manner using common sense. The aim is not to respect procedural requirements per se but to ensure that the Commission is equipped with relevant and timely information on which to base its decisions. Similarly, the depth of analysis should 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. Exceptions to these requirements are possible but must validated and justified externally.

- There may be cases where it is not possible or 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 cases, there may be a political imperative to move ahead quickly, an emergency that requires a rapid response, a need to adhere to specific deadlines in legislation which cannot be respected on the basis of a normal planning or a need to protect security-related or confidential information.

- For major initiatives, exceptions from the Guidelines can be requested at the time the initiative undergoes political validation (via D*e*cide). For other initiatives (and for cases arising after validation), requests for exceptions should be sent to the Director responsible for smart regulation in the Secretariat-General who will decide in consultation with the First Vice-President. The following functional mailbox should

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be used for such requests: **SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu**

- Whenever relevant, 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 or inception impact assessment). The Toolbox provides more information on exceptions.

- Questions about their interpretation or application can be obtained from the responisble units in the Secretariat-General using the functional mailboxes below:

Aspects of better regulation	Functional mailbox
Planning	**SG-PLANNING@ec.europa.eu**
Evaluation & fitness checks	**SG-EVALUATION-AND-SIMPLIFICATION@ec.europa.eu**
Impact assessment	**SG-IMPACT-ASSESSMENT-GUIDELINES@ec.europa.eu**
Stakeholder consultation	**SG-STAKEHOLDER-CONSULTATION@ec.europa.eu**
Feedback mechanisms	**SG-STAKEHOLDER-FEEDBACK@ec.europa.eu**

- To avoid undue delays and to maximise 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 continuously monitor the impact of the better regulation Guidelines and propose, if needed, ways to eliminate any source of administrative burden or undue procedural delay based on experience. 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 regulatory 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; DGs must ensure that appropriate centres of expertise (or functions) and training are available to support the proper implemention of 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[2] 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

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[1]   COM(2015)215

[2]   The Commission has a policy on data, information and knowledge management which helps support policymaking by maximising the use of data (SWD(2016) 333). In this context, the EU Open Data Portal is important as a source and repository of open data.

where necessary at EU level and in a way that does not go beyond what is needed to resolve the problem. Better regulation also provides the means to mainstream sustainable development into the Union's policies.

Better regulation applies to new and to existing initiatives. Through evaluations and other means, the Commission is constantly collecting and analysing information about the performance of the Union's policies. The aim is to ensure that objectives continue to be met without imposing unnecessary costs on society. As such, any proposal to revise existing legislation must look at whether there is potential to simplify and to reduce regulatory costs but without undermining the aims or benefits of the legislation. Where no simplification or cost reduction is possible, this must also be reported. The Commission's Regulatory Fitness programme (REFIT) provides a framework for this work.

Better regulation covers the whole policy cycle – policy design and preparation, adoption, implementation (transposition, complementary non-regulatory actions), application (including monitoring and 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 policy possible. These relate to planning, impact assessment, stakeholder consultation, implementation and evaluation.

Figure 1. The EU Policy cycle
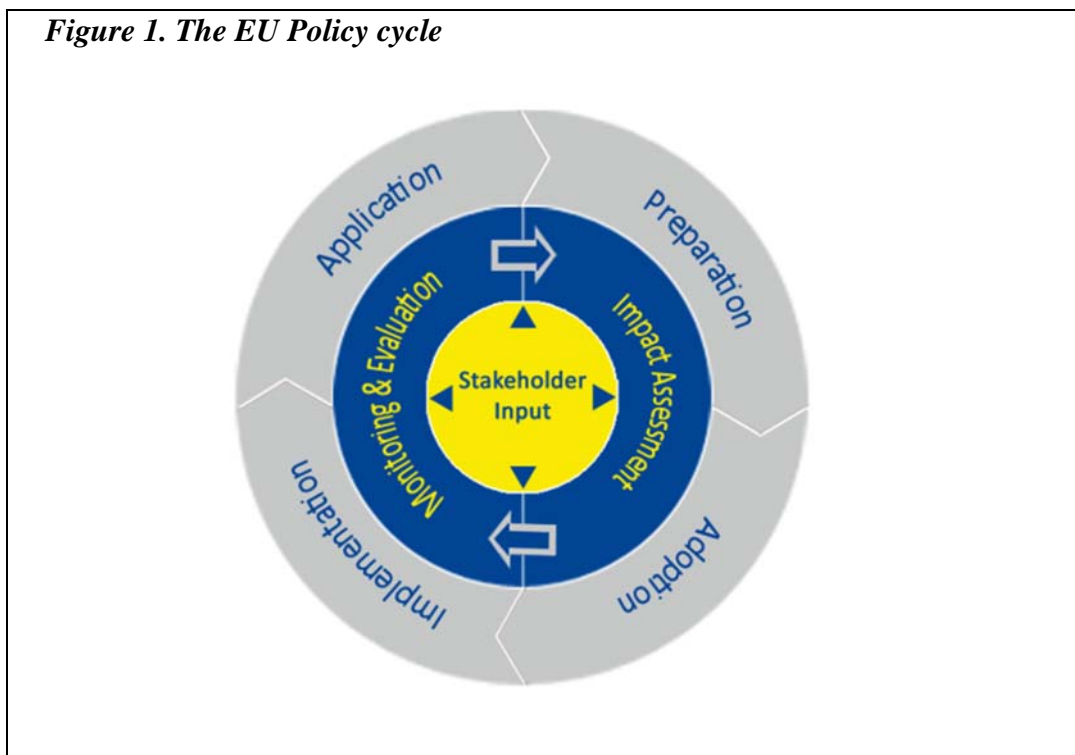
The different phases are closely interrelated and to recognise better the connections and to ensure greater coherence, the previously separate guidance documents have been brought together into a single streamlined and integrated better regulation guide. These Guidelines replace the previous standalone guidelines which addressed separately impact

assessment, evaluation, implementation and also include new guidance on planning and stakeholder consultation[3].

Better regulation is a shared commitment of all of the EU institutions. An Interinstitutional Agreement on Better Law-Making[4] was signed by the European Parliament, the Council and the Commission on 13 April 2016. It replaces the previous agreement from 2003 and the interinstitutional accord on impact assessment from 2005. The agreement addresses annual and multi-annual programming as well as all aspects of the policy cycle. The agreement sets out the various commitments of the three institutions to deliver high-quality Union legislation which is efficient, effective, simple, clear and which avoids overregulation and administrative burdens for citizens, public authorities and businesses, especially SMEs. More detailed information has been prepared to guide its implementation in the Commission.[5]

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 guidelines[6] and the Commission's annual work programmes[7]. 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, the active engagement with stakeholders and the preparation of initiatives including translation[8]. These activities take time, need resources to deliver timely results and require a level of political validation proportionate to the nature of the inititiave under consideration.

The first step in the planning process is therefore to define the scope of the planned initiative and seek the appropriate level of political validation to develop the idea further. D*e*cide is the main planning tool used in this process[9]. The details on which initiatives must be uploaded in D*e*cide, and on which validations are required, are provided in the instructions of the Secretary-General[10] which complement the Working Methods of the

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[3] 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.

[4] OJ L 123, 12.5.2016, p.1.; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC

[5] https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/IIABL.aspx

[6] http://ec.europa.eu/priorities/docs/pg_en.pdf

[7] http://ec.europa.eu/atwork/key-documents/index_en.htm

[8] Communication (2016) 2000 describes the role of translation in the Commission's decision-making process including the limits on document length and translation deadlines.

[9] D*e*cide is the Commission's IT platform for managing the preparation of initiatives.

[10] https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx

European Commission 2014-2019.[11] They are outlined in detail in Chapter II on Planning and in the associated Toolbox.

Box 2. Scoping, political validation and interservice work

- **Political validation** is required to move beyond the informal consideration of a possible initiative and to start the substantive prepatory work including engagement with stakeholders.

- The level of political validation depends on the nature and importance of the inititiave. **"Major initiatives"** should, in principle, be entered into D*e*cide 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. "Other initiatives" should be validated by the lead Commissioner or by the Director-General of the lead DG as appropriate.

- <u>Political validation must be understood as giving the green light to start the substantive preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudges the outcome of any impact assessment process, stakeholder consultation or later political discussion in the College.</u>

- For major initiatives and for evaluations (including fitness checks), once political validation is granted, **roadmaps** or **inception impact assessments** must be finalised and published as quickly as possible. They explain to external stakeholders what the Commission is considering and allow them to provide early feedback.

- **Roadmaps** are used for initiatives which do not require an impact assessment. The reasons justifying the absence of an impact assessment will be included.

- **Inception impact assessments** are used for initiatives subject to an impact assessment. These set 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.

- A roadmap is prepared for each **evaluation or fitness check**. This specifies the context, scope and purpose of the evaluation and outlines the proposed approach.

- All roadmaps (including for evaluations and fitness checks) and inception impact assessments are published by the Secretariat-General on the Commission's website[12] so that citizens and stakeholders are informed and can provide initial feedback (including data and information they may possess) on all aspects of the intended initiative and where applicable its impact assessment.

- Evaluations, impact assessments, stakeholder consultations, policy proposals and implementation plans must be discussed collectively by the services[13] within **an**

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[11] C(2014)9004; http://ec.europa.eu/transparency/regdoc/rep/3/2014/EN/3-2014-9004-EN-F1-1.Pdf

[12] http://ec.europa.eu/info/law/better-regulation/initiatives

[13] 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

> **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 and innovation, SME impacts, economic, social impacts, environmental impacts and scientific/analytical methods).
>
> - The launch of the interservice consultation must be agreed politically (in a similar way to the validation of new initiatives). In addition, where an initiative is supported by an impact assessment, a positive opinion of the Regulatory Scrutiny Board is required in order for the initiative to be presented to the Commission for decision.

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 to support evaluations, impact assessments, the preparation of initiatives and political decisions. It is good practice to plan stakeholder consultations using a simple, concise consultation strategy that identifies and targets relevant stakeholders with a range of conultation activities in order to gather 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 secure an inclusive approach where all interested parties have the opportunity to contribute to the timely development of effective policies. Consultation activities should allow reasonable time for respondents in order to encourage informed and effective contributions from all relevant stakeholders. Feedback should be given to respondents about how their information and views were used. Public consultation is an essential element of all impact assessments, evaluations and fitness checks.

3.3. Evaluation/fitness checks

Policy preparation should be supported by both evaluations and 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 policymaking at the Union level.

Evaluations gather evidence to assess how 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 and/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.

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 the 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, assess the impacts of these options and describe how the expected results will be monitored. The Commission's impact assessment system follows an integrated approach that assesses the environmental, social and economic impacts of a range of policy options thereby mainstreaming sustainability into Union policymaking.

3.5.   Quality control

Staff working documents (SWD) 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 fitness checks and selected evaluations. The Board issues opinions based on the requirements of these Guidelines. DGs are expected to modify their reports to reflect the Board's opinion. For initiatives supported by impact assessments, the Commission's working methods stipulate that a positive opinion is needed from the Board before an interservice consultation can be launched. The 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 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 'implementation plans' (in the form of a 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.

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.

The Secretariat-General is responsible for the preparation of the better regulation Guidelines. 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

- Political validation at the appropriate level[14] is required before substantive work on an initiative can start in earnest and for stakeholders to be engaged. In most cases, this requires a valid entry in D*e*cide[15] (c.f. point 3 below). No public consultation or interservice consultation should be launched for initiatives which have not been politically validated.

- "Major" new initiatives require political validation from the lead Commissioner, Vice-President and First Vice-President following an entry created in D*e*cide. In principle, this should be at least 12 months prior to the envisaged adoption date. Once the initiative is validated, a roadmap or inception impact assessment should be prepared, agreed with the Secretariat-General, and published as rapidly as possible.

- "Other" initiatives also require a D*e*cide entry and they are directly validated by the responsible Commissioner or the Director-General of the lead DG. This should happen at least 3 months ahead of adoption with the exception of evaluations and fitness checks which need to be validated 12 months ahead of the envisaged completion date. As a general rule, evaluations and fitness checks also require the publication of a roadmap.

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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 cycle[16] and on the basis of the political priorities[17] of the Commission President and the Commission work programme (CWP)[18].

Effective and efficient EU action starts with good and timely planning. New initiatives including evaluation work must receive political validation *before* the substantive 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 start the substantive preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudges the outcome of any impact assessment process or later political discussion in the College.**

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[14] More detailed information is provided in the Toolbox and GoPro about the classification of initiatives and the planning and political validation processes.

[15] D*e*cide is a tool designed to help the Commission screen and manage the flow of initiatives in line with the President's Political Guidelines
https://intragate.ec.europa.eu/decide/sep/entrance?Lizard_v3.0.28.10251-2016-12-14T09:38:52.639+01:00#/welcome-screen/

[16] https://myintracomm.ec.europa.eu/sg/spp/Pages/index.aspx

[17] http://ec.europa.eu/priorities/docs/pg_en.pdf

[18] http://ec.europa.eu/atwork/key-documents/index_en.htm

> **Substantive work may start and the necessary resources attributed only if political validation has been obtained from the appropriate level.**

2.   POLITICAL VALIDATION FOR THE DIFFERENT TYPES OF INITIATIVES

It is the responsibility of each Directorate-General to consider carefully if its envisaged initiative needs corporate validation (either as a "major" or "other" initiative - see Table 1 below) and whether the initiative needs a D*e*cide entry or not.

If a D*e*cide entry is created, the lead DG needs to set out clearly the key aspects of any proposed initiative, such as the political importance and sensitivity, the magnitude of the expected impacts, relevant links with other policy areas and prior knowledge about divergent or sensitive stakeholder views. The scope of the information to be provided (via the relevant fields in D*e*cide) and the required level of detail depends on the type of intiative and the required politcal validation. The information entered into D*e*cide should be concise but sufficiently detailed to support the political validation process.

Table 1. Political validation of initiatives and linked requirements				
Initiative type		Who validates?	Roadmap or inception IA?	ISG needed?
"Major" initiatives (*Decide entry at least 12 months prior to adoption*)	All major initiatives	FVP & VPs & Commissioner in close collaboration with the President	Yes	Yes
"Other" non-major initiatives (*Decide entry*)	Initiatives which are neither "major" nor evaluations or fitness checks (*Decide entry at least 3 months before adoption*)	Commissioner	No	No
	Evaluations & fitness checks (*Decide entry at least 12 months before completion*)	DG (*Management plan*)	Yes	Yes
Initiatives handled outside D*e*cide		DG	No	No

When creating a D*e*cide entry with a view to submitting the envisaged initiative for political validation at the appropriate level, the following questions should be answered in each case:

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- Is the initiative **"major" or "other"**?[19] This information is the starting point to guide the level of the ensuing political validation. In case an initiative is entered as "other", a clear and meaningful justification should be provided;

- What are the **key characteristics** (type) of the initiative? (evaluation or new initiative, legislative/non-legislative/or not yet determined, legal basis, Commission work programme item or not, envisaged adoption date, etc.);

- What are the **scope and the objectives** of the initiative? What is the problem the initiative seeks to tackle and the objectives it aims to achieve? What is the political context and how would the initiative contribute to established political priorities?;

- Why **should the EU act**? Why can the Member States not achieve the objectives by themselves? What is the value added of EU action (subsidiarity principle)?;

- Which **better regulation tools** are envisaged (evaluation, impact assessment, implementation plan and public consultation)? Which tools are not envisaged and why?

Methodological advice regarding the selection of the appropriate type of act can be sought via the functional mailbox SG HELPDESK PROCEDURES. For advice concerning the inclusion of an initiative in D*e*cide, either as "major" or "other" initiative, questions can be addressed to the functional mailbox SG PLANNING. GoPro and the Secretariat-General's planning website (MyIntracomm) also provide useful information.

The scope and format of roadmaps and inception impact assessments are further explained in the Toolbox.

In addition to selecting the right procedure, good planning also implies taking account of the time needed to meet the various procedural requirements including scrutiny by the Regulatory Scrutiny Board, political validation to launch the interservice consultation and the time needed for translations[20].

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[19] More information is provided on the handling of "major" vs "other" initiatives in the Toolbox and in GoPro.

[20] C(2016) 2000 sets out the page limits, language regimes and translation deadlines.

Figure 1: Planning and validation in the policy development process

① CWP = Commission Work Program - ② IP = Implementation Plan - ③ RSB= Regulatory Scrutiny Board - ④ FC=Fitness checks _ _ _ = where applicable

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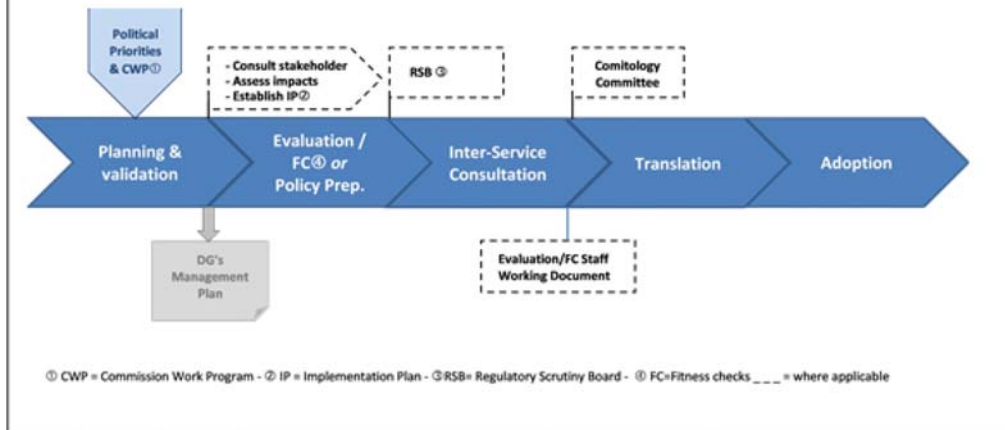
Chapter III
Guidelines on impact assessment

Key requirements

- IAs must set out the logical reasoning that links the problem (including subsidiarity issues), its underlying causes, 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.

- IAs must compare the policy options on the basis of their economic, social and environmental impacts (quantified costs and benefits whenever 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 following the "SME test" in the Toolbox; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.

- Initiatives supported by an impact assessment (IA) must have a validated entry in D*e*cide, an inception impact assessment published for stakeholder feedback. An interservice group (ISG) must also be established to steer the preparation of the IA. This ISG may be chaired by the lead DG or by the Secretariat-General for politically important files. 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.

- The draft IA report must be presented to the Regulatory Scrutiny Board for its scrutiny.

- A positive opinion of the Board is necessary before a formal interservice consultation can be launched. The RSB will generally only issue two opinions.

- The IA report must be complemented by a 2 page executive summary sheet available in all languages.

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1.   INTRODUCTION

Who should read these Guidelines?

All officials involved in preparing 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 Toobox. 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 linked to the preparation of an impact assessment.

What is an impact assessment and when is it required?

The impact assessment process is about gathering and analysing evidence to support policymaking. 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.

Impact assessment 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, impact assessment is only an aid to policy-making/decision-making and not a substitute for it.**

All new financial interventions which entail significant expenditure (in excess of €5 million) should be accompanied by an ex-ante evaluation as required by the Financial Regulation. The major programmes of the multi-annual financial framework will generally be accompanied by impact assessments which fulfil the requirement for an ex-ante evaluation but which also entail consultation of stakeholders and scrutiny by the Regulatory Scrutiny Board.

> **An impact assessment 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 initiative[21].

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 and seek confirmation through the political validation process.** Following validation, an **inception IA should be prepared by the lead DG and agreed by the Secretariat-General. It is then published as early as possible by the Secrtariat-General on the Commission's web site[22] with a view to inform stakeholders and seek their feedback**.

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.

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

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[21] See Tool #9 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.).

[22] http://ec.europa.eu/info/law/better-regulation/initiatives

(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. It is recommended that a member of the lead DG's impact assessment support service participate in the ISG;

(2)   Following publication of the inception IA on the Commission's website, stakeholders will be able to provide feedback and evidence in relation to the problem, possible policy options and their likely impacts and subsidiarity considerations. This feedback needs to be considered and integrated into the work of the ISG as appropriate;

(3)   The preparation of a consultation strategy by the ISG including a mandatory 12-week internet-based public consultation[23]. The consultation strategy should ensure that stakeholders' views are sought on all key impact assessment questions;

(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 (RSB) 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 interservice 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 that supports a new initiative. The timing and organisation of the two processes may need to be carefully planned therefore.

An IA report presents the final results of the impact assessment process and accompanies the draft initiative through the Commission decision-making process. The Commission's **Regulatory Scrutiny Board** scrutinises the quality of all draft IAs and issues one or more opinions on the draft IA report which are also available during the decision-making process. A positive opinion of the RSB is required before an initiative can proceed.

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

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[23]   Where the evaluation and IA are prepared in parallel ("back to back") it is possible to conduct only one public consultation as long as relevant stakeholders are consulted on all the main elements of the IA.

2. THE KEY QUESTIONS AND PRINCIPLES OF IMPACT ASSESSMENT

Impact assessment 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 be of a high quality[24].

The questions an impact assessment should answer	
1.	*What is the problem and why is it a problem?*
2.	*Why should the EU act?*
3.	*What should be achieved?*
4.	*What are the various options to achieve the objectives?*
5.	*What are their economic, social and environmental impacts and who will be affected?*
6.	*How do the different options compare (effectiveness, efficiency and coherence)?*
7.	*How will monitoring and subsequent retrospective evaluation be organised?*

The process of finding answers to these questions is necessarily iterative. The 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.

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[24]   See details in Tool #1 on *Principles, procedures and exceptions*.

(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-related issues. The conclusions of the IA report should be supported by the analysis of stakeholder views and justification given where there are any significant differences. The synopsis report summarising the results of stakeholder consultations 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 policymakers 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 definition of the problem and its underlying causes (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 size and 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. These evaluations will also describe issues related to the application of Union law such as infringements and other problems related to the existing intervention.

A problem can be caused by several factors, such as the existence of market failures, behavioural biases, regulatory inefficiencies or a failure to respect fundamental rights. A problem may already have negative consequences or simply present a risk of such conceequences. 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 size and 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 policymakers 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 that 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 subsidiarity[25], i.e. Union action should be necessary and deliver added value compared to the actions of the Member States at central, regional or local levels.

In areas outside its exclusive competence, the IA should verify whether EU action 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 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 principle[26].

The following key questions should be reviewed when assessing whether or not the subsidiarity principle is respected: 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 to action taken solely at the level of the Member States due to its scale or effectiveness.

This assessment is likely to be an iterative process. Preliminary analyses in the inception impact assessment 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

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[25] See Article 5 of the Treaty on European Union.

[26] http://ec.europa.eu/dgs/secretariat_general/relations/relations_other/npo/

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.

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.

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, what the initiative aims to achieve 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 (such as simplification and improved efficiency of existing interventions);

- 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;

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

Objectives should be as S.M.A.R.T.[27] 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

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[27] Specific, Measurable, Achievable, Relevant and Time-bound.

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

When designing the policy options, <u>always</u> 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 as well promoting the principles of eGovernment[28];

- The option of improving implementation and enforcement of existing legislation; or simplifying existing legislation, or improving the efficiency of existing interventions by reducing unecessary regulatory costs (including administrative costs);

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[28] For example, the eGovernment Action plan 2016-2020 COM(2016) 179 and the principles of "digital by default", "once-only" and "cross-border by default".

- Options that take account of new technological developments and ICTs to lower the costs of implementation whilst ensuring timely data availability. All new initiatives should be "digital and internet ready" and operate effectively both in the digital and the physical worlds[29];

- Alternative policy approaches: e.g. different policy content or approaches to reach the objective;

- Alternative policy instruments: e.g. non-regulatory alternatives; self- or co-regulation[30]; market-based solutions, regulatory alternatives; international standards[31], or a mix;

- Alternative scope: for instance, is the "think small first" principle taken into account; are micro-enterprises excluded from the scope of any proposed legislation[32].

Consider options which have been proposed by stakeholders[33] and/or are likely to be proposed during the legislative process but do not discard *a priori* options with little support or facing strong opposition[34].

(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 go beyond 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**.

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[29] Adaptive Governance and Internet inclusive Legislation

[30] See the principles for better self- and co-regulation in the Toolbox and at https://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice; and the community of practice: https://ec.europa.eu/digital-single-market/en/community-practice-better-self-and-co-regulation

[31] 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.

[32] 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*.

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

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

- "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 can 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 improve them further. 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 and innovation, 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, policymakers should know to what extent different policy 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 finalising.

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 actions realistically be taken in practice (for example, risks of non-compliance may high if compliance costs for business are substantial but this risk may be reduced if public authorities are obliged to promote 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. Failure to identify a significant impact may affect the overall comparison of options or weaken the case for the Commission's proposal later on.

Where relevant, the impact assessments should examine the impact of the different options on fundamental rights and the potential exposure to fraud in the context of spending programmes. In the Interinstitutional Agreement on Better Law-Making,[4] the Commission has also committed to identify the costs and/or missed benefits of not acting at Union level (the "cost of non-Europe"[35]). This will complement the assessment of EU added value undertaken in the context of any preceding evaluation or fitness check.

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.

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[35] Where no Union legislation exists, the "cost-of non-Europe" are the potential benefits which are forgone by deciding not to introduce new Union legislation. In other cases, where Union legislation already exists, the cost of non-Europe would be the benefits forgone if that legislation is repealed.

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 reusing what exists already should not be overlooked. A "digital screening" and possible further ICT impact analysis may be needed.[36]

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 subcomponents (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;

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[36] See Tool #27 on *The digital economy and society & ICT systems*

- 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 qualitatively and quantitatively whenever possible[37]. Quantification of impacts will not be possible in all cases but it is expected that efforts are systematically made for REFIT initiatives.[38] This allows a more transparent presentation of the benefits arising from simplification and measures to reduce unnecessary burdens that do not undermine policy objectives. Similarly, impacts should be monetised 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 results[39].

There are several methods to quantify impacts, both in terms of overall methodological approach[40] 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 ideal 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 monetise, or quantify, some impacts does not mean they should not be taken into 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 and the reasons for not having undertaken quantification

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[37] 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.

[38] See Tool #2 on *The Regulatory Fitness programme and the REFIT Platform.*

[39] Ranges of outcomes or confidence interval should then be provided rather than precise results.

[40] For instance, general vs. partial equilibrium approaches, bottom up vs. top down methods.

explained in the IA report. 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 evidence[41], including on illustrative examples, while also referring to stakeholder views. They should acknowledge limits and clearly distinguish between facts, expert opinions and stakeholder views. If a broad order of magnitudes cannot be given, 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 ongoing 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 monetised 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 <u>and</u> for affected parties. Potentially disproportionate impacts (e.g. on fundamental rights, on SMEs[42], 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

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

[42] See Tool #22 on *The SME test* (impacts on SMEs).

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 summarise and present the results of the impact analysis in way which is accessible to the non-specialist. 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 policymakers 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 multicriteria 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 monetised (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);[43]

- The coherence of each option with the overarching objectives of EU policies (coherence).

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[43]   Alternatively, the extent to which objectives can be achieved for a given cost (cost effectiveness).

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?

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, policymakers 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 cost 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. The Interinstitutional Agreement on Better Law-Making[4] envisages a more systematic use of monitoring and evaluation provisions in basic acts to measure the performance of Union legislation and to improve the quality of subsequent evaluations and impact assessments.

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.

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. The IA report should be transparent, objective and balanced as it helps inform the Commission's decision-making and presents the evidence base underpinning the Commission's decision. Annexes should be used for the more detailed and technical parts of the analysis. The report should be presented as a Staff Working Document. A template for the format of the impact assessment report can be found on the relevant pages of GoPro.

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 should be sufficient accompanied by annexes as appropriate.

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.

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

It is useful to check the consistency of the legal proposal or initiative with the conclusions of the impact assessment. 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 certain 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? Has the recast technique been considered for proposed amendments to existing legislation (see Chapter IV)? Do the draft provisions 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?;

- Have potential impacts on innovation been considered?

- Has the need to include monitoring and evaluation provisions been considered (see Chapter V)?;

- Do the draft legal provisions take into account the challenges and opportunities offered by developments in ICTs (e.g. simplified monitoring and information reporting, reduced administrative burdens, etc.)?;

- 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, developing countries, 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 have committed themselves in the Interinstitutional Agreement on Better Law-Making to discuss its content and quality as well as to provide additional analyses to support any substantive amendments they propose and to take full account of any additional materials the Commission may make available.

Chapter IV
Guidelines on preparing proposals, implementation, and transposition

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Key requirements

- Implementation plans (in the format of a 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 a high quality legal text and explanatory memorandum.

- The Commission must justify in its proposals when it requires the Member States to provide explanatory documents to help it to carry out its task of overseeing the transposition of Directives.

- 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 (correct transposition).

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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*[44], 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 guidance 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

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[44] Article 291 (1) TFEU.

implementation of EU law. This chapter complements the subsequent chapter which deals with how to monitor the application/effects of Union policies.

2. ANTICIPATE IMPLEMENTATION PROBLEMS AND FACILITATE TRANSPOSITION: IMPLEMENTATION PLANS[45]

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. Enforcement costs for public authorities may vary substantially between policy options.

- 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 by 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 potential backlogs) and costs for the use of the judicial system which falls on public authorities.

The stakeholder 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 States[46].

Pursuant to the Interinstitutional Agreement on Better Law-Making[4], the European Parliament, the Council and the European Commission have committed themselves to promote greater transparency about "gold-plating". This should be achieved by providing information in the national transposing measure itself or in complementary materials

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[45] This guidance replaces the guidance provided by the Annex II of the Note dated 7/01/2013 (Ares(2013) 12012).

[46] Article 288 TFEU

notified by the Member States to the Commission. The Commission cannot insist that such information be provided.

When is an implementation plan needed?

An implementation plan (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 directives with a limited or very technical scope or which do not require transposition measures[47], 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.

Interservice consultation on the implementation plan

The preparation of an IP should be flagged in D*e*cide before launching an interservice consultation. If no IP is planned, this should be justified in D*e*cide. The Secretariat-General will verify and if necessary discuss justifications. The IP should be prepared as a staff working document and accompany the proposal in interservice consultation and as background to the discussions in the institutions. More guidance is provided in the Toolbox[48].

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 Toolbox along with additional information on how to prepare Commission guidance related to implementation of Union law by the Member States.

Where appropriate, the implementation plan should be updated after adoption of the act by the Legislator to reflect important changes that will affect how the legislation is to be transposed and implemented by the Member States.

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[47] For example, Directives updating provisions related to (inter) institutional issues such as comitology.

[48] See Tool #36 on *The implementation plan.*

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 legislation[49] and on the use of codification[50] and recast[51] techniques have established a common approach.

The Joint Practical Guide for people drafting European Union legislation[52] builds upon the agreed principles. In addition, the Quality of Legislation team in the Legal Service has developed the Drafters' Assistance Package (DAP)[53] 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 2. *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

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[49]   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).

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

[51]   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).

[52]   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

[53]   http://www.cc.cec/wikis/display/dap/Home

immediately codifying the new amendments with the existing provisions of the earlier act. It results, therefore, 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.

The Commission has given a commitment to the European Parliament and the Council to make greater use of the recast technique when preparing amendments to Union legislation[54].

Services should always consider using the recast technique when amending existing legislation. Advice should be sought at an early stage in the preparation of a new initiative from the Legal Service when determining whether recast is appropriate in a given case. In particular, the Legal Service's quality of tegislation team can offer guidance and practical assistance[55]. More information is also available in DAP. The translation of recast proposals is more demanding and more time is needed to translate into all language versions.[9]

What is codification?

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. The distinctive feature of codification is that, in contrast to recast, no substantive changes may be made to the earlier act.

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 governed by the Interinstitutional Agreement on an accelerated working method for official codification of legislative texts. **In addition, where the recast technique is not appropriate, the Commission has agreed systematically to present a proposal for codification as soon as possible after the adoption of an amending act unless it presents reasons for not doing so.[56]**

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.

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[54] Pursuant to the §46 Interisntitutional Agreement on Better Law-Making

[55] SJ juristes-reviseurs@ec.europa.eu

[56] Purusant to §46 Interinstitutional Agreement on Better Law-Making;

The Commission is committed to the use of **common commencement dates** for EU regulations and decisions affecting businesses generally. Proposed Decisions, Regulations and delegated acts 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 3. 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 envisage when and how *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[57]

The purpose of the explanatory memorandum is to explain the Commission's proposal. It is required for all legislative proposals and non-legislative proposals for adoption by the Council or by the EP and the Council[58]. It is transmitted to the other Institutions together with the accompanying proposal and is available to the public. The explanatory 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 policy:

- **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 it necessary to achieve the objectives).

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[57] See Tool #38 on *Drafting the explanatory memorandum*.

[58] A simpler explanatory memorandum also exists for delegated acts which are not directly covered by this guideline although elements of the Guidelines and tool may still be relevant. In addition, there are templates adapted to initiatives taken pursuant to Article 218 TFEU (see GoPro and MyIntracomm).

Explain the choice of instrument and why it is considered the most suitable act for achieving the objective.

- Summarise results of any **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, publicly available information).

- To explain why **no impact assessment** has been prepared where one would have usually been prepared according to these Guidelines[59].

- **Impact assessment**:

  - How the impact assessment has been revised to reflect the opinion(s) 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:**

  - 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 minimises 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.[60]

- **Implementation plans, monitoring, evaluation and reporting arrangements:** Refer to the implementation planning associated with the measure, including the monitoring, evaluation and reporting framework to be applied to assist with its

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[59]   See Tool #9 on *When an IA is necessary*.

[60]   See Tool #27 on *The digital economy and society and ICT systems.*

implementation and application and to report on its performance. Alternatively, explain why no implementation plan is necessary.

- **Explanatory documents (for directives):** Explain if the proposal requires explanatory documents on the transposition and why (see later section).

4.   DELEGATED ACTS AND IMPLEMENTING ACTS

The Interinstitutional Agreement on Better Law-Making contains a common understanding on the use of delegated acts (see Chapter I, section 2). This sets out the standard legal provisions which should be used to draft empowerments in basic acts as well as the steps to be followed when preparing new delegated acts and the control mechanisms for the European Parliament and the Council. The key commitment is that experts from the Member States are consulted on each draft delegated act and that the European Parliament and the Council are kept informed and can send experts to the relevant expert group meetings preparing the delegated act.

A legal framework is aleady in place for implementing acts and the respective procedures and control mechanisms[61]. Better regulation principles apply to the preparation of delegated and implementing acts as specified in these Guidelines and the Toolbox.

In addition, the Commission has decided that the draft legal texts of delegated and implementing acts (subject to certain exceptions) will be put onto the Commission's web site in order to allow stakeholders to provide feedback during a period of 4 weeks. Further details can be found in separate guidance in relation to delegated and implementing acts[62] as well as in the toolbox.

5.   THE LINK BETWEEN EU LAW AND MEMBER STATE TRANSPOSING MEASURES: EXPLANATORY DOCUMENTS[63]

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 a Member State's legislation links with EU legislation[64].

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

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[61]   Regulation (EU) 182/2011, OJ L 55, 28.2.2011, page 13.

[62]   https://myintracomm.ec.europa.eu/sg/comitology/Pages/index.aspx

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

[64]   The policy is contained in: (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 and (3) point 44 of the Interinstitutional Agreement on Better Law-Making).

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 issues to consider are similar to those when considering whether to prepare an implementation plan.

The Commission should weigh up the following:

- 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 initative being prepared?

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:

- 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.

The Commission has also committed to justify, to the European Parliament, those cases for which it will not request explanatory documents. Although such justification may be shorter than those cases requiring explanatory documents, they should nonetheless be based on the considerations mentioned above.

Justification for explanatory documents in Commission initiatives

For all new proposals for Directives, and draft delegated acts, a justification should be prepared as part of the explanatory memorandum on why explanatory documents are requested (or not).

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

"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.With regard to this Directive, the Legislator considers the transmission of such documents to be justified."

In cases where the services propose to request explanatory documents, a standard recital should directly be included in the directive adopted by the Commission as a delegated or implementing act:

"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 as delegated or implementing acts, the justification for explanatory documents should be provided orally during discussions with the member States (i.e. in the expert groups for delegated acts and comitology committees for implementing acts). This can then be reflected in the summary record of the committee meeting).

If Member States fail to provide explanatory documents the responsible Commission service is encouraged to contact the competent national authorities and invite them to fulfill their obligation.

6.   MONITORING IMPLEMENTATION

Compliance assessment[65]

The Commission is committed to more systematic monitoring of the implementation of legislation.[66],[67] This is done, inter alia, by conducting compliance assessments of both transposition and conformity of Directives. Compliance assessment is two-staged:

First, the services carry out a **transposition check (completeness),** assessing the status of the transposition of the directive concerned. If Directives are not completely

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[65]   This term covers transposition and conformity check

[66]   C(2016) 8600, OJ C18, 19.1.2017, p 10. EU Law: Better results through better application.

[67]   COM (2012) 746 final.

transposed, services propose to launch an infringement procedure under Article 258 or, where a legislative Directive is concerned, in conjunction with Article 260(3) TFEU[68].

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. Detailed guidance is provided in the Toolbox.

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 need for better performance monitoring is recognised in the Interinstitutional Agreement on Better Law-Making which sets out the need to consider systematically monitoring and evaluation clauses for new Union legislation[69]. The Toolbox provides more information on how to prepare such provisions[70].

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 Toolbox[71]. In such cases, there will also be a need to monitor the performance of such approaches against the policy/legislative principles underpinning them[41], 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.

Guidance documents containing legal interpretation of EU law

Commission documents often provide guidance to Member States and/or stakeholders in applying and implementing EU law. Such guidance may contain interpretation of EU law, which, according to the case law of the Court of Justice of the European Union, may legally bind the Commission. Therefore, guidance documents have to be endorsed by the College unless such documents are part of the Commission's normal administrative operations. Further guidance is provided in the Toolbox.

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

[69] Pursuant to §22 of the Interinstitutional Agreement on Better Law-Making.

[70] See Tool #42 on *Legal provisions on monitoring and evaluation*

[71] See Tool #18 on *The choice of policy instruments*.

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.

- Consider including monitoring and evaluation provisions in each new Commission proposal in line with the interinstitutional agreement on better law-making.

- 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.

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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.[72] More detailed guidance is also available in the accompanying Toolbox.

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.

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[72]   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 behaviour than one-off data collection exercises.

The monitoring (and evaluation) arrangements should first be outlined in the impact assessment and be included in the Commission's proposal where appropriate in line with the Interinstitutional Agreement on Better Law-Making[73]. These arrangements may need to be revised following adoption of the intervention by the 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 needs 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	*What evidence needs to be collected?*
2	*When and how should evidence be collected?*
3	*Who will collect the evidence and from whom?*

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.

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[73] Paragraphs 22 and 23 of the Agreement

Minimise overlap: The EU, Member States, Agencies and 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 or is otherwise protected by rules on data protection, it is recommended that it is made available via the EU Open Data Portal[74] 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 reuse, to create new products and services and efficiency gains in administrations. Facilitating access to public data will also foster the participation of citizens in policymaking 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 intervention[75].

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.

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[74]   For more information see: http://open-data.europa.eu/en/data/

[75]   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.

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.

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

A basic act may often require the Commission to prepare an implmentation report. These 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 every 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. As far as possible, all these systems and solutions should be "open", i.e. favouring the use of open standards and open data.

Timing of the evidence gathering needs to be considered in relation to the timescale over which the intervention is implemented and applied and any 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 the final policy outcome is only expected far into the future or where it will not be possible to monitor the outcome directly, 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 European (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 Tool on monitoring arrangements 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: Indicators[76]

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 stakeholders (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.

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

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Chapter VI
Guidelines on evaluation (including fitness checks)

Key requirements

- Evaluations aim to inform policymaking by assessing existing interventions regularly and ensuring that relevant evidence is available to support the preparation of new initiatives ("evaluate first" principle). Specific guidance exists for evaluations undertaken in parallel with impact assessments ("back-to-back").

- All evaluations must have a planning entry in D*e*cide and must be steered by an interservice steering group (ISG) including a member of the lead DG's evaluation function or unit. Representatives from relevant DGs and the Secretariat-General must be invited to the ISG.

- An evaluation roadmap summarising the context, purpose and scope of the upcoming evaluation and outlining the expected approach must be published for all evaluations. Stakeholders must be able to provide feedback on the roadmap, which the lead DG must assess.

- All evaluations must follow a clearly defined, robust methodology intended to produce objective findings.

- A consultation strategy must be published for all evaluations which includes a mandatory 12 week public consultation covering the main elements of the evaluation.

- As a minimum, evaluations must assess effectiveness, efficiency, relevance, coherence and EU added value or explain why this is not done. Assessment of efficiency should always aim to quantify regulatory costs and benefits and identify burdensome or complex aspects of legislation and its implmentation.

- All evaluations must assess all significant economic, social and environmental impacts of EU interventions (with particular emphasis on those identified in a previous IA) or explain why an exception has been made.

- The evaluation process, evidence base, analysis and findings must be presented in a staff working document, using a specific template.

- Evaluation conclusions must pinpoint the lessons learned thereby providing input to future policy development.

- The following files related to the evaluation must be published centrally:

  (1) The evaluation roadmap;

  (2) (if applicable) Terms of reference, final deliverables from contractors;

  (3) The staff working document and an executive summary (in French, German and English) where these are required;

  (4) The Regulatory Scrutiny Board opinion (if applicable).

- At the end of an evaluation, appropriate follow-up actions must be identified and fed into the decision-making cycle.

1. INTRODUCTION

Who should read these Guidelines?

All officials involved in the preparation of an evaluation or a fitness check should read these guidelines[77] 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, programmes and legislation including those governed by the Financial Regulation and its Implementing Rules.
>
> Certain activities will not generally require an evaluation according to the approach set out in these Guidelines. These activities include:
>
> - Individual projects, groups of projects or sub-activities where their findings will feed into an overarching evaluation. This is particularly relevant for (spending) programmes where there may be many projects or sub-activities that require some degree of assessment that has a narrower scope than evaluation as defined here. It is also the case for external programmes where findings coming from evaluations of country programmes, specific delivery methods/tools or elements of certain themes feed into larger or overarching evaluations including legal instruments;
>
> - Evaluating an agency where aspects of the agency's performance will be evaluated together with the associated programme (executive agencies) or policy;
>
> - A limited set of actions within an EU intervention which are not expected to lead to changes to the wider intervention e.g. a Directive which contains a clause requesting the Commission to evaluate/review/assess the definition of XX after one year and decide if it is appropriate;
>
> - Performance at an early point in the implementation of an intervention, when information on the longer term changes (results and impacts) is not yet available;
>
> - The internal administrative policies of the Commission (translation, interpretation, human resources and security, the Publications Office and certain areas of Eurostat).
>
> However, this chapter still provides useful information to guide a more proportionate assessment of such activities.
>
> Practically, a separate D*e*cide entry and staff working document would not be required. The consultation strategy and evaluation criteria would normally cover a narrower scope.
>
> Where a Directorate-General has doubts about the degree of application and the steps which should be followed, they should discuss the approach with the Secretariat-General, preferably during the annual discussions establishing the evaluation plan.

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[77] The Guidelines set out the key requirements and obligations for evaluation and replace the previous (2004) guidelines and (2007) standards.

What is evaluation?

> *Evaluation* is an **evidence-based judgement** of the extent to which an existing intervention is:
>
> – **Effective**;
> – **Efficient**;
> – **Relevant** given the current needs;
> – **Coherent** both internally and with other EU interventions; and
> – Has achieved **EU added value**.

Evaluation is a tool to help the Commission learn about the functioning of EU interventions and to assess their actual performance compared to initial expectations. By evaluating, the Commission takes a critical look at whether EU activities are fit for purpose and deliver their intended objectives at minimum cost (i.e. avoiding unncessary costs or burdens). Evaluation also provides a key opportunity to engage stakeholders and the general public.

Evaluation goes beyond an assessment of *what* has happened; **it 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.

Evaluation *looks for evidence of causality* – i.e. did the intervention (help) bring about the expected changes or were there other unintended or unexpected changes? Beyond listing outputs and describing changes, evaluations should investigate any links between the observed changes and the EU intervention. Generally, evaluations should be carried out only after 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 the elements of an evaluation (e.g. reports, implementing reports, monitoring exercises, audits, and studies including cumulative cost assessments) it is unlikely that any of these sources will on their own address all of necessary issues in order to qualify as an evaluation.

What is a fitness check?

Traditionally, Commission evaluations have been conducted on individual interventions, but the increased focus on performance has led to the creation of a new type of evaluation - the *fitness check*[78].

> A *fitness check* is an evaluation of a group of interventions which have some relationship with each other (normally a common set of objectives), justifying a joint analysis.

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[78] The concept of a fitness check was introduced in COM (2010) 543 final – Smart Regulation in the European Union

A fitness check assesses whether the group of interventions[79] 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 and trying to quantify any synergies (e.g. improved performance, simplification, lower costs, reduced burdens) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies, implementation problems and/or obsolete measures) within the group of interventions which may have appeared over time, and help to identify the cumulative impact of the interventions, 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 interventions can 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. Their particular strength is in addressing the cumulative effects of the applicable framework - these are not addressed by evaluations of individual interventions and the cumulative effects do not necessarily correspond to the sum of effects identified through such individual evaluations. Fitness checks can provide economies of scale and place a greater focus on overall objectives and performance.

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 impact assessment work from the outset.

– **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, the separate elements of a specific programme or activity, or between activities.

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[79] 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.

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, wherever possible, precede impact assessment[80].

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 economy[81]. 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 further enforced within the Commission's Internal Control Framework (principle 12)[82].

> ### Evaluation is required where:
>
> - 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 invites the Commission to present new proposals by a certain date, care must be taken to ensure that the planning allocates sufficient time for the evalauation and the impact assessment.

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[80] 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.

[81] SEC (2007)213 *Responding to Strategic Needs: Reinforcing the use of evaluation.*

[82] The internal control framework C(2017) 2373: http://ec.europa.eu/budget/library/biblio/documents/control/C_2017_2373_Revision_ICF_en.pdf .

The key steps in an evaluation are[83]:

1. **Political validation:** generally evaluations to be conducted by a Directorate-General are confirmed during the management plan process. At an appropriate point in time, each individual evaluation is introduced and validated in D*e*cide;

2. Drafting of the **evaluation roadmap** by the lead DG, for agreement with the Secretariat-General. This roadmap provides a first description of the evaluation design, communicating the context, purpose and scope of the evaluation and outlining the proposed approach. The roadmap is published as early as possible by the Secretariat-General on the Commission's website[84]. Publication of the roadmap will provide greater transparency and enable stakeholders to provide their feedback;

3. Establish an interservice group (ISG) to steer the evaluation. The ISG must be involved in all the key steps of the evaluation after the publication of the roadmap up until the launch of the interservice consultation on the staff working document (design and conduct). The ISG may also be consulted on any associated report/communication to the European Parliament and Council. The ISG must include a representative from the lead DG's evaluation function and a representative of the Secretariat-General;

4. Agree a **consultation strategy with the ISG**, complying with the requirements set out in Chapter VII, **including a 12 week internet-based public consultation**[85];

5. Prepare the **staff working document which responds to the issues in the roadmap, presents the analysis and answers the evaluation questions.** A short **executive summary** presenting the findings of the evaluation process may also be written. For those **evaluations selected for scrutiny by the Regulatory Scrutiny Board (RSB)**, the draft evaluation staff working document (SWD) must be submitted to the **RSB** and the Board's comments incorporated into the SWD;

6. Launch the **interservice consultation** for the SWD;

7. **Publish** the staff working document and any supporting contractors' (final) study report with associated terms of reference (or technical specifications) centrally. **Where required by the basic legal act,** transmit the staff working document to

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[83] Further more detailed information on each individual step is provided in the Toolbox Chapter 6 *Evaluation and fitness checks*.

[84] http://ec.europa.eu/info/law/better-regulation/initiatives

[85] 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 public consultation at some point over the lifetime of the evaluation. Where the evaluation and IA are undertaken in parallel ("back to back") only one public consultation is needed 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 public consultation may be waived as long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. See also Tool #1 on *Principles, procedures and exceptions*.

the Parliament and the Council together with a short Commission report/communication;

8. **Disseminate** the **evaluation findings** and encourage active discussion and debate on the findings with stakeholders;

9. 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 legislator where this is necessary.

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 value[86]. 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 available[87]. 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.

Transparent Judgement[88]: 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

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[86]   See Tool #47 on *Evaluation criteria and questions*.

[87]   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. See Tool #45 on *How to undertake a proportionate evaluation.*

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

bias or uncertainty in it. Where possible, sensitivity and/or scenario analysis should be conducted to help test robustness of the analysis[89]. 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 the decision-making process) and the amount of reliable data which is available.

The starting point for an evaluation is to consider how the intervention was expected to work. This requires identification of the different steps and actors involved in the intervention which in turn allows identification of the expected cause and effect relationships. There are many different ways to do this and Figure 1 illustrates one (traditional) way to describe how the different components of evaluation can be linked together[90]. The intervention logic is an important tool for both communication and analyisis. The following considerations are linked to the intervention logic:

- Evaluations should try to establish to what extent the intervention is responsible for the observed changes.

- 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 counter-factual situation (i.e. what the situation would be if EU laws had not been adopted).

- When causal evaluation is not possible, or only at disproportionate effort, EU evaluations have to rely on qualitative, reasoned arguments (backed by the appropriate quantitative and qualitative evidence) about the likely role/contribution of an EU intervention to the changes observed.

Evaluations compare critically what has actually happened to what was expected to happen:

- Usually this is done by devising a set of evaluation questions related to the five standard evaluaton criteria.

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[89] See Tool #57 on *Analytical methods to compare options or assess performance*.

[90] Further guidance on how to create an intervention logic is provided in the Tool #46 on *Designing the evaluation*.

- There may also be additional considerations for judging performance depending on the timing and purpose of the evaluation and the questions being asked (e.g. the baseline and other points of comparison).

- The evaluation must be informed by earlier impact assessments covering the same intervention.

- Where the impact assessment has paid particular attention to certain stakeholder groups, or categories of impacts (e.g. economic, social, environmental), the subsequent evaluation must perform the corresponding complementary retrospective analysis or explain why this has not been possible[91].

Figure 1: *The different components of the intervention logic*
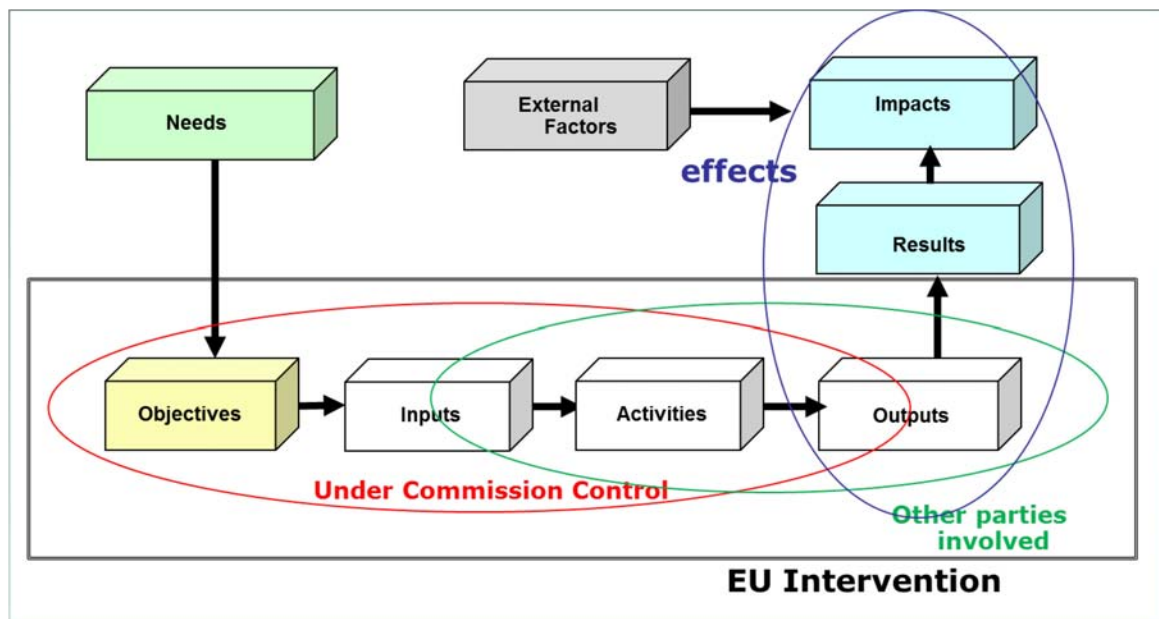
3. **KEY QUESTIONS AN EVALUATION MUST ANSWER**

The questions an evaluation must answer[92]	
1.	*What is the current situation?*
2.	*How effective has the EU intervention been?*
3.	*How efficient has the EU intervention been?*

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[91] 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 legislator.

[92] These questions should not be used as direct questions in consultation activities. Questions in consultations should be formulated in a way that the replies provide insights which enable the evaluation officer to respond to the evaluation questions.

The questions an evaluation must answer[92]	
4.	*How relevant is the EU intervention?*
5.	*How coherent is the EU intervention internally and with other (EU) actions?*
6.	*What is the EU added value of the intervention?*

All evaluations must answer the above listed questions[93], 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.[94]

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?

- What are the appropriate points of comparison against which to judge changes?

- Where things are – what progress has been made over time? Have their been problems related to the implementation and application of the intervention (perhaps evidenced by infringement procedures)?

- 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.

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[93] The evaluation of a single intervention may, on an exceptional basis, omit one or two of the five evaluation criteria subject to agreement of the Secretariat-General. Clear justification for such omission must then be provided in the evaluation roadmap and repeated in the final evaluation staff working document. Fitness checks always consider the five criteria.

[94] Further information is provided in Tool #47 on *Evaluation criteria and questions*.

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 are linked (or not) to the EU intervention.

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives, using appropriate points of comparison (including from a prior impact assessment). 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 unsuccessful 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*
> - What have been the (quantitative and qualitative) effects of the intervention?
> - To what extent do the observed effects link to the intervention?
> - To what extent can these changes/effects be credited to the intervention?
> - To what extent can factors influencing the observed achievements be linked to the EU intervention?
> - For spending programmes, did the associated EU 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 policymaking, 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

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choices (e.g. as demonstrated via different Member States) achieved the same benefits at less cost (or greater benefits at the same cost).

Efficiency analysis can differ depending on the type of intervention being evaluated. Typical efficiency analysis will include an examination of administrative and regulatory costs and look at aspects of simplification – these are important for _all_ evaluations. Evaluations and fitness checks should aim to quantify regulatory costs and benefits and to identify burdensome and complex aspects of EU legislation and its implementation in the Member States as well as any subsequent implementing or delegated act adopted by the Commission. **Where appropriate, evaluation findings should pin-point areas where there is potential to reduce inefficiencies (particularly unnecessary regulatory costs) and simplify the intervention.** This may require a series of different points of comparison or benchmarks to be identified, depending on the questions asked/answers sought.

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. These costs can be associated to different aspects of an intervention and judged against the benefits achieved.[95]

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 all 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 of the intervention justified, given the changes/effects it has achieved?

- To what extent are the costs associated with the intervention proportionate to the benefits it has generated? What factors are influencing any particular discrepancies? How do these factors link to the intervention?

- To what extent do factors linked to the intervention influence the efficiency with which the observed achievements were attained? What other factors influence the costs and benefits?

- How proportionate were the costs of the intervention borne by different stakeholder groups taking into account the distribution of the associated benefits?

- Are there opportunities to simplify the legislation or reduce unnecessary regulatory costs without undermining the intended objectives of the intervention?

- If there are significant differences in costs (or benefits) between Member States, what is causing them? How do these differences link to the intervention?

- How timely and efficient is the intervention's process for reporting and monitoring?

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[95] Further information is provided in Tool #58 on the *Typology of costs and benefits.*

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 policymakers 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 and hence touches on aspects of design. Things change over time. Certain objectives may be met or superseded; needs and problems change and new ones arise. Relevance analysis is very important because if an intervention does not help to address current needs or problems then it does not matter how effective, efficient or coherent it is no longer appropriate. This is why there is a strong link between relevance analysis and the criteria of EU added value which assesses whether action continues to be justified at the EU level. Often the starting (comparison) point when answering relevance questions is the current situation, although there may be other key points in the past or (near) future which should also be considered.

> *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 of the intervention (still) correspond to the needs within the EU?
>
> - How well adapted is the intervention to subsequent technological or scientific advances?
>
> - 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 ongoing actions. The evaluation of coherence involves looking at how well or

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not different actions work together. The comparison points for coherence may vary according both to time, and to the level of coherence being considered.

Checking internal coherence means looking at how the various components of the same 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) or EU interventions in developing countries.

The focus on coherence may vary depending on the type of evaluation and is particularly important in fitness checks, where coherence analysis will look for evidence of synergies or inconsistencies between 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 counterfactual.

EU added value[96] looks for changes which it can reasonably be argued are due to the EU intervention over and above what could resasonably have been expected from national actions by Member States. 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. EU added value analysis should, where

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[96]   For further information see SEC(2011) 867 final *The added value of the EU budget*. Also see Tool #5 on *Legal basis, subsidiarity and proportionality*.

applicable, be done with reference to the subsidiarity analysis conducted in any related IA.

The sources and nature of this additional value vary from intervention to intervention. It is, in particular, useful to distinguish the EU added value of a policy measure in general (such as an EU regulation to foster the single market) and that of an EU spending programme per se. In both cases, EU added value may be the results of different factors: coordination gains, legal certainty, greater effectiveness or efficiency, complementarities etc. In all cases, concluding on the continued need for the intervention at EU level may be difficult as measuring EU added value is challenging.

In areas where the EU has exclusive competence, the answer to the question of EU added value may simply involve restating the reasons why the EU has exclusive competence or by referring to the efficiency and effectiveness analysis. 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 reasonably have been expected from Member States acting at national and/or regional levels?

- What would be the most likely consequences of stopping or withdrawing the existing EU intervention?

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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 study 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 evaluation SWD will communicate the results and conclusions of the evaluation: (i) to policymakers, helping to inform their decision-making and (ii) to stakeholders, sharing 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. A template for the format of the evaluation SWD can be found on the evaluation pages of GoPro.

The SWD presents in a self-standing and non-technical manner the process, evidence and analysis, and is likely to be around 50-60 pages (excluding annexes but including tables

and figures). The process followed for the evaluation may influence the length of the evaluation SWD, but even 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 document, the evaluation SWD must provide sufficient detail to enable the reader to follow the evidence and logic and to understand the answers and conclusions without having to read any supporting materials.

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 study) as well as summarised in the synopsis report[97], to be added as an annex to the SWD. All external material used (reports, scientific findings etc.) should also be systematically referenced. Where there is no requirement to report to the European Parliament and Council, a short executive summary (maximum length two pages) must also be prepared and translated into English, French and German, providing an easily accessible overview of the headline findings from the evaluation.

The Regulatory Scrutiny Board will scrutinise the evaluation SWD of the major evaluations and fitness checks it selects, and the related interservice consultation cannot be launched before the RSB has issued its opinion. The package sent to the RSB should include the draft evaluation SWD and associated executive summary (if relevant), the minutes of the last ISG meeting and where applicable the relevant contractors' study and associated quality assessment.

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, the final evaluation staff working document must be published centrally alongside the final evaluation roadmap, consultation strategy and related consultation documents, terms of reference (or technical specifications) and the associated contractor's final study (if applicable) and the opinion of the Regulatory Scrutiny Board (if applicable).

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 considered[98]. It is best practice to solicit feedback from stakeholders which can then feed into follow-up activities.

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[97] See Chapter VII

[98] Further information on dissemination can be found in Tool #50 on *Disseminating the evaluation findings*.

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 help with 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 an impact assessment or improving guidance or further monitoring. Identifying and sharing the planned follow-up actions is part of accepting responsibility and accountability for EU actions and ensures transparency.

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 the European Parliament and the Council 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).

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, a Communication launching a consultation or Green Paper. The key elements should be outlined prior to requesting validation and be outlined in the roadmap/inception impact assessment on which stakeholders can provide feedback.

- After the feedback period, the consultation strategy and consultation documents must be finalised and agreed by the interservice group (ISG) or by the Secretariat-General and other associated services if no ISG is established.

- A 12 week internet-based public consultation must be part of the consultation strategy for initiatives supported by impact assessments, evaluations and fitness checks as well as for Green Papers (unless an exemption has been granted).

- The consultation strategy needs to set out the language coverage of each consultation activity. Public consultations on Commission Work Programme priority initiatives must be made available in all official EU languages. All other public consultations need to be made available in at least English, French and German. Additional translations must be provided for consultations on initiatives of broad public interest and justified in the consultation strategy.

- Stakeholders must be able to provide feedback on each roadmap (including for evaluations) or inception impact assessment, on legislative proposals adopted by the College and on draft implementing and delegated acts[99].

- Any consultation activity must fulfil the Commission's minimum standards for consultation, as outlined in these guidelines(but not the opportunities to provide feedback on roadmaps, inception impact assessments, proposals, impact assessments, delegated acts and implementing acts).

- A report outlining the overall results of the consultation work and providing feedback to stakeholders (synopsis report) must be published on the consultation website and, where applicable, added as an annex to the impact assessment/evaluation report. The report should include a summary of the feedback received on roadmaps or inception impact assessments as well as other relevant input received in parallel to the formal consultation work.

1.   INTRODUCTION

Who should read these guidelines?

All officials involved in the preparation of legislative or policy initiatives 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.

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[99]   Draft delegated and implementing acts as well as draft measures subject to regulatory scrutiny (RPS/PRAC measures); certain exceptions apply, see section 4.1.

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More detailed guidance is also available in the Toolbox which accompanies these guidelines. 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 initiatives benefits from considering the input and views provided by citizens and stakeholders, including those who will be directly affected by the policy but also those who are involved in ensuring its correct application. Stakeholder consultation can also improve the evidence base underpinning a given policy initiative. Early consultation can avoid problems later and promote greater acceptance of the policy initiative.

In addition, the Commission has a duty to identify and promote the general public interest of the Union in its policy initiatives 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 Union[100], "*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*".

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2.   SCOPE AND DEFINITION OF STAKEHOLDER CONSULTATION

Stakeholder consultation is a formal process by which the Commission collects information and views from stakeholders about its policies.

Stakeholder engagement 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 dialogue[101]).

In these guidelines, stakeholder consultation means all consultations with stakeholders in the process of preparing a policy initiative or evaluating an existing intervention.

It does not apply to:

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

- Opinions provided by expert groups involved in the preparation of Delegated Acts;

- Stakeholder consultations prepared by any EU agency or body of the Commission which precede the Commission's finalisation of draft Delegated and Implementing Acts;

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[100]   http://europa.eu/about-eu/basic-information/decision-making/treaties/index_en.htm

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

- European Citizen's Initiatives' submitted under Article 11 (4) of the TEU;

and does not replace 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)[102];

For consultations in the area of environment, the guidelines apply without prejudice to the requirements under Regulation (EC) N° 1367/2006.

3. GENERAL PRINCIPLES AND MINIMUM STANDARDS FOR STAKEHOLDER CONSULTATION

Stakeholder consultation is governed by four principles and five minimum standards taking proportionality into account.[103] 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 policymaking 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)

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[102] 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 Toolbox.

[103] 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.

consultations should be published on the internet and announced at the "single access point"[104];

(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 (public) consultations should be published and displayed on websites 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 <u>always</u> be consulted when preparing a Commission legislative or policy initiative or when performing an evaluation or fitness check and on Communications which launch a consultation exercise or Green Papers.

Stakeholder engagement can in principle take place **throughout the whole policy cycle**. However, formal stakeholder consultations can only be launched for initiatives which have received political validation by the appropriate political level (c.f. Chapter II on Planning).

As part of promoting greater transparency, stakeholders should be consulted or be able to provide feedback on the following[105].

Box 3. Mandatory consultation and feedback requirements[106]

Mandatory open, internet-based public consultation (minimum 12 weeks)[107]:

- *Initiatives with impact assessments.* Consultations are based on consultation documents including questionnaires, background information, the inception IA etc.;

- *Evaluations.* Consultations are based on consultation documents including questionnaires and background information, the roadmap, etc.;

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[104] https://ec.europa.eu/info/consultations.

[105] For more details see *Summary of documents on which stakeholders are consulted or can provide feedback* in the 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.

[106] The portal 'contribute to lawmaking' provides access to all consultation and feedback mechanisms: http://ec.europa.eu/info/law/contribute-law-making_en

[107] 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.

- *Fitness checks.* Consultations are based on consultation documents, including questionnaires, background information, roadmaps, etc.;

- *Commission Communications* with the explicit purpose of launching a consultation process. The consultation is based on the Communication itself as adopted by the Commission;

- *Green Papers.* The consultation uses the Green Paper as adopted by the Commission.

Stakeholders must be able to give feedback on:

- Roadmaps for evaluations and fitness checks, and roadmaps and inception impact assessments for a period of 4 weeks after publication.

- Draft delegated acts and implementing acts of general application and draft measures following the regulatory procedure with scrutiny (4 weeks). There are limited exceptions to outlined in the Toolbox[108] such as the need for urgent action or where the feedback would bring no added value.

- Legislative proposals adopted by the College and, where applicable, the accompanying impact assessments (8 weeks).

- How to improve existing legislation, at any time via the website 'Lighten the load'

5. WHO IN THE COMMISSION SERVICES IS RESPONSIBLE FOR CONSULTATION ACTIVITIES?

The responsibility for managing stakeholder consultation activities is decentralised to the Commission service in the lead 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.

The lead Commission service must start preparing the consultation strategy early in the preparatory process of the initiative. For major initiatives, a first reflection on the consultation strategy is already required at the time of requesting validation. After political validation, the consultation strategy should be finalised and **endorsed by the interservice group (ISG)** established for the policy initiative[109]. If no interservice group is established or if no roadmap/inception impact assessment is needed, the consultation strategy is finalised by the Secretariat-General and, where relevant, associated Directorate-Generals. The interservice 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.

The key elements of the consultation strategy must be included in the roadmap or inception impact assessment on which stakeholders can provide feedback. It also allows stakeholders to plan for subsequent consultation activities.

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[108] See Tool#56 on *Stakeholder feedback mechanisms*. Delegated acts and implementing acts are included in the D*e*cide planning tool where an indication should be provided about posting the draft act for stakeholders to provide feedback.

[109] See Table 1 in chapter II (Planning) for which initiatives an ISG should always be set up.

After the feedback period on the roadmap/inception impact assessment has closed, the consultation strategy may need to be updated based on the feedback received. The Secretariat-General is responsible for launching all public internet-based consultations on the 'Contribute to EU law-making' website[110]. This site cross-links to the web page constructed by the lead DG to host the consultation and related documents. However, the corporate "contribute to EU law making" webpage must first announce the consultation before the lead DG publicises its own dedicated webpage.

External consultants can support or 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 these Guidelines.

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 policymaking.

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 the sound design of all consultation work that is to be conducted in the course of preparing an evaluation or initiative (consultation strategy).

Consultation is not a one-off event, but a dynamic, ongoing 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:

- Sets out clearly the scope of the consultation and its objectives;

- Identifies all relevant stakeholders that may have an interest in the policy matter;

- Determines the most appropriate consultation activities, methods and tools, which ensures accessibility and considers the appropriate communication methods to promote the consultation. The strategy should consider:

  - the scope and objectives;

  - the opportunity for all identified stakeholders to express their views;the adequate language coverage of consultation activities depending on the

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[110] https://ec.europa.eu/info/law/contribute-law-making_en

scope and outreach[111]; the aim to collect relevant input of highest possible quality;

- the required time and resources to prepare and carry out the different consultation activities;

- Proportionality to the expected scope and impact of the initiative it supports.

- Foresees the creation of a consultation webpage.

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

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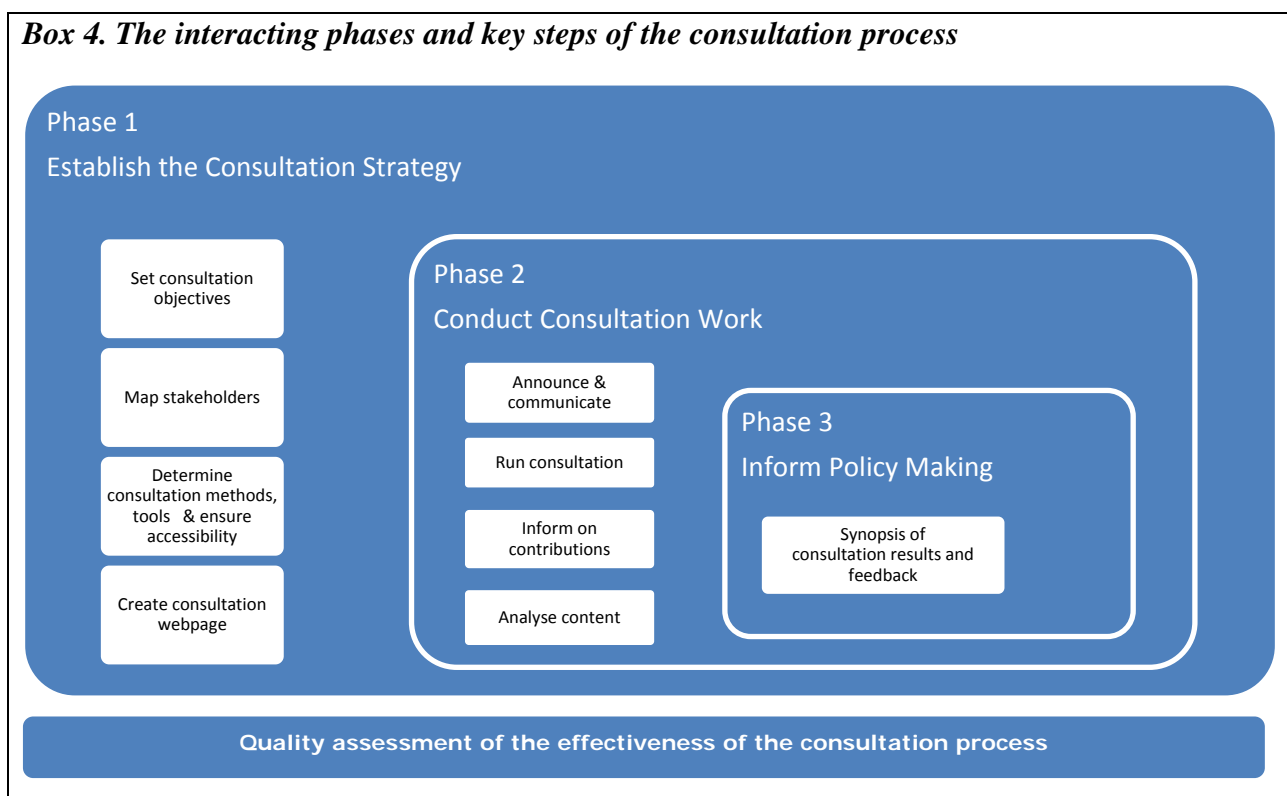
A consultation strategy[112] is always case-specific and should be defined early in the preparation process of the initiative, impact assessment, evaluation or fitness check. The consultation strategy may need to be adjusted throughout the policy preparation phase, in order to take into account policy developments or conclusions drawn from the application of other better regulation tools.

The consultation strategy should cover the four key steps set out in the graph above (Box 4):

6.1.1. Set consultation scope and objectives

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

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[111] See box 'key requirements' in the beginning of Chapter 7 and the Toolbox, Tool #53 on *The consultation strategy.*

[112] For details see Tool #53 *The consultation strategy.*

- 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 ideas[113], collect views and opinions[114], gather factual information, data and knowledge[115]; and test existing ideas and analysis[116].

Issues to consider when defining consultation objectives
• The *context, scope and expected impacts of the initiative* and the *stage in the policy development process*.

• The *data collection and consultation background* of the initiative under preparation:
 	
   • Available data through other sources (reports, statistics, complaints, etc);
 	
   • consultations that have already taken place;
 	
   • future consultations that will take place after the current one and their respective objectives.
 	
 This should help identify the information already available and the additional elements sought from the stakeholder consultation.

• The *scope of the consultation*:
 	
   • 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?

• The difference between collecting views or opinions (subjective) and collecting data or facts (objective).
Clear *communication of the objectives* on the consultation webpage 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.

The scope of consultation activities differs depending on the type and scope of the initiative or evaluation, 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:

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

[114] 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.

[115] 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

[116] 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.

Mandatory scope of consultations in impact assessments, evaluations and fitness checks[117,118]
Initiatives accompanied by impact assessments[119]: Stakeholders must be consulted on all IA elements in the IA process. The key issues which must be addressed in the consultation strategy, including in the public consultation, are therefore: • The problem to be tackled; • The issue of subsidiarity and the EU dimension to the problem; • The available policy options; • When modifying existing interventions, the scope for efficiency improvement (regulatory cost reduction) and simplification measures not affecting the achievement of objectives; • The impacts of the policy options.
Evaluations and fitness checks[120]: The combined consultation activities defined in the consultation strategy must together cover the five mandatory evaluation criteria. However, individual consultation activities (such as the public consultation) may omit one or more of these criteria: • Effectiveness of the intervention; • Efficiency of the intervention in relation to resources used (including the existence of unnecessary costs and legal complexities from the point of view of the achievement of the objectives); • 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 objectives; • The EU added value resulting from the intervention compared to what could be achieved by Member State action only.

6.1.2. Map Stakeholders

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

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[117] Where the evaluation and IA are conducted "back to back" only one public consultation need be conducted as long as relevant stakeholders are consulted on all the main elements of the IA.

[118] Where the evaluation is of an activity conducted outside the EU or where the internet is not a practical support tool, the mandatory public consultation may be waived as long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. Before applying exceptions, the lead DG must contact the Secretariat-General.

[119] For details, see chapter III on Impact assessments.

[120] 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 involves[121]:
• Identification of stakeholder categories relevant for or interested in the concerned policy area(s),
• Prioritising the stakeholder categories to engage with 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'[122] and the 'Transparency register'[123] 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 issues[124].

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.

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[121] See the Tool #53 on *The consultation strategy* for guidance on stakeholder mapping.

[122] https://webgate.ec.europa.eu/notifications/homePage.do?locale=en#en

[123] http://ec.europa.eu/transparencyregister/public/homePage.do?locale=en#en

[124] For information on data protection rules see the better regulation Toolbox.

> **Box 5. Stakeholder types**
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> 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_ the different stakeholder categories that the 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 businesses), location (including those in third countries), type of activity, whether they are public or private, established 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 remote 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

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limited capacity, a pre-selection of participants in the consultation event may be necessary.

6.1.3. *Determine consultation methods, tools & ensure accessibility*

The most appropriate consultation methods and tools[125] 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 evaluation or 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 and design of the consultation activities;
>
> 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.

Consultation methods

Consultation methods encompass public or targeted consultations. For some initiatives, a public consultation is mandatory (see Box 3). The selected methods should reflect the consultation objectives and the target group(s) identified through the stakeholder mapping:

- **Public consultation** reaches a wide spectrum of respondents without, however, ensuring full representativeness as respondents are self-selected.. The relevance of opinions collected needs, therefore, to be thoroughly assessed particulalry where response rates are low or large campaigns have been identified.. 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 events[126].

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[125]   See the Toolbox for an overview of consultation methods and tools.

[126]   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.

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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.)[127]; and

- Timing requirements.

In practice, effective consultation often requires a combination of written consultation tools (used for both public and targeted consultations) and more direct interactions with stakeholders. Consultation documents, including questionnaires, should cover sufficient languages in order to reach targeted stakeholders. This should be identified in the consultation strategy in respect of each consultation activity. In any case, public consultations on priority initiatives in the Commission's work programme (Annex I) need to be translated into all official languages. [128] Any other public consultation needs to be made available in, at least, English, French and German but additional translations should be provided if the initiative is likely to generate broad public interest.

If the consultation is intended to provide statistically representative results then appropriate tools should be envisaged such as surveys (e.g. Eurobarometer).

Mandatory timeframes for consultation and feedback		
Mandatory open, internet-based public consultation:	*How long?*	*When?*
- Initiatives with impact assessments - Evaluations - Fitness checks	Minimum 12 weeks[129]	Decision on case-by-case basis
- Consultative Communications - Green Papers		After adoption by the Commission
Stakeholders must be enabled to give feedback on:	*How long?*	*When?*
- Roadmaps for evaluations and fitness checks	4 weeks	After publication
- Roadmaps, inception impact assessments	4 weeks	After publication

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[127] See Tool #53 on *The consultation strategy*; and Tool #54 on *Conducting the consultation activities and data analysis*.

[128] For details see Tool # 53 *The consultation strategy*

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

• Draft Delegated Acts[130]	4 weeks	After conclusion of the interservice consultation in parallel with Member State experts.
• Draft Implementing Acts[154]	4 weeks	After conclusion of the interservice consultation and before the vote in the Comitology Committee
• Legislative or policy proposals adopted by the College and, where applicable, the accompanying impact assessments	8 weeks	After adoption by the Commission, from the moment all language versions of the document are published

6.1.4.   Create a consultation webpage

Establish a consultation webpage on the Europa websites for the evaluationb or policy initiative under preparation. Publish the consultation strategy or its content, including the planned dates of the various consultation activities, as soon as known. Dates for consultations will also be included in the Commission's consultation planning calendar, which is published on the Contribute to EU law-making europa webpage.

Update all information about the various consultation activities linked to a given initiative. Communication materials relating to a consultation should be clear and concise.

Specific subpages for the various consultation work should be created (e.g. public consultation, stakeholder conference, etc.).

The link to an **public** consultation webpage will be posted on the 'Contribute to EU law-making' 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 used[131].

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:

- • Announce and communicate;

- • Run consultation;

- • Inform on contributions;

- • Analyse content.

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[130]   For exact scope, see Tool #56 on *Stakeholder feedback mechanisms*.

[131]   For further information, please see the Toolbox.

6.2.1. 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.

Box 6. Ways to publicise consultation activities

- Press conference, including issuing a press release and/or the possibility of a more in-depth briefing for journalists;

- Midday express and newsletters;

- Speeches delivered during relevant events;

- Placing announcements in relevant publications; adding links on websites and proposing articles for either general and/or more specialised media;

- Commission's blogs and social media;

- Commission Representations 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 a public consultation is launched, certain stakeholders will be automatically alerted via their registration with the Transparency Register or the Notifications system of the Commission[132].

- Contacting interested parties or organisations.[133]

6.2.2. Run the consultation and provide acknowledgment

The practical organisation and facilitation of any consultation activity needs full attention. There should be sufficient resources 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 public consultations for initiatives for which no ISG exists, by the Secretariat-General after consultation of interested DG's where relevant.

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[132] https://webgate.ec.europa.eu/notifications/homePage.do?locale=en

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

> **The quality of consultation documents determines the quality of contributions and thus the quality of input to policymaking.**

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 subgroups 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 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 that the identity of stakeholders and their interests should be mentioned in order to ensure consideration of the contribution[134]. Make sure that the personal and background information is requested from respondents before they reply as this will allow subsequent analysis of replies disaggregated by the stakeholder categories you target (e.g. if individual SMEs cannot identify themselves as such in their reply, it is not possible 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 processed as a separate category "non-registered organisations/businesses"[135] unless the contributors are recognised as representative stakeholders through Treaty provisions[136].

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 minimise work, individual or collective acknowledgments of receipt could be automatically generated at the entry point.

In case contributions are published within 15 days after the end of a consultation activity, the publication will replace a separate acknowledgment of receipt.

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[134]   See also Box 5 under step 4, bullet on the Transparency Register

[135]   See Tool #53 on *The consultation strategy*

[136]   European Social Dialogue, Art. 154-155 TFEU

6.2.3.   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

Contributions to a consultation must be published. They 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.

Respondents have the following options as regards pulication of their contributions:

- Publication of the contribution with personal information;

- Anonymised publication of the contribution (without the name/name of the organisation);

Collection, handling and publication of personal data should respect the relevant data protection rules[137] and be specified in the privacy statement[162], to be published on the consultation page.

Inform on key issues of the contributions

It is good practice to prepare and publish on the consultation website a short factual summary on 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 factual summaries of consultation activities help increase transparency and provide the basis for further analysis and feedback to stakeholders on how the consultation has informed policymaking.

Summarise contributions	
Give a concise and balanced overview of contributions received during a specific consultation activity	
Give factual information on input received	• Who contributed? • Whom are they representing? • What aspects are addressed?

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[137]   See Tool #54 on *Conducting the consultation activities and data analysis.*

	• What are their views and concerns? • Which communication channels were used for contributions?
Stay neutral	• Document the input as received: Avoid qualifying it, taking position or giving feedback
Aggregate at an appropriate level	• Cluster information
Inform on the process	• Inform on what was done so far in terms of consultation activities and on the next steps
Add disclaimer	• 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.

6.2.4. *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. Eurobarometer[138]).

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 the content of contributions:

- Do the contributions respond to the questions/expectations?

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[138]   http://ec.europa.eu/public_opinion/index_en.htm

- 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 scope and objectives in the consultation strategy (Phase 1).

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(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 versus opinions). The questions could be structured as indicated under (i).

- Tools for the processing and analysis of different types of data are described in the better regulation Toolbox[139].

6.3.   Phase 3 – Inform policymaking and provide feedback

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

6.3.1.   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 should accompany the initiative through interservice 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 integrated into the IA report or evaluation SWD as an annex.

Further guidance on format and content of the synopsis report is provided in the better regulation Toolbox[140].

Explanatory memorandum

For legislative proposals, reference to the outcome of the stakeholder consultation should be made in the explanatory memorandum. Further guidance on elements to be included is provided in the better regulation Toolbox[166].

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[139]   See Tool #54 on *Conducting the consultation activities and data analysis.*

[140]   See Tool #55 on *Informing policymaking- the synopsis report*.

7.   QUALITY CONTROL

Internal quality assessment of the consultation process

With the view to improve future consultations and stakeholder engagement, 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 interservice group or, in case no ISG has been established, with the services associated for the initiative, including the Secretariat-General.

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 evaluation or 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 policymakers?)

Glossary

Term	Meaning
DecidePlanning	D*e*cide is the Commission's tool for identifying, managing and tracking the most important initiatives which proceed to adoption by the College. D*e*cide Planning is the first module which manages the political validation process of new initiatives. Once an envisaged initiative is validated in Planning, it follows its course to the other modules of D*e*cide (Consultation and Decision). D*e*cide entries provide information about the type of initiative, its timing and content, the adoption procedure and other procedural elements. They contain a link to roadmaps (where applicable) and indicate whether an impact assessment (IA) and/or implementation plan (IP) is being prepared.
Application	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.
Consultation strategy	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.
Evaluation / evaluation SWD	Evaluation is an assessment of the effectiveness, efficiency, coherence, relevance and EU added-value of one single EU intervention. An evaluation (SWD) is prepared by the lead service and presents the findings and conclusions about the evaluation. The quality of *major* 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.
Feedback mechanism	Feedback mechanisms offer an opportunity for citizens and stakeholders to express general views on a specific document (Roadmap, IIA, draft conferred legislation, legislative proposals and accompanying impact assessment, established legislation), not based on specific questions or consultation background documents.
Fitness check / fitness check report	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 *major* 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.
Gold-plating	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 addresses of its national law that go beyond the requirements or standards foreseen in the transposed EU legislation.

Impact	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.
Impact assessment / impact assessment report	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. 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.
Implementation	Implementation describes the process of making sure that the provisions of EU legislation can be fully applied. 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.
Implementation plan	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 or inception impact assessment indicates whether an implementation plan will be established.
Inception impact assessment	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.
Interservice (steering) group	An interservice group comprises representatives from interested DGs or services who collectively undertake the better regulation processes. Interservice groups are required for the preparation of major initiatives, entailing impact assessments, stakeholder consultations, evaluations and fitness checks.
Initiative	An initiative is a policy instrument prepared at EU level to address a specific problem or societal need.
Intervention	Intervention is used as an umbrella term to describe a wide range of EU activities including: expenditure and non-expenditure measures, legislation, action plans, networks and agencies.
Intervention logic	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 evaluations.
Monitoring	Monitoring describes the process of tracking the implementation and

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	application of EU legislation by the Commission or the progress of spending programmes.
REFIT	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.
Regulatory Scrutiny Board	A body inside the Commission which scrutinises draft impact assessment reports and selected evaluations /fitness checks and issues opinions with a view to improving their quality or providing guidance for the future.
Roadmap/Inception impact assessment	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 policymaking process. A more developed roadmap is prepared for initiatives supported by impact assessments (an inception impact assessment).
SME	SME is the abbreviation for micro, small and medium-sized enterprises. SMEs are defined comprehensively in Commission Recommendation 2003/361.In simple terms, they are 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.
Stakeholder	Stakeholder is any individual citizen or an entity impacted, addressed or otherwise concerned by an EU intervention.
Stakeholder consultation	Stakholder consultation is a formal process of collecting input and views from citizens and stakeholders on new initiatives or evaluations/ fitness checks, based on specific questions and/or consultation background documents or Commission documents launching a consultation process or Green Papers. When consulting, the Commission proactively seeks evidence (facts, views, opinions) on a specific issue.
Transposition	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.