



Better regulation "Toolbox"

This Toolbox complements the better regulation guideline presented in SWD(2017) 350

It is presented here in the form of a single document and structured around various chapters containing individual tools. It is also available and intended to be used as a series of web-based tools which are downloadable from the Commission's better regulation web site. https://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en

In general, the Toolbox presents guidance, tips and best practice. Users are not expected to read and apply each individual tool but to use the Toolbox selectively and with common sense. However, some aspects of the Toolbox must be applied because they are linked to the requirements of the better regulation Guidelines, the Commission's working methods or political commitments given by the Commission. These are explained in the first Tool #1 on *principles, procedures and exceptions*. Questions about this Toolbox can be sent to units C1, C2, C3 and C4 of Directorate responsible for Smart Regulation and the Work Programme in the Secretariat-General.

The better regulation Toolbox is used internally in the Commission and therefore contains references to internal procedures as well as intranet pages not publically available.

Better regulation Toolbox

This Toolbox complements the main Guidelines on better regulation in staff working document (SWD (2017) 350). It provides more specific and operational guidance to those involved with the various better regulation instruments.

The Toolbox is structured around 8 main chapters:

- Chapter 1 presents the key principles and concepts underpinning better regulation at the European Commission;
- Chapters 2 presents tools for carrying out an impact assessment (IA);
- Chapter 3 presents tools for assessing specific impacts, whether they are estimated prospectively in the context of IAs or retrospectively when carrying out evaluations or fitness checks;
- Chapter 4 provides a short summary of how to facilitate and verify the transposition and conformity of EU law;
- Chapter 5 describes how to establish monitoring systems;
- Chapter 6 provides guidance on how to carry out evaluations and fitness checks;
- Chapter 7 lays out how to consult stakeholders in the context of better regulation;
- Chapter 8 summarises methods to identify, assess and quantify costs and benefits and provides insight into how to use visual aids and present quantitative data.

The tools below cover the relevant aspects of all new initiatives and existing policy interventions. They are advisory in nature and following them is not compulsory unless required by the main better regulation Guidelines. Each chapter of the Guidelines indicates the key compulsory requirements and for clarity these are replicated at the beginning of the Toolbox chapters on impact assessment, evaluation and stakeholder consultation.

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Chapter 1

General Principles of Better Regulation

TOOL #1. PRINCIPLES, PROCEDURES & EXCEPTIONS

1. COMMON BETTER REGULATION PRINCIPLES AND PROCEDURES

Through its better regulation policy, the Commission has committed to design, deliver and support the implementation of high quality interventions. Better regulation covers the whole policy cycle – planning, adoption, design, implementation, application (including enforcement), evaluation and revision. All EU interventions – legislative or non-legislative, spending programmes or other measures – aim to achieve certain objectives through one or several means, in line with the goals and responsibilities set by the EU Treaty.

The European Parliament, Council and the Commission concluded a new Interinstitutional Agreement on Better Law-Making¹. The three institutions recognise their joint responsibility to deliver high-quality legislation:

- In areas where it has the greatest added value for European citizens and strengthen the competitiveness and sustainability of the Union's economy;
- Which delivers the Union's policy objectives in the simplest, most efficient and effective way possible;
- Which avoids overregulation and unnecessary administrative burdens for citizens, administrations and businesses and particularly SMEs; and
- Which is designed to facilitate its transposition and practical application.

All better regulation activities within the Commission are governed by a set of common principles and follow established processes. They apply to all DGs and services involved in the preparation, implementation, application or evaluation of EU interventions and associated stakeholder consultations. They build on the separate standards for stakeholder consultation² and evaluation³. The application of these principles and procedures should provide a rigorous evidence base to inform decision-making and contribute to making Commission activities more effective, coherent, useful, relevant and efficient. It should also enhance transparency, participation, learning and accountability.

The aims of better regulation practices:	
<i>Embedded in the planning and policy cycle</i>	Evidence from all preparatory and analytical work, including stakeholder consultations, should be available to feed into the policy development process. Lessons from implementation and evaluations form part of the “evaluate first” approach to policy development. Possible implementation challenges and monitoring arrangements should always be considered in impact assessments (IAs).
<i>Of high quality</i>	The basis of any stakeholder consultation should be clear, concise and

¹ OJ L 123, 12 May 2016, p1. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC>

² COM(2002)704; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:en:PDF>

³ SEC(2007)213; http://ec.europa.eu/smart-regulation/evaluation/docs/eval_comm_sec_2007_213_en.pdf

	include all necessary information to facilitate responses. The Commission's impact assessments, fitness checks and evaluations should conform to the requirements of the better regulation Guidelines; the Regulatory Scrutiny Board provides an independent check.
<i>Evidence-based</i>	Better regulation instruments should be based on the best available evidence; or provide a transparent explanation of why some evidence is not available and why it is appropriate to act in the absence of evidence. Evidence includes quantitative and qualitative information as well as stakeholder opinions.
<i>Participatory/ Open to stakeholders' views</i>	Ensure wide participation throughout the policy cycle. The Commission should seek and consider a wide range of views and ensure that all relevant parties have had the opportunity to express their opinions. Open web-based public consultations should be mandatory elements of any consultation strategy associated with an evaluation, fitness check or impact assessment as well as for Commission Communications launching a consultation process and Green Papers. Stakeholders should be given sufficient time to respond (12 weeks for consultation) or prepare responses (4 working weeks for meetings). In addition, 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 relevant draft implementing and delegated acts
<i>Respect for principles of subsidiarity and proportionality</i>	Better regulation instruments should explain how respect for these two principles is ensured. EU action should be relevant and necessary, offer value beyond what Member State action alone can deliver and not go further than is necessary to resolve the problem or meet the policy objective.
<i>Comprehensive</i>	All relevant economic, social, and environmental impacts of alternative policy solutions should be considered. Stakeholders' views should be collected and presented on all key issues.
<i>Coherent/ conducted collectively</i>	Coherency across different policy domains and between related policy instruments is important. New initiatives, impact assessments, consultations and evaluations should be prepared collectively by all relevant services in the framework of interservice groups.
<i>Proportionate</i>	The better regulation instruments should be used in a way that is proportionate to the type of intervention or initiative, the importance of the problem or objective, and the magnitude of the expected or observed impacts.
<i>Transparent</i>	Being clearly visible to the outside world is important if initiatives are to be understood and credible. Results of evaluations, impact assessments and consultations should be widely disseminated. Stakeholder responses should be acknowledged and consultation results widely disseminated through a single access point. The reasons for disagreeing with dissenting views should be explained.
<i>Unbiased</i>	Evidence should inform political decisions - not the other way around.
<i>Appropriately resourced and organised</i>	Sufficient human and financial resources should be available to enable each evaluation, impact assessment or consultation to deliver a timely and high quality result. DGs should establish centres of expertise (or functions) to support better regulation activities throughout the policy cycle.

2. USE OF THE BETTER REGULATION TOOLBOX

The Toolbox presents guidance, tips and best practice. However, the requirements of the better regulation Guidelines, the Commission's working methods or political commitments mean that some elements must be applied. The introductory part of each chapter of the better regulation Guidelines describes these mandatory elements/actions.

These requirements are repeated at the start of each chapter of the Toolbox to provide greater clarity.

Users of the Toolbox are not expected to read and apply each individual tool but to use the Toolbox selectively and with common sense when they need additional guidance.

3. EXCEPTIONS FROM THE PROCEDURAL REQUIREMENTS OF THE BETTER REGULATION GUIDELINES

The better regulation Guidelines should be applied flexibly and in a proportionate manner that reflects the circumstances of each individual initiative. What matters is that the spirit of the Guidelines (and tools) is applied and that high quality IAs, evaluations etc. result. The Secretariat-General can be consulted about the practical application of the Guidelines in individual cases.

There will, however, be occasions when certain procedural steps or processes cannot be done or need to be shortened or simplified for good reasons (e.g. political urgency, the need to respect confidentiality and security concerns etc.). Such exceptions from the requirements of the Guidelines and Toolbox are possible but prior approval is necessary. This should be done in the following ways:

- When a major initiative⁴ is first presented for political validation, the need for flexibility or an exception should already be described (and justification provided) in the relevant fields of the Decide IT platform. The decision of the First Vice-President will then explicitly cover the intended exception;
- If an exception is required following the validation of a major initiative, or if the initiative is validated within the lead DG (as for evaluations and fitness checks), DGs must seek **approval from the** Director responsible for smart regulation in the Secretariat-General in consultation with the Cabinet of the First Vice-President.

All such requests for exceptions should be sent to the following functional mailbox and should describe (1) what is being requested; (2) why it is needed.

SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu

All approved exceptions should be documented in the relevant IA report (*Annex I*) or evaluation SWD or fitness check report (*Annex on procedural information*) as well as the explanatory memorandum accompanying a Commission proposal.

⁴ See Tool #6 on *Planning and validation of initiatives*

TOOL #2. THE REGULATORY FITNESS PROGRAMME AND THE REFIT PLATFORM

1. WHAT IS THE REFIT PROGRAMME?

REFIT is the Commission's regulatory fitness and performance programme established in 2012 to ensure that EU law is 'fit for purpose'. It is a process under which existing legislation and measures are analysed to make sure that the benefits of EU law are reached at least cost for stakeholders, citizens and public administrations and that regulatory costs are reduced, whenever possible, without affecting the policy objectives pursued by the initiative in question.

2. WHAT IS A REFIT INITIATIVE?

In the context of its work programme for 2017, the Commission decided that all initiatives to change existing EU legislation should aim to simplify and deliver the policy objectives more efficiently (i.e. by reducing unnecessary regulatory costs). All initiatives to amend existing legislation are, therefore, included in the REFIT programme unless the lead DG can justify at the time of validation why no simplification or cost reduction is possible or until none is subsequently found in the preparatory work.

The key point is that services should always seek to identify opportunities to reduce regulatory costs and to simplify the existing legislation (including by digitisation) without negatively affecting the achievement of the underlying policy goals.

When services find no such opportunities, they should be able to justify why. When possibilities to simplify and reduce regulatory costs are identified, then the Commission has committed itself to quantify these benefits⁵. In cases where quantification is not feasible, a justification should be given.

These REFIT aspects will be a key consideration in the political validation of the initiative, when the Regulatory Scrutiny Board scrutinises impact assessments and when political approval to launch an interservice consultation is considered.

Practically, the following steps should be followed:

- All initiatives that envisage an amendment to existing legislation should have an entry in Decide planning and be validated politically (see Tool #6 on Planning and validation of initiatives). All such initiatives are presumed to be a part of the REFIT programme unless otherwise justified and accepted in the political validation process.
- The inception impact assessment (or the roadmap) should include an assessment of the potential to simplify and reduce regulatory costs without undermining the intended objectives of the legislation ("REFIT potential"). This will allow stakeholders to provide feedback on REFIT aspects.

⁵ See Tool #58 on the standard *Typology of costs and benefits* used in the Commission's approach on better regulation

- In the early phases of its work, the lead DG, together with support of the interservice group, should examine the "REFIT potential" on the basis of analytical work, consultation activities, use of external consultants etc. and quantify the potential simplification and cost savings.
- By the time of the request to launch the ISC, the lead DG should be able to:
 - Present quantified estimates of the potential to simplify and reduce unnecessary regulatory costs together with the measures that would be necessary to realise these benefits.
 - Explain any difficulties or obstacles relating to the quantification of reductions in regulatory costs or why it has not been possible to quantify these impacts.
 - **In cases where there no scope to simplify or reduce regulatory costs was identified**, the lead DG should justify why the initiative should no longer be considered a REFIT initiative;
- The REFIT-related work should be presented in the impact assessment report scrutinised by the RSB. Where no impact assessment is prepared, the REFIT-related work should be presented in the letter launching the interservice consultation.
- The explanatory memorandum should replicate/summarise the information above in the relevant sections. In addition, and wherever possible, a **burden reduction objective** for tackling unnecessary regulatory costs should be presented for the specific legislation (see COM(2017) 651). This objective should be based on the REFIT-related findings of the impact assessment and any earlier evaluation or fitness check (described above). This objective should be quantified wherever possible. The European Parliament and the Council are encouraged to take account of the burden reduction objective in their legislative work and by the Member States in respect of their transposition and implementation of the legislation at national level.

3. EVALUATIONS AND FITNESS CHECKS

Pursuant to the better regulation Guidelines, all evaluations and fitness checks should assess the performance of an existing intervention against the same five criteria of effectiveness, efficiency, relevance, coherence and EU added value. This means that all evaluations and fitness checks should systematically identify the costs associated with delivering the objectives of an intervention, assess their necessity and attempt to quantify them. There is no need, therefore, to promote or reinforce the "REFIT aspects" of any particular fitness check or evaluation by including it in the REFIT programme. To put it another way, all evaluations and fitness checks contribute to the REFIT programme but there is no need to attach the REFIT label to any individual evaluation or fitness check.

4. WHAT IS THE REFIT SCOREBOARD?

The Commission reports on the implementation of the REFIT programme through an annual scoreboard. This describes the state of play of each REFIT initiative including any follow-up on the opinions expressed by the REFIT Platform.

5. WHAT IS THE REFIT PLATFORM?

The Commission established the REFIT Platform in May 2015. The Platform brings together high-level experts from all Member States, from the European Economic and Social Committee and the Committee of the Regions and from business, social partners, and civil society appointed through an open and transparent process⁶. The Platform aims to identify unnecessarily complicated, costly or burdensome legislation and provides valuable inputs to the Commission's REFIT programme.

The Platform considers the concerns and suggestions raised by stakeholders, the Commission and/or Platform members and makes concrete suggestions to the Commission. The Commission has undertaken a political commitment to follow-up on all opinions of the REFIT Platform or explain why it cannot. The Commission will report periodically on the the Platform's activities.

The Secretariat-General involves all relevant Commission services in the work and discussions of the Platform and helps prepare the possible follow-up to the opinions agreed by the Platform.

⁶ See the REFIT Platform website for further information (http://ec.europa.eu/smart-regulation/refit/refit-platform/index_en.htm)

TOOL #3. ROLE OF THE REGULATORY SCRUTINY BOARD

1. WHAT IS THE REGULATORY SCRUTINY BOARD?

The Regulatory Scrutiny Board (RSB or Board) is an independent body within the Commission which scrutinises the quality of impact assessments, evaluations and fitness checks. The Board provides quality assurance to the political level of the Commission. It helps ensure that initiatives take into account all available evidence and stakeholders views before political decision makers consider what action to take, if any.

The RSB comprises a chairperson and six members. All seven are appointed by the Commission to serve full-time for a three-year non-renewable term. The chairperson and three members come from within the Commission services. The three remaining members are recruited from outside the Commission. The Board acts independently and prepares its opinions autonomously. It does not seek or take instructions from within the Commission, nor from any other national or EU institution, body, office or agency. All Board members act in their personal capacity. They share collective responsibility for the decisions of the Board.

The Board's rules of procedure cover its mandate and proceedings. The Board publishes its opinions on the Commission's website at the same time as the corresponding evaluation or impact assessment is published. It has also started to publish a list of all the draft reports that it has considered.

A Secretary to the RSB and a small team from the European Commission's Secretariat-General support the activities of the Board. This includes analytical and administrative support, such as planning and preparation of Board meetings, interactions with the services and associated follow-up.

2. SUBMISSION OF DOCUMENTS TO THE RSB

The RSB will scrutinise all impact assessments, all fitness checks and selected evaluations. The list of fitness checks and evaluations that the RSB wishes to scrutinise will be notified to DGs and services and made available on MyIntracomm⁷ early in each calendar year. The list is based on DG's evaluation planning, management plans and information in Decide and the Commissions' work programme. The RSB will normally issue an opinion on each impact assessment report, fitness check and evaluation staff working document it scrutinises.

Draft evaluations that are not selected for specific scrutiny by the RSB should nonetheless be submitted to the Board if, and when, the corresponding IA is submitted for scrutiny. In these cases, the RSB will issue a single opinion covering both the quality of the evaluation and the impact assessment.⁸ Where an evaluation is selected for scrutiny

⁷ https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/board.aspx

⁸ See Tool #52 on *Back-to-back evaluations*; where the evaluation SWD can also be integrated as an annex to the IA report (if the RSB has not selected the evaluation for scrutiny) and where the RSB will generally only issue a single opinion covering both the evaluation and IA elements in the report.

by the RSB, a separate opinion will be issued for it notwithstanding that it may have been prepared back-to-back with an impact assessment which will receive its own opinion.

Once the preparatory work has been completed, the draft IA report or the evaluation SWD or fitness check report should be submitted to the RSB for its quality check. The tables below summarise which documents need to be transmitted to the RSB.

Impact Assessments	
What?	• Note signed by the Director General of the lead DG addressed to the chair of the RSB. • Draft IA report (SWD). • IA summary sheet accompanying the IA report (SWD). • Minutes of the meeting of interservice group that has been preparing the IA report immediately prior to submission of the IA report to the RSB. • Links to where important underlying reports or studies can be found which underpin the IA report. • Underlying evaluation SWD, if this evaluation has not been scrutinised separately by the RSB.
When?	• The lead DG should reserve a slot at a future meeting of the RSB at which the IA report will be discussed. In general, the slot should be reserved at least 3 months before the RSB meeting. • This slot should reflect the envisaged timing of the political initiative, the time needed to adapt the IA report in light of the Board's opinion(s) and the time needed to complete a formal interservice consultation and formal adoption by the College. • The draft IA report should be submitted to the RSB at least 4 weeks before the RSB meeting where the draft IA report will be discussed. • In a few exceptional cases, the RSB may decide that the draft impact assessment report does not need to be discussed at a formal meeting of the Board but can be dealt with via written procedure. This can only be decided on a case-by-case basis once the draft IA report has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.
How?	• All correspondence about the reservation of slots should be sent to the functional mailbox: REGULATORY SCRUTINY BOARD@ec.europa.eu • Transmission of the draft IA report and associated documents should be via ARES. It is helpful if these documents are also sent to the RSB's functional mailbox with copies to the Head of Unit of the RSB's secretariat (SG-C2). SECEM can also be used for confidential or sensitive files. • All other questions and enquiries should be sent to the RSB's functional mail box.
Resubmissions	

	• Where the RSB issues a negative opinion, the lead DG will have to incorporate the Board's recommendations into a revised IA report, to discuss those changes with the ISG and to submit a revised report to the RSB. • The RSB will aim to issue a revised opinion within 4 weeks following resubmission. In most cases, the opinion will be issued following a written procedure. However, the RSB may wish to hear the lead DG again in a meeting. In such cases, the RSB secretariat will organise an appropriate slot in consultation with the lead DG.

Fitness checks and evaluations selected for scrutiny by the RSB	
What?	• Note signed by the Director General of the lead DG addressed to the Chair of the RSB. • Draft evaluation SWD/fitness check report (SWD). • Executive summary of the evaluation SWD or fitness check report. • Minutes of the meeting of interservice group that has been preparing the evaluation report immediately prior to submission of the draft evaluation report to the RSB. • Quality assessment discussed and agreed by the ISG. • Any report prepared by consultants (where relevant).
When?	• The lead DG should reserve a slot at a future meeting of the RSB at which the evaluation/fitness check report will be discussed. In general, the slot should be reserved at least 3 months before the RSB meeting. • In line with the "evaluate first" principle, the fitness check report or evaluation SWD should usually be reviewed by the RSB ahead of the submission of the corresponding impact assessment. • The draft evaluation/fitness check report should be submitted to the RSB at least 4 weeks before the RSB meeting that will discuss the draft evaluation SWD or fitness check report. • In a few exceptional cases, the RSB may decide that the draft evaluation report does not need to be discussed at a formal meeting of the Board but can be dealt with via written procedure. This can only be decided on a case-by-case basis once the draft evaluation SWD or fitness check report has been submitted to the RSB and will depend on the quality and lack of complexity of the case at hand.
How?	• All correspondence about the reservation of slots should be sent to the functional mailbox: REGULATORY SCRUTINY BOARD • Transmission of the draft evaluation/fitness check report and associated documents should be via ARES. It is helpful if these documents are also sent to the RSB's functional mailbox with copies to the Head of Unit of the RSB's secretariat (SG-C2). SECEM can also be used for confidential or sensitive files. • All other questions and enquiries should be sent to the RSB's functional

	mail box.
<i>Follow-up</i>	
	• The lead DG is expected to incorporate the Board's recommendations into a revised fitness check report or evaluation SWD and to discuss the changes with the relevant ISG. • A negative opinion does not prevent the launch of an interservice consultation on the fitness check report or evaluation SWD. However, the lead DG may wish to submit a revised SWD or report to the RSB. In such cases, the Board will aim to issue an opinion within 4 weeks usually by written procedure. In some cases, the lead DG may be invited to a meeting with the RSB which will be organised by the Board's secretariat in consultation with the lead DG.

3. QUALITY CHECKLISTS AND MEETINGS OF THE RSB

The secretariat to the RSB will send out a quality checklist⁹ to the lead DG at least 3 days ahead of the meeting scheduled to scrutinise the draft IA report or draft evaluation/fitness check SWD. In case of a written procedure, the DG will receive the quality checklist (to which the DG is expected to respond in writing) within the same timing. This checklist will present an initial assessment together with certain questions intended to guide the discussion during the RSB's meeting.

On a voluntary basis, the lead DG may submit additional information in response to the issues raised in the checklist at least one working day before the proposed meeting of the RSB.

The lead DG should communicate to the RSB (via the functional mailbox) who will represent the lead DG at the RSB's meeting. Except in cases of restricted RSB meetings, attendance is generally limited to 5 persons and it is recommended that somebody from the DG's internal better regulation support function also attend. The DG should be represented at the appropriate level (usually by a Director).

4. OPINIONS OF THE REGULATORY SCRUTINY BOARD

In principle, the RSB delivers its opinion within no later than 3 days following the relevant meeting. This is delivered in ARES but may be sent via SECEM in some cases to ensure confidentiality.

The RSB's opinions can be positive or negative for impact assessments (IAs), evaluations or fitness checks and the RSB will, in principle, issue a maximum of two opinions. For an impact assessment, a positive opinion is required before the interservice consultation (ISC) on the related proposal can be launched. While there is no formal need for a positive opinion to launch the ISC in the case of draft evaluation SWDs or fitness check reports, these are expected to be improved in line with the Board's recommendations (see below).

⁹ The checklist templates are available on the relevant better regulation GoPro and MyIntracomm pages.

- **Positive opinion:** The Board may issue two types of positive opinion:
 - A positive opinion which sets out recommendations for improvement. The author service should take due account of the Board's recommendations and introduce any adjustments before seeking approval for launching the ISC.
 - A positive opinion with reservations and required adjustments to address important deficiencies. The author service is obliged to take due account of the Board's recommendations and to introduce any required adjustments before seeking approval for launching the ISC.

The ISG should have the opportunity to consider the revised version of the report or evaluation SWD together with a draft of the underlying initiative/proposal (in the case of IAs) before the launch of the ISC. In any event, during the ISC the Secretariat-General pays special attention to the way IA reports and evaluation SWDs have been revised to reflect the Board's opinion and the way in which an IA report appropriately covers all relevant items of the draft initiative. The resulting considerations may be reflected in the response of the Secretariat-General during the ISC.

- **Negative opinion:** Such an opinion is issued when the RSB concludes that the report contains serious shortcomings and substantial improvements are needed on a number of significant issues.

In the case of an IA, the lead DG should improve the analysis significantly and submit a revised version of the report for a new opinion. If serious concerns persist, this second opinion may still be negative and will, in principle, be final. For evaluations and fitness checks, the lead DG may decide to submit a revised report or evaluation SWD to the Board for its scrutiny before seeking approval for launching the ISC but this is not mandatory.

For **Impact Assessments**, the RSB's opinion is published once the related initiative has been decided by the College. Where the College decides not to proceed with a given initiative, the IA supporting that decision may be published as well. It is best to consult the Secretariat-General in such circumstances as political authorisation may be necessary before publication takes place.

Where the Commission reports formally to the Legislator on an **evaluation**, the RSB's opinion will be published following adoption by the College of the report (COM document). In other cases, the opinions of the RSB will be published once the evaluation SWD or fitness check report has been cleared for publication by the services following a formal interservice consultation.

TOOL #4. EVIDENCE-BASED BETTER REGULATION

1. INTRODUCTION

Compiling a robust information or evidence base is an essential component of better policymaking. Evidence is needed both to evaluate existing interventions and to substantiate a need for new ones. Particular care needs to be taken regarding the credibility and transparency of evidence on which policy conclusions or recommendations rely upon. It is equally important to distinguish objective information from opinions which may be gathered through the stakeholder consultation.

Collecting evidence is a costly and time consuming activity. It is important to plan ahead to ensure that all necessary information will be available, bearing in mind the need to present as much quantitative information as possible. You should, therefore, use as broad range of evidence as possible, while ensuring its transparency and robustness.

2. ANTICIPATING THE EVIDENCE NEED - EVIDENCE MAPPING

The **evidence needs** should be identified early on. The lead DG should draw on the expertise of interservice steering group members to assist in the process. The first step should involve identifying existing **information sources** and their availability.

Evidence is collected, analysed and interpreted to create information that is suitable for decision-making:

Quantified data	• Defines. • Measurable information about quantities. • Can be mathematically verified. • Amenable to statistical manipulation.
Qualitative data	• Describes. • Characterisation by description of e.g. events, reasons, causes, effects. • Verification through e.g. peer-review, triangulation from multiple sources. • Clarity on underlying interest needed to ensure transparency and contextual comprehension.
Opinion	• Personal views.

In case of an agreed "back-to-back"¹⁰ approach the evidence mapping should identify the information and evidence requirements for the evaluation and impact assessment work.

Evidence mapping through desk research helps to determine what is already known and what new data/analysis could be required. Typically, it relies on a wide range of different

¹⁰ See Tool #52 on *"Back-to-Back" evaluations and impact assessments*.

sources such as previous reports (e.g. research, foresight, monitoring, and evaluation or impact assessment (IA) reports), studies, statistical publications, newspapers, magazine and journal content. The Commission library¹¹ provides officials with access to journals and academic publications. Information obtained through desk research is very often used to help design the course of the analysis and clarify key questions as well as to validate/sense-check the results of new analysis undertaken as part of the process.

If **information gaps** are identified, decisions need to be taken on whether and how to obtain the missing information in line with the principle of proportionate analysis. The reasons behind these decisions need to be explained in the IA report, fitness check report or evaluation SWD. The involvement of stakeholders needs to be considered and specified in the consultation strategy.¹² Requests for information into the stakeholder consultation should form part of the impact assessment or evaluation process.

3. FORESIGHT AND FORWARD-LOOKING TOOLS

Foresight and other forward-looking tools complement quantitative modelling with a system thinking and long-term approach that is developed through qualitative and participatory methods involving all relevant stakeholders. They facilitate thinking out-of-the-box. The objective is to engage with different possible futures (e.g. providing alternative futures) and challenge present assumptions thereby broadening the policy horizon. It creates an experimental and safe space to discuss, explore and assess the consequences of disruptive events and potential sources of radical change. Such forward-looking processes will help identify targets and new ways for policy interventions in a more systemic manner. It contributes to connect research and science activities to societal challenges by strengthening the engagement of stakeholders and citizens in policymaking. This will contribute to the resilience of the formulated policy initiative.

Developing and using system thinking and anticipatory intelligence may take place at a stage prior to impact assessment to identify topics or different options and relate them to their dynamic and changing context. These forward-looking tools bring a multidisciplinary dimension to policymaking allowing linkages across policy silos.

Foresight can play different functions in support to the policymaking cycle. Foresight tools and methods will enable problem analysis with a systems approach, facilitate interservice collaboration, and allow consideration of emerging challenges and trends in technology and society which could be otherwise overlooked. These approaches are well established in strategic planning practice, and are already in use within the Commission¹³ and the European Parliament¹⁴.

¹¹ <https://myintracomm.ec.europa.eu/corp/cl/EN/Pages/index.aspx>

¹² See Tool #53 *The stakeholder consultation strategy*.

¹³ L 347/974 http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/sp/h2020-sp_en.pdf; European forum on forward looking activities – EFFLA, Policy Brief N° 14, Towards standards in Forward Looking Activities for the EC http://ec.europa.eu/research/innovation-union/pdf/expert-groups/effla-reports/effla_pb_14_-_towards_a_foresight_standard.pdf

An important source of anticipatory intelligence is the review of existing forward-looking material produced by specialised agencies, think-tanks and research groups. Scanning initiatives, for example making use of big data, opens up new sources of information.

There are four main functions and benefits of applying foresight to policymaking as illustrated in the table below. Foresight can **inform policy** by generating insights regarding the dynamics of change, future challenges and options that can be used as an input to policy conceptualisation and design. A second function is to **facilitate policy implementation** by enhancing the capacity for change within a given policy field by building a common awareness on future challenges, as well as facilitating new networks and visions amongst stakeholders. A third function is related to **embedding participation in the policymaking** process by facilitating the participation of civil society. Finally, foresight can **support policy definition** as it translates outcomes from the collective process into specific options for policy definition and implementation. All these functions contribute to reconfiguring the policy system in a way that makes it more apt to address long-term challenges.

Function	Outcome	Benefit for policy
Informing policy	Understanding of change Visions of change	Long-term orientation Additional source for information (based on a broad variety of views) Awareness of future challenges
Facilitating policy implementation	Networks, shared visions	Better receptivity of actors for policy objectives due to ownership of results therefore easier implementation
Embedding participation in policymaking	Transparency of policymaking process	Better identification of citizens with policy (legitimacy)
Supporting policy definition	Generation of strategic options together with policymakers	Direct support in strategy development and implementation

4. TRANSPARENCY AND ROBUSTNESS

The author service and interservice steering group should constantly check the quality of the work being undertaken, ensuring that it is evidence-based and free from bias. Thorough, robust and reliable research, data collection and analysis are core activities when conducting an assessment and drawing the conclusions. Any limitations to the method applied or the data collected should be clearly discussed over the course of the assessment, addressed where possible and reported in the final report.

It is important that data are of sound quality, reflect reality and are representative. However, not all data are equally robust and it is therefore important to consider how the data were collected and whether there is any associated uncertainty. Gathered data may

¹⁴ The European Parliament has created a Unit on 'Scientific Foresight' to ensure that the knowledge generated through foresight projects and processes is adequately communicated to MEPs.

be biased, incomplete or suffer from other imperfections – all of which need to be taken into account when drawing conclusions. *Prima facie*, data from accredited sources such as national or international statistical offices or agencies can be used with greater confidence than data from non peer-reviewed literature or from interested stakeholders.

For reasons of transparency and credibility, the sources of all data used should be cited in the relevant IA report, evaluation SWD or fitness check report, if and how it was validated, and what the uncertainties and diverging views are (if any), clarifying the level of consensus among experts or the scientific community regarding the issue at hand. In addition, where data or other information has been provided by outside parties, but is not used, the relevant SWD or report should explain the reasons why. Publication of non-confidential data in an easily accessible format facilitates peer reviewing and enhances the transparency of analysis.

The specification of models, methods and underlying assumptions has a crucial impact on the outcome of the analysis and thus on the quality of the evidence base. Data sets should ideally be analysed using different methods – this helps to avoid a one-sided approach and a biased end result. A separate tool has been developed in connection with the use of models and the need to consider quality assurance and uncertainty¹⁵ which may also be relevant for some aspects of evaluation.

Peer review methods are often used to maintain quality standards and provide credibility, for instance, to determine an academic paper's suitability for publication. Triangulation can also facilitate validation of data through cross verification from two or more sources. In particular, it refers to the application and combination of several research methodologies in the study of the same phenomenon. It enhances confidence in results if different methods lead to the same result. If they point to different conclusions, you should consider and report on the reasons behind these differences.

As regards expertise, three determinants of quality of advice can be distinguished: excellence; the extent to which experts act in an independent manner; and pluralism.¹⁶ The assembled expertise sufficiently covers the topics to be addressed, any direct or indirect interest in the issue at stake has been declared and addressed, and both mainstream and divergent views are included.

When using evidence gathered through stakeholder consultation, the specific interest of stakeholders providing the information should be borne in mind. Attempts should be made to validate the robustness of the results and to double-check against the arguments of other stakeholder groups. Peer-reviewing or benchmarking with information from independent third parties, official statistics or other surveys/studies can significantly enhance the quality of such information. The same applies to information gathered via expert groups consisting of stakeholder representatives, organisations and Member States' authorities. On the other hand, when using models, further confirmation should also be sought e.g. by asking stakeholders in how far and why the results make sense to them. Where information from stakeholders is used as the main evidence to support specific conclusions (for instance, where other data is not available), the methods used to

¹⁵ See Tool #62 on *The use of analytical models and methods in IA or evaluation*.

¹⁶ COM(2002) 713 final

acquire such information should be robust and comprehensive. A specific tool has been developed on the analysis of data/information received through the consultation of stakeholders.¹⁷

On the one hand, it is important to encourage good qualitative and quantitative data collection and analysis. On the other hand, the emphasis should be on the careful interpretation of all types of data and analysis, comparing how information from different sources is complementary or contradictory. Collecting reliable and robust evidence is not simply about including more quantitative or qualitative data in the report; it is about allowing policymakers to make well-informed decisions.

In addition, the emergence of Big Data¹⁸ and data analytics in the landscape of scientific analysis should be considered. Open data policies as well as digital data coming from the every day's use of information and communication technology devices have created new possibilities for analysis, in particular in social sciences and economics.

5. INFORMATION SOURCES AND PROVIDERS

The different types of evidence stated above can be obtained from multiple sources listed below.

Evaluations
The Commission is committed to the "evaluate first" principle. This means that existing policies and legislation should be evaluated objectively before any revision is contemplated. Such evaluations may cover multiple policy instruments in a particular policy field (fitness checks¹⁹) where interactions between instruments can be explored and assessed. Information used in evaluations may come from monitoring systems, expert sources such as Member State competent authorities or from regulated entities or consultancy studies contracted out by the Commission. In addition it can be helpful to look for evaluation being carried out in Member States as well as to see what issues Member States have been dealing with when implementing new measures. Experience of third countries should also be taken into account where relevant.
Data and statistics providers
Information may come from public organisations who maintain statistical information. Data may equally be provided by private organisations such as consultants, trade associations or commercial databases. Lead services should have a good knowledge of the available sources (and their reliability) for their specific area of responsibility. The tools in this guidance provide

¹⁷ See Tool #54 on *Conducting the consultation activities and data analysis*.

¹⁸ Big data is a broad term for data sets so large or complex that traditional data processing applications are inadequate. Challenges include analysis, capture, search, sharing, storage, transfer, visualisation, and information privacy. Analysis of data sets can find new correlations, to "spot business trends, prevent diseases, combat crime and so on.

¹⁹ http://ec.europa.eu/smart-regulation/evaluation/docs/fitness_checks_2012_en.pdf

links to data sources relevant for their specific types of impacts.

Eurostat²⁰ is the statistical office of the European Union and provides statistics at European level (from data collected by statistical authorities of Member States) using harmonised methodologies that enable comparisons between countries and regions. Eurostat provides free access to an online statistics database and publications.

Eurobarometer²¹ monitors public opinion in Member States and provides results representative of the targeted populations on major topics (e.g. enlargement, social situation, health, culture, environment, information technology the Euro, defence, etc.) You can request a Eurobarometer survey in the context of DG COMM's annual programming²² depending on the Commission's priorities.

The Joint Research Centre (JRC) is the European Commission's in-house science service which collects and analyses data and operates models to provide sound scientific advice.

Open Data portals facilitate free access to and reuse of public sector produced information. The **EU Open Data Portal**²³ is a single point of access to a range of data produced by the institutions, agencies and other bodies of the EU. Some countries and regions have their own public data portals. In addition, the EU strategy of Open Access²⁴ provides free access to EU-funded research results, including scientific publications and research data. The EU Bookshop publishes studies prepared by the EU institutions.²⁵

Many **international organisations and institutions** compile useful statistics and reports about energy, environment, agriculture, trade etc. A few relevant examples are given below:

- United Nations: <http://data.un.org>
- Organisation for Economic Co-operation and Development: <http://stats.oecd.org/>
- International Energy Agency: www.iea.org
- World Trade Organization: www.wto.org
- World Bank: <http://data.worldbank.org>
- International Monetary Fund: www.imf.org
- International Labour Organisation: www.ilo.org

Trade associations also often collect and collate information which is specific to a particular economic sector. For example:

- EU oil industry (Fuels Europe): www.fuelseurope.eu

²⁰ <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>

²¹ http://ec.europa.eu/public_opinion/index_en.htm

²² <https://myintracomm.ec.europa.eu/corp/comm/AtAGlance/Pages/Eurobarometer.aspx> .

²³ <http://open-data.europa.eu/en/data/>

²⁴ <https://www.openaire.eu/search/find>

²⁵ <https://bookshop.europa.eu/en/home/>

- European car manufacturers (ACEA): www.acea.be
- European Steel Association (EUROFER): www.eurofer.org
- Farming/agri-business (COPA COGECA): <http://www.copa-cogeca.be>
- Commercial data banks can be consulted against a fee and should therefore be budgeted for.

Experts

The Commission frequently calls on external specialists to provide input. Expertise can be obtained in different ways, e.g. through expert groups or external consultants.

Expert groups²⁶ composed of individuals appointed in their personal capacity are a prime source of expertise for gathering evidence. Expert groups consisting of stakeholder representatives, organisations or Member States' authorities can bring information regarding practical experience in a given policy area. They also represent specific interests, which need to be well accounted for.

Expert groups do not make binding decisions, but may formulate opinions and recommendations or submit reports. Details about all expert groups can be found on a dedicated public register²⁷ which ensures transparency about group composition and interests. When creating and operating an expert group (or similar entities) you should follow the dedicated guidance²⁸. More widely, a set of principles and guidelines²⁹ apply whenever Commission departments collect and use external expertise.

Scientific experts: The prime sources of scientific evidence are permanent bodies at EU level that have been established with the purpose of providing robust and reliable expertise in the policy areas of their mandates: Decentralised EU Agencies (such as EFSA, ECHA, EMA, ECDC, EASA), scientific committees set up by the Commission (such as SCENIHR), and the Joint Research Centre. The selection procedures and working methods of these bodies guarantee a high level and a broad range of expertise, prevention of conflicts of interest and transparency, including as regards to any persisting uncertainty and divergent views.³⁰

You may also use available Commission online tools for the collection of expertise such as **SINAPSE**³¹ which enables the creation of e-communities, as communication platforms that facilitate the involvement of external experts in the process.

Consultants can provide input into but cannot replace the Commission's assessment. The lead DG and the ISG should work closely with the consultant to ensure that the results are of sufficient quality and that they can be used accordingly.

²⁶ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2>

²⁷ <http://ec.europa.eu/transparency/regexpert/>

²⁸ C(2010) 7649 final, SEC(2010) 1360 final

²⁹ C(2002) 713

³⁰ For more information on expertise in the context of risk assessment, please see the Tool #15 on *Risk assessment and management*.

³¹ <http://europa.eu/sinapse/>

Stakeholders

Besides collecting views, stakeholder consultation can be also used for **collecting information** (e.g. data, lessons from implementation). However, you need to *verify* that the consultation method you use is appropriate for collecting the required type of information³². When using evidence gathered through consultation bear in mind the specific interest of stakeholders providing you with the information and try to validate the robustness of the results. Peer-reviewing or benchmarking with other surveys/studies or consultation activities can significantly enhance the quality of such information.

³² See Tools #53, #54 and #55 on stakeholder consultation.

TOOL #5. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

1. INTRODUCTION & LEGAL BASIS

The Union can only act in areas where the Treaties confer competence. In addition, all Union actions are governed by the overarching principles of subsidiarity and proportionality³³. These principles are important. In areas not falling under its exclusive competence, the Union should only act where the principle of subsidiarity is respected. In all cases, Union actions should be restricted to what is necessary to achieve the objectives defined in the Treaties. Non-compliance with the principles of subsidiarity and proportionality may be used as a reason to challenge the lawfulness of Union acts before the Union's courts. In addition, national Parliaments have a specific role in scrutinising the Commission's respect of the subsidiarity principle³⁴. The impact assessment (IA) report should, therefore, set out **qualitative and quantitative information** to support the case for EU level action.

The IA report should describe the appropriate legal basis for action derived from the Treaty. For IAs, the choice of legal basis must be based upon the nature of the main/predominant objective and content (e.g. health, environment, internal market, etc.).

Box 1. Choice of the internal market legal base

- The internal market legal basis is commonly used as a legal basis for EU initiatives. You should be aware that its use has been criticised by some stakeholders who argue that alternative legal bases are more appropriate (health, environment etc.);
- Measures adopted on the basis of Article 114 of the Treaty of the Functioning of the European Union (TFEU) should genuinely aim to improve the conditions for the establishment and functioning of the internal market. Mere disparities between national rules and an abstract risk of future obstacles to trade or a distortion of competition are not sufficient. Action may be justified to prevent the likely emergence of such obstacles and the elimination of appreciable distortions of competition³⁵;
- The nature of the particular market should, therefore, be characterised in terms of the market participants, the extent of cross-border trade, presence/market share of companies from other Member States, territorial restraints on trade, share of foreign workers, ease of cross-border purchasing, rules related to the use/movement of capital, etc.;
- In addition, how big are the obstacles and barriers to the free movement of people, goods, services and capital? How many actors are affected in how many Member States? What are the additional costs of complying with different national rules assuming a person or business wants to operate in more than one Member State?

³³ Article 5(1) of the Treaty on European Union.

³⁴ Protocol No 2 of the TFEU on the application of the principles of subsidiarity and proportionality.

³⁵ Case C-376/98 *Federal Republic of Germany v European Parliament and the Council of the European Union*, para 84.

2. SUBSIDIARITY

The principle of subsidiarity aims to ensure that policy measures not falling under the exclusive competence of the Union are decided at a level which is as close as possible to the citizen and at Union level only where necessary.

An analysis of EU added value is also important when evaluating existing interventions. In relation to evaluation, it is often difficult to identify what the situation would be like in the absence of the EU intervention, although useful reference may be made to the baseline scenario from a previous IA. In evaluation, the EU added value questions are the flip side of the impact assessment subsidiarity analysis – looking to draw conclusions on the actual added value from EU action over and above that which could have been achieved by the Member States.

Box 2. Why a good analysis of subsidiarity is important

The Commission is bound by Protocol No 2 of the TFEU to review (and subsequently to maintain, amend, or withdraw) any proposal it makes where a sufficient number of reasoned opinions are received from national Parliaments regarding the non-respect of the principle of subsidiarity (i.e. more than one third of the 56 votes allocated to national Parliaments or one quarter in the of field freedom, security and justice on the basis of Article 76 TFEU).

The subsidiarity principle does not apply in areas where the Union has exclusive competence such as commercial policy or competition (see Article 3 TFEU). In addition, in other areas it is exceptionally considered that the Union has an exclusive competence “by nature”. These are budgetary and institutional matters where it is clear that only the Union can, or even has to act, and where the action of the Member States is not possible (e.g. the draft budget, own resources, the multiannual financial framework regulation, while the individual MFF programmes follow their particular legal bases, the citizens' initiative, the comitology regulation, rules on access to documents of the EU institutions and bodies, data protection rules for the institutions, establishment of a European Voluntary Humanitarian Aid Corps, codifications of existing legislation).³⁶

In other areas, and where competence has been conferred on the Union, subsidiarity means that the Union should only act:

- **If, and in so far as, the objective of the action cannot be achieved sufficiently by the Member States (at national, regional and local levels); but can rather**
- **be better achieved at Union level by reason of the scale or effects of the proposed action.**

Subsidiarity should be assessed at an early stage of the IA process and as part of the EU added value assessment in an evaluation or fitness check. It should complement the problem definition section of an IA report which should establish the "EU relevance" of the problem (for an IA) or the intervention (for an evaluation) which should be described and quantified as far as possible.

³⁶ Internal practical guidelines on the implementation of Protocol 2 on the application of the principles of subsidiarity and proportionality (Ref. Ares (2013)1752339, of 5 June 2013), p. 6.

Subsidiarity needs to be verified for both legislative and non-legislative initiatives. The emphasis of the analysis should be to assess whether or not action at the national level is/would have been sufficient to achieve the objective of the initiative and whether in consequence, by reason of the scale or effects of the proposed measure, Union action would have an added value compared to action by the Member States.

The following steps can help when assessing subsidiarity:

I. Verify whether the Union has exclusive competences or not	
Question	Does the legal basis (action under consideration) fall within one of the areas where the Treaty gives the Union exclusive competence (as defined by Article 3 of the TFEU) or is it an exclusive competence by its nature (i.e. where only the Union can/must act; see below in the section on relevant issues)?
If yes	State in the report that the subsidiarity principle is being respected (for example: "Trade policy and the negotiation of international trade agreements are areas of exclusive EU competence pursuant to Article 207 of the Treaty and therefore the subsidiarity principle does not apply").
If no	move to step II and III below
Relevant issues	The point of departure is shared competence. Exclusive competence applies in the areas defined in Article 3 of the TFEU. In addition, the Commission takes the view that in exceptional cases, certain legislative acts can be considered as falling under exclusive competence by their nature. These mainly concern budgetary and institutional matters where it is clear that only the Union can (or even must) act such as the draft budget, own resources, the multiannual financial framework regulation, the European Citizens' Initiative, the Comitology Regulation, Rules on access to documents of the EU institutions, data protection rules, the establishment of a voluntary humanitarian aid corps. Codification of Union law is an exclusive competence whilst recast is not and it is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism.

II. Perform the necessity/relevance test	
Question	Can/have the objectives of the (proposed) action be(en) achieved sufficiently by Member States acting alone?
Relevant issues	A key part of the analysis should be to qualify the "Union relevance" of the initiative being considered. The greater the relevance the more likely Member State action alone will/would have be(en) insufficient. Key issues/questions to consider are: • How does the problem (e.g. negative externalities) vary across the national, regional and local levels of the EU? • Is the problem widespread across the EU or limited to a few Member States? • Does the problem have the same or different underlying cause across the EU?

	• How do the views/preferred courses of action of national, regional and local authorities differ across the EU? • To what extent do Member States have the ability or possibility to enact appropriate measures? • Would national action or the absence of EU level action conflict with the Treaty or significantly damage the interests of other Member States? • Are there transnational/cross-border aspects to the problem? Have these been quantified? • Will there be increased costs or problems if action is left only to the Member States?
If yes	Union action in the area cannot be justified. In the context of IAs, the initiative under consideration should be abandoned or refocused as appropriate. In the context of evaluations, the recommendation should clearly stipulate that EU intervention can no longer be justified.
If no	Illustrate the specific limits of Member States' action, their underlying drivers, and why they would/have not be(en) "sufficient". Move to next step.
Examples	Relevant situations could involve cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital, or common challenges (such as migration) or serious risks that could affect large parts of the Union (e.g. pan-epidemic health risks).

III. Perform the EU added value test

Question	Can/have the objectives of the proposed action be(en) better achieved at Union level by reason of the scale or effects of that action?
Relevant issues	Key issues/questions to consider are: • Are there clear benefits from EU level action? • Are there economies of scale? Can the objectives be met more efficiently at EU level? • Are there benefits in replacing different national policies and rules with a more homogenous policy approach? • Will the functioning of the internal market be improved? If so, how will it be improved?³⁷
If yes	Explain why for the case at hand, explicitly describing both the advantages and the disadvantages that Union action may have relative to Member States action.

³⁷ It is insufficient merely to find differences between national laws. There must be more than an abstract risk that such differences could present an impediment to the exercise of the fundamental freedoms.

	The principle of subsidiarity is complied with.
If no	Union action in the area would not be justified on the basis of subsidiarity. In the context of IA, the initiative under consideration should be abandoned or refocused as needed. In an evaluation this may lead to a recommendation to consider modifying the scope or stopping the intervention.
Examples	Situations where EU action produces clear benefits compared to action at Member State level by reason of its scale or its effectiveness or efficiency. Equivalent legal rights for individuals and business can ensure equity and remove distortions of competition.

Assessing subsidiarity is not always a black and white case as evidence may not univocally point in one direction. It is therefore important to **gather stakeholders' views**. When presenting the assessment in the IA/evaluation, **general statements and circular reasoning should be avoided** in favour of concrete arguments specific to the issues being analysed. Points should be substantiated with qualitative, and where possible, quantitative evidence³⁸.

National Parliaments and the Committee of the Regions have rights and powers to monitor the application of the principle of subsidiarity and they will critically examine any related analysis provided by the Commission alongside its proposals.

Don't just say:	Explain that:
The subsidiarity principle is respected because the initiative's objectives cannot/could not be achieved sufficiently by Member States.	Action by Member States could not solve the problem for the following reasons (e.g. spill-over effects, insufficient scale of the project...)
EU action is/has been necessary to level the playing field	Only EU action could eliminate the costs (of up to €X on average) that EU enterprises incur to apply for additional authorisations in every EU host country they wish to operate in.
EU action is/has been needed to avoid the fragmentation of the internal market	EU action is needed to eliminate the following obstacles faced by producers to enter into other national markets.... As shown in the problem section, this is estimated to...
EU action is/has been needed due to the strong diversity of policies/practices across Member States.	The negative consequences resulting from diverse/non-harmonised policies/practices lead to significant market entry obstacles, such as higher establishment costs amounting up to.....

³⁸ To be referred to rather than repeated if already presented in the problem analysis.

Box 3. Illustrative examples of qualitative subsidiarity analyses³⁹

- Portability of digital on-line content: SWD(2015) 270 (section 3, page 19).
- Emissions from non-road mobile machinery: SWD(2014) 282 (section 3.5, page 16).
- Protective measures against plant pests: SWD(2013) 169 (section 2.6, page 21).
- Indices/benchmarks in financial instruments and transactions: SWD(2013) 316 (section 6, page 18).

3. PROPORTIONALITY

The content and form of Union action must not go beyond what is necessary to meet the objectives of the Treaties⁴⁰. Respect for the principle of proportionality is about ensuring that the policy approach and its intensity match the identified problem/objective. Proportionality should be clearly referred to in the SWDs reporting the results of the IA⁴¹, evaluation or fitness check.

The following questions should help in assessing whether a measure adheres to the principle of proportionality:

- Does the initiative go beyond what is necessary to achieve the problem/objective satisfactorily?
- Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)
- Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?
- Does the initiative create unjustified financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
- Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?
- Is there a solid justification for the choice of instrument - regulation, (framework) directive, or alternative regulatory methods?
- While respecting Union law, are special circumstances applying in individual Member States taken into account?

³⁹ http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2016_en.htm

⁴⁰ Article 5(4) of the Treaty on European Union.

⁴¹ In the context of IA, proportionality is a key criterion to consider in the comparison of the policy options.

Case law examples of disproportionate/proportionate measures	
<i>Fedesa</i> ⁴²	The prohibition on the use of hormones in livestock rearing was proportionate because other measures (such as consumer information) would have been less effective in relation to the objective of ensuring public health. This objective was also sufficiently important to outweigh the economic impacts on the livestock industry.
<i>ABNA</i> ⁴³	Union legislation was adopted which concerned making information available about the content of animal feed so that contaminated ingredients could be identified more rapidly. However, the requirement that producers of animal feed provide the precise composition of feedstuffs to customers was disproportionate in relation to this objective as it needlessly infringed the economic interests of feed manufacturers (who wanted to safeguard secret feed formulations) who were already obliged to indicate the ranges of composition of each ingredient on labels attached to the animal feed they sold.
<i>Affish</i> ⁴⁴	An EU Decision to ban the import of Japanese fish into the EU was challenged for being disproportionate in relation to public health objectives. Not all Japanese fish factories had hygiene problems but because it was not practical to check the hygiene standards of all Japanese fish factories and because a representative sample had been checked, it was deemed proportionate to ban all imports of Japanese fish.
<i>Swedish Match</i> ⁴⁵	The prohibition of tobacco for oral use in Union legislation was proportionate notwithstanding intellectual property rights and the right to pursue a trade or profession in the EU. The objective of public health protection and the lack of alternative effective measures justified the ban's proportionate nature.
<i>Cotton Support</i> ⁴⁶	The reform of the cotton support scheme under the Common Agriculture Policy reduced direct support by 65% (but complemented by an additional crop-independent single farm payment). This was deemed to be manifestly disproportionate in respect of the objective of maintaining cotton production because the Council had not considered employment costs of cotton production or the economic impacts on cotton "ginning" undertakings when exercising its discretion.
<i>Kadi</i> ⁴⁷	Council Regulation (EC) No 881/2002 imposed certain anti-terrorism measures (assets freeze) against certain persons. These measures represented a disproportionate interference with the right to property because there were no procedural safeguards enabling the affected persons to have their case heard by national authorities.

⁴² [C-331/88 Queen, v Minister of Agriculture, Fisheries and Food and Secretary State for Health ex. Parte Fedesa et al. \[1990\] ECR I-4023.](#)

⁴³ [Joined cases C-453/03, C-11/04, C-12/04 and C-194/04; ABNA Ltd and Others v Secretary of State for Health and Others \[2005\] ECR I-10423;](#)

⁴⁴ C-183/95 *Affish BV v Rijksdienst voor de Keuring van Vee en Vlees* [1997] ECR I-4315

⁴⁵ [C-210/03 Swedish Match AB and Swedish Match UK Ltd \[2004\] ECR I-11893](#)

⁴⁶ [C-310/04 Spain v Council \(Cotton support scheme\) \[2006\] ECR I-7285](#)

⁴⁷ [Joined Cases C-402/05 and C-415/05 Yassin Kadi and Al Barakaat International Foundation v Council and Commission \[2008\] ECR I-6351](#)

TOOL #6. PLANNING AND VALIDATION OF INITIATIVES

1. INTRODUCTION

Each new initiative (including evaluation work) must have a separate planning entry in Decide⁴⁸ and **must receive political validation at the appropriate political level *before*** new substantive work can start and before publishing a roadmap or inception impact assessment, launching stakeholder consultation activities or conducting an interservice consultation.

Initiatives handled within Decide – these are generally called 'corporate' items - are classified into "**major**" and "**other**" (see below). In addition, some routine activities are handled completely outside of Decide by the lead DG. The requirements on inclusion in Decide as well as the necessary level and applicable process of political validation process varies according to the type of initiative and is described in detail in GoPro and on the Secretariat-General's planning website⁴⁹.

Generally speaking, 'major' initiatives are those with the greatest political significance and greatest potential impacts and which require, therefore, corporate validation beyond that of the lead Commissioner. However, there is no single rule or criterion to apply when classifying an initiative. Several factors need to be assessed in conjunction:

- *The character of the foreseen act (legislative or not).* If the initiative is of legislative character it has to be considered as 'major' (both new proposals and revisions);
- *The policy content.* If the initiative formulates policy choices or takes a policy stance and is addressed to the other institutions (thus committing the Commission), then it should be considered as 'major';
- *The expected impacts.* Any initiative subject to a formal impact assessment needs to be considered as 'major' (irrespective of the type of act/instrument);
- *The political importance/sensitivity of the initiative and its subject matter.* Any important or sensitive Commission initiative has to be considered as 'major' (irrespective of the type of act/instrument) (see more on sensitivity below).

This implies that as a general rule legislative proposals are major initiatives by default whereas for non-legislative initiatives the form is not the determining factor as the policy content and/or sensitivity and/or significant impacts can turn an otherwise 'other' initiative into 'major' (e.g. a delegated/implementing act subject to an impact assessment, a report taking an active policy stance or addressing a sensitive subject area, etc.)

Overall, the type of act/instrument is, therefore, the primary criterion to take into account. Accordingly, legislative initiatives and policy documents (such as Communications and

⁴⁸ Decide is the IT tool for managing the Commission's decision-making process: https://intragate.ec.europa.eu/decide/sep/entrance?Newt_v3.2.0.11040-2017-02-27T16:29:32.962+01:00#/welcome-screen/

⁴⁹ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY>; and <https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

Green and White Papers) addressed to the other EU Institutions should *always be considered as major initiatives*. For other types of acts/instruments - and in particular for delegated and implementing acts - the classification 'major' vs 'other' depends on the content/nature (policy, impacts, sensitivity) of the concrete initiative and it has to be *assessed on a case-by-case basis*.

Ultimately, the lead DG should consider whether there is a justified need for a corporate validation, beyond the level of the lead DG and its responsible Commissioner.

Political sensitivity means that the initiative is likely to provoke a great degree of public attention (and possibly adverse reactions) in the EU institutions and beyond. Such sensitivity needs to be signalled through the dedicated 'political scrutiny' box in Decide, and this is particularly relevant for delegated and implementing acts. Where the sensitivity is only recognised later after validation, the check box in Decide still needs to be ticked as this will activate a change in the required political validation at the (interservice) "Consultation" stage; the related interservice consultation will need to be authorised at three levels: Commissioner, Vice-President and the First Vice-President even if the initiative was validated as 'other' in Planning.

In case of doubt the SG Panning Team should be contacted for advice.

Initiatives which receive political validation ('major' or 'other') appear automatically in 'planned' status in Decide. Initiatives which are not (yet) validated – be they 'major' or 'other' – should not be subject to interservice consultations; a systematic check is carried out via Decide.

In case an initiative submitted is not granted political validation, this negative decision of the Commissioner/Vice-President/First Vice-President is shared with the lead DG via Decide, with an explanation of the main reasons and clarification on whether the initiative can be resubmitted at a later stage/more appropriate moment or with a revised content. Accordingly, the lead DG can decide to rework and resubmit the initiative or to cancel it.

The lead DG is responsible to ensure regular updating / correcting of the main parameters of its initiatives. This is essential as Decide tracks the complete lifecycle of an initiative and is also used to report internally and externally on the status and the main elements of Commission initiatives under preparation.

In case of a change that fundamentally alters the type, nature or the scope of the initiative this might require a new validation. In some cases this might imply the need for a re-classification of an initiative originally introduced as 'other' into 'major' and thus lead to the need for a new and different political validation cycle. However, if these changes have been decided closely before or during the interservice consultation, they have to be assessed and confirmed as part of this consultation and not via a new validation in Decide Planning.

2. KEY PLANNING AND VALIDATION STEPS BY TYPE OF INITIATIVE

"Major" initiatives	
Which acts?	- Legislative proposals, including amendments, updates and revisions - Recommendations for the opening of negotiations of international agreements (negotiating mandates).

	• Policy Communications or other policy documents addressed to the other institutions • Any Commission initiative that is sensitive or politically important • Any Commission initiative subject to a formal impact assessment
Decide entry?	Mandatory (at least 12 months prior to envisaged adoption date)
Political validation by	Commissioner(s), VP(s) and the First VP, in close cooperation with President's Cabinet
Roadmap or Inception IA needed?	Mandatory
ISG required	Yes (chaired by lead DG or the SG for important/sensitive cases) N.B. Substantive work of the ISG commences only after the initiative is validated.
Exceptions from better regulation requirements	Any desired exception from the better regulation guidelines should be signalled at the validation stage in Decide so that this can be considered during the validation process. Requests for exceptions which arise after validation can be addressed to the relevant functional mailbox in Tool #1(Principles, Procedures & Exceptions).
Tips for making entries in Decide	• The lead DG creates a new planning entry in Decide [selecting corporate/new/major as type of initiative] by completing the required information fields for the initiative in question. These fields include: – The main procedural elements such as legal base, type of act, CWP item or not, foreseen adoption date, etc.; – The following key aspects 'Short description and objectives', 'Problem definition / Context', 'Subsidiarity/Added value', 'Better Regulation Tools'. This information has to be concise (max 4000 characters for each category) but sufficiently detailed and clear to facilitate a meaningful decision on validation. • The lead DG is responsible for updating the planning entry if an important element changes. If the change alters the type, nature or the scope of the initiative the SG needs to re-assess and decide if the initiative has to undergo a new validation cycle.

"Other" initiatives (excluding evaluations and fitness checks)	
Which acts?	• Routine delegated and implementing acts not having significant impacts • Commission reports addressed to other institutions (including those presenting the outcome of evaluations or fitness checks) • Recommendations for the signature/conclusion of international agreements.
Decide entry?	Mandatory (at least 3 months prior to the envisaged date of adoption)
Political validation by	Commissioner
Roadmap/ Inception IA needed?	Not required
ISG required	No
Exceptions from better regulation requirements	Any desired exception from the better regulation guidelines should be addressed to the relevant functional mailbox in Tool #1 (Principles, Procedures & Exceptions).
Tips for making entries in Decide	• The lead DG creates a new planning entry in Decide [selecting corporate/new/other as type of initiative] and explains – via a dedicated field under 'general information' – why this initiative does not need to be considered

	as a "major" initiative (e.g. no significant impacts, not politically sensitive, etc.). • The main procedural elements have to be indicated in Decide: type of act, legal base, foreseen adoption date, etc. • In all cases where an "other" initiative is reclassified as "major" – following the SG's assessment or reflecting fundamental changes in the preparatory process - a new Decide entry needs to be created and it has to be resubmitted following the 'major' validation workflow.

Evaluations & fitness checks ⁵⁰	
Which acts?	Evaluations and fitness checks
Decide entry?	Mandatory (at least 12 months prior to the envisaged completion of the evaluation)
Political validation by	Director-General through the Management Plan endorsement
Roadmap needed?	Mandatory
ISG required	Yes N.B. ISG can only be launched once the initiative is validated.
Exceptions from better regulation requirements	Any desired exception from the better regulation Guidelines should be addressed to the relevant functional mailbox in Tool #1 (Principles, procedures & exceptions). Exceptions should be agreed before publication of the roadmap.
Tips for making entries in Decide	• The lead DG creates a new planning entry in Decide [selecting corporate/evaluation/other as type of initiative]. "Evaluation" has to appear explicitly also in the title of the initiative. • If the evaluation SWD is accompanied by a Commission report to the other Institutions, the report needs to be validated as part of a single evaluation entry. • In particular cases the evaluation entry can be merged into (and thus appear as) a "back-to-back" entry also covering the ensuing legislative proposal (IA). • The main procedural elements have to be indicated in Decide: type of act, legal base, foreseen completion date, etc.

DG internal work plan (handling outside Decide)	
Which acts?	<i>(non exhaustive list for illustration)</i> • Commission decisions of administrative and routine nature • Intermediate legislative acts, e.g. modified Commission proposals, Opinions on Council common positions • Financing decision

⁵⁰ Evaluations or fitness checks are to be considered "non-major" as a general rule. They should be introduced and validated as 'major' initiatives *in the rare and specific case* where the evaluation SWD is accompanied by a Commission Communication which is addressed to the other Institutions and which aims at giving more political weight/a higher profile to the presentation of the outcome of the evaluation. In this case the Communication (if already decided at the time of the when the evaluation is to be validated) needs to be considered and validated as an integrated part of a single evaluation entry in Decide.

	• Information notes for the Commission / Communications to the Commission • Staff working documents (except those related to evaluations/ fitness checks) • Decisions granting delegated powers (empowerment and delegations) • Infringement, competition and state aid cases, trade defence cases, enforcement action under international trade rules • Commission notices on the interpretation of EU law (unless sensitive or important)
Decide entry?	Not required
Political validation by	Director-General/ Commissioner
Roadmap or Inception IA needed?	Not required
ISG required	No

TOOL #7. DRAFTING OF ROADMAPS, EVALUATION ROADMAPS AND INCEPTION IMPACT ASSESSMENTS

1. INTRODUCTION

Roadmaps and inception impact assessments provide the first opportunity for the Commission to explain to stakeholders why a particular initiative is being prepared and what it aims to achieve. It is an important opportunity for the Commission to engage with stakeholders and to receive feedback on the Commission's initial ideas and appreciation of the problems the initiative aims to tackle and to ask for relevant data. It is important, therefore, that the roadmaps and inception impact assessments are written in a clear non-technical way that will maximise the involvement of stakeholders and enable them to prepare for the subsequent consultation activities the Commission services will organise.

Roadmaps and inception impact assessments can also be the basis for early bilateral discussion between the Regulatory Scrutiny Board (RSB) and the lead DG on the expected content of impact assessments, fitness checks, and evaluations that are selected for RSB scrutiny.

While the general logic remains the same, the format/template of roadmap is slightly different and adapted to the specific nature of the initiative. In particular, for initiatives that will undergo impact assessment (IA), an inception impact assessment should be prepared. For evaluations and fitness checks an evaluation roadmap needs to be drafted whereas for particular cases where evaluations and impact assessments are undertaken with significant overlap a specific combined or "back-to-back" template can be used.

2. PREPARATION AND PUBLICATION OF ROADMAPS

In principle, each major initiative (including evaluations or fitness checks) needs to be accompanied by a roadmap or inception impact assessment⁵¹ unless an exception is granted⁵².

Roadmaps and inception impact assessments should be finalised bilaterally by the lead DG and the Secretariat-General, with no formal role for any Cabinet. Drafts need to be submitted to the Secretariat-General via Decide once political validation has been granted for the initiative. Finalised roadmaps or inception impact assessments also need to be uploaded by the lead DG in Decide. They are then published by the Secretariat-General and stakeholders can provide feedback during a period of 4 weeks directly via the relevant webpage on *EUROPA*.⁵³ No public consultation should be launched before the publication of the related roadmap.⁵⁴

⁵¹ For autonomous agreements presented by the social partners pursuant to Article 155 TFEU, no roadmap/inception impact assessment is necessary.

⁵² See Tool #1 on *Principles, procedures and exceptions*.

⁵³ Europa site 'Contribute to EU law-making' https://ec.europa.eu/info/law/contribute-law-making_en

⁵⁴ See Tools #53, #54 and #55 on stakeholder consultation.

Roadmaps are published with the date of publication indicated and they should be considered as documents reflecting the Commission's thinking at that point in time; they do not need to be reviewed and updated. For impact assessments, fitness checks, and evaluations that are selected for RSB scrutiny, the RSB may initiate an early bilateral discussion with the lead DG on the expected content of the report, based on the roadmap or inception impact assessment. These discussions are informal and cannot prejudice in any way the eventual deliberations of the Board on the final draft report.

The lead DG or the Secretariat-General may also ask advice regarding methodological issues and the application or interpretation of the better regulation Guidelines to the RSB. These discussions are informal and cannot prejudice in any way the eventual deliberations of the Board on the final draft report.

The first ISG meeting should be held only once political validation is obtained and the finalised roadmap or inception impact assessment should be shared with its members for information. The roadmap or inception impact assessment does not prejudice discussions in the ISG about consultation activities (which may differ from the limited presentation in the roadmap or inception impact assessment) or the content of any impact assessment or evaluation.

Published roadmaps, evaluation roadmaps and inception impact assessments are open for feedback from citizens and stakeholders for a period of 4 weeks. This allows comments to feed usefully into the further preparatory work of the initiative, including the preparation and management of external studies and contracts as well as finalisation of the stakeholder consultation strategy.⁵⁵

3. TEMPLATES FOR ROADMAPS AND INCEPTION IMPACT ASSESSMENTS

The templates for roadmaps and the inception impact assessment are available from GoPro⁵⁶ and MyIntracomm⁵⁷. The templates contain instructions and useful tips on how to complete the various sections. In addition, the sections below provide some additional guidance on some horizontal and commonly encountered issues.

3.1. All roadmaps and inception impact assessment

Consultation Strategy

The roadmap or inception impact assessment should set out the envisaged stakeholder activities in an initial consultation strategy⁵⁸. Where none is planned, a justification should be provided⁵⁹.

⁵⁵ See Tool #56 on *Stakeholder feedback mechanisms*.

⁵⁶ https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/roadmaps.aspx

⁵⁷ <https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

⁵⁸ See Tool #53 on *The consultation strategy* for more information on how to design a consultation strategy.

3.2. Initiatives supported by roadmap or inception impact assessment (not evaluation)

Describing the problem

Defining the problem correctly is probably the single most important step in the preparation of a new initiative because if the problem (and its causes) is poorly understood then it will be difficult to design policies that will be effective on the ground. The tool on how to define problems should be consulted before drafting the roadmap or inception impact assessment⁶⁰.

DGs often present the absence of a policy framework, database or legislation etc. as being a problem. This is not correct because these new elements are in fact potential policy responses which would need to be assessed in terms of their impacts. Problems should be described in terms of the known negative consequences of a situation for society, individuals or sectors (e.g. pollution impacting health and the environment, unnecessary costs to business due to barriers in the functioning of the internal market; infringement of fundamental rights; unacceptable risks to safety; etc...). These problems should be quantified wherever possible and at least in the IA report if it is not yet possible to provide quantitative information in the roadmap or inception impact assessment.

Subsidiarity

The aim of the subsidiarity test⁶¹ is to ensure that the EU acts only where justified. It should be clear that the Member States cannot solve the problems by themselves and that action at EU level has added value over and above what action at national level would deliver. The test should be applied for new initiatives but also where the revision of existing legislation is envisaged.

Is an impact assessment necessary?

The reasons why an impact assessment will not be prepared should be presented in the roadmap. The tool on when an IA is necessary gives a comprehensive description on what to consider⁶². Generally, an impact assessment is necessary and useful where there are expected to be significant impacts and the Commission has a choice on what to propose or present. This applies equally to implementing acts and delegated acts as well as to new legislative proposals, and non-legislative initiatives that announce actions with readily identifiable impacts.

For some policy Communications it is often difficult to know whether an IA is necessary. As a rule of thumb, the more definitive and precise the policy follow-up then the greater the likelihood that an impact assessment will be necessary. Thus a policy

⁵⁹ A formal exception should be sought if no public consultation is envisaged; see Tool #1 on *Principles, procedures and exceptions*.

⁶⁰ See Tool #14 on *How to analyse problems*.

⁶¹ See Tool #5 on *Legal basis, subsidiarity and proportionality*.

⁶² See Tool# 9 on *When an IA is necessary*.

Communication which only sets out in broad terms the problems and broad areas for future action will not need an impact assessment.

3.3. Issues specific to evaluation roadmaps

The evaluation roadmap outlines the:

- Context of the evaluation briefly describing the expected role and original objectives of the EU intervention(s) being evaluated. It also explains why the intervention(s) is (are) being evaluated (e.g. legal requirement). There is no need to provide a fully developed intervention logic at this point, but the non-expert reader should be able to understand in broad terms, what the initiative was expected to achieve (its policy objectives) and how this was expected to happen.
- Purpose and scope⁶³ of the evaluation, explaining what the evaluation will deliver and how its results will be used. The scope should set out clearly what actions, time period and geographical area will be covered by the evaluation and what will not (with any associated justification for excluding e.g. certain articles, covering only a shorter period or not all EU Member States). Unless duly justified and agreed via the exemption process, the evaluation should cover the five criteria (effectiveness, efficiency, relevance, coherence and EU added value). The roadmap should not detail all possible EU interventions that could be covered under coherence, but should identify key policy areas which will be looked at.

3.4. Overlapping ("back-to-back") evaluations and impact assessments

Political urgencies or timing constraints may arise so that there is some degree of overlap between the evaluation and the impact assessment so that they carried out in a "back-to-back" manner.

The intention to conduct a back-to-back evaluation/IA should be clearly specified when the initiative is presented for political validation. This should also indicate the expected degree of overlap of the two processes which will define the subsequent steps to be followed.

Where there is only limited overlap, the evaluation roadmap should be published first and the inception impact assessment should follow at a later point in time. Ideally, the results of evaluation studies etc. should feed into the inception impact assessment (and its problem definition) and the stakeholder consultation activities.

Where there is a more significant overlap⁶⁴, or where the two exercises run in parallel, one combined roadmap/inception impact assessment should be published. This template is available from the MyIntracomm pages as for other roadmaps.

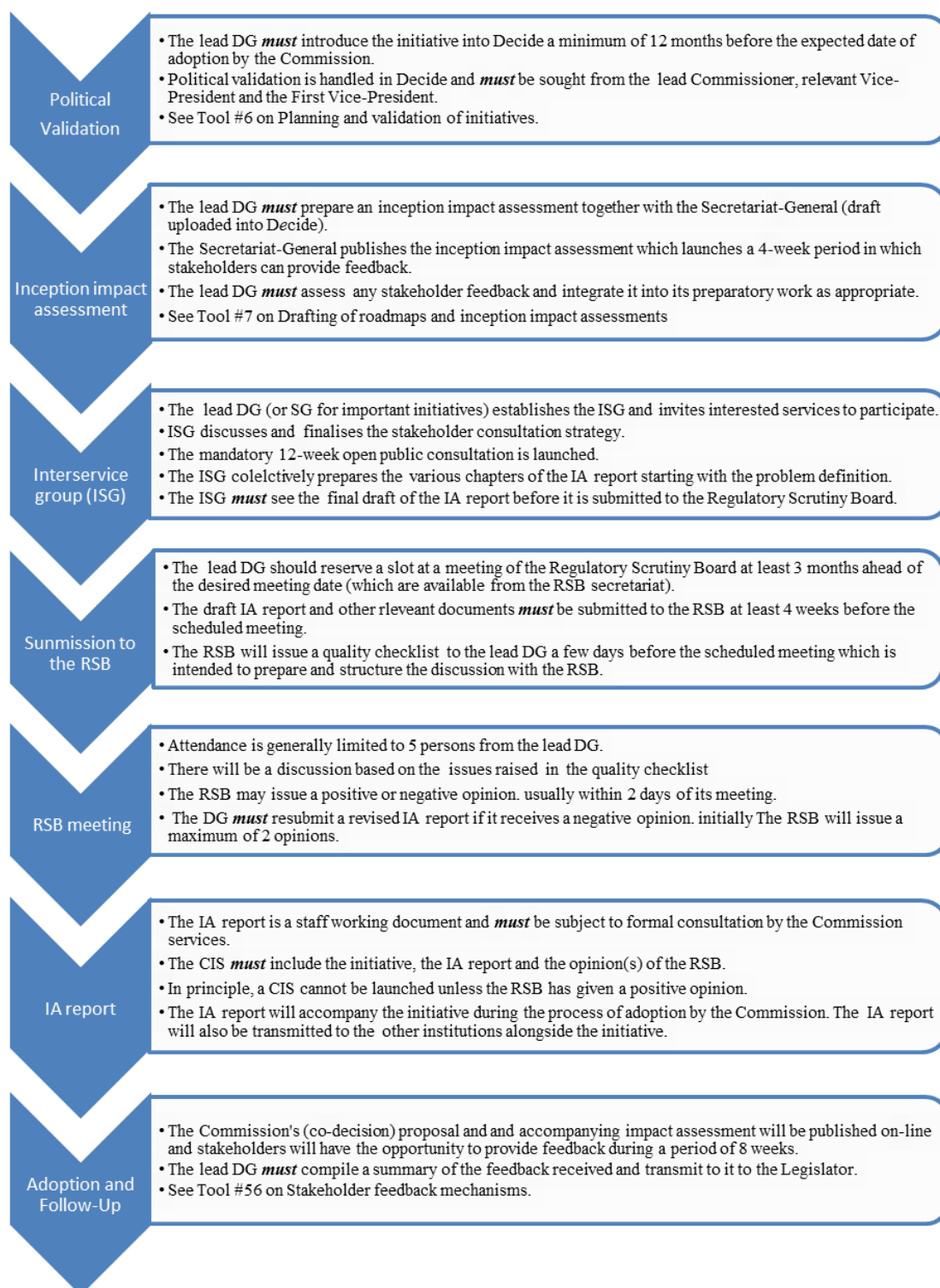
⁶³ See Tool #46 on *Designing the evaluation*.

⁶⁴ In any event, whether separate roadmaps are used or only one "back-to-back" format, two distinct planning entries should ideally be created in Decide for (1) the evaluation and (2) the follow-up proposal.

Chapter 2

How to carry out an Impact Assessment

Key steps and requirements for impact assessment



TOOL #8. WHAT STEPS SHOULD I FOLLOW FOR AN IA?

1. INTRODUCTION

An IA takes on average around a year to complete but this may be longer or shorter depending on the significance of the foreseen policy impacts, data availability, the stakeholder consultation strategy/process, the iterative nature of the impact assessment process itself, the urgency of the associated initiative, etc. Impact assessment, therefore, requires **careful planning and sufficient time in order** that the individual steps and required analyses can be completed in the desired timeframe and to ensure that the necessary evaluation⁶⁵ or fitness check is also completed in time. Otherwise, it will be difficult to meet the standards required by the better regulation Guidelines and produce a good quality impact assessment which is useful in the decision-making process and which meets the critical expectations of stakeholders.

2. IS AN IA NECESSARY?

A specific tool has been prepared to help in assessing whether an impact assessment is necessary to support a particular policy proposal⁶⁶. This assessment takes place within the more general process of policy planning and the preparation of roadmaps/inception impact assessments.

3. THE DETAILED STEPS IN PREPARING THE IA

The preparation of an impact assessment will involve the following steps:

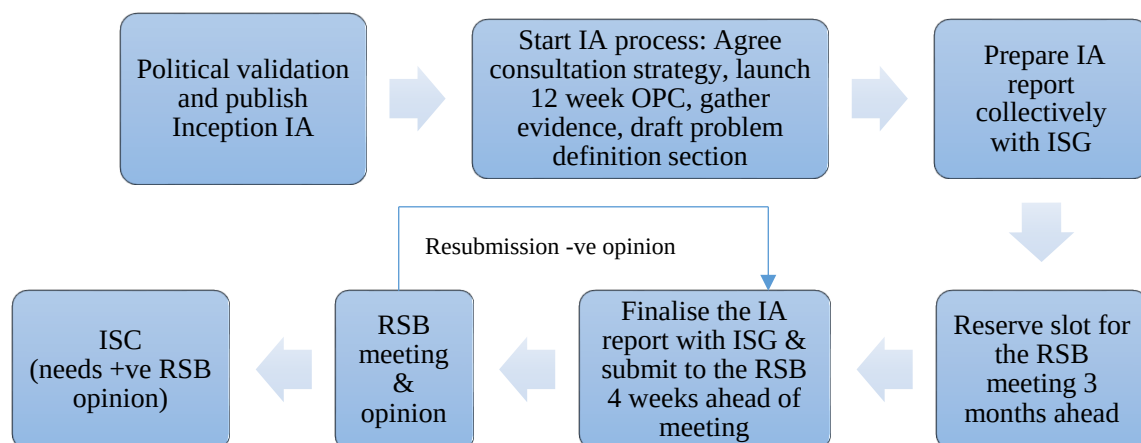
- (1) The lead DG should finalise the **inception impact assessment** together with the Secretariat-General. This should set out the key elements of the impact assessment including the problem definition, objectives, policy options and an initial appraisal of the impacts of the policy options and data needs. The Secretariat-General publishes the inception impact assessment (after uploading into Decide).
- (2) The creation of an Interservice Group (ISG) which will steer the IA process and collectively prepare the IA report;
- (3) The collection and analysis of relevant data and expertise, foresight and consultation of stakeholders including consideration of any feedback from stakeholders on the inception IA in respect the next steps in the IA process.
- (4) Data needs can already be identified in the inception IA;
- (5) Drafting of the impact assessment report together with members of the ISG;

⁶⁵ An evaluation or fitness check will only be necessary where there is an existing policy or legislative framework in place.

⁶⁶ See Tool #9 on *When an IA is necessary*.

- (6) A quality review of the draft IA report by the Regulatory Scrutiny Board (RSB);
- (7) Adaptation of the draft IA report in response to the opinions of the Regulatory Scrutiny Board prior to launching the interservice consultation on the associated initiative/proposal (together with the IA report). The final version of the IA report should summarise how it integrated the RSB's recommendations;
- (8) Adaptation of the draft IA report to take on board comments made during the ISC.

Box 1. Process to prepare a typical impact assessment



The time needed will depend on the evidence which is already available, the need to rely on the results of study contracts etc. Typically up to 12 months although can be significant shorter.

Specific tools have been prepared to assist in the process of gathering evidence, conducting a stakeholder consultation and analysing impacts⁶⁷ as well as in relation to the content of the IA report⁶⁸. Details are provided below for the other aspects.

Interservice Group (ISG)	
The Interservice Group should review all the key elements of the IA and the policy initiative. The group should discuss the full draft IA report before it is submitted to the Regulatory Scrutiny Board (RSB) and its revised version (and underlying policy proposal) before the launch of ISC.	
Who?	The Group is chaired either by the Secretariat-General for initiatives in the Commission's Work Programme (and certain other important initiatives) or by the relevant DG or service. The relevant DG's IA support function/unit should provide support to those drafting the IA report.
	All DGs with policies likely to be affected by the initiative or that will contribute to the objectives of the initiative should be invited to participate along with the relevant policy coordination unit of the SG and the Legal

⁶⁷ See Tool #4 on *Evidence-based better regulation*; Tool #53, #54 and #55 relating to stakeholder consultation; and Tool #62 on the use of *Analytical models and methods in IA or evaluation*.

⁶⁸ See Tool #12 on the *Format of the IA report*.

	Service. In addition, DGs with core expertise in specific areas such as economic analysis (e.g. ECFIN), scientific research and analytical models (e.g. JRC), social impacts (e.g. EMPL), SMEs, competitiveness (e.g. GROW), environment (e.g. ENV), fundamental rights (JUST), innovation (RTD), digital/ICT (CNECT) etc. should also participate where appropriate to ensure that the IA calls upon all relevant expertise in the Commission services.
	The invitation should take the form of a note from the Secretary-General (where the SG chairs the ISG) or the Director-General of the lead DG to those of the identified DGs asking to nominate a representative.
	Existing interservice groups can be used to steer the IA work particularly where an interservice group has been used to conduct a related evaluation or fitness check. The interservice group should also be used to prepare and discuss the related policy proposal.
	Consultants may be invited to make presentations regarding supporting studies or contracts but should leave the meeting when substantive discussions take place between ISG members. The lead DG should make sure the confidential nature of internal ISG discussion remains protected.
Why?	Lead services should not view the IA process and the ISG as a hurdle in the preparation of a proposal but rather as a tool to enhance the quality of their impact assessment report and of the proposal. By mobilising the expertise available across the relevant DGs, ISG discussions broaden perspectives and help to identify data, stakeholders, aspects of the problem, policy alternatives, significant impacts and mitigating measures that might otherwise be missed. Involving other services in the preparation of the IA and taking into account their different perspectives should also anticipate (and solve) problems that would have in any case emerged later in the process (e.g. during interservice consultation). In so doing, the ISG helps ensuring the coherence of your proposal with the policy objectives and initiatives of other DGs. You should also remember that the IA report needs to be clear for the non-expert reader. Colleagues from other areas are a good test of whether your arguments are clear and easy to follow. The ISG is the best way to ensure that a DG's views are taken into account by the lead DG. It is important, therefore, to plan participation well in advance and to participate proactively. Do not only flag concerns but suggest ways to solve them contribute as relevant to the analysis in your area of expertise and make concrete textual proposals for the IA report. As far as possible, make sure the position expressed in an ISG is representative of the position your DG is likely to take during the ISC.
When?	An ISG is established as soon as the initiative has been politically validated. ⁶⁹

⁶⁹ See Tool #6 on *Planning and validation of initiatives*.

	The ISG should meet as many times as needed to cover the important elements of the impact assessment process (problem definition, objectives, policy options and impacts). The ISG should also discuss the final draft of the IA report before it is submitted to the Board. It will comment on subsequent changes to the IA report to take on board RSB comments. At least at the last meeting of the ISG before the ISC, the group will discuss the legislative proposal in parallel to its IA. More meetings (and/or email consultations in between meetings) can also be envisaged, particularly in the case of complex initiatives developed over a long period. Meetings may also follow the timing of other milestones such as an external study or a stakeholder consultation.
How?	The ISG should be involved in all IA work phases. It should always discuss intermediate results (e.g. of modelling work or supporting studies) and IA report drafts. It should ideally be involved in the preparation of terms of reference for external studies and the drawing up of the scope of possible modelling work. The ISG <u>should agree</u> the design of stakeholder consultation strategy and any consultation documents. It should discuss any feedback received from stakeholders on the Inception IA.
	Meetings should be well prepared with <u>invitations and documents being circulated at least one week in advance</u>. Similarly, ISG members should be given <u>at least one week</u> to provide written comments on drafts of the IA report. Minutes of meetings should be prepared which record transparently and accurately the views of the ISG members.
	The lead DG is advised to establish a collaborative work space for sharing documents which facilitates more flexible participation by DGs. The minutes of the last ISG meeting should be attached to the covering note when the IA report is submitted to the RSB.

4. ADOPTION BY THE COLLEGE AND THE ROLE OF THE IMPACT ASSESSMENT REPORT

The IA report and the executive summary sheet are presented as two separate staff working documents and are subject to ISC alongside the legislative proposal, Communication or Delegated/Implementing Act or other relevant instrument. All opinions of the RSB in relation to the IA report must also be included in the ISC.

You may need to make final adjustments to the IA report to take on board comments made during the ISC. The final version of the IA report should briefly explain how the Board's recommendations led to changes compared to the earlier draft(s)⁷⁰.

The IA report and executive summary are also presented to the College alongside the initiative intended for adoption. The Commission does not adopt these SWDs but merely takes note of them. The SWDs will also be transmitted to the other institutions with the instrument adopted by the College.

In addition, the Commission's political appreciation of its final proposal should be set out in the explanatory memorandum, which should recapitulate the proposal's compliance

⁷⁰ See Tool #12 on the *Format of the IA report*.

with the subsidiarity, proportionality and better regulation principles, including the results of the IA, consultations and evaluations.

The fact that an IA has been produced should also be mentioned in the press release when the proposal is adopted by the Commission. The corresponding link to the IA report should be provided.

The Secretariat-General will publish the final IA report and the executive summary sheet on the Europa IA website along with the proposal and the RSB opinion(s). In certain cases, such as when information is confidential and sensitive, a decision to restrict or delay the publication may be considered. You should consult the Secretariat-General (SG.C.2) for further guidance on this. There are also corporate rules about to manage and publish studies which are used to inform impact assessments.⁷¹

When the final proposal adopted by the Commission deviates significantly from the options assessed in the impact assessment, the explanatory memorandum⁷² should clarify the likely impacts of this change.

NB: You should produce an IA report even when the conclusion of your analysis is that you should not proceed with a proposal. These IA reports should explain why it was decided not to take action. The RSB will examine them, and they will be published on the Europa website as staff working documents. In cases where the Commission has been specifically asked by the other institutions to consider a proposal but will not do so (on the basis of the IA) then a short memorandum (accompanied by the IA report) may need to be adopted by the Commission which delegates authority to the lead Commissioner or Director-General to communicate the findings of the IA process to the other institutions. In such cases it is advisable to consult the GREFFE⁷³.

5. USE OF THE IA REPORT BY THE EUROPEAN PARLIAMENT AND THE COUNCIL

You should use your IA actively when presenting the merits of the proposal during the legislative process. Based on the options analysis, it should also help explain why the Commission has chosen not to go for certain solutions, anticipating issues which may be raised by the European Parliament or the Council.

Relations with the European Parliament and Council on IA are governed by inter-institutional agreements⁷⁴. Within this framework, the other Institutions have made a commitment to assess the impact of substantial amendments they make to Commission proposals where they consider this to be appropriate and necessary in the particular legislative procedure. The Commission may, on its own initiative or at the invitation of the European Parliament and/or the Council, also decide to complement its original IA and the EP and the Council are committed to take full account of this additional material.

⁷¹ https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/studies.aspx

⁷² See Tool #38 on *Drafting the explanatory memorandum*.

⁷³ <https://myintracomm.ec.europa.eu/corp/sg/en/egrefe/Pages/contacts.aspx>

⁷⁴ Interinstitutional Agreement on Better Law-Making; OJ L123, 12 May 2016, p. 1.

The European Parliament has developed internal capacity to review the quality of the Commission's IAs, to carry out complementary analyses and to assess substantive amendments introduced in the legislative process.

In any event, the European Parliament and the Council take an increasing interest in the Commission's impact assessments and you should insist on presenting your IA work to them and to share information about data and methods used. You may also be invited to submit complementary analysis. Such requests need to be addressed on a case-by-case basis by the Commission. Any additional information would normally be provided in the form of non-papers validated through the Groupe de Relations Interinstitutionnelles (GRI).

In all cases where the Commission is asked to provide additional information, you should consult SG.C.2 as early as possible to obtain advice on how to proceed. The Commission is responsible for presenting its impact assessments to the Council and **under no circumstances should the Commission's contractors be involved** in such presentations.

TOOL #9. WHEN IS AN IMPACT ASSESSMENT NECESSARY?

An impact assessment (IA) is required when the **expected economic, environmental or social impacts of EU action are likely to be significant**.

The benchmark criterion of "significant impacts" applies both to the macro- and the micro-level. This implies that IA is not only required for proposals expected to have far-reaching impacts on the economy or society as a whole, but also for initiatives likely to have a significant impact on a particular economic sector, type of economic actor (e.g. SMEs), societal group or geographical area or environmental compartment. Clearly, the appreciation of what is considered "significant" will depend on expert judgment and should take into account the results of associated evaluations. The roadmap or inception impact assessment should already set an initial appreciation of the expected significant impacts on which stakeholders can provide feedback.

However, an IA should be carried out only when it is useful. An assessment of whether an IA is needed should therefore be done on a case-by-case basis and reported on in the roadmap when an IA is deemed not to be necessary.

In principle, such an **assessment is likely to conclude that no IA is needed when:**

- There is **little or no choice available for the Commission**. For instance when the Commission is implementing previous policy decisions already subject to an IA, or when it is specifying technical details with limited discretion available, or transposing an international agreement with no significant margin for variations, or where a previous evaluation has identified very specific problems (or means to simply or remove unnecessary regulatory costs) and an IA would not provide any further useful information in relation to the preparation of a legislative proposal that is narrowly focused on remedying the identified problems etc.; **or**
- **Impacts cannot be clearly identified** ex ante (for instance, in the case of broad policy communications); **or**
- Impacts are **small** (for instance, the repeal of a redundant act)⁷⁵.

Where no materially different policy choices are available but directly identifiable impacts are expected to be significant, these should preferably be assessed and transparently presented through an appropriate tool (explanatory memorandum, ad hoc staff working paper, etc.).

Further guidance to help judge whether an IA is necessary is provided below.

⁷⁵ Please note that it is the ultimate impact that counts. Thus, a small direct negative impact could still be large for certain stakeholders (SMEs etc.) or have a significant effect because it cumulates with other pre-existing negative factors or generates important indirect/secondary effects.

A. Initiatives for which the need for an IA should be assessed⁷⁶
New legal acts
Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts ⁷⁷
Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law ⁷⁸
White papers
Policy communications
Action Plans
Recommendations
Recommendations for the negotiation of international agreements.
Social partner agreements pursuant to Articles 154-155 TFEU ⁷⁹ .
Financial programmes (i.e. all basic acts for spending programmes and financial instruments) ⁸⁰

In the specific case of white papers, action plans and policy communications, the requirement to carry out an IA (and its depth of analysis) will primarily depend on the level of ambition and the degree of commitment planned and the degree to which it binds the Commission. Communications announcing, for instance, ambitious commitments (say a ten-year strategy to achieve certain environmental targets) will most likely require an impact assessment because the impacts of such a commitment are likely to be significant and broadly identifiable already at such a general stage of policymaking.

In the case of Recommendations, an IA is generally not necessary but will depend on the level of detail (i.e. the degree of specificity/flexibility) set out in the provisions and the significance of the likely impacts that would stem from their implementation by Member States. A staff working document (i.e. not subject to the procedural requirements of an

⁷⁶ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁷⁷ Repeals to remove legislation which has been superseded by new legislative provisions are neither subject to an IA nor require a roadmap. Repeals announced in the Commission Work Programme equally do not require a roadmap or an IA as the Commission has already taken a decision informed by the available evidence (for instance the results of an evaluation).

⁷⁸ A key determining factor will be whether the Commission has any policy discretion over the content of its transposing measures.

⁷⁹ See Tool #11 on *Social partner initiatives*.

⁸⁰ See Tool #10 on *Financial programmes and instruments*.

impact assessment) presenting potential impacts and policy approach is likely to be more proportionate in most cases.

Other initiatives may not require an IA at all (e.g. Communications clarifying the Commission's approach to policy decisions already taken, or announcing more in-house type of work, such as the setting-up of expert groups, etc.). In such cases, any relevant supporting analytical material could rather be presented in a technical staff working document accompanying the initiative.

Whenever it is concluded that no IA is needed, this must be flagged and explained to the public through the roadmap. When pertinent, the roadmap, and any other relevant public document, should clearly signal that an IA would accompany any follow-up initiative with directly identifiable significant impacts.

Each year the Commission adopts **hundreds of delegated acts and implementing acts**. For each delegated act or implementing act, an assessment should be made as to whether an impact assessment is necessary. This is so even in cases where the Commission is taking decisions based, for example, on scientific advice from a scientific body or agency. An impact assessment will be necessary where there are likely to be significant impacts and where the Commission has discretion about the measures which could be taken (including whether to act at all). For example, a scientific body may recommend a safe exposure level to a particular chemical but the Commission has the choice of how best to manage the risks of exposure to that chemical.

In addition, where the Commission is likely to deviate from the recommendations of an Agency then an IA is also likely to be necessary. Where an impact assessment makes no sense because the Commission has no discretion, there may still be significant impacts about which it is useful to present information to the College. In such cases, a SWD can be prepared or information presented in the explanatory memorandum in the case of delegated acts.

There are initiatives for which no impact assessment is required a priori:

Type ⁸¹	Reason
Administrative decisions	Lack of significant impact (or relevance for policymaking)
Enforcement of EU law (competition law enforcement cases, infringement decisions, etc.)	Lack of policy alternative as decision parameters are set by existing EU (case) law.
Trade defence cases and enforcement action under international trade rules	Lack of policy alternatives
Budgetary procedures and measures, Financing Decisions and programme management decisions	Lack of policy alternatives/ex-ante evaluation not required

⁸¹ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

Commission reports /scoreboards	No policy decision, lack of impacts
Communications to the Commission	No policy decision, lack of significant impacts
Economic governance: recommendations, opinions, adjustment programmes	Specific processes supported by country specific analyses
Green papers	No policy decision, lack of significant impacts
Legal alignments	Lack of policy alternatives / no significant direct impacts
Legal codifications	Lack of policy alternatives / no significant impacts
Staff working documents	No Commission decision, lack of significant impacts
Conclusion, signature and provisional application of Bi/multi-lateral agreements with Third Countries: conclusions signature, provisional application and/or prolongation of existing protocol.	Lack of policy alternatives given finalisation of negotiations

<i>EU agencies and IAs</i>
• Whenever specific legislative procedures mandate an EU agency to carry out the main policy-design work and prepare an IA-like document, no Commission IA is necessary a priori. • The Commission's internal rules on better regulation and impact assessment do not apply to EU agencies⁸². However, the lead DG should ensure that the agency's analysis broadly meets the Commission's consultation and IA standards and takes responsibility/ownership for the quality of the assessment. • The lead DG should (in consultation with the Secretariat-General) consider whether the Commission's initiative would benefit from further analysis and a complementary IA due to its complexity, or the significance of the expected impacts or where the Commission is likely to deviate from the advice of the relevant agency or indeed where the Agency's work does not meet the Commission's usual standards. • During policy preparations, the lead DG may decide itself or be asked by the SG or other Commission services to supplement the agency analysis if duly justified and/or – in consultation with the SG – to undergo scrutiny by the Regulatory Scrutiny Board. In the latter case, the lead DG is responsible for submitting a draft IA report to the RSB in accordance with the better regulation Guidelines and this Toolbox.

⁸² Many agencies have established their own arrangements on better regulation as part of the agency's mandate (particularly in areas such as stakeholder consultation).

TOOL #10. FINANCIAL PROGRAMMES AND INSTRUMENTS

1. INTRODUCTION

This tool explains the links between the requirements of the Financial Regulation and the requirements of the Commission's better regulation policy in respect when preparing basic acts for spending programmes and financial instruments ("financial programmes")⁸³.

The remainder of this tool sets out when an ex-ante evaluation should be performed and when the ex-ante evaluation should take the form of an impact assessment which is informed by stakeholder consultation (including an open public consultation) and which is scrutinised by the Regulatory Scrutiny Board. An ex-ante evaluation (or impact assessment) supports new financial programmes and instruments while a retrospective (ex-post) evaluation assesses the functioning of existing programmes and instruments.

2. WHEN IS EX-ANTE EVALUATION OR IMPACT ASSESSMENT REQUIRED?

According to the Financial Regulation, all programmes or activities involving significant expenditure (i.e. in excess of €5 million) should be subject to both ex-ante and retrospective evaluations. This is to ensure conformity with the principle of sound financial management. In some cases, an impact assessment is required rather than an ex-ante evaluation but an impact assessment still satisfies the requirements for ex-ante evaluation under the Financial Regulation.

Generally, an impact assessment is only prepared where there are expected to be significant impacts and where there is a clear policy choice to be made by the Commission. In addition, the depth of analysis presented in Commission impact assessments should be proportionate to the magnitude of the expected impacts. Based on this, and the requirements to perform ex-ante evaluations under the Financial Regulation, the following approach should be followed when preparing new financial programmes:

- An impact assessment should be prepared for the major programmes of the multi-annual financial framework according to the standard requirements for impact assessments set out in the better regulation Guidelines.
- For all other financial programmes and instruments, an ex-ante evaluation should be prepared where this is required by the Financial Regulation.

⁸³ Financial instruments provide support for investments by way of loans, guarantees, equity and other risk-bearing mechanisms and complement the traditional allocation of grants. Financial instruments can also help to mobilise additional public or private investments and provide a variety of investments for better performance including greater financial discipline at the level of supported projects. Innovative financial instruments play an increasingly important role in EU budget spending. They concern financial support other than pure grant funding and are meant to leverage public and private funding and consist, for example, of debt and equity instruments such as those under Horizon 2020.

3. PROCEDURAL STEPS

An **ex-ante evaluation** is a staff working document of the Commission services that is linked to the Commission's proposal. GoPro provides more detail on the rules to be followed when preparing SWDs⁸⁴. The following steps map out the process:

- Planning entry in Decide and political validation of the initiative;
- Roadmap to present the initiative (programme/instrument);
- Where relevant, the SWD should be prepared collectively with the other relevant services in an interservice group;
- Finalisation of the SWD must be preceded by a formal consultation of services together with the legislative proposal.

The better regulation Guidelines and Toolbox set out the procedural requirements for preparing an **impact assessment**.⁸⁵ These include a formal open public consultation and scrutiny by the Regulatory Scrutiny Board.

4. THE CONTENT OF EX-ANTE EVALUATION

An ex-ante evaluation should include the following elements:

- (1) **Problem analysis and needs assessment.** The basic rationale of a financial programme is no different to that of a regulatory initiative; i.e. a problem is identified which requires public intervention. The problem analysis should provide the basis for formulating realistic and relevant objectives for the intervention and demonstrates the need for the intervention.

The specific tool related to the identification of problems in the context of an impact assessment is therefore relevant and should be used. The needs to be met should be outlined for the short or long-term;

The lessons learned from evaluations of previous or similar programmes (including centrally managed instruments) should be used to identify the problems that need to be addressed in the new programme;

A detailed analysis of the situation, motivations and interests of the key actors should provide an assessment of the needs of beneficiaries that should also shape the objectives of the programme.

- (2) **EU added value:** The financial programme should generate added value over and above what would be generated in the absence of the programme - i.e. over and above what the Member States do nationally. This added value might arise because of the increased scale of the intervention, efficiency savings from

⁸⁴ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Commission+staff+working+documents>

⁸⁵ See Tool #8 on *What steps should I follow for an IA*.

EU-level action, supporting cross-border actions, etc. The financial programme should be complementary and coherent with other interventions in order to build synergies and may often complement or reinforce existing national actions and programmes. Relevant information can be found in the tool on subsidiarity and proportionality (in relation to the EU added value test)⁸⁶ and in the tool relating to the five criteria used for evaluation of EU interventions (which includes EU added value)⁸⁷.

- (3) ***Policy and management objectives:*** Well-defined objectives should be developed which link logically with the identified problems. These objectives should clearly describe what the intervention is meant to achieve and how it contributes to wider Union policies and objectives. The objectives will provide the benchmark against which the success of the intervention will be assessed and provide the basic framework for a future ex-post evaluation (also see monitoring). Again, the process of objective setting is no different to that in the context of an impact assessment and the relevant tool on setting objectives is highly relevant and should be used⁸⁸.
- (4) ***Policy options, including associated risks:*** Alternative policy options and delivery mechanisms should be identified. In most cases there are alternative ways to achieve an objective. For instance, alternative approaches may be identified at the level of:

Intervention strategies: for example, financial assistance, regulation, information and networking activities;

Instruments: for example, grants, interest subsidies, guarantees, loans, financial instruments. The reasons to allow the use of one or more instruments (or combinations) should be identified and explained;

Channels of intervention: direct support to the main beneficiaries, support to intermediate actors such as NGOs;

Levels of intervention: the level of intervention can be varied, for example, through the rate of assistance or through narrow/wide definitions of target groups.

This part of the ex-ante evaluation should also analyse what risks will be connected to the implementation of the intervention in order to identify appropriate mitigating measures. Different types and level of risks may influence one particular delivery mechanism over another as could the findings of an earlier evaluation. Alternatively, the risk associated with a particular programme or option could lead to the decision not to proceed at all.

⁸⁶ See Tool #5 on *Legal basis, subsidiarity and proportionality*.

⁸⁷ See Tool #47 on *Evaluation criteria and questions*.

⁸⁸ See Tool #16 on *How to set objectives*.

- (5) **Results and impacts:** The report should assess the expected results and impacts, in particular economic, social and environmental impacts of the different options. It should also evaluate the volume of appropriations, human resources and other administrative expenditure to be allocated with due regard to the cost-effectiveness principle. On this basis, the options should be compared, on the basis of their effectiveness and efficiency and other criteria such as risks and coherence (i.e. internal coherence of the proposed programme or activity and its relation with other relevant instruments). This should allow the most appropriate options and instruments to be identified.
- (6) **Monitoring and evaluation:** Appropriate indicators should be established which will be used to monitor the performance of the programme (in relation to the chosen objectives) and be used in its subsequent evaluation. This work on monitoring and evaluation will also form the basis of legal provisions which should be considered for inclusion in the Commission's proposal for a basic legal act.⁸⁹

5. THE CONTENT OF AN IMPACT ASSESSMENT FOR FINANCIAL PROGRAMMES AND INSTRUMENTS

Whenever the ex-ante evaluation takes the form of an impact assessment (see section 2), you should clearly indicate in your IA report that it also serves the purpose of ex-ante evaluation and fill in the obligatory Legislative Financial Statement⁹⁰.

As regards the content, it should cover all of the elements of an ex-ante evaluation. However, its format should be brought into line with the standard IA report, adding relevant sub-sections as relevant (e.g. relation to risk and cost-effectiveness assessments). The IA report should also include an assessment of the results of stakeholder consultations, including the 12-weeks open public consultation, and also refer to the opinion of the Regulatory Scrutiny Board. The standard 2-page executive summary should also be prepared and presented as a separate staff working document (translated into all languages).

6. GUIDANCE ON SPECIFIC ISSUES TO ADDRESS?

While section 4 specifies the minimum content of an ex-ante evaluation, this section provides further guidance on the specific issues that should be addressed with regard to spending programmes and financial instruments. The degree to which these issues will be assessed should remain proportionate to the amount of expenditure and resources involved, and will also depend on the political context and the time constraints.

⁸⁹ See Tool #41 on *Monitoring arrangements and indicators*; and Tool #42 *Legal provisions on monitoring and evaluation*.

⁹⁰ Available at: <https://myintracomm.ec.europa.eu/budgweb/en/Pages/index.aspx>. In filling in the Legislative Financial Statement you should coordinate with your financial unit

6.1. Spending programmes

- The ex-ante evaluation or IA for a spending programme should:
 - Use the financing available under the existing financial framework as the baseline scenario for programmes that already exist (including absorption levels, eligibility rules);
 - This helps to explain what changes are being put forward for the next financial period compared to past spending levels. Such a baseline scenario should take into account lessons learnt as well as the foreseen evolution of the 'exogenous' factors, such as GDP or employment levels. It should also reflect policy measures that have already been agreed, but which will come into force only in the future (including policies in other areas);
 - However, it will often be useful to include a policy option which would discontinue EU action to provide greater information to decision makers given that a positive political decision is in any event needed to continue with any spending programme⁹¹.
- Focus the options for implementation on issues such as:
 - Programming (priority setting, allocation of resources, adjustments during the programme duration, rationale for grants versus financial instruments);
 - Management provisions and requirements regarding the prevention of errors, irregularities or fraud (audit, controls), conditionality, monitoring, evaluation requirements with due attention to administrative burden and proportionality;
 - Simplification (on-line tools, selection procedures, outputs and results payments versus lump-sums, ineligibility of certain costs), options for management (full externalisation, externalisation plus technical assistance, direct management, shared management, decentralised management)⁹².
- Consider the different types of budgetary cost:
 - Direct financial assistance or support (to beneficiaries or third parties) from the EU budget;
 - Co-financing (or contribution) from Member State budgets which are directly tied to the EU expenditure or which are a direct consequence of the EU spending;
 - Human resources needed to manage the intervention;

⁹¹ See Tool #17 on *How to identify policy options*.

⁹² See e.g. Guidelines for the establishment and operation of executive agencies: <http://ec.europa.eu/transparency/regdoc/rep/3/2014/EN/3-2014-9109-EN-F1-1-ANNEX-1.PDF>

- Other administrative expenditure for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc.).
- Assess (financial and operational) risks associated with the identified options, for which you may need to seek additional expertise (e.g. from your financial unit, internal audit service and OLAF).
- Screen for compatibility with:
 - The relevant State aid rules in case the proposal involves aid to undertakings which falls under the notion of State aid as defined by Article 107(1) TFEU⁹³; and
 - International rules on subsidies to which the EU has committed itself in the context of the World Trade Organisation (WTO) or in Free Trade Agreements (FTAs) with third countries;⁹⁴
- When comparing the options, summarise all financial aspects as detailed in the Financial Statement. All figures in this statement have to be properly accounted in this section;
- Focus on improving evaluation arrangements and monitoring indicators, particularly in cases where deficiencies in the current arrangements have made it difficult to assess the performance of current programmes while avoiding undue administrative burden. Specify how progress in disbursement, use and impacts of the allocated amounts will be followed up.

6.2. Financial instruments

When preparing a proposal for financial instrument, you will need to pay particular attention to:

Problem analysis:

- Identify market imperfections or failures, or sub-optimal investment situations and assess investment needs in view of the policy objectives.
- Demonstrate that identified market needs cannot be addressed appropriately and in a timely manner through either market-led activities or types of Union intervention other than funding by a financial instrument, such as regulation, liberalisation, reform or other policy action.

⁹³ DG COMP can assist in this assessment

⁹⁴ DG TRADE can assist in this assessment

Subsidiarity analysis:

- Demonstrate that Union-level financial instruments address identified market needs more appropriately than similar financial instruments at national or regional level, including those financed by European Structural and Investment Funds (ESIF).
- Take into account factors such as difficult access to funding at national level (in particular for cross-border projects), economies of scale or strong demonstration effects linked to the diffusion of best practices in the Member States.

Option identification:

- Determine the most efficient mode for delivering the financial instrument and demonstrate that the planned financial instrument is consistent with:
 - New and existing financial instruments, avoiding undesirable overlaps and achieving synergies and economies of scale while taking account of lessons learnt from existing instruments;
 - Financial instruments and other forms of public intervention addressing the same market environment, avoiding inconsistencies and exploring potential synergies.

Analysis of impacts:

- Assess the proportionality of the envisaged intervention with regard to the size of the identified funding gap and the expected leverage effect of the planned financial instrument.
- Assess the likelihood and possible costs of market distortions and crowding-out of private funding through the financial instruments and identify means to minimise negative effects of such distortions.
- Examine additional qualitative effects, such as the diffusion of best practice, the effective promotion of Union policy objectives throughout the implementation chain or the access to specific expertise available from actors involved in the implementation chain.

TOOL #11. SOCIAL PARTNER INITIATIVES

Before submitting proposals in certain social policy fields (see Box 1), the Commission must respect the two-stage consultation procedure of the European social partners⁹⁵ stipulated in Article 154 TFEU. In particular:

- Social partners must be consulted on the **possible direction of EU action**, in the first stage of consultation, and on the **content of the envisaged proposal**, in the second consultation⁹⁶.
- During both stages, social partners may inform the Commission of their wish to initiate a negotiation process for a social partners' agreement in the policy area, as provided for in Article 155 TFEU. In such a case, the Commission suspends its initiative for the duration of the negotiations. If these are successfully concluded, social partners may request their agreement be implemented by the Commission presenting a proposal for a Council decision.
- In addition, for agreements reached on their own initiative (i.e. not further to the Commission's first or second stage consultation procedure), the social partners may also ask the Commission to present a proposal for a Council Decision.

Box 1. Article 153(1) TFEU

With a view to achieving the objectives of Article 151, the Union shall support and complement the activities of the Member States in the following fields:

- (a) improvement in particular of the working environment to protect workers' health and safety;
- (b) working conditions;
- (c) social security and social protection of workers;
- (d) protection of workers where their employment contract is terminated;
- (e) the information and consultation of workers;
- (f) representation and collective defence of the interests of workers and employers, including co-determination, subject to paragraph 5;
- (g) conditions of employment for third-country nationals legally residing in Union territory;
- (h) the integration of persons excluded from the labour market, without prejudice to Article 166;
- (i) equality between men and women with regard to labour market opportunities and treatment at work;
- (j) the combating of social exclusion;
- (k) the modernisation of social protection systems without prejudice to point (c).

⁹⁵ Social partners include employers' organisations and trade unions engaged in the European social dialogue. In order to be recognized, they should meet the representativeness criteria as set by the COM(93) 600 and Commission Decision of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level, COM(1998) 2334; OJ L 225, 12.08.1998, p.27.

⁹⁶ To note that the Treaty-based two-stage consultation procedure with social partners does not fall under the regular minimum standards for consultation, but follows separate arrangements.

In the context of social partners' agreements for which the signatories request the Commission to present a proposal for implementation by a Council decision in accordance with Article 155 TFEU, better regulation principles must be applied without prejudice to the role and autonomy the TFEU entrusts upon them, the Commission's task to facilitate their dialogue and the need for overall transparency.

Accordingly, the Commission invites the social partners to make publicly available the text of any agreement for which they may request the Commission to present a proposal for implementation by a Council decision in accordance with Article 155 TFEU.

Whenever the impacts of the agreement are likely to be significant, before taking its decision, the Commission will carry out a proportionate impact assessment which will focus in particular on the representativeness of the signatories, the legality of the agreement vis-à-vis the EU legal framework and the respect of the subsidiary and proportionality principles. Given the transparency of the process and the role entrusted to the social partners by Article 155 TFEU, no additional public consultation will be necessary.

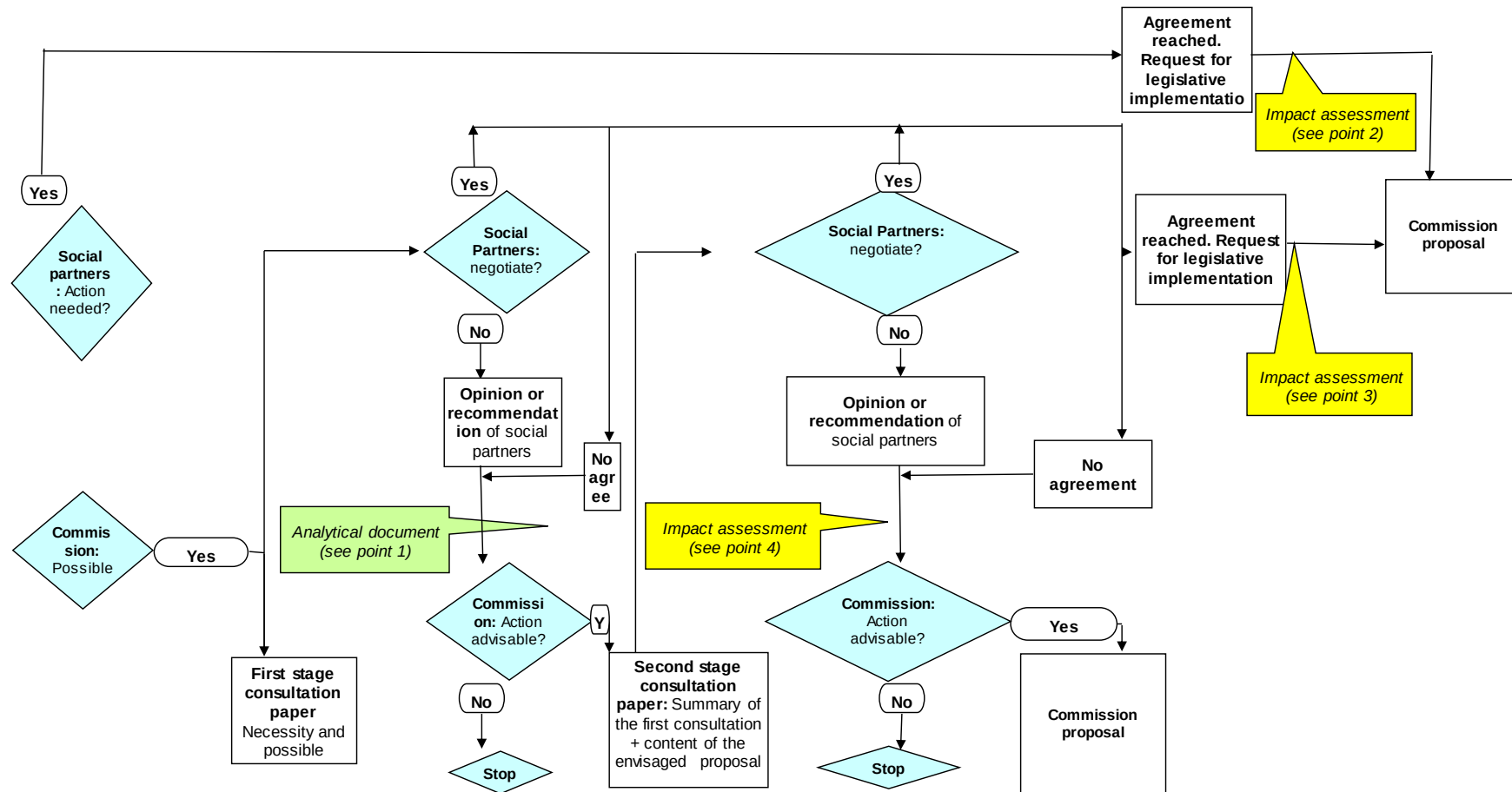
The table below details the policymaking process and the outlines the scope and/or depth of the required impact assessments.

I. For the social partners' consultations prescribed by Art. 154
<i>(1) Before the second stage of consultation</i>
- At this stage, the Commission's decision whether to launch the second stage of consultation on the content of the envisaged proposal should be informed by a so-called 'analytical document'. In order to respect fully the autonomous decision-making of the social partners, such an analytical document should not identify a 'preferred policy solution'. Instead, it should focus on analysing the problem which EU action should address, present the objectives, analyse the impacts of the measures under consideration and explore the value added of EU action. - The analytical document shall be based on necessary analysis and information and shall take into account the results of the first stage social partners' consultation⁹⁷.
II. For social partners' agreements as provided for in Art. 155
<i>(2) When considering an agreement concluded at the social partners' own initiative</i>
At this stage, the impact assessment should inform the Commission's decision whether or not to accept a social partners' agreement concluded at their own initiative, and consequently to present a proposal for a Council decision. Since the Commission cannot amend the text of the agreement but only accept or reject it, the impact assessment should only analyse the measures defined in the agreement against the baseline scenario.
<i>(3) When considering an agreement by the social partners after Art. 154 consultation</i>
At this stage, the impact assessment should inform the Commission decision

⁹⁷ Stakeholder consultation guidelines and the minimum consultation standards do not apply at this stage.

whether or not to accept a social partners' agreement concluded after the Commission has launched one or two stages of consultation, and consequently to propose implementation by a Council decision. • The impact assessment should provide for the same assessment as under (2) above but would not need to revisit the need for EU action when this has already been covered by a previous analytical document – i.e. (1) above. In such case, a reference to the previous analytical document should be added.
III. For Commission initiatives in social policy fields under Art. 153
<i>(4) When considering a proposal in the absence of a social partners' agreement</i>
In the absence of a social partners' agreement after second stage consultation, the Commission may still decide to put forward a proposal. In such cases, the decision should be informed by a standard IA which would draw upon the analytical document prepared after the first stage of consultation – see (1) above.

Summary of the policymaking processes for social partner initiatives



TOOL #12. FORMAT OF THE IA REPORT

1. INTRODUCTION

The impact assessment report should present the key information generated by the impact assessment process. The IA report will take the form of a staff working document which the College takes note of when it considers whether to adopt a new political initiative. The report should, therefore, prioritise information which is relevant to assist the College in reaching a decision on a specific initiative. The impact assessment report will also be transmitted to the other institutions and made public.

DGs should use the standard format described below for the report which will ensure consistency across the Commission. Certain information and specific annexes must be presented in the report. This is to ensure that politically important issues such as subsidiarity, proportionality, sustainability, environment, social impacts and economic impacts (including competitiveness and impacts on small and medium sized enterprises (SMEs)) are systematically addressed. It should also be clear who will be affected by the initiative and how.

The main IA report should be complemented by an **executive summary sheet** not exceeding 2 DGT standard pages. This summary sheet should be presented as a separate staff working document and be translated into all EU languages. The IA report and executive summary sheet templates can be downloaded from GoPro.⁹⁸

2. GENERAL REQUIREMENTS FOR THE MAIN IA REPORT

The following general requirements should be respected:

- The IA report should be written using non-technical language with non-expert readers in mind. The benchmark length should be **30-40 pages** (excluding annexes, glossary of abbreviations and annexes but including tables and figures). If DGs believe there is a need to go beyond this, they should signal and discuss this with the secretariat of the Regulatory Scrutiny Board⁹⁹ prior to submission of the draft report;
- The IA report should be a self-standing document which follows the standard structure set out below. It should provide the reader with a complete picture of the main assessment results, while more detailed information or explanations should be provided in the annexes¹⁰⁰;

⁹⁸ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Impact+assessment+report+and+executive+summary>

⁹⁹ Requests to be sent to the functional mailbox [Regulatory Scrutiny Board@ec.europa.eu](mailto:Regulatory_Scrutiny_Board@ec.europa.eu)

¹⁰⁰ However, in line with the principle of proportionality, the length of the different sections may for certain types of initiatives be adapted to reflect the focus of the analysis. For instance, for delegated or implementing acts, the IA report would generally be more extensive on the sections describing the outstanding options for decision and their likely impacts, while the problem and subsidiarity sections would be relatively limited, mainly summarising/referring back to relevant analysis of the IA of the basic act.

- The IA report should use the template provided in GoPro but must have a standard cover page created in Legiswrite¹⁰¹ and be transmitted to at least one of the institutions (in order to receive an SWD serial number);
- The report should contain a table of contents, a list of abbreviations and a glossary explaining technical concepts;
- Underlying data, statistics, information, expert contributions and stakeholder views should all be referenced particularly where choices are made or conclusions reached based on them. Whenever possible, direct hypertext internet links should be provided.
- Stakeholder views should be integrated throughout the text of the IA report. You should include a description of the views of the different stakeholder groups and highlight whether the views differ across or within these groups. In particular, you should be clear which options are supported by the various stakeholder groups and about the reasons where stakeholder preferences or opinions have not been followed. Where social partners¹⁰² have been consulted a dedicated section should report on the positions taken by them.

3. DETAILED STRUCTURE AND CONTENT OF THE MAIN IA REPORT

The report should follow the structure below. Each section indicates the information/issues that should be covered. They do not replace the main IA guidance, which provides the complete picture of issues to address under each key question. Generally you have flexibility in how to respond proportionately to the questions in the main Guidelines and how to structure the relevant sub-sections of the IA report. However, some issues should be reported in all IA reports.¹⁰³

Section 1. Introduction: Political and legal context

Issues to cover:

- What is the prevailing political/legal context as to why the initiative is being brought forward now?
- Are there relevant European Council conclusions, Council conclusions, EP resolutions or College decisions?
- Are related initiatives also under preparation? Which issues will each initiative tackle?

¹⁰¹ [Legiswrite template CP-025\(SG-050\) – SWD linked;](#)

¹⁰² See Tool #11 on *Social partner initiatives*

¹⁰³ The proportionate impact assessment undertaken in support of social partners' agreements should moreover contain an assessment of the representativeness of the signatories and a legality check of the agreement in respect of Union law (see Tool #11 on social partner initiatives)

Section 2. What is the problem and why is it a problem?

Issues to cover:

- What is the issue or problem that may require action? What is the size/scale of the problem? Is there a cross-border dimension? Why is it a problem?
- Consider using a visual aid to depict the various problems and their links to drivers, objectives and policy options¹⁰⁴.
- Who is affected by the problem? In what ways, and to what extent? Whose behaviour would have to change to improve the situation?
- Was a fitness check/evaluation carried out of the existing policy framework? If not, why not? What did the evaluation/fitness check conclude? Is this reflected in the description of the problems?
- All initiatives to revise existing legislation are by default considered to be REFIT initiatives and must consider whether there is a problem in terms of the legislation being unnecessarily complex or imposing unnecessary costs.
- What are the main drivers? What are the market failures, regulatory failures or behavioural biases which are responsible for the observed problem? What evidence is there?
- How would the problem evolve, i.e. will the problem continue to exist?
- Will the character of the problem be the same in light of developments such as the internet, telecommunications, social media etc.?

Section 3. Why should the EU act?

Issues to cover:

- Does the EU have the right to act under the Treaty? What is the appropriate legal basis?
- Does the legal basis (action under consideration) fall within one of the areas where the Treaty gives the Union exclusive competence (as defined by Article 3 of the TFEU)? If so the subsidiarity principle does not apply.

Necessity of EU action:

- A key part of the analysis should be to qualify the "Union relevance" of the initiative being considered. The greater the relevance the more likely Member State action alone will/would have be(en) insufficient. Key issues/questions to consider are:
- How does the problem (e.g. negative externalities) vary across the national, regional and local levels of the EU?

¹⁰⁴ See Tool #65 on *How to use visual aids and present quantitative data*.

- Is the problem widespread across the EU?
- Does the problem have the same underlying cause across the EU?
- How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
- To what extent do Member States have the ability or possibility to enact appropriate measures?
- Would national action or the absence of EU level action conflict with the Treaty or significantly damage the interests of other Member States?
- Are there transnational/cross-border aspects to the problem? Have these been quantified?
- Will there be increased costs or problems if action is left only to the Member States?

EU-added value test:

- Are there clear benefits from EU level action?
- Are there economies of scale? Can the objectives be met more efficiently (less costly) at EU level?
- Are there benefits in replacing different national policies and rules with a more homogenous policy approach?
- Will the functioning of the internal market be improved? If so, how will it be improved?

Section 4. What should be achieved?

Issues to cover:

- Objectives link the analysis of the problem (and its drivers) to the options for the policy response. They set the level of policy ambition, fix the yardsticks for comparing policy options and determine the criteria for monitoring and evaluating the achievements of implemented policy.
- Objectives should be Specific, Measurable, Achievable, Relevant and Time-bound (i.e. 'S.M.A.R.T').
- When objectives are multiple and interrelated, it is important to highlight the links between them, particularly any possible trade-offs.
- What are the general policy objectives? These are the Treaty-based goals which the intended policy contributes to.
- What are the more specific objectives to which the policy options should correspond? These set out concretely what the policy intervention is meant to achieve. They should be broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution. For each identified problem, there should be a set of specific objectives which form part of the intervention logic: problem-drivers-specific objectives-policy options.
- How do they link to the problem? How do the objectives relate to each other, i.e. are there any synergies or trade-offs?

- For those legislative revisions for which problems of legislative complexity and/or unnecessary costs have been identified, there should be a specific objective relating to the desire to simplify and improve the efficiency of existing legislation.
- Are these objectives consistent with other EU policies and with the Charter for fundamental rights?
- Operational objectives are expressed in terms of the deliverables of individual policy actions. As such, they are typically option-specific. These should not, therefore, be reported in the same place in the IA report as the general and specific objectives. They should be reported in the section referring to the preferred policy option (if one is presented) and in relation to monitoring and evaluation.

Section 5. What are the various options to achieve the objectives?

Issues to cover:

Baseline

- A baseline is needed from which the impacts of the policy options will be assessed. This should be quantified as far as possible. It will also be relevant to include expected socio-economic developments (aging, GDP growth, etc.) as well as important technological/societal developments such as the pervasive nature of the internet and social media which by themselves are bringing about large changes. The baseline should also be set for an appropriate time horizon and the need to allow for impacts to be realised.
- In most cases, the baseline is a "no policy change" scenario which includes all relevant EU-level and national policies and measures which are assumed to continue in force. In addition, Commission proposals but not yet adopted legislation should also be included. Where it is clear that a subsequent legislative procedure will deliver a substantially different outcome to the Commission's original proposal, this outcome should also be reflected in the baseline.
- Where two or more initiatives are presented together, each IA report should use the same baseline but should describe the likely consequences of the other initiative in terms of possible changes to the baseline. It may also be relevant to consider an alternative baseline/sensitivity case to demonstrate the impacts of the other initiative.
- A complicating factor is that the policy or legislation itself might envisage that it will come to an end on a given date ("sunset clause") and that a positive decision of the Commission and Legislator will be necessary to put in place a new policy regime. Examples include targets to be attained by a given year in areas such as energy efficiency or spending programmes which are linked to a particular multi-annual financial programme. In such cases it can be difficult to decide on the appropriate baseline. Two options are possible:
 - Explicitly include the "sunset clause" in the baseline, notably if a comprehensive evaluation concludes that the policy is ineffective. Policy options would then include establishing a new action and the impacts would be measured against a no-policy baseline. This approach should however be avoided if there are clear political commitments to continue the policy in some form or another, or if a comprehensive evaluation concludes that the policy is effective.

- Include a continuation of the current policy approach in the baseline, even if it formally comes to an end, notably if a comprehensive evaluation concludes that the policy is effective. Given that the College or Legislator could (theoretically) decide not to propose or enact legislation, this approach should usually be accompanied by a policy option which would explicitly repeal the current policy and would demonstrate the cost of the Union not acting ("the cost of non-Europe").
- The Commission has made a commitment under the Interinstitutional Agreement on Better Law-Making to present the costs associated with not acting at EU level ("the cost of non-Europe") wherever this is feasible in its impact assessments.

Options

- What are the possible regulatory and non-regulatory options for meeting the objectives and tackling the problem? All major options that are supported by stakeholders should a priori be included in the analysis.
- Each policy option should identify (i) each new action that will have to be undertaken; (ii) the addressee of the obligation; and (iii) by when the obligation must be completed. Identification and quantification of impacts will be easier if options are described clearly in this way. However, for some initiatives it may not be possible to define options so precisely (e.g. general policy strategies or trade agreements).
- Policy options should be closely linked to the drivers of the problems and the identified objectives: a clear logic should underpin the intervention under consideration. Policy options should also be internet ready.
- The option of changing nothing should always be considered (also known as the baseline scenario) and it is highly recommended to include a non-regulatory option, unless a decision of the College has already ruled this out or an obligation for legal action exists.
- Who would be targeted by the different policy options? Have different digital solutions been considered particularly in respect of implementation and reduction of administrative burdens?
- Applying the Think Small Principle: Micro-SMEs should a priori be exempted from new regulations unless appropriately justified and "lighter" regimes considered for SMEs generally.
- All initiatives to revise existing legislation are by default considered to be REFIT initiatives. Options should reflect the objective to exploit the identified potential for simplification and improvement of regulatory efficiency without affecting the overall objectives of the legislation.
- Which options have been discarded at an early stage and why? Be particularly specific and precise for discarded options enjoying significant support among (certain groups of) stakeholders.

Section 6. What are the impacts of the different policy options and who will be affected?

Issues to cover:

- What are the likely economic, social and environmental impacts of each of the short-listed options? All three board categories of impacts must be covered unless one or other are clearly not relevant. Whenever this is the case, the IA report must explicitly say so.
- List positive and negative impacts, direct and indirect, intended and unintended, including those outside the EU. Where possible, the costs of not acting at EU level should also be identified ("cost of non-Europe") as this is a commitment given by the Commission pursuant to the Interinstitutional Agreement on Better Law-Making¹⁰⁵.
- The costs and benefits of the initiative should be identified according to the standard typology of costs and benefits (Tool #58) and must be quantified (and monetised) wherever possible as per the better regulation Guidelines. Reasons should be given where this is not possible:
 - **Regulatory charges** include fees, levies and taxes etc.;
 - **Substantive compliance costs** cover investments and expenses incurred by businesses and citizens and public authorities in order to comply with substantive obligations contained in a legal rule (e.g. equipment, labour, materials, external services, etc.);
 - **Administrative costs** are incurred by businesses, citizens and public authorities, NGOs etc. when undertaking administrative activities needed to comply with obligations to provide information;
 - **Enforcement costs** are incurred by public authorities linked to the implementation of legislation and include monitoring, enforcement and adjudication.
 - **Indirect costs** are costs incurred by stakeholders that are not directly targeted by the policy option/initiative. Such costs are usually transmitted via price changes, quality changes or changes in the availability of goods/services produced in the regulated sector.
 - **Direct regulatory benefits** include the improved well-being of individuals or the environment (e.g. health, safety, improved environmental status, etc.) and market efficiency improvements such as costs savings, information availability, enhanced product and services for end-users.
 - **Indirect benefits** include spill-over effects from compliance by the regulated entity with the new obligation; wider macroeconomic benefits (GDP, productivity, employment rates, etc.); and other non-monetisable benefits such as fundamental rights, social cohesion, reduce gender discrimination, improved security/stability etc.

¹⁰⁵ See Tool #17 on *How to identify Policy options* for more detail on the meaning of the cost of non-Europe and how to estimate it.

- The IA report should also identify and present the benefits of measures to simplify and improve regulatory efficiency:
 - **Cost savings/reduction** is the reduction in the overall aggregated costs associated with compliance, regulatory charges, administrative activities and enforcement activities. This should be the outcome of the assessment on the potential to simplify and reduce regulatory costs in relation to REFIT. These are measured according to the unchanged scope of the existing legislation.
- **Impact on SMEs:** The IA report must include reference to the result of the SME test as well as of the assessment of SME impacts, as far as possible including quantitative estimates of administrative and compliance costs. If such impacts have not been identified to be significant, this should be stated in this section.
- **Impact on competitiveness:** The IA report must include reference to impacts on the most affected business sectors and on their competitiveness. If such impacts have not been identified to be significant, this should be stated in this section.
- **Describe who would be affected** (e.g. businesses, citizens, workers, consumers, public administrations, regions, third country actors) and how. Annex 3 also requires a description of the actions/measures that need to be undertaken by those affected by the measure. Specify uncertainties and how the estimated impact may be affected by changes in parameters;
- Specify which impacts are likely to change over time and how (one-off and recurrent);
- Outline what are the potential obstacles that might be encountered for an effective implementation of the option and compliance by Member States and targeted entities?

Section 7. How do the options compare?

Issues to cover:

- Compare the options (preferably in a table format) indicating:
 - The extent to which they would achieve the objectives (effectiveness);
 - Their respective key economic, social and environmental impacts and benefit/cost ratio, cost-effectiveness (efficiency), other means of ranking options such as multi-criteria analysis; and
 - The coherence of each option with other EU policy objectives, including the Charter for fundamental rights, and with other policy initiatives and instruments (coherence);
- Highlight the trade-offs and synergies associated with each option;
- The likely uncertainty in the key findings and conclusions and how these might affect the choice of preferred option;
- Which policy option is preferred and why? Alternatively, explain why no preferred option is presented (e.g. inconclusive comparison of options)?
- An explanation as to how the options, and in particular the preferred one, conforms to the principles of subsidiarity and proportionality given the size and nature of the identified problem.

- The following questions should help in assessing whether a measure adheres to the principle of proportionality:
 - Does the initiative go beyond what is necessary to achieve the problem/objective satisfactorily?
 - Is the scope of the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test)
 - Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?
 - Does the initiative create a financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? If yes, is this cost minimised and commensurate with the objective to be achieved?
 - Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?
 - Is there a solid justification for the choice of instrument - regulation, (framework) directive, or alternative regulatory methods?
 - While respecting Union law, are well-established national arrangements and special circumstances applying in individual Member States respected?
- The section comparing the options should also present in aggregated (tabulated) form the direct costs and benefits determined in the section on the impacts of each option.

Section 8. The preferred option

Issues to cover:

- Which policy option is preferred and why? Alternatively, explain why no preferred option is presented (e.g. inconclusive comparison of options)?
- Where an impact assessment addresses many policy actions/problems, the accumulated proportionality is difficult to assess without any indication of the preferred options for the component parts. Where no overall preferred option will be specified, consideration should at least be given to narrowing the range of possibilities.
- The information on costs and benefits should be broken down as far as is possible according to each identifiable action/obligation of the preferred option.
- All amendments of existing legislation are considered REFIT initiatives a priori. As such, there is an obligation to explore the potential to simplify and improve the efficiency of that legislation (e.g. by reducing regulatory costs) in impact assessments supporting. This section should be used to report on the analysis undertaken to simplify and improve the efficiency of the legislation. Where no simplification or efficiency improvement is possible, the reasons should be explained clearly. Similarly, reasons should be provided if it has not been possible to quantify impacts. The following table should be used to summarise the findings.

REFIT Cost Savings – Preferred Option(s)		
Description	Amount	Comments

(1) Estimates are with respect to the baseline of the unchanged legislation;

(2) Please indicate which stakeholder group is the recipient of the cost saving in the comment section;

(3) For reductions in regulatory costs please describe the measure/action which gives rise to the cost saving (e.g. actions to reduce compliance costs, administrative costs, regulatory charges, etc.) and whether it is a recurrent cost saving.

Section 9. How would actual impacts be monitored and evaluated?

Issues to cover:

- Plan for future monitoring and evaluation – consider what should be monitored and evaluated and when. There is a commitment in the Interinstitutional Agreement on Better Law-Making to consider systematically monitoring and evaluation provisions in new basic acts of Union law. In particular:
 - Identify core monitoring indicators for the main policy objectives against which progress will be evaluated;
 - Verify that monitoring arrangements are in place from the outset and evaluations are designed and scheduled¹⁰⁶ in a way whereby the results can be used as input for future impact assessments.
- For the preferred policy option:
 - Identify operational objectives and the corresponding monitoring indicators;
 - Further specify what would be monitored, from when will monitoring start, by whom and how the results will be used, and when the future evaluation will be undertaken.

Annexes that must be included in the impact assessment report

Annex 1: Procedural information concerning the process to prepare the impact assessment report and the related initiative.

- Identify the lead DG; Agenda planning/Work Programme references;
- Organisation and timing: provide the general chronology of the IA and specify which DGs participated in the interservice group and how many meetings of the group were held;
- Consultation of the RSB. Briefly explain how the Board's recommendations have led to changes compared to the earlier draft. This should be presented in tabular format –

¹⁰⁶ In both terms of having data already available and the right moment in the Strategic Planning and Programming cycle.

the first column identifying the Board's recommendation and the second column how the IA report has been modified in response;

- Explain which evidence has been used in the impact assessment together with sources and any issues regarding its robustness (i.e. has the information been quality assured?)
- External expertise. Describe how expert advice has been used in the IA process, including scientific expertise and/or use of Commission expert groups. Describe any studies/work carried out to feed into the IA by external consultants, with references and internet links where available.

Annex 2: Stakeholder consultation

- This annex is the synopsis report of all stakeholder consultation activities undertaken¹⁰⁷ with a focus on the impact assessment it informs. The annex should not exceed 10 standard DGT pages (1500 characters per page).
- The aim of this annex is (i) to inform policymaking on the outcome of all consultation activities; and (ii) to inform stakeholders on how their input has been taken into account and to explain why certain suggestions could not be taken up.
- The content of the annex should include:
 - A key outline of the consultation strategy, referring to the consultation objectives as defined, identified stakeholders and selected consultation methods and tools. If no public consultation has been performed or if the usual duration of 12 weeks has been shortened an explanation should be given;
 - Indicate if the Commission's minimum standards have all been met, and, if not, why not;
 - Documentation of each formal consultation activity, including, if applicable, an explanation as to how and why the initial consultation strategy was modified;
 - Information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached;
 - Short description of the methodology and tools used to process the data.
 - Description of the results of each consultation activity, including qualitative and interpretative analysis; if different consultation activities have been undertaken in the context of the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions in relation to contributions and main stakeholder categories;
 - Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses). The information should include the share of contributions and their viewpoint.

¹⁰⁷ See Tool #55 on *Informing policymaking – the synopsis report* for the specific content requirements

- For ad hoc contributions received outside the formal consultation context, a separate paragraph should be added describing the origin of the contributions received including identification of the type of stakeholder and their represented interests,
- Where applicable, a paragraph summarising the feedback received on the roadmap or inception impact assessment.
- Explanation on how the information gathered in the context of the consultation work as well as feedback received has been taken into account into the further work on the initiative, evaluation or fitness check. Where relevant, this should include explanation on why certain widely supported views were not, or not entirely, considered.
- If national Parliaments have contributed, it is recommended to inform in a separate paragraph which national Parliaments contributed (Member State and chamber) and what issues they addressed.
- In particular, the annex should provide:
 - Details of how, who and on what you consulted upon. You should explain how you ensured that all relevant stakeholders have had an opportunity to provide an opinion on all key IA elements;
 - The results should preferably be presented for each key IA element and differentiated across stakeholder groups (including social partners);
 - This should include information about any diverging views between or within stakeholder groups - as well as between the public and targeted consultations, according to different dimensions within the main stakeholder categories (e.g. regional, occupational, etc.).

Annex 3. Who is affected by the initiative and how?

This annex should clearly set out the **practical implications of the initiative for a representative enterprise and/or public administration** (or particular groups or individuals if directly regulated). It should always be prepared and be based on the preferred policy option (where this is specified). Without reproducing the provisions of the legal text, it should indicate which key obligations will have to be fulfilled and over what timescale. It should describe in a proportionate manner the actions that the enterprise or public authority might need to take in order to comply with the obligations under the proposed intervention and indicate wherever possible the likely costs to be incurred in meeting those obligations. For example, the frequency and complexity of financial reporting for SMEs.

The costs and benefits of the initiative should be quantified (wherever possible) including any reductions (or increases) in regulatory costs. The entries should follow the assessment of impacts in section 6 and presented in a tabular formats (see below). If such quantification is not possible, the reasons why should be given. Where no preferred option is specified, the information should be presented for each of the retained options.

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

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option(s)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct costs						
	Indirect costs						
Action (b)	Direct costs						
	Indirect costs						

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

Annex 4. Analytical methods used in preparing the impact assessment.

When IA analysis relies on modelling or other analytical techniques, a dedicated annex presenting the following information should be included:

- A brief description of the model/methods used which addresses:
 - The developer of any model and its nature (public/private/open source) ;
 - Model structure and modelling/analytical approach with any key assumptions, limitations and simplifications;
 - Intended field of application and appropriateness of the model/technique for the specific impact assessment study presented;
- Validation and peer review with relevant references;
- The extent to which the model/technique and input data have been discussed with external experts;
- Explanation of the likely uncertainty in the analytical results and the likely robustness of the results to changes in underlying assumptions or data inputs;
- Explanation as to how uncertainty has been addressed or minimised in the analytical work with respect to the policy conclusions; and
- The steps taken to assure the quality of the analytical results presented in the IA;
- A concise description of the baseline(s) scenario used in any modelling exercise in terms of the key assumptions, key sources of macroeconomic and socio-economic data, the policies and measures the baseline contains and any assumptions about these policies and measures (such as the extent to which they are deemed implemented by the Member States, or their estimated impact following implementation).

Optional Annexes

Annexes can be used to present additional technical material particularly to support the information presented in the main body of the impact assessment report (e.g. a more detailed description of the concerned market or monitoring indicators). Annexes should not be excessively long, be restricted to information which is relevant and pertinent to the overall purpose of the impact assessment and contain references and hypertext links to external information sources wherever possible (rather than reproducing the material in the IA report).

TOOL #13. HOW TO UNDERTAKE A PROPORTIONATE IA

The IA process should provide the Commission with comprehensive evidence-based answers to the key IA questions. However, the scope and depth of **the analysis should be proportionate** and consistent with the importance/type of initiative and the nature and magnitude of the expected impacts (e.g. legislative/non-legislative, REFIT initiative, implementing measures, etc.). This relates not only to the IA report but to all stages of the IA process.

1. THE APPROPRIATE SCOPE AND DEPTH OF ANALYSIS

Setting the appropriate depth and scope of the overall analysis implies deciding:

- The *resources and time allocated to the overall IA process*, including data collection, stakeholder consultation and conducting external studies;
- The *relative effort required to answer each of the IA key questions* (i.e. should more resources be invested in verifying the existence of a problem or in analysing alternative options?);
- The *specific focus of each step of the analysis* (i.e. should the comparison of policy choices focus on broad options or on alternative measures within a given policy approach? At which level of aggregation should impacts be assessed? On which specific issues is it worth drilling down?).

It is the **responsibility of the lead DG, in cooperation with the interservice group**, to determine the level of analysis taking into account all relevant factors as well as any unsurmountable constraint in the availability of time, resources and data. Setting the level of analysis is likely to be an **iterative process**. It should be done as **early** in the planning process as possible and be discussed with your DG's IA support unit and within the ISG. Indications should also be provided in the inception IA. Proportionality might have to be **adjusted flexibly** as the analysis evolves and as the stakeholder consultation unfolds.

For transparency, whenever drafting the IA report, think about the opportunity of briefly justifying those choices regarding the level of analysis which might be disputed.

2. FACTORS AFFECTING THE LEVEL OF ANALYSIS

The proportionate level of analysis varies from case to case but is influenced by some general factors and the nature of the particular policy instrument.

2.5. General factors

<i>The political importance of the initiative under consideration</i>
Does it relate to a Commission priority (promoting growth and jobs, regulatory fitness etc.)? Does it cut across several policy fields? Is it particularly controversial? Could it raise concerns related to subsidiarity and proportionality? Are there polarised views on the best policy option? Is the initiative particularly important in the interinstitutional context or for certain Member States? etc.
The IA should provide sufficient evidence to respond to the concerns likely to arise during

the internal decision-making process or after Commission adoption and anticipate an assessment of potential amendments or alternative solutions that may be raised in the interinstitutional decision-making process.
<i>The stage of policy development</i>
If an initiative breaks new ground , it is important to systematically analyse the problem to be addressed, carefully assess the necessity and added value of EU action and consider a wide range of options for action. Resource investment, data collection and stakeholder consultation efforts should be commensurate.
When reviewing existing legislation , an evaluation should be the starting point. Its results should be used to verify whether the legislation is still necessary and in line with the subsidiarity principle, and which specific provisions should be modified having proven ineffective, excessively costly or outdated.
When preparing the IA for a delegated act or an implementing measure , the subsidiarity analysis carried out for the basic legislation is likely to be sufficient. The new IA should focus on the actual outstanding decision at stake, related options and their impacts. Similarly, an IA for transposing an international agreement into EU law should focus on whatever margin of discretion exists for the Commission.
<i>The magnitude and complexity of the problem being addressed</i>
The more complex the problem being addressed and the more pervasive its implications for society, the economy and the environment, the greater the need for an in-depth analysis. On the other hand, the smaller and more focussed the problem, the more the need to discuss on the basis of evidence the opportunity of acting at the EU level in line with the principle of being small on small things and big on big things.
<i>The significance of the expected impacts</i>
In terms of their absolute and relative size but also their relevance for specific stakeholders (SMEs, specific sectors, etc.). The analysis should focus on assessing those (intended and unintended) impacts that are expected to be more significant. The greater the likely impact, the more thorough the assessment should be and the greater the efforts to collect data and quantify impacts (keeping in mind that some impacts may not be quantifiable). Similarly for the impacts that are likely to be irreversible.
<i>The risk of negative unexpected consequences</i>
Could getting the policy wrong have significant negative unexpected consequences? The more likely this is, the greater the need to acknowledge and, to the extent possible, assess the risks and likely consequences.

2.6. Nature of the policy instrument

The appropriate level and focus of the analysis is also linked to the type of policy initiative, in particular by looking at how stringent requirements it would impose on Member States, citizens, businesses or any other economic/institutional actor.

A Regulation will directly impose obligations and its impacts will be more certain. This calls for a more detailed assessment, quantifying likely impacts as far as possible.

The impacts of a Recommendation will depend to a greater extent on the level of details set out in the provisions and the way in which Member States are likely to implement them. The assessment of its impacts will then need to factor in possible policies that might be taken at national level. In such cases, a detailed quantitative assessment might be disproportionate if that information cannot be easily gathered.

The degree of ambition/political commitment expressed in a Communication will determine the appropriate depth of its accompanying IA analysis. Some Communications announce ambitious commitments (e.g. a 10-year strategy to achieve defined environmental targets) that will most probably lead to significant impacts during a long period. Other Communications may announce initiatives that are likely to have more limited impact and might even not need an IA at all¹⁰⁸.

Bearing in mind that in the end it is the content rather than any formal classification that determines the degree of analysis, **the following table illustrates how impact assessments may differ for different types of initiatives.** It will often be the case that the exact form of your initiative will only become clear in the course of the assessment of the different options. The indicative guidance below, together with the criteria established above, will help you to establish the right level of analysis for your IA.

Box 1. Non-legislative initiatives with clear policy commitments such as Communications, White Papers, Strategy Papers and Action Plans.

The IA should focus on:

- Relevant problems and drivers building on retrospective evaluation of existing policy framework (where relevant);
- Identification of general and specific objectives;
- Subsidiarity analysis to explain the necessity and added value of EU action;
- Identification of different options for action;
- A description of the most significant potential impacts of the different options, clearly linked to the objectives; focus on trends, causalities and mechanisms; more detail will be needed according to the significance of the commitments proposed;
- Identification of need for follow-up IAs and data necessary for future actions if impacts cannot be fully assessed at this stage.

The IA should avoid:

- Extensive work to establish operational objectives. This may be more appropriate for follow-up impact assessments;
- An excessive description of policy context and duplication of objectives already outlined in the main initiative itself.

¹⁰⁸ See Tool #9 on *When an impact assessment is necessary*.

Box 2. Legislative instruments

IA should focus on:

- Detailed description of problems/challenges, and how they are likely to evolve;
- Detailed subsidiarity analysis to explain the necessity and added value of EU action;
- Short and more detailed description of general and specific objectives respectively;
- Identification of options. If the range of feasible options is limited by obligations to respect fundamental rights, political constraints or previous policy, analyse different implementation options, levels of ambition, priority setting and/or choices of instruments;
- Thorough assessment of the most significant economic, social and environmental impacts for all options, as far as possible in quantitative terms;
- Identification of operational objectives for the preferred option and the corresponding monitoring indicators;
- In case of a **REFIT initiative**: clearly spell out the simplification benefits and quantify these as far as possible (including any reductions in regulatory costs);
- Clear identification of who will be affected and how; measurement of regulatory costs and benefits;

IA should avoid:

- Disproportionate general discussion on policy context, wide policy options, high-level impacts.

Box 3. Implementing Acts and Delegated Acts

IA should focus on:

- Main outstanding decisions and related options, namely, where the basic act leaves scope for Commission choice, where the Commission may consider deviating from advice given by specialised agencies, and/or where impacts are likely to be significant (and have not been covered in the basic act IA);
- Identification of specific objectives relating to the outstanding decisions, linked to the objectives/requirements of the basic legislation;
- Thorough assessment of impacts in relation to the options, taking full account of relevance of technical detail and using quantification to the extent possible in particular of regulatory costs and benefits;
- Identification of operational objectives for the preferred option and the corresponding monitoring indicators.

IA should avoid

- Repetition of analysis covered by the IA of the basic act (e.g. in relation to the overall problem, subsidiarity principle, objectives, etc.)
- Redoing relevant analysis undertaken by specialised agencies, to the extent that the lead DG judges this analysis to be credible and carried out in line with Commission IA principles; such analysis should on the contrary feed into an IA as appropriate.

Separate guidance has been prepared in respect of expenditure programmes and financial instruments¹⁰⁹ and initiatives in the social policy field pursuant Articles 154-155 TFEU¹¹⁰.

3. EXAMPLES OF PROPORTIONATE ANALYSIS

The proportionate level of analysis varies from case to case. The table sets out illustrative examples of impact assessments for various types of initiative which have been submitted to the RSB in the past. For the more complex case of a legislative proposal the good practice is broken down further to key sections of the IA report.

Type of initiative		Example of proportionate IA
Legislative proposal	Problem definition	• SWD(2013) 430 Aviation ETS regional measures • SWD(2013) 108 Weights and measures for road vehicles in national and international traffic
	Subsidiarity	• See tool on subsidiarity and proportionality
	Quantification of impacts	• SWD(2013) 427 Standard VAT return • SWD(2013) 531 Annex 12: Emissions controls on medium sized combustion plants (air pollution package)
	SME impacts	• See tool #22 on <i>The SME test</i>
	Monitoring and evaluation	• SWD(2013) 222 Electronic invoicing in public procurement
White Paper		• SWD(2014) 217 EU merger control
Communication		• SWD(2014) 159/160 Strategy to reduce fuel consumption and CO₂ emissions from HGVs
Delegated Act		• SWD(2015) 189 packaging of medicinal products • Liquidity coverage ratio
Implementing Act		• SWD(2014) 203 <i>de minimis</i> aid in the fishery and aquaculture sector
Council Recommendation (Int ^l negotiations)		• SWD(2015) 289/290 EU Mexico Free Trade Agreement
Social Partner Agreements (154-155 TFEU)		• SWD(2014) 226/227 working time arrangements in the water transport sector • EU social partners' agreement concerning the implementation of the ILO Work in Fishing Convention, 2007
Financial programmes (basic acts)		• SEC(2011) 1541/1542 Proposal for a Regulation on the establishment of a Programme for the Environment and Climate Action (LIFE) • SEC(2011) 1452/1453 Proposal for a Regulation establishing a Programme for Business Competitiveness and small and medium-sized enterprises (2014-2020)

¹⁰⁹ See Tool #10 on *Financial programmes and instruments*.

¹¹⁰ See Tool #11 on *Social partner initiatives*.

TOOL #14. HOW TO ANALYSE PROBLEMS

1. INTRODUCTION

The first step of an IA is to verify the existence of a problem¹¹¹ and to (i) identify who is affected; (ii) estimate the scale of the problem; (iii) analyse its causes; and (iv) assess the likelihood that the problem will persist in the absence of EU policy intervention. The findings from evaluations, fitness checks, implementation reports and infringement-related information should form an integral part of the problem definition.

The answers to these questions should give decision makers the information necessary to decide whether a policy response is warranted. Care should be taken when identifying problems as this aspect is most often criticised by the Regulatory Scrutiny Board. Moreover, every impact assessment is underpinned by an intervention logic which connects logically the problem to its drivers and the objectives and policy options. If the problem is ill-defined, the IA will be unlikely to present well the assessment of effective policy options.

Box 1. Tips and commonly encountered issues

- A commonly made mistake is to conclude that a problem exists because a policy framework, regulatory measure, database etc. does not yet exist at EU level. These "missing elements" are not problems per se but may in fact be possible policy solutions to an appropriately defined problem.
- The problems and their causes are often not supported by sufficient tangible evidence. For example, without solid evidence it is difficult to explain why a market failure exists in a professional (business to business) situation where the professional actors should presumably be aware of the problem and correct their behaviour accordingly.
- If the information or statistics are available, it is also informative to present the problem (and related causes/drivers) in a spatially disaggregated way using maps or other visual aids¹¹². Such visualisations will also help when considering the issue of subsidiarity.
- Where the problems and drivers are numerous or complex/interrelated then it is often a good idea to use visual aids to describe them and to link them through to the objectives and policy options (e.g. problem trees, tables linking problems-drivers-objectives-options)¹¹³.
- It is important that the problem analysis identifies the roles, issues and drawbacks for stakeholders so that the initiative can be designed in a way that tackles effectively the behaviour of the various actors that would need to change.

¹¹¹ It is sometimes useful to think not of a problem but of a "need" which should be addressed as is often the case in the context of preparing financial programmes and financial instruments.

¹¹² See Tool #33 on *Territorial impacts*.

¹¹³ See Tool #65 on *How to use visual aids and present quantitative data*

2. THE FIVE KEY ISSUES TO ASSESS

When analysing a problem, the following five issues should be covered.

A. Establish what the problem is and why it is problematic (i.e. its negative consequences).	
Why?	To identify the issues that might have to be addressed by an EU intervention.
How?	Clearly but succinctly describe the current situation (the status quo). This should present the findings of relevant evaluations and fitness checks.
	Show what, and whose, behaviour would need to change and why.
	Briefly recalling any relevant political objectives as expressed in, for instance, Commission Communications, Council Conclusions and European Parliament Resolutions.
	Consider whether there may be additional (or related) problems linked to the pursuit of general objectives and principles such as international issues (international regulatory or market changes, international agreements or competitiveness disadvantages) lack of coherence with EU development objectives etc.

B. Assess the magnitude and EU dimension of the problem	
Why?	To show whether a problem is relevant or not.
How?	The extent to which a problem can be quantified or even "monetised" varies from case to case. You should, however, make (and show) the effort to collect and use all the evidence that can help to give an idea of the importance and scale of the problem.
	Explore the relevance of possible cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital. These aspects link clearly to the assessment of subsidiarity. ¹¹⁴

C. Establish the causes ("drivers") and assess their relative importance.	
Why?	To help identify policy options which address the problem.
How?	Map the main underlying causes (drivers) of the problem. Classify the main underlying causes by type, so as to determine whether the main underlying cause lies in people's behaviour or in some other source (see below).
	While an exhaustive list of all possible causes and sub-causes is not needed, you should approach this part of the analysis with an inquisitive mind.
	Identify what drives the behaviour that would have to change to address the problem.

¹¹⁴ See Tool #5 on *Legal basis, subsidiarity and proportionality*.

	Isolate those drivers that play a major role in determining a problem and differentiating those that could be targeted by the initiative from those falling outside of the scope because they are targeted by other initiatives or are outside the remit of EU competence. Relevant interactions among drivers should also be identified.
	Consider using a problem tree to depict graphically the relations between drivers, problems and their consequences.

D. Identify who the relevant stakeholders are

Why?	To help target your consultations and prepare the analysis of problem drivers and distribution of impacts.
How?	Identify those (EU and non-EU) stakeholders who are affected by the problem and those whose behaviour causes it. These could be subsets of the same group (e.g. a specific cohort in the general population). Relevant groups will depend on the nature of the problem. You should, however, think beyond the narrow boundaries of the specific policy sector. Whenever relevant, you should distinguish within categories (i.e. micro, small, medium-sized and large enterprises), assess the way in which different types of agents (e.g., vulnerable vs. non-vulnerable individuals) react to the problem matter at hand, look at non-EU actors (i.e. developing countries, non-EU producers etc.) and differentiate across Member States and/or EU regions.

E. Describe how the problem is likely to evolve with no new EU intervention.

Why?	To verify if the need for a possible policy initiative is going to persist. To set a no-policy change or baseline, scenario against which the impacts of policy options will be measured and compared ¹¹⁵ .
How?	The nature of the baseline scenario will depend on the methodological choices made in the IA and will range from an evidence-based qualitative assessment to a fully-fledged modelling scenario. The baseline scenario is different from the status quo because your analysis should look at the likely evolution of the identified problem drivers and show how this will affect the existence and magnitude of the problem. The influence of societal developments like the internet should be factored in if possible and appropriate ¹¹⁶ . To do this you should consider recent trends and implementation of existing policy at all relevant levels (Member States, EU, international). Policy changes that have already been adopted (but not yet implemented)

¹¹⁵ See Tool #17 on *How to identify policy options*.

¹¹⁶ See Tool #27 on *The digital economy and society & ICTs or systems*.

	should also be taken into account. The same applies to EU proposals put forward by the Commission but not yet approved by the Legislator.
	The hypotheses underlying the analysis should be explicit and well justified.
	Whenever future trends in some underlying drivers are particularly uncertain and/or highly significant for the expected development of the problem, this should be highlighted and some form of sensitivity analysis considered (namely by presenting alternative scenarios)

3. WHAT IS THE UNDERLYING PROBLEM DRIVER

The first step of an IA is to identify and characterise the problem to be addressed. In order to solve the problem, its underlying causes (or "**drivers**") should also be identified. This is important for two reasons. First, it is impossible to design alternative policy interventions and study how these would tackle the problem without knowing how the underlying drivers are affected (this link between problem-drivers and policy options is usually referred to as the "**intervention logic**"). Second, the nature of the problem (in terms of size, geographic scale, the market actors) plays a key role in the justification of public policy action.

A public policy intervention may be justified when:

- (1) **A market fails**, i.e. when market forces fail to deliver an efficient outcome (defined as a situation where no one can be made better off without someone else being made worse off).
- (2) **Regulations fail**, i.e. when public policy action appeared justified and was implemented but failed to solve the problem satisfactorily or helped create new problems (e.g. two divergent regulations create an obstacle to the proper functioning of the internal market).
- (3) **Equity** (or other) considerations imply the efficient outcome may not be the most desirable one for the policy in question.
- (4) **Behaviours are biased** and individuals do not decide based on their own best interests.

Each of these categories of problem driver is described in greater detail below in general non-expert terms. For more robust and technical analysis, the reader is invited to consult any general economics textbook.

3.1. Market failures

A. Externalities	
Issue?	Market prices do not reflect how one activity produces costs or benefits for other activities.
Relevance?	Market outcomes are based on prices. If these do not reflect the real costs and benefits to society, then market outcomes will not be optimal from the point of view of society. Decisions are taken without considering how they can affect others. We talk of positive

	or negative "externalities" because the manner of one person's actions affecting another's well-being is "external" to his or her decision-making.
Examples	Consumers do not take into account the cost of the pollution generated in the production of the goods they consume. More pollution than socially optimal is thus generated.
	When deciding to use a car, drivers do not take into account the costs that increased congestion would impose on others.
	When fishing, companies do not take into account the effect this may have on the rate of reproduction of the overall stock of fish in the area. Overfishing ensues.
	Vaccinating oneself reduces the chances of catching a disease for oneself but also for everybody else. Since this is not taken into account by individuals, less vaccination than optimal may take place under voluntary programmes.
	In network industries, prices do not reflect the fact that the value of a product (say a social network) increases with each new customer. The same may hold in the case of certain technologies.
Possible policies ¹¹⁷	Either aim to ensure prices better reflect ("internalise") the externality (for instance through a tax or a subsidy) and then let the market determine a new (improved) outcome or directly correct the market outcome (for instance, through regulation of the particular activity such as emissions controls on industrial installations).

B. Public goods	
Issue?	Insufficient supply of public goods.
Relevance?	Private sector producers will not supply public goods to people because they cannot be sure of making an economic profit. This is because of the nature of public goods. One person's consumption of a public good does not reduce the amount available for consumption by others. And once supplied, a public good is available to be consumed by everybody in society. It is difficult, therefore, and/or undesirable from a societal perspective to charge individuals directly for consuming the good or service in question and consumers can take a "free ride" without having to pay for the good or service.
Examples	National defence is a public good as all people in a nation "consume" the same amount of national defence (provided by the government) and the benefits for each person do not depend on how much a person contributes towards providing it. Other examples are public health and welfare

¹¹⁷ This is a non-exhaustive list providing examples of policies that have been used to target specific drivers.

	programmes, or preparedness for natural disasters.
Possible policies	Public goods are provided collectively by the government, and then financed through taxation of individual households and businesses.

C. Non-existent or weak competition

Issue?	Non-existent or weak competition between suppliers of goods and services.
Relevance?	Article 120 of the TFEU requires the Member States and the Union to conduct their economic policies in accordance with the principle of an open market economy with free competition that favours an efficient allocation of resources. If firms face no, or only weak competition, then the quantity and quality of goods and services they produce may fall short of the socially efficient level.
Examples	Signs of insufficient competition are unusually high profits, or prices which are much higher than marginal cost, or signs of collusion between firms to fix prices as may be possible when there is only one enterprise (monopoly) or a limited number of firms supplying the market from either within the EU or globally. Where technology is such that it is efficient for a single firm to supply the entire market, we talk of economies of scale and a resulting "natural" monopoly. Network industries – transport, energy, and telecommunications – may exhibit some features of natural monopolies (c.f. retail energy suppliers, residential telephone cables).
Possible policies	Regulation can prevent abuses of significant market power by ensuring third party access, tendering rules to ensure competitive bidding to prevent abuse or price regulation.

D. Markets are missing or incomplete

Issue?	A market does not exist or is unable to develop completely.
Relevance?	Goods and services which are needed or wanted by society are not produced.
Examples	Private finance may not be available for all major new infrastructures such as bridges or roads because the revenue generated by imposing user charges would be insufficient. Potential students may be unable to pay for their education by borrowing against their expected future earnings. As a result the workforce is less skilled than would be optimal.
Possible policies	Government subsidies or financial incentives may create the right conditions for the market to establish itself and develop. Governments or State-operated/guaranteed bodies may provide the necessary services.

E. Split markets – Principal-Agent	
Issue?	A misalignment of incentives exists
Relevance?	Socially desirable (and economically rational) actions are not undertaken because market actors have different objectives that are not aligned.
Examples	Since tenants usually pay energy bills, landlords do not have the incentive to provide the most energy efficient appliances (such as a refrigerator or lighting systems) or improve a building energy performance. A ship owner is not responsible for the fuel costs under a charter party and therefore has a reduced incentive to commission the building of a fuel efficient ship or in making modifications to improve the fuel efficiency.
Possible policies	Financial incentives such as taxes can change/encourage different behaviour and/or the take-up of different products. Regulation can redefine the characteristics of products able to be placed on the market or overcome the landlord-tenant problem by, for example, increasing the renovation rate of buildings.

F. Imperfect information	
Issue?	Market players may have imperfect information leading to sub-optimal societal outcomes.
Relevance?	Information is needed for markets to operate efficiently. Buyers need to know about the quality of the good or service to assess its value. Sellers, lenders and investors need to know about the reliability of a buyer, borrower or entrepreneur. Information also needs to be available equally to all market participants. Where it is not, the "asymmetry" can lead to sub-optimal decisions (e.g. a buyer may make the wrong choice because he is not in possession of the same information as the seller – or another buyer - is about product/service quality).
Examples	As information on the energy consumption of different models of household appliances, or passenger cars, or the nutritional content of foodstuffs is costly to acquire, consumers' choices may not take these factors into account when buying. Since lenders cannot easily/cheaply distinguish between good and bad borrowers, they have difficulties distinguishing between borrowers willing to pay a high interest rate because of the high return on the activities to be financed from those willing to commit to a high rate because they do not expect to pay back the funds. As a result, credit may simply be rationed. This is particularly relevant for the smallest enterprises. Since the costs to collect and process information on creditworthiness are largely fixed, they are more likely to be higher than the expected profits as the loan size decreases.
Possible policies	Voluntary or mandatory labelling schemes with relevant information can inform consumer choice and enhance demand for better performing products. Markets can be regulated to ensure that all participants receive the same information at the same time.

3.2. Regulatory Failures

Intervention by public authorities to resolve market failures can fail to achieve a socially efficient allocation of resources. This can be the result of several factors.

First, public authorities may not arrive at the best solution for society in the first place. For example, public authorities may be unduly influenced by the (partial) information provided by one or more specific interest groups when designing new regulation (so-called "regulatory capture").

Secondly, public intervention may be quite simply **poorly designed**, thus failing to achieve its objectives, achieving them with unnecessary high costs or targeting the wrong objectives. Even when achieving its objectives, public intervention may still have **unintended negative consequences**, such as favouring incumbents, creating barriers to entry and innovation or leading to excessive cumulative regulatory costs for an industry (no matter how well justified each individual regulatory initiative affecting the industry may be).

Thirdly, public intervention may be **poorly implemented and/or enforced**.

Finally, public intervention may simply become **out of date** as the world evolves and problems and drivers change.

As many Commission initiatives concern areas where EU legislation already exists, regulatory failures should always be considered as one possible source of the problem. To do this, you should first and foremost rely on an **evaluation** of the existing policy framework that should be carried out prior to the impact assessment according to the Commission's "evaluate first" principle.

3.3. Equity

Achievement of equity/social objectives may also provide important reasons for policy intervention because even a perfectly competitive and efficient economy can produce outcomes that are unacceptable in terms of equity. Moreover, a growing body of research suggests that inequality can hurt economic growth.¹¹⁸

The definition of socially desirable outcomes depends on values and beliefs. While there is no single definition of the concept of equity, the three most common concepts of equity relate to **equity of endowments, processes, and outcomes**.¹¹⁹

Initial endowments of individuals may differ and that can give some individuals an (unfair) advantage to compete in the market economy. E.g. being born into a well situated and educated family can better equip children with skills and abilities to function in the market economy. Public intervention can reduce those differences and improve the **equity of endowments**. (E.g. improving the housing conditions of poor households can

¹¹⁸ Cingano, F. (2014), "Trends in Income Inequality and its Impact on Economic Growth", OECD Social, Employment and Migration Working Papers, No. 163, OECD Publishing, Paris. DOI: <http://dx.doi.org/10.1787/5jxrjncwv6j-en>

¹¹⁹ Microeconomics for Public Decisions by Anne C. Steinemann, 2011, Askmar publishing

improve physical and mental health of children and consequently improve their skills levels.)

Equity of process suggests that people in similar circumstances should be treated equally, for example having equal access to services or employment. When this is not the case, there is then a need for public intervention for example to tackle discrimination based on race, gender, sexual orientation, age or disability.

The interventions to improve the **equity of outcomes** aim at correcting outcomes that are purely based on the abilities of individuals, for example by supplementing market income with tax/benefits schemes. The interventions to improve the equity of endowments and of processes can greatly contribute to that.

Equity considerations should consider also **intergenerational equity** - needs and outcomes for future generations (e.g. those activities of the present generation do not worsen the situation of future generations).

Protection and fulfilment of fundamental rights afforded to citizens of the Union may also provide grounds for intervention.

3.4. Behavioural biases

Markets forces will deliver an efficient outcome as long as there are no market failures and individuals act in their own best interest. However, there is a growing body of evidence showing that this is not always the case since **individuals' choices may vary systematically according to specific aspects of the decisions they face and/or the context in which their decisions are made**. In such cases, market forces will not achieve an efficient outcome and a public intervention may be justified which better reflects individuals' actual behaviour.

Box 2. Illustrative examples

- The Consumer Rights Directive 2011/83/EC prohibits the use of pre-ticked boxes for online sales because evidence has shown that decision makers are drawn towards default options regardless of their value.
- The traditional fuel economy data (miles per gallon) used in the USA in the past led to biased choices because small differences were much more important for fuel inefficient vehicles than for efficient vehicles. Accordingly, US Fuel economy labels for new cars now include annual fuel costs and fuel consumed per unit distance travelled since these data can be easily understood and compared (as running costs vary linearly with distance travelled).
- When domestic energy consumers in the UK were observed not to switch to cheaper suppliers, the choice to be made was simplified by forcing all suppliers to limit the number of tariff options and to present simplified information including an indication of the cheapest tariff.

Four key issues identified by behavioural analyses are particularly relevant for both the justification of a policy and its design. First, choices are influenced by the simplicity of information and the range of available options. Second, people are drawn towards more convenient options, especially default options. Third, the prominence of options or attributes can affect how they are weighed in decisions. Fourth, research has also identified clear decision-making errors such as the failure to take account of non-linear

aspects such as the costs due to compound interest. Regulations can be designed in ways that recognise these behavioural traits and de-bias decision makers and promote better decisions (and using less intense measures such as "nudging" behaviour in the desired direction).

The non-exhaustive list presented below provides more examples of biases that have been tackled by *behaviourally-trialled* or *informed* policy initiatives.¹²⁰

A. Default bias	
Issue?	People are inclined to let the <i>default</i> rule dictate their decisions.
Relevance?	Neoclassical economic models assume that consumer preferences are revealed (i.e. that consumers know what they want). In reality, the evidence shows that consumers' preferences can be influenced by the way options are presented to them.
Examples	In online contracts, ancillary services (e.g. travel insurance when we want to buy an airline ticket, or a seat reservation when we want to buy a train ticket) used to be proposed with pre-checked boxes. The available evidence proved that consumers were much more likely to buy them than if they had been proposed with pre-checked boxes.
	A cross-country investigation shows that the rate of organ donors is significantly higher (above 90%) in countries where organ donation is an <i>opt-out</i> choice, and much lower in countries where this is an <i>opt-in</i> choice.
Possible policies	The EU Consumer Rights Directive, which came into force in June 2014, clearly limits the use of pre-checked boxes (Art. 22). This ensures a more neutral <i>choice architecture</i> , and makes sure that money stays by default in consumers' pockets.

B. Information overload	
Issue?	People have a limited ability to deal with voluminous and complex information.
Relevance?	Traditional economics assumes that information provision maximises consumers' ability to act in their own self-interest and make better choices as it reduces asymmetric information or uncertainty. Notwithstanding, evidence shows that information provision is often insufficient, namely when consumers are unable to process the information due to its sheer volume and/or level of complexity.
	Relatedly, too much information might also lead to procrastination or inaction, as individuals might avoid making a decision due to fear

¹²⁰ See *Behavioural Insights Applied to Policy: European Report 2016*, Sousa Lourenço Ciriolo, Rafael Almeida (2016), for a definition of such initiatives.

	that regret outweighs the gains from choosing.
Examples	In financial services, regulators have used behavioural insights to improve financial consumer protection by helping consumers to better compare and select products for their investment needs. Namely, available evidence from retail investment services showed that simplification and standardisation of product information reduces the negative impact of framing effects in investment decisions and helps consumers make more optimal choices.
Possible policies	The Regulation on Packaged Retail and Insurance-based Investment Products (PRIIPs), requires short standardised documents with key information on investment products in a clear and understandable manner are made available to investors.

C. Social norms	
Issue?	People influence, and are influenced by, what others do.
Relevance?	Price-based approaches are commonly used to affect consumers' behaviour. However, evidence shows that social factors, such as social norms, reciprocity and fairness, can exert a powerful influence on behaviour. Social norms are rules of behaviour that affect the way we interact with others by signalling the appropriate behaviour. In other words, normative feedback (e.g. comparing the individual's behaviour to that of others) can significantly influence individual behaviour.
Examples	Available evidence shows that normative feedback on how one's electricity consumption compares to that of neighbours can encourage households to consume less electricity.
Possible policies	The US energy company OPower has introduced social norms to promote reductions in households' energy consumption.

TOOL #15. RISK ASSESSMENT AND MANAGEMENT

1. INTRODUCTION

Assessing risks¹²¹ is complex and often requires in-depth expertise and specialist knowledge spanning various policy fields. The purpose of this tool is, therefore, to introduce the key concepts rather than to explain how to assess risks and prepare risk management measures. It also provides guidance on how risk assessment may contribute to the Commission's impact assessment process.

Risk assessments are carried out in a wide range of policy areas across the Commission and the EU's decentralised agencies, including in relation to natural disasters, security, human/animal/plant health, environment, functioning of IT systems, financial markets, energy supply, air traffic, amongst others.

Such risk assessments can support different types of policy decisions or actions taken by the Commission¹²² including implementing risk management approaches determined in the basic legislation¹²³.

In cases where impacts are likely to be significant, sufficient discretion exists for the Commission on the scope of potential risk management measures and/or the decision deviates from the advice of risk assessors, an impact assessment may be required¹²⁴. A proportionate IA should also be carried out for every decision invoking the precautionary principle which should set out the elements necessary for the exercise of the principle¹²⁵. In such cases, the results of the risk assessment are fed into the IA process.

2. WHAT IS HAZARD AND RISK?

A hazard is any source of potential damage, harm or adverse effects on something (e.g. the environment) or someone. Risk is the chance or probability that a person or something will be harmed or experience an adverse effect if exposed to a hazard.

In today's society, where potential risks are numerous and interrelated, **risk can be identified** on the basis of a wide range of evidence including past experience, monitoring data, expert opinions, etc. Note that risk may not be related exclusively to the problem itself but also to the alternative measure(s) to reduce the initial risk.

¹²¹ Note that risk in the context of risk assessment explained here presents a result of natural or manmade hazards and NOT uncertainty in a wider sense, as described in the Tool #62 on The use of analytical models and methods.

¹²² Note that EASA can also take risk management decisions.

¹²³ In areas such as food/feed safety, animal health, plant health, animal welfare, medicinal products, medical devices, cosmetics, biocides, chemicals.

¹²⁴ Emergency measures (to prevent contagion/spread of a disease etc.) would generally be exempt.

¹²⁵ COM(2000) ; Communication on the precautionary principle

Box 1. Hazard and risk

- Hazard is a function of the inherent properties of the agent/event in question whereas risk is a function of both the hazard and of the potential likelihood and extent of being exposed to the hazard. In other words, while hazard represents an abstract danger, risk expresses the combination of the level of hazard and the likelihood of its occurrence.

Risk = Hazard (expressed in terms of its negative impact) x Likelihood of its occurrence.

- While the two variables are not independent of each other and while the impacts of the hazard depend on preparedness or preventive behaviour (as is the case of natural hazards), the risk should be expressed as a functional relationship rather than a simple multiplication of both variables¹²⁶.

3. HOW TO ASSESS RISK?

In conjunction with the in-house expertise of the Commission services¹²⁷, risk assessment requires mobilisation of **broad scientific expertise** – the more complex the situation, the broader the expertise needed (i.e. natural, physical, social, economic, etc.). Risk assessment may be carried out by **permanent bodies or services at EU level, such as:**

- Decentralised EU agencies (such as EFSA, ECHA, EMA, ECDC, EASA¹²⁸);
- Scientific committees set up by the Commission¹²⁹ (such as SCENIHR, SCHER);

These bodies have been established, *inter alia*, for risk assessment purposes at EU level, and should be approached systematically when policy areas covered by their mandate and expertise are involved. They may also be approached in case of a need to complement and/or validate risk assessments or scientific input from **other bodies or sources such as:**

- Permanent bodies at national or international level (such as WHO);
- Expert groups consisting of individuals appointed in their personal capacity and set up on an ad hoc basis;
- External consultants; or
- Conferences, Stakeholders' workshops, focus groups etc.

The Joint Research Centre can support risk assessment by providing tools and models used in the assessment process as well as validating risk assessment methodologies. The

¹²⁶ For more details, see for example SEC(2010)1360.

¹²⁷ With the exception of JRC that is referred to later on as a dedicated scientific body

¹²⁸ European Food Safety Authority, European Chemicals Agency, European Medicines Agency, European Centre for Disease Prevention and Control, European Aviation Safety Agency.

¹²⁹ Scientific Committees are permanent expert groups governed by specific rules of procedure.

JRC can also provide expert judgements where risk assessment bodies provide conflicting opinions or in cases where there is large scientific uncertainty.

Where the risk assessment feeds into the IA process, the interservice group should be consulted on the sources and the scope of the risk assessment and on the need to complement and/or validate the results. In cases where risk assessment is not carried out by one of the permanent bodies at EU level (as listed above), particular attention should be paid to ensuring wide coverage of scientific expertise and to the integrity of experts, as well as to the possible need for a combination of several sources of expertise.

Although the definition and stages of risk assessment may differ across policy areas and practitioners, its purpose remains the same – to assess the risks. The following **three steps** can be identified:

- (1) Identify and characterise the hazard, i.e. identify and characterise the inherent properties of the agent/phenomenon in terms of potential negative effects (on population, environment etc.), establish the causal relationship between the hazard and its effect, describe the negative effect and determine its severity (e.g. occurrence of mutations, changes in the cell structure, etc.). Special attention should be paid to induced or secondary hazards (e.g. contaminated river flood).
- (2) Assess the likelihood of its occurrence, i.e. estimate the likelihood of the hazard (for the population, environment etc.) to occur¹³⁰.
- (3) Characterise risk, i.e. on the basis of results from previous steps, determine quantitatively (e.g. death, injury, production loss) and if not possible, qualitatively, the level of risk under given assumptions and uncertainties. Although the level of risk can be difficult to express in monetary terms (e.g. in the case of non-market impacts on environment and health), methods exist that can be used to monetise them¹³¹.

Uncertainty is inherent in every stage of risk assessment. Irrespective of the different definitions and classifications of uncertainty¹³², the key is to understand how important such uncertainty is and, on that basis, understand the reliability of the risk assessment. In order to do so, uncertainty needs to be carefully evaluated¹⁴⁷ and transparently reported on, even when it cannot be modelled or expressed in quantitative terms (e.g. because it is difficult to foresee the unknown unknowns, especially for new products or technologies).

¹³⁰ To be understood as the likelihood of the damage materialising – in chemical risk assessment for example, despite exposing the population to a chemical, the body may have the potential to eliminate it without causing damage.

¹³¹ See Tool #59 on *Methods to assess costs and benefits* (including non-market impacts).

¹³² For example, one of the classifications of uncertainty in the risk assessment literature differentiates between (aleatory) uncertainty of a statistical nature, i.e. stemming from the variability of systems, and the lack of knowledge (i.e. epistemic uncertainty, such as the lack of knowledge about the causal link between the hazard and its effect or the combined effects of different hazards, leading to uncertainty about the model and its parameters/assumptions). Another strand of literature emphasizes the difference between risks, to which the instrument of calculus of probabilities can be applied, from uncertainty, where such a computation is impossible. Richer taxonomies used in ecology distinguish between risk, uncertainty, ignorance and indeterminacy.

4. HOW SIGNIFICANT IS THE RISK?

The significance of risk is determined by the so-called risk (or tolerability) criteria. These criteria may range from scientifically identified tolerable thresholds and controllability to risk-benefit trade-offs (including, inter alia, availability of substitutes), risk perceptions (for example in case of emerging risks) or societal values (for example, related to equity or personal freedom considerations). The risk criteria may be defined in the existing legal basis or, more generally, by an existing risk management approach and past experience.

By comparing these risk criteria with the assessed risk, the risk manager can evaluate whether the risk is tolerable or not:

An **intolerable risk** is so significant that risk management measures should be taken to eliminate the hazard and/or the exposure. However, it should be noted that the elimination of one risk, for example by banning a particular hazardous chemical, could result in its replacement by another, potentially more significant but uncertain risk (i.e. substance with unknown effects on human health). Where it is not possible to eliminate an intolerable risk (e.g. in the case of natural hazards), it should be at least be reduced by mitigation and preparedness measures.

A **tolerable risk** may be worth reducing through actions by private and/or public actors. Even where there is no or a negligible risk (sometimes also called “acceptable” risk), there could be reasons for public or private intervention (e.g. on a voluntary basis). Public perception of a risk may for example require an effective risk communication/awareness strategy.

The tolerability of risk needs to be evaluated even when it is not possible to (a) carry out a comprehensive risk assessment (because of the lack of knowledge), or to (b) determine the risk with sufficient certainty (as the sensitivity analysis may conclude¹³³). Even in such cases, the guiding principles for assessing the tolerability of risk remain the risk criteria - which may already reflect the desired strength of evidence or level of protection¹³⁴. Proportionate risk management measures may then be based on the precautionary principle together with collection of additional evidence and review¹³⁵.

5. RISK MANAGEMENT

Risk management measures may include bans or limitations, but equally market-based instruments such as insurance or incentive schemes – which should be considered where

¹³³ See Tool #62 on *The use of analytical models and methods in IA and evaluation*.

¹³⁴ For example, tolerable but highly uncertain risks often become intolerable when the environment, human, animal or plant health is at stake. See e.g. Article 191 TFEU for the environmental policy.

¹³⁵ The Communication on the application of the precautionary principles sets out the requirements for the application of the principle including assessments of costs and benefits, risk assessment etc..See COM(2000) 1 final.

possible as they are less restrictive and lead to an internalisation of negative effects (and thus an efficient outcome)¹³⁶.

In principle, risks can be transferred to a third party (e.g. by insurance) and/or mitigated by:

- Reducing the hazard (e.g. through performance standards for products and processes, emissions, etc.);
- Limiting the likelihood (e.g. through preventive, protective and control-related measures, information and education etc.); or
- A combination of both (in cases where both hazard and likelihood can be influenced and multi-hazard situations more generally).

The optimal level of risk reduction is found where the marginal costs of risk reduction equal the marginal reduction in risk. Where marginal values are unknown or too difficult to assess, total costs and total reduction of risk (i.e. benefit) can be used to determine whether such measures generate net benefit and are therefore socially desirable. It is important to take into account the impact on innovative activities – and the possible foregone benefits in addressing emerging risks in the future.

When **assessing the risk management options**, it should be recalled that:

- The assessment of risk (reduction) resulting from alternative risk management measures may necessitate additional input from the risk assessment bodies unless already provided as part of the original risk assessment;
- Zero risk is unlikely to be achievable or come at prohibitive costs/effort;
- There might be benefits that could be foregone by banning a substance or a product – for example where a pharmaceutical product has serious side effects but represents the only way to cure a disease;
- There may be impacts and/or likelihoods that are not possible or appropriate to quantify but that should be taken into account nevertheless (e.g. where robust monetary values are not readily available as in the area of security, freedom and biodiversity or where the high level of uncertainty renders any quantification meaningless);

One of the key preconditions for the effectiveness of risk reduction measures is the feasibility of their implementation, monitoring and enforcement – which need to be carefully assessed and adequate arrangements made.

¹³⁶ See Tool #18 on *The choice of policy instrument*.

6. HOW CAN RISK ASSESSMENT CONTRIBUTE TO THE IA PROCESS?

Risk assessment		IA process	Main actor(s)
1.	Identify potentially significant risk(s)	Identify problem	Lead DG together with ISG (with input from risk assessors where relevant)
	Identify how and by whom the risk assessment will be carried out		
2.	Assess risk(s) and uncertainty	Assess problem and baseline	Risk assessors
	Complement and/or validate the risk assessment if needed		
3.	Identify risk criteria and evaluate risk	Define objectives	Lead DG together with ISG (with input from risk assessors where needed)
4.	Develop risk management options to eliminate, transfer or reduce risk	Develop options	
5.	Use risk assessment to assess impacts, use sensitivity auditing to assess uncertainty	Assess options	
6.	Plan for communicating risk, reducing uncertainty, adapting the risk management approach if necessary, monitoring new/existing risks etc.	Outline monitoring and evaluation arrangements	

7. INFORMATION SOURCES AND BACKGROUND MATERIAL

7.1. On risk assessments:

- Commission Communication on the precautionary principle (COM(2000)1)
- Commission Staff Working Paper: Risk Assessment and Mapping Guidelines for Disaster Management, SEC(2010)1626 final
- Inventory of Crisis management Capacities in the European Commission and Community Agencies (last update: 2009) available at ECHA and EFSA: e.g.
 - <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>
 - <http://www.efsa.europa.eu/en/efsajournal/doc/2664.pdf>
 - [IRGC, White paper on risk governance: Towards an integrative approach, 2005.](#)
 - [DEFRA, Guidelines for Environmental Risk Assessment and Management, 2001.](#)

On uncertainty:

- IPCS, 2008. Uncertainty and data quality in exposure assessment. Part 1: Guidance document on characterizing and communicating uncertainty in exposure assessment. Harmonization Project Document No. 6. WHO.

- Brian Wynne, Uncertainty and environmental learning. Reconceiving science and policy in the preventive paradigm: Global Environmental Change, 1992.

On the collection and use of scientific expertise:

- Communication from the Commission on the collection and use of expertise by the Commission: Principles and Guidelines, COM(2002)713 final
- [Commission Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies, 2013.](#)

TOOL #16. HOW TO SET OBJECTIVES

1. INTRODUCTION

Objectives link the analysis of the problem (and its drivers) to the options for the policy response. They set the level of policy ambition, fix the yardsticks for comparing policy options and determine the criteria for monitoring and evaluating the achievements of implemented policy.¹³⁷

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

Objectives setting	
<i>After the analysis of the problem</i>	
General	These are the Treaty-based goals which the policy aims to contribute to.
Specific	These set out concretely what the policy intervention is meant to achieve. They should be broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution i.e. the specific objectives are part of the intervention logic: problem-drivers-specific objectives-policy options.
<i>After identifying the preferred option (and when completing the monitoring and evaluation section)</i>	
Operational	These are defined in terms of the deliverables of specific policy actions. As such, they are typically option-specific . These should not, therefore, be reported in the same place in the IA report ¹³⁸ as the general and specific objectives but reported in the section referring to the preferred policy option and in relation to monitoring and evaluation.

While general, specific and operational objectives will generally be needed for a legislative initiative, only general and specific objectives will be needed for a communication setting out broad policy objectives. Whereas for implementing legislation, there will be no need to set out general objectives which will have been discussed in the context of the basic act.

2. S.M.A.R.T. OBJECTIVES

Objectives should be Specific, Measurable, Achievable, Relevant and Time-bound (i.e. 'S.M.A.R.T').

¹³⁷ See Tool #41 on *Monitoring arrangements and indicators*; and Tool #42 on *Legal provisions on monitoring and evaluation*.

¹³⁸ See Tool #12 on *The format of the IA report*.

What are S.M.A.R.T. objectives?	
Specific	Objectives should be precise and concrete enough not to be open to varying interpretations by different people.
Measurable	Objectives should define a desired future state in measurable terms, to allow verification of their achievement. Such objectives are either quantified or based on a combination of description and scoring scales.
Achievable	Policy aims should be set at a level which is ambitious but at the same time realistically achievable.
Relevant	The objectives should be directly linked to the problem and its root causes.
Time-Bound	Objectives should be related to a fixed date or precise time period to allow an evaluation of their achievement.

When objectives are multiple and interrelated, it is important to highlight the links between them, particularly any possible trade-offs. When problems are complex and have many underlying drivers, numerous objectives are often identified, be they general, specific or operational. In these cases, an "objectives tree" can be used to depict graphically the relations among different goals¹³⁹.

Example of a hierarchy of policy objectives

GENERAL	SPECIFIC	OPERATIONAL
Better protect the health and safety of users of Personal Protective Equipment (PPE)	Ensure high quality of products protecting against high risks including a high quality of their production process Ensure the reliability and high quality of conformity assessment activities carried out by notified bodies Ensure traceability of products	Remove inconsistencies in the list of products subject to the most stringent conformity assessment procedure Specify common criteria for the assessment, monitoring and control of Notified Bodies to be applied equally throughout the EU.
Create a level playing field for PPE economic operators	Ensure consistency of conformity assessment services carried out by notified bodies Improve market surveillance mechanisms and tools	Clarify the requirements for EC type-examination certificates Simplify and clarify the requirements for the technical file Require the EC Declaration of conformity to accompany every product
Simplify the European regulatory environment in the field of PPE	Ensure consistent application of the legislation Ensure the requirements are practicable	Clarify the scope of the Directive Simplify the applicable conformity assessment procedures Clarify the requirements set out in ANNEX II

Source: SWD(2014) 118 final

¹³⁹ See Tool #65 on *How to use visual aids and present quantitative information*.

TOOL #17. HOW TO IDENTIFY POLICY OPTIONS

Identifying alternative policy option is, in most cases, an iterative process. The aim is to consider as many realistic alternatives as possible and then narrow them down to the most relevant ones for further analysis.

1. THE 5 STEPS TO FOLLOW

The following five steps are suggested in order to identify a realistic set of options:

- (1) Construct a baseline from which the impacts of the policy options will be assessed;
- (2) Start by compiling a wide range of alternative policy options;
- (3) Identify the most viable options;
- (4) Double check the suitability of the retained policy options; and
- (5) Describe in reasonable detail the key aspects of the retained policy options to allow an in-depth analysis of the associated impacts.

I. The Baseline

- In most cases, the baseline is a "no policy change" scenario which includes all relevant EU-level and national policies and measures which are assumed to continue in force. In addition, Commission proposals but not yet adopted legislation should also be included. Where it is clear that a subsequent legislative procedure will deliver a substantially different outcome to the Commission's original proposal, this outcome should also be reflected in the baseline. Where two or more initiatives are presented together, each IA report should use the same baseline but should describe the likely consequences of the other initiative in terms of possible changes to the baseline; it may also be relevant to consider an alternative baseline/sensitivity case to demonstrate the impacts of the other initiative.
- Where the IA concerns regulatory initiatives based on a legal obligation for the Commission to act (e.g. through delegated or implementing acts), the baseline should be construed as a "no action" reference scenario which, in principle, should be discarded as a valid policy option.
- The baseline should include the ongoing impacts associated with the Union deciding not to take any further policy action although it is unlikely that Union action would resolve all such impacts.
- It will also be relevant to include expected socio-economic developments (aging, GDP growth, etc.) as well as important technological/societal developments such as the pervasive nature of the internet and social media which by themselves are bringing about large changes. The baseline should also be set for an appropriate time horizon. The length of the latter depends on the likely lifetime of any individual option and on the need to allow for impacts to be realised.
- A complicating factor is that the policy or legislation itself might envisage that it will come to an end on a given date ("sunset clause") and that a positive decision of the Commission and Legislator will be necessary to put in place a new policy regime. Examples include targets to be attained by a given year in areas such as energy efficiency or spending programmes which are linked to a particular multi-annual financial programme. In such cases it can be difficult to decide on the

appropriate baseline. Two options are possible:

- Explicitly include the "sunset clause" in the baseline if, for example, a comprehensive evaluation concludes that the policy is ineffective. Policy options would then include establishing a new action and the impacts would be measured against a no-policy baseline. This approach should however be avoided if there are clear political commitments to continue the policy in some form or another, or if a comprehensive evaluation concludes that the policy is effective.
- Include a continuation of the current policy approach in the baseline even if it formally comes to an end; where, for example, a comprehensive evaluation concludes that the policy is effective. Given that the College or Legislator could (theoretically) decide not to propose or enact legislation, this approach should usually be accompanied by a policy option which would explicitly repeal the current policy and would demonstrate the cost of the Union not acting ("the cost of non-Europe").
- The most appropriate approach will have to be decided on a case-by-case basis and take into account the degree of political commitment to a continuation of the current policy and the results of evaluations and fitness checks which may question the validity of the current approach. In either case, it is important to present transparently the "true" impacts of the various policy options.

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

Why?	To think outside the box and avoid regulatory bias.
	To show other parties that their preferred policy option has been considered (and explain why it might not be pursued).
How?	Ask yourself: what could affect the drivers of a problem? What could influence behaviours in a manner that would address the problem/help achieving the policy objectives? Answer with an open mind, trying to identify as many policy responses as possible. Then identify which policy instruments could be used to deliver these measures. Consider the widest range of instruments, from the less intrusive to the more interventionist and from the more classical tools to those suggested by the more recent developments in relevant academic fields, like behavioural economics and social psychology.
	Policy options should be closely linked to the drivers of the problems and the identified objectives: a clear logic should underpin the intervention under consideration. Policy options should also be AGILE and internet ready ¹⁴⁰ .
	Do not forget to ask for stakeholders' ideas and opinions.
	Make sure to consider those options that can count on considerable support

¹⁴⁰ See Chapter III of the better regulation Guidelines and the Tool #27 on *The digital economy and society & ICTs/systems*.

	among stakeholders, experts, policymakers, Member States and other EU institutions including options that can demonstrate the “cost of non-Europe” as the Commission has committed to do.
	However, do not exclude a priori options with little support or facing strong opposition by some groups.
What?	You should make sure that you always consider at least the following:
	<i>Alternative policy responses</i>
	Consider alternative types of policy responses to reach the objective as regards the content/design of the measure. For instance:
	Could the objectives be reached through alternative basic policy approaches? If there are clear arguments in favour of a particular general policy approach, are there different options for the more detailed parameters of the initiative?
	When EU policy already exists in an area and it is not producing the desired effects, consider the option of "doing less" – i.e. can it be streamlined, simplified or even repealed (where the Treaties do not lay down a specific obligation to act)?
	Whenever EU policy already exists, could the objective be reached by improving implementation and/or enforcement of existing legislation? Ways to facilitate better policymaking by Member States could also be considered.
	Where they exist, international standards (or regulatory solutions of similar ambition implemented by third countries) should be considered with a view to avoid unnecessary regulatory differences.
	Consider non-regulatory alternatives (such as self- or co-regulation ¹⁴¹), market-based solutions which should respect the best-practice principles developed by the Commission services ¹⁴² .
	When revising an existing intervention, you should always consider ways to achieve the existing objectives more simply and cheaply and to limit the administrative burdens of those affected by the policy. For example, consider whether the use of digital technologies could contribute to reducing administrative burdens (and where relevant consider reusing existing solutions for electronic identification, signature, delivery and invoicing, etc.).

III. Screen your options	
Why?	To focus the analysis on the viable options.
How?	Excluding options at this stage should be easy to justify. Reasons should be as clear, self-evident and incontrovertible as possible.

¹⁴¹ See the principles for better self- and co-regulation in the appendix to Tool #18 on *The choice of policy instruments*.

¹⁴² <http://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>.

	The key <u>criteria for screening</u> the viability of your options are:
	<i>Legal feasibility</i>
	Options should respect the principle of conferral. They should also respect any obligation arising from the EU Treaties (and relevant international agreements) and ensure respect of fundamental rights. Legal obligations incorporated in existing primary or secondary EU legislation may also rule out certain options.
	<i>Technical feasibility</i>
	Technological and technical constraints may not allow for the implementation, monitoring and/or enforcement of theoretical options.
	<i>Previous policy choices</i>
	Certain options may be ruled out by previous Commission policy choices or mandates by EU institutions.
	<i>Coherence with other EU policy objectives</i>
	Certain options may be ruled out early due to poor coherence with other general EU policy objectives.
	<i>Effectiveness and efficiency</i>
	It may already be possible to show that some options would incontrovertibly achieve a worse cost-benefit balance than some alternatives.
	<i>Proportionality</i>
	Some options may clearly restrict the scope for national decision-making over and above what is needed to achieve the objectives satisfactorily.
	<i>Political feasibility</i>
	Options that would clearly fail to garner the necessary political support for legislative adoption and/or implementation could also be discarded.
	<i>Relevance</i>
	When it can be shown that two options are not likely to differ materially in terms of their significant impacts or their distribution, only one should be retained.

IV. Check the suitability of the set of retained options	
Why?	To make sure the impact analysis will properly inform political decisions.
How?	The baseline scenario can never be discarded as it provides the basis for determining the impacts of the other options.
	All options should be realistic. Do not artificially select the baseline, a "pre-selected preferred" option and a "straw-man" option.
	If you are having difficulty identifying even two credible alternatives to the baseline, think harder or consider a different level of option aggregation (sub-options, alternative detailed parameters, implementation modes, etc. - see below). Alternatively, provide a strong justification for the fact that only the baseline and an alternative option are retained for in-depth analysis.
What?	You will often have two sets of options, one for the content of the policy and

	one for the delivery instruments (regulation, directive, etc.).
	You will also have to choose the level of aggregation of your policy options: broad alternative options, alternative packages of measures, individual sets of measures targeting specific issues to be bundled together at the end of the analysis or a mix of high-level options and sub-options. Different methodological choices are possible, each with its pros and cons. The best choice depends upon the specificities of the case at hand, notably the number of problems to address the extent of spill-overs from one measure to another, the nature of the problem, the logic of the intervention etc. In choosing the options, it is important to focus in on those elements being most critical for the Commission to decide on (i.e. those with significant impacts). More detailed analysis of choices at a micro level is useful during the technical preparations of a proposal and should be included in the IA report when significant impacts depend upon it. Otherwise, considering a different level of aggregation may be more appropriate for the main text of the IA report. The Commission has committed to explain the "cost of non-Europe" of its initiatives as part of the Interinstitutional Agreement on Better Law-Making. There is no clear or agreed definition of this term but it represents the opportunity cost of not acting at EU level. More practically, there will be initiatives where it is appropriate to include an option to repeal a given policy (such as existing policies or programmes which come to a clearly defined end and where the baseline assumes the continuation of the policy or programme). The impact of such an option gives a direct estimation of the costs associated with the Union not acting in a given area. In addition, where the Union acts for the first time in a given area, the benefits of EU action relative to the baseline also represent the cost of non-Europe.

V. Outline the retained options in greater depth	
Why?	To allow the identification of the impacts of alternative options. For transparency.
How?	Options should be sufficiently well developed to allow you to differentiate them on the basis of their performance in achieving the identified objectives. The retained options should thus not be described vaguely. It should be clear how they would be implemented, monitored and/or enforced, by whom and over what timeline and whether complementary actions might be necessary to ensure effective implementation (e.g. actions of a self or co-regulatory nature). Enough detail on their actual content should be provided. It is recommended to express the options in terms of the specific actions that will have to be undertaken by various stakeholders. This facilitates the analysis (and quantification) of impacts and provides insights on the key elements for political choice (e.g. level of benefits and costs, distributional impacts, impact on SMEs, citizens, EU competitiveness, sustainability, etc.). Similarly, remember that you will have to finalise the analysis of compliance with the subsidiarity principle as well as show the proportionality of any preferred option.

TOOL #18. THE CHOICE OF POLICY INSTRUMENTS

1. INTRODUCTION

A range of regulatory and non-regulatory instruments or combinations of instruments may be used to reach the objectives of the intervention. The merits of each alternative should be considered rigorously taking into account the following:

Action at Union level is governed by the **proportionality principle** which means that action should not go beyond what is necessary to achieve the objective. Proportionality is about matching the policy intervention to the size and nature of the identified problem and its EU (subsidiarity) dimension in particular¹⁴³;

The choice of instrument should take into account the experience obtained from the **evaluation of the existing policy framework** as an initiative is often not starting from scratch. For example, an evaluation may find that a voluntary approach has not been effective so this choice is likely to be rejected. In addition, coherence with other related policy instruments will have to be considered for example to exploit synergies (e.g. compliance monitoring by competent authorities) and to avoid undermining the effectiveness of existing instruments or raising compliance costs.

Policy instruments at the EU level can be placed into the following broad categories although there may be overlaps or combinations (such as obligations to accept mutual recognition of alternative rules and standards):

- (1) "Hard" legally binding rules;
- (2) "Soft" regulation;
- (3) Education and information;
- (4) Economic instruments.

2. "HARD" LEGALLY BINDING EU RULES

Binding legal rules are used to specify the behaviour required of organisations or individuals. It is appropriate to address activities with potentially serious risks of impacts for the economy, the environment or individuals and where legal certainty and enforcement backed by legal sanctions are necessary. It may also be the only available option if there is no scope for "softer" self-regulatory actions by business organisations or when such approaches have failed. Alternatively, binding acts may be used to establish essential requirements or framework which are supported by "soft" instruments such as technical standards.

When well designed, such hard rules provide clarity as to the behaviour which is expected, making it relatively straightforward to identify non-compliant behaviour. However, regulators will need to have the capacity, resources and sector specific

¹⁴³ See Tool #5 on *Legal basis, subsidiarity and proportionality*.

knowledge to make the legislation work effectively. In addition, the "one size fits all" approach of uniform standards may not capture the variation in compliance costs across economic operators, which introduces inefficiencies and raises overall costs of the policy. Such command and control approaches may be beneficial as a starting point, when regulators are faced with a significant problem yet have too little information to support a market-based instrument (or where the incentives for trading are limited) means the gains of a market-based instrument would be outweighed by the costs.

In the EU context, Article 288 TFEU establishes three types of binding acts:

Regulations are directly applicable in all Member States and binding in their entirety. Regulations are used most commonly where it is important to achieve a uniform implementation of a policy intervention such as in the internal market or the governance of mergers.

Directives are binding on the Member States to which they are addressed in respect of the result to be achieved but the specific form and methods are left to national authorities to decide. Directives should, as far as possible, be general in nature and cover the objectives, periods of validity and essential requirements, while technicalities and details should be left to the Member States to decide. A proper balance should be struck between general principles and detailed provisions in order to avoid excessive delegated acts to supplement the legislative act. Framework directives set out general principles, procedures, and requirements for legislation in different sectors. Subsequent 'daughter' directives are then adopted with specific rules for individual products, sectors etc.

Decisions are binding in their entirety on those to whom the Decision is addressed (e.g. individuals, companies or Member States).

Box 1. Examples

- The National Emissions Ceilings Directive¹⁴⁴ sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.
- The Working Time Directive¹⁴⁵ stipulates that too much overtime work is illegal. The directive sets out minimum rest periods and a maximum number of working hours, but it is up to each country to devise its own laws on how to implement this.
- The Machinery Directive¹⁴⁶ sets detailed health and safety rules for placing on the market and/or putting it into service including market surveillance of machinery. The Directive sets out only the essential health and safety requirements while more detailed specifications are given in voluntary harmonised European standards (i.e. "technical standards" see section 3.2) adopted on the basis of a request made by

¹⁴⁴ Directive 2010/75/EC

¹⁴⁵ Directive 2003/88/EC

¹⁴⁶ Directive 2006/42/EC

the Commission.

- The Biocides Regulation sets out the detailed rules concerning the making available on the market and the use of biocidal products¹⁴⁷;
- The Effort Sharing Decision¹⁴⁸ establishes each Member State's greenhouse gas emission reduction targets up to 2020 in sectors outside of the Emissions Trading System.

3. "SOFT" REGULATION

When the subsidiarity and proportionality analysis of possible ways to address a given problem demonstrate that traditional law instruments (regulations, directives, decisions) are not necessary, the Commission may resort to "soft", more flexible approaches instead. A range of policy instruments is available, including Recommendations, technical standards, "pure" voluntary bottom-up initiatives (self-regulation) to legislation-induced co-regulatory actions. In practice, it is often hard to define the exact nature of a given soft regulatory approach. Thus, the list of instruments below is only illustrative, with many hybrid solutions also possible.

3.1. Self-regulation and co-regulation

Self-regulation is where business or industry sectors formulate codes of conduct or operating constraints on their own initiative for which they are responsible for enforcing. However, pure self-regulation is uncommon and at the EU level it generally involves the Commission in instigating or facilitating the drawing up of the voluntary agreement.

Self-regulation by the relevant industry can in suitable cases deliver the policy objectives faster or in a more cost-effective manner compared to mandatory requirements. They also allow greater flexibility to adapt to technological change (e.g. in the ICT-related areas of activity) and market sensitivities. Voluntary agreements work when the interests of society and the industry grouping coincide; otherwise it is unlikely that industry will voluntarily take the necessary steps without external influence such as the Commission, or other parts of civil society such as NGOs. A challenge of such approaches is to ensure that the desired policy outcome is delivered in practice as the conventional enforcement mechanisms associated with regulation are not available.

Co-regulation is a mechanism whereby the Union Legislator entrusts the attainment of specific policy objectives set out in legislation or other policy documents to parties which are recognised in the field (such as economic operators, social partners, non-governmental organisations, standardisation bodies or associations). Recognition of such public-private arrangements may be done through cooperation agreements or in Union legislation. Under this "light" regulatory approach, the relevant policy initiatives establish the key deadlines and mechanisms for implementation, the methods of monitoring the application of the legislation and any sanctions. Co-regulation can combine the advantages of the binding nature of legislation with a flexible self-regulatory approach to implementation that draws on the experience of the parties concerned and

¹⁴⁷ Regulation (EC) No 528/2012

¹⁴⁸ Decision No 406/2009/EC

can foster innovation. Co-regulation can remove barriers to the single market, simplify rules and can be implemented flexibly and quickly. The New Legislative Framework type of legislation (see box 4) falls within this category.

Box 2. Examples of self & co-regulation

Reduction of CO₂ emissions from cars

The Commission previously recognised voluntary agreements with the European, Japanese and Korean car manufacturers to reduce the CO₂ emissions of their new vehicles, but which were subsequently replaced by regulation. These commitments were recognised by the Commission in form of several Recommendations. On 7 February 2007, the Commission adopted two parallel Communications: a Communication setting out the results of the review of the Community Strategy to reduce CO₂ emissions from passenger cars and light-commercial vehicles and a Communication on a Competitive Automotive Regulatory Framework for the 21st Century (CARS21). The Communications underlined that progress had been made towards the target of 140g CO₂/km by 2008/2009, but that the Community objective of 120 g CO₂/km would not be met by 2012 in the absence of additional measures. The Communications proposed an integrated approach with a view to reaching the Community target of 120g CO₂/km by 2012 and announced that the Commission would propose a legislative framework to achieve the Community objective by focusing on mandatory reductions of emissions of CO₂ to reach an objective of 130g CO₂/km for the average new car fleet by means of improvements in vehicle motor technology.

Better internet for kids: industry organising itself answering a call from the Commission

'The CEO coalition to make a better internet for kids'¹⁴⁹, launched in December 2011 in response to voiced requests from the Commission, is a cooperative voluntary intervention designed to respond to emerging challenges arising from the diverse ways in which young Europeans go online. Companies-signatories to the Coalition committed to take positive action to make the internet a safer place for kids by means of establishing a five-step action plan.

The civil society and researchers have also been involved in the negotiations of these agreements. They provided evidence of the (then) current state of play for child safety online, best practices, voiced opinions. The main civil society organisations involved were those active in the area of child safety. The Commission functioned as a "broker" of trust, providing logistics and making sure all interested parties were invited in all negotiations, as well as providing publicity to the initiative.

One year after the launch of the Coalition, the signatories have made statements on how they implemented the action plan and proposed recommendations for improvement. At this stage the Commission has not appointed any independent expert to monitor the implementation although DG CNECT continues to follow the initiative but without concrete milestones/actions.

The success of self- and co-regulation depends in essence on several key factors which include: representativeness, transparency, legal compliance and effective implementation

¹⁴⁹ <https://ec.europa.eu/digital-single-market/en/self-regulation-and-stakeholders-better-internet-kids>

and monitoring.¹⁵⁰ The Commission services have prepared a set of best practice principles which should be reflected in all self and co-regulation initiatives¹⁵¹ (see attached appendix). These are divided into two phases: the inception phase and the implementation phase. In the inception phase, every self and co-regulation initiative should be open to all interested parties sufficiently representing the sector/area at stake, that in good faith are willing to accomplish clearly defined objectives in compliance with the legal framework (EU and/or national). In the implementation phase, each self and co-regulation initiative should be transparent as to the means of financing, be open to iterative improvements, and have built-in monitoring arrangements and evaluation mechanisms allowing for fair dispute resolution and sanctions.

The self and co-regulation initiatives cannot a priori be excluded from any policy area. However, based on the information available in the monitoring database run by the EESC¹⁵², they are present in areas covered by 15 DGs of the Commission. The bulk of them (80%) remains within the remit of six DGs, i.e. GROW, SANTE, EMPL, CNECT, FISMA and JUST.

Box 3. Experience of voluntary agreements under the Ecodesign Directive

- Directive 2009/125/EC establishes a framework for the setting of ecodesign requirements for energy-related products. Ecodesign aims at reducing the environmental impact of products, including the energy consumption throughout their entire life cycle. Mandatory and voluntary approaches within the same instrument.
- Implementing measures impose legally binding design criteria or recognise voluntary agreements. Two voluntary agreements have been implemented regarding the energy consumption of Complex Set Top Boxes within the European Union; and the environmental performance of imaging equipment on the European Market.
- Self-regulation appears to work best when a broad cross section of the market sector can be included which also lessens the risk of free-riders;
- Transparency is important to monitor performance of the agreement. Reliable and objective information should be available from independent entities.
- A credible system to ensure compliance with commitments is vital and should involve a body outside of the direct control of the parties to the agreement.
- Administrative and other costs of governing a voluntary agreement should be assessed during the IA process so that a fair comparison is made to alternative policy approaches (such costs include independent compliance monitoring, meetings with parties to the agreement, the internal resources in the Commission to manage/update the agreement, etc.)

¹⁵⁰ Based on EESC SMO report "European Self- and Co-Regulation" (http://www.eesc.europa.eu/resources/docs/auto_coregulation_en--2.pdf), July 2013 and re-affirmed in the own initiative opinion adopted on April 22 <http://www.eesc.europa.eu/?i=portal.en.int-opinions.32859>.

¹⁵¹ <http://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>

¹⁵² <http://www.eesc.europa.eu/?i=portal.en.smo-database>

3.2. Technical standards

Standards are private and voluntary documents developed by recognised standardisation bodies that set out specifications and other technical information with regard to various kinds of products, materials, services and processes. They provide a common understanding among businesses, other stakeholders and public authorities on the commonly recognised state of the art and they are frequently reviewed and revised. They are developed internationally by the international standardisation bodies and in Europe by the European standardisation organisations (ESOs, see Box 4). European standardisation is a key instrument for consolidating the Single Market, supporting the competitiveness of European industry in a global market, harmonising conflicting national standards and facilitating cross-border trade in a less intrusive manner than technical regulations. The Commission has an active standardisation policy¹⁵³ and co-operation agreements¹⁵⁴ with the ESOs.

Regulation (EU) No 1025/2012¹⁵⁵ sets the legal framework for the Union to use voluntary European standardisation as a recognised policy tool in support of Union legislation and policies for the products and for the services. It sets procedures for the Commission to request the ESOs to develop voluntary European standards or European standardisation deliverables which e.g. can be used to specify how to comply with generally worded legal requirements. Such standards can avoid regulation (like “harmonised standards”) or they permit legislation which concentrates only on the essential requirements and where technical details can be left to voluntary standards.

The Regulation sets also requirements for ESOs about the transparency of their standardisation work programmes and standards, requirements on stakeholder participation and allows the Commission to finance the ESOs when they execute specific tasks on the basis of Commission requests. The Regulation aims to ensure that the European standardisation process is sufficiently inclusive allowing all stakeholders, including SMEs, consumers, workers’ and environmental organisation to contribute (see Box 4).

Box 4. European standards: A key instrument for the single market in goods and services

- A European standard is a standard that has been adopted by one of the three recognised¹⁵⁶ European standardisation organisations (ESOs): the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) or the European Telecommunications Standards Institute (ETSI).
- The ESOs are private organisations and they bring together industry, other

¹⁵³ http://ec.europa.eu/growth/single-market/european-standards/policy/index_en.htm

¹⁵⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52003XC0416%2803%29>

¹⁵⁵ OJ L 316, 14.11.2012, p. 12–33

¹⁵⁶ Annex I of Regulation (EU) No 1025/2012 on European standardisation

stakeholders and the national standardisation bodies of EU/EEA and of some neighbouring countries. Once a European standard is developed and agreed, the National standardisation bodies, who are members of the ESOs, should transpose it as a national standard and they must withdraw all conflicting national standards. Moreover, more and more European standards are also adopted as identical national standards outside EU/EEA around the world. The ESOs have also close co-operation with international standardisation bodies and they transpose ISO/IEC standards as equivalent European standards.

- The ESOs develop European standards and other deliverables mainly as a response to specific needs that have been identified by businesses and other users of standards. Since late 1980s the Commission has issued standardisation requests to the ESOs when specific voluntary standards are beneficial to support objectives of the Union.
- Around 20% of the European standards or other deliverables published by the ESOs have been developed in response to specific standardisation requests (“mandates”) issued by the Commission. Most of these standards are known as 'harmonised standards'¹⁵⁷ which support application of Union’s harmonisation legislation for products (**New Legislative Framework**¹⁵⁸). In such cases, a standard may provide 'presumption of conformity' with the essential requirements of the relevant legislation.
- DG GROW manages the Commission's relationship with the ESOs and provides tools, databases and guidance on how to use voluntary European standards to support Union legislation and policies. It also co-ordinates the preparation of standardisation requests¹⁵⁹ to the ESOs (see SWD(2015) 205)¹⁶⁰.

Regulatory use of private technical standards, (i.e. a reference to technical standards in Union legislation) should be limited, as far as possible, to European standards adopted by the ESOs and requested by the Commission using its standardisation requests. This is because of the public-private partnership established between the Union and the ESOs and the recognition of ESOs by Regulation (EU) No 1025/2012. In addition, referenced European standards may be established on the basis of Commission requests to the ESOs; Regulation (EU) No 1025/2012 sets high inclusiveness and transparency requirements for the ESOs and all European standards are available as national standards in all Member States.

There are two principal referencing techniques:

- *Indirect referencing* to technical standards (preferred referencing technique), and
- *Direct referencing* to technical standards.

Indirect referencing is where Union legislation makes a collective reference to unspecified harmonised or other European standards adopted on the basis of a

¹⁵⁷ http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm

¹⁵⁸ http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

¹⁵⁹ http://ec.europa.eu/growth/single-market/european-standards/requests/index_en.htm

¹⁶⁰ http://ec.europa.eu/growth/single-market/european-standards/vademecum/index_en.htm

Commission request and where the Commission subsequently publishes and updates the exact references of such standards in the *Official Journal* (C series) in line with Article 10(5)-(6) of Regulation (EU) No 1025/2012. In this case, the Commission, in its standardisation request, defines the overall scope for the requested standards and sets generic requirements as to their content. After the standardisation work, the Commission assesses whether the requirements set in its request were fulfilled before publishing the references of the standards in the *Official Journal*. In addition, a Member State and the European Parliament may challenge the standard, in line with Article 11(1) of the Regulation (EU) No 1025/2012, following publication of the references in the *Official Journal*.

Where indirectly referenced technical standards, even when voluntary, confer a legal effect, such technical standards fall under Article 267 of TFEU meaning that the Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning the validity and interpretation of such standards.¹⁶¹

Direct referencing (to standards in Union legislation) is a technique where the relevant Union legislation itself contains an exact reference to a standard or parts thereof as set by the Legislator. If direct referencing to technical standards is used, the relevant Union act should also foresee a procedure for updating these references e.g. by using Delegated Acts. Union legislation should be drafted carefully taking account of the different nature of binding Union acts and the voluntary nature of technical standards. Voluntary technical standards may, however, confer a legal effect like harmonised standards in Union harmonisation legislation for products.

Independently of the referencing techniques used, all references to technical standards which confer legal effect should be to a specific dated edition of the technical standard (dated references). With undated references, the Legislator would effectively lose control over the amendment of Union acts.

Box 5. Regulatory use of private technical standards in Union legislation

Issues to be considered when indirectly referencing voluntary harmonised European standards within the meaning of Article 2(1) c) and Article 10(6) of Regulation (EU) No 1025/2012:

- Voluntary standards cannot override national legislation.
- Essential or other legal requirements given in the Union act itself should be suitable to be supported by technical specifications given in voluntary and consensus based harmonised European standards elaborated by private European standardisation organisations.
- The domain where technical specifications for products or for services are needed should be mature enough to allow elaboration of technical specifications having a status of voluntary standards.
- Considering the voluntary nature of harmonised European standards the essential or other legal requirements should be sufficiently comprehensive, self-standing and understandable to be applied directly by economic operators even without

¹⁶¹ Case C-613/14

harmonised European standards. If this is not the case, and harmonised standards are still selected as a policy option, it should be considered whether alternative technical specifications should be available in the absence of any harmonised standards.

- Whether ESOs, in co-operation with relevant stakeholders, will have resources and/or willingness to accept the relevant future standardisation request (an Implementing Act) in order to elaborate the requested harmonised European standards.
- Overall time needed to draft and adopt the Commission's standardisation request and to elaborate a minimum set of harmonised European standards by the ESOs considering the date by which the proposed Union act should be fully enforceable.

3.3. Recommendations

Recommendation is a legal instrument that encourages those to whom it is addressed to act in a particular way without being binding on them. A Recommendation enables the Commission (or the Council) to establish non-binding rules for the Member States or, in certain cases, Union citizens¹⁶². A Recommendation can be used when there is not sufficient evidence that would justify a need of a binding legislative instrument, or in policy areas where the EU has supporting competence, complementing the action of Member States, and cannot by definition be prescriptive. Given the non-binding character of a Recommendation, which per se cannot guarantee that action will be taken by all Member States, detailed monitoring and evaluation arrangements should be foreseen and presented in the IA.

Box 6. Example of Recommendations:

- **Commission Recommendation** on access to a basic payment account – this IA assesses several instruments¹⁶³
- **Council Recommendation** on the validation of non-formal and informal learning¹⁶⁴

3.4. Open Method of Co-ordination

The open method of coordination (OMC), created as part of employment policy and the Luxembourg process, has been defined as an instrument of the Lisbon strategy (2000).

The OMC provides a framework for cooperation between the Member States, whose national policies can thus be directed towards certain common objectives. Under this intergovernmental method, the Member States are evaluated by one another (peer pressure), with the Commission's role being limited to surveillance. The European Parliament and the Court of Justice play virtually no part in the OMC process.

¹⁶² E.g. [Recommendation 2002/236/EC](#)

¹⁶³ http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2011/sec_2011_0906_en.pdf

¹⁶⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0252:FIN:EN:PDF>

The open method of coordination takes place in areas where Union action cannot supersede Member State competence such as employment, social protection, social inclusion, education, youth and training.

It is based principally on:

- jointly identifying and defining objectives to be achieved (adopted by the Council);
- jointly established measuring instruments (statistics, indicators, guidelines);
- benchmarking, i.e. comparison of the Member States' performance and exchange of best practices (monitored by the Commission).

Depending on the areas concerned, the OMC involves so-called "soft law" measures which are binding on the Member States in varying degrees but which never take the form of directives, regulations or decisions. Thus, in the context of the Lisbon strategy, the OMC requires the Member States to draw up national reform plans and to forward them to the Commission. However, youth policy does not entail the setting of targets, and it is up to the Member States to decide on objectives without the need for any European level coordination of national action plans.

4. EDUCATION & INFORMATION

EU objectives may be reached by ensuring that citizens, consumers and producers are better informed. This type of policy instrument includes information and publicity campaigns, training, guidelines, disclosure requirements, and/or the introduction of standardised testing or rating systems.

The instrument can be cost-effective and it is easily adaptable to changing situations. It is generally most useful in those areas where:

- The lack or costs of collecting information is shown to be a key driver of the problem;
- The limited effectiveness of an existing piece of legislation is due to lacking information/clarity on how to comply with it (or enforce it).

A good example of an effective consumer information scheme is the energy labelling of energy using products¹⁶⁵.

5. ECONOMIC INSTRUMENTS

Market-based instruments (MBIs) include:

- taxes,
- charges,

¹⁶⁵ Directive 2010/30/EC; http://ec.europa.eu/energy/efficiency/labelling/labelling_en.htm

- fees;
- fines;
- penalties;
- liability and compensation schemes;
- subsidies and incentives;
- deposit-refund systems;
- labelling schemes; and
- tradable permit schemes.

The use of market based instruments most likely involves legislation, in form of hard regulation (a directive or a regulation). There are numerous definitions for market-based instruments based on different approaches and applications. The OECD defines economic instruments as tools that “affect estimates of the costs and benefits of alternative actions open to economic agents”¹⁶⁶. Or to put it more simply, if a tool affects the cost or price in the market, then it is a market-based economic instrument. This definition focuses on the economic signals and incentives. If it changes the cost or price of a good, service, activity, input or output then it is a market-based instrument.

MBIs – due to their economic nature – are most commonly used in the environmental policy area where they fit very well as a tool to cater for market failures/externalities. For an incentive effect, MBIs rely on individuals and/or firms having the ability to respond to the price signal. Market-based instruments can be applied to different components – e.g. on the inputs and hence change the production costs, or on the outputs and hence change the price. In some situations a change in cost will result in a change of the price (if the cost changes can be passed on to the consumer) and in other cases there will be less pass-through. The change in behaviour may not be immediate after prices change as it depends on elasticity of demand, which in the short term is in fact usually inelastic as there might not be adequate alternatives or substitutes or the ability to change consumption patterns.

Tradable offsets and permits allow producers to negotiate with each other and agents to ensure overall compliance, without this being necessarily enforced on all producers at the same level. The main advantage of tradable offsets and permits is their flexibility and cost-effectiveness. They allow potentially major reductions in compliance costs, since these can be redistributed to firms facing the lowest adjustment costs. Moreover, they may be easier to police since they offer incentives to firms to comply. Their main disadvantage is their potential complexity related to issues such as the need to ensure a satisfactory initial distribution of permits. The most obvious example of such an instrument is the EU's Emissions Trading System¹⁶⁷.

¹⁶⁶ Organisation for Economic Co-operation and Development (OECD). 1994. *Managing the environment: the role of economic instruments*. OECD, Paris.

¹⁶⁷ Directive 2003/87/EC, 13 October 2003, OJ L 275, 25.10.2003, p.32

Taxes, charges and fees are potentially useful policy instrument to influence **private** behaviour towards public objectives. They also raise revenues. As other market-based instruments, they provide flexibility and cost-effectiveness and can be used to ensure that users pay the social price of their consumption. At the EU level, the ability to co-ordinate taxes is limited due to the need for a unanimous decision by the Council. When tax instruments are used to attain specific policy objectives, it must be ensured that they are in compliance with EC rules on state aid. The most recent example of such an approach is the proposal to overhaul the outdated rules on the taxation of energy products in the European Union and take into account both their CO₂ emissions and energy content¹⁶⁸.

6. COMBINATIONS OF INSTRUMENTS AND BEHAVIOURAL INSIGHTS

Some combinations of instruments are naturally complementary. New legislation or Recommendations can be informed by behavioural insights. Relevant examples are the ban of pre-checked boxes in the Consumer Rights Directive or the Recommendations on Online Gambling which put forward behavioural solutions to tackle irresponsible gambling. The use of economic incentives (e.g., taxation, tax reductions) and information disclosure can also be informed by behavioural evidence, notably when issues related to social norms and information overload are shown to be relevant.

Information disclosure is unlikely to be wholly effective on its own but they will nonetheless be important to complement other instruments. Monitoring is also likely to be needed to ensure the success and credibility of voluntary initiatives undertaken by industry. Economic instruments in the form of tax reductions coupled to binding rules can incentivise more effectively the desired behaviour (such as an investment in low-carbon technologies). Another example is the phase-out of leaded petrol in the European Union in 2000 which was accompanied in most Member States by a reduction in the duty level of unleaded petrol.

Some combinations can be counterproductive and should be avoided. More generally, where combinations of policy instruments are envisaged, they should aim to be mutually supportive and carefully calibrated to achieve policy goals in the most effective and efficient way.

More effective policy instruments could emerge if insights provided by behavioural sciences and empirical studies are available. Assumptions about the behaviour of individuals and businesses based on classical rational choice theory are not necessarily corroborated by observed evidence. Behavioural sciences may help bridge the gap between conventional assumptions that are adopted in most models and the observed biases in such a way to obtain a realistic representation of the problem matter and of its determinants. The IA tool on problem drivers provides several examples where the design or the intensity of the instrument is affected by behavioural insights¹⁶⁹.

¹⁶⁸ http://ec.europa.eu/taxation_customs/taxation/excise_duties/energy_products/legislation/index_en.htm

¹⁶⁹ See Tool #14 on *How to analyse problems*

Appendix

Principles for Better Self- and Co-Regulation

1. Conception

1.1. Participants

Except in cases where the competitive nature of an initiative makes this inappropriate, participants should represent as many as possible of potential useful actors in the field concerned, notably those having capacity to contribute to success. In case some organisations, notably SMEs, do not have the capacity to commit directly to the action, they may be represented by a relevant umbrella organisation.

Where, at launch, not all possible parties have come on board, later engagement should remain possible, and the conditions for it should be clearly stated. Participants are each fully accountable and respected for their specific contributions.

1.2. Openness

Envisaged actions should be prepared openly.

The preparatory phase should include the involvement of any interested parties: public authorities, enterprises, legislators, regulators and civil society. Public authorities should be ready to convene, moderate or observe, as most helps the process and if deemed appropriate.

The initial blueprint, or "concept agreement", for any action should be multi-stakeholder and developed in a concerted and collaborative way involving open exchange between interested parties. Where the field is too large to be effectively managed, the leaders of the action may select those mainly having capacity to contribute to success. Others wishing to support the initiative should be able to join deliberations with interested parties on terms that contribute to the process of decision-making.

The preservation of a similar degree of open governance in the operation of any resulting agreement is equally desirable. The initiative and its constitutive texts must therefore be widely publicised and easily accessible.

1.3. Good faith

Participants of different sizes and types have different contributing capacities. The different capabilities of participants, including the situation of SMEs, and smaller non-profit organisations, should be taken into account when designing the envisaged action.

Participants should bring to the preparatory process all information available to them that can contribute to a full analysis of the situation. Similarly, in launching an action, participants should ensure that their activities outside the action's scope are coherent with the aim of the action.

Both in developing and in executing self- and co-regulatory actions, participants are expected to commit real effort to success. They retain the possibility to withdraw, should the action fail to reach the agreed objectives.

1.4. Objectives

The objectives of the action should be set out clearly and unambiguously. They should start from well-defined baselines, both for the issue on which change is being pursued and for the commitments that participants have made. They should include targets and indicators allowing an evaluation of the impact of the action undertaken. **EN 2 EN**

1.5. Legal Compliance

Initiatives should be designed in compliance with applicable law and fundamental rights as enshrined in EU and national law. Participants are encouraged to have recourse to existing guidance¹ provided by public authorities. In case of doubts, an assessment clarifying, inter alia, impact and complementarity with the *acquis* and with the Charter of Fundamental Rights should be conducted.

2. Implementation

2.1. Iterative improvements

Successful actions will usually aim for a prompt start, with accountability and an iterative process of "learning by doing". A sustained interaction between all participants is required. Unless the action covers a short time-span, annual progress checks should be made, against the chosen objectives and indicators, as well as any available broader background data.

2.2. Monitoring

Monitoring must be conducted in a way that is sufficiently open and autonomous to command respect from all interested parties. Each participant shall monitor its performance against the agreed targets and indicators. Monitoring results are shared by each actor for discussion with the participants as a whole, and are made public. A monitoring framework or template will be commonly agreed. The results of the monitoring will be aggregated where possible. This should be done in a way that is transparent and objective.

2.3. Evaluation

Evaluation will allow participants to assess whether the action may be concluded, improved or replaced. The participants regularly and collectively assess performance not only against output commitments, but also as to impact. This should identify any shortfall in expected collective impact, any scope to improve the efficiency or effectiveness of the action, and any other desirable improvements.

2.4. Resolving disagreements

Disagreements inevitably arise involving either participants or others. As part of the iterative process of improvement, such disputes should receive timely attention, with a view to resolving them. These procedures may be confidential.

In addition, complaints by non-participants should be submitted to a panel of independent assessors which consist of majority of non-participants. The outcome of their work is made public. Non-compliance should be subject to a graduated scale of sanctions, with exclusion included and without prejudice to any consequences of non-compliance under the terms of the Unfair Commercial Practices Directive.

2.5. Financing

Participants to the action will provide the means necessary to fulfil the commitments. Public funders or others may in addition support the participation of civil society organisations lacking fully adequate means themselves to play their appropriate role. Such financial support should be made publicly known.

Chapter 3

How to identify impacts in impact assessments, evaluations and fitness checks

TOOL #19. IDENTIFICATION/SCREENING OF IMPACTS

The identification ("screening") and assessment of the most significant impacts is a core task of every impact assessment. However, once an initiative has been adopted and is applied it is important to monitor and ultimately evaluate to see whether the impacts originally foreseen by the IA actually materialise and to what extent. This section looks at the initial identification of impacts from the IA perspective, but the typology of impacts will also be important for evaluations and fitness checks.

1. DIRECT AND INDIRECT BEHAVIOURAL CHANGES AND POLICY GOALS

A policy option should aim to address the identified problem by causing direct and indirect changes to the behaviour of those influencing it (i.e. the problem drivers). These changes are also likely to have a bearing on the attainment of other policy goals. **The first step of impact analysis is the identification of this chain of impacts.**

A. Start by considering direct behavioural changes	
Why?	As a direct result of an option, someone somewhere will be incentivised to do something differently than would have been the case without the policy intervention.
Who?	Those directly affected by an initiative. In the case of a legislative proposal, these include the addressees of any regulatory obligation, the public authorities responsible for implementation and enforcement and those who are expected to be the final beneficiaries of the proposal.
	It is suggested to refer to the following categories of potentially affected groups for your analysis: Citizens – Whenever changes are widespread and do not affect any particular subgroup. Consumers – Whenever users of a particular product/service are affected. Workers – Whenever employees in general or in a specific industry are affected. Enterprises – Businesses in general or in a specific sector. It is also useful to distinguish enterprises according to their size (micro, small, medium and large) whenever they are to be subjected to different regulatory requirements (i.e. exemptions and special regimes) or are likely to be affected differently by the same policy measure. Public authorities – Distinguish between EU, national and sub-national levels as appropriate. Third countries – Whenever they are directly affected. Relevant subgroups of countries (main trading partners, developing countries, etc.) and, within countries, entities (businesses, citizens etc.) should be used.
	The above list is indicative and different groupings should be used whenever relevant given the specific nature of the initiative and its direct implications for specific groups (for instance, <i>regions, innovators, researchers, students, youth, elderly, genders, immigrants, people suffering from discrimination or physical disadvantages</i> , etc.).

What?	To identify direct impacts, ask whether the option under consideration would imply new regulatory obligations? If so, what actions would the targeted parties (businesses, citizens, public authorities etc.) have to take to comply with such obligations? How would they need to change their behaviour?
	Would the option exempt certain actors from the regulatory obligations (e.g. micro enterprises) or cover specific regimes (e.g. for SMEs)? What impact would this have?
	What additional actions would need to be taken to implement, monitor and enforce a new legislative requirement?
	Is any other action expected to be taken as a direct result of the option under consideration?
Examples	Removal from the market of certain (dangerous) products; Requiring pollution abatement equipment to be fitted to industrial installations or vehicles; providing consumers with additional information to influence their purchasing behaviour; being able to pay less for EU-level patenting because of reduced translation requirements etc.

B. Consider indirect behavioural changes

Why?	Direct changes will often prompt indirect (or second-order) changes and so on. These can be as important as the primary effects and may provide an important link in the chain of actions leading to the solution of the problem.
Who?	Indirect behavioural changes may regard both those directly affected as well as others. The same grouping list as above can be used for the analysis (but a different set of groups may be relevant for second-order impacts).
What?	Consider those second round effects that are both a direct consequence of the primary changes or further removed (typically the result of changes in the price and/or quality/availability of the goods and services produced in the regulated sector).
Examples	Thanks to a new regulatory measure, EU companies can obtain EU patents at a reduced cost (first round). Thanks to this, the profitability of research and development in the EU is increased. All else equal, this increases incentives for R&D spending (second round).
	Thanks to a new labelling requirement, potential consumers of a given electric good can compare data on energy efficiency more easily (first round). As a result, they increase consumption of more energy efficient products (second round). At the same time, companies' costs increase due to the need to respect the new labelling requirement (first round). Given the existing market structure, these increased compliance costs are transferred on the price of the good. Demand for the good decreases (second round). The net effect needs to be determined.

C. Consider ultimate impacts on relevant public policy goals

Why?	All of the changes identified will eventually affect the state of the world relative to the "no policy change" or baseline scenario.

What?	The analysis should first identify what all these changes imply for the attainment of the specific and general objectives of the initiative in question.
	Secondly, the analysis should look at how other public policy objectives may be (positively or negatively) impacted by the option under consideration.
	The set of potentially relevant public policy objectives is defined by the existing EU/Commission policy commitments, the Commission's political priorities and, ultimately, the EU Treaty. They include goals related to the economic, social and environmental fields and to fundamental rights. They can all be considered intermediate goals to the ultimate goal of maximising societal welfare.
	Specifically relevant objectives will vary from initiative to initiative and from option to option.
	An indicative table is provided in the tables below. Specific IA tools or indicative lists of issues are provided for most of them. You should refer to them whenever relevant.

At the end of this process, you should have mapped out all potentially relevant impacts according to affected parties and areas of relevance. The next step is to identify which of these impacts are likely to be significant and thus in need of a more focussed analysis.

In the IA process, a stepwise approach is followed:

- (1) Identify the impacts of the selected policy options;
- (2) Single out those impacts which are likely to be significant; and
- (3) Assess the latter quantitatively wherever possible otherwise qualitatively.

2. STEP 1: IDENTIFICATION OF POTENTIAL IMPACTS

The table below summarises the key impacts which should be screened objectively in order to identify all potentially important impacts – considering both positive/negative, direct/indirect, intended/unintended as well as short/long-term effects. A (well-justified) choice should then be made on the most significant impacts to be retained for more detailed analysis. More detailed about the individual impacts¹⁷⁰ follows at the end of this section.

¹⁷⁰ The obligation to screen these impacts is the consequence of the Treaty on the Functioning of the European Union (Articles 8-14).

Overview of key impacts to be screened ¹⁷¹		
Economic	Social	Environmental
Macroeconomic environment	Employment	The climate
Competitiveness, trade and investment flows	Working conditions	Efficient use of resources (renewable & non-renewable)
Operation/conduct of SMEs	Income distribution, social protection and social inclusion (of particular groups)	Quality of natural resources/fighting pollution (water, soil, air etc.)
Regulatory burdens on business	Public health & safety and health systems	Biodiversity, including flora, fauna, ecosystems and the services they provide and landscapes
Increased innovation and research	Job standards and quality	Reducing and managing waste
Technological development / Digital economy	Education and training, education and training systems	Minimising environmental risks
Third countries and international relations	Crime, terrorism and security	Protecting animal welfare
Functioning of the internal market and competition	Preserving the cultural heritage / multi-lingualism	International environmental impacts
Energy independence	Governance and good administration	
Deeper and fairer economic and monetary union		
Consumers and households		
Property rights		
Public authorities (and budgets)		
Economic and social cohesion (specific regions and sectors)		
Impacts in developing countries		
Sustainable development		
Fundamental Rights • Dignity • Freedoms • Gender equality, equality of treatment and opportunities, non-discrimination, rights of persons with disabilities. • Solidarity • Citizens' Rights • Justice		

3. STEP 2: SELECT THE SIGNIFICANT IMPACTS

Not all impacts for all possible stakeholders need to be examined. You should select the most relevant ones on the basis of the principle of proportionate analysis taking into account the following factors.

¹⁷¹ A helpful description of the main impacts can be found at <http://www.liaise-kit.eu/impact-area/impact-areas>

<i>The relevance of the impact within the intervention logic</i>
All key parameters of an option that will directly contribute to the achievement of the policy objectives should be retained for further analysis as their evaluation is a necessary condition for assessing the effectiveness and efficiency of an option.
In the case of legislative proposals, this implies <u>always</u> retaining for further analysis the changes required to comply with, and to implement and enforce, the proposed legal provisions.
<i>The absolute magnitude of the expected impacts</i>
The analysis should also focus on those impacts with the greatest magnitude.
<i>The relative size of expected impacts for specific stakeholders</i>
While some impacts may be small in absolute terms, they may be particularly significant for some specific party due to: • The relative size of the latter - for instance, micro and small enterprises. • The concentrated nature of the impacts - on specific regions, industry, and stakeholder groups, etc. • The cumulative impact that new obligations may have on any actor which is already subject to significant direct regulatory compliance and/or implementing and enforcement obligations.
<i>The importance of impacts for Commission horizontal objectives and policies</i>
When the analysis of impacts shows that there are potentially significant trade-offs between the objectives of the initiative (and its effects) and other politically important objectives, the relevant impacts should be analysed in depth.

The expected significance of impacts should be assessed in terms of changes relative to the baseline. 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.

At the end of this process, you should have selected those significant impacts that need to be further analysed and have a good idea of their sign (positive or negative) and of whom they would benefit or burden. The choice of impacts to be retained for deeper assessment should be clearly justified.

4. STEP 3: ASSESS THE SIGNIFICANT IMPACTS

Significant impacts should be assessed qualitatively and, whenever possible, quantitatively.

The key principles to be followed in analysing them are detailed in the main Guidelines covering impact assessment.

There is no single best method which would apply to all possible Commission initiatives. There is, however, an obligation to make the most sensible methodological choice given the specificities of the case at hand, the availability of data and the requirement to carry out a proportionate analysis.

For methodological guidance:

Seek the advice of your DG (or the Secretariat-General) impact assessment support function as well as that of the specific help desks set up in various DGs for specific types of impacts.

Refer to the various tools on how to assess impacts,¹⁷² costs and benefits¹⁷³ and to the other tools of relevance for the initiative in question.

The tables below can be consulted for further details on each key impact category.

Economic impacts	Key impacts
Operating costs and conduct of business	• Will it impose additional adjustment, compliance or transaction costs on businesses? • How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? • Will it lead to new or the closing down of businesses? • Are some products or businesses treated differently from others in a comparable situation? • How are individual Member States affected?
Administrative burdens on businesses	• Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)?
Trade and investment flows	• How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? • How will investment flows be affected and the trade in services? • Will the option give rise to trade, customs or other non-trade barriers? • Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered?
Competitiveness (sectoral) of business	• What impact does the option have on the cost of doing business which includes the costs of intermediate inputs (e.g. energy) and production related factors such as labour and capital? • What impact does the option have on a business' capacity to innovate i.e. its ability to produce more/higher quality products and services that meet customers' expectations? • What impact does the policy option have on a business' market share and comparative advantages in an international context (e.g. imports, exports, investment flows, trade barriers, regulatory convergence, etc.)?
Position of SMEs	• What is the impact of identified additional costs and burdens on the operation and

¹⁷² Chapter 3 of the Toolbox

¹⁷³ See Chapter 8 of the Toolbox.

Economic impacts	Key impacts
	competitiveness of SMEs and micro SMEs in particular?
Functioning of the internal market and competition	• What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc.?
Innovation and research	• Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production methods, technologies and products? • Does it affect the protection and enforcement of intellectual property rights (patents, trademarks, copyright, other know-how rights)? • Does it promote or limit academic or industrial research? • Does it promote greater productivity/resource efficiency?
Public authorities	• Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? • Does it bring additional governmental administrative burden? • Does the option require the creation of new or restructuring of existing public authorities?
Consumers and households	• Does the option impact consumer's ability to benefit from the internal market or to access goods and services from outside the EU? • Does the option affect the prices, quality, availability or choice of consumer goods and services? • Does the option affect consumer information, knowledge, trust or protection? • Does the option impact the safety or sustainability of consumer goods and services? • Does the option impact vulnerable consumers?
Specific regions or sectors	• Does the option have significant effects on certain sectors? • Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? • Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?
Third countries and international relations	• Is the option compliant with legal commitments such as WTO Agreements and Free Trade Agreements, Economic Partnership Agreements, investment protection agreements and other preferential trade arrangements? • Does it affect EU foreign policy and EU/EC development policy? Does it comply with the obligation of Policy Coherence for Development? • What are the impacts on third countries with which the EU has preferential trade arrangements? Does it affect the interest of the ACP group of states party to the Cotonou Partnership Agreement? • Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries?
Macroeconomic environment	• Does it have overall consequences of the option for economic growth and employment? • How does the option contribute to improving the conditions for investment and the

Economic impacts	Key impacts
	proper functioning of markets? • Does the option have direct impacts on macro-economic stabilisation?

Social impacts	Key questions
Employment	• To what extent are new jobs created or lost? • Are direct jobs created or lost in specific sectors, professions, regions or countries? Which specific social and or age groups are affected? • Are there significant indirect effects which might change employment levels? • Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses? • To what extent does the option influence opportunities and incentives of workers/specific groups to work (i.e. supply of labour through labour market participation or mobility?
Working Conditions	• Does the option affect wages, labour costs or wage setting mechanisms? • Does the option affect employment protection (the quality of work contracts, risk of false self-employment? • Does the option affect undeclared work? • Does the option affect work organisation? • Does the option affect occupational health and safety? • Does the option affect the exercise of labour standards? • Does the option affect social dialogue? • Does the option affect access to vocational training and career development advice? • Does the option affect participation, information and consultation schemes for employees?
Effects on income, distribution, social protection and social inclusion	• Does the option affect peoples'/households' income and at risk of poverty rates? • Does the option affect inequalities and the distribution of incomes and wealth? • Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds. • Does the option affect the financing and organisation of social protection systems? • Does the option affect the access to and quality of basic goods and services particularly for those subject to social exclusion and from disadvantaged backgrounds?
Governance, participation and good administration	• Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? • Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? • Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? • Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? • Does the option make the public better informed about a particular issue? Does it affect the public's access to information? • Does the option affect political parties or civic organisations?

Social impacts	Key questions
	• Does the option consider eGovernment principles?
Public health and safety and health systems	• Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)? • Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise, air, water or soil quality? • Will it affect health due to changes energy use and/or waste disposal? • Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? • Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)? • Does the option affect the quality and/or access to health services and the financing and organisation of health systems? • Does the option affect the cross-border provision of services, referrals across-borders and cooperation in border regions?
Crime, Terrorism and Security	• Does the option improve or hinder security, or impact on crime or terrorism risks? • Does the option affect the criminal's chances of detection or his/her potential gain from the crime? • Is the option likely to increase the number of criminal acts? Does it have an impact on a specific type of crime (money laundering, corruption, illicit production and trafficking, cybercrime, etc.)? Will it divert people away from/ or prevent crime? • Does it affect law enforcement capacity to address criminal activity? • Will it have an impact on security interests? • Does it affect the victims of crime and witnesses or their rights?
Education & training, and education & training systems	• Does the option affect the level of education and training outcomes? • Does the option affect the skills used by individuals? • Does it have an effect on the education and mobility of workers? • Does the option affect the access of individuals to education or and/or vocational and continuous training and quality? If so, how are different social groups affected? • Does it affect the cross-border provision of services, referrals across-borders and cooperation in border regions? • Does the option affect the financing and organisation of education and training systems? • Does it affect universities and academic freedom/self-governance?
Culture	• Does the proposal have an impact on the preservation of cultural heritage? • Does the proposal have an impact on cultural diversity? • Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?
Social impacts in third countries	• Does the option alter the recognition of the International Labour Organisation's core labour standards and other ratified ILO Conventions (classified as up to date by the ILO) and the implementation of the ILO Decent Work Agenda in third countries? • Are there employment, social protection and poverty impacts in non-Member States (including developing countries)?

Environmental Impacts	Key questions
Climate	• Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane, nitrous oxide, etc.) into the atmosphere? • Does the option affect economic incentives set up by market based mechanisms (MBMs) created by Union law (e.g. first and second round incentives and price signals under the EU's Emission Trading System) • Does the option affect the emission of ozone depleting substances (CFCs, HCFCs etc.)? • Does the option affect our ability to adapt to climate change?
Air quality	• Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc.)?
Water quality and resources	• Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources?
Biodiversity, flora, fauna and landscapes	• Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? • Does it affect protected or endangered species or their habitats or ecologically sensitive areas? • Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones? • Does the option affect the scenic value of protected landscape?
Soil quality or resources	• Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?
Waste production, generation and recycling	• Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?
Efficient use of resources (renewable & non-renewable)	• Does the option affect the use of renewable resources (fish etc.) and lead to their use being faster than they can regenerate? • Does it reduce or increase use of non-renewable resources (groundwater, minerals etc.)?
Sustainable consumption and production	• Does the option lead to more sustainable production and consumption? • Does the option change the relative prices of environmental friendly and unfriendly products? • Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc.? • Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?
International environmental impacts	• Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?
Transport and the use of energy	• Does the option affect the energy intensity of the economy? • Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc.)

Environmental Impacts	Key questions
	used in energy production? • Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? • Does it increase or decrease vehicle emissions? • Will the option increase/decrease energy and fuel needs/consumption?
Animal welfare	• Does the option have an impact on health of animals? • Does the option affect animal welfare (i.e. humane treatment of animals)? • Does the option affect the safety of food and feed?
The likelihood or scale of environmental risks	• Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms?
Land use	• Does the option have the effect of bringing new areas of land ('Greenfields') into use for the first time? • Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?

Fundamental rights Impacts	Key questions
General	• What fundamental rights are affected? • Are the rights in question absolute rights (which may not be subject to limitations, examples being human dignity and the ban on torture)? • Do the options have both a beneficial and a negative impact, depending on the fundamental rights concerned (for example, a negative impact on freedom of expression and beneficial one on intellectual property)?
Dignity	• Does the option affect human dignity, the right to life or to the integrity of the person? • Does the option raise (bio) ethical issues (cloning, use of the human body or body parts for financial gain, genetic research/testing, use of genetic information)? • Would it entail risks in terms of torture and inhuman or degrading treatment or punishment? • Would it have an impact in terms of forced labour or trafficking in human beings?
Individuals, private family freedom of conscience and expression	• Does it affect the right to liberty of individuals? • Does the option affect the right to private life privacy (including their home and communications)? • Does it affect an individual's right to move freely within the EU? • Does it affect the right to marry and to found a family or the legal, economic or social protection of the family? • Does the option affect freedom of thought, conscience and religion? • Does it affect freedom of expression and information? • Does it affect freedom of assembly and of association? • Does it affect the freedom of the arts and science?

Fundamental rights Impacts	Key questions
Personal data	• Does the option involve the processing of personal data? • Who processes personal data and for which purpose? • Are the individual's right to access, rectification and objection guaranteed? • Was the data processing activity notified to the competent authority? • Do the data processing/transfer chains imply also international transfers and if so are there any specific safeguards in place in case of international transfers? • Is the security of the data processing activities provided for from a technical and organisational point of view? • Are any safeguards which render the interference into the right of data protection proportionate and necessary provided for? • Are appropriate/specific review and oversight mechanisms in place?
Asylum and protection of removal, expulsion or extradition	• Does the option affect the right of asylum and does it guarantee the prohibition against collective expulsion or extraditions to states of individuals where they risk being subject to death penalty, torture or degrading treatment.
Property rights and the right to conduct a business.	• Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? • If yes, will there be a complete loss of property? If so what are the justifications and compensation mechanisms? • Does the option affect the freedom to conduct a business or impose additional requirements increasing the transaction costs for the economic operators concerned?
Gender equality, equality treatment and opportunities, non – discrimination, and rights of persons with disabilities	• Does the option safeguard the principle of equality before the law and would it affect directly or indirectly the principle of non-discrimination, equal treatment, gender equality and equal opportunities for all? • Does the option have (directly or indirectly) a different impact on women and men? • How does the option promote equality between women and men? • How does the option entail any different treatment of groups or individuals directly on grounds of sex, racial or ethnic origin, religion or belief, disability, age, and sexual orientation? Or could it lead to indirect discrimination? • Does the option ensure respect for the rights of people with disabilities in conformity with the UN Convention on the rights of persons with disabilities? How? (see http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010D0048).
Rights of the child	• Does it strengthen or restrict the rights of the child (or group)? What is the justification for a possible restriction? • Does the option take into account the principle of the best interests of the child? • Does the option help to promote the protection of the rights of the child? In doing so, does it also take into account the rights and principles of the UN Convention on the Rights of the Child? If so, which articles may be concerned? • How are the guiding principles of the UN CRC promoted in the option? • Does the option impede any of the guiding principles of the UNCRC? • What steps have been taken to improve or compensate for any adverse effects of the option? • Has the child's right to be heard on all matters that affect him/her been respected? • Does the option contribute to the promotion of child-friendly justice systems adapted to the needs, age and maturity of a child?

Fundamental rights Impacts	Key questions
Good administration, Effective remedy/ Justice	• Will the administrative procedures in place become more burdensome? • Will they guarantee the right to be heard, the right of access to the file with due regards to professional and business secrecy as well as the obligation of the administration to give reasons for its decisions? • Is the individual's access to justice affected? • In case that the policy option affects rights and freedoms guaranteed by the law of the Union, does it foresee the right to an effective remedy before a tribunal? • If the policy options concerns criminal law or envisages criminal law sanctions, have safeguards been provided ensuring the presumption of innocence and right of defence, the principles of legality and proportionality of criminal offences and penalties, as well as the right not to be tried or punished twice in criminal proceedings for the same criminal offence?

TOOL #20. SECTORAL COMPETITIVENESS

1. INTRODUCTION

Sectoral competitiveness is directly related to productivity. Productivity growth is determined by improvements in the quality and quantity of inputs and technological progress - i.e. a sector's propensity to innovate. In the long term, the growth in living standards will depend on a nation's or firm's ability to improve productivity.

Box 1. Article 173(1) of the TFEU: Competitiveness of the EU economy

- The Union and the Member States shall ensure that the conditions necessary for the competitiveness of the Union's industry exist. For that purpose, in accordance with a system of open and competitive markets, their action shall be aimed at:
- Speeding up the adjustment of industry to structural changes;
- Encouraging an environment favourable to innovation and to the development of undertakings throughout the Union, particularly small and medium-sized undertakings;
- Encouraging an environment favourable to cooperation between undertakings;
- Fostering better exploitation of the industrial potential of policies of innovation, research and technological development.

EU initiatives are likely to affect competitiveness when they affect at least one of the following:

- A sector's capacity to produce products at a lower cost and/or offer them at a more competitive price (cost/price competitiveness). The cost of an enterprise's operations includes the cost of inputs (including resources such as raw materials and energy) and production factors which may be directly or indirectly affected by the policy proposal;
- The quality or the originality of a sector's supply of goods or services (innovative competitiveness); technological development and innovation (of products and/or processes) are of primary importance for both the cost of inputs and the value of outputs;
- Effective market competition and undistorted access to markets including inputs and materials, public procurement, etc.;
- The sector's market shares on international markets.

In addition, the right framework conditions in terms of capital markets, skilled labour, research and effective legal systems and public administrations can also foster improved competitiveness.

The tool below presents a 12-step operational guide on how to assess impacts on sectoral competitiveness¹⁷⁴. It may also be relevant to address how a sector's competitiveness

¹⁷⁴ [The full version of the guidance where you can find more details is also available SEC \(2012\) 91.](#)

impacts upon the competitive position of a particular Member State or the Union itself if this is relevant.

2. ARE IMPACTS ON SECTORAL COMPETITIVENESS POTENTIALLY SIGNIFICANT?

The principle of proportionate analysis means that not all IAs need to assess sectoral competitiveness in depth. The first question to be answered is whether an initiative is likely to have a significant effect on sectoral competitiveness or not.

Step 1. Does the IA require detailed analysis of impacts on sectoral competitiveness?

You may use the checklist proposed here as a tool to assess whether a policy intervention is likely to have such impacts. The example in Box 2 illustrates this analytical tool with a proposal to ban the use of hazardous materials in EU industrial products. The checklist contains general questions about the size of the expected impacts on the drivers of competitiveness and market shares. The questions do not require an in-depth study or quantitative techniques to answer them. For this first scan, you can use only your expertise. You may not be able to give a straightforward yes/no answer to all of them. For instance, the size of the effect may be hard to foresee without data and assumptions. Alternatively, the sign of the impact on competitiveness may be ambiguous or even change over time.

Box 2. Is the ban of use of hazardous material likely to have a significant impact on enterprise competitiveness in terms of:

Cost and price competitiveness	Positive	Negative
Cost of inputs		Yes
Cost of capital		Yes
Cost of labour	Yes?	
Other compliance costs (e.g. reporting obligations)s		Yes
Cost of production, distribution, after-sales services		Yes
Price of outputs (e.g. price controls)	No	
Capacity to innovate		
Capacity to produce and bring R&D to the market	Yes	
Capacity for product innovation	Yes	
Capacity for process innovation (including distribution, marketing and after-sales)	Yes	
Access to risk capital	n/a	n/a
International competitiveness		
Market shares (single market)	Yes	
Market shares (external markets)		Yes
Revealed comparative advantages	cannot say	

Only completing those answers that seem straightforward may be enough to decide whether an IA needs to look in greater depth at the impacts on sectoral competitiveness. When there is considerable uncertainty (i.e. many blanks or question marks in the checklist), a further analysis of the impacts on sectoral competitiveness could still be warranted.

Step 2. How deep should we go?

The magnitude of the expected impacts and its importance are key determinants. The type of policy intervention also offers useful pointers.

The assessment of impacts may be mainly qualitative for those proposals that are likely to have only a limited impact on competitiveness or for which it can be shown that a deeper analysis would be disproportionate. Services should strive to include quantitative elements (and if possible carry out a quantitative estimation of impacts) in those cases where impacts are expected to be particularly significant. The analysis may be limited to the direct effects (i.e. the impact on the directly affected sectors), or extended to indirect effects if these are also likely to be significant and it is possible (and proportionate) to analyse them.

Ideally, the final input into the IA report from the **qualitative screening** would be a short analysis with the following elements that also presents the economic reasoning where appropriate (even where no significant impact is expected):

- (1) Affected sectors;
- (2) Identified impacts on these sectors of policy options;
- (3) Qualitative estimate of the nature and magnitude of impacts;
 - How big is the expected impact?;
 - Is it a direct or indirect result of the intervention?; and
 - When is it expected to occur?;
 - Is the impact transitory or permanent (duration of the impact)?;
- (4) The probability that the impact will take place;
 - How likely is the impact?;
 - Does it depend on critical assumptions?

Step 3. Which sectors are affected?

In a competitiveness analysis, you should take into account direct and indirect, positive and negative effects and account for short and longer-term effects. You should consider impacts on the sectors directly affected by the policy initiative as well as those indirectly affected within and outside of the supply chain.

Indirect impacts are triggered by changes in relative prices and changes in supply and demand for inputs and outputs on the relevant markets of the targeted sector. They may occur in parallel or with a delay (second round effects) relative to the direct effects. They

are important for two reasons. First, they may be greater than the direct effects if they affect many sectors within or outside the supply chain. Second, they can alter the overall expected benefits/costs if they have an opposite sign to the direct effects. The indirect impacts can affect downstream or upstream sectors as well as markets for complementary or substitutes goods.

Some policies may affect many business sectors (e.g. employment or energy policies). In these cases, you should look at the distribution of impacts across sectors. In these cases, you may need to take into account labour, energy, resource and capital intensities to better "size" the distribution of impacts, identify the most adversely affected sectors and analyse their chances to sustain the policy intervention. Some sectors may also be concentrated geographically across the EU leading to a territorially heterogeneous distribution of impacts.

Step 4. What is the effect on SME competitiveness?¹⁷⁵

You may need first to look at the share of SMEs in the affected sectors, and if it is high to follow the four steps of the SME test which is already an integral part of the IA process.

The objective of competitiveness proofing in respect to SME competitiveness would, therefore, be to reinforce the application of the SME test to the respective sector(s), by applying the concept of cost, innovative and market competitiveness.

Particular attention may be necessary for micro businesses (under 10 employees) as they may have fewer resources for taking on any possible compliance costs or administrative burdens.

Step 5. What is the effect on cost and price competitiveness?

A policy proposal may have impacts on the cost of business operations and thus on returns on investment and investment flows. It may impose direct compliance costs on affected sectors, or it may increase costs indirectly due to the change of behaviour of suppliers, consumers, employees and investors in result of the intervention. The questions below can help you identify those impacts.

- (1) Does the proposal reduce or increase **compliance** costs of the affected sector(s) e.g. new information requirements, use of new equipment, additional staff?
- (2) Does the proposal affect **the prices and cost of intermediate consumption** e.g. price of availability of raw materials, by introducing restrictions on use of hazardous substances?
- (3) Does the proposal affect the **cost of capital** e.g. price and availability of financing?
- (4) Does the proposal affect **the cost of labour** e.g. through changes in retirement age, minimum wages, social insurance contributions, promoting/restricting labour mobility?

¹⁷⁵ See Tool #22 on *The SME test*.

- (5) Does the proposal affect the **cost of energy**?
- (6) Does the policy proposal affect **consumer's choice and prices** e.g. availability of certain products, banning marketing of certain products or the quality of goods?
- (7) Does the policy measure have an impact on the level of competition in the sector in question or in other related sectors of importance?¹⁷⁶
- (8) Until now, you would have identified most of the changes in compliance and operational costs. Now you should consider the cost implications:
 - What would be the adjustment costs for enterprises (incl. workforce)?;
 - Would the sector need a major restructuring such as closing of production lines, substitution of technologies, substitution of skills, etc.?;
 - Might it lead to closing down of enterprises?;
 - Would SMEs or microbusinesses be able to meet the cost of restructuring?

Step 6. What is the effect on the enterprises' capacity to innovate?¹⁷⁷

Impacts on innovation competitiveness may be assessed examining the potential impact on:

- (1) Enterprises' capacity to carry out R&D leading to innovation in their products, which can be further traced to the impact of the proposal on:
 - Supply of skills needed by the sector;
 - The efficiency of protection of intellectual property rights.
- (2) A sector's capacity to bring to the market new products (goods/services) or improve the features of the current ones (*capacity for product innovation*), which depends crucially on technical skills and the application of new technologies;
- (3) The capacity to innovate processes and product related services, including distribution, marketing and after-sales services (*process innovation*), which depends on the supply of management and organisational skills and talents; and
- (4) The ability to access risk capital.

If it is deemed that the measure could have a significant effect on innovation, a more thorough assessment should be undertaken making use of the Tool#21 on *Research & innovation*.

¹⁷⁶ See Tool #23 on *Competition*.

¹⁷⁷ See Tool #21 on *Research and innovation*.

Step 7. What might be the effect on the sector's international competitiveness?

The assessment of impacts on competitiveness would not be complete without taking into account the possible differential impact of policy options on domestic and foreign firms. For instance, if a policy proposal is likely to increase costs for EU producers (by e.g. introducing stricter product-safety requirements on the EU market), it may not affect EU manufacturers' relative prices and market shares if their competitors face the same requirements and there are no suitable cheaper substitutes. However, if the policy affects the production process (e.g. through stricter resource use or pollution standards), or raises labour costs (e.g. through new safety-at-work requirements), then European manufacturers may be at a competitive disadvantage vis-à-vis firms located elsewhere.

The typical questions you may ask are:

- (1) What is the likely impact of the assessed option on the competitive position of EU firms with respect to non-EU competitors?
- (2) What is the likely impact of the assessed option on trade and trade barriers?
- (3) Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist?
- (4) Is it likely to cause cross-border investment flows, including the relocation of economic activity towards or outside the EU?

See also the Tool #26 on *External trade and investment*.

3. QUANTIFYING THE IMPACTS

Quantification of impacts on competitiveness may require descriptive statistics, input-output analysis using national or sectoral accounts, applied general equilibrium modelling or other econometric exercises. For policy proposals that affect a diverse set of sectors, models such as computable general equilibrium (CGE) and macro-econometric input-output models can be used to quantify overall impacts.

The steps suggested below give an overview of possible outputs of the quantitative analysis, rather than specific tools and methods to deliver them, as these would depend on the issue at hand. These steps build on the output of the five steps of the qualitative screening.

Step 8. Provide evidence on the structure and performance of directly affected sector(s)

A quantitative assessment of the sector's performance should ideally be based on:

- (1) The weight of the targeted sector in the EU economy as measured by its share in value added and employment, regional and national concentration of the sector, etc.;
- (2) The number and distribution of firms, including the share of SMEs, and its concentration ratio;
- (3) Its labour productivity or total factor productivity;

- (4) Its profitability as measured by net profit margin; return on assets;
- (5) Its market share of the world market; and
- (6) The flow of Foreign Direct Investment (ratio of inward/outward FDI stock to value added).

You should take stock of existing sectoral studies and ex-post evaluations. The Commission has completed a number of industrial and market studies, as well as ex-post evaluations of policies.

You might also find the relevant statistical data in the Eurostat Structural Business Statistics, PRODCOM and COMEXT databases. See the end of this tool for more information on data sources.

If desk research is insufficient, you may consult the websites and publications of the respective business associations or concerned social partner organisations.

Step 9. Provide data evidence on indirectly affected sectors

If the qualitative screening shows significant indirect impacts (positive or negative), it may be advisable to replicate the steps above for other sectors in or outside the value chain that may be most affected.

Step 10. Quantify additional compliance and/or operational costs related to the assessed option

This step is the quantitative counterpart of Step 5. If feasible, it may be useful to complete the sector profiling with an overall cost breakdown (cost of labour, raw materials, energy etc.) and with cumulative costs of legislation for the sector¹⁷⁸.

Step 11. Quantify the expected impacts on the capacity of affected enterprises to innovate

This analysis should ideally include several input and output indicators on sector innovations. The data from the EU Industrial R&D Investment Scoreboard¹⁷⁹ and the Eurostat Community Innovation Survey¹⁸⁰ constitute a reasonable starting point. Data may also be obtained from the industrial chamber of the corresponding sector. The tool on assessment of impacts on innovation can provide more information on this issue¹⁸¹.

¹⁷⁸ See Tool #58 on *The typology of costs and benefits*; and Tool #59 on *Methods to assess costs and benefits*.

¹⁷⁹ <http://iri.jrc.ec.europa.eu/reports.htm>;

¹⁸⁰ http://epp.eurostat.ec.europa.eu/portal/page/portal/science_technology_innovation/data/database; the description of the dataset can be found here: <http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/cis>

¹⁸¹ See Tool #21 on *Research & innovation*

Step 12. Quantify the expected impacts on affected sectors' international competitiveness

There is a host of standard indexes that are intended to reflect the international position of an economy and its firms. Some of the most commonly used are:

The *ratio of inward FDI stock to value added* indicates the contribution of FDI to capital formation and signals the attractiveness of the host country.

- The *ratio of outward FDI stocks to value added* is an indicator of corporate strength, where companies venture abroad to seize opportunities from foreign markets and resources.
- Export market shares show how much of the total 'world' export is covered by the export of a particular country for each industry. They reflect the capacity to respond to external demand or open up new markets in direct comparison to international competitors.
- Revealed Comparative Advantage (RCA) compares the share of a given industry's exports in the EU's total manufacturing exports with the share of the same industry's exports of a group of reference countries.
- Relative Trade Balance (RTB) compares the trade balance of a particular commodity to the total volume of trade, exports plus imports.
- Relative Unit Labour Costs (RULC) measures the cost of labour in a given industry relative to its productivity (unit labour costs) and relative to the corresponding index in another country.

See also the tool on assessment of impacts on trade and investment.

4. HOW TO MINIMIZE ANY NEGATIVE IMPACTS ON SECTORAL COMPETITIVENESS

If the analysis made under the previous section shows that certain sectors are disproportionately affected or disadvantaged, you should consider using possible mitigating measures. The objective is achieving the policy objectives whilst not compromising the competitiveness of EU industries. The list below sets out some of the approaches you might consider.

- Full or partial exemption of certain sectors or subsectors. This might include less onerous compliance requirements or deeming a certain subset of rules not applicable to certain sectors (e.g.: The Data Protection Regulation sets different requirements for e-mail vs. traditional mail marketing);
- Extended transition/compliance periods before the rules come into force where, for example, a service or product needs to be redesigned to be compliant (e.g. some Ecodesign schemes are introduced by phases where lighter compliance requirements are set for the introductory phase);

- Varying requirements by type and/or size of business or type of product/service. For example, SMEs are only required to register but not to be fully licenced; or exempting smaller businesses from having to register or from paying fees; or setting more ambitious CO₂ emissions targets for vans vs. passenger cars as the payback period due to improved fuel economy is much shorter for vans.

When considering mitigating measures, it is always important to consider the relevant trade-offs. For instance, excessively extending transitional periods or varying requirements by type of business may entail a risk of privileging certain types of enterprises and, therefore, harming fair competition.

The relevant sections in the tools on the SME test, impacts on trade and investment and impacts on innovation can provide more details on how to minimize any negative impacts in these areas.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. EU Studies on industrial competitiveness

Studies providing in-depth understanding of the driving factors for competitiveness in different sectors can be found in the EU Bookshop and on the Commission's webpages covering different industrial sectors¹⁸².

5.2. EU databases

- [AMADEUS](#): Firm-level database containing comprehensive information on around 19 million companies across Europe. It can be used to research individual companies, search for companies with specific profiles, and for general analysis.
- [BACH - Bank for the Accounts of Companies Harmonised](#): Aggregated and harmonised information on the financial statements of non-financial companies from 11 Member States (AT, BE, DE, DK, ES, FI, FR, IT, NL, PT, SE, UK), Japan and the United States; 3 firms' size classes (small, medium-sized and large enterprises); 23 sectors or subsectors based on NACE; time series of nearly 20 years; 95 items, including assets, liabilities and the profit and loss account. It is used to analyse the assets, liabilities, financial position and profitability of enterprises, according to their sector and size class.
- [COMEXT](#): Value (euros) and quantity (number of items, kg, m², m³, etc.) of goods traded between Member States and non-EU countries; share of EU in world trade; external trade of EU, the Member States and main third countries by the Standard International Trade Classification product group; EU trade by Member State, by partner and by product group; plus various EU aggregations (eurozone, EU25, EU27, etc.). Annual and monthly data are available for 1995 on.
- [Community Innovation Survey](#): The Community Innovation Survey (CIS)¹⁸³ based innovation statistics are part of the EU science and technology statistics. Surveys are

¹⁸² <https://bookshop.europa.eu/en/home/>; <http://ec.europa.eu/enterprise/sectors/>

¹⁸³ <http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/cis>

carried out with two years' frequency by EU Member States and a number of member countries of the European Social Survey. Compiling CIS data is voluntary to the countries, which means that in different surveys years different countries are involved. The CIS is a survey of innovation activity in enterprises. The harmonised survey is designed to provide information on the innovativeness of sectors by type of enterprises, on the different types of innovation and on various aspects of the development of an innovation, such as the objectives, the sources of information, the public funding, the innovation expenditures etc. The CIS provides statistics broken down by countries, type of innovators, economic activities and size classes.

- [EU Industrial R&D Investment Scoreboard](#): The Scoreboard is a benchmarking tool which provides, every year since 2004, reliable up-to-date information on R&D investment and other economic and financial data (including net sales, profits, capital investments, market capitalisation, number of employees) for the top world corporate R&D investors (1.000 companies based on the EU and 1.000 companies based outside the EU). The data in the Scoreboard are published as a four-year time series to allow further trend analyses to be carried out, for instance, to examine links between R&D and business performance.
- [EU KLEMS Growth and Productivity Accounts](#): For detailed sectoral productivity and total factor productivity for quantitative studies focusing on technical change in the industry (manufacturing) up to 2007.
- [EU Science and technology database](#): R&D, innovation data, patent statistics, knowledge-intensive sectors, human resources in science and technology.
- [EUROFOUND](#): Eurofound provides information, advice and expertise on living and working conditions, industrial relations and managing change in Europe for key actors in the field of EU social policy on the basis of comparative information, research and analysis.
- [European Labour Force Survey](#): The EU LFS is a large household sample survey providing quarterly results on labour participation of people aged 15 and over as well as on persons outside the labour force. All definitions apply to persons aged 15 years and over living in private households. Persons carrying out obligatory military or community service are not included in the target group of the survey, as is also the case for persons in institutions/collective households.
- [PRODCOM](#): Statistics on the production of goods in the Member States, measured by value (euros) and by the volume (kg, m2, number of items, etc.) and classified according to the Prodcom list (see classifications).
- [SBS - Structural Business Statistics](#): Describes the behaviour (structure, conduct and performance) of businesses across the EU, via a number of enterprises, persons employed, turnover, value-added, investment, productivity, SME share of added value and employment. It covers industry, trade and services (data available for the EU-27 and for the Member States). The statistics can be broken down to a very detailed sectoral level (several hundred economic activities based on NACE classification).

5.3. International databases

- [COMTRADE](#) is a UN database on International Merchandise Trade Statistics. More than 1.75 billion trade records starting from 1962 together with analytical tables which cover trade values and indices for individual countries and regions.
- [IEA Statistics & Balances](#) (International Energy Agency). For energy prices, fossil fuel prices, etc.
- [IMF balance of payments](#) (International Monetary Fund)
- [OECD.Stat](#): Contains data on main EU competitors to assess the evolution of EU international competitiveness. Statistics cover OECD members and the following areas:
 - Industry and Service Statistics;
 - Structural Analysis (STAN) Databases including Input-Output databases;
 - Structural and Demographic Business Statistics (SDBS) including Structural Business Statistics per economic sector;
 - International Trade by Commodity Statistics (ITCS); and
 - Productivity Levels and GDP per capita.
- [UNCTAD](#): For data on foreign direct investment (FDI) to assess import and adoption of technical change through capital investment.

6. SUPPORT

- Questions or feedback regarding the application of this guidance can be sent to the competitiveness proofing help desk in DG GROW through its **functional mailbox**:
[GROW COMPETITIVENESS IMPACT HELPDESK@ec.europa.eu](mailto:GROW_COMPETITIVENESS_IMPACT_HELPDESK@ec.europa.eu)
- If impacts on competitiveness are likely to be significant, GROW should be part of the interservice group.
- See SEC (2012) 91 for the Operational guidance for assessing impacts on sectoral competitiveness within the Commission Impact assessment system - A "Competitiveness Proofing" Toolkit for use in impact assessments.

TOOL #21. RESEARCH & INNOVATION

1. INTRODUCTION

This research and innovation Tool provides clear guidelines for analysing the interaction between new or revised EU legislation (including spending programmes) and innovation. In addition, it outlines a series of design considerations and operational instruments that can be used to make legislative proposals more forward-looking and innovation-friendly. The Tool is not limited to looking at impacts on technological innovation but can also be used to look at other forms of innovation such as social, business model and public sector. Other tools in the Toolbox can also be used to identify and assess impacts flowing from innovation.

The assessment of the potential impact of legislation on research and innovation starts with the type of legislation and its overall objectives. Please consider whether, and to what extent, the initiative may have positive or negative impacts on research and innovation capacity at the firm, sector or EU level. For example:

- (1) In creating (or reducing) barriers to innovation or weakening (or strengthening) the incentives for investing in innovation.
- (2) Creating opportunities or incentives for innovation that could better support the achievement of policy objectives.
- (3) Affecting specific research and innovation regulation (e.g. patent law, technology transfer legislation) or spending programmes. These will have an effect on the incentives and rewards, as well as perhaps the location choice of research, development and market entry.

DG Research and Innovation is available to support the analysis, provide further guidance and help in the design of EU initiatives at the request of, and in cooperation with, the lead DG. The Scientific Advice Mechanism (SAM)¹⁸⁴ can also play a role in cases where the scientific understanding and interpretation of evidence is critical to making policy choices; this latter mechanism complements the routine assistance of the JRC in better regulation work.

2. THE STEPWISE APPROACH

Step (1) Broaden consultation to capture the research and innovation angle

Depending on the extent to which solving the problem is likely to have significant impacts on innovation and research, questions on these aspects should be a central element of the consultation strategy (for which separate guidance exists¹⁸⁵). The public online stakeholder consultation should include questions on potential impacts on research and innovation, on emerging techniques and technologies and on impacts on companies

¹⁸⁴ <https://ec.europa.eu/research/sam/index.cfm>

¹⁸⁵ See Tools #53, #54, and #55 on Stakeholder consultation

scaling-up in size.¹⁸⁶ The public consultation should reach out to relevant stakeholders, in particular start-ups.

There is a risk that this sort of consultation exercise will predominantly identify the views of existing and incumbent firms and therefore may not fully take into account the impact on or possible creation of new business models, new firms or new technologies and services. This should be taken into account in the analysis of responses received.¹⁸⁷ This risk can also be mitigated by targeted consultation with research and innovation ecosystem actors, for instance through round tables, focus group meetings, hearings etc. DG RTD will help to identify key stakeholders and facilitate engagement.

Step (2) Assess potential impacts on research and innovation

The checklist below provides an indicative set of questions to assess whether the proposed initiative affects research and innovation¹⁸⁸.

Impact on research and innovation	Y/N
<i>Does the measure affect the research, testing or demonstration phase?</i>	
Does the intervention impact the generation of new ideas , their adaptation and application (e.g. from the knowledge base to industry)?	
Does it affect the cooperation (e.g. circulation of data, research results or researchers) between public and corporate R&D ?	
Does the proposed intervention potentially affect the establishment of, access to and functioning of R&D infrastructures ?	
Could the measure add or ease an administrative burden to testing, piloting or demonstrating new goods, services and products?	
Could compliance costs and time for the development of innovative technologies/solutions be affected?	
Does the intervention provide an equal playing field for public and private actors?	
<i>Does the measure affect application of innovative solutions or to bring them to market?</i>	
Is the intervention in an area with a relatively fast pace of innovation ?	
Could the initiative affect the introduction of future innovative solutions that may better achieve its policy objectives?	
Could the measure affect the innovation dynamics of specific markets ?	
Could the measure add or remove an administrative burden to bringing new goods, services and products on the market?	
Will the proposed initiative stimulate multi-disciplinary scientific research?	

¹⁸⁶ See COM(2016) 733; Europe's next leaders: the Start-up and Scale-up Initiative which contains actions to help start-ups and scale-ups that are also linked to SME and internal market impacts.

¹⁸⁷ See Ashford/Renda, 2016. <https://www.ceps.eu/publications/aligning-policies-low-carbon-systemic-innovation-europe>

¹⁸⁸ See Tool #20 on *Competitiveness* for guidance on how to quantify the impact of legislation on the capacity of enterprises to innovate.

<i>Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?</i>	
Could the legislation change the innovation incentives and choices for R&D investments?	
Could the intervention lead to a difference in innovation investment incentives in the EU compared to third countries?	
Could the intervention create or influence a preference for keeping a firm size below a certain limit?	
Could the intervention affect the incentives for companies to scale up in Europe?	
Will the proposed initiative lead to societal innovation?	

If the assessment leads to the conclusion that the proposed initiative has an impact (positive or negative) on research and innovation, further analysis on the specific impacts should be carried out of the policy options. Services should elaborate further on what the expected impacts are in the impact assessment report¹⁸⁹. DG RTD will support in developing an evidence base for policy options and the relation with innovation through the screening of relevant projects funded by Union RTD programmes. In specific cases, RTD can also provide additional assistance through short-term service contracts.

Step (3) Address legislative design considerations

The overall interaction between a policy option and innovation depends on a range of factors, including regulation design, implementation and enforcement. This section will help you to understand (i) the potential impact of the design of your proposal on research and innovation behaviours and outcomes, (ii) how to mitigate negative impacts on research and innovation and (iii) how innovation can be leveraged to better achieve policy objectives. Questions may not be relevant for all types of policies.

The table below describes a number of ways in which regulation and innovation interact. The description of each issue is followed by a series of questions designed to facilitate further reflection on whether and how it might be relevant to the options being considered in the impact assessment.

If you answer 'yes' to a question, please consider what steps you can take to maximise R&I capacities and the potential of innovation to achieve policy objectives. Where possible, the table points to specific instruments in Step 4 that can be applied to address the identified challenge. These are, however, by no means the only instruments that can be used.

¹⁸⁹ See Tool #8 on the *Format of the IA report*.

Legislative design considerations	Y/N	Relevant tools
<i>Flexibility and future-proofing¹⁹⁰</i> As far as possible legislation should remain open to innovative solutions that will help to achieve the policy objective of the measure being considered. It should aim for technology neutrality, and seek to avoid lock-in to one particular technology solution or technique. As a general rule, the less prescriptive and detailed a measure is, the more room it leaves for potential innovation. Very prescriptive and detailed regulation can create barriers to entry for innovative solutions, even if the innovation could contribute to policy goal of regulation.		
Does the measure give operators as much flexibility as possible while ensuring that the policy objective will be met? Has the impact on innovation of the proposed measure been examined in the context of the proportionality test?		
Does the proposed measure contain targets? Is it designed to allow for the possibility of emerging technologies or processes that could better meet or exceed these targets?		2, 4, 5
Are any definitions used such that they will not become outdated with the appearance of new innovations?		3
Are provisions included that will allow for regular updates of the measure in case of rapid technological developments?		3
Is the legislation being proposed to address a time-specific issue?		3
Is the proposed measure adaptable to technological and scientific progress throughout the new sciences developments?		
<i>Compliance costs</i> All compliance costs divert resources from other purposes, potentially including research and innovation. Compliance costs may also discourage innovation if they fall disproportionately on innovators compared to incumbents, for example because of the costs of testing and obtaining authorisation. Testing and authorisation processes for regulatory compliance may require spending on research – this is sometimes considered "defensive" R&D as opposed to R&D that itself aims to develop new technologies, processes or products.		
Have you taken steps to reduce the likelihood that the compliance costs of the policy option will divert resources from R&I activities?		2, 4, 5
Does the policy option seek to achieve a balance between requirements for "defensive" R&D and incentives for R&D into novel solutions?		4, 5
Have you taken steps to reduce unjustified variation in compliance costs between incumbents and potential innovators?		1, 2, 4, 5
Have you taken steps to ensure that compliance costs do not create a particular obstacle for innovative SMEs?		1

¹⁹⁰ EU legislation is future proof if it is proactive and forward-looking and provides the maximum legal clarity and certainty (Future Proof Legislation, EESC Opinion, 2016).

Regulatory certainty and clarity Regulatory uncertainty can hamper investment, including investment in R&I, because it increases risk and potentially also the cost of finance. Regulatory uncertainty can take different forms. It may be caused by real or perceived instability: is the regulator likely to change the regulatory framework in the foreseeable future? It may also be caused by a gap or lack of clarity in regulation, when it is unclear whether or not an innovation would comply. There are trade-offs between the need to reduce regulatory uncertainty and the need to maintain flexibility.		
Will the proposed measure minimise regulatory uncertainty?		
Does the policy option create clarity concerning the classification and treatment of emerging technologies where possible?		1, 2
Will the proposed measure expire at a certain date or is there a date fixed for its review and possible modification? If so, does it strike the right balance between providing regulatory certainty on the one hand and the possibility for adaption to scientific and technological progress on the other?		3
Timing and stringency There is a balance to be struck with regard to the stringency of regulations. On the one hand, a regulation that is overly stringent or imposes requirements within an unrealistic timeframe may encourage the market to use existing solutions. This can hamper investment and the deployment of solutions. On the other hand, the need to meet ambitious standards can stimulate radical innovation, provided regulation leaves sufficient time and is sufficiently stable to allow the market to develop new solutions.		
Does the initiative introduce new requirements within a timeframe that is in line with the market's investment and innovation cycle?		
The single market and harmonisation and interactions with other policies A lack of harmonisation between Member States, and even between EU Member States and other countries, can discourage investment in the development of innovative solutions and create barriers to market access. The creation of a well-functioning single market can encourage investment in the scaling up of innovations.		
Will the proposed measure help to ensure a harmonised approach across the EU? Will it effectively address any identified problems created by differences in implementation in different Member States?		
Could the implementation of the legislation result in inconsistent requirements or regulatory practices between Member States in relation to innovative solutions?		
Is the proposed initiative aligned with requirements at the international level (e.g. international standards)?		
Does the proposal consider potential interactions with cross-sectoral legislation or requirements governing different sectors?		

Step (4) Apply tools to leverage the potential of innovation and reduce negative impacts

This section provides a non-exhaustive list of instruments and approaches that can be used to improve the design of your legislation to make it more innovation friendly and to leverage innovation to better achieve your policy objectives. These options have specific characteristics that need to be taken into account on a case-by-case basis in order to assess their case-specific relevance and opportunity.

DG RTD can provide additional expertise and practical guidance to help you to apply these tools.

Please also refer to Tool #15¹⁹¹ for support in assessing whether the choice of different policy instruments (e.g. directives versus regulations) could allow you to achieve better outcomes for innovation.

1. Experimentation clauses

An experimentation clause enables the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to innovative technologies, products or approaches, even if they do not conform to all existing legal requirements.

Experimentation clauses can be appropriate when detailed product or technological characteristics have to be defined in legislation, but the policy goal could be met in the future by different, innovative solutions. They may also be proposed with the express intention of encouraging innovation and experimentation. A sophisticated experimentation clause is sometimes referred to as a regulatory sandbox – a framework that allows innovations to be tested in a real-world environment subject to regulatory safeguards and support.

The **Framework Directive on the Approval of Motor Vehicles** (2007/46/EC) defines the process by which Member States certify that a vehicle model meets EU safety, environmental and production requirements. Article 20 (*Exemptions for new technologies or new concepts*) allows Member States, subject to authorisation from the Commission, to approve technologies or concepts even though they do not meet certain requirements. Pending the Commission decision on whether to authorise the exemption, the Member State may grant provisional approval that is valid only on its territory. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0046&from=FR>

2. Outcome-oriented legislation

Outcome-oriented legislation sets a measureable objective without prescribing the exact mechanisms by which the objective is to be achieved. It gives concerned organisations the flexibility to decide how to achieve the objective.

Outcome-oriented legislation should, in principle, be the preferred option unless there is a clear need to define the exact mechanisms by which the objective is to be achieved. It avoids creating a situation of lock-in to a particular technology or approach, and creates a more level playing field for innovative technologies or approaches to compete against incumbents.

The **Regulation on personal protective equipment** (2016/425) lays down requirements for the design and manufacture of personal protective equipment to ensure the protection of the health and safety of users. The technical specifications listed in Annex II of the Regulation do not prescribe the specific technology or materials to be used provided they do not adversely affect the health or safety. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425>

¹⁹¹ See Tool #18 on *The choice of policy instruments*

3. Sunset clauses

Sunset clauses terminate or repeal some or all provisions of a legal text after a specific date, unless further legislative action is taken to extend them. They can be used to ensure that legislation does not become an obstacle to innovation in rapidly changing market or technological environments. They can also serve as a tool for legislative experimentation, as they allow the lawmaker to test a new legal approach or regulatory framework for new technologies in a clearly delimited way. The risk of regulatory uncertainty must however also be taken into account when considering their use.

The **European Union Agency for Network and Information Security (ENISA)** was created in 2004 for an initial period of five years. Article 25 of Regulation (EC) No 460/2004 specified that its operations must be evaluated in order to determine whether its mandate should be extended. Under Regulation (EU) 526/2013, ENISA received a new seven year mandate, with a possibility of extension following an evaluation (Article 32, 36). The temporary mandates reflect the rapid evolution of information and communication technologies, the changing threat landscape and the evolution of Union policy in this field.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:165:0041:0058:EN:PDF>

4. Test of alternatives

A test of alternatives requires applicants for regulatory approval to consider potential alternatives, and to justify why their chosen solution is the optimal way to meet the policy goals underlying regulation. Applied rigorously, the requirement to examine alternatives has the potential to encourage innovation and the search for new approaches to existing goals.

A test of alternatives may be relevant when projects, products or technologies have a negative impact on a core regulatory objective like consumer or environmental protection or even fail to meet standards, but a regulator nonetheless has reason to approve due to their wider benefits. In such cases, a test of alternatives can help to ensure that the desired wider benefit is achieved using the best available technology.

The **Environmental Impact Assessment Directive** (2011/92/EU) defines the environmental impact assessment to be applied by Member States when authorising projects likely to have significant effects on the environment. Article 5 specifies that developers must submit an outline of the main alternatives they have studied, and explain the reasons for their choice, taking into account the environmental effects.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0092&from=EN>

5. Top-runner approach

The top-runner approach refers to legislative provisions that envisage the updating of a requirement in order to reflect higher performance levels that have become possible because of scientific or technological progress. If an innovation achieves a higher performance level, then that performance level becomes the new requirement. The top-runner approach encourages innovation by rewarding first movers, since other market operators are obliged to adopt that innovation – or seek their own innovation that performs equally well or better.

The **Industrial Emissions Directive (2010/75/EU)** aims to protect human health and the environment by reducing harmful industrial emissions. Member State authorities may grant operating permits for industrial installations only if those installations do not

exceed certain emission levels. The emission levels are set according to what can be achieved by Best Available Techniques, as defined in a Commission Implementing Decision. Article 74 provides for the periodic updating of the Best Available Techniques and the acceptable emissions level in accordance with scientific and technological progress.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0075&from=EN>

Combining different approaches and instruments

In practice legislation may combine different instruments and approaches.

For example, the Industrial Emissions Directive (2010/75/EU) includes provisions that correspond to the top-runner approach (Article 74), outcome-oriented legislation (Article 15, paragraph 2) and an exemption mechanism (Article 15, paragraph 5).

REACH (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) combines the test of alternatives with the top-runner approach (Articles 55, 60 and 61).

3. INFORMATION SOURCES

Further information on how to screen initiatives/legislation from the innovation perspective; and detailed examples of where innovation acts as a barrier or driver for innovation are presented in the “Better Regulation for Innovation Driven Investment at EU level”¹⁹² and the Report on the screening of the Regulatory Framework¹⁹³.

- **[Towards an Innovation Principle Endorsed by Better Regulation](#)**. EPSC Strategic Note, Issue 14, 30 June 2016.
- **Assessing the Impacts of EU Regulatory Barriers on Innovation**, Technopolis, 2017.
- **[Regulatory screening: A short guide on the innovation effects of regulation](#)**. DG RTD 2014.
- **[Better regulations for innovation-driven investment at EU level](#)**. DG RTD 2016.
- **The impact of regulation on innovation**. Blind, K., NESTA working paper, 2012.
- **How can EU Legislation enable and/or disable innovation?** J. Pelkmans, A. Renda. European Commission, 2014.
- **Regulation and Innovation: evidence and policy implications**. BERR Economics Paper N4. 2008.
- **[Regulation and R&I policy: comparing Europe and the USA](#)**. Renda, European Commission, June 2016.

¹⁹² https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf.

¹⁹³ <https://ec.europa.eu/research/innovation-union/pdf/KI-04-13-129-EN-N-RegulatoryScreening.pdf>.

4. SUPPORT¹⁹⁴

- Information about the content or application of this tool: RTD-BR@ec.europa.eu.

¹⁹⁴ For further background material and examples, please consult DG RTD intranet page <http://intranet-rtd.rtd.cec.eu.int/evaluation/impact-assessment.php>.

TOOL #22. THE "SME TEST"

1. INTRODUCTION

SMEs are the backbone of the EU economy, creating more than 85% of new jobs in Europe. Due to their size and limited resources, SMEs can be affected by the costs of regulation proportionately more than their bigger competitors. At the same time, the benefits of regulations tend to be more evenly distributed over companies of different sizes. SMEs may have limited scope to benefit from economies of scale. SMEs find it more difficult to access capital and their cost of capital is often higher than for larger businesses.

The Commission aims to improve the overall approach to entrepreneurship, permanently anchor the "Think Small First" principle in policymaking and to promote growth of SMEs (and start-ups in particular) by helping them tackle the remaining problems which hamper their scaling-up. Legislation, administrative rules and procedures should be simple, easy to understand and to apply. SMEs' interests should be taken into account at the very early stages of policymaking in order to make legislation more SME friendly.

In addition, it is Commission policy¹⁹⁵ to exempt micro-enterprises from EU legislation wherever possible or introduce special regimes so as to minimise the regulatory burden on them. The results of the analysis of the impacts on SMEs must be presented in the Commission's reports given the important role of SMEs in the economy.

Box 1. The need to assess potential impacts on SMEs

- Potential impacts on SMEs should be considered and reported systematically in all impact assessment reports¹⁹⁶.
- The assessment should be proportionate: the depth of analysis should reflect the significance of the expected effects on SMEs.
- If relevant and proportionate, the SME Test requires consultation of SME stakeholders to establish the nature and magnitude of the impacts an initiative might entail for SMEs.
- If significant impacts are expected, these should be assessed in more depth.
- When the selected policy option imposes a disproportionate burden on SMEs compared to bigger enterprises, mitigating measures should be considered.

Small and medium-sized enterprises are defined at Union level¹⁹⁷. The main factors determining whether an enterprise is an SME are the staff headcount and either turnover

¹⁹⁵ COM(2011) 803

¹⁹⁶ See Tool #12 on the *Format of the IA report*; and further guidance on how to present the results of the SME Test: <https://connected.cnect.cec.eu.int/docs/DOC-134986>

¹⁹⁷ Defined in [Commission Recommendation 2003/361/EC](#) and its subsequent amendments.

or balance sheet total¹⁹⁸. A firm that is controlled or controls other companies (through ownership, partnership or other linkages) needs to include part or all of the staff headcount, turnover or balance sheet data from those companies too. The definition of an SME is important in the context of access to finance and EU support programmes and for competition policy. For the purposes of impact assessment, it is recommended to use the headcount criterion. Financial criteria (turnover or balance sheet total) may also be used, but the related data are less readily available and their application can entail a disproportionate administrative effort in this context. Applying the SME definition in full, i.e. taking ownership links into account, can be burdensome in certain cases and is therefore not recommended for non-financial purposes. Please contact the *SME Test helpdesk* (see later section for details) for further explanation or assistance.

2. HOW TO IDENTIFY IMPACTS ON SMEs

Any backward or forward looking assessment should analyse whether SMEs are disproportionately affected or disadvantaged compared to large companies. If so, alternative mechanisms or flexibilities in approach that might help SMEs to comply should be considered when reviewing the policy initiative. **SMEs need to be taken into consideration in each of the analytical steps of better policymaking.**

The SME Test comprises four steps:

- (1) Identification of affected businesses;
- (2) Consultation of SME stakeholders;
- (3) Measurement of the impact on SMEs;
- (4) Assessment of alternative mechanisms and mitigating measures.

Step (1) Identification of affected businesses

During this stage, you should establish whether and which SMEs (e.g. micros) are among the likely affected population. In some cases, this will be clear. In others, you will need to identify the characteristics of the affected businesses/sector(s), such as the distribution of businesses per size-class (micro, small, medium or large enterprises). Relevant sources of information¹⁹⁹ should be explored. These could also include information available from organisations representing SMEs' interests. Examples of elements to consider include:

- Proportion of the employment concerned in the different categories of enterprises affected;

¹⁹⁸ Meeting the staff headcount criterion is mandatory in order to be considered an SME. However, an enterprise may choose to meet either the turnover or the balance sheet total ceiling.

¹⁹⁹ A useful starting point to find this information are the Structural Business Statistics produced by Eurostat, see <http://ec.europa.eu/eurostat/web/structural-business-statistics>

- Weight of the different kinds of SMEs in the sector(s) (micro, small and medium ones);
- Links with other sectors and possible effect on subcontracting; for instance, there may be an impact not only on the targeted sector but also on its suppliers or customers; such indirect impacts should also be taken into account.

If the preliminary assessment leads to the conclusion that one or more class of SME is affected, further analysis should be carried out.

Step (2) Consultation that captures the SMEs angle

If SMEs are potentially affected (or if there are doubts as to the extent of the influence on SMEs), then SME dimension should be a central element of the consultation strategy (for which separate guidance exists²⁰⁰). In addition to an open public consultation, consultation activities may involve specific targeted actions such as round table discussions, focus group meetings, hearings targeting SME representatives, SME Panels or specific consultations – carried out with the assistance of the Enterprise Europe Network - aimed at providing inputs into the SME Test section of the Impact Assessment, etc.²⁰¹ Wherever it is deemed useful and relevant, the start-up community should also be targeted by the consultation activities.

The SME dimension in Public Consultations is explained in Tool #53 The consultation strategy.

3. HOW TO MEASURE IMPACTS ON SMEs

Step (3) Measurement of the impact on SMEs

For each policy option, the distribution of the costs and benefits of the proposals with respect to the business size (**differentiating between micro, small, medium and large enterprises**) should be analysed qualitatively and, if possible and proportionate, quantitatively²⁰². A one-size fits all approach for all SMEs has so far not proved effective or efficient as the impact on micro-companies is likely to differ substantially from the impact on medium sized ones. Therefore, where relevant and feasible, costs and benefits accruing to each size-class of SMEs should be presented and analysed separately. It is equally important to assess the impacts of SME specific or mitigating measures, where they already exist. Quantification of costs and benefits is often difficult and evidence sources should be used to the maximum such as studies, stakeholder consultations, calls for evidence etc.

²⁰⁰ See Tools #53, #54 and #55 on stakeholder consultation

²⁰¹ DG GROW unit H2 coordinates the preparation of these panels

²⁰² See Tool #58 on the *Typology of costs and benefits*; and Tool #59 *Methods to assess costs and benefits*

As part of the overall assessment of competitiveness, it is important to establish the extent to which the proposal affects SMEs' competitiveness or the business environment in which they operate compared to larger organisations²⁰³.

Whenever a threshold is being considered to differentiate the application of a given option on companies, the effects of the threshold on the potential scaling-up of companies should be assessed.²⁰⁴

It is likely that an EU measure would have direct and indirect impacts on SMEs – both positive and negative. The direct benefits such as improved working conditions, increased competition etc. should (at some stage) be reflected in reduced costs to SMEs. Yet, these benefits may be offset by various regulatory costs²³² some of which may be disproportionately felt by SMEs, notably:

- Compliance costs (created by the obligation to pay fees or duties; and costs created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards (e.g. the purchase of new equipment, training of staff, additional investments to be made));
- Administrative costs – created by the obligation to provide information on the activities or products of the company including one-off and recurring administrative costs (e.g. resources to acquire or provide information). This type of costs can be expressed in working hours which makes comparison across Member States easier.

Cost and impacts identified for SMEs should be compared with those of large enterprises. For this purpose, you can for instance **compare the overall costs identified to the number of persons employed to obtain the average cost per employee**²⁰⁵. You could also **compare the costs identified to the total overhead or turnover of the company**²⁰⁶.

In addition, consider the following elements:

- Possible impacts on barriers to entry, competition in the market and market structure, for example in terms of possibilities for SMEs to enter markets;²⁰⁷
- Possible impact on innovation.²⁰⁸

²⁰³ See Tool #20 on *Sectoral competitiveness*

²⁰⁴ For example, in the proposal amending Directive 2013/34/EU disclosure of income tax information by certain undertakings and branches, MNE Groups with a total consolidated group revenue exceeding €750 million will be required to prepare the Country by country reporting. The threshold effect was expressly considered in the IA.

²⁰⁵ It is recommended to use the ranges of the SME definition: 0-9, 10-49, 50-249 and 250+ employees.

²⁰⁶ Representative samples of different size of companies can also be used.

²⁰⁷ See Tool #24 on the *Internal market*

Box 3. Examples of good forward-looking assessments of impacts on SMEs

Examples of summaries of results include:

- Annex 5 to the impact assessment report on Electronic identification and trust services for electronic transactions in the internal market²⁰⁹ (2012) summarises all 4 steps of the SME test. It gives an overview and evidence that SMEs specific concerns were taken into account.
- Impact assessment report on the directive on combating late payment in commercial transactions²¹⁰ contains an annex dedicated to the SME test.

4. HOW TO MINIMIZE ANY NEGATIVE IMPACTS ON SMEs

Step (4) Assessment of alternative options and mitigating measures

The abovementioned analysis may show that micro, small and/or medium sized enterprises are facing a relatively higher burden than large companies and that specific measures, where they already exist, have not proven to sufficiently or adequately address the SME needs. In such case, one might consider the use or the revision of specific measures in order to ensure a level playing field and the respect of the proportionality principle.

The choice of specific measures will be made on a case-by-case basis, including an assessment whether they should apply to all SMEs or, for example, to the micro-enterprises only. However, if there is clear evidence that excluding micro-enterprises would mean that the initiative would not be able to achieve its goals or would undermine other Treaty-based goals or fundamental rights, they should be covered but the possibility to apply adapted solutions should be assessed.

When defining the scope of a mitigating measure, you can make a dynamic reference to the SME definition²¹¹ (for instance in the recitals) and spell out in the Articles of the legislation which criteria and thresholds exactly define the scope of the mitigating measure. Take into account that implementing the whole SME definition or part of it entails an administrative cost, therefore the simpler the criteria, the better. The SME definition criteria are not the only option that can be used (e.g. see Box 3, WEEE directive).

A non-exhaustive list of mitigating measures to be considered includes:

- Complete or partial size-related exemptions (e.g.: businesses below certain thresholds do not have to comply with certain specific obligations when this does not invalidate the original purpose of the legislation);

²⁰⁸ See Tool #21 on *Research & innovation*

²⁰⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0135&from=EN>

²¹⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0315&from=EN>

²¹¹ By using the following reference: "as defined in Commission Recommendation 2003/361 and its subsequent amendments".

- Temporary reduction or exemptions (Example: transition periods during which SMEs are exempted or longer intervals for certain obligations);
- Tax reductions or direct financial aid to compensate costs incurred provided this is compatible with existing legislation on competition or international trade;
- Reduced fees (Example: when these fees are particularly high and/or represent a fixed cost that would be felt disproportionately by SMEs);
- Simplified reporting obligations (Example: in the area of statistics, explore possible synergies with already existing reporting obligations);
- Specific information campaigns or user guides, training and dedicated helpdesks/offices (Example: specific help-desks providing tailored information for small businesses);
- Systematically consider general simplification initiatives which can particularly benefit SMEs (Example: possibility to use on-line facilities such as digital compliance assistance tools, simplified inspections).

When assessing possible mitigating measures, it is important that the costs this could produce are also fully considered and included in the final impact (cost-benefit) assessment. This includes the impacts on larger businesses of any SME specific measures or exemptions and also the effect on the potential scaling-up of companies.

Box 4. Examples of mitigating measures²¹²

- SMEs with fewer than 250 persons would not need to comply with the requirement of the Commission proposal on women on company boards, requiring companies that have less than 40% of non-executive directors to apply transparent selection procedures based on neutral selection criteria in order to attain 40% by 1 January 2020.
- Member States can opt to exempt micro distributors selling non-toxic pesticide formulations from the provisions of Directive 2009/128/EC.
- Small shops selling electrical and electronic devices do not need to reserve extra space to meet take-back obligations under the new Directive on Electric and Electronic Waste. The take-back obligation only applies to retail shops larger than 400m².
- Under the general Data Protection Regulation (EU) 2016/679, the obligations of data controllers and processors are calibrated to the size of the business and/or to the nature of the data being processed. For example:
 - SMEs need not appoint a data protection officer unless their core activities require regular and systematic monitoring of the data subjects on a large scale or if they process special categories of personal data such as that revealing racial or ethnic origin or religious beliefs.
 - SMEs need not keep records of processing activities unless the processing they

²¹² http://ec.europa.eu/smart-regulation/impact/best_practices_examples/docs/eu/lighter_regimes_for_smes_oct_2013.pdf

carry out is not occasional or likely to result in a risk for the rights and freedoms of data subject.

- SMEs will not be under an obligation to report all data breaches to individuals, unless the breaches represent a high risk for their rights and freedoms. .
- EU: Self-employed drivers benefitted from a longer lead-in time before rules on the organisation of their working time (Directive 2002/15) came into effect in 2009.
- Micro-enterprises can now choose simpler ways of showing that any one-off construction products they put on the market meet applicable product standards according to Regulation 305/2011.
- The Commission has made proposals to make it easier for SMEs to participate in public procurement. Bidders for public tenders can provide self-declarations, rather than original documents or certificates, showing that they meet eligibility criteria. Only the winning bidder would be asked to provide the original documents. Breaking tenders down into smaller lots will be encouraged. Together with a greater use of e-procurement, these modernised rules in the proposed Public Procurement Directive would facilitate the participation of SMEs in contracts worth about 18% of EU GDP.
- SMEs are encouraged, but not obliged, to carry out an energy audit according to the new Energy Efficiency Directive 2012/27/EU. Member States may set up support schemes for SMEs, including if they have concluded voluntary agreements, to cover costs both of an energy audit and of the implementation of the highly cost-effective audit recommendations.
- SMEs that are inspected by the European Medicines Agency or use their scientific advice or services benefit from fee reductions of 90%.
- Member States would be forbidden from charging micro-businesses a fee for the licence required to trade in drugs precursors under the Commission's proposal.
- Member States would be forbidden from charging micro-businesses fees under the under the Commission's Food and Feed Controls proposal.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- [SME test webpage](#)
- Report of the Expert Group: [Models to Reduce the Disproportionate Regulatory Burden on SMEs](#)  (2007) and [annex](#) 

EU SME policy framework:

- [Small Business Act - COM/2008/394](#)
- [Review of the "Small Business Act" for Europe - COM/2011/0078](#)
- [Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises: COM/2011/803](#) 
- [Smart regulation - Responding to the needs of small and medium - sized enterprises](#)  COM/2013/122

- [Definition of SMEs in the context of access to financial incentives: Commission Recommendation 2003/361/EC](#) 
- [The revised User Guide to the SME definition](#) 
- [Structural Business Statistics \(Eurostat\)](#)
- [SME performance review \(European Commission\)](#)

6. SUPPORT

SME Test Helpdesk: GROW-SBA@ec.europa.eu

TOOL #23. COMPETITION

1. INTRODUCTION

Competitive markets encourage enterprises to be efficient and innovative, thereby creating more choice for consumers, reducing prices and improving the quality of goods and services. Increased competition contributes to the functioning of the internal market and typically improves a country's economic performance, opens business opportunities to its citizens and reduces the cost of goods and services throughout the economy. When governments intervene in markets to regulate the behaviour of businesses, this can restrict competition further than is really necessary to achieve the desired policy objectives.

2. ARE IMPACTS ON COMPETITION POTENTIALLY SIGNIFICANT?

The checklist below has been developed by the OECD as part of their competitive framework to screen policies for potential detrimental effects on competition. **A more detailed analysis as introduced in sections 3, 4 and 5 should be performed in case of a positive reply to any of the questions in the checklist in Box 1 below.**

Box 1. The competition checklist

Further assessment (and reflection about possibly better policy options) should be performed if a proposed policy option may have any of the following effects:

(A) Limit the number or range of suppliers

This is likely to be the case if the policy option:

- Grants 'exclusive rights' for a supplier to provide goods or services (e.g. many municipalities sign a long-term contract with one single supplier of water, electricity, rail transport, etc.).
- Establishes a license, permit or authorisation process as a requirement of operation (e.g. requirements that only companies which fulfil certain minimum requirements for formal education may perform a certain service).
- Limits in other ways the ability of certain types of suppliers to provide a good or service (e.g. public procurement requirement for suppliers to have many years of experience, will keep out new business and start-ups).
- Significantly raises cost of entry or exit by a supplier (e.g. if it takes too long due to administrative requirements to set up a new firm or too long to close an inefficient firm).
- Creates a geographical barrier to the ability of companies to supply goods or services or to invest capital (e.g. by strict rules for regional development projects).

(B) Limit the ability of suppliers to compete

This is likely to be the case if the policy option:

- Limits suppliers' ability to set the prices for their goods or services (e.g. minimum and maximum prices).
- Limits freedom of suppliers to advertise or market their goods or services (particularly for potential entrants).

- Sets standards for product quality that provide an advantage to some suppliers over others (e.g. by requiring a particular technology or by setting unduly strict standards that are difficult or impossible for the large majority of existing producers to meet) that are above the level that some well-informed customers would choose.
- Significantly raises costs of production for some suppliers relative to others (especially by treating incumbents more favourably than new entrants, for instance exempting incumbents from new rules for a certain period of time or under specific conditions).

(C) Reduce the incentive of suppliers to compete

This may be the case if the policy option:

- Creates a self-regulatory or co-regulatory regime which risks collusion or setting high entry barriers by sector associations.
- Requires or encourages information on suppliers' production levels, prices, sales or cost structures to be published (which could allow cartels to be better policed and the punishment of members if they offer consumers better conditions than those agreed).
- Exempts the activity of a particular industrial sector or group of suppliers from the operation of general competition law (e.g. the EU insurance sector and the motor vehicle retail sector benefit from block exemption regulations that other sectors do not benefit from).

(D) Limit the choices and information available to customers

This may be the case if the policy option:

- Limits the ability of customers to decide from which supplier they purchase (e.g. allowing sale of certain products, for instance e-cigarettes, only in certain type of licensed shops or pharmacies).
- Reduces mobility of customers between suppliers of goods or services by increasing the cost of changing suppliers (recognising this some EU legislation disallow charging consumers for switching cost, for instance on mobile phone services).
- Allows suppliers to confuse customers with misleading, unreliable or rapidly changing information that prevents them from shopping effectively (e.g. telecom liberalisation in some countries may temporarily have led to a multitude of ever changing tariffs that confused, rather than helped consumers to make good choices).

3. KEY CONCEPTS OF COMPETITION POLICY

The first step in a competition analysis is to define the relevant market or markets and to consider concepts such as market power.

The **relevant market** is the market affected by the proposed policy initiative. It combines the characteristics of the products (and services) and their geographic availability, as follows:

A relevant product market comprises all products (and services) which consumers regard as interchangeable or substitutable by reason of their characteristics, their prices and their

intended use (e.g. luxury sports cars are not considered by consumers to be close substitutes with small economy cars, so would not be in the same market).

A relevant geographic market comprises the area in which the firms concerned are involved in the supply of products (and services) and in which the conditions of competition are sufficiently homogeneous (significant differences may include, for example, trade barriers, consumer preferences, language...).

Market power is defined as the ability of a firm to raise prices above competitive levels in a profitable way. Market power can arise due to a variety of reasons and last for a shorter or longer time period. A firm may be able to temporarily increase prices above competitive levels. However, in the absence of market power, such price increases are unsustainable because customers can then switch to other competitors. In assessing competition effects, the key issue is to determine whether the proposed option can lead to an increase in market power, with implications for prices, efficiency and innovation. Any assessment of market power will have to be made in the relevant market.

Once the relevant market (or markets) has been clearly defined, some variables that describe the **structure of the market** should be considered in order to allow for an assessment of whether there may be a negative impact on competition. Those variables include:

- The number of firms;
- The market shares;
- The relative position of competitors;
- The existence of potential entrants; and
- The power of buyers and suppliers.

All these variables will impact on the ability of consumers to switch to competitors in case of a price increase and so will be relevant in assessing market power.

An additional key component of a competition assessment is the evaluation of **barriers to entry**, defined as factors that might hinder the entry of new firms into the relevant market. When important barriers to entry characterise a market, any new regulation imposing additional constraints on competition can cause significant harm. Different types of barriers to entry include:

- Natural barriers, such as strong economies of scale, i.e. cost advantages enterprises obtain due to scale of operation, with cost per unit of output generally decreasing with increasing scale as fixed costs are spread out over more units of output;
- Sunk cost related barriers, i.e. costs that cannot be recovered when a firm chooses to exit a market (e.g. set-up costs that cannot be recouped, advertising expenditure, etc.);
- Barriers created by the conduct of incumbent firms, for example high switching cost and limited access to networks; and

- Regulations by government or professional bodies can impose additional entry barriers (e.g. legal restrictions on new entry in certain sectors (for example licenses, patents, exclusive rights); costly bureaucratic procedures to start new businesses; local professional body certifications (e.g. medicine, law)).

4. PRACTICAL ASSESSMENT OF IMPACTS OF OPTIONS ON COMPETITION:

The following list of questions may help you in your assessment. The proportionality of analysis, as with any aspect in the IA process, will depend on the significance of the competition effects. As a rule of thumb, the higher the market power identified in the relevant market, the more careful your assessment should be (e.g. in a very atomized market structure with low entry barriers, market power is very limited). Please also note that not all of the questions may be relevant for your particular project/initiative.

Impacts	Key questions
Impacts on existing firms?	<u>What is the impact on the cost of meeting the regulation?</u> (1) Is the policy option creating additional costs for existing firms? In case the policy option introduces licences or permits, are additional costs quantifiable? (2) What kind of costs will they impose? Are they mainly fixed (or non-recurring) costs or mainly variable (or recurring) costs? An increase in fixed costs may represent an additional entry barrier. (3) How large are the costs relative to businesses' annual sales revenues? (4) Does the answer in (3) vary by the size of the business? For example, are small businesses more adversely affected? (5) Does the answer in (3) depend on the (old versus new) vintage of a business's capital? For example, are companies with older production facilities more adversely affected? (6) Does the answer in (3) depend on other characteristics of the firms or of the market(s)? (Location, vertically/horizontally integrated, incumbents vs. entrants etc.). For instance, are firms located in different places (urban vs. rural, coastal vs. internal etc.) likely to be impacted differently? <u>What is the impact on the exit of firms?</u> (1) Will these costs/requirements lead some businesses to exit the market? (2) Which businesses are more likely to exit? For instance, can we conclude whether small or large businesses will exit? Can we conclude whether businesses with older vintage of production facilities will leave? In some cases, it could be relevant to make a distinction between the incumbent, dominant supplier and competing firms, which should be encouraged to grow. (1) Does the regulation limit growth opportunities of existing

Impacts	Key questions
	competitors? (2) Does the regulation favour the incumbent over existing competitors? <u>What is the impact on the anti-competitive behaviour of firms?</u> (1) Will it increase the incentive for anti-competitive behaviour of firms (collusion, etc.)? (2) Has there been collusion in the history of the sector? If so, this information should be accounted for in the decision-making process (DG COMP can help to provide such information).
Impacts on entry of new firms?	(1) Does the policy option restrict entry: For all types of entrants? For example, if there is a regulation that limits the total number of pharmacies per 5,000 people, this applies to all types of pharmacies and will limit the extent of competition in the market in a very explicit manner. For specific types of firms? Does it affect new firms/new plants more than incumbent businesses? Does it affect small and medium entrants more than large undertakings? Does it affect foreign firms and not national firms? (2) Does the policy option limit the access to specific resources (e.g. input products, know-how, distribution channels)?
Impacts on prices?	(1) Are prices paid by consumers likely to increase? If yes, what are the likely major factors that will cause prices to rise? An increase in production costs? An increase in market power? Greater information sharing and cooperation among businesses leading to collusion?
"Non-price" impacts on consumers?²¹³	(1) Will the regulation affect the quality and variety of products and consumer choice? If for instance, the regulation sets a minimum of quality standard; or creates barriers to entry. (2) Will the regulation affect the incentive to innovate? If, for example, the regulation creates high barriers to entry through offering long protection periods of reduced entry to incumbents; or prohibits advertising.
Impact on upstream and downstream markets?	Given a firm, its upstream markets are all the market of its suppliers. Its downstream markets are the markets of its clients (that can be both consumers and other firms along the value chain). (1) To what extent is the relevant sector vertically integrated? i.e. do firms own or control other firms in either upstream or downstream markets? Is the policy option likely to affect

²¹³ See Tool #32 on *Consumers*

Impacts	Key questions
	firms that are vertically integrated in a different way compared to firms that are not (e.g. because of the difference in switching costs)? Will the policy option create incentives to increase vertical integration in the market, thereby potentially increasing the entry barriers? (2) How will the bargaining power of buyers be affected? (3) How will the bargaining power of suppliers be affected?

5. HOW TO MINIMIZE NEGATIVE IMPACTS ON COMPETITION

The initial assessment of the competition impact of a policy option may conclude that there are significant risks that competition is weakened. In that case, it is necessary to determine if there is any other feasible policy approach that is less likely to distort competition while still achieving the policy objectives.

The question to ask is whether the anti-competitive elements or provisions are ***strictly necessary*** to attain the policy objectives, or if they could be amended to reduce/eliminate their negative impact on competition. There may be cases where no valid alternative options can be found. Nonetheless, before reaching such conclusion, a thorough analysis of all possible alternative options should be carried out.

Less restrictive measures that can be used in place of more restrictive ones include:

(1) *Tailored transition periods/provisions when adopting new legislation.*

New rules and regulation may place a heavy burden on existing firms who made their investments in production facilities and started operations under the older rules. Since significant changes in the existing structure can be prohibitively costly, in specific cases existing firms can either be exempt or given a specific time-frame to conform. The extent of the adjustment period may also be conditioned on firm-specific characteristics such as technology, vintage of capital, and firm size.

In such cases, it may be useful to carefully consider the implication of transition clauses. It is important to bear in mind that provisions imposing asymmetric standards on existing firms versus newer producers may deter new entry, dampen new investment by incumbent businesses, and allow continuation of inefficient production.

(2) *Using economic incentives rather than regulation to deal with externalities.*

Externalities include environmental, economic, health, safety or other costs/benefits generated by a product and not reflected in its price or cost.²¹⁴

Regulation of the quantity supplied, price or characteristics of externality-generating products or activities is one possible approach of attempting to correct for these

²¹⁴ If a product or activity generates external costs (e.g. negative environmental effects), it will tend to be oversupplied as its full costs are not reflected in its price or marketplace return. Equally, if a product or activity generates external benefits (e.g. technology spill-overs), it will tend to be undersupplied.

externalities. An alternative approach is to use economic incentives, such as subsidies, taxes, or fees, to "internalise" these products' externalities, so it is reflected in their market price. When feasible this approach uses competitive market forces to determine efficient prices, quantities and product characteristics instead of attempting to estimate and regulate outcomes. Another alternative is to create market solutions where none existed before.

Example: The EU Emission Trading System (ETS), by creating emissions rights and permitting trading of these rights, reduced the anticompetitive impacts of setting new emission standards.

(3) *Ensuring adequate consumer information rather than mandatory product characteristics.*

Protecting consumers is often used as a reason to establish mandatory product characteristics. While health and safety protection should generally be achieved by means of product design and manufacture, in some cases, adequate information disclosure may be sufficient, allowing consumers to make informed decisions.

Example: Setting labelling requirements to disclose the content of food products instead of banning those products.

(4) *Voluntary rather than mandatory product specifications.*

Setting product specifications and quality norms is often necessary and may serve the public interest. At the same time, stringent rules and regulation on content and minimum quality can, in some cases, clash with consumer preferences and disadvantage those consumers (e.g. low income consumers) who may prefer to pay a lower price for lower quality.

Voluntary standards can permit suppliers to signal that their products meet certain standards, while allowing them to provide other products that do not meet the standards if some consumers prefer such products (provided that they do not entail additional significant risks).

Example: The EU Ecolabel is a voluntary label helping consumers to identify products and services that have a reduced environmental impact throughout their entire life cycle; it promotes environmental excellence without limiting consumers' choice.

(5) *Reliance on competition law/competition enforcement rather than sector specific regulation to deal with inappropriate competitive behaviour.*

As an alternative to regulation, competition law and competition enforcement provide a generally effective framework for preventing business practices when they are likely to harm competition and consumers, while allowing such practices when they promote competition, innovation and consumer benefits.

Example: In the pharmaceutical sector, patent settlement agreements between originator and generic companies may result in anticompetitive practices, e.g. delaying generic market entry to the detriment of European consumers. The EU approach has been targeted at monitoring the situation and assessing problematic cases individually. As a result, the type of settlements that are likely to raise competition concerns has decreased

significantly in importance and number, while at the same time the overall number of settlements has steadily increased.

6. INFORMATION SOURCES AND BACKGROUND MATERIAL

- The OECD Competition Assessment Toolkit²¹⁵ contains the checklist mentioned above and many useful examples for assessment steps and better option development.
- *Volume 1 ("Principles")* contains a checklist and basic explanations about the interaction between regulation and competition for readers who are not experts in competition policy.
- *Volume ("Guidance")* contains further explanations and examples for readers who want to perform an analysis of competition effects in ex-ante or ex-post assessments of policy instruments.
- *Volume 3 [forthcoming late 2014] ("Operational Manual")* contains further practical examples and recommendations how to conduct a competition assessment regarding a single policy instrument or regarding the situation in a whole sector.
- The following book provides one of the best introductions to competition policy that colleagues in DG Competition recommend:
- *Motta, Massimo (2004): Competition Policy - Theory and Practice, Cambridge University Press.*
- More information about EU competition policy is available on DG Competition's website. Its consumer webpage gives an easily understandable overview for non-experts: http://ec.europa.eu/competition/index_en.html

²¹⁵ <http://www.oecd.org/competition/assessment-toolkit.htm>

TOOL #24. INTERNAL MARKET

1. INTRODUCTION

The Treaty establishes an objective to create a common market with full respect for the four pillars of free movement covering goods, services, capital and workers while paying due attention to legitimate and proportionate public policy interests. In the internal market, all citizens²¹⁶ and companies are treated equally and in a non-discriminatory manner and where the cross-border provision of goods and services should be as easy as within each individual Member State.

The proper functioning of the internal market may constitute the objective of an initiative. It may also constitute an important interest to be borne in mind where the main aim of the initiative is different.

The application of legal bases geared towards the proper functioning of the internal market may raise questions and the Legal Service should be consulted in case of doubt. A few non-exhaustive remarks regarding Article 114 TFEU (by way of prominent example) are described in Box 1 below.

Box 1. Article 114 TFEU

- Article 114 of the Treaty on the Functioning of the European Union provides the legal basis for actions in the area of single market:

"(...) The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market."

- Measures adopted on the basis of Article 114 TFEU should objectively and effectively aim to improve the conditions for the establishment and functioning of the internal market. The risk of impaired functioning of the internal market should be sufficiently concrete: mere disparities between national rules or an abstract risk of infringements of fundamental freedoms or of distortion of competition are not sufficient. Action may also be justified to prevent the likely emergence of such obstacles.
- Article 114 should not be used as legal base if the establishment and functioning of the internal market is secondary or incidental to another objective (e.g. health or environment protection).

All Commission policies should be assessed for their potential effect on the functioning and effectiveness of the internal market. This impact assessment tool consists of a series of questions to help you identify different angles in which your proposal may influence the internal market.

²¹⁶ The term citizen is used in this fiche to comprise different relevant (sub-) groups, including consumers, workers and professionals.

In case it is intended to rely on Article 114, having regard to the criteria set out above, the problem definition should include an analysis of the situation of the internal market. The impact analysis section should also discuss the possible impacts of the different options on the functioning and effectiveness of the internal market.

2. IDENTIFYING PROBLEMS RELATED TO THE INTERNAL MARKET

The questions below can be used at various stages of the IA process. They are relevant for both problem definition and analysis of options:

(1) *Questions to describe market structure, identify internal related problems, market failures their size and drivers*²¹⁷:

- What are the trade flows of goods/services inside the EU and/or between Member States? How many companies do provide relevant goods/services in the EU? Do they operate cross-border? Do they perform intra-EU sale/purchase of goods/services? Are there specific Member States where they operate and others where they are absent – why? What are the revenue and market shares of companies from other EU Member States and of cross-border provision of goods/services? Do companies operate in foreign markets through establishment (e.g. by setting up a branch, subsidiary, joint venture, etc.), or through posting of workers or by providing services?;
- What are the skill and qualification structures of employees/professionals in the EU and in the Member States? How many do work in other Member States? Do they work as posted workers or are they employed on a temporary or permanent basis? Are there barriers imposed by authorities, professional bodies, labour unions, employers (e.g. in contracts or standards or certificates) or other – are they especially burdensome for foreigners/targeting foreigners/foreign qualifications or diploma?;
- If there is no/little cross-border trade, is this because of the type of goods/services that foreign companies provide? Are these goods and services really not tradable? Are there other reasons (e.g. supply or demand specificities at national level like climate, consumer preferences, language, culture)?;
- Are there barriers imposed by market participants (such as territorial constraints on retailers, exclusivity contracts or cooling off periods preventing competition following the termination of a contract)?;
- Can customers buy cross-border (e.g. can they buy in internet stores of the same company located in another Member State)? Is there a discrimination based on origin/nationality/residence – are they treated differently than locals when buying in another Member State for example by receiving different prices, different

²¹⁷ See Tool #14 on *How to analyse problems*

terms and conditions such as ways of payment, delivery options, possibility to return, guarantee, redress, insurance?;²¹⁸

- Are there market-imposed obstacles to the free movement of capital? (e.g. Stock Exchange Rules on listings, additional requirements for reporting or requirements to use certain standards such as Accounting Standards, etc.)? Are any of these especially targeting foreign capital providers? Are there differences in treatment in providing financing by financial institutions (e.g. venture capitalists) to companies (especially SMEs) based on their country of establishment? Are there any differences in treatment by type of funding?
- Are there any barriers to cross-border mobility of citizens or businesses that are caused by poor administrative cooperation or information exchange between public authorities?

(2) Question to identify regulatory failures:

- Is the matter under consideration regulated in some Member States? Are there Member States with no rules at all? What are the underlying reasons in both cases, and are they still valid? Is there a risk for regulatory arbitrage if some Member States have rules and others not? How were the rules implemented in practice? (E.g. rules on protection of "whistle blowers");
- Is the regulatory framework harmonised? Do companies/citizens face different rules/requirements in each Member State?
- In case of different national rules, is there a mutual recognition principle²¹⁹ in place? How does it work? If not, why not?
- Are there regulatory barriers to foreign companies from accessing the market?
- Are they justified by overriding public policy interest? Are they proportionate? Are they cumbersome?²²⁰ For example, is there a need for obtaining permits, certificates, licences, attestations, passing of exams, provision of certified / translated copies of documents; number of documents to be submitted, need for audit, length of procedures; legal form or shareholder requirements, different accounting or reporting rules. Are the rules easy to comply with (e.g. electronically via Points of Single Contact; e-procurement platforms) and are translations readily available?
- Are certain rules more cumbersome for foreigners? (E.g. need for translation, need to appoint a local representative, need for

²¹⁸ Please note that certain EU acts restrict non-discrimination principle, e.g. Rome I Regulation (EC 593/2008) grants the consumer protection of his own national law in case the trader directs its activities to the Member States where the consumer is domiciled. The principle is that consumers should not have lower level of protection than in their home Member States.

²¹⁹ The existing mutual recognition principle covers trade in certain goods as well as recognition of professional qualifications.

²²⁰ See Tool #23 on *Competition*.

additional certificates). Are certain rules easier for foreigners? (E.g. mutual recognition means that companies can accept standards/certificates of other Member State). Is there scope for simplification?

- Is there gold plating – adding local rules to harmonised ones? If so, what are the reasons? Could they discourage cross-border activity? Are there rules in other fields that affect the area under consideration?
- Are the procedures to be followed clear, transparent and publicly available? For example, selection mechanism of tender winner in public procurement, non-publication of tenders; lack of meaningful information about regulated professions;
- Can companies/citizens enforce their rights easily?
- Can different levels of law enforcement encourage/discourage cross-border activity? (E.g. rules exist but are not used);
- What is the cost in terms of time and money to enforce your rights? (E.g. length of court proceedings, etc.)?
- Does the regulated market structure create barriers? For example, very long contracts awarded by authorities that form a barrier to market entry (e.g. highway long term concessions). Is there centralisation favouring large scale (national) suppliers (e.g. medicines)?;
- Does the country of origin/establishment influence the ability to access/transfer capital (e.g. obtaining a bank loan, Venture Capital, listing on stock market, acceptance of payment with a debit/credit card issued in other Member States)? Is the cost of access/move of capital higher for foreigners?

3. ASSESSING IMPACTS RELATED TO THE INTERNAL MARKET

Box 2. Key questions for assessing impacts

- What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers?
- Will it lead to an increase/reduction in consumer choice²²¹, higher/lower prices due to less/more competition, the creation/elimination of barriers for new suppliers and service providers, the facilitation/prevention of anti-competitive behaviour or emergence of monopolies, market segmentation, more or less convergence of consumer and business conditions across the EU, etc.?

Impact assessments might look into problems directly related to obstacles/barriers to the freedom of movement of people, goods, services and capital in the Single Market (a possible corresponding objective being to remove market distortions for companies, workers and consumers). An impact assessment might also look into other policy issues,

²²¹ See Tool #32 on *Consumers*.

but the options under analysis could impact the functioning and effectiveness of the Single Market. As a general rule, you should be careful not to concentrate only on long term or short term effects as costs are usually born in the short term while benefits generally materialise in the long term.

You should also consider the distribution of impacts. Some benefits and/or costs may concern, or concentrate among, selected groups only. Therefore, you need to identify the stakeholders, regions or Member States who will be most affected (e.g. in a given sector, benefits can be similar for all companies, but costs to SMEs can be bigger (as % of turnover or better profit margin) than for large companies)²²².

You could further consider using benchmarks to assess the level and effectiveness of market integration, such as goods market and services markets, trade between Canada and USA, trade between US states or trade between EU/EEA Member States.²²³

3.1. Identification and measurement of potential direct impacts of options

Based on the evidence gathered in the problem definition phase regarding the additional barriers/burdens borne by citizens and companies involved in cross-border activities, the most probable direct impacts on internal market of the policy options should be identified and measured, including their impact on the identified barriers/burdens.

This should be done by identifying the potential costs and benefits under the various policy options in relation to the baseline scenario of complying with all the national rules for a company that wants to do business in another Member State, or the extra burden a citizen would face when trying to work/shop in another Member State.

In order to estimate the costs and benefits of EU action, you need to have adequate data on the situation in the Member States. This data should ideally describe the current situation in the Member States, as well as projected savings/costs due to EU action. You may use a variety of data sources, including constant monitoring of the situation in the Member State, expert groups, representative surveys (e.g. Eurobarometer), dedicated enterprise surveys (Enterprise Europe Network, SME panels), external studies and public consultations²²⁴.

In many cases, the main benefit of internal market harmonisation/rules lies in cost savings following the replacement of 28 different national rules and procedures that companies and citizens face with one harmonised EU regime or by creating the 29th (EU) regime (e.g. costs of patenting fees for an EU unitary patent vs. 28 national patents).

To estimate the potential savings of the internal market / the costs of ‘no-internal market’ you could consider the following conceptual model:

(1) Calculation of individual company/citizen savings/costs following the replacement of national regimes by an EU-wide one.

²²² See Tool #22 on *The SME test*.

²²³ See Tool #26 on *External trade and investment*.

²²⁴ See Tool #4 on *Evidence-based better regulation*.

- ‘Baseline scenario’ (national rules/regimes): what is the cost per company of following the current regime(s) assuming that it wants to cover/serve all Member States (e.g. obtaining patent protection in each Member State)? Under alternative scenarios e.g. only a subset of Member States and related costs can be considered such as following the actual behaviour of companies who choose to protect their patent only in a limited number of Member States).
- ‘EU scenario’(harmonised EU rules/regime): what is the cost of following just one EU regime (e.g. obtaining EU unitary patent)

(2) *Extrapolating the above individual-level costs and benefits/cost savings (for companies or citizens) to the whole sector/market or population.*

To make this kind of calculation, detailed data per company and Member State on the costs related to the current regime(s) is necessary (e.g. one-off and recurring costs for each procedure, including required staff and working time, legal representation, translation costs, etc.). In addition, you need to estimate (ranges of) the costs that a future single EU regime would impose and changes in company behaviour regarding cross-border trade and investment that would follow.²²⁵

To extrapolate the above calculated costs and benefits to estimate the cumulative costs and benefits for the whole sector/market or population, and eventually the whole EU, a distinction has to be made between static and dynamic scenarios:

- In a static scenario, one takes the number of companies that are active cross-border as given and uses it to multiply the cost estimates per company obtained under point (1) for both 28 regimes and the EU regime for all scenarios analysed under the baseline.
- In a dynamic scenario, estimation is needed of the expected change in the number of companies' active cross-border in the baseline case and, following the EU regime. The cost estimates per company obtained under point (1) then have to be multiplied by the number of companies active cross-border in a new dynamic baseline and the estimated number of companies active cross-border under the new harmonised EU regime, respectively.

For quantifying costs you may also consider following the **Single Market Gap** procedure suggested by CEPS in their 2014 study for the European Parliament on "Indicators for Measuring the Performance of the Single Market – Building the Market Pillar of the European Semester"²²⁶.

3.2. Identification and measurement of the Single Market benefits

You should strive to assess the benefits of the internal market especially for consumers, companies and employees. These could be direct (e.g. free movement of citizens) and indirect (e.g. more choice and lower prices due to increased trade and competition).

²²⁵ See Tool #59 on *Methods to assess costs and benefits*

²²⁶ For more explanation and detailed examples, [see page 70 of the full report](#).

The benefit analysis is usually qualitative due to inherent measurement difficulties. However, whenever possible use should be made of quantitative measures. Some examples are presented below on how to measure market integration:

Benefit	Measurement
Trade creation: trade between Member States, improved value chains, outsourcing of goods and services, more trade in internal border regions (especially for services dependent on geographical proximity).	Export/Import to GDP, degree of price dispersion/convergence, wage dispersion/convergence
More competitive markets: leads to bigger choice, higher quality and lower prices to consumers, continuity of supply, lowering switching cost.	Foreign Direct Investments (outward and inward) to GDP, delivery of services through establishing affiliates; Hirschman-Herfindahl index (HHI); dispersion of consumer prices and their evolution over time; choice and switching in consumer markets; consumers' and businesses' confidence in cross-border (online) transactions ²⁵⁷ .
Gains in efficiency/productivity: economies of scale and scope.	These efficiency gains measured using unit labour costs — defined as the ratio of total labour costs (total hours worked multiplied by the hourly wage) to Gross Value Added, deflated by the Gross Value Added price index. Productivity increases due to backward- and forward-linkages in the value chain/across sectors.
Innovation: sufficient demand to recuperate development cost for product and process innovation.	Expenditure in Research, Development and Innovation (RD&I), number of personnel employed in RD&I activities, number of patents and innovative activity. Expenditure for digital transformation of business models.
Free movement of people: job opportunities in other Member States, studying abroad, labour mobility, commuting, 'brain gain'	EU citizens working in another Member State as % of total labour force, number of exchange students, cost of qualification recognition procedures; international comparisons also indicate that cross-border mobility between EU Member States is limited compared to other regions (such as United States, Canada or Australia).
Free movement of capital: More investing opportunities, diversification	Interest rate convergence, foreign listing, share of foreign assets/liabilities in financial sector
Policy influence and synergies, cooperation and coordination	Synergies from having common approach, common institutions, elevating influence of individual MS. Coordination of policies (reduced likelihood of retaliatory actions, addresses coordination failures) Mainly qualitative description.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

3.3. Identification and measurement of the Single Market costs

The same holds for the analysis of costs. A list of potential sources is given below.

Cost	Explanations
Trade diversion	Preference to trade within EU rather than with outside world (share of trade with non-EU countries).
Adaptation cost	Cost for companies to face bigger competition. Possible unemployment in non-competitive sectors. Different market structure (players, supply chains).
Employment and companies	Potential for loss of employment in uncompetitive/unregulated sectors/companies (at least in short term), bankruptcy of underperforming companies; ‘brain drain’; other possible social impacts and/or fundamental rights impacts. ²²⁷
Impact on national budgets	Tax arbitrage, tax avoiding schemes; unemployment benefits for redundant workers.
Costs for EU budget	The functioning of the Single Market might require dedicated administrative bodies financed by Member States.
Administrative costs	Costs for companies to comply with new information requirements.
Compliance costs of regulation	Cost of applying EU rules.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

4. HOW TO MINIMISE NEGATIVE IMPACTS ON THE INTERNAL MARKET

The institutions are in principle bound by the fundamental freedoms of the Treaties. As a consequence, certain negative impacts on the internal market may be outright prohibited. This applies in particular to discriminations based on nationality or residence. Impacts that would lead to the illegality of the measure need in all cases to be excluded.

For the purpose of minimising potential negative impacts on the functioning of the internal market beyond these legal requirements, and depending on the circumstances, you can consider including the following into your options.

In relation to the content of a policy option:

- Promoting standardisation (e.g. IFRS accounting rules for listed companies; codes of conduct, European standards, model documents, eGovernment action plan principles, European catalogue of standards, DSI technical specifications and standards, etc.);
- Promoting transparency and information (preferably in multiple languages) – e.g. setting information points/one stop shops for (e.g. Points of Single Contact), digital by default and digital once-only principles;
- Limiting any unnecessary administrative and private obstacles to cross-border movement/trade;

²²⁷ See Tool #29 on *Employment, working conditions, income distribution social protection and inclusion*.

- Mutual recognition, harmonisation and best practice dissemination;
- Exploiting synergies and/or implementing relevant mitigating measures in other related policy areas (competitiveness, social/employment, fundamental rights).

In relation to the policy instrument:

- Regulations can limit the risk of "gold-plating" associated with the transposition by Member States of Directives;
- Consider an EU regime of common rules that could be applied in cross-border situations without changing national rules (e.g. the European Common Sales Law);
- Limiting to a bare minimum the number of implementation options in directives;
- Use of IT solutions to foster access to information (e.g. e-procurement; SOLVIT; Points of Single Contact);
- Exchange of information between authorities (e.g. Internal Market Information system, RAPEX);

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- "Indicators for Measuring the Performance of the Single Market – Building Market Pillar of the European Semester".
[http://www.europarl.europa.eu/RegData/etudes/STUD/2014/518750/IPOL_STU\(2014\)518750_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2014/518750/IPOL_STU(2014)518750_EN.pdf).
- Optimal Integration in the Single Market: A Synoptic Review.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224579/bis-13-1058-europe-economics-optimal-integration-in-the-single-market-a-synoptic-review.pdf

TOOL #25. PREVENTION OF FRAUD

1. INTRODUCTION

Fraud can have a significant negative impact on EU policies, both financial and reputational. Financial fraud affects the objectives of EU action by reducing the amount of financial support available for achieving the desired positive impacts. Non-financial fraud can undermine the trust that citizens and other stakeholders have in the Union's actions and institutions and impair product safety, consumer protection and public health where certification is obtained fraudulently.

For most policy proposals, (the reduction of) fraud is not a primary impact to be assessed in the accompanying impact assessment (IA). It should however in all proposals be considered as an indirect or second round impact²²⁸ when assessing different options in the IA, both in financial and reputational terms.

Taking the anti-fraud dimension into consideration in the IA would help both the policymaker and the Legislator better understand the wider implications of the risks associated to various policy options and allow them to identify mitigating factors at an early stage. Taking fraud into account in the IA should come in addition to consulting OLAF in the context of interservice consultations and should complement OLAF's fraud proofing efforts under the Commission Communication on fraud proofing (COM(2007) 806 final)²²⁹. OLAF has an anti-fraud website which can provide assistance and support.²³⁰

2. DEFINITION OF FRAUD

The Convention on the protection of the European Communities' financial interests²³¹ defines fraud, both in expenditure and revenue, in its first Article as follows:

- (1) For the purposes of this Convention, fraud affecting the European Communities' financial interests shall consist of:
 - (a) in respect of expenditure, any intentional act or omission relating to:
 - the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds from the general budget of the European Communities or budgets managed by, or on behalf of, the European Communities;

²²⁸ See the better regulation Guidelines page 26, 3rd bullet point

²²⁹ COM(2007) 806 final Prevention of fraud by building on operational results: a dynamic approach to fraud-proofing

²³⁰ <https://myintracomm.ec.europa.eu/serv/en/fraud-prevention/Pages/FraudPrevention.aspx>

²³¹ Official Journal of the European Communities, C 316, Volume 38, 27 November 1995

- non-disclosure of information in violation of a specific obligation, with the same effect;
 - the misapplication of such funds for the purposes other than those for which they were originally granted;
- (b) in respect of revenue, any intentional act or omission relating to:
- the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the illegal diminution of the resources of the general budget of the European Communities or budgets managed by, or on behalf of, the European Communities;
 - non-disclosure of information in violation of a specific obligation, with the same effect;
 - misapplication of a legally obtained benefit, with the same effect.

The definition above focuses on the financial impacts of fraud. Non-financial impacts can take many forms and cannot be captured by a single definition. However, the common feature is the intention to defraud. This distinguishes fraud from errors or mistakes. The act or omission is made intentionally, very often for personal gain.

Because of the fraudulent intention of the person or organisation committing the act or omission, they will also try to hide it. This makes detection difficult.

Box 1. Examples of fraud

Fraud with financial impact

A beneficiary of European funds has submitted documents stating the beneficiary has fulfilled its contractual obligations, whereas, in reality, it did not implement the project at all. EU funds are thus not used to pursue the desired outputs.

Fraud with non-financial impact

A European production company has provided documentation stating that its products meet certain quality criteria. Based on that documentation, the producer has obtained a European certification for its products. Although the false representation by the producer does not have negative financial consequences for the EU, it will have a negative impact on the reputation of the European certification.

3. ASSESSING OPTIONS FOR FRAUD

OLAF's experience with preventing and investigating fraud shows that the design of (spending) programmes is the first step in effective fraud prevention. OLAF and other Commission services have encountered many types of fraud that had negative economic and social impacts. When screening policy options for fraud, it is important to keep in mind that fraud – or its (partial) avoidance – is often not a direct impact, but an indirect or second round impact, which could require some imagination, factual assumptions and approximation to establish.

The assessment of the impact of fraud on the policy proposal should be integrated as much as possible in the assessment of other (significant) impacts by asking the following questions:

- How can deception adversely affect the desired impacts of this policy?;
- To what extent do the options identified rely on statements or documentation from parties involved in the implementation?;
- Are there significant differences in terms of negative impact of fraud between the different identified options?;
- What is the nature of the identified impact? Does the impact depend on the type of management, the area of spending, or on other particularities?;
- With regard to the type of management, which financial implementation mechanism will be followed and how does this influence the impact of fraud? E.g. will financial assistance be provided through procurement, grants, financial instruments, etc.?

4. HOW TO REDUCE THE NEGATIVE IMPACT OF FRAUD

Fraud is per definition hidden and a reduction of fraud is therefore by nature difficult to measure with precision. However, there are several options / actions that can reduce negative impacts at an early stage of policy development and could be taken into account in IAs.

- **Increase transparency.** Increase the transparency of the envisaged policy options, for example by requiring to make certain statements public or publish findings about the implementation of the policy, with due respect for the protection of personal data.
- **Diversify the sources of information.** Where funding relies on contractors' or beneficiaries' statements on their compliance with the financing conditions or certification criteria, the policy makers should think of ways of collecting information from other sources for verification purposes.
- **Include the anti-fraud dimension in the framework of checks and audits.** When designing control measures in the programme that oversee the compliance of stakeholders, make sure that checks and audits take account of an anti-fraud perspective. In ex-ante controls, the aim would be to prevent fraud, whereas ex-post controls are an important tool for the detection of fraud.
- **Prevent conflicts of interest.** When one of the components of the policy being assessed is to work with independent experts, prevention of conflict of interest should be envisaged. This could take the form of self-declarations on the absence of conflict of interest by the experts and exclusion or other sanctions when conflicts of interest are detected (and the self-declaration turned out to be inaccurate).

5. STANDARD ANTI-FRAUD CLAUSE

OLAF has developed a standard anti-fraud clause for inclusion in legislative proposals that involve EU expenditure. The fraud clause was developed on the basis of OLAF's investigative experience and addressed issues that could be relevant for the impact assessment as well. This fraud clause is for example used in the Horizon2020 programme and is presented in this tool for consideration.

Box 2. Standard anti-fraud clause - Protection of the financial interests of the Union

- (1) The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and inspections and, if irregularities are detected, by recovery of the amounts unduly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
- (2) The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot checks and inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under the programme.
- (3) OLAF may carry out investigations, including on-the-spot checks and inspections in accordance with the provisions and procedures laid down in Regulation (Euratom, EC) No 2185/96²³² and Regulation (EU, Euratom) No 883/2013²³³, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under the programme.
- (4) Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct audits and investigations, according to their respective competences.

6. SUPPORT

OLAF Unit D.2 (Fraud prevention, reporting and analysis) can provide further assistance:

OLAF-FMB-D2@ec.europa.eu

²³² Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities, OJ L 292, 15.11.1996, p. 2.

²³³ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999, OJ L 248, 18.9.2013, p. 1.

TOOL #26. EXTERNAL TRADE AND INVESTMENT

1. INTRODUCTION

External trade and investment are powerful engines for growth and job creation. As tariffs have largely been dismantled, disproportionate regulatory requirements or unnecessarily divergent regulations have become the main barrier to trade. It is more difficult to identify them and to quantify their impacts than it is for tariffs or measures applied at borders. This is particularly true for services which, given their intangible nature, are often hard to identify in statistics and other analyses.

Regulations and standards adopted in pursuit of various public policy objectives may constitute technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) and other non-tariff measures (NTM) which can have significant impacts on both exports and imports, requiring firms to spend resources to adapt their products, duplicate testing of safety requirements, undergo burdensome certification procedures, interpret and comply with several sets of legislation, etc.

EU legislation must comply with the EU's existing international legal commitments. The EU is legally bound by a large number of international trade agreements: first and foremost, the World Trade Organisation Agreements; but also bilateral and multilateral agreements containing provisions on trade in goods, services, intellectual property or investment matters, some of which go considerably further than the WTO Agreements. It is important, therefore, to ensure that EU legislative proposals are consistent with international legal commitments.

While the IA certainly does not constitute a legal assessment of the WTO compliance of regulatory measures, it is important that services systematically take account of the broad legal obligations associated with our trading regime in the formulation of policy options.

Any option which is clearly in breach of the EU's international legal obligations should be discarded at an early stage.

2. SCREENING OF OPTIONS AGAINST THE EU'S INTERNATIONAL LEGAL COMMITMENTS

When designing the options, the following issues should be considered:

2.1. Consistency with the WTO Agreements

The WTO Agreements cover a wide range of issues. A full-fledged analysis of WTO compatibility can only be done by specialist lawyers. However, at the stage of identifying options in the context of an IA, it is important to rule out those that would in all likelihood lead to an outcome incompatible with WTO obligations. The IA should focus only on options that are, in principle, legally viable. In this regard, certain basic questions should systematically be considered when designing the options:

- Does the option allow imported goods or foreign service suppliers to enter the EU market?

- Does the option ensure non-discrimination (legally or in fact) between imported goods or foreign service suppliers, and EU goods or EU service suppliers (national treatment principle)?
- Does the option ensure non-discrimination (legally or in fact) between goods or services of different third countries (most-favoured nation principle)?
- If the option involves product requirements that would be covered by the Technical Barriers to Trade Agreement²³⁴, can you demonstrate that the requirements are proportionate to the objectives pursued?
- If the option regulates the movement of goods on sanitary or phytosanitary grounds, is it based on a risk assessment supported by sound scientific evidence?
- Is the option compliant with rules on subsidies, intellectual property and procurement?

Box 1. Trade agreements and the pursuit of legitimate public policy objectives

Article XX of the General Agreement on Tariffs and Trade (GATT) allows governments to adopt trade-restrictive measures in order to, among others, protect public morals and human, animal, or plant life or health, provided that they do not entail unjustifiable discrimination or constitute disguised protectionism²³⁵.

The Sanitary and Phytosanitary Measures Agreement or SPS

- WTO Members can set their own standards based on a risk assessment underpinned by science. Restrictive measures should be applied only to the extent necessary to protect human, animal, or plant life or health. They should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.
- WTO Members must rely on international standards, guidelines and recommendations where they exist. However, if those international standards do not achieve the required level of protection, WTO Members may use measures which result in higher standards if there is scientific justification.
- The SPS agreement includes provisions on control, inspection and approval procedures. Governments must provide advance notice of new or changed sanitary and phytosanitary regulations, and establish a national enquiry point to provide information.

The Technical Barriers to Trade Agreement (TBT)

- The agreement seeks to ensure that technical regulations, standards, testing and certification procedures do not create unnecessary obstacles to international trade. Domestic measures shall not be more trade-restrictive than is necessary to fulfil a legitimate objective.
- Procedures used in order to decide whether a product conforms with relevant

²³⁴ Please refer to http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

²³⁵ http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm#TRS

technical regulations have to be fair and equitable. The agreement discourages methods that would give domestically produced goods an unfair advantage and encourages mutual recognition of standards and procedures.

- WTO Members are required to establish national enquiry points and to keep each other informed through the WTO. Around 900 new or changed regulations are notified each year.

2.2. Consistency with the EU's Free Trade Agreements or the customs union with Turkey

The EU has free trade agreements (FTAs)²³⁶ or other trade agreements with many countries in the world (South Korea, Colombia, Peru, Central America, Southern Mediterranean countries, Chile, Mexico, South Africa, etc.), and is currently negotiating several others. The more recent agreements contain detailed provisions on regulatory matters, some dealing with specific sectors (cars, electronics, pharmaceuticals etc.). They also regulate – in more detail than the WTO Agreements – trade in services, investment or intellectual property; and often have further-reaching provisions on procurement. The customs union with Turkey focuses mainly on border measures, but also seeks to promote the convergence of laws in areas such as intellectual property rights (IPR) and competition.

2.3. Consistency with investment protection provisions/agreements

Investment protection provisions can be found in Member State agreements²³⁷, and in the Energy Charter Treaty; and will be found in FTAs currently under negotiation or in future specific investment agreements. Generally, they cover discrimination against investors and their investments, unlawful expropriation (including indirect expropriation) without a public purpose, compensation provisions and arbitrary treatment of the investment. Any option that is clearly in breach with the EU international legal obligations should be discarded upfront.

2.4. Other legal effects

Two additional elements should be considered when designing the options. Through Agreements on Conformity Assessment and Acceptance of Industrial Products²³⁸ (ACAAs) with some neighbouring countries, the EU has “expanded its regulatory space” in some particular sectors. In these sectors, ACAA-countries have aligned their law to the EU acquis and would, therefore, be affected by any legislative changes. When designing an option in a sector covered by an ACAA, attention should be paid to the administrative capacity of partner countries to implement this new EU legislation.

²³⁶ For further detail, please refer to <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/>

²³⁷ For a list of investment agreements between Member States and third countries, see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:131:0002:0098:EN:PDF>

²³⁸ For more on ACAA, please see http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/aca-neighbouring-countries/index_en.htm.

On the other hand, the EU has concluded Mutual Recognition Agreements (MRAs) with some trade partners (US, Japan, Canada, Australia, New Zealand, and Switzerland) which cover some specific sectors. In some situations new EU rules (for example on testing of products) might not apply to all our imports.

3. HOW TO ASSESS IMPACTS ON EXTERNAL TRADE AND INVESTMENT

A series of questions should be examined when analysing the potential economic impact of the options considered:

3.1. Which economic agents should be considered?

A regulation may have a trade impact on various types of firms. Producing firms are also consumers of intermediate goods and services produced by other firms (such as raw materials, components or business services). The linkages between firms (the so-called value chains) are growing in importance as firms increasingly outsource parts of their production to subcontractors, often abroad. The impact analysis should therefore not restrict itself to the direct effects of the options on the specific sector concerned, but should also consider the sectors and firms along the value chain. The EU's main trading partners are US, China, Russia, Switzerland, Norway, Turkey, Japan, and Canada.

It is also important, for instance when consulting stakeholders in the IA context²³⁹, to provide equal opportunities for third country operators and EU importers to express their views. Open trade, and the competition it generates, usually benefits retailers and wholesalers, allowing them to increase sales and/or profits and/or create jobs. Firms that need to source goods or services abroad for their production activities similarly benefit. Some operators may however be negatively affected by exposure to greater competition from foreign firms. Consumers as a group generally benefit from open markets, which increase choice. They may also benefit from lower prices (though this will be dependent on the price sensitivity of the market).

3.2. How will the options affect European exports?

Exporters will be directly affected by measures which increase the costs of production in the EU, and thus either reduce their profit margins or render their products more expensive (i.e. less competitive) in third markets. Exporters which are part of value chains and dependent on inputs from third countries will also be affected by barriers affecting their imports (see 3.3).²⁴⁰

3.3. How will the options affect European imports, and value chains in general?

The costs of compliance with a new regulation may make imported products or operators uncompetitive and have, therefore, the effect of an indirect trade barrier, even if the legislation as such is not (formally) restrictive or discriminatory. Many EU firms are dependent on inputs from firms based in third countries. Shutting EU firms off from

²³⁹ See Tools #53, #54, and #55 on stakeholder consultation

²⁴⁰ See Tool # 20 on Sectoral competitiveness

global value chains may jeopardise economies and jobs (importers also contribute to jobs and growth in Europe).

As a general rule, the analysis should consider effects throughout the whole value chain, in respect of EU firms dependent on imports but also EU firms competing with imports. The relationship between sectors within the EU can be found in EUROSTAT's input-output table, while the relationship between sectors in the EU and sectors in third countries can be found in the UN Broad Economic Categories (BEC) classification (see also www.wiod.org).

3.4. How will the options considered affect investment flows?

Could the options considered affect costs to such a degree that it could have an impact on investors' foreign direct investment (FDI) decisions? For both EU and foreign firms, there is a risk of relocation if a regulation is thought to be too costly. Conversely, if a regulation is seen as comparatively inexpensive to comply with, it can provide incentives for further FDI in the EU.²⁴¹ Policy options may also affect decisions on investment location through other means than costs.

For an example of an IA analysis of investment flows, please see the Impact Assessment on an investment agreement between the European Union and the Republic of China.²⁴²

3.5. Does the option affect the potential for trade in services?

Trade in services differs in character from trade in goods in that it may be "invisible" and non-tangible. Virtually all commercial services are tradable, if not by traditional cross-border trade, then by accessing the foreign market as an investor and selling services through a local affiliate. Assessment of policy options affecting service providers from third countries should be undertaken.

3.6. Could developing countries be affected?

Article 208(1) of the Treaty on the Functioning of the European Union (TFEU) sets a legal obligation to ensure policy coherence for development (PCD) by providing that the EU "*shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries*".

Developing countries are very heterogeneous. The 2012 Communication on "Trade, Growth and Development" sets new policy orientations for the EU's policy on trade and development for the next decade. In particular, it prioritises Least-Developed Countries (LDCs) and other countries most in need.²⁴³ The following questions should be examined in particular:

- (1) *Are the products covered by the proposal disproportionately produced in developing countries, particularly LDCs and other countries most in need?***

²⁴¹ See Tool # 20 on *Sectoral competitiveness*

²⁴² The IA report is available at http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2013/swd_2013_0185_en.pdf

²⁴³ See Tool #34 on *Developing countries*

The ACP-EU Partnership Agreement²⁴⁴ obliges the EU to inform the ACP States in good time of any intention to take a measure which might affect their interests. The CARIFORUM-EU Economic Partnership Agreement contains a similar obligation with regard to bananas, rice, rum and sugar.

(2) *Will the proposal have an impact on the competitiveness of exports from developing countries, particularly LDCs and other countries most in need?*

Developing countries should not face obstacles that make their preferences (preferential access to the EU market through lower or zero tariffs) impossible to use in practice, i.e. situations where their cost competitiveness from the preferences is eroded by the costs imposed on them by the regulations. Adjustment costs are normally much higher and may be prohibitive for firms in developing countries. This needs to be considered when enacting regulations for products which are important exports for developing countries.

Such an analysis is particularly important for LDCs and other developing countries very dependent on a few export commodities and therefore easily affected disproportionately by the proposal. Particular attention should be paid if vulnerable groups in the developing countries are affected negatively.

3.7. *Will the proposal increase or decrease regulatory convergence with the main trading partners?*

Unnecessary regulatory differences between the EU and its trading partners can reduce or even prevent trade and investment. Beyond the internationally applied regulations and international norms or agreements with which the EU is legally bound to comply (e.g. the WTO TBT, SPS agreements), it is important to verify whether the proposal will be in line with any other non-binding international arrangements between the EU and third parties, or with initiatives which the Commission or Member States are pursuing at a global level (i.e. harmonisation of technical regulations or standards in UNECE, ICAO or ITU).

It is also important to assess whether the options considered will contribute to greater regulatory convergence with the EU's main trade partners (such as US, Japan, China).

When developing a new regulation or standards, the analysis should include an assessment of the main regulations affecting the products/services covered by the proposal in major third countries' markets, and a comparison between these regulations and the options considered.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON EXTERNAL TRADE AND INVESTMENT

Unnecessary trade distortions can be avoided or minimised by considering the following elements:

²⁴⁴ Article 12 of the Cotonou Agreement, signed in Cotonou on 23 June 2000, revised in Luxembourg on 25 June 2005 and revised in Ouagadougou on 22 June 2010.

- When the European Commission gives a mandate to standardisation bodies to develop a new standard, those bodies should be instructed to consider, as a basis for European standards, international standards that are in use in the global marketplace. This is in line with the WTO TBT Agreement.
- The TBT and SPS agreements in the WTO require all WTO members to notify draft technical regulations and conformity assessment procedures that might have a significant impact on international trade to the WTO TBT and SPS committees for scrutiny. This forum provides a good opportunity to avoid unnecessary trade friction with third countries before technical regulations are adopted and develop into barriers.
- The Commission has a number of regulatory dialogues or high level platforms with third countries in a multitude of areas, ranging from product safety, information society, raw materials and energy to financial services, in particular with the US, but also with China, Japan and Russia. If the issue to be addressed by the draft legislation is discussed in some form by an existing regulatory dialogue with a third country, it will be useful to take account of the state of play of discussions so as to avoid any contradictory outcomes and unnecessary trade barriers.

5. INFORMATION SOURCES AND BACKGROUND INFORMATION

- For further DG TRADE support, documents and guidance please find a dedicated functional mailbox: trade-and-investment-impacts@ec.europa.eu
- For information about [WTO rules](http://www.wto.org/english/docs_e/docs_e.htm), see http://www.wto.org/english/docs_e/docs_e.htm
- For a list of EU trade agreements see <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/> and for a list of investment agreements between Member States and third countries see <http://ec.europa.eu/trade/policy/accessing-markets/investment/>
- Information is available from the following freely available databases about:
 - which countries produce and export to the EU the goods or services covered by an initiative and what is the value of this trade (EU imports)
 - to whom the EU exports the goods or services covered and the value of the trade
 - which countries invest in the sector/s in the EU affected by the legislation and what is the value of these flows and stocks of investments
- [EUROSTAT – COMEXT that include the EU28 imports and exports](http://ec.europa.eu/eurostat/data/database) of goods with all partners and all products disaggregation (see <http://ec.europa.eu/eurostat/data/database>).
- [WITS and UN COMTRADE that cover trade in goods](#) of all countries in the world with all the partner countries.

- [EUROSTAT – Balance of Payments statistics](http://ec.europa.eu/eurostat/data/database) that covers trade in services and FDI by partner country and product (see <http://ec.europa.eu/eurostat/data/database>).
- To [distinguish between final goods and input goods](#), please refer to the United Nations Broad Economic Categories (BEC).
- Hyperlink to Communication on Competitiveness proofing http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2012_0091_en.pdf

TOOL #27. THE DIGITAL ECONOMY AND SOCIETY & ICT ISSUES

1. INTRODUCTION

Digital technologies²⁴⁵ such as the internet, social media and mobile devices have already transformed daily life but their influence is expected to grow yet further. The design of digital and non-digital policies will need, therefore, to capture these digital influences.

New initiatives should also be coherent with the Digital Single Market and be fit-for-purpose in both digital and physical worlds. The implementation of almost any new EU legislation will also require the support of ICT systems²⁴⁶. Early identification and analysis of these ICT requirements will make it easier to design timely solutions that are acceptable to stakeholders including Member State administrations.

2. THE “DIGITAL CHECK”

The “digital check” in Table 1 comprises a series of questions designed to identify the precise digital aspects or ICT needs of each new initiative. If a digital dimension is identified, DG CNECT and/or DG DIGIT should be asked to participate in the relevant interservice group and to help with any detailed assessment and analysis.

<i>Table 1. "Digital check": questions to identify support needs</i>	YES
Are the expected evolution of the problem and the baseline significantly influenced by digital technologies? (see section 3 below)?	Discuss with DG CNECT and inform DG DIGIT (and/or seek help from external experts)
Does a particular policy option respond to problems only in the physical world (and not in the digital world)?	Discuss with DG CNECT and inform DG DIGIT (and/or seek help from external experts)
Might the option considered be incoherent with the EU's digital policies currently in place (such as eGovernment action plan ²⁴⁷ , reuse of existing solutions for electronic identification, signature, delivery and invoicing), under development or revision, and might the option have an impact on digital infrastructures/service levels (see sub-section 3.5.3 below)?	Discuss with DGs CNECT and DIGIT (and/or seek help from external experts)
ICT systems / solutions	
Is there a need to support the initiative by establishing new or revising existing ICT solutions?	Discuss with DG DIGIT
Is there a need to develop, migrate and/or operate any kind of new or existing IT system, network or service over the internet or private networks. It could be that ICT is in the core of the legislation or a supporting driver of it.	

²⁴⁵ Note that for explanations on specific Information Technology terms and acronyms, you can refer to the [DG CNECT Glossary](#) and [List of Acronyms used in DG CNECT](#).

²⁴⁶ For example, cross-border exchange of information between authorities such as criminal records, asylum seekers' data and passenger data; the delivery of online public services to citizens and/or business such as business registries, land register data, professional certifications; and information processing and publication through web-based Portals, etc.

²⁴⁷ COM(2016) 179

<i>Examples:</i> • Member States competent authorities apply checks using the <u>Schengen Information System II</u> at the Schengen area borders and policy and judicial authorities cooperate in relation to criminal matters; • Member States administrations cooperate by making use of the <u>Internal Market Information system under the IMI Regulation (EU) No 1024/2012</u>; Member States <u>interconnect their business registers</u> and notify each other about changes to those registers.	
Is there a need to establish new or change existing business processes that handle information/data in an electronic/automated manner? "Business process" means a sequence of activities to produce a specific result. Today, most of those activities can be automated by IT systems and tools and executed through electronic workflows that collect, store, retrieve, consult, filter, exchange, report data (text, image, or video). <i>Examples:</i> • The Commission receives a request by organisers to run a "signature collection" campaign in line with the European Citizens Initiative Regulation. Signatures have to be <u>collected by the organisers and validated</u> by the national competent authorities and the Commission to be informed of the result; • Industrial installations and aircraft operators have to <u>report</u> on CO₂ emissions under the EU's Emissions Trading System; • National authorities have to <u>exchange information</u> on criminal records. • National authorities have to harmonise and exchange geospatial environmental information for e-reporting obligations.	Discuss with DG DIGIT
Is there a need for managing information electronically in a secure manner or with respect to data protection regulation that would mandate specific ICT measures? Sensitive data must be treated with care. If any option refers to such a need, it is highly possible that special IT security measures should be taken to ensure exchange, integrity and confidentiality of this data, such as encryption, secure hosting, limited access, etc. <i>Example:</i> • Competent national authorities wishing to <u>exchange citizens' data</u>, even if it is on paper that has been digitally scanned, must do so in a secure manner.	Discuss with DG DIGIT
Would business processes require secure identification and authentication mechanisms or electronic trust services (c.f. eIDAS Regulation)	Discuss with DG DIGIT

3. ASSESSING IMPACTS RELATED TO THE DIGITAL ECONOMY AND SOCIETY

3.1. Problems, problem drivers and the baseline

If digital drivers are not addressed sufficiently, the nature and scale of the problem may not be well characterised. A **digital drivers checklist** is described below will help ensure that *digital issues and drivers are duly taken into account at the problem definition stage and in the corresponding baseline scenario*.

Dependence of the problem definition and related baseline scenario on digital drivers	YES	NO	Not yet sure

Q1.	Are there internet or other digital drivers ²⁴⁸ which bring (or are likely to bring) significant changes to the current situation and/or to the size, scale or scope of the problem (e.g. physical versus digital worlds)? How rapidly is the problem changing and how robust is the baseline with respect to rapidly changing technology trends?	See Q2	Justify in the IA, under the baseline scenario, why the digital/internet drivers identified are not expected to have any significant effect on the problem.	Check with DG CNECT or external experts whether all relevant digital/internet problem drivers have been identified and whether their overall effects on the problem under the baseline scenario might be significant.
Q2.	Are the overall effects of these combined drivers likely to alleviate the main problem you identified, or to worsen it (or to otherwise change it)? To what extent/with what speed?	See Q3	No further action needed than to justify in the baseline scenario this expected absence of overall effect from the combination of digital or internet drivers identified.	Discuss with DG CNECT or external experts to validate the likely overall impact of these combined drivers on the problem in the baseline scenario.
Q3.	Have you realistically included the effects of these digital/internet drivers within the baseline scenario (no-change option), under the time horizon of the policy intervention; or are there unknown factors still to be taken into account under the various options considered?	No further action	Discuss with DG CNECT, possibly JRC's modelling team and/or external experts how to include these effects in the baseline scenario (or their uncertainties across the options).	Discuss with DG CNECT, possibly JRC's modelling team and/or external experts how to include better these effects in the baseline scenario.

3.2. Identifying digital problems

When identifying feasible policy options the basic principle is **not to discriminate between online and offline implementation/outcomes** (when both types of transactions exist/are being used). This means that:

- All sales channels should be treated equally whether they are physical stores or online sellers;
- Requirements to provide information should apply to all information sources and means (even if the way it is delivered, presented or standardised is different). Electronic information provisioning requirements can in some cases amplify impacts, as the information can be reused (including across the value chain).

Digital solutions/components should be considered as part of the process of developing policy options. These components could enhance the effectiveness/increase the benefits and/or lower the costs of some of the other envisaged options, or support their implementation/enforcement/monitoring/retrospective evaluation.

Box 1. Examples of digital components/solutions

- **Information-based options/solutions** - the most frequent digital options, focusing

²⁴⁸ See appendix 1 for more information on digital drivers.

either on information provision (downlink), retrieval (uplink) or exchange (with both uplink and downlink communications/peer communications).

- **Monitoring-based options/solutions** - focusing on retrieving observed information (not just focusing on texts or transactions, but the information can also be in the form of images and/or sound) or status (e.g. to test the availability/continuity of service or correct working of some systems).
- **Interoperability-focused options/solutions** – often used to overcome Single Market obstacles (e.g. by replacing national standards by EU standards or facilitating the uptake of cross-border services through open interfaces/multilingual support/interfaces).
- **Artificial Intelligence, Decision-Support Systems or other automated solutions:** the policy objectives may sometimes be met by implementing or deploying automated devices systems or decision-support systems which, based on certain inputs/observations or the status/value of specific sets of subsystems/indicators, trigger with some degree of automation specific sets of actions. Resorting to such highly advanced technologies can dramatically change the impacts of a proposed policy initiative.

Deciding between different types of digital options may not be possible immediately and require in-depth analysis with stakeholders - given that different approaches have different implications for them (in terms of costs/benefits/responsibilities/empowerment). Hence a variety of digital options and suboptions may need to be retained for further analysis. Alternatively, where such in-depth analysis cannot be done as part of an initial EC policy initiative, implementation concerns can be left to future implementing legislation.

Also, in areas of fast technological change, alternatives to legislation may be available to reach a given objective.²⁴⁹

3.3. Identifying digital options or components

Assessing the impacts of policy options with digital components is no different to the assessment of non-digital impacts²⁵⁰. Certain aspects are, however, relevant to these digital components and which should be considered where relevant:

- **Timely implementation of the legislation:** Addressing early the technical implications of a digital policy option is key to ensuring that the policy proposal can be implemented in the timeframe foreseen.
- **Enforceability** of the digital policy options proposed: The cross-jurisdictional, decentralised nature of the internet can easily be overlooked, as can the (legal) technical means to ensure effective implementation. As a result, some policy initiatives may not deliver their intended objectives. For example, restrictions and national bans on websites can be circumvented with technologies such as Virtual

²⁴⁹ See Tool #18 on *Policy instruments*.

²⁵⁰ See Tools #19 to #35 on identifying various impacts.

Private Networks and TOR²⁵¹ which are widely and legally available. In policy proposals where internet technology plays a central role, it is important to *consult with a wide range of stakeholders, including from the technical internet community*.

- In an online environment, cost savings may accrue from a digital option for compliance checks which avoid the need for physical checks. For example, a simple computer programme can check every store in a particular jurisdiction within seconds, thus making the policy enforcement potential much larger at much lower costs.
- A digital option that proposes the efficient reuse of existing solutions/components and/or avoids the duplication of developments across various stakeholders or Members States will help to reduce the overall administrative burden.
- A digital solution which ensures flexibility, e.g. to allow for future expected changes in the further uptake or development of technology (such as the "Internet of Things") will also potentially save costs that would arise later.
- Digital options may remedy problems linked to the provision of transparent/timely/precise information on a market in which competition is imperfect. Enhanced competition may in turn boost creativity/innovation and bring about further (indirect) socio-economic benefits.
- The internet or other digital infrastructures often have indirect multiplier effects, in particular when information exchange flows are created among industrial communities or social networks, or where new uses/processes/values emerge from multi-party exchanges, for instance emerging digital platforms for services, sharing, exchange and/or collaboration.
- There may on the other hand be some one-off effects. For example, the impact of information provision could diminish sharply over time as new habits emerge or as stakeholders develop novel ways of reducing the value or comparability of information. Such one-off impacts should also be taken into account where relevant (limiting impacts).

Where implementation of new EU legislation requires the support of digital solutions, *the related costs should be assessed as precisely as possible*. If these are considered early, there will be a greater opportunity to minimise these costs:

- Notably by identifying some light/best fit for purpose solutions (avoiding heavy and long-to-develop solutions which insufficiently reflect the specific roles of different stakeholders in the value chain of a sector, or which are insufficiently flexible - notably where needs are not exhaustively known/may change over time)²⁵².

²⁵¹ TOR is free software for enabling online anonymity and resisting censorship. It is designed to make it possible for users to surf the internet anonymously.

²⁵² This is a core part of DG CNECT's internet readiness support.

- Through the reuse of existing solutions²⁵³.

Note that the costs of a digital solution depend on both functional and non-functional requirements, so it is necessary to check also whether the digital option entails:

- Security requirements (in relation to elements such as data integrity, confidentiality, non-repudiation, identification, authentication, authorisation or data protection);
- Resilience requirements (e.g. continuity of service/recovery time, levels of service/graceful degradation modes, degree of flexibility/evolutionary properties);
- Specific user requirements (e.g. in terms of user interfaces, multilingual support etc.).

Impacts should be considered where the policy options analysed may affect the digital technologies/infrastructures themselves, in particular the internet as a critical infrastructure in Europe, or the incentives for the deployment and uptake of broadband services. During the preparatory work of the ISG, the following aspects should be considered wherever relevant:

- **Consistency with existing legislation, as well as with on-going policy developments**, to avoid incoherent regulatory requirements or conflicts with digital policy targets:
 - All the options considered should be compared in terms of their *alignment with other EU legislation* - especially those of cross sectorial nature, such as: the eIDAS Regulation (EU) No 910/2014 on electronic identification in the internal market, the data privacy Directive²⁵⁴, cybersecurity and protection of minors, the Directive 2014/55/EU on electronic invoicing in public procurement, the Services Directive 2006/123/EC, the revised Directive 2013/37/EU on the reuse of public sector information, the e-Government Action Plan²⁵⁵ etc. – and their encapsulation in EC Strategic Agendas such as the **Digital Single Market (DSM)** and the Public Service Modernisation (PSM).
 - Existing legislation may have implications on specific/sectorial legal and policy instruments because of their cross-cutting nature²⁵⁶, such as the *interoperability*

²⁵³ Support is offered by DG DIGIT to help assess the feasibility and costs of ICT systems - see section 4.

²⁵⁴ See https://secure.edps.europa.eu/EDPSWEB/edps/Consultation/Reform_package

²⁵⁵ COM(2016) 179

²⁵⁶ In the case of the eIDAS Regulation, for example, an increasing number of legal and policy instruments include the need for electronic identification and/or trust services, e.g. identification of legal entities in the field of taxation; identification of natural and legal persons when establishing single-member private limited liability companies online plus the update of anti-money laundering directive, implementation of a "European Social Security Number"; introduction of a unique and persistent identifier in the financial sector plus ECB / EBA recommendations for security on Internet payments, etc.

strategy/framework, the *open data strategy* (favouring the use of specific data/meta-data standards wherever possible, and the open publication of public data in these formats) or the *reusability principle* (favouring open/shared developments and the reuse of existing open source components where it proves more efficient).

- **Consistency with internet principles:** The Commission is committed to preserving a number of *basic principles concerning the Internet* which are outlined in the [Communication](#) on Internet policy and governance²⁵⁷, and the recently adopted [NetMundial](#)²⁵⁸ principles for **internet governance**. Where a proposal can have impacts related to these basic principles, these need to be carefully analysed in the Impact Assessment.
- **Impacts on the technical infrastructure of the internet:** There may also be a need to consider the *impacts* in relation to the *evolving technical infrastructure of the internet*. In some cases, legislative proposals would imply that *additional compliance costs are generated*, e.g. if the proposal requires engineering changes on the technical infrastructure of the internet, or on services running on top of the internet. Proposals which by implication require *data traffic to respect such jurisdictional boundaries* need to be carefully scrutinised for feasibility and implicit costs, as well as regarding the creation of new, or removal of existing, barriers to *cross-border commerce*. Identifying any expected direct/indirect impact on the *EU deployment and/or uptake of broadband services* is also relevant.

4. ASSESSING IMPACTS RELATED TO INFORMATION AND COMMUNICATION TECHNOLOGIES/SYSTEMS (DG DIGIT)

Assessing the impacts of the ICT solutions that may be needed to support the initiative follows three basic steps:

- Step I: Define the scope of the ICT assessment;
- Step II: Prepare the ICT assessment;
- Step III: Assess the ICT impacts.

At this stage, you should have identified and broadly designed policy options that are ICT-based. You should now analyse them further along the following lines:

²⁵⁷ COM(2014) 72, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2014:0072:FIN:EN:PDF>

²⁵⁸ <http://netmundial.br/wp-content/uploads/2014/04/NETmundial-Multistakeholder-Document.pdf>

(3) Step I: Scope of the ICT assessment:

When you define the scope of the ICT solution/option you should ensure that:

- **Interoperability** is taken into account: Ensure that you refer to the **European Interoperability Framework (EIF)**²⁵⁹ that provides a basic set of recommendations and principles to achieve interoperability and you consider standards and best practices for systems architectures, data management, semantic definition of data, etc.
- **Business processes are described in a harmonised manner**: Business needs presented in the proposed options, the prevailing option and the legal text should be harmonised as for the description of their processes across the specific policy legislation and across policies. Bear in mind that there are some **core business needs** that should be addressed in similar ways. Examples are: reporting, e-Signature/e-Identification, exchange of information, etc. When it comes to describing your business requirements, make sure that you reuse existing descriptions, by addressing yourself to colleagues working for similar initiatives or to DG DIGIT. The latter has been mandated, in the frame of the Synergies and Efficiencies Communication²⁶⁰, to lead the Digital Transformation Agenda in the Commission, part of which is to ensure the harmonisation of the corporate business processes, and of those which are common in the various policy programmes. The intention is that **common businesses are phrased in a standardised way in the legal bases**, allowing for a maximum of convergence.
- Each of the policy options can be implemented through various **technical scenarios**. In other words, one should explain how each policy option can be implemented, from an ICT point of view. When building the technical scenarios you should think of:
 - Including elements such as the **ICT architecture** (centralised, decentralised, hybrid, etc. depending on the structure and flow of data and the type of processes to implement), **ICT technology** (open source or commercial software), **standards and specifications** (open, proprietary), **security** (level can vary depending on data availability, confidentiality and integrity), requirements related to **hosting** (cloud or not, geographical limitations, redundancy, fail-over);
 - **Reusability** of ICT solutions and data:
 - Reusing existing ICT solutions will minimise costs and accelerate implementation time. Reuse can be understood as the case of one Commission DG benefitting from a solution developed by another DG, possibly tackling similar needs (e.g. programme management, reporting, alerting, secure exchange of data, etc.). It can also concern existing solutions developed at the Member States' level. The Commission is in

²⁵⁹ http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf. Please notice that the EIF is under revision. The updated instrument is expected by the end of 2016. The EIF is supported by ISA² Programme²⁵⁹ which is managed by DG DIGIT

²⁶⁰ SEC(2016) 170 final, 4.4.2016, Synergies and Efficiencies in the Commission – New Ways of Working

the course of producing a cartography of solutions (ICT tools, frameworks, specifications, etc.) open to be shared and reused;

- “Reuse” could also be understood as the maximum use of existing data. Data collected in the course of similar initiatives in the same policy area or across policies, should be shared to the maximum extent possible. “Open data” should also be used as information sources wherever relevant alongside cross-cutting examples such as geospatial data and infrastructures.

(4) Step II: Prepare the ICT assessment

- It is important to identify those **stakeholders** who will be specifically affected by the technical scenarios in order to identify and characterise the associated impacts (costs and benefits).
- Identify the **complete list of costs and benefits types** concerned, mapped previously to the various stakeholders;
- Identify and list **requirements**²⁶¹ related to each technical scenario. Requirements vary according to the exact policy needs. Think of the following when setting these requirements:
 - Which are the processes to automate and the affected users and IT systems?
 - What is the volume of data to manage (number of users affected, transactions)? What is the type of data (data format, transformation needed, metadata, and reference data)? How will data be collected (e.g. from national base registries) and flow/exchanged? Are there any authentication, authorisation, confidentiality, integrity requirements involved in relation to accessing and using of this data?
 - Is linguistic translation involved?
 - Is it required in the proposed initiative that European, international or national ICT standards or specifications should be followed? If not, are there any such standards or specifications available to facilitate the design of the technical scenario?
 - What are the technical requirements related to the ICT solution and its architecture (e.g. infrastructure, technology, network, reliability, usability, performance, scalability, accessibility, security, extensibility, testability, hosting)?
- **Map requirements to ICT costs**, using tools such as the VAST²⁶² taxonomy of five categories of costs, namely for **infrastructure** (hardware i.e. network, servers, storage and software i.e. licences, libraries), **development** (i.e. analysis and process re-

²⁶¹ Requirements can be business, functional or non-functional, depending on the amount of detail available to perform the ICT assessment.

²⁶² [Value Assessment Tool guidelines, European Commission, Directorate-General for Informatics, 2010.](#)

engineering, programming, project management, testing, etc.), **maintenance** (corrective maintenance and evolving), **support/helpdesk** and **training**. The above will allow estimation of the **Total Cost of Ownership (TCO)** of the ICT solution. We recommend using a five-year period for the estimates;

- **Map requirements to ICT benefits**, i.e. improved well-being and market efficiency, indirect compliance benefits, wider macroeconomic benefits and other non-monetisable benefits.
- **Define the data collection methods**. There are several ways to collect (big or traditional) sets of data, including desk research, interviews, focus groups, questionnaires and surveys, workshops, etc. Map the stakeholders to these methods to ensure that input is received by all of them in the most appropriate way.
- **Define the assessment criteria**. These should include:
 - **Efficiency**, the least-costly technical scenario.
 - **Effectiveness**, the best value for money technical scenario;
 - **Coherence**, choosing the technical scenario the most aligned with the EU objectives, strategies and priorities. This concerns areas such as interoperability, electronic identification, e-procurement, use of information in the public sector, open data, data protection. Coherence has to be sought also with the **ICT Governance, methods and tools of the Commission**, in particular when the Commission is amongst the stakeholders (e.g. to develop, host, operate, maintain or support an ICT solution at its premises);
 - **Technical feasibility**, related to quality criteria (e.g. functional completeness, performance, compatibility, usability, portability, security, etc.). Technical scenarios proposed should comply with requirements such as the *IT systems software and quality* ones derived from ISO/IEC 25010:2011.

It is advised that the assessment uses the **Multi Criteria Analysis Weighted Sum Model**, where assessment criteria (or their subcriteria) receive weights reflecting their importance. The prevailed technical scenario is the one that receives the **highest score**.²⁶³

(5) Step III: Assess the ICT impacts

- Collect data from the relevant stakeholders. Cross-check the coherence, reliability and validity of the data collected, by applying different methods, using different data sources and/or consulting different experts (triangulate). Use the **RACER** (Relevant, Accepted, Credible, Easy to monitor, and Robust against manipulation) technique to control data quality.
- Evaluate how well the scenarios meet the assessment criteria defined above. Assessment criteria could be of both types, **quantitative** or **qualitative**. For quantitative assessments, estimate the monetary value (monetised costs minus

²⁶³ See Tool #63 on *Multicriteria analysis*

monetised benefits). This is usually the case for efficiency, some or all of effectiveness, as well as for other assessment criteria as appropriate.

- **IT governance of the Commission:** It is often possible that the Commission itself is also impacted in terms of ICT by the proposed legislation. In case this occurs and regardless of the policy area or budget concerned, the ICT governance bodies²⁶⁴ should be involved and established rules and processes should be respected. *ICT experts should transmit any request for advice or evaluation to the ICT governance bodies as appropriate.* This will allow streamlining policy and related ICT development in the Commission, will ensure good planning and efficient use of resources.

5. SUPPORT

5.1. DG CNECT support on digital issues

Digital issues and Internet-Readiness checks are best addressed early (from the planning/inception IA stage) and along the whole duration of the impact assessment. If early screening suggests that digital aspects may constitute key issues, DGs are invited to request DG CNECT's support, either through the DG CNECT representative in your interservice group or the CNECT Better Regulation Functional Mailbox: CNECT-BR@ec.europa.eu.

In particular, DG CNECT's contribution includes:

- Advice on matters of best practice and modernised methods through state-of-the-art methods to more easily handle complexity, and their supporting digital tools;
- Helping to increase the effectiveness of data collection and analysis (e.g. through "big data" approaches or by pooling some open public data sources), of stakeholders' consultation processes, or of Interservice Steering Group collaboration;
- Facilitating the comparison of options across differing impact dimensions (economic, social and environmental - including trade-offs and distribution of impacts, such as among different types of stakeholders/territories or timelines), based on options' comparison criteria (effectiveness, efficiency and coherence).
- Support on new mandatory internet-readiness checks, towards adaptive governance and internet-inclusive legislation policymaking, meaning legislation that is fit for purpose on the internet as well as in the physical world. Such checks should clarify whether internet drivers are sufficiently taken into account in the baseline, whether some digital options could address the objectives more effectively, efficiently and with greater coherence with digital policies, and whether some digital solution can facilitate future monitoring/evaluation plans (to lower related administrative costs).

²⁶⁴ <http://www.cc.cec/itservices/en/content/corporate-it-governance-coordination-support>

- DG CNECT has additional materials available to help in the practical application of this tool.²⁶⁵

5.2. DG DIGIT support

For advice linked to the development or interfacing of ICT systems and their implications especially in terms of cost and the possibility of **reusing solutions** developed (by the Commission services, programmes such as the ISA and ISA², or the Member States), please contact DG DIGIT unit B6 via the DIGIT-ISA-ICT-IMPACT-ASSESSMENT@ec.europa.eu or ISA2@ec.europa.eu functional mailboxes.

In particular, DG DIGIT's contribution includes:

- A **method**²⁶⁶ the DGs can use either on their own or with the help of DIGIT to perform their assessments;
- A **service**²⁶⁷ ("assessment of ICT implications of EU legislation) to the Commission's DGs wishing to perform their assessments;
- A digital screening of published inception impact assessments/roadmaps to identify legislation bearing ICT impacts. Results are published in a register of roadmaps²⁶⁸;
- DG DIGIT has additional materials available to help in the practical application of this tool.²⁶⁹

²⁶⁵ <https://myintracomm.ec.europa.eu/serv/en/Pages/connect.aspx>

²⁶⁶ http://ec.europa.eu/isa/actions/03-ict-implications-assessment/3-1action_en.htm

²⁶⁷ <http://www.cc.cec/itservices/en/content/assess-ict-implications-eu-legislation>

²⁶⁸ <https://webgate.ec.europa.eu/CITnet/confluence/x/PgXcHw>

²⁶⁹ <https://myintracomm.ec.europa.eu/serv/en/Pages/digit.aspx>

Appendix 1

Detailed guidance on how to identify digital issues and develop digital options

The digital dimension should be taken into account at a number of essential steps in the IA development process, as further detailed and illustrated below:

1) Identifying digital issues and drivers

Find below some illustrations of clearly identified digital issues and drivers.

Box 2. Digital technologies at the problem definition stage

- Financial markets make use of information flows and internet-mediated orders as well as automated decision systems which analyse events and risks and in turn make instantaneous decisions. This can lead to multiplying the effects of some local actions.
- The internet, web-services and social networks have an increasing role in aggregating information about people and organisations. This changes the way in which information is collected and used for many public and private purposes – e.g. to monitor competitors, data mine/filter job applicants, check the reputation of a service provider, communicate with staff, capture (or create) the needs of customers.
- These new trends in internet-mediation should be taken into account to reflect the present reality and its development because:
 - Information delivery is never "neutral" but largely influences decisions (this is why advertisement is a growing business model for internet services);
 - Information flows are usually asymmetrical which can lead to detrimental outcomes for those with an information deficit (e.g. consumers with allergies not managing to get full information about the contents of food they need to purchase). So as the prevalence of internet-based information grows (via e-commerce) specific public action may be required to remedy the information deficit on the internet (e.g. by publishing directly on the internet public interest information collected by public administrations²⁷⁰, or by obliging/encouraging other parties to do so).
 - Digital drivers can be agents for rapid change. The internet tends to reinforce the dominance of incumbent IT leaders/mediators so that strategic alliances can have undue effects of the market structure in the digital world (which competition law needs to scrutinise).

2) Detailed guidance on developing digital policy options

A. Online and offline options

When defining the objectives of a policy proposal and seeking to identify feasible policy options which can help meet these, the basic principle is not to discriminate between online and offline implementations/outcomes (when both types of transactions exist/are being used). Sales channels, whether physical stores or online sellers, should be treated

²⁷⁰ Under the EU's Open Data policy - see [Directive 2003/98/EC of on the reuse of public sector information](#) ('PSI Directive') as amended by [Directive 2013/37/EU](#)

on an equal footing; information provisioning requirements should apply to all information sources and means (even if the way it is delivered, presented or standardised is different); electronic information provisioning requirements can in some cases modify impacts, as the information can be reused. Properly conceived guidance and rules should also be applicable to internet-based implementations.

B. Types of information and communication technology-based options

It may be useful to distinguish between various types of ICT-based options that can help meet a given policy objective, according to the main focus of these options:

- **Information-based options:** this is the most frequent ICT-based option, covering options focusing either:

- on the provision of information, for example to provide rail or public transport timetable/disturbance information electronically/just in time (and not just on standard paper displays in railway stations), or to ensure that electronic commerce services are subject to equivalent requirements as those which apply to direct sales in shops (so the contents of labels displayed on products be also included in some standard manner in e-commerce, transactions, including e.g. internet catalogues and product displays), or to send information or updated instructions to staff.
- on the retrieval of information (e.g. collecting users' information – such as the location or identification of the terminal or end-point used, or further user data collected through cookies – for future uses or to determine e.g. which service entry point to link them to/in what language), for example using satellite images or GSM signals from road users to capture traffic data on mean speeds/main bottlenecks or to detect/react timely to accidents.
- or on the exchange of information (thus including both uplink and downlink communications, as well as peer communications) such as booking services.

Monitoring-based options (e.g. through satellite imaging, video monitoring, network monitoring, aerial thermography etc.) – a type of option which focuses on information retrieval - though the information retrieved is not limited to/focused on texts or transactions, but spans images to sound (using varieties of formats) – or on status check (e.g. to test/check the availability/continuity of service/correct working of some systems).

Interoperability-focused options: may help to remove obstacles to the free movement of goods/services within the European Union (e.g. overcoming national **standards** or extending a service with multilingual interfaces), interoperability/multilingual support solutions can be attained through standardisation/meta-standardisation or semantic/ontological approaches.

Artificial intelligence, Decision support systems or automated solutions: the policy objectives may sometimes be met by implementing or deploying automated devices systems or decision support systems which, based on certain inputs, observations or the status/value of specific sets of subsystems/indicators, triggers with some degree of automation some specific sets of actions (e.g. triggering the closure of the stock exchange once the number of parallel transactions per second exceeds a certain threshold; triggering information to road users where an unusual level of congestion is reached).

Such implementations should be considered as they have the potential to modify the impacts of a proposed policy initiative.

Irrespective of whether an IT-focused option is the preferred option, all the options analysed should include consideration of IT/Internet aspects.

C. Relevant issues for information and communication technology-based options

In the case of information-based options, consider:

- not just one-shot information, but the overall information flows and data supply chains needed to ensure continued accuracy/timeliness/desired effects of information (and consider alternatives/complementation between active and passive modes of sharing information – i.e. information push or pull mechanisms or a combination of both) according to various stakeholders' needs
- continuous information flows versus up-to-date reference information/databases which can be consulted at any time.

When analysing the requirements (in order to later assess the ensuing costs) related to an ICT-based option (whether a new or modified ICT-based system/subsystem or service), you also need to take into account overall system and technical requirements, such as to ensure continuity of service and handle mean/peak volumes (e.g. in case of crises) and related resilience mechanisms (and how these accrue to the various stakeholders). In particular, you may need to consider several of the following issues:

- Safety (e.g. is the human-man interface of a new train onboard system compatible with the driver's concurrent tasks/attention requirements? Might multilingual interfaces be needed?);
- Security (e.g. against intrusions, data theft, identity theft etc.)/reputation/trust mechanisms;
- Capacity/capabilities (e.g. minimum/maximum number of transactions per time unit, maximum response times, in-built multilingual support);
- Asymmetries (in uplink/downlink communication requirements) versus peer mechanisms;
- Reliability/quality assurance/service levels/continuity of service/resilience;
- Interoperability/openness/maintainability/scalability/ease of updating or upgrading;
- Mean/maximum transaction cost/components cost/lifecycle cost, resulting payback period.

3) Developing digital policy options

There are now a number of precedents for legislating by proposing to share some information on the internet so that targeted users can easily access it and take it into account. Research in behavioural sciences has shown that the effects of offline versus online information access can be widely different, and/or complementary. It is essential to engage with relevant stakeholders and in-house specialists in DG CONNECT in order

to envisage novel or more efficient ways of enacting policies. Detailed work is necessary, for example to compare the respective impacts on users of receiving a piece of paper versus having a screen pop-up declaring something to them, as one example.

Box 3. Online information flows for the Ecodesign of Energy Related products

- The example concerns what to oblige Manufactures and e-Sellers of energy related products to do in relation to consumer information provision.
- Responsibility is apportioned in terms of data integrity and provision right through the chain.
- By specifying that data should flow between manufacturers and eSellers (not that eSellers display pictograms for example) ensures that all product relevant data now flows on the internet, is available to all, is verifiable and up to date.
- This also dramatically reduces costs to business who are obliged only to make available what they already possess (the manufacturers) or to integrate the "new" data in a specified format – which is the day to day business of online sellers i.e. the change could be integrated into natural business cycles with little or no cost or disruption.
- We have (therefore) also greatly facilitated the work of third parties such as the WWF or Test Achats or Which Magazine all of whom are interested in exploiting this data transparency for the benefit of the ordinary consumer.
- The availability of this data "in the ether" also means it is very simple and cost effective for Member States to monitor compliance – eCommerce sites are there to be "discovered" and a single competent computer programmer can write a program to trawl all sites selling into a jurisdiction to check conformity in a very short time.
- This high level of online compliance drives better compliance performance in the physical world

A future challenge will be to design legislation from inception with the internet in mind given that internet based or internet mediated commercial and social activities are now so prevalent. How, for example, should one design-in consumer protection or information provision obligations for purely digital goods (film, music or the software for driving a 3D printer) where data is presented on screens or holographs by talking heads or avatars.

Appendix 2

ICT solutions reuse potential

The table below gives an indicative list of established services or initiatives that can inspire the potential reusability of existing ICT solutions as a whole or part of the ICT dimension of the proposed options.

Sources of reusability		
Information source	When and how should I use it?	Where to find?
<i>European Interoperability Cartography (EIC)</i>	To search for and discover existing solutions that can be reused by EU public administrations to build up digital services.	https://joinup.ec.europa.eu
<i>Trans-European Systems Cartography</i>	To identify and reuse trans-European systems or their modules developed to support EU policies.	https://joinup.ec.europa.eu/asset/eia/assetrelease/cartography-tool-v101
<i>Join-up</i>	To look for interoperable and freely reusable IT solutions (including semantic data specifications) federated by more than 20 repositories all over the world. Also, to share and collaborate via the set-up of "communities of interest".	https://joinup.ec.europa.eu/
<i>Open Data Portal</i>	To locate, use, reuse, link and distribute EU data (research, financial, demographic, etc.) for commercial and non-commercial purposes.	https://open-data.europa.eu/
<i>GOVIS2</i>	To identify other possibly reusable ICT systems/modules of the Commission, implementing the same policy or business needs, e.g. user authentication, exchange of information between Member States, interconnection of registries, dissemination of information through portals, programme management, financial management, etc. <i>Please note that access to GOVIS2 is subject to rights granted by your IRM.</i>	https://psxl.psteering.com/EC/Home.page
<i>DIGIT Service Catalogue</i>	To identify and use a variety of services provided by DIGIT to end users, IT professionals, business owners and contract specialists.	http://www.cc.cec/itservices/en

The table below gives an indicative list of established methods, frameworks and services that can help – depending on the ICT nature of the proposed options – to better set the ICT implementation rules.

Methods, frameworks and services		
Source of information	When and how should I use it?	Where to find?
<i>EIRA (European Interoperability Reference Architecture)</i>	EIRA should be used when it comes to designing new or assessing existing architectures both at EU and national level.	https://joinup.ec.europa.eu/asset/eia/description
<i>Advisory services on Project Management, IT development, business process management</i>	If the whole or part of the ICT solution is to be implemented by the Commission, compliance with architecture frameworks, project management, business process management, IT development methodologies is necessary.	http://www.cc.cec/itservices/en/services/175
<i>DIGIT Hosting services</i>	If the solution is to be implemented by the Commission, the hosting services of DIGIT is the proposed solution for testing and potentially for operations.	http://www.cc.cec/itservices/en/services/67

TOOL #28. FUNDAMENTAL RIGHTS & HUMAN RIGHTS

1. INTRODUCTION

Fundamental rights²⁷¹ afford basic legal protection for political, social, procedural rights to individuals and legal entities. They cover a wide range of issues from human integrity, property and privacy rights, rights to conduct business, to free movement, equal treatment, children's rights, rights of persons with disabilities, rights of citizens in their dealings with the EU institutions, procedural safeguards and much more. Respect for the Charter of Fundamental Rights of the European Union (the Charter) in Commission acts and initiatives, is a binding legal requirement²⁷². EU legal acts can be challenged before national courts as well as the European Court of Justice for failure to respect the Charter.

The need to ensure compliance and promotion of fundamental rights is not limited to legislative proposals but should be considered in all Commission acts and initiatives. To help in the implementation of this obligation, the Commission has developed an assessment methodology based on a Fundamental Rights Check-list which should be used by all Commission departments.

The fundamental rights analysis contributes to better policy definition and public acceptance of Commission initiatives and facilitates the legal analysis of compliance with the Charter of a subsequent draft legislative proposal.

This tool gives an overview of the most salient points to consider when assessing fundamental rights in impact assessments. It complements the operational guidance on taking account of *Fundamental Rights in Commission IAs* which explores these issues in greater depth and provides relevant examples²⁷³.

When assessing the impacts of initiatives with effect outside of the EU, consideration would have to be given to international human rights instruments. An example is the impacts on **Rights in an External Trade** context for which further guidance exists on how to address human/fundamental rights in impact assessments supporting Trade agreements²⁷⁴.

Box 1. Fundamental Rights

- The Charter contains provisions on rights, freedoms and principles divided into six titles: Dignity, Freedoms, Equality, Solidarity, Citizens Rights, Justice. The seventh title, General provisions, governs the interpretation and application of the Charter.

²⁷¹ For pragmatic reasons, the impact assessment of initiatives with only an internal EU dimension should focus on the analysis of fundamental rights (guaranteed by the Charter of Fundamental Rights), while for initiatives with an external dimension the analysis should focus on human rights which may be different to the fundamental rights guaranteed by a partner country and which arise from international treaties and customs.

²⁷² As expressed in the Charter of Fundamental Rights and other legal documents.

²⁷³ http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2011_0567_en.pdf

²⁷⁴ See DG TRADE guidance on the analysis of human rights impacts in trade impact assessments

- The Charter rights are of relevance to all EU policies and the institutions.
- Some of the rights enshrined in the Charter are absolute and cannot be ‘limited’ or ‘restricted’ no matter how important the policy objective pursued would be. While the Charter itself does not explicitly list which rights are absolute, case law of the European Courts indicates that the prohibition of torture and inhuman or degrading treatment or punishment (Article 4 of the Charter) and the prohibition of slavery or servitude (Article 5 of the Charter) are protected in absolute terms.
- Other rights can be subject to limitations if necessary but only to the extent that such limitations respect the strict requirements set out in Article 52 of the Charter which reads: *‘Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.’*

2. STEP BY STEP ASSESSMENT

Aspects of fundamental rights may be of relevance in the problem definition. This may be the case in particular where the Union intends to act in order to protect individuals against interferences with fundamental rights.²⁷⁵

Depending on the nature of the problem and the policy context, respect for fundamental rights may be presented as one of the general or specific/operational objectives. This will ensure that at every step of the impact assessment, the relevant aspects will be consistently addressed from the perspective of these objectives (link between objectives and problem analysis, identification of policy options, assessment and comparison of options, future monitoring and evaluation activities).

In order to ensure an evidence-based assessment, questions on fundamental rights should be addressed during the early preparatory stage of any envisaged initiative, i.e. when the initial roadmap is being prepared. Stakeholder consultations and studies should include collection of data on any potential fundamental rights aspect. If an early screening suggests that any policy options may raise substantial questions about fundamental rights requiring further guidance, you should consult colleagues from SJ and DG JUSTICE (and DG EMPL as regards the rights of persons with disabilities²⁷⁶) who could also be invited to participate in the IA work of the interservice group. The EU Agency for Fundamental Rights²⁷⁷ (FRA) also provide a source of valuable information relating to fundamental rights, e.g. through providing relevant information or data or carrying out research, surveys and studies. The European Data Protection Supervisor (EDPS) can advise about ensuring compliance with rights to privacy and the protection of personal data.²⁷⁸

²⁷⁵ See Tool #14 on *How to analyse problems*.

²⁷⁶ EMPL-RIGHTS-DISABILITIES@ec.europa.eu

²⁷⁷ <http://fra.europa.eu/en>

²⁷⁸ https://edps.europa.eu/edps-homepage_en

2.1. Policy options and analysis of impacts

Since limitations to fundamental rights can only be justified if they meet with the requirement of necessity and proportionality, a simple cost/benefit analysis is not sufficient when assessing impacts on fundamental rights of a policy option.

In order to ensure that the correct methodology is used, all identified policy options should therefore be screened against the Fundamental Rights Check-list.

Box 2. Fundamental Rights Check list

- What fundamental rights are affected? (Screening the foreseen policy options against the Fundamental rights ‘**key impact questions**’ section in the **Tool on the identification and screening of impacts** provides a first indication as to which fundamental rights will be concerned).
- Are the rights in question absolute rights? (Examples being, the ban on torture and the prohibition of slavery or servitude).
- **If it is concluded that the examined policy option limits an absolute right - it should be discarded already at this stage and a further analysis under points 3-6 is not needed.**
- What is the impact of the various policy options under consideration on fundamental rights? This step aims at identifying, for all different stakeholders concerned any positive impacts (promotion of fundamental rights) or negative impacts (limitation of fundamental rights)?
- Do the options have both a beneficial and a negative impact, depending on the fundamental rights concerned (*for example, a negative impact on freedom of expression and beneficial one on intellectual property*)
- **Should the analysis reveal that the policy option would have no material impact on fundamental rights or only positive impacts on fundamental rights there is no need for further analysis under points 5 and 6.**
- **If by contrast you have identified possible limitations to fundamental rights, please consider the following for each individual limitation:**
 - Would the limitation of/negative impact on fundamental rights be provided for by law, in a clear and predictable manner?
 - Would any such limitation/negative impact:
 - Genuinely meet an objective of general interest of the Union or protect the rights and freedoms of others (this step should identify which objective of general interest or the rights and freedoms of others)?;
 - Be necessary to achieve the desired aim? (This step should examine if the policy option is appropriate and effective for attaining the policy objective pursued without going beyond what is necessary to achieve it? Why is no equally effective but less intrusive measure available?);²⁷⁹

²⁷⁹ The European Data Protection Supervisor has produced additional guidance materials for application in the fields of access to documents and data protection: <https://secure.edps.europa.eu/EDPSWEB/edps/EDPS/Publications/Papers>

- Be proportionate to the desired aim?;
- Preserve the essence of the fundamental rights concerned?

Finally, if the examination concludes that the need to attain the general interest objective would justify maintaining a policy option that would cause an **interference** to one or several fundamental rights, it should be considered which safeguards would be necessary to ensure that the negative impact would not amount to a violation of the fundamental right.

3. FURTHER INFORMATION

While the Charter itself, as well as its Explanations²⁸⁰ constitutes the main reference documents, there are also a number of other resources that can be used to identify the rights that could be affected by a particular initiative:

- **The Commission Charter Strategy**²⁸¹ sets out the Commission's approach to implementing the Charter of Fundamental Rights;
- The Commission staff working paper on **Operational Guidance on taking account of Fundamental Rights in Commission Impact Assessments**²⁸² gives additional detail on how to apply the Fundamental Rights checklist;
- While not representing an official Commission position, the Fundamental Rights Agency's "**Charterpedia**" can be a useful tool to obtain a quick and easy overview of the content of the various Charter rights as well as the relevant case-law²⁸³. To develop a deeper understanding of a certain fundamental right guaranteed by the Charter, you should consult the case law of the European Court of Justice, the European Court of Human Rights and when appropriate, the opinions and general comments of the UN human rights monitoring committees.
- **The European Convention on Human Rights** is also relevant for the interpretation of the Charter on Fundamental Rights.²⁸⁴

²⁸⁰ Charter of Fundamental Rights of the European Union
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:EN:PDF>;
 Explanations relating to the Charter
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:303:0017:0035:en:PDF>

²⁸¹ http://ec.europa.eu/justice/news/intro/doc/com_2010_573_en.pdf

²⁸² http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2011_0567_en.pdf

²⁸³ <http://infoportal.fra.europa.eu/InfoPortal/infobaseShowContent.do>.

²⁸⁴ <http://www.echr.coe.int/Pages/home.aspx?p=home>

TOOL #29. EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION AND INCLUSION

1. INTRODUCTION

This tool covers three categories within the broad category of social impacts: impacts on 1) employment, 2) working conditions and 3) income distribution, social protection and inclusion, including impacts on perspectives and life-situations of people in, or at risk of poverty.²⁸⁵ They are likely to be the most frequently encountered social impacts (next to health issues) in an impact assessment or an evaluation.

The types of impacts are diverse, complex (affecting different population subsets, territories and economic sectors) and strongly connected with economic and environmental impacts. There may be trade-offs where social impacts point in different directions. A policy change could encourage the creation of new jobs in a sector/region while at the same time lowering job quality for workers in this – or another – sector. Careful consideration needs to be given as to how to compare these diverging impacts. Being able to draft a comprehensive picture of the social impacts is an important element for political debate.²⁸⁶

2. ARE IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION AND INCLUSION POTENTIALLY SIGNIFICANT?

This section helps to a) identify possible impacts, b) map relevant stakeholders (or social groups) that will be impacted by the initiative and c) select the significant impacts.

To help identify potential impacts, sections 2.1 to 2.3 below include a number of relevant **questions** accompanied by illustrative examples. Social impacts, positive as well as negative ones, often materialise in the long run, therefore it is important to differentiate between short- and long-term impacts.

In order to effectively **map stakeholder or social groups**, keep in mind those who might not be your usual interlocutors, especially the groups from **disadvantaged backgrounds** (like children from poor households or people with migration or minority background). In practice, it is useful to start by examining whether there are any systematic impacts on well-defined groups (for instance by gender, age, income, disability, level of education and training, migration or minority background). A gender perspective should in particular always be considered. The assessment of potential impacts on gender should take into account the existing differences between women and men in the given policy field.

²⁸⁵ According to the Horizontal Social Clause of the TFEU (Art 9), the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health in defining and implementing its policies and activities.

²⁸⁶ Contact DG EMPL Evaluation and Impact Assessment Unit for further reference, information sources, background material and methodological issues.

Involvement of stakeholders can facilitate the work as social partners (employers' and workers' representatives) and civil society organisations have a good knowledge of how a proposal might affect the group they represent and Member States may have relevant experiences to share (see section 4.1 of this tool on key stakeholders in the EMPL area). There is also a general requirement to consult social partners regarding 'social impacts'²⁸⁷.

The aim of the assessment should be to identify the most significant impacts and the social groups which are likely to be the most affected by them. For those impacts, a thorough assessment will need to be undertaken.

The identification of those groups for whom there may be significant negative impacts may help to foresee resistance and may point to mitigating measures to reduce negative impacts.

2.1. Impacts on the level of employment

Impacts on the level of employment can be expected whenever demand or supply for labour changes. For example, labour demand increases if companies want to employ more people due to increase in demand for their products. Labour supply increases when more people are available and willing to work.

The main question is **whether there will be more or fewer jobs (more or fewer hours worked) overall or for specific social groups**. It will give you an indication whether a larger/smaller workforce will be needed and/or whether redistribution of labour is to be expected (e.g. between sectors or occupations).

The following questions and illustrating examples explore various dimensions of employment impacts.

(1) To what extent are new jobs created or lost?

Options improving access to funding for SMEs can create new industrial activity that can employ directly or stimulate indirect job creation through the purchases of goods and services from suppliers. Free trade agreements can create new jobs by increasing exports and demand for certain domestically produced goods, but also destroy jobs by replacing other domestically produced goods with imported ones.

(2) Are direct jobs created or lost in specific sectors, professions, qualifications, regions or countries or a combination thereof? Which specific social groups are affected?

Initiatives fostering greener energies might increase the need for certain skills (e.g. installation of photovoltaic panels) to the detriment of others (e.g. skills needed in extracting coal). Creation of jobs in new renewable sectors can be at the cost of employment in traditional extractive industries (skill-mismatch) and regionally unbalanced (e.g. jobs created at the off-shore wind-farms and lost in coal mining regions).

²⁸⁷ See Article 2 of Commission Decision 98/500/EC requiring the consultation of the relevant sectoral social dialogue committee on developments at Community level having social implications.

Reforming the common agricultural policy for wine-growing is expected to have no employment impact in those Member States with (almost) no wine-growing, very little impact in those Member States where the sector had already undergone significant reforms and significant, impact in those Member States where such reforms had not yet taken place. However, depending on the respective structure (age of farmers, size of farms), these impacts can differ even in those countries.

(3) *Are there indirect effects which might change employment levels?*

New industrial activity can stimulate indirect job creation through increased purchasing power of newly employed workers (e.g. retail or leisure).

Initiatives fostering green energies might increase the need for certain skills but raise wages at the same time with a complex effect on employment levels. This might also increase the need for training and trainers leading to indirect employment impacts.

(4) *Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses?*

Delays in the acknowledgement and certification of new qualifications or a lack of arrangements to provide for a transition can create significant employment problems.

Initiatives improving energy efficiency of buildings might increase demand for workers in construction sector with relevant skills. If the necessary skills are not available (e.g. lack of relevant educational/training programmes, non-recognition of skills acquired abroad) the effectiveness of the policy risks to be limited.

Transition between winning and losing sectors/occupations/skills/regions is not automatic. A worker losing a job in the car manufacturing or agriculture sector may not become a health or domestic service sector worker within a couple of months and without support/training. While analysis often implies easy adaptation processes, an important aspect of employment-related impacts requires explicit consideration for timing and sequencing of the intervention.

(5) *To what extent does the option influence the availability and willingness of workers/specific groups to work (i.e. supply of labour through labour market participation or labour market mobility)?*

A number of factors can influence the supply of labour: tax and benefit systems, relative earnings, barriers to entry into profession/occupation, work-life balance policies, work intensity and working conditions, length of working life, the occupational/or geographical mobility of labour, migration policies.

An initiative aiming at regulating professions (e.g. by requiring a specific degree or special exam) can act as a barrier to entry, hold back the labour supply and limit occupational mobility, but it can at the same time support the safety and quality of the goods or services provided.

Work-life balance policies that help parents to balance professional and family responsibilities by increasing their availability/willingness to work can have a positive impact on labour market participation of women.

Initiatives shortening the length of compulsory education, increasing the age of retirement or supporting active ageing (like better ergonomics of working places, reskilling etc.) can increase the supply of labour of specific age groups and therefore total labour supply.

An initiative improving transport infrastructure and transport services can enhance the geographical mobility of workers by reducing the time and/or costs of travelling. More workers would be able to daily/weekly commute to cities/regions where jobs are available without the need to relocate. The geographical mobility of workers can be improved also through initiatives on property markets (e.g. affecting rents, conditions for mortgages etc.).

2.2. Impacts on working conditions

Impacts on working conditions are more difficult to capture and cover a broader range of outcomes. Initiatives that enhance creation of business-friendly environment and liberalisation and/or deregulation of activities are likely to have an impact on working conditions.

The following questions and illustrating examples explore various dimensions of impacts on working conditions:

(1) *Does the option affect wages, labour costs and/or wage setting mechanisms?*

Initiatives changing income taxation or social security systems can impact **wages and labour costs**.²⁸⁸ Elements to be considered are: i) a relative dimension of wage: wage dispersion, changes in income-distance to another group of workers considered as reference group, or ii) its absolute dimension: wages which are insufficient to allow for a decent standard of living.

Impacts on labour costs should be assessed in conjunction with changes in (labour) productivity. For example, initiatives introducing obligatory employers' training or health and safety requirements can increase labour costs. However, this may not be negatively correlated with the competitiveness of goods produced as those measures can increase the productivity of workers due to better skills and reduced absenteeism.

The **wage setting mechanism** affects the level or conditions of minimum wages, the coverage of workers by collective agreements and negotiating power of social partners.

(2) *Does the option affect directly or indirectly employment protection, especially the quality of work contract or false self-employment?*

Employer-driven flexibilisation of working hours and reduction of job security makes employees' income less predictable and leads to instable living conditions. Initiatives

²⁸⁸ Wages (or earnings) are the compensation that workers (employees) receive for their work. They safeguard labour income and are positively correlated with consumption. Net wages are calculated as a difference between gross wages, social contributions payable by the employee and any amounts which are due to government, such as income taxes. Labour costs are broader concept and reflect employers' expenditure on personnel. They include wages and salaries paid to employees, social contributions payable by the employer and other costs, such as taxes on labour, training costs, costs related to working cloths etc.

aimed at increasing competition or technology driven activities leading to new forms of work (e.g. a sharing economy) can reduce job security. Initiatives fostering entrepreneurship and self-employment can have a positive impact on job creation, but they can also undermine employees' rights and protection if the initiative lead to "false self-employment".²⁸⁹

Typically problematic contractual arrangements are: frequent use of short-term contracts, excessive use of traineeships, employment relations which do not give access to social security schemes, very short lay-off periods, no fixed volume of working hours, forced and false self-employment, very strong involvement of temporary work agencies.

On the other hand, very protective employment protection legislation can adversely affect segmentation of the labour market with large differences in costs and rights between permanent and non-standard forms of work.

(3) *Does the option affect risk of undeclared work?*

Undeclared work can take various forms, from completely undeclared work (e.g. a care assistant taking care for elderly people without signing any contract) to situations where only part of the work and income is undeclared (e.g. IT specialist working in a big company officially earning the minimum salary while receiving an additional amount by his employer "cash-in-hand"). It has negative effects on workers (e.g. lack of security, reduced benefits, poor working conditions), employers (e.g. unfair competition) and on the states (e.g. unpaid taxes and social security contributions).

Initiatives changing income taxation or social security systems, work or responsibilities of public administration, recognition of qualifications or initiatives in the area of migration are some of the examples that can impact the risk of undeclared work.

(4) *Does the option affect the work organisation?*

Work autonomy, level of teamwork and job rotation, pace of work and work intensity are important elements of work organisation. Work organisation can influence various aspects of working conditions (physical risk factors, work-related health and safety risks, work-life balance, or in general the satisfaction with working conditions) and therefore have an impact on labour productivity.

Liberalisation of activities (e.g. ground-handling in aviation sector) can stimulate growth and job creation but aggravate the working conditions of the workers (e.g. work in shifts or split-work). Work organisation can change as a consequence of industrial restructuring but also with the introduction of new technologies. For example, the development of IT and GPS tracking systems can reduce the work autonomy and increase the work intensity. On the other hand, the IT development can support flexible working arrangements and in some cases contribute to better work-life balance.

²⁸⁹ In the case of false self-employment, workers are obliged to adopt a self-employee status while having a contract with a single firm that avoids paying social security payments.

(5) Does the option affect health and safety at work?

Health and safety at work encompasses several elements such as: safety and health aspects; organisation and adaptation of the workplace and working environment so as to ensure the health and safety of workers; ensuring adequate personal protective equipment limiting exposure to potentially harmful agents or situations (including exposure to risks leading to MSDs; to physical agents such as noise or vibration; to radiation; to chemical agents, carcinogens and mutagens; to biological agents etc.), proper protective and preventive framework for work in a particularly challenging work environment/sector; or a combination thereof. Health problems do not only originate from physical strain at the workplace, but also from the overall psychological stress to which an employee is exposed. Therefore, aspects such as stress levels, tight/unsocial working hours and reconciling work and private life should also be considered.

Satisfying work and good working conditions constitute a value in itself, but their absence leads to discontent and can also produce significant negative effects on workers (e.g. death, disability, poor health, injuries, loss of present and future income, direct and indirect medical costs and rehabilitation costs), employers (e.g. absenteeism, lower productivity, production disturbances, damage to equipment and to a company's image, administrative and legal costs, negative impacts on insurance premiums); governments (e.g. sickness payments, increased health expenditure, increased social security expenditure (for disability or early retirement), tax revenue losses, direct and indirect medical and rehabilitation costs, administrative and legal costs).

Initiatives reducing regulatory burden by introducing, for example, less stringent requirements to monitor the working place, to guarantee preventive work clothes or to ensure preventive medical check-ups can increase health risks.

(6) Does the option affect the social dialogue?

Social partners (trade unions and employer's organisations) **determine** working conditions and carry out wage negotiations. Social dialogue between employers' and employees' representatives is an important mechanism for conflict resolution and can be a means to internalise external effects which take place at sectoral level.

Social dialogue within a company can be impacted by initiatives that, for example, exempt SMEs from ensuring the representation of workers in the management. Attention needs also to be paid to the extent to which the option affects the autonomy of social partners in the areas for which they are competent. Does it, for example, affect the right of collective bargaining at any level or the right to take collective action?

(7) Does the option affect access to vocational learning and to career development/advice? How are different social groups affected?²⁹⁰

Training/lifelong learning opportunities (including their availability and affordability) and returns to it (recognition of skill acquired in other companies or in other Member States) can influence career perspectives and employability of workers in the long-run. Employers offering training opportunities can be more attractive among job seekers and

²⁹⁰ See also Tool #30 on *Education culture and youth*

thereby increase the pool of potential work candidates. Career advice can improve the match between job and worker, increase job satisfaction and productivity and reduce staff turnover. Tax reforms or financial incentives can have an impact on companies' willingness to invest in VET and career development.

Initiatives exploiting IT development and supporting distance learning can improve the availability of training opportunities for a large part of population, but might be still unavailable to some groups, such as people with low incomes or living in poverty that can't afford to buy a computer or have an internet connection or disabled due to a lack of digital accessibility.

(8) *Does the option help/endanger the effective exercise of labour standards in the EU?*

Labour standards largely rely on national legislation or social partner agreements. European level intervention can have an impact on these arrangements even without explicitly intending to do so, by e.g. setting new rules in an adjacent area; by changing the structure of a market; by introducing standards for consumers which could have – positive or negative – impacts on workers or by concluding external agreements (e.g. free trade agreements).

The normative interpretation of these impacts, i.e. whether a change should be considered as improvement or not, depends on the context. In this sense, discussing and presenting these issues in an impact assessment report enhances the transparency of policy debates.

2.3. Impacts on income distribution, social protection and inclusion

These impacts relate to social fairness considerations, including social inclusion and protection of people against various risk and needs throughout their life and interventions, which affect the tax system, changes to the transfer system, most Commission financial instruments (such as the Structural Funds, but also the CAP), and also liberalisation or deregulation efforts have income distributional impacts. Similarly, changes in legislation, for instance concerning equal opportunities/reconciliation or access to services for disabled people or people from disadvantaged backgrounds can affect their attitudes and their chances on the labour market.

The following questions and illustrating examples explore various dimensions of impacts on income distribution, social protection and inclusion:

(1) *Does the option affect people/households' income and risk of poverty?*

Disposable income is an important indicator of social status and of someone's living standard. If it falls below a certain threshold, people will risk becoming poor and/or having to rely on social assistance. The **three dimensions of poverty** comprise: low work intensity, material deprivation and relative poverty.²⁹¹

²⁹¹ **Work intensity** is the ratio between the number of months that household members of working age worked and the total number of months that could theoretically have been worked. Very low work intensity refers to situation where people living in the household worked less than 20.0 % of their total potential. **Material deprivation** is the inability to afford a selection of nine items that are considered to be necessary or desirable. Those who are unable to afford four or more out of nine items

As examples, initiatives leading to job losses (part 2.1 above) are very likely to have an impact on income and risk of poverty by increasing the number of unemployed or inactive people with low income and households with low work intensity. This is even more pertinent when there are few re-employment opportunities or the people losing jobs are from vulnerable groups (e.g. older workers, low qualified). Initiatives deteriorating working conditions (part 2.2 above) are also likely to have an impact on income and risk of poverty by increasing the number of people with low income when wages are reduced. If policies fostering green energies increase the price of energy this can increase household spending and aggravate energy poverty.

(2) *Does the option affect inequalities and the distribution of incomes and wealth?*

Increasing income inequalities threaten social cohesion and can be linked to a number of factors such as wage dispersion, tax wedge or social protection systems.

Initiatives such as moving from direct taxation (e.g. taxing the income) to indirect taxation (e.g. increased VAT) raise the disposable income of certain population groups (the workers) but reduce other groups' towards poverty and negatively affect their chances to participate fully in society (inclusion). This may be counter-balanced by increased job opportunities created by the reduced labour cost. The overall impact on risk of poverty would have to take into account the extent of such opportunities and the chances that the unemployed would be able to take advantage of them. A policy change may also have a distributional impact if existing inequalities are aggravated. If for example, only high skilled jobs are created this could increase the inequality with lower skilled people who already have more difficulties to find a job.

(3) *Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds?*

Social services play a crucial role in improving quality of life and providing social protection against the risks and needs associated with unemployment, parental responsibilities, sickness and healthcare, invalidity, loss of a spouse or parent, old age, housing, and social exclusion.

Access to and quality of **social protection benefits** depends on the eligibility, duration and level of benefits, type of risks covered and rights to receive benefits when moving to another Member States beyond the obligatory rights. They will be likely affected by the initiatives that affect the organisation and financing of social protection systems (e.g. insurance vs solidarity; range of membership, private vs public provision; tax financed vs contribution based) as well as the cross-border provision of services, referrals across-borders and cooperation in border regions (e.g. provision of services by public employment services).

are considered to be severely materially deprived. **At-risk-of poverty** (AROP) rate is the share of people with an equivalised disposable income (after social transfers) below 60% of the national median equivalised income after social transfers. This indicator measures low income in comparison to other residents in that country, which does not necessarily imply a low standard of living.

The changes would have to be assessed in view of their direct impact on the beneficiaries and also on their motivation impact on people who might leave or enter the scheme or other schemes. For instance, raising pension ages may encourage more people to join disability schemes.

(4) Does the option affect the access to and quality of basic goods and services, particularly for those subject to social exclusion and from disadvantaged backgrounds?

Basic goods and services include, for instance, food, energy, water, transport, banking services, digital services, healthcare, education and training and housing. The list can vary, although the Europe 2020 poverty target stems from a definition of material deprivation²⁹². It might be important to assess the access and quality of these goods and services especially for people not covered by social protection schemes.

Interventions increasing the price of basic good/services, e.g. energy prices, can aggravate material deprivation/social exclusion of certain categories of the population. On the other hand, initiatives aiming at increasing access to basic services, such as a bank account or internet can increase social inclusion. Social services of general interest can play a crucial role in improving life quality²⁹³.

2.4. Which impacts are potentially significant?

Among four criteria to identify potentially significant²⁹⁴ impacts for more detailed assessment the following two are especially relevant for social impacts:

- **Relative size of expected impacts for specific stakeholders** (*i.e. Are certain categories of stakeholders or regions/countries/sectors particularly affected?*) For example, new rules (e.g. labelling, selling restrictions) regarding a particular product might have more serious consequences in terms of employment in those EU regions specialised in its production. Big job losses in a small region without viable alternatives for re-employment can be an example of a significant impact. The size of the EU population with no access to basic bank services is pretty modest. Still, regulations that would render those services more expensive/less accessible can have important negative consequences for that population.
- **The importance of impacts for EU objectives and policies** – (*i.e. Could potential social impacts of the initiative undermine other EU initiatives?*) E.g. initiatives that would lead to significant job losses, negatively impact health and safety at work or with significant impacts on households' income could undermine Europe 2020 targets to increase employment rates and reduce the number of people that are at risk of poverty and social exclusion.

²⁹² http://ec.europa.eu/eurostat/statistics-explained/index.php/Material_deprivation_statistics_-_early_results

²⁹³ <http://ec.europa.eu/social/main.jsp?catId=794>

²⁹⁴ i) The relevance on the impact within the intervention logic, ii) the absolute magnitude of the expected impacts, iii) the relative size of expected impacts for specific stakeholders and iv) the importance of impacts for Commission horizontal objectives and policies. See step 2 in Tool #19 for more details.

A detailed assessment could be envisaged for potentially **politically sensitive impacts**, such as impacts that could be considered as unfair (e.g. initiatives reducing tax burdens for companies and increasing those for workers), impacts where costs and benefits are unevenly distributed among Member States (e.g. groups of countries with positive impacts vs group of countries with negative impacts) or disproportionate (e.g. far greater burden for small businesses compared to big).

3. HOW TO ASSESS IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION AND INCLUSION?

Given the diversity of impacts and affected groups, we propose you start with a **systematic qualitative scoping**: going first through types of impacts and then social groups to be affected and in which way. Any assessment should focus on a **limited number** of impacts. A good and operational approximation is to identify the 3 to 6 issues (combination of impact and group affected) which are the most important from a social perspective.

Although the focus of the analysis should be on the most significant ones, your impact assessment should still acknowledge the less important ones and you should briefly explain why they will not be assessed in detail.

3.1. What to pay attention to in assessing impacts?

Level of analysis and distributional impacts: The transition of employment between winning and losing sectors (or regions, qualifications, occupations) is not automatic. For employment and social impacts it is important to understand where the adjustment occurs and therefore *net effects are not very informative*.²⁹⁵ In the presence of important distributional effects, *global (aggregate) figures could be misleading as they might hide controversial trade-offs*. Disaggregated analysis can help you to look for alternative options or mitigating measures to minimise potentially negative impacts. As an example, a trade agreement can be beneficial for the overall EU economy but have important opposite effects in different regions or sectors. Likewise, liberalisation measures in the transport sector should generally lead to lower prices for transport users but also to prohibitive prices for people living in remote areas. Moving from direct to indirect taxation raises the disposable income of certain population groups but reduces other groups to poverty and negatively affects their chances to participate fully in society. In such cases, calculating the average general impact on the total population could be misleading, and would be insufficient.

Different labour markets and institutional context: European countries have organised their labour markets and welfare states in a number of ways, relying to various degrees on market, family and the State. The functioning of the labour market (e.g. social dialogue or labour market legislation) and different institutional settings can influence the direction and the magnitude of the social impacts. Those differences require an analysis at a national level or alternatively grouping of countries in clusters based on the similarity of their institutions. E.g. the transition of employment between winning and losing sectors is expected to be faster and more successful in countries with well-

²⁹⁵ Net job changes are difference between gross jobs created and destroyed (lost).

developed and efficient active labour market policies and public employment services. When a particular policy initiative is expected to have negative effects on job quality, Member States with strong union presence could face stronger opposition to it, but they could also be able to reduce the negative effects or secure mitigating measures via social dialogue.

Sectoral and regional dimension: If the impacts are not economy-wide but concern a specific sector only, it is always better to refer to a NACE classification sector. When moving away from the NACE classification, consistent and reliable data is more difficult to get. However, if the impacts refer only to part of the sector, or parts of different sectors, it is reasonable to either adjust the NACE data source, or if possible refer directly to those parts affected. For regional impacts it is essential to align with the NUTS classification.

3.2. Can impacts be quantified and what is the availability of data?

A **quantitative analysis** can be easier to undertake when assessing impacts on **employment and income levels** as those impacts are quantitative in nature (e.g. number of jobs can be easily counted, wages, labour costs, disposable income are expressed in monetary units).

In other areas, such as **working conditions**, **impacts are qualitative by nature and converting them into quantitative units will require the use of an indicator that acts as a proxy.**²⁹⁶ E.g. the 'number of occupational accidents' can be used as a proxy to assess safety at work. Days of workers' sickness in a certain sector, short-term contracts or part-time work indicate potentially problematic situations – however, this might also happen for other reasons (it is therefore crucial to understand the underlying causes or drivers). In these areas, the first step is to define reasonable indicators which allow at least a qualitative assessment of the expected direction and possible significance of the impact. These indicators will be rather context specific – as for example in the situation of work contracts – and will normally be a compromise between accuracy and precision and the costs and time required to collect and process the necessary information.

In some areas, you will most probably **analyse impacts qualitatively**. E.g. the impact on the access to social security services might be quantified (e.g. number of social services users), but the impact on its quality will be analysed qualitatively. Similarly it will be difficult to quantify impact related to social inclusion.

Complete, credible and EU wide comparable data is particularly important in the case of a quantitative analysis, but also your qualitative assessment will need to be underpinned with facts or examples. The availability of sound and up-to-date data will also condition the level of analysis. If impacts are concentrated on small groups it will be difficult or impossible to find suitable data or a reasonable model. An inventory of the sources of data more relevant to the impacts covered in this tool is provided in section 4.2.

²⁹⁶ See Tool #41 on *Monitoring arrangements and indicators*.

3.3. Using models in assessing social impacts?

The qualitative scoping is necessary to decide whether and which (if any) formalised model can be employed. The softer the instrument envisaged (e.g. improved policy coordination between Member States) the more important it is to explain and verify the causal chains between the measure and the expected impacts, while less can be expected from an assessment based on a formalised model.

If 'qualitative scoping' suggests ***considerable impact on income distribution or on employment on a large part of society, a model should be used, where possible.***

Quantitative approaches to assessment range from relatively simple measurement, mainly based on past observations, to counterfactual analysis and up to highly complex formalised (and data consuming) models, like Computable General Equilibrium (CGE) models or econometric models of the (world) economy.

The use of the model will be case specific.²⁹⁷ Some very well-known models, e.g. the input-out model, deliver results at a macro level and you will have to complement them with qualitative assessment to assess the distributional impacts. You may capture distributional impacts using augmented CGE models. If the expected impacts are restricted to certain sectors, a partial equilibrium model seems suitable to quantify those impacts. Otherwise, general equilibrium models might be more appropriate.

When using the models pay attention to the **underlying assumptions about the labour market**. For example, Computable General Equilibrium (CGE) models generally assume full employment of all factors and perfectly competitive markets (which is far from the reality in many Member States' labour markets). In addition, there are strong differences among the Member States' institutional contexts related to the employment and social areas.

Box 1. Things to keep in mind when assessing social impacts:

- Always use a combination of qualitative and quantitative tools for your assessment as certain impacts covered by this tool might not be quantifiable, models available might rely on controversial assumptions and you will most often not be able to carry out a sound analysis using a single method/model.
- The most practical solution to a lack of EU wide data and strong differences in the functioning of national and regional economies, labour markets and institutional contexts, is in-depth research on 'typical' target groups or "clusters" of Member States with similar characteristics.
- When assessing impacts do differentiate between one-off and recurrent costs/benefits, as well as, between short-term and long-term impacts. This is particularly important for the impacts covered in this guidance as positive impacts often materialise in the long run while negative impacts hit sooner.

²⁹⁷ For further information on methods and models see Tools in Chapter 8. For an overview of models to be used for assessing social impacts see Annex 1 in *Review of Methodologies applied for the assessment of employment and social impacts* (2010) and table 4.3 in *Assessing the Employment and Social Impacts of Selected Strategic Commission Policies* (2009), available at <http://ec.europa.eu/social/main.jsp?catId=760&langId=en>

- Always keep potential distributional effects in mind and take into consideration potential synergies and trade-offs. For example, new information obligations for a certain product/service should enhance consumer protection but it can also lead to higher prices.
- When important negative effects are identified, ask yourself whether there aren't ways to mitigate them. Possible solutions could include an exception for the most disproportionately affected stakeholders (e.g. SMEs or vulnerable groups) or other mitigating measures, such as longer implementation periods, training and job search measures to support people losing jobs. Think about the ways to use the EU funds (e.g. ESF and EGF).
- The softer the instrument envisaged (e.g. improved policy coordination between Member States), the more important it is to explain and verify the causal chains between the measure and expected impacts, and the less can be expected from an assessment based on a formalised model.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

4.1. Stakeholders in EMPL area

- Social partners (employers' and workers' representatives) via Sectoral Social Dialogue Committees, Cross-industry social dialogue and Social dialogue texts database. Contact EMPL Social Dialogue Unit in case you need more information.
- European umbrella NGO networks to promote social inclusion, gender equality and to represent and defend the rights of people exposed to discrimination. (Overview of networks at <http://ec.europa.eu/social/main.jsp?catId=330>)
- Member States via Employment Committee (EMCO) and Social Protection Committee (SPC). Contact EMPL Coordination Unit in case you need more information.

4.2. Key EU-level data sources

- **The European Union Labour Force Survey (EU LFS)** is the most important survey for labour market data, providing monthly/quarterly/annual data on employment, unemployment by sectors, age, qualification, sex, migrant background, per countries/regions. Micro-data are available upon request. It is available on EUROSTAT: <http://ec.europa.eu/eurostat/web/lfs/data/database>
- **Other labour market statistics at EUROSTAT** are available on statistics on job vacancies, earnings, labour costs, labour market policy, labour disputes based on various surveys. Micro-data are available upon request, <http://ec.europa.eu/eurostat/web/labour-market/statistics-illustrated>
- The **European Working Conditions Survey** enables monitoring of long-term trends in working conditions in Europe. Themes covered include employment status, working time arrangements, work organisation, learning and training, physical and psychosocial risk factors, health and safety, worker participation, work-life balance, earnings and financial security, as well as work and health. Micro-data are available upon request. It is available on the European Foundation for the Improvement of

Living and Working Conditions (Eurofound):
<http://www.eurofound.europa.eu/ewco/surveys/index.htm>

- **The European Quality of Life Survey (EQLS)** examines both the objective circumstances of European citizens' lives and how they feel about those circumstances and their lives in general. It looks at a range of issues, such as employment, income, education, housing, family, health and work-life balance. It also looks at subjective topics, such as people's levels of happiness, how satisfied they are with their lives, and how they perceive the quality of their societies. European Foundation for the Improvement of Living and Working Conditions (Eurofound). Micro-data are available upon request. It is available at Eurofound <http://www.eurofound.europa.eu/european-quality-of-life-surveys-eqls>
- **The European Company Survey (ECS)** gives an overview of workplace practices and how they are negotiated in European establishments. It is based on the views of both managers and employee representatives. Micro-data are available upon request. It is available at Eurofound: <http://www.eurofound.europa.eu/surveys/ecs> .
- For health and safety, Eurostat's statistical data on accidents at work, and work-related problems are available: **European Statistics on Accidents at Work (ESAW)**, and the **LFS ad hoc modules on accidents at work** and **European Occupational Diseases Statistics (EODS)** and **Statistics on work-related health problems**.

Important information about occupational safety and health (OSH) management arrangements in enterprises can be drawn from the European Survey of Enterprises on New and Emerging Risks (ESENER), by EU-OSH²⁹⁸.

- **The European Union Statistics on Income and Living Conditions (EU-SILC)** collects comparable multidimensional micro-data on an annual basis on income, poverty, social exclusion and living conditions and is available on EUROSTAT: http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/eu_silc Micro-data are available upon request.
- **The European system of integrated social protection statistics (ESSPROS)** provides a coherent comparison between European countries on social benefits to households and their financing: http://epp.eurostat.ec.europa.eu/portal/page/portal/social_protection/data
- **The Continuous Vocational Training Survey (CVTS)** provides comparable statistical data on continuing vocational training, skills supply and demand, training needs; the forms, contents and volume of continuing training; the enterprises own training resources and the use of external training providers and the costs of continuing training. The fourth Continuous Vocational Training in Enterprises Survey, conducted in 2011, is the most recent available wave of data collection: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Continuing_vocational_training_statistics Micro-data are available upon request.
- **The Adult Education Survey (AES)** covers participation in education and lifelong learning activities (formal, non-formal and informal learning) including job-related activities, characteristics of learning activities, self-reported skills as well as modules on social and cultural participation, foreign language skills, IT skills and background

²⁹⁸ <https://osha.europa.eu/en/surveys-and-statistics-osh/esener>

variables related to main characteristics of the respondents. After a pilot version of the survey in 2007, the second wave of data collection took place in 2011.
http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/adult_education_survey

- **Skills forecast by CEDEFOP** provide comprehensive information on the future labour market trends in Europe looking at employment growth, developments in sectors, the types of job opportunities that may emerge, changes in qualification levels and demographic trends. Micro-data are available upon request.
<http://www.cedefop.europa.eu/en/events-and-projects/projects/forecasting-skill-demand-and-supply/data-visualisations>
- **The Programme for the International Assessment of Adult Competencies (PIAAC).** The Survey measures the key cognitive and workplace skills. It includes 3 elements: direct-assessment of skills (literacy, reading, numeracy, problem solving in technology-rich environment), collection of information about the skills use (the survey asks adults how intensively and how frequently they use cognitive, interaction and social, physical and learning skills at work) and background information (e.g. education, social background, engagement with literacy and numeracy and ICTs, languages, current activity of respondents, employment status and income, health status, volunteering, political efficacy and social trust.) Micro-data are available upon request. <http://www.oecd.org/site/piaac/>
- **World Input-Output Database (WIOD)** allows analysing impacts of the global value chain on skilled and non-skilled labour demand across countries 27 EU countries and 13 other major countries in the world for the period from 1995 to 2011.
http://www.wiod.org/new_site/home.htm
- **EUKLEMS** database which allows the analysis of productivity and growth.
<http://www.euklems.net/>
- Cross-country intangible investment data website, **INTAN-INVEST** is an open access database on intangible assets that allows the linking of employment data at macro level. intan-invest.net

4.3. Other useful sources

This is a non-exhaustive list of potentially useful sources in the area of employment, working conditions and income distribution and inequality

- **Employment, Social Affairs & Inclusion Directorate General (DG EMPL)** –It coordinates and monitors national policies; promotes the sharing of best practices in fields like employment, poverty and social exclusion and pensions; makes laws and monitors their implementation in areas like rights at work and coordination of social security. It provides information and analysis. It provides analysis of various employment and social topics as well as descriptions of EU-funded projects.
<http://ec.europa.eu/social/home.jsp?langId=en>
- **Eurofound** - European Foundation for the improvement of Living and Working Conditions. It provides information, advice and expertise on living and working conditions, industrial relations and managing change in Europe.
<http://www.eurofound.europa.eu/>
- **Cedefop** – European Centre for the Development of Vocational Training. It provides information, advice and expertise on vocational education and training, identification of skills needs, understanding of qualifications and development of lifelong learning.
<http://www.cedefop.europa.eu/en>

- **OSHA** – European Agency for Safety and Health at Work. It develops, gathers and provides reliable and relevant information, analysis and tools to advance knowledge, raise awareness and exchange occupational safety and health (OSH) information and good practice which will serve the needs of those involved in OSH.
<https://osha.europa.eu/en> <https://osha.europa.eu/en>
- **European platform against poverty and social exclusion.**
<http://ec.europa.eu/social/main.jsp?langId=en&catId=961>
- **European Social Policy Network (ESPN)** provides the Commission with independent information, analysis and expertise on social policies
(<http://ec.europa.eu/social/main.jsp?catId=1135&langId=en>)
- **Skills Panorama** (EC/CEDEFOP) is a central access point for data, information and intelligence on skill needs in occupations and sectors that provides a European perspective on trends in skill supply and demand and possible skill mismatches, while also giving access to national data and sources.
<http://euskillspacepanorama.cedefop.europa.eu/>
- **ILO** – International Labour Organisation brings together governments, employers and workers representatives of 187 member States, to set labour standards, develop policies and devise programmes promoting decent work for all women and men. ILO provides good quality data and analysis of various employment and social topics. The <http://www.ilo.org/global/research/lang--en/index.htm>
- **OECD** – Organisation for Economic Co-operation and Development brings together 34 Member States and provides a forum in which governments can work together to share experiences and seek solutions to common problems. OECD provides good quality data and analysis of various employment and social topics available in their library (<http://www.oecd-ilibrary.org/>), (<http://www.oecd.org/>)

TOOL #30. EDUCATION AND TRAINING, CULTURE AND YOUTH (ETCY)

1. INTRODUCTION

Investing in a high level of education and training has positive impact on individuals (e.g. higher chance to be employed) and the economy/society as a whole (higher productivity, innovation capacity, competitiveness and social cohesion and sustainable growth). Education and training fuels employability, productivity and adaptability and improves the ability of an economy to generate and absorb innovation. Any measure that helps improving the efficiency or performance of education and training systems (expressed, for example, as higher skills, better qualifications or a lower share of school drop-outs) helps Europe to sustain economic growth and social benefits.

Box 1: Relevant provisions of Treaties

- Article 9 TFEU obliges the EU to take into account the requirements linked to a **high level of education and training** in defining and implementing its policies and activities.
- Article 3.3 TEU invites EU to "respect its rich **cultural diversity** and ensure that Europe's cultural heritage is safeguarded and enhanced" and Art 167.4 TFEU invites EU to "take **cultural aspects** into account in its action under other provisions of the Treaties"
- Article 165 TFEU invites the EU to encourage the **participation of young people** in democratic life in Europe.
- Article 166 TFEU concerns the EU implementing a vocational training policy which shall support and supplement the action of Member States while fully respecting the responsibility of the Member States for the content and organisation of vocational training.

2. ARE IMPACTS ON ETCY POTENTIALLY SIGNIFICANT?

In order to identify potential impacts on ETCY a few key questions should be asked regarding each area. These can be interlinked and can be of different magnitude, one off or recurrent with regards transitory or permanent effects that take place. In addition, distinction between direct and indirect impacts should be made.

2.1. Education and training

Is the initiative/policy designed to make a contribution to the achievement of a high level of education and training? Is there any impact on education and training systems, their financing, performance or efficiency? Is there an impact on school autonomy or academic freedom?

Does the option contribute to implementing lifelong learning?

Does the initiative have an impact on access to education and training (from early childhood to adult learning) especially for learners from disadvantaged backgrounds?

Does the option contribute to preventing or remediating early school leaving?

Does the option have an impact on educational outcomes especially for learners from disadvantaged backgrounds?

Does the initiative contribute to social inclusion or non-discrimination in education and training?

Does the initiative contribute to enhancing civic and intercultural competences? What is the link to the level of knowledge, skills and competences of individuals (or groups of individuals) as well as their ability to sustain employment, growth and innovation? Is the quality of teaching both in formal and informal learning settings affected by a policy option?

Does the option affect the access to skills formation? Does it impact on the skills used by individuals (e.g. by increasing the relevance for labour market needs, by improving the visibility and comparability of skills and qualifications, etc.).

The initiatives that enhance the accessibility of people to acquire a core set of skills can improve access to good jobs and fuller participation in society. Initiatives that affect the quality and relevance of skills formation (e.g. vocational training) facilitate the transition to employment and maintain and update the skills of the workforce. Initiatives that can impact on validation and recognition of skills and qualifications increase the use of acquired skills and foster labour market mobility both internally and abroad.

Impacts on different education and training sectors need to be taken into account. These include pre-school, primary/secondary school, vocational education and training (VET), higher education, adult learning, non-formal learning through youth work. These impacts need to be considered in the light of different societal groups/age cohorts, regions and sectors.

Screening should not be restricted to a particular societal group or age cohort, but should comprise (a) societal groups with different background and living conditions, (b) different regions/countries and (c) different economy sectors.

2.2. Culture

Is there an impact on cultural diversity?

The 2005 UNESCO convention on the protection and promotion of cultural diversity, to which the EU is a party, defines cultural diversity as 'the manifold ways in which the cultures of groups and societies find expression. These expressions are passed on within and among groups and societies.

Is there an impact on cultural heritage?

The Treaties require the EU to safeguard and enhance Europe's cultural heritage and to "contribute to the flowering of the cultures of Member States, while respecting their national and regional diversity and at the same time bringing common cultural heritage to the fore". The Treaty also recognises the specificity of heritage for preserving cultural diversity and the need to ensure its protection in the single market. Cultural heritage is both tangible (buildings, sites, etc.) and intangible (traditions, music etc.), and it includes landscapes. It may for example be affected by EU initiatives on environmental protection, transport or energy efficiency (impact on historic buildings, natural

landscapes). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

Are individuals' access to and participation in cultural and creative activities affected?

Participation in culture is a fundamental right²⁹⁹. It usually covers both attendance (passive) and participation (active) in cultural activities, and is measured through quantitative and qualitative surveys, including household expenditure surveys, to gauge the economic consumption of culture.

2.3. Youth

Is there an impact on social inclusion and integration of youth?

Provided that youth present a group particularly prone to certain measures, and can often face risk of exclusion and insufficient socio-economic integration, analysis of how these can affect this group is necessary to avoid possible negative outcomes. Wellbeing and the ability to participate in democratic life³⁰⁰, including in cross-border programmes and activities, should also be taken into account.

Is there an impact on learning opportunities in respect to youth?

Identifying these is important due to the fact that youth is a vital part of educational activities, while education and training plays a key role in development of this group. Potential impacts on youth in terms of learning opportunities can be thus analysed by reviewing the section on impacts with respect to youths.

Is there an impact on labour market, continuity of transition between education and professional performance in respect to youth?

Aspects such as effects on activation of young people in terms of employment and self-employment, period between leaving education and finding first job, transition from internships to work contract, as well as potential impacts on population of young people out of employment, education and training should be considered in this part.

Box 2: Policies known to have impacts on ECTY

Education

- Changes in expenditure scheme – e.g. reallocation of spending from higher to lower levels of education, expanding coverage in specific regions, low-income areas
- Changing financing scheme – e.g. introduction of school fees, switching to/from community to state financing providing incentives for individuals or enterprises to get involved in education and training.
- Systemic changes – e.g. changing governance structures in education and training to involve social partners in organisation, delivery and financing of learning;

²⁹⁹ See Art. 27 of [Universal Declaration of Human Rights](#)

³⁰⁰ For example, participation in social and civic activities and organisations, volunteering, opportunities to express opinions in decision-making processes

introducing reforms in schooling material, altering school systems, targeting specific studying programmes (increasing numbers of students on VET, reducing numbers of students of particular specialisation at universities). • Policies influencing fiscal stability as they can limit public resources and investments in education. • Policies reforming digital markets, economy and society – the potential of ICT's to enhance the way people and institutions teach and learn. • Social policies and inclusion can help disadvantaged families (both younger and older age groups) participate or not in education, policies on maternity/parental leave can influence decisions to put children in crèche as well as gender policies. • Migration and border control policies might prevent student exchanges and/or influence knowledge, skills and competences shortages. • Trade and foreign investment policies exploit favourable economic conditions and can influence the fast-improving skills and competences of emerging markets' workers.
<i>Culture</i>
• Policies related to digital revolution. • EU laws on intellectual property rights or VAT. • Policies impacting cultural heritage – example of IA on Directive on the return of cultural objects unlawfully removed from the territory of a Member State (recast)³⁰¹
<i>Youth</i>
• Policies impacting education • Policies impacting labour market • Policies impacting health

3. HOW TO ASSESS IMPACTS ON ECTY?

The following section aims at describing how to measure impacts that are significant in the areas listed above. The suggestions provided outline the most widely used methods of assessment including illustrative examples of possible impacts in some areas. Some of the indicators may overlap.

3.1. Education and training

Assessing impacts on education and training can be based on different components, with list provided below:

3.1.1. Education and training systems

Evidence suggests that Europe's education and training systems provide graduates with skills and competences that are only partially relevant to the demand of the real market place. Significant differences persist in the effectiveness of national education and

³⁰¹

<http://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52013SC0189&from=EN>

training systems (young adults with nominally equivalent levels of educational attainment from different Member States scoring with considerable differences in competence tests. Moreover, education systems across Europe too often amplify rather than reduce social and economic inequalities.

3.1.2. Education expenditure – investing in skills, qualification and new technologies

Investing in people through providing better education and skills will raise productivity, employability and will generate economic growth, social benefits and prosperity in general.

Statistics on these can be found at different levels of aggregation (national, regional, level of education, private/public), providing insight on expenditure levels both per student and overall. It is important to measure in monetary terms how the various stages of learning processes are supported and how they interact with investment in skills. In addition, it is useful to gather statistics on investing in new technologies serving learning processes paving the way for smart innovation.

3.1.3. Levels of literacy, numeracy and digital numeracy

Levels of literacy, numeracy and digital numeracy significantly affect a population's potential to contribute to a developed society. They are one of the most important indicators in terms of education as well as a frequent target of new policies.

3.1.4. Level of knowledge, skills and competencies

Increasing the level of knowledge, skills and competences of individuals has a great potential to create social value, to drive innovation and entrepreneurship and to reinforce Europe's strong social foundations. Demand and supply for skills and competencies are ultimately guided by demographics, labour force quality and participation in education and training. As skills disparities between countries contribute to macro-economic imbalances and negative spill overs between them, educational outcomes (not necessarily systems) need to converge towards high levels of skills and competences. The digital transformation of the economy, the changes in work organisation and the dynamics in sectoral specialisation create new demands for skills leading to skills gaps and mismatches with the needs of the labour market.

Gathering information on levels of knowledge, skills and competencies (current and future needs) can serve as essential guidance for comparison of these among different sectors, countries (there are significant national and regional disparities in skills distribution) and can provide guidance for analysis of potential impacts. Equally important is to assess if an initiative has an impact on the visibility and comparability of skills and qualifications (e.g. validation/recognition) and therefore on the opportunities for individuals to use the acquired skills in the labour market (either in the home country or abroad).

3.1.5. Level of progress on early childhood education and care

Early childhood education and care refers to teaching and focusing on young children as regards the care aspect and development of social skills in the period before starting compulsory education. Statistics on these are regularly monitored with the aim of reaching targets levels for the EU.

3.1.6. Tertiary education attainment

Being one of primary goals of the EU 2020 Strategy, high level of tertiary education attainment is viewed as one of key ways to promote a well-developed society, fostering growth and innovation despite the fact that there is some evidence of skills mismatches in terms of those with a tertiary education being employed on positions requiring lower qualifications.

3.1.7. Adult participation in lifelong learning

In order to foster coherence of learning processes it is necessary to support lifelong learning as a continuum of human development. Furthermore, higher levels of participation in lifelong learning impacts positively on work performance.

3.1.8. Teachers and educators

Quality of teaching is essentially influenced by preparedness of teachers. Here important areas are: improving entry routes to, and the quality and relevance of initial teacher training; ensuring attractiveness of the teaching profession; improving teachers' access to high quality continuing professional development and empowering teachers to practice innovative teaching.

3.1.9. Early school leavers statistics

High levels of early school leavers adversely affect the transition from school to work, with unemployment levels among early leavers being considerably higher than average.

3.1.10. Provision of scholarships/contributions to disadvantaged students

In order to foster equality among students and to facilitate the access to education and training for every individual, it is necessary to take into account how scholarships and contributions are provided for particular groups of students.

3.1.11. Statistics on recent graduates' participation in the labour market

In order to facilitate better transition of young adults into labour market, there is an increasing need for the provision of high quality traineeships, apprenticeships and dual vocational education and training systems as the transition process is easier for those students who have participated in such programmes.

3.2. Culture

When carrying out an assessment of impacts on culture, and in accordance with the list above, the following aspects should be taken into account:

3.2.1. Cultural diversity

EU initiatives which may result in reducing consumer choice in cultural goods can, for example, have an impact on cultural diversity, e.g. merger of large audio-visual companies could reduce consumer choice in music or film.

3.2.2. Cultural heritage

Cultural heritage is both tangible (buildings, sites etc.) and intangible (traditions, music etc.), and it includes landscapes. It may for example be affected by EU initiatives on environmental protection or energy efficiency (impact on historical buildings). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

3.2.3. Participation in culture

Economic policies can affect cultural activities. As an example new EU initiative on VAT or on crowd-funding can have an impact on the way cultural sector is funded by public or private means; broadband availability affects access to culture (e.g. online collections/event tickets); or reduced funds for cultural events/sites raises prices, or causes closure.³⁰²

3.2.4. Youth

Youth is particularly prone to certain measures which might affect their transition from dependent childhood to adulthood in terms of social and economic integration, social inclusion, solidarity and labour market. Impacts on employment, social conditions and education of this group can often be of higher magnitude compared to other cohorts thus this aspect should be taken into account when measuring such impacts. For a specific example on assessment of impacts see Box 3. Measures can also have an impact on young people's ability and interest to participate in social/civic activities, such as volunteering, or to get involved in decision-making that directly affects them.

As a part of the everyday life of the majority of European youth, formal education and training, non-formal learning (courses outside school, etc.) or informal learning by engaging in meaningful activities (e.g. voluntary work) plays an important role in development of young adults. Thus for those policy options which affect aspects of educational activities, it will be necessary to estimate the impacts of these effects on youth development. For detailed list of corresponding impacts on education and training, please see above.

Box 3 : Example of cost-benefit assessment in The Youth Guarantee approach³⁰³

- The Youth Guarantee approach is tackling youth unemployment with assuring that all young people under 25 get a good quality and concrete offer (e.g. job, apprenticeship, traineeship) within 4 months from either leaving formal education or becoming unemployed.
- In the study a cost-benefit analysis is included with estimates on what are current costs of leaving young people out of employment, education or training and what would the costs of implementation of The Youth Guarantee be. The Youth Guarantee recommended involving youth representatives in designing and implementing the Youth Guarantee scheme so that the guarantee can be tailored to

³⁰² Eurobarometer on Cultural access and participation
http://ec.europa.eu/public_opinion/archives/ebs/ebs_399_en.pdf

³⁰³ <http://ec.europa.eu/social/main.jsp?catId=1079> and
http://eurofound.europa.eu/sites/default/files/ef_files/pubdocs/2012/54/en/1/EF1254EN.pdf

respond to young people's expectations.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON ECTY

Box 4: Example of best practices in Open Up Education initiative³⁰⁴

The aim of this initiative is to introduce innovative teaching and learning for all through new technologies and Open Educational Resources (OER) and promote best practices across Member States. Particular examples:

- 'University of the Greater Region' project – using Open Courseware³⁰⁵ in raising cross-border cooperation between geographically close universities of Germany, Luxembourg, France and Belgium.
- Open Education Europa Portal³⁰⁶ presents a large-scale platform for open education offering a common space for practitioners, policy-makers and members of academia and assists in fostering innovative strategies to transform learning methods.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

The basic data and information sources that can help in assessing the policy impacts in areas of education, culture and youth (ECY) are outlined below. More detailed information, background materials and guidance can be found on internal DG EAC web pages³⁰⁷.

5.1. Education and training

The core quantitative information and data required are described and further annually assessed in the European Education and Training Monitor³⁰⁸. This annual report illustrates, in a succinct document, the evolution of education and training systems across Europe. It takes into account a variety of benchmarks and indicators, as well as recent studies and policy developments.

Additional useful sources of information include:

- **Eurostat** – data on participation rates, staff, financing, investment, training, ICT related to education, educational attainment, participation in adult learning, continuing vocational training, etc. (UOE questionnaire, Labour Force Survey, Adult Education Survey, Continuing Vocational Training Survey);

³⁰⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0341&from=EN>

³⁰⁵ Form of organising OER by presenting it as a complete set of materials including syllabus, <http://www.openeducationeuropa.eu/en> presentation of the content, exercises etc.

³⁰⁶ <http://openeducationeuropa.eu/>

³⁰⁷ <https://myintracomm.ec.europa.eu/dg/eac/governance-tools/ensuring-quality/evaluation-and-impact-assessments/impact-assessments/Pages/Impact-Assessments.aspx>

³⁰⁸ http://ec.europa.eu/education/tools/et-monitor_en.htm

- **OECD**³⁰⁹ – information on teachers and their professional development (TALIS), annual study on students' performance (PISA), assessment of adults' skills (PIAAC);
- **EURYDICE**³¹⁰ – data and analyses of the European education landscape, national descriptions, comparative thematic analyses, evidence-based reviews on specific issues, quantitative indicators and secondary analyses, trends and reforms;
- **CEDEFOP**³¹¹ – indicators and annual studies on vocational education and training, thematic secondary comparative analyses and skills forecasts;
- **CRELL**³¹² (JRC) - secondary comparative analyses on education and lifelong learning using the results from large scale surveys, conceptual work on the definition of indicators and prospective analyses;
- **IPTS**³¹³ (JRC) - secondary comparative analyses, definition of indicators and prospective analyses on ICT, OER and creativity by delivering;
- **EENEE**³¹⁴ – analysis and reports by network of experts in the field of economy of education and training;
- **NESET**³¹⁵ - analysis and reports by network of experts in the field of equity in education and training.

5.2. Culture

- Cultural diversity: 2005 UNESCO convention on the protection and promotion of the diversity of cultural expressions;³¹⁶
- Participation in culture: 2013 Eurobarometer on cultural access and participation³¹⁷: Household expenditure surveys;
- Public policy in the area of culture, including funding: 2013 EENC report on trends in public funding for culture,³¹⁸

³⁰⁹ <http://www.oecd.org/education/>

³¹⁰ http://eacea.ec.europa.eu/education/eurydice/index_en.php

³¹¹ <http://www.cedefop.europa.eu/EN/publications.aspx>

³¹² <https://crell.jrc.ec.europa.eu/>

³¹³ <https://ec.europa.eu/jrc/en/institutes/ipts>

³¹⁴ <http://www.eenee.de/eeneeHome.html>

³¹⁵ <http://www.nesetweb.eu/>

³¹⁶ <http://www.unesco.org/new/en/culture/themes/cultural-diversity/diversity-of-cultural-expressions/the-convention/convention-text/>

³¹⁷ http://ec.europa.eu/public_opinion/archives/ebs/ebs_399_en.pdf

5.3. Youth

- The EU Dashboard of Youth Indicators³¹⁹ provides some 40 indicators across different sectors that provide a comprehensive picture to illustrate the situation of young people.
- EU Youth Reports every three years describe relevant policy measures taken in support of young people and an analytical overview of the situation of young people, at EU level and in Member States.
- An expert group set up by the Council of Youth Ministers reported on "Developing the creative and innovative potential of young people through non-formal learning in ways that are relevant to employability"³²⁰.
- The study on the value of youth work³²¹ depicts the contribution of youth work in different fields of action relevant to young people.
- The Eurobarometer surveys specifically address the opinions of young people:
 - 395 "Youth in Europe" (2014),
 - 375 "European Youth: Participation in Democratic Life" (2013),
 - 319 "Youth on the Move" (2011).

³¹⁸ <http://www.eenc.info/category/eencdocs/reports-documents-and-links/>

³¹⁹ http://epp.eurostat.ec.europa.eu/portal/page/portal/employment_social_policy_equality/youth/indicators)

³²⁰ http://ec.europa.eu/youth/library/reports/creative-potential_en.pdf

³²¹ http://ec.europa.eu/youth/library/study/youth-work-report_en.pdf

TOOL #31. HEALTH IMPACTS

1. INTRODUCTION

The Treaty (Article 168 TFEU) states that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities", which also relates to the approximation of laws in the single market (Article 114 (3) TFEU). Furthermore, the Charter of Fundamental Rights (art. 35) establishes that "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices."

Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed and less likely to be socially excluded. A healthy workforce is more productive, and healthcare services and health industries (pharmaceuticals, medical devices, and health research) are an important knowledge-intensive economic sector that enables people to maintain and improve their health and creates a steady demand for workers.

2. ARE IMPACTS ON HEALTH POTENTIALLY SIGNIFICANT?

Health impact is a horizontal concern across many policies. In general, health impacts should be examined if a proposal affects or could affect in the short or/and long term the health and safety of individuals or populations or the national healthcare systems. Furthermore, a number of policies not primarily addressed at the healthcare systems are nonetheless influencing the rules that relate to the provision and quality of healthcare services by impacting on their staff, equipment, communication and infrastructure. For example, if a policy changes the rules on lifting weights at work, this may have an effect on staffing a hospital, as more nurses may be needed to lift patients.

EU legislation and policies can have an impact on health, either directly or indirectly. An example for direct impacts is legislation banning asbestos³²². It has a direct health impact, as asbestos was proven to cause cancer. An indirect impact on health could result from a modification of the socio-economic and environmental determinants of health³²³ which also influence morbidity and mortality. Typically improvements in road safety would reduce the number of accidents and the number of people injured in road accidents. Similarly, changes in air quality impact on respiratory conditions.

³²² Directive 1999/77/EC

³²³ For a conceptual clarification on Social Determinants of health and action, see a discussion paper prepared by the WHO (apps.who.int/iris/bitstream/10665/44489/1/9789241500852_eng.pdf) and WHO (2003) The solid facts: social determinants of health (www.euro.who.int/document/e81384.pdf)

Box 1. Questions to help identify whether there might be health-related impacts

Direct impacts

- *Does the option create (or reduce) health risks or does it affect the safety of patients?*
For instance by modifying chemical substances (e.g. chemicals, pesticides in food, contaminants, etc.) or other factors (e.g. radiation, noise etc.) bearing an influence on the natural environment and the human body (e.g. air, soil and water quality, noise, unsafe consumer products³²⁴)
- *Does the option affect the effectiveness and sustainability of healthcare and long-term care services?*
- *Does the option affect the access of certain populations (including vulnerable ones) to medicinal products and information, health or long-term care services?*
In particular by impacting on their availability, quality, affordability and cost?

Indirect Impacts

- *Does the option influence the socio-economic environment that can determine health status?* In particular working conditions, income, education and training, housing, nutrition, energy consumption, transport, etc.
- *Does the option directly or indirectly target population's lifestyle-related determinants of health such as diet, physical activity, use of tobacco, alcohol or drugs?*

For all direct and indirect effects it should be examined if a specific population (including risk groups such as children, persons with disabilities, (pregnant) women, elderly, low-income groups) or specific geographical areas are affected differently and disproportionately by the option, resulting in increased (or reduced) inequalities in health status³²⁵.

In any case, the identification of significant impacts on health of a proposal/option should be informed by the outcomes of stakeholder consultation. The specific expertise of health stakeholders may prove valuable in identifying and properly assessing the impact on health of a given option.

3. HOW TO ASSESS IMPACTS ON HEALTH?

There is no uniform methodology to analyse and assess impact of policies on human health. The identification of the most appropriate methodology to use will depend on the characteristics or nature of the options under assessment³²⁶. To assess impacts on health

³²⁴ See the Tool #32 on *Consumers*.

³²⁵ Linked to this analysis is also the dimension of discrimination (e.g. in the access to healthcare) on grounds of e.g. racial, ethnic or social, religion, or belief, disability, age or sexual orientation, see possibly other thematic fiche by DG JUST?

³²⁶ For an example of choice of indicators, please see: “Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task available at: http://ec.europa.eu/health/strategy/evaluation/index_en.htm

it is necessary to have at least a general knowledge of public health³²⁷ policies and health systems³²⁸ and identify the populations and timeframe concerned. These elements are necessary for the estimation of costs and benefits.

3.1. Methods

Choosing the right methodology for assessing health impacts depends on the specific policy context. First of all, it is recommended to check how the same or similar potential health impacts have already been dealt with in existing Commission IAs, at Member State level or by third parties more generally³²⁹.

To assess direct and indirect health impacts monetary and non-monetary methodologies can be used.

The non-monetary approaches can be used to quantify the health benefits of a given intervention without monetizing it; to compare different intervention for the same specific health problem using cost and health outcomes (cost-effectiveness analysis) or in cases in which it is needed to compare different interventions for different health problems (cost-utility analysis).

The monetary approaches can be used if the aim is to present a comprehensive comparison of costs and benefits, although such analysis may not always prove to be possible or the most appropriate when evaluating options impacting human health (note that monetisation is not suitable when looking at the health of a specific individual).

The IA should aim to quantify the costs of the proposal as well as its benefits as much as possible, and measure impacts concerning implementation of policies to the extent it is proportionate to do so. The IA should be transparent on how data were gathered and from which sources to generate monetised information. In addition uncertainties as regards quantification of costs or benefits (for instance due to the lack of reliable information) should be clearly spelled out to avoid a misleading impression of certainty.

³²⁷ According to the World Health Organisation, public health refers to “all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases. Thus, public health is concerned with the total system and not only the eradication of a particular disease”.

³²⁸ Health systems are defined as those systems that aim to deliver healthcare services to patients – be they preventive, diagnostic, curative, and palliative – whose primary purpose to improve health (see: COM(2014) 215 final).

³²⁹ See for instance the “Public health England” website that provides a gateway to Health Impact Assessments (www.apho.org.uk/default.aspx?RID=44539)

Non-monetary approaches³³⁰

- **Quality Adjusted Life Years (QALY)** measures health *gains*. It uses available information on objective improvements in health/quality of life (QoL) and combines it with the duration of that improvement. The longer the life expectancy, the higher the QALY gain (therefore, a QALY gain would be highest for interventions aimed at children). QALY is commonly used in economic evaluations of specific health interventions (e.g. a medicine may result in QALY gains and its cost-effectiveness is calculated as "EUR per added QALY")³³¹. Values are generally derived from surveys of patients and doctors (stated preferences) and represent an average among different social groups. QALYs allow aggregation over the number of individuals affected. One can use equal weights for each individual or adjust weights to reflect preferences for particular target groups. Future life years may be discounted using a common discount factor.
- **Disability Adjusted Life Years (DALY)** measures the number of quality adjusted years *lost* because of illness/disability in comparison to the benchmark scenario (in general good health status without disability). Originally a measure of the burden of disease³³², it is also used to estimate the cost-effectiveness of interventions in terms of cost per DALY averted are calculated as the sum of Years of Life Lost (YLL – number) and Years Lost due to Disability (YLD). Values for YLL are derived from Life Expectancy, and values for YLD are calculated on the prevalence of specific conditions that are age-weighted and discounted (basing on attitude surveys).
- **Healthy Life Years (HLY)**³³³ indicates the number of years a person of a certain age can expect to live without disability. They are therefore less sensitive to health impacts than QALYs and DALYs. HLY is included in the set of indicators used in the Europe 2020 strategy. In 2012, HLY at birth in the EU was at 61.3 years for males and 61.9 years for females.

Monetary approaches

- **Preference Based approaches.** The aim of the preference based approaches is to compare the benefits of different policy options by placing an implicit monetary value on health benefits as is, for example, often done in the transport sector to inform decision on safety measures. While the use of preference based approaches can raise

³³⁰ For a discussion of the comparative merits of QALYs and DALYs, see: Sassi (2006), Calculating QALYs, comparing QALY and DALY calculations, Health Policy Plan (21/5): 402-408. (doi: 10.1093/heapol/czl018) (<http://heapol.oxfordjournals.org/content/21/5/402.full.pdf+html>)

³³¹ For an example of the use of QALY, see: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2163_en.pdf and http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2956_en.pdf

³³² See the WHO Global Burden of Disease reports (www.who.int/topics/global_burden_of_disease/ and <http://www.healthdata.org/>) including for additional information on weighting and discounting.

³³³ For general information on HLY, see www.ec.europa.eu/health/indicators/healthy_life_years/index_en.htm; for more specific information on the indicator, see www.ec.europa.eu/eurostat/cache/metadata/en/tsdph100_esmsip.htm

ethical concerns and criticism, they cannot – and do not seek to – place a monetary value on life.

These methods analyse individuals' stated or revealed preferences with respect to small changes in low-probability risks: while no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time. This can be measured by using the concepts of Willingness To Pay (WTP) for an improvement or Willingness To Accept (WTA) compensation for a worsening³³⁴. Two concepts that make use of these methodologies are the Value of a Statistical Life (VOSL) and the Value of a Statistical Life Year (VOLY)^{335, 336}.

Box 2. VOSL and VOLY approaches

Value of Statistical Life (VOSL)

- The VOSL is derived by investigating individuals' *WTP for a lower risk of mortality*, divided by that risk reduction. As such, the VOSL method does not measure the value of a life *per se*, instead it puts a monetary value on the willingness to accept slightly higher or lower levels of risk.
- The OECD has undertaken both a literature review and primary analysis to better understand the right values to use in policymaking. It proposed a range for the average adult VOSL for the EU of USD 1.8 million – 5.4 million (2005-USD), with a base value of USD 3.6 million. These base values and ranges should be updated as new VOSL primary studies are conducted³³⁷.

Value of Statistical Life Year (VOLY)

- The VOLY measures more generally the *WTP for an increase of one additional year of life expectancy*. However, as the VOLY is deemed constant across lifetime, assessments using VOLY and VOSL can produce conflicting results according to the demographics of the population considered.
- Overall, it should be noted that neither VOSL nor VOLY provides a measure of the quality of life. Ideally, a more comprehensive assessment would combine preference-based approaches with non-monetary approaches (outlined in the section above, on Non-monetary approaches).

³³⁴ See Tools #59 on *Methods to estimate costs and benefits*.

³³⁵ For more in-depth analysis of the Value of a Statistical Life, including a discussion of VOLY, see: http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01. For an example of use of VOLY and VSL in a recent cost-benefit analysis on air quality effects on health, see: http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP_CBA_corresponding_to_IIASA11_v2.pdf

³³⁷ http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmenthealthandtransportpolicies.htm#Executive_Summary

- **Accounting style' approaches.** The 'accounting style' approaches measure only certain aspects of health impacts and should be therefore treated with caution.

The **Cost of Illness method** is a rather simple measure comprising only the medical expenses related to the incidence of an illness. If an option lowers the rate of occurrence of an illness the saved medical expenses can be estimated and constitute a benefit. Conversely, if an option leads to an aggravation of a health situation, one can state the associated relevant costs.

However, the usefulness of this method is limited as it often does not include other indirect costs to society such as loss of hours worked, or how people value their own health. Also, in some situations it leads to perverse results: for example, an action that kills somebody who otherwise would have spent time in hospital would be seen as a benefit using the COI approach.

The **human capital method** tries to measure the loss of future earnings in case of disability or premature death. It can also be interpreted as a measure of the loss to social welfare caused by death / disability / lower productivity. However, this method leads to different values of lives depending on the projected future earnings (which could raise ethical concerns) and does not account for people who are outside the workforce. Average values could be used to lessen these concerns or if the individuals affected by an option cannot be identified precisely enough.

It is recognised that there are areas in which quantification is particularly complex or where it is inherently difficult to predict with accuracy the potential costs or benefits of a policy option (e.g.: regarding introduction of new products, services or technologies). In this case, quantitative assessments may be presented as ranges to take into account the possible margin of error or uncertainty associated with forecast costs and benefits.

Box 3. Assessment of Impacts Health vs Health Technology Assessment

- The assessment of impacts on health can build on methods typically used for Health Technology Assessment (HTA).
- HTA is the systematic evaluation of properties, effects, and/or impacts of health technology (diagnostic and treatment methods, medical equipment, pharmaceuticals, etc.) which often relies on economic modelling for the quantification results. For instance, Quality Adjusted Life Years (QALYs, see below), are often used in HTA in relation with reimbursement decisions. In this context, substantial research was conducted on the concept of monetary thresholds for QALYs (i.e. threshold below which an intervention would be cost-effective). Dialysis costs (USD 50,000 / QALY in the USA; GBP 20,000 to 30, 0000 in the UK; and EUR 10,000 to 80,000 in the NL) have been used as a standard to retrospectively analyse reimbursement decisions. The WHO has emphasised the importance to adjust the threshold to the income of the country (suggesting using 3 times GDP per Capita instead)³³⁸. However, there are only a limited number of countries that define such threshold in practice.
- Overall, HTA tools can be useful to quantify the effects of a proposal on health. However, these tools should be used carefully outside the HTA context due to a

³³⁸ <http://www.who.int/choice/cost-effectiveness/en/>

number of methodological constraints (e.g. the intervention population for HTA is very precisely defined, as well as the timing and nature of interventions etc.).

4. CONTEXT SPECIFIC ESTIMATES

Where policy specific estimates of the health impacts can be obtained – and are considered reliable – they should be used in the impact assessment. However, where no such research has been undertaken, prior estimates from other policy areas indicated above should be used as approximations.

In all circumstances, both the quantitative and monetary estimates should be mentioned. For example the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

In any case, the monetary results (costs and benefits) should be discounted, and sensitivity analysis to see how changes in the parameters affect the results should be performed. The European Network for Health Technology Assessment (EUnetHTA) works on elaborating methodological guidelines for health economic evaluations (including a reflection on discounting³³⁹).

The European Chemicals Agency (ECHA) has developed reference WTP values for the monetisation of health endpoints by Member States (when preparing "restrictions" on the use of chemicals)³⁴⁰. These are presented in the table below:

Health outcome	Value (in 2012 €) ^a
Premature death (generic) ^b	€3,500,000 (lower value) €5,000,000 (higher value)
Cancer morbidity (generic) ^c	€410,000/case
Statistical pregnancy ^d	€21,600/case (lower value) €40,700/case (higher value)
Very low birth weight ^e	€126,200/case (lower value) €405,500/case (higher value)
Birth defect, minor ^e	€4,300/case (lower value) €41,800/case (higher value)
Birth defect, major external ^e	€25,700/case (lower value) €329,800/case (higher value)
Birth defect, major internal ^e	€128,200/case (lower value) €711,800/case (higher value)
Mild, acute dermatitis (two weeks) ^f	€227/case

³³⁹ <http://www.eunetha.eu/>

³⁴⁰ https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

Severe, chronic dermatitis (periodic flare ups) ^f	€1,800/year (lower value) €12,000/year (higher value)

^a 2012 is used as baseline year because the survey studies were conducted then. It should be noted though that the values need to be inflation-adjusted when used in applications for authorisations or restriction proposals;

^b This value represents the marginal trade-off between survival probability and income (also known as “Value of Statistical Life” or “Value of a Prevented Fatality”). Notably, the VSL values obtained in ECHA (2014c) are consistent with recent meta-analyses of VSL studies, see Section 4 of ECHA (2016) for references;

^c This value expresses the WTP to avoid any disutility caused by the cancer morbidity in addition to premature death, see ECHA (2014c) and Section 4 of ECHA (2016) for more details;

^d This value reflects the WTP of couples with infertility problems to conceive, see ECHA (2014b) and Section 3 of ECHA (2016) for more details;

^e Detailed descriptions of the symptoms evaluated are given in ECHA (2014b);

^f Detailed descriptions of the symptoms evaluated are given in ECHA (2014a).

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. Consultation

- DG SANTE can assist in identifying appropriate health policy stakeholders at EU level, who would be able to help determining or evaluating a possible impact on health. For health impacts related to environmental impacts, DG Environment can assist in identifying appropriate stakeholders at EU level.
- The **EU Health Policy Forum**³⁴¹ is a group of about 50 European stakeholder organisations committed to health: public-health non-governmental organisations and patients' organisations, organisations representing health professionals and trade unions, health service providers, health insurance bodies and businesses.
- The independent non-food **scientific committees**³⁴² provide scientific advice on consumer safety, public health and the environment when the Commission prepares proposals.
- SANTE's **Expert Panel on effective ways of investing in health** can provide advice on direct and indirect health impacts and other health and healthcare related topics.

Finally, the **HTA Network**³⁴³ and the Joint Action on HTA³⁴⁴ can help identifying or gathering relevant Health Technology Assessment (HTA).³⁴⁵

³⁴¹ http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm

³⁴² Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR).

³⁴³ The Health Technology Assessment Network is a voluntary Network set up under Article 15 of Directive 2011/24. It gathers mainly Ministries of Health or authorities responsible for decisions on HTA, appointed by Member States. Its scope of activities is on strategic issues. It is supported by the Joint Action on HTA (EUnetHTA- see below) for technical issues. http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

³⁴⁴ EUnetHTA is a Joint Action, co –funded by the Health Programme of the European Commissions (DG SANTE) and participating organisations. It gathers mainly national and regional HTA bodies, performing HTA at national/regional level. Its scope of activities is on scientific and technical issues. (see: <http://www.EUnetHTA.eu>)

5.2. Methodological tools

Health and the Environment

- HEIMTSA (Health and Environment Integrated Methodology and Toolbox for Scenario Assessment): a first attempt at monetising a range of health impacts³⁴⁶
- INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe)³⁴⁷
- Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012³⁴⁸

URGENCHE/PURGE & EU (methodologies for quantifying the health impact under different policy scenarios for the reduction of greenhouse gas emissions / methodological framework to assess the overall risks and benefits for health of GHG mitigation policies).

Economic valuation

- National Institute for Health and Care Excellence: How NICE measures value for money in relation to public health interventions³⁴⁹
- WHO Guide to Cost effectiveness³⁵⁰

Health Impact Assessments

- Health Impact Assessment website of 'Public Health England'³⁵¹
- DYNAMO-HIA (2011) Development of a dynamic modelling tool to assess health impact of policies
- European Policy Health Impact Assessment – EPHIA (2004)³⁵²

³⁴⁵ Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues and impacts related to the use of a health technology (e.g. a medicine, medical equipment or rehabilitation method).

³⁴⁶ <http://www.heimtsa.eu/>

³⁴⁷ <http://www.intarese.org/about>

³⁴⁸ http://www.sdu.dk/en/om_sdu/institutter_centre/ist_sundhedstjenesteforsk/forskning/forskningsenheder/sundhedsfremme/forskningsprojekter/rapid

³⁴⁹ <http://publications.nice.org.uk/how-nice-measures-value-for-money-in-relation-to-public-health-interventions-lgb10b/introduction>

³⁵⁰ http://www.who.int/choice/publications/p_2003_generalised_cea.pdf

³⁵¹ http://www.apho.org.uk/default.aspx?QN=P_HIA

- WHO toolbox on Health Impact Assessment³⁵³
- Health inequalities in Health Impact Assessments³⁵⁴
- EU Health Systems Performance Assessment tool³⁵⁵

5.3. Studies

- ECHA (2016) Valuing selected health impacts of chemicals.
- OECD (2012) Mortality Risk Valuation in Environment, Health and Transport Policies³⁵⁶
- EU-OSHA (2014) Estimating the cost of accidents and ill-health at work: A review of methodologies³⁵⁷
- European Observatory on Health Systems (2007) study on the effectiveness of HIA³⁵⁸
- Marsh et al. (2012) Estimating cost-effectiveness in public health: a summary of modelling and valuation methods³⁵⁹
- Roberta Ara, Allan Wailoo (2012) Using Health State Utility Values in Models Exploring the Cost-Effectiveness of Health Technologies³⁶⁰
- Divajeva et al (2014) Economics of chronic diseases protocol: cost-effectiveness modelling and the future burden of non-communicable disease in Europe³⁶¹

³⁵² http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf and http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_frep_11_en.pdf

³⁵³ <http://www.who.int/hia/tools/en/>

³⁵⁴ <http://www.equityaction-project.eu/about/health-inequalities>

³⁵⁵ http://ec.europa.eu/health/health_policies/impact/assessment_tool/index_en.htm

³⁵⁶ http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha181u6rm.x-oecd-live-01

³⁵⁷ <https://osha.europa.eu/en/publications/reports/estimating-the-costs-of-accidents-and-ill-health-at-work/view>

³⁵⁸ <http://www.euro.who.int/en/about-us/partners/observatory/studies/effectiveness-of-health-impact-assessment-the>

³⁵⁹ <http://www.healtheconomicsreview.com/content/2/1/17>

³⁶⁰ <http://www.sciencedirect.com/science/article/pii/S1098301512016087>

³⁶¹ www.biomedcentral.com/1471-2458/14/456

- CEPS, Economisti Associati (2013) Assessing The Costs And Benefits Of Regulation³⁶²

5.4. Data sources

- EUROSTAT : Including the European Core Health Indicators (ECHI)³⁶³,
- Health at a glance: Europe – an EU publication, issued once in 2 years in collaboration with the OECD³⁶⁴,
- OECD Health Statistics (on Health Expenditure, Health care resources, Health care activities)³⁶⁵
- WHO, WHO Regional office for Europe³⁶⁶
- European Observatory on Health Systems and Policies³⁶⁷
- The Cost-Effectiveness Analysis (CEA) Registry, Boston, MA³⁶⁸.
- The Cochrane Collaboration – systematic reviews³⁶⁹
- PubMed - the free US resource for research and medical publications³⁷⁰

³⁶² www.ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

³⁶³ http://ec.europa.eu/health/indicators/echi/list/index_en.htm and http://epp.eurostat.ec.europa.eu/portal/page/portal/health/health_care/data/database

³⁶⁴ http://ec.europa.eu/health/reports/european/health_glance_2012_en.htm and <http://www.oecd.org/els/health-systems/health-at-a-glance.htm>

³⁶⁵ <http://www.oecd.org/health/health-systems/>

³⁶⁶ <http://www.who.int/research/en/> and <http://www.euro.who.int/InformationSources>

³⁶⁷ http://www.euro.who.int/observatory/publications/20020522_1

³⁶⁸ <http://research.tufts-nemc.org/cear4/Home.aspx>

³⁶⁹ <http://www.cochrane.org/>

³⁷⁰ pubmed.gov

TOOL #32. CONSUMERS

1. INTRODUCTION

Many EU policies directly affect consumers. It is the case especially in such areas as product safety, internal market, trade, competition, financial services, transport, telecommunications or energy.³⁷¹ In many cases a policy proposal concerning the functioning of markets and the activities of businesses affects directly or indirectly the behaviour or the interests of consumers, and may either benefit consumers, and/or reduce harm to consumer or alternatively create harm to consumers.

Box 1. Legal basis

Art. 38 of the Charter of Fundamental Rights of the EU requires EU policies to ensure a high level of consumer protection. The Treaty establishes that 'consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities' (TFEU, art. 12), and that '... the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.' (TFEU, Art. 169)

Consumer issues are a **horizontal concern** owing to products and markets becoming increasingly complex, the needs of an ageing society and economically vulnerable populations, the consequences of the economic crisis, the need to encourage more sustainable consumption patterns, increasing information overload and new demands on consumers in making the best choices in liberalised markets. Assessing adequately the general and diffuse nature of consumer impacts is of key importance for identifying benefits and costs of EU citizens.

The **European Consumer Agenda** is based on the notion of empowered consumers who can actively participate in the market and make it work for them by exercising their power of choice and by enforcing their rights properly. It is built around four main objectives designed to increase consumer confidence in the market by: a) ensuring their safety, b) providing consumers with information and education on their rights; c) securing means of redress and stepping up enforcement; and d) identifying new emerging challenges such as vulnerable consumers and unsustainable patterns of consumption.

2. ARE IMPACTS ON CONSUMERS POTENTIALLY SIGNIFICANT?

According to an established definition, '*consumer*' means any natural person who is acting for purposes which are outside his trade, business, craft or profession.³⁷²

³⁷¹ http://ec.europa.eu/consumers/eu_consumer_policy/consumer_issues_in_other_policies/index_en.htm

³⁷² It should be noted that natural persons may also act partly for professional purposes and still benefit from the status as a consumer – see recital of the Consumer Rights Directive 2011/83/EU OJ L 304, 22.11.2011, p. 64. In the case of dual-purpose contracts, where the contract is concluded for purposes partly within and partly outside the person's trade (and the trade purpose is so limited as not to be predominant in the overall context of the contract), that person should also be considered as a consumer

In some situations, impacts on businesses might serve as a proxy for consumer impacts which are ultimately passed through to consumers.³⁷³ While in some circumstances consumers might best be thought of as individuals, in other cases **households** may be the more relevant unit to consider.³⁷⁴ Special care should be taken of the potential role of children as influencers in the buying decision process.

A common understanding of **consumption** is a prerequisite for an adequate assessment of impacts on consumers. This term can relate to durable or non-durable products and services. The three phases of consumption are: procurement (purchase, inheritance, borrowing, exchange etc.), use and disposal.

When screening for potentially significant impacts on consumers, the following questions should be asked:

(1) *Would the option impact consumer's ability to benefit from the internal market or to access goods and services from outside the EU?*

Policies ensuring that a consumer is not made subject to discriminatory requirements based on his nationality or place of residence (non-discrimination principle³⁷⁵) enhance consumers' potential to engage in cross-border shopping within the internal market.

(2) *Would the option affect the prices, quality, availability or choice of consumer goods and services?*

Policies increasing competition and/or decrease costs of business will likely lead to lower **consumer prices**, higher **quantity of goods and services** and possibly also **more quality** (such as longer product lifetime), **more choices** for consumers and also prevent unfair commercial practices. This would be particularly true when firms have substantial market power – at the limit, monopoly power.

(3) *Would the option affect consumer information, knowledge, trust or protection?*

Policies reducing **asymmetric access to information**³⁷⁶ or excessive costs of accessing information may remedy a market failure, allow consumers to make more rational decisions and are likely to increase consumer trust and protection. Markets particularly prone to such asymmetries are e.g. second hand cars, financial intermediation, insurance, real estate processed food and beverages, catering and restaurants. Information

³⁷³ A firm is simply a legal entity, and hence any negative impacts on firms must ultimately be passed on, whether to the firms' shareholders, workers, or customers. It is understood that the same impacts should not be accounted as business and as consumer impacts in the assessment.

³⁷⁴ E.g. in the case of consumption of goods for children under parental care.

³⁷⁵ OJ L 376, 27.12.2006, p. 60, art. 20.

³⁷⁶ Extreme examples of asymmetric access to information are unfair commercial practices, such as disclosing incomplete or selected information via labelling, advertising, or other means. They are prohibited by the Unfair Commercial Practices Directive. A related issue are **negative externalities** in the market for free services in the digital economy. This business concept requires payment in form of personal information from customers, allowing control over massive volumes of data on service users which may then be commercialised and processed by third parties without the data subject's knowledge.

asymmetries are also at play e.g. in cases of unsubstantiated or misleading environmental claims³⁷⁷ which undermine consumers' trust and ability to assess these claims correctly through the choices they make in the marketplace.

In case of a '**Principal-Agent**' problem the consumer (principal) may not always be able to ensure that the agent correctly implements his preferences due to a mismatch of their incentives.³⁷⁸

Trust in the effective and efficient enforcement of consumer rights and the availability of adequate **redress mechanisms** across EU borders contribute to the adequate functioning of the Single Market. This is particularly important as the digital revolution makes cross-border shopping easy, but also increases the opportunities for rogue traders to engage in **unfair commercial practices**.

(4) *Would the option impact the safety or sustainability of consumer goods and services?*

Direct communication channels to consumers are **logos, labels and product claims** on a product (or in its advertising). They can help consumers to assess and compare products on the market or to guide them towards more sustainable, healthy and responsible choices.

(5) *Would the option impact vulnerable consumers?*

It is important to identify how potentially vulnerable consumers may experience a change in order to ensure that the option protects their health, safety and economic interests and does not make it hard for them to buy (or to decide in an informed way on buying) essential goods and services. A wide range of economic and non-economic factors can contribute to consumer vulnerability in specific markets. **Consumer vulnerability** can mean belonging to a socio-economic group likely to be less empowered, or lacking full capacity to operate as consumer.³⁷⁹ Consumer vulnerability is a dynamic concept, and **every consumer may become vulnerable** in certain situations, e.g. due to changes in life situations or because of the complexity of goods, services or marketing practices that make it difficult to verify the validity of their choice.³⁸⁰ Commercial practices which are likely to materially distort the economic behaviour of consumers that are particularly vulnerable because of their mental or physical infirmity, age or credulity in a way which

³⁷⁷ http://ec.europa.eu/consumers/consumer_evidence/market_studies/docs/environmental-claims-report-ecs-2013_en.pdf

³⁷⁸ This type of 'moral hazard' is particularly relevant in the finance industry and also in healthcare where there is regularly a separation between the patients, the medical practitioner who decides on treatment, and the government or private insurance who pays. See IA tool on problem drivers

³⁷⁹ This can be due to e.g. low income, low education, disabilities, diseases or specific behaviours such as credulity or addictive behaviour, developmental and affect comprehension, reasoning and judgement (children, adolescents and the elderly).

³⁸⁰ E.g. because of lack of technological expertise, time pressure, cognitive overload, lack of transparency of offers, lack of easily available, understandable and balanced information or ignorance concerning long term effects of use.

the trader could reasonably be expected to foresee shall be assessed from the perspective of the average member of that group.³⁸¹

How significant these impacts are will depend on **the number and group(s) of consumers** who could be affected, specifically **vulnerable consumers**; the nature and magnitude of **risks and uncertainties; benefits and costs** which the options could generate, both monetary and non-monetary; and the individual, household and **societal implications of consumers' decision-making**.

3. HOW TO ASSESS IMPACTS ON CONSUMERS?

Assessing consumer impacts is a multifaceted, complex exercise that covers multiple dimensions (including both price and non-price aspects) and that needs to be tailor-made to the particular issues at hand. A broad array of analytical methods and policy tools can be used in combination.³⁸² Rather than offering a full-fledged account of how to do so, the purpose of this tool is to introduce key concepts of consumer impact assessment, namely consumer welfare, detriment and conditions.

3.1. Consumer welfare

Consumer welfare refers to the individual benefits derived from the consumption of goods and services. It is typically measured using the concept of **consumer surplus**, i.e. the difference between what a consumer is willing to pay for a product and what he actually has to pay. When measured over all consumers, consumers' surplus is a measure of aggregate consumer welfare.³⁸³

The Single Market, the globalisation and digitalisation of markets allow consumers to benefit from a much wider choice of products. Market studies of the Consumers Directorate estimate these **consumer welfare gains**.³⁸⁴

Whilst models of perfect competition and imperfect information primarily measure the cost of goods or services, their quality and availability on the supply side of the economy;³⁸⁵ recent advances in behavioural economics have stressed the importance of

³⁸¹ OJ L 149, 11.6.2005, p. 27, art. 5(3).

³⁸² For the assessment of consumer health impacts, e.g. related to product safety, the IA tool on assessing Health Impacts is the source of choice.

³⁸³ In theory, individual welfare is defined by an individual's own assessment of his/her satisfaction, given prices and income. Exact measurement of consumer welfare therefore requires information about individual preferences <http://stats.oecd.org/glossary/detail.asp?ID=3177>.

³⁸⁴ E.g. the potential from increased e-commerce and a fully functioning internal market in *Consumer market study on the functioning of e-commerce and internet marketing and selling techniques in the retail of goods* http://ec.europa.eu/consumers/archive/consumer_research/market_studies/docs/study_ecommerce_goods_en.pdf; *Study on the functioning of the market for internet access and provision from a consumer perspective in the European Union* http://ec.europa.eu/consumers/consumer_evidence/market_studies/internet_services/index_en.htm.

³⁸⁵ See Tool # 23 on *Competition*.

demand side factors such as the limits of consumer rationality and self-interest, consumers' incoherent preferences, consumers' ability to access, absorb and analyse information as well as consumers' vulnerabilities, which all affect how consumers make choices in the marketplace.

Behavioural economics studies how people make actual choices, based on rigorous observation of behaviour rather than assumptions. Whereas traditional economics assumes that people can be treated as self-interested, rational and independent agents making choices based on consistent preferences, behavioural economics show that factors such as **bounded information processing abilities, systematic biases and heuristics** (decision-making shortcuts), **and social influence limit consumers' capacity to make a 'rational' decision**. People's behaviour can be altruistic, contradictory, not fully rational, time-inconsistent, and influenced by social norms. Thus, policy design will be better-informed and more effective if it takes consumers' limited, possibly biased, and socially influenced decision-making into account. Some of the commonly documented biases are:

- Status quo bias: letting the default rule determine our decision;
- Myopia: choosing a small reward today over a larger one later;
- Loss aversion: preference towards avoiding loss than to acquiring gains;
- Overconfidence: subjective confidence in judgment is greater than objective accuracy.

3.2. Consumer detriment

Assessment of impacts on consumers can be viewed in terms of negative effects on consumer welfare, i.e. welfare losses (financial, health, quality of life). This **consumer detriment is a measure of harm** that consumers may experience when market outcomes fall short of their potential. Consumer detriment can be structural or personal.

Box 2. Types of consumer detriment

- **Structural detriment** — the loss of consumer welfare due to market failure or regulatory failure, measured by consumer surplus as described above.
- **Personal detriment** — the personal experience of those consumers for whom something goes wrong, rather than to consumers in aggregate, benchmarked against reasonable expectations. This will generally be a survey-based exercise inquiring on financial and non-financial detriment (e.g. time losses, psychological detriment). When consumers obtain redress from their supplier (e.g. a replacement product, refund or compensation) this may partly or wholly offset the detriment suffered.

Assessing impacts on personal detriment is particularly useful when evidence is needed on how structural detriment may change and where it is difficult to quantify impacts on structural detriment itself.³⁸⁶

However, there may be cases in which reducing personal detriment does not improve the overall functioning of the market but simply protects a small group of consumers at the expense for others. In such instances, it should be carefully evaluated whether such policy truly represents an improvement in **fairness**.³⁸⁷

3.3. Consumer conditions

Better consumer conditions contribute to maximizing the welfare of consumers. The framework for measuring consumer conditions comprises three main dimensions: knowledge, awareness and trust³⁸⁸ with respect to consumer legislation and market conditions; compliance with consumer legislation and enforcement; and consumer complaints and resolution of disputes between consumers and retailers. These dimensions follow the logic of the three main stages of a transaction (before, during, and after) between a consumer and a retailer.

4. HOW TO MINIMIZE NEGATIVE IMPACTS ON CONSUMERS

A broad array of policy tools can be used in combination to increase consumer welfare or to reduce consumer detriment.

Box 3. Example: Impact Assessment on the comparability of fees related to payment accounts, payment account switching, and access to payment accounts with basic features - SWD(2013) 164 final

- Consumer information and confidence - Clear and comparable information on bank fees and switching enables consumers to understand how much they are charged for (changing) their account and results in them being able to compare offers and potentially switch providers for a better deal. Addressing direct and indirect financial (opportunity) costs of actually switching increases consumers' confidence in seeking to switch to products that are better suited for their needs and helps them reap the benefits of an efficient and competitive market.
- Consumer prices - Removing barriers to switching for 'locked-in' customers enables them to shop around and to benefit from lower prices and an increased level of services.
- Consumer choice - Online shopping offers a wider choice and potentially lower prices for products and services and opens the potential of shopping throughout the

³⁸⁶ E.g. in the internet access market a principal barrier for switching reported by consumers were the expected direct costs, in particular the penalty for leaving a provider before the contract expires which can be remedied by limiting the maximum duration of internet service provision contracts.

³⁸⁷ As in the case of improving the situation for vulnerable consumers or protecting consumers against very severe negative outcomes, such as injury from unsafe product.

³⁸⁸ E.g. Consumers' **knowledge** of their rights, **awareness** of relevant institutional actors relevant in field and **confidence** in market conditions.

internal market for consumers that may remain geographically local. Enhancing access to a payment account increases consumers' opportunities to make use of e-commerce, as the majority of transactions require a credit card or bank transfer and other means of payment are usually more expensive and inconvenient.

- Vulnerable consumers – Nowadays rental payments may be required to be done by standing order and salaries are frequently paid via bank transfer only. Access to a bank account can cut hurdles in relation to employment or renting property and would benefit vulnerable consumers like students, long-term unemployed, and migrants etc.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

To build a knowledge base, the Consumers Directorate gathers relevant information by **monitoring markets** and national **consumer conditions** and by studying **consumer behaviour**. How the Single Market works for consumers is monitored in two stages: Identifying malfunctioning markets and horizontal issues of concern through the [Consumer Scoreboards](#); and in-depth analysis of these markets/issues through **market studies** to identify the main problems and suggest policy solutions. **Behavioural trials** allow comparing alternative policy options and tailoring policy remedies before their implementation. This work is underpinned by the development of **methodological tools**, e.g. for measuring consumer detriment.

The information presented here is to be seen as a starting point for analysis and is not exhaustive. You are encouraged to consult the [Consumer Evidence web page](#) for further advice.³⁸⁹ To ensure the integration of consumer interests and concerns in all relevant EU policy areas, the [European Consumer Consultative Group \(ECCG\)](#) may be consulted whenever a policy proposal will likely affect consumers. The Consumer Affairs Directorate can also assist in identifying further appropriate consumer policy stakeholders.

5.1. Methodological tools and data sources

- The **Consumer Conditions Scoreboard** examines progress in the **integration of the EU retail market**. The main data source of the Scoreboard is EU-wide [consumer and retailer surveys](#).
- The **Consumer Markets Scoreboard** tracks the **performance of over 50 consumer markets** across the EU, Iceland and Norway.³⁹⁰ The main data source for the Scoreboard is the EU-wide [Consumer Market Monitoring Survey](#).
- Harmonised data on **consumer complaints** are included into the Consumer Markets Scoreboard.³⁹¹

³⁸⁹ Guidance is also provided e.g. by the OECD's [Consumer Policy Toolkit](#) and work on Consumer Impact Assessment by the [Canadian Office of Consumer Affairs](#).

³⁹⁰ They are based on the indicators of comparability, trust, problems and complaints, overall satisfaction with respect to expectations, choice and switching.

³⁹¹ The Commission adopted a [Recommendation](#) to ensure complaints' data comparability across the EU.

- Findings of [in-depth market studies of underperforming sectors](#) and of transversal studies have influenced policy with tangible benefits for EU consumers. Market studies³⁹² can be carried out through the [Consumer Market Studies Framework Contract](#).
- The [2011 Consumer Empowerment Report](#) provides a detailed portrait of Europe's consumers. Consumer knowledge deficits and risks of information overload are analysed in [Knowledge-enhancing Aspects of Consumer Empowerment](#).
- A mapping of the concept of consumer detriment and a framework for assessment can be found in [An analysis of the issue of consumer detriment and the most appropriate methodologies to estimate it](#). The [Handbook to assess consumer detriment](#) offers guidance on how to apply the consumer detriment methodology.
- [Applying Behavioural Sciences to EU Policy-making](#) covers issues to consider when incorporating behavioural insights into the design, implementation and monitoring of policies. Ex-ante behavioural testing of the effectiveness of policy interventions can be carried out through the [Framework Contract for the Provision of Behavioural Economic Studies](#). *Seven Points to Remember when Conducting Behavioural Studies in Support of EU Policy-making* highlights the main issues that policy officers need to be aware of when carrying out such behavioural testing.

The **helpdesk** for assessing consumer impacts provides tailored information and specific guidance: JUST-CONSULT-E1@ec.europa.eu

If impacts on consumers are likely to be significant, DG JUST should be invited to participate in the interservice group preparing the impact assessment and initiative.

³⁹² These studies include consumers' opinion surveys, stakeholders' surveys, the collection of prices for goods/services, surveys based on mystery shopping methodology and behavioural experiments.

TOOL #33. TERRITORIAL IMPACTS

1. INTRODUCTION

Living conditions as well as industrial structures, infrastructure endowment and geographical conditions vary substantially across the EU. EU's cohesion and regional policies are designed to mitigate these differences and ensure that poorer regions have means to address regional challenges. In spite of good progress in convergence across Europe on many parameters, there is still significant dispersion within the EU. Still many policy measures address specific territorial areas or have specific consequences concentrated in certain territories. For example, efforts to ensure more sustainable fishing is likely to have spatially differing impacts which vary according to the distribution of fisheries and their conservation status. In addition, the reduction of poverty and social exclusion is a common Europe 2020 objective, but the extent of the problem varies a lot across countries and regions.

The territorial dimension may be relevant for impact assessments for two reasons.

- First, the impacts associated with the **problem** are often heterogeneously distributed across the Union. This means that the design of effective policy options will also bring about an uneven geographical distribution of impacts (costs and benefits).
- Second, a policy option may act unevenly to produce heterogeneous territorial impacts even where a problem is not necessarily unevenly distributed across the territory of the Union.

In policy cases, where there is no particular territorial dimension, obviously there is no need for a detailed assessment of the territorial impacts.

2. HOW TO ASSESS IMPACTS ON TERRITORIES OF POLICY OPTIONS

The impact on territories can be assessed using qualitative and quantitative methods as well as specific tools developed to support impact assessments or the consultation process.

The approach relies on a description of the spatial distribution of four items:

- (1) The degree to which the problem or driver to be addressed is concentrated in some (types of) areas, Member States or regions;
- (2) The capacity of EU policies to respond to the problem/implement the policy;
- (3) The degree to which stakeholders indicate a need for a policy response in the relevant areas and regions?
- (4) The effectiveness of the policy response and its potential impact, which sums up the former issues.

In some cases, the risk of asymmetric territorial impact is obvious. In other cases, only experts familiar with the issue can assess the risk of such asymmetric impacts.

Box 1. Example of the 2009 White Paper on adapting to climate change

- The impact assessment supporting the White Paper discussed
 - the spatial distribution of climate change (item 1).
 - A description of the ecosystems and human systems described the capacity to respond (item 2).
- The assessment discussed the actors, including those at the local and regional level, involved in setting up adaptation strategies (item 3).
- The potential territorial impact (item 4) depended on the interaction of the previous three items.

A correct assessment of the territorial dimension of the problem will help shaping properly targeted policy options. It can also avoid conducting policies in those areas and regions, where no policy response is needed. This could create legal, compliance or administrative costs.

The relevant territorial unit or grouping may vary from case to case and should be proportional to the question at hand. It could be specified at the Member State level or in terms of geographical characteristics such as for instance coastal areas, mountainous regions or densely populated areas. In other cases, there may be a need for singling out those administrative regions which are disproportionately affected by a certain policy measure.

3. CHARACTERISING THE PROBLEM

Spatially relevant statistics and information and statistics are routinely collected, aggregated and made available by local and regional authorities, Member States, the Commission and other EU agencies and bodies (see section 4 for some examples). This can be used to characterise a particular problem and to understand whether the problem is characterised by territorial impacts which are unevenly distributed across the Union.

Box 2. Examples where the problem is spatially uneven

- The sensitivity of terrestrial and aquatic ecosystems to acid rain varies across the Union as a function of the underlying geological rock and soil types which means that some air pollution emissions sources contribute more to the environmental damage than others once transport in the atmosphere is considered. The ecosystem sensitivity can be mapped.
- Measurement by the Member States show that the quality of bathing waters and rivers varies across the Union this can be overlaid with spatial information about the various economic activities which occurs in river basins across the Union.
- The relative wealth of regions in the Union varies significantly which is taken account of in the Union's cohesion and state aid policies. Similarly, unemployment varies significantly across the Union.
- Susceptibility to a changing climate will vary across the Union. Some regions will be susceptible to flooding, encroachment of the sea whilst others are sensitive to reduced rainfall and drought.

If the nature of the problem is spatially varying then it is important to characterise this early in order that policy options can be designed properly but also in order to be able to assess the territorial impacts associated with each of the policy options.

The IA process requires that a baseline be constructed to show how the problem is likely to evolve in the absence of policy intervention. If the data allows, a projection should be made to show to what extent the problem is likely to grow in the future. Projections with a sub-national component including demographic, economic and land use projections can help to show the likely evolution of the issue at stake.

If the spatial distribution of an issue cannot be measured directly, it can sometimes be derived from case studies or the scientific literature. In some cases, another measure with a similar spatial distribution can be used as a proxy indicator. For example, opening up trade in textile sector may mean that regions with an uncompetitive textile industry will see high redundancies in that sector. If no data is available on the regional competitiveness of the textile industry, regional employment growth in that sector may help to assess which regions could be more vulnerable.

4. MODELLING INTERACTIONS

A model can support an impact assessment, especially if the policy addresses a problem driver that is strongly linked to other issues. For example, trade policy can have an impact on the agricultural sector or new transport infrastructure can influence economic growth and land use changes. The Joint Research Centre has developed six models³⁹³ with a sub-national component, including RHOMOLO, LUISA and TRANSTOOLS. Ideally, all models would use the same baseline scenario based on Eurostat's and ECFIN's long term projections.

5. TOOLS TO SUPPORT THE QUANTITATIVE ASSESSMENT OF TERRITORIAL IMPACTS

[ESPON](#) has developed a tool to help summarise this information into an overall impact. With the [ESPON ARTS](#) instrument one can assesses policy impacts using a vulnerability approach. This approach uses three elements: exposure, sensitivity, and impact. This excel-based instrument allows people by following a process of 9 steps to get a quick impression of the territorial impact based on exposure and sensitivity. Different combinations can easily be tested. An online version including options for seeing impacts on maps is currently being developed and will be available at www.espon.eu.

For territorial impact analysis at the regional (NUTS2) level, the model RHOMOLO developed by the Joint Research Centre and DG REGIO can be used to analyse the impact on economics outcomes such as GDP, employment, investments, prices, exports and wage. There is a simplified web version of the model that can be used as a first approximation of the impact of policies affecting total factor productivity, labour productivity or transport costs, <http://rhomolo.jrc.ec.europa.eu>. For more complex impact assessment exercises, DG JRC can be contacted to run tailored simulations.

³⁹³ See the Modelling Inventory and Knowledge Management System (MIDAS) <http://midas.jrc.it>

For policies with an expected impact mainly at the sub-regional level or when regional boundaries are crossed by the same policy without affecting whole regions, the JRC can also provide support with the impact assessment through the Land Use model LUISA.

6. CONSULTATIONS CAN HELP TO REVEAL ASYMMETRIC IMPACTS

The stakeholder consultation process foreseen in the impact assessment can be used to collect data and information about the issue to be addressed and the impact of the policy option from outside the European Commission. Stakeholders may have access to more information and thus be in a good position to judge the risk of an asymmetric impact. Therefore, the consultation could include a question to check whether the public or the stakeholders expect the policy to have an asymmetric impact.

Box 3. Public consultation

- Sample questions:
 - According to your knowledge and information, is this problem concentrated in certain areas, regions or Member States?
 - Do you expect that this policy will have a disproportionately large impact on certain areas, regions or Member States? If yes, please indicate which ones and why.
- Under the 'Protocol on Cooperation between the Commission and the Committee Regions' (2012) the 'Commission services may ask for support from the Committee in preparing its assessment'. This may be particularly useful if the consultation investigates asymmetric impacts on regions or local authorities.³⁹⁴

7. HOW TO MINIMIZE ANY NEGATIVE IMPACTS ON TERRITORIES

Taking into account potential asymmetric impacts can increase the effectiveness and the efficiency of the policy. It can increase political support for a policy, boost the benefits while addressing excessive spatial concentrations of the costs.

If costs are distributed in a highly asymmetric manner, the policy could be adjusted to reduce the costs of the policy on the most affected regions. If the policy itself cannot be adjusted, mitigation measures including the creation of another instrument to reduce the burden on these regions or areas should be investigated. The territorial assessment can also help the relevant regions and areas by making them aware of the EU policies under development so that they will be able to prepare and take most advantage of the policy once implemented.

Three short examples can illustrate how negative territorial impacts can be reduced:

- (1) Reducing the concentrations of an airborne pollutant in cities to uniform level within a single deadline may be more difficult to achieve in some cities than others. Concerns about such difficulties may lead to pressure to allow higher concentrations. Assessing territorial impacts could identify such risks and ensure

³⁹⁴ Contact the SG-C2 for further information

that the EU policy would be able to allow cities with very high concentrations a longer time frame – based on clear criteria - to reach the necessary quality threshold, should they so wish.

- (2) State aid policy also differentiates its approach according to the level of development of a region and to the size of the market. For example, different possibilities to award state aid apply to areas with an abnormally low standard of living, to outermost regions and regions with low population density.
- (3) Growing global trade integrations tends to benefit the EU, but some regions specialised in a sector vulnerable to further trade integration/globalisation may face a high number of redundancies. The European Globalisation Adjustment Fund (EGF) was set up, in part, to address such negative asymmetric impacts. The EGF provides one-off, time-limited individual support geared to helping workers who have suffered redundancy as a result of globalisation.

Policies can be adjusted in five ways to address highly asymmetric territorial impacts:

- Adjust the policy for the entire Union or some of its parts (as for example State Aid policy does);
- Grant more time to implement a policy in some parts of the Union (as was done for the urban waste water directive during the accession negotiations);
- Exempt those parts of the Union which are unaffected by the problem from the policy;
- Use existing policies to address asymmetric territorial impacts (for example by using Cohesion Policy);
- Create a new instrument to address asymmetric territorial impacts if/when they arise (for example the European Globalisation Adjustment Fund)

8. INFORMATION SOURCES AND BACKGROUND MATERIAL

- Assessing territorial impacts: operational guidance on how to assess regional and local impacts within the Commission Impact Assessment system, SWD (2013) 3 final³⁹⁵.
- **Regional typologies:**
 - **Local typologies:** Cities and their commuting zones: The degree of urbanisation is described in this [article](#) and can be visualised interactively using the [statistical atlas](#) (General and regional statistics, chapter 14)
 - **Sub-national data sources:** Eurostat has been expanding its sub national data offer in the recent years in two dimensions, more domains covered and more detailed geographical levels see [website dedicated to sub-national statistics](#).

³⁹⁵ http://ec.europa.eu/smart-regulation/impact/key_docs/docs/cswd_ati_en.pdf

- **In** addition, Eurostat publishes [geographical information](#) such as reference topographic layers and specific thematic layers.
- **The JRC** develops geo-referenced datasets at European and global scale, many of which are relevant for regional or territorial analysis. These datasets cover themes as natural hazards and risk prevention, distribution of species, climate change, agriculture, land cover, soil data, etc.
- An updated inventory³⁹⁶ of available datasets can be retrieved from the JRC Reference Data and Service Infrastructure (RDSI): <http://rdsi-portal.jrc.it:8081/web/guest/home>
- Additionally, the JRC operates and maintains the INSPIRE geoportal giving access to data and services from Member States: <http://inspire-geoportal.ec.europa.eu/discovery/>

³⁹⁶ For Commission services, this inventory can also be searched using the INSPIRE@EC Geoportal: <https://webgate.ec.europa.eu/inspire/geoportal/catalog/identity/login.page>

TOOL #34. DEVELOPING COUNTRIES

1. INTRODUCTION

Assessing systematically the likely effects of different policy initiatives on developing countries is a requirement based on Article 208(1) TFEU, which stipulates that the EU “shall take account of the objectives of development co-operation in the policies that it implements which are likely to affect developing countries”. This constitutes the legal basis of a concept generally known as “Policy Coherence for Development” (PCD). Practically, the application of the PCD principle means recognizing that some EU policy measures can have a significant impact outside of the EU which may contribute to or undermine the Union's policy objectives concerning development. Through PCD, the EU seeks to take account of development objectives in all of its policies that are likely to affect developing countries, by minimising contradictions and building synergies between different EU policies to benefit developing countries and by increasing the effectiveness of development cooperation. PCD is therefore a fundamental element of the EU's development cooperation objectives, i.e. the reduction and eradication of poverty in the world in the long term. Are impacts on Developing countries potentially significant?

Developing countries are very heterogeneous in their social, political and economic structure. While impacts on the most relevant countries will have to be established on a case-by-case basis, as a general rule, the focus should be put primarily on the impacts on Least Developed Countries and other countries most in need.³⁹⁷

The EU defined five global PCD challenges where policy impacts should be given particular attention.³⁹⁸ These are: trade and finance; ensuring global food security; addressing climate change; making migration work for development; strengthening the links between security and development. Potential impacts on human rights in developing countries may also need to be addressed.³⁹⁹

While it can sometimes be cumbersome to identify potentially significant impacts and to distinguish between direct or indirect impacts, many of the EU measures that are likely to have an impact on developing countries are already well-known (see Box 1 for a non-exhaustive list of these compiled by OECD⁴⁰⁰).

³⁹⁷ An updated list of Developing Countries and Least Developed Countries can be found, respectively, at the World Bank's and IMF's official websites.

³⁹⁸ The Council Conclusions on PCD of 18/11/2009 endorsed these five priority areas in view of having a more targeted, effective and strategic approach to PCD in the EU. The five priority areas are not carved in stone. The Council itself in the above conclusions underlined that they may evolve over the years, even though they have remained stable since 2009. See <http://consilium.europa.eu/uedocs/cmsUpload/st16079.en09.pdf>

³⁹⁹ See Tool #28 on *Fundamental rights and human rights*.

⁴⁰⁰ This list is based to a large extent on an OECD publication (2012). See OECD, Policy framework for policy coherence for development, WP n°1, 2012.

Box 1. Measures known to have impacts on developing countries*Trade and finance:*

- Regulatory measures in the management of EU production (e.g. fisheries) can affect exports and prices of products in developing countries, thereby distorting trade and undermining the local production, food security and livelihoods in these countries;
- Tariff barriers or export subsidies for EU products (e.g. agriculture) can affect the exports, commodity prices, and prices of processed products exported from developing countries to the EU and thereby undermine local production (for domestic or export markets), food security and livelihoods in developing countries;
- Measures regulating the behaviour of private actors such as multinational enterprises also active in developing countries; or measures impacting on the (re)distribution of value added along international integrated production chains (e.g. fair trade initiatives);
- Measures affecting movement of capital such as investment or remittances and the conditions of investment in developing countries, both in positive and negative ways (e.g. measures fighting tax evasion and dealing with tax havens);

Ensuring global food security:

- Regulatory measures regarding food safety and quality, animal welfare and environmental protection in the EU, which may present unintended non-tariff trade barriers to direct/indirect food exports into the EU from developing countries;

Making migration work for development:

- Initiatives affecting movement of people (e.g. migration policy) and conditions for travel of developing countries' citizens to and from the EU;

Strengthening the links between security and development:

- Measures affecting the attribution of development aid, investment or domestic resource mobilisation in developing countries;
- Measures and initiatives affecting fragile states or the EU intervention in international security issues;

Addressing climate change:

- Measures regarding climate change mitigation and achieving the international agreed warming limit level; measures affecting adaptation needs of developing countries.

2. HOW TO ASSESS THE IMPACTS ON DEVELOPING COUNTRIES?

The scope and depth of the analysis will be determined, on a case-by-case basis, by the likely impacts of the proposed action. In some cases (e.g. for new regulatory proposals that affect products produced primarily in developing countries) a "fully-fledged analysis", i.e. detailed, substantial and quantified analysis will have to be undertaken. In other cases, a fully-fledged quantitative assessment will not be possible (because data is not available), or not proportionate (because the cost incurred in gathering such data would not be justified in the light of the magnitude of the initiative's likely impact). In the latter case, the analysis may generally be rather broad in its problem description and objectives, and the analysis of impacts may not require detailed quantitative data. In this

context, a qualitative analysis/overview of the impact of EU policy options on developing countries is a valid approach.

It is also important to consider possible other factors potentially playing a role in the final negative/positive impact (e.g. other international actors, local legislation, etc.) and determine whether it would be transitory or permanent. Furthermore a qualitative estimate of the main political risks (possible sources include past EP and Council or civil society comments/criticism on this or similar policy/measure) should be provided.

2.1. Qualitative/Descriptive assessment

This kind of assessment can illustrate the magnitude of impacts listed as significant, or it can serve as a first step in the assessment followed by further quantitative analysis.

A list of potential impact areas and guiding questions that should be taken into account when carrying out a qualitative assessment (accompanied by possible further quantitative analysis) is presented in the table below.

Category of impact	Potential impact areas particularly and guiding questions concerning developing countries
Economic impacts	Who are the developing countries' producing (and exporting to the EU) the goods/services affected? Are these least developed countries?
	What is the impact on proportion (esp. in value) of the trade between these developing countries and the EU, in particular regarding the trade balance of developing countries?
	What is the likely impact on price volatility?
	What are the impacts on proportion between the purchase of raw materials and finished products from developing countries?
	What is the impact on the competitiveness of exporters in developing countries in terms of intended or unintended trade barriers?
	What are the impacts on the initiative on intellectual property rights, standards, and technology and business skills in developing countries and on their capacity to trade their goods (towards the EU or between themselves)?
	What is the impact on food security for local population (e.g. by impacting on price of commodities or food on world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on different population groups (urban vs. rural, small vs. large scale farmers)?
	What are the impacts on international and domestic investment flows (outflows and inflows including FDI) in the developing countries?
	What are the impacts on the private sector in developing countries (including competitiveness, access to finance, access to market)?

Social impacts ⁴⁰¹	What are the impacts on labour market (e.g. creation of job or decrease in employment level, impacts on different groups of workforce – low-skilled vs. high skilled workforce, wages level, working conditions)?
	What are the impacts on main stakeholders and institutions affected by the proposal?
	What is the impact on poverty levels ⁴⁰² and inequality in developing countries?
	What are the impacts on gender equality and on the most vulnerable groups of society?
	What is the impact on human rights ⁴⁰³ in the development countries?
	What is the impact on migration in developing countries (rural-urban or international)?
	What is the impact on food security for the local population (e.g. by impacting on price of commodities or food on world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on different population groups (urban vs. rural, small vs. large scale farmers)?
Environmental impacts ⁴⁰⁴	How does it impact ecosystem approach?
	What is the impact on emission targets in developing countries?
	What is the impact on chemicals authorisation as well as on use and waste management?
	What is the impact on green economy development, both globally and in partner countries?
	What is the impact on the low carbon technology transfer and its availability in developing countries?
	What is the impact on the biodiversity (mono-cropping, deforestation) and global or local food security?
	What is the impact on the management and use of natural resources, e.g. minerals, timber, water, land, etc.?
	Are these options consistent with our support (under development cooperation policy) to responsible approaches to natural resources management such as FLEGT ⁴⁰⁵ , EITI ⁴⁰⁶ or Kimberley agreement ⁴⁰⁷ ?

⁴⁰¹ See Tool #29 on *Employment, working conditions, income distribution, social protection and inclusion*

⁴⁰² Those people that stay below the poverty line

⁴⁰³ See Tool #28 on *Fundamental rights and human rights*.

⁴⁰⁴ For additional information see tool on Methods to assess costs and benefits and on Resource Efficiency

In some circumstances, a comprehensive literature review can provide the necessary elements for a sound assessment of the expected effects. For instance, the qualitative assessment of the likely effects of the Common Agricultural Policy (CAP) post-2013 Regulation in developing countries was based on a literature review, which covered all the transmission mechanisms between the EU and developing countries that could have been envisaged. The likely effects of the CAP post-2013 Regulation in developing countries were estimated to be negligible.⁴⁰⁸

2.2. Quantitative assessment

In some cases, a detailed, substantial and quantified analysis is advisable (e.g. for new regulatory proposals that substantially affect products produced in developing countries, e.g. the Regulation on the common organization of the market in bananas). Such an analysis of impacts is likely to require detailed quantitative data to establish a causal link between the policy option and its impact and analytical tools that entail modelling techniques⁴⁰⁹.

No single analytical approach is recommended given the broad range of policy options that might need to be considered and the constraints on human and financial resources that might be available for the assessment. Moreover, several analytical/methodological approaches have been used in the past for similar types of policy option and each gives satisfactory results. More of different analytical tools can be used together in order to cover various elements in stake, with possibility of combination. The various analytical approaches include:

- **Econometric analysis:** Gravity models have been widely used for estimating the impact of trade and non-trade barriers to trade (e.g. standards). These models can be adopted to analyse the set of affected developing countries with a so-called “control group”, allowing for a proper counterfactual analysis.⁴¹⁰
- **Computable General Equilibrium (CGE) models:** There are a number of well-established CGE models that can be used to yield results in ex-ante assessments. Results obtained from such models capture relations between different macro

⁴⁰⁵ The Action Plan on Forest Law Enforcement, Governance and Trade (FLEGT) is the European Union response to illegal logging that was adopted in 2003. http://ec.europa.eu/environment/forests/illegal_logging.htm

⁴⁰⁶ The Extractive Industries Transparency Initiative is a global coalition of governments, companies and civil society working together to improve openness and accountable management of revenues from natural resources. <https://eiti.org/eiti>

⁴⁰⁷ The Kimberley Process (KP) is a joint government, industry and civil society initiative to stem the flow of conflict diamonds – rough diamonds used by rebel movements to finance wars against legitimate governments. <http://www.kimberleyprocess.com/>

⁴⁰⁸ http://ec.europa.eu/agriculture/policy-perspectives/impact-assessment/cap-towards-2020/index_en.htm - Annex 12

⁴⁰⁹ For the list of plausible models see tool on the use of analytical models

⁴¹⁰ For more details see, for instance, Joshua D. Angrist & Jörn-Steffen Pischke (2009), "Mostly Harmless Econometrics: An Empiricist's Companion", Princeton University Press.

indicators providing full scale information on given economy be it on national or regional level. Widely used GTAP8 model serves in simulating world trade and production providing for assessment of likely impacts on economic performance after introduction of certain measure (change in tax rates, price levels, investment activity, consumption patterns, production technology, etc.)^{472,411}. For examples on how to use modelling in IA see Box 2.

Box 2. Example of a modelling study

The CEPR Study used to simulate the likely effects of the Transatlantic Trade and Investment Partnership (TTIP) on the EU, which is based on the so-called GTAP8 model, is a good illustration of modelling studies that can potentially be used in IA.⁴¹² This is a well-established Computable General Equilibrium model to analyse tariff and non-tariff barriers to trade. If this model were to be applied to an appropriate level of aggregation (i.e. various groups of Developing Countries or, in special circumstances, individual developing countries), isolating trade diversion effects from other effects and substantiating important assumptions on other indirect effects towards the developing, it could prove to be a reliable tool for an assessment of the likely effects on developing countries. The responsible DGs could explore the opportunity of co-operating with the JRC to establish a sound application of this methodology to analyse and measure the impact their proposed policy measures on the developing countries.

3. HOW TO MINIMISE NEGATIVE IMPACTS ON DEVELOPING COUNTRIES?

Mitigating measures are of significant importance with regard to developing countries as being particularly vulnerable compared to economies of the developed world. From an array of mitigating measures those with minimal impacts on overall effectiveness should be chosen. For examples of such viable measures see Box 3.

Box 3. Examples of mitigating measures

- The Common Agricultural Policy (CAP) post-2013 Regulation is accompanied by an evaluation framework to measure ex-post the performance of the CAP with the EU development cooperation objectives. This monitoring is based on appropriate indicators and shall provide a consistent and dynamic picture of performance of the CAP vis-à-vis its stated development objectives.
- When the Economic Partnerships Agreements were negotiated, a number of mitigating measures were envisaged, including:
- At least 80 % of customs import duties would be phased out by African Caribbean Pacific (ACP) Group of States over 12 years; following negotiations, the period was extended to 15 years (in some cases to 20 or even 25 years) and in one case a lower 75 % threshold was accepted.
- All export duties/taxes should be phased out; following negotiations, it was

⁴¹¹ For a detailed description of the GTAP8 see, for instance, Aguiar, Angel H., McDougall, Robert A., and Narayanan, G. Badri (ed.), (2012), "Global Trade, Assistance, and Production: The GTAP 8 Data Base", Center for Global Trade Analysis, Purdue University

⁴¹² See http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

accepted that existing duties/taxes may continue and new ones introduced in specific cases for development reasons, including industrial development, infant industry protection, and food security, environmental or fiscal reasons.

- Exceptional difficulties should be dealt with traditional safeguard clauses: after negotiations, specific provisions were added to protect infant industries, food security and rural development, and bilateral safeguard clauses were provided for in cases of import surges from the EU, with lower triggers than those of multilateral safeguards under WTO rules.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

Box 4 provides examples of sources on information already available and on databases than can support the analysis of the different dimension of the IA on Developing Countries.

- **Tool knowledge already available.** In order to identify and obtain existing relevant sectoral studies, the lead service should contact in priority the DGs DEVCO, RTD and JRC. Commissioning an expert study on given subject might also be an option (contact DG DEVCO for available experts and use of relevant framework contracts). In addition, relevant ex-post evaluations, previous IAs regarding similar countries/sectors as well as provision of literature review can serve as good starting point.
- **Databases to support economic and social assessments.** The most comprehensive database in terms of coverage of cross-country, cross-time information on developing countries currently publicly available is the World Development Indicator database (WDI), which contains useful information on several dimensions of poverty (economic, protective, political and human socio-cultural). As regards data on international prices, they can be found on the International Comparison Programme (ICP).⁴¹³
- **Databases on Trade and FDI flows.** EUROSTAT, via the COMEXT database, has also extensive data on imports and exports of goods with developing countries. The UN COMTRADE can also be used to gather import data for the EU, as opposed to the actual export data from the developing countries (which can prove to be a great advantage as import values for developing countries are generally more reliable than export values. The UNCTAD and OECD have data bases regarding foreign direct investments and DG TRADE also developed a market access database. The DAC OECD data base reports complementary information on this. In terms of data on the measurement of standards/NTMS, the FP7 NTM project can be helpful.
- **Databases to support the environmental assessment.** As regards the environmental impacts on developing countries, relevant data can be found at the [United Nations Framework Convention on Climate Change](#) , the [Convention on](#)

⁴¹³ The ICP is a worldwide statistical exercise established at the end of the 1960s. Its objective is to compare the GDP of various economies to '... determine their relative size, productivity and material well-being'. This comparison is done using purchasing power parities.

[Biological Diversity](#), [Global Climate Change Alliance](#) and the [Forest Law Enforcement, Governance and Trade](#).

TOOL #35. RESOURCE EFFICIENCY

1. INTRODUCTION

Resource efficiency means using the Earth's limited resources in a more sustainable manner while supporting economic growth and providing jobs⁴¹⁴. A benefit of improved resource efficiency is the creation of more value with fewer resources which increases productivity, reduces environmental degradation and decouples economic growth from resource use.

Resource efficiency applies to all resources that underpin the functioning of our economy and society. This includes metals, minerals, energy carriers, biomass, water, air, land, soil and biodiversity amongst others and applies throughout their life cycle (e.g. from extraction, transport, transformation and consumption to the recycling and reuse of secondary raw materials and the treatment of waste).

Resource efficiency is one of the main drivers of companies' competitiveness. European manufacturing firms spend, on average, 40% of their costs on raw materials, with energy and water pushing this to 50% of total manufacturing costs⁴¹⁵. In contrast, labour costs represent only 20% of manufacturing costs. Studies suggest that these resources could be used more efficiently.

2. IS RESOURCE EFFICIENCY RELEVANT FOR YOUR IMPACT ASSESSMENT?

An initiative may relate to resources in several ways:

- It may increase or decrease resource use and thereby affect the environment and/or businesses and/or the cost to society of resource use;
- It may affect the availability and/or quality of resources (e.g. specific raw materials for wind farms or for IT clouds), sometimes even leading to security of supply issues.

In general, impacts on resource efficiency will need to be considered when the policy initiative relates to activities that:

- Rely on resources and their management such as energy production, industry, agriculture etc.;
- Contribute to the depletion or degradation of resources (such as mining, fisheries, transport, etc.) or are impacted by such depletion or degradation;
- Influence the price and accessibility of resources in the EU such as taxation and trade policy;

⁴¹⁴ COM(2011)571

⁴¹⁵ COM(2014) 440

- Contribute, even indirectly, to the creation of new demand, markets, skills and business models (e.g. in innovation, telecommunication, education and training and employment policy fields; recycling, revised design of products, new markets from ecosystem services, leasing).

Where resource efficiency is clearly a significant issue then the following more detailed questions may help you characterise further the problem.

In relation to the quantitative aspects of resources:

- (1) What resources are affected (in the definition of the problem and for individual policy options)?
- (2) How important are these resources for specific sectors and from a wider economic or social perspective (e.g. for other sectors or social groups)?
- (3) Is the availability of these resources limited?
 - (a) In terms of quantity, quality, access, import dependency, in time?
 - (b) Is it a critical raw material for the EU? Is there a strong geopolitical dimension to the availability of a particular resource? (In terms of security and ethics of the supply). Are we close to critical thresholds in terms of quantity or quality of the resources at stake, or in terms on natural ecosystems' capacity to provide certain services? (e.g. pollination services for agriculture)
 - (c) Are there conflicting interests over a resource? (E.g. between economic sectors, regions or economic sectors and civil society)? How will these develop?
 - (d) Is the current or future availability of a resource dependent on, or in competition with, other resources? (e.g. land and water for food versus other biomass products)
- (4) Can the resource be substituted by another one? How easily? (cost, access, timing, potential impacts on other resources)
- (5) Are economic and R&D perspectives and technological change likely to modify the current situation, in terms of substitutes and uses of certain resources?

In relation to the price of the resources:

- (6) What is the past and expected price evolution for the resource?
- (7) What are the incentives for business and society to use resources efficiently?
 - (a) Do property rights and markets exist for key resources? Some elements of our natural capital are not valued, even though they are necessary to economic prosperity and social well-being (e.g. ecosystem services such as the provision of clean air and water).

- (b) Do price signals truly reflect the full costs of using resources and their environmental impacts throughout their life cycle? Are price signals distorted by environmentally harmful subsidies?

In answering these questions, it is possible to identify whether and to which extent resource efficiency is part of the problem definition. If this is the case, it may then also be necessary to reflect it in your objectives and options and their analysis.

3. HOW TO ASSESS IMPACTS ON RESOURCE EFFICIENCY

As for all other impacts, quantitative data on resource efficiency are not always easy to find. One source of information to start from is the **European Resource Efficiency Scoreboard**⁴¹⁶, hosted by Eurostat. It presents a set of 30 indicators for assessing resource efficiency in the EU and the Member States and for monitoring the progress towards a resource-efficient and circular economy. It is structured around:

- (1) Lead indicators:
 - (a) Resource productivity;
 - (b) Domestic material consumption (accompanied by EU Raw material consumption);
- (2) Dashboard indicators focusing on:
 - (a) Land: (i) Productivity of built-up and non-built up artificial areas; (ii) Built-up areas;
 - (b) Water: (i) Water exploitation index; (ii) Water productivity;
 - (c) Carbon: (i) Greenhouse gas emissions per capita; (ii) Energy productivity; (iii) Energy dependence; (iv) Share of renewable energy in gross final energy consumption;
- (3) Specific indicators focussing on the sub-themes from the resource efficiency Roadmap:

Transforming the economy:

- (a) Turning waste into a resource: (i) Generation of waste excluding major mineral wastes; (ii) Landfill rate of waste excluding major mineral wastes; (iii) Recycling rate of municipal waste; (iv) Recycling rate of e-waste; (v) Supporting research and innovation: Eco-innovation index;
- (b) Getting the prices right: (i) Environmental tax revenues - % of total revenues from taxes and social contributions; (ii) Energy taxes by paying sector;

⁴¹⁶ http://epp.eurostat.ec.europa.eu/cache/REIs/REIs_EN_banner.html

Nature and ecosystems:

- (a) Biodiversity: (i) Common birds index; (ii) Area under organic farming; (iii) Landscape fragmentation and connectivity;
- (b) Safeguarding clean air: (i) Urban population exposure to air pollution by particulate matter; (ii) EU urban population exposed to PM10 concentrations exceeding the daily limit value
- (a) Land and soils: (i) Soil erosion by water - area eroded by more than 10 tonnes per hectare per year; (ii) Gross nutrient balance in agricultural land (nitrogen and phosphorus);

Key areas:

- (a) Addressing food: Daily calorie supply per capita by source;
- (b) Improving buildings: (i) Final energy consumption in households; (ii) Final energy consumption in households by fuel;
- (c) Ensuring efficient mobility: (i) Average carbon dioxide emissions per km from new passenger cars; (ii) Pollutant emissions from transport; (iii) Modal split of passenger transport; (iv) Modal split of freight transport.

The scoreboard indicators cover the period from 2000 to 2015 for EU and MSs, subject to data availability and are regularly updated. While the structure of the scoreboard is fixed, the component indicators might be revised and newly available indicators may be added to cover better some areas.

The Resource Efficiency scoreboard can, therefore, have a double role in your impact assessment:

- It provides a list of issues relevant for resource efficiency; and
- It provides a first set of data that can underpin the analysis in an IA.

Furthermore, more data and indicators will be available when the [Raw Materials Scoreboard](#)⁴¹⁷ currently being developed becomes operational.

Additional data sources could also be considered, depending on whether the initiative requires an analysis at macro, meso or micro level. For proposals relating to a specific economic sector, sectoral data should also be considered, when available, given the importance of resource efficiency for sectoral competitiveness⁴¹⁸.

The **following questions** could also help you analysing, even if only qualitatively, the impacts of your options on resource efficiency:

Questions mostly related to the economic pillar:

⁴¹⁷ <https://ec.europa.eu/eip/raw-materials/en/content/eip-raw-materials-monitoring-and-evaluation-scheme>

⁴¹⁸ See Tool #20 on *Sectoral competitiveness*

- Do some options consider the potential economic opportunities linked to resource efficiency? (e.g. developing markets for secondary raw materials);
- Are resources used in ancillary activities considered (e.g. packaging)?
- Will it help businesses to use resources more efficiently?
- Are competition, innovation and consumers' choice affected? (e.g. less product variety if some resources are banned, or more variety as substitutes are created);
- Has the "rebound effect" been considered? (i.e. an improvement in resource efficiency is offset by an increase in consumption);
- Are the durability, reparability, reusability and recyclability of products assessed?

Questions mostly related to the environmental pillar:

- Do the options involve trade-offs with other resources or ecosystem services, considering the full supply chain and all environmental impacts? (e.g. using less land but more water to produce the same quantity of crops)
- Do the options encourage substitution of high-impact resources by resources with less impact on the environment?
- Could the same amount of resources be used in a less environmentally-harmful manner?
- Is the option likely to lead to a situation of lock-in into a resource intensive system?
- Is spatial allocation of economic activities and their impacts considered?

Questions mostly related to the social pillar:

- Are consumer behaviour and changes in consumption patterns considered?
- Will a different use of a resource create new jobs, or cause existing jobs to be lost?
- Will a different use of a resource lead to the need for new skills, or make some existing skills outdated?
- Does the change in resources used lead to health impacts?
- How does the option affect future generations?
- Does the extraction of the resource at stake have any other social or societal impact (e.g. migration, social unrest)?

4. HOW TO MINIMIZE NEGATIVE IMPACTS AND MAXIMIZE POSITIVE IMPACTS ON RESOURCE EFFICIENCY

Consistency of the foreseen options with resource efficiency should be checked, by asking the following questions:

- Are the options consistent with Resource Efficiency principles (reduce, reuse, recycle, substitute, safeguard and value)? If an option clearly violates resource efficiency objectives, then it could be discarded for lack of consistency with overarching EU policy objectives.
- Do the options consider how information about resource efficiency could be enhanced? (E.g. by using more environmental labelling or by increasing awareness, through soft measures)
- When relevant, are options analysed based on a Life Cycle Assessment⁴¹⁹ along the whole value chain or using sector-specific resource modelling? Have re-use, recycling, cascading uses and circular economy aspects been considered?
- Is mitigation of possible negative resource efficiency impacts considered (complementary to the main options)?
- Can less resource intensive alternatives lead to the same outcome (e.g. natural solutions such as a flood plains developed in place of dikes or embankments)?
- Have Market-Based Instruments been considered to tackle resource efficiency issues?
 - By taxing polluting practices;
 - Through a reduction of Environmental Harmful Subsidies that might favour environmentally harmful practices;
 - Is the creation of new markets considered, allowing for the pricing of resources previously considered as without value (as without market) – ex: the creation of European Trading Scheme (ETS) for greenhouse gas emissions.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

The IA function of DG ENV (Unit A.2) can assist on issues raised in this IA tool. If resource efficiency is an important element in your IA, DG ENV is also ready to participate in the impact assessment steering group.

5.1. About Resource Efficiency in general:

- [European Commission website:](#)
- [European Environment Agency website:](#)
- [International resource panel website:](#)
- [Stakeholders: Online Resource Efficiency Platform:](#)

⁴¹⁹ See Tool #59 on *Methods to estimate costs and benefits*

5.2. About resource efficiency targets and indicators:

- Resource Efficiency scoreboard database:
http://ec.europa.eu/environment/resource_efficiency/targets_indicators/index_en.htm
http://epp.eurostat.ec.europa.eu/portal/page/portal/europe_2020_indicators/ree_scoreboard
- [Resource Efficiency scoreboard Highlights 2014:](#)
- Examples of past IAs where Resource Efficiency aspects were considered (non-exhaustive list):

SWD ref	Title of the proposal	Resource Aspect considered	Main Sections
SWD (2014) 57	Amending several Commission Regulations with regard to labelling of energy-related products on the Internet	Information deficit with regard to energy efficiency	Problem definition
SWD (2014) 153	Regulation laying down a prohibition on driftnet fisheries	Resource conservation, threshold level of a resource	Problem definition, objectives, impact analysis
SWD (2014) 160	Strategy for Reducing Heavy-Duty Vehicles Fuel Consumption and CO ₂ Emissions	Missed economic opportunities of not reducing pollution; technological development to reduce pollution	Problem definition, baseline
SWD (2014) 162	Regulation implementing Directive 2009/125/EC with regard to small, medium and large power transformers	Alternative resources; resource saving	Baseline, impact analysis
SWD (2014) 207	Amending several waste-related Directives	Missed economic opportunities of not using waste; dependency on raw materials; pollution	Problem definition, impact analysis
SWD (2013) 5	Directive on the deployment of alternative fuels infrastructure	Resource dependency; uptake of new resources	Problem definition, baseline
SWD (2013) 65	Directive establishing a framework for maritime spatial planning and integrated coastal management	Conflicting use over resources leading to missed economic opportunities	Problem definition, baseline, impact analysis
SWD (2012) 66	Amending Directive on placing on the market of portable batteries and accumulators containing cadmium intended for use in cordless power tools	Change in resources used for producing same kind of product; Life Cycle Analysis; new business opportunities arising from resource efficiency	Baseline, analysis and comparison of impacts

5.3. **About the assessment of ecosystems and the services they provide**

- Mapping and Assessment of Ecosystems and their services:
http://ec.europa.eu/environment/nature/knowledge/ecosystem_assessment/index_en.htm
- Natural Capital Accounting:
http://ec.europa.eu/environment/nature/capital_accounting/index_en.htm

Chapter 4

Implementation, transposition & preparing proposals

TOOL #36. THE IMPLEMENTATION PLAN

Where an implementation plan is required it should follow the format below⁴²⁰:

This Implementation Plan is provided for information purposes only. It does not legally bind the Commission on whether the identified actions will be pursued or on the form in which they will be pursued.

(1) Title: "Implementation Plan for XXX (title of the proposal)".

(2) Contact point:

The contact details of the responsible person/service in the DG should be provided. If a functional mailbox or related website exists, it is recommended that these be indicated as well.

(3) Deliverables and implementation challenges

The IP should list the various actions which are needed to implement the legislative act and identify the main implementation challenges (emerging from the work done in the impact assessment and/or the assessment of the services). These could include, for example:

- Technical challenges: for example, the proposal might be complex (e.g., in cases where different legal acts are required in order for the proposal to be adopted);
- Compliance challenges: for example, the new institutional framework foreseen in the proposal might entail costs that need careful planning (risk of insufficient financial and human resources);
- Timing challenges: for example, a justified short transposition deadline which requires early action on the part of the Member States;

(4) Support Actions:

*Examples of Possible Commission Actions*⁴²¹:

- Setting up a network to exchange information on transposition (existing working group or creation of the new network, contact person or Unit);
- Setting up a website or forum where all transposition-related information would be placed (together with the possibility to ask questions);
- Providing training sessions to Member States in the relevant area of EU law;
- Peer reviews;
- Issuing interpretative/guidance documents;
- Organising bilateral and/or multilateral meetings with Member States;

⁴²⁰ This replaces the model provided in the Annex I of the Note dated 7/01/2013 (Ares(2013) 12012).

⁴²¹ The different actions undertaken at level of services (information exchanges etc.) should not prejudice or pre-empt possible later decisions of the College on the correct transposition.

- Providing a platform for an exchange of good practice in implementation;
- Preparing an information campaign or contributing to a campaign in Member States.

Example of Possible Member State Actions:

- Ensuring there is a network responsible for the implementation phase in Member States;
- Preparing an impact assessment on potential implementation problems related to national legislation;
- Informing the Commission in advance about any potential problems related to implementation as soon as they are identified;
- Sharing information related to implementation;
- Sharing information in response to monitoring indicators;
- Preparing 'explanatory documents' on transposition (where applicable);
- Setting up a website where all relevant transposition-related information would be placed;
- Ensuring that sufficient resources are made available at national level;
- Providing training;
- Consulting the Commission on draft transposition measures;
- Awareness-raising among the target groups.

The above lists are not exhaustive. Actions should be tailored to the specific legislation and its context. The Commission and Member States should agree on the best way to monitor the implementation and progress made towards the policy objectives.

The IP actions could be presented in tabular form for the Commission and Member States respectively (see example below). In order to clearly distinguish between the assistance offered before and after the transposition deadline, a timeline should be prepared with the most important steps to be taken for each implementation phase (the transposition and application stages should be dealt with separately).

<i>Implementation challenge</i>	<i>Support action</i>	<i>Timing</i>

TOOL #37. TRANSPOSITION CHECKS

1. A TWO-STAGE SYSTEMATIC APPROACH

To ensure the full effectiveness of Article 258 and Article 260(3) TFEU, a clear line is to be drawn between infringements for failure to notify national transposition measures and infringements for non-conformity and assessed in two distinct checks: **Transposition check** and **conformity check**.

1.1. Transposition check

As Member States have to transpose directives in a complete way, every obligation of the directive to be transposed should be covered by the check. Hence, the transposition check should ensure that the national transposition measures notified by the Member State cover each obligation contained in each article and sub-article/paragraph of the directive, as well as annexes where relevant.

In a first step, services carry out a *prima facie* check. In case of partial transposition, the services then clearly identify the provisions which have not been completely transposed.

Box 1. Examples of incomplete transposition

- The concept of completeness of transposition measures in terms of geographic scope is relatively straightforward.⁴²² For instance, when, for federally organised Member States, certain regions have not yet transposed or are erroneously not covered by the national implementing measures, the directive is incompletely transposed in terms of geographic scope;⁴²³
- The concept of completeness of transposition measures in terms of substantive scope means that every obligation of a directive should be reflected in the national transposition measures.⁴²⁴ Therefore, all obligations contained in a directive's articles, paragraphs and subparagraphs fall within the scope of the transposition check. For example, if a provision contains an obligation, and the subparagraphs contain specific derogations therefrom, both should be checked during the transposition check.⁴²⁵ Hence if national transposition measures contain only the general obligation, but not the derogations, it is evidence of non-transposition.
- Occasionally, Member States notify transposition measures that merely specify a framework for future implementation. For example, a Member State could notify a measure stating that 'The Minister decides on the methodology for calculating a building's energy performance through a decree.' Nothing specific has been

⁴²² See the guidance in Box 48, SEC(2010)922/3.

⁴²³ For an example, see Case [C-428/04, Commission v. Republic of Austria \[2006\]](#) ECR I-3325.

⁴²⁴ See the guidance in Box 48, SEC(2010)922/3.

⁴²⁵ For an example, see Case [C-350/02, Commission v. Kingdom of the Netherlands \[2004\]](#) ECR I-6213, para. 41, where failure to notify implementing measures for a sub-article (article a of directive 97/66/EC) is qualified as incomplete transposition.

transposed, only the national authority responsible for transposition has been identified. These so-called "empty shell" transpositions are to be considered as a failure to notify, and such non-compliance should be spotted during the transposition check.

The transposition check starts upon the expiry of the transposition deadline; it may even start before (to be decided by the competent service) if national transposition measures for individual Member States have been received in advance. All acts need to be checked against transposition deadlines.

The Commission aims at completing the transposition check within six months after the transposition deadline expires. If Member States fail to notify the transposition measures by the deadline, an infringement procedure will be launched as soon as possible. In that case, the six-month period will start when the measures are notified.

Member State notifications that are not clear and precise (e.g. 'shoe-box notifications' in which Member States notify the Commission a large number of measures, that are not relevant for the transposition of the directive at hand) should not be accepted. If the Commission's services receive such an unclear and imprecise notification, an informal contact with the Member State should take place. In line with jurisprudence of the CJEU, the Commission may also launch an infringement procedure for failure to notify and/or a breach of Article 4(3) TEU if the notification is not 'sufficiently clear and precise'.⁴²⁶

If Commission services are considering complex proposals for directives, they should request explanatory documents from Member States.⁴²⁷ As such a request may only be submitted with the proposal for a directive itself, it is essential that implementation issues are already taken into account during the preparatory phase.

1.2. Conformity check

This check entails the assessment of the compatibility of the national implementing measures with the Directive's provisions/obligations, including definitions.

Box 2. Issues related to incorrect transposition or bad application

- The implementation of parts of provisions of directives that require subsequent administrative practice or judicial interpretation in order to be applied in specific cases should normally be assessed within the conformity check. This holds

⁴²⁶ See C-427/07, *Commission v. Ireland* [2009] ECR I-6277, paragraph 107: 'the information which the Member States are thus obliged to supply to the Commission must be clear and precise. It must indicate unequivocally the laws, regulations and administrative provisions by means of which the Member State considers that it has satisfied the various requirements imposed on it by the directive'; C-456/03, *Commission v. Italy* [2005] ECR I-5335, para. 27; C-96/81, *Commission v. Netherlands* [1982] ECR I-1791, paragraph 8.

⁴²⁷ For information on the policy on explanatory documents, see point (5) of Tool #38 in the Better Regulation Toolbox ("Drafting the Explanatory Memorandum").

especially true for so-called 'open norms' that grant significant discretionary power to national administrations.⁴²⁸

- Frequently, directives contain provisions that require Member States to notify specific reports/action plans/facilities. These provisions often contain separate deadlines and are different from the general obligation to notify transposition measures. Non-compliance with such provisions should be classified as bad application, as opposed to a failure to notify.⁴²⁹ Therefore, they are not part of the transposition check;
- For directives requiring the setting-up of national enforcement bodies, structural issues with the national regulatory body should be examined during the conformity check.⁴³⁰

As a general rule, the conformity check should start only once the previous phase of the transposition check, including a possible infringement procedure for failure to communicate transposition measures, has been completed. Exceptionally, a conformity check may be started in parallel to an ongoing transposition check for well-defined parts of a directive which have been identified as being completely transposed and which are clearly distinct from the provisions that require transposition measures which have not yet been notified.

Box 3. Example on running parallel the transposition check and the conformity check

A Member State notified transposition measures for almost all provisions of a directive and only residual, non-essential parts have not been transposed. In this case, it is appropriate that the conformity check can already start for the well-defined parts of a Directive which have been identified as being completely transposed.

The Commission aims at completing the conformity check within 16 to 24 months from the date of the communication of the national transposition measures.

If during this subsequent conformity check the service finds that the Member State has not notified all the measures necessary for full transposition, the service should launch an infringement procedure for late notification in relation to the parts that are missing⁴³¹.

Reports on conformity assessment from external contractors need to be verified by the Commission; any final decision that is taken based on such reports should be the result of an independent assessment by the Commission services.

⁴²⁸ Open norms are those rules that depend for a large extent on judicial interpretation and that enable judges to administer justice in individual cases; examples of open norms are terms such as "unnecessary", "disproportionate", "fair", "adequate" and "requisite legal standard".

⁴²⁹ For an example, see provision 11(1) of [Directive 2000/60/EC](#).

⁴³⁰ For an example, see article 3 of [Directive 2002/21/EC](#).

⁴³¹ SEC(2010)923/3 Box 48

Given that compliance studies may feed into infringement proceedings, they should not be published or disclosed before the compliance check is completed and a decision whether to pursue the matter or not is made. Requests for access to such studies will be assessed in the context of Article 4(2), third indent of Regulation No. 1049/2001..⁴³²

If available, services should use the information contained in implementation plans when they assess the risks regarding correct transposition of the directive.

Compliance assessment should feed into the evidence base used for effective evaluation; therefore, the conformity check should lead to a clear tangible result in the form of a written document containing the assessment results.

There should be close cooperation between the Commission service that drafts and negotiates the directive and the service that checks the compliance of national transposition measures. This can be achieved via co-ordination mechanisms, such as task forces involving policy and enforcement units or via integrated units covering all the activities of the policy cycle for a specific piece of legislation.

⁴³² See especially Case [T-111/11, ClientEarth v. European Commission \[2013\]](#), n.y.r.; Case [T-29/08, LPN v. Commission \[2011\]](#) ECR II-6021; Case [T-36/04, API v. Commission \[2007\]](#) ECR II-3201; Case [T-109/99, Petrie and Others v. Commission \[2001\]](#) ECR II-3677; Case [T-105/95, WWF v. Commission \[1997\]](#) ECR II-313.

TOOL #38. DRAFTING THE EXPLANATORY MEMORANDUM

1. WHEN IS AN EXPLANATORY MEMORANDUM NECESSARY?

All Commission proposals and delegated acts should include an explanatory memorandum (although a simpler form is used for delegated acts which covers (i) context of the delegated act; (ii) consultations prior to the adoption of the act; (iii) legal elements of the delegated act).

2. WHAT IS THE PURPOSE OF THE EXPLANATORY MEMORANDUM?

The purpose of the explanatory memorandum is to explain the reasons for, and the context of, the Commission's proposal drawing on the different stages of the preparatory process. It presents the results of the better regulation processes and tools used to prepare the initiative including opportunities for legislative simplification and reducing unnecessary regulatory costs. It also serves as a basis for the examination of the proposal by national Parliaments under the subsidiarity control mechanism (Protocol No. 2 to the Treaties).

The explanatory memorandum should be available in the same languages as the proposal it introduces and in principle should not exceed 15 pages (although in particularly complex cases a longer text may be justified). It is transmitted to the other Institutions together with the accompanying act and is available to the public through EURLex. The explanatory memorandum is however not published in the Official Journal and has no legal effect.

The explanatory memorandum should not be confused with the recitals, which are part of the act itself and are thus published in the Official Journal.

3. THE CONTENT OF THE EXPLANATORY MEMORANDUM

The Commission should summarise the context of the proposal, how it complies with the principles of conferral (i.e. reasons for the choice of legal basis), subsidiarity and proportionality and with smart regulation principles, as well as with fundamental rights. It should also explain the choice of a legal instrument. The explanatory memorandum ensures the transparent exercise by the Commission of its right of initiative. Therefore it should be reader-friendly, clearly worded, concise and written with the non-specialist in mind.

The specific content of the explanatory memorandum should respond to various obligations, including Protocol No 2 on the application of the principles of subsidiarity and proportionality, and the Commission's better regulation agenda, including the inter-institutional agreement on better law-making.

The most significant proposals will have been subject to fitness checks or evaluations of the existing policy framework, to impact assessment and informed by stakeholder consultation. The results of this preparatory work should be reflected in the explanatory memorandum.

The explanatory memorandum should include the following elements:⁴³³

(1) CONTEXT OF THE PROPOSAL

- Reasons for and objectives of the proposal:
 - Describe the reasons behind the proposal or the existing problem(s) that the proposal is meant to tackle (e.g. obstacle to free movement, dangerous products, environmental pollution, etc.).
 - State if this is a REFIT initiative.
 - State the relevant institutional background of the proposal (e.g. mandate from the European Council, undertaking by the Commission to revise an act, Commission work programme, reply/ reaction to a legislative initiative resolution of the EP, reply/ reaction to a European Citizens' Initiative, etc.).
- Consistency with existing measures in the area:
 - Mention any important Union measures and initiatives already undertaken in the relevant area (existing legislation, linked policy proposals, white or green papers) or comparable initiatives in the Member States.
 - Provide a clear description of the similarities and differences between the proposal and any existing acts (e.g. different field of application, complementarity etc.).
 - Explain the timing of the proposal (why the proposal is presented now) and the sequencing of proposals related to the same policy sector.
- Consistency with other Union policies
 - Mention links with other Union policies, in particular in cases of "mainstreaming" (economic, competition, employment, environment, equal opportunities, etc.). Keep this part short and avoid overlaps with the "impact assessment" section.

(2) LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- Legal basis

In accordance with the interinstitutional agreement on better law-making, the Commission should, in a clear and complete way, justify the legal basis of the proposal, especially where it would seem that several options exist.

⁴³³ The template presented in this tool is not entirely appropriate for proposals adopted under Article 218 TFEU. Specific templates should be used which will be available on GoPro/Myintracomm following the revision of the current Vademecum on the external action of the European Union: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/External%20representation%20of%the%20EU>

- Explain what the legal basis of the proposal is. When several feasible options seem to exist, justify the choice on the basis of objective criteria.
- Clarify whether the concerned policy area falls under an exclusive or shared competence or under other categories of competence (support and coordination competences).
- Subsidiarity (for competences other than exclusive)

Demonstrating the compliance of the proposal with the principles of subsidiarity and proportionality is a fundamental part of the explanatory memorandum. Avoid standard phrases that merely state that the proposal respects these principles.

- Explain what the Union dimension of the problem is. While respecting Union law, are well-established national arrangements and special circumstances applying in individual Member States respected?
- Necessity test: Why can the objectives of the proposal not be adequately achieved by Member States? Is the scope of action limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?;
- Effectiveness test: What is the most effective solution – that achieved by Union action or that achieved by possible national means? What specific added value is expected by the envisaged Union measure and what would be the cost of taking no action at all?
- Proportionality

Explain the scope of chosen policy option:

- Does the option go beyond what is necessary to achieve the objective satisfactorily?
- Will the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?
- Explain the choice of instrument:
 - Has the simplest form of Union action (instrument) been chosen; and is this choice consistent with the pursued objective and effective enforcement?
 - Is there a solid justification for the choice of instrument - Regulation, (framework) Directive, or alternative regulatory methods?

(3) RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

In support of evidence-based policymaking, the purpose of this section is for the Commission to explain the preparatory analytical work undertaken, including ex-post evaluations of existing provisions, stakeholder consultation, the collection and use of expertise and impact assessments.

If no evaluation, consultation activity or impact assessment has been undertaken, this section should explain why.

The section should provide a short overview of the main findings and how they have been taken account in the final proposal – for further details references should be made to relevant Evaluation, consultation and Impact Assessment reports.

- Evaluation/fitness Check and related opinions of the Regulatory Scrutiny Board
 - Summarise the results of any ex-post evaluations/fitness checks of existing measures related to the policy objectives, clarifying the link to the identified problems the proposal aims to tackle. Provide links to available SWDs, studies or reports;
 - In case the RSB issued an opinion on the evaluation/fitness check (or made comments on the evaluation/fitness check included in the related IA report), summarise the Board's findings and explain how they were taken into account;
 - Describe approved exceptions from the procedural requirements of the better regulation Guidelines together with an appropriate justification.
- Stakeholder consultation
 - Describe the consultation(s) made and the tool(s) used (written public consultation, consultation targeted at pre-selected organisations, hearings, etc.).
 - State briefly the main sectors and/or institutional bodies that responded, giving an objective and balanced summary of their answers. Avoid vague wording such as "the associations consulted broadly welcomed this initiative". Provide link to published consultation results/reports (e.g. on "the Europa 'Consultation Portal"⁴³⁴).
 - Summarise how the results of the consultation were taken into account in the proposal and, where appropriate, explain where the Commission's views diverge and why;
 - Describe approved exceptions from the procedural requirements of the better regulation Guidelines together with an appropriate justification.
- Use of expertise

If the Commission has relied on expertise⁴³⁵, describe the methodology used, the range of expertise consulted, the advice received, how it was taken into account and, where appropriate, indicate how to access any publicly available information (e.g. website).

- Impact assessment and opinion of the Regulatory Scrutiny Board

⁴³⁴ https://ec.europa.eu/info/consultations_en

⁴³⁵ See Tool #4 on *Evidence-based better regulation*.

A summary presentation of the main elements of the impact assessment (IA) process serves to strengthen the motivation underlying the proposed policy choice, and to show that the careful assessment of alternative policy options and foreseen impacts have been fully taken into account by the Commission. Given that some elements of the impact assessment process are reported on under other sections in the explanatory memorandum, this section should focus on the assessment of alternative policy options and their impacts, as set out below.

The sections below should be completed on the basis of other available analysis or information.

- Where relevant, explain why the proposal is not supported by an impact assessment. Reference should be made to the initial political validation, the Roadmap where the question about the need for an impact assessment is addressed and also to the better regulation Guidelines and the Tool #9 on when an IA is necessary;
 - Describe approved exceptions from the procedural requirements of the better regulation Guidelines together with an appropriate justification;
 - Provide the links to the IA summary sheet and the positive opinion of the Regulatory Scrutiny Board. Where no positive opinion was issued, a clear justification should be given for proceeding with the initiative;
 - 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. Quantified estimates of the impacts should be provided wherever possible and reasons given where this is not possible;
 - Summarise the main content of the Regulatory Scrutiny Board's opinion(s) and explain how they were taken into account.
 - If the final policy proposal deviates from the options assessed in the impact assessment, clarify in which way it deviates from these options and what the likely impacts would be of this change.
- Regulatory fitness and simplification

This section aims at providing targeted information on the regulatory fitness of the final proposal and the extent to which regulatory burdens are minimized and proportionate to the objective to be achieved. **All revisions of existing legislation are expected to assess the potential to simplify the legislation and to identify, quantify (wherever possible) and reduce any unnecessary regulatory costs. This REFIT-related work should be reported in impact assessments, evaluations and fitness checks which support the initiative.**

In particular, this section of the explanatory memorandum should outline:

- If the proposal includes a revision of existing legislation and if the possibility to simplify the legislation and/or reduce unnecessary costs has been identified, then

the explanatory memorandum should explain how these possibilities will be exploited by the proposal without undermining the objectives of the legislation. In addition, and wherever possible, a **burden reduction objective** for tackling unnecessary regulatory costs should be presented for the specific legislation (see COM(2017) 651). This objective should be based on the REFIT-related findings of the impact assessment and any earlier evaluation or fitness check (described above in relation to the simplification of legislation and identifying any unnecessary regulatory costs). This objective should be quantified wherever possible. The European Parliament and the Council are encouraged to take account of the burden reduction objective in their legislative work and by the Member States in respect of their transposition and implementation of the legislation at national level.

- If there is no scope to simplify or reduce regulatory costs a short justification should be provided;
 - Who will be affected and how? What will the affected parties have to do in order to comply and what will public authorities have to do to ensure compliance?
 - Why microenterprises are not exempted from the scope of the initiative, and whether there is a "lighter" regulatory regime for SMEs generally⁴³⁶;
 - How the expected compliance costs for SMEs and any other relevant stakeholders have been minimized (providing quantitative estimates as far as possible);
 - How any negative effects on sectoral EU competitiveness or on international trade have been minimized;
 - How the proposal is "internet ready" and consistent with the operation of the internet, social media and other digital developments. Will the proposal operate effectively in both the digital and physical worlds?⁴³⁷
- *Fundamental rights*: Where the proposal has consequences for fundamental rights, explain how the fundamental rights obligations have been met⁴³⁸.

(4) BUDGETARY IMPLICATIONS

Briefly outline the budgetary implications of the initiative (if any) and, where appropriate, refer to the "financial statement" showing the budgetary implications and the human and administrative resources required.

⁴³⁶ See Tool #22 on *The SME test* for examples of mitigating measures for SMEs.

⁴³⁷ See Tool #27 on *The digital economy and society & ICTs or systems*.

⁴³⁸ See Tool # 28 on *Fundamental rights and human rights*.

(5) OTHER ELEMENTS

- *Implementation plans, monitoring, evaluation and reporting arrangements:* Reference should be made to the implementation planning associated with the measure, including reference to the monitoring, evaluation and reporting framework to be applied to assist with its implementation and application and to report on its performance.
- *Explanatory Documents:* The need for providing Explanatory Documents on the transposition of directives should be explained, including why they are necessary for the Commission to carry out its task of overseeing the transposition of directives.
- *Variable geometry:* In case of proposals under Title V of part three TFEU (justice and home affairs), particular arrangements apply to the UK and Ireland (protocol 21), Denmark (Protocol 22) and to different EU Member States and associated countries depending on their participation in Schengen (protocol 19). The implications of the proposal on these countries should be explained where relevant.
- *More detailed explanation of the specific provisions of a proposal:* In addition to the general explanation of the reasons for the Commission proposal, it is advisable to provide more information on the provisions, adding a commentary for each chapter or article. Such a commentary may focus just on selected key articles including those provisions intended to simplify the legislation or tackle unnecessary regulatory costs. This additional text should have added value for the future interpretation of the act to be adopted. A more detailed commentary may be useful for explaining any new ideas in the proposal (in particular if such an explanation goes beyond the general framework of the explanatory memorandum). An article-by-article commentary may be very useful after adoption of the directive in the event of difficulties in the interpretation of a particular provision. A more detailed explanation may also be useful when codifying or rewriting a text, so that provisions in the old text taken over (and codified) in the new one can be indicated.

TOOL #39. GUIDANCE DOCUMENTS CONTAINING LEGAL INTERPRETATION OF EU LAW

1. INTRODUCTION

Commission documents frequently provide guidance to Member States and/or stakeholders in applying and implementing EU law. Such guidance may contain interpretation of EU law.⁴³⁹ In such cases, according to the case law⁴⁴⁰ of the Court of Justice of the European Union, Commission guidance documents may produce legal effects, i.e. they may legally bind the Commission. **Therefore, such documents have to be endorsed by the College.** Examples of documents for which College approval is necessary are guidance documents through which the Commission uses its political discretion, granted to it by the Treaty on the Functioning of the European Union or by EU legislation, or in which the Commission gives a legal interpretation of significant importance that results in new or modified policy developments.

2. GUIDANCE DOCUMENTS CONCERNED

College endorsement is required for guidance documents that contain interpretation of EU law, including interpretation provided in the framework of implementation plans,⁴⁴¹ unless such documents are part of the Commission's normal administrative operations

Box 1. Interpretation of EU law

The interpretation of EU law means that the document sets out a position on how one or more EU law provisions should be interpreted and/or applied. This is typically the case when, for example:

- An EU law provision can be understood in various ways and the guidance document sets out the Commission's understanding (or defines the Commission's interpretation);
- The guidance document clarifies whether a certain activity falls under the scope of a given EU legal instrument;
- The Commission adjusts its earlier position after a Court judgment that gives a certain margin of manoeuvre or discretion to the Commission.⁴⁴²

⁴³⁹ The Commission has an autonomous power to issue guidance documents (Article 292 TFEU referring to the Commission's power to issue recommendations) so the legislator may not impose obligation to issue guidance. Frequently, however, legislative measures contain such obligations. See, for example, Annex I, points (a) and (b), to Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions.

⁴⁴⁰ Point 67 of the judgment in case T-472/12 – Novartis v Commission, Point 37 of the Opinion of AG Mazak in case C-527/07, point 108 of Case T-376/12 of 10 July 2014, Greece vs. Commission; point 72 of joined cases T-61/00 and T-62/00, APOL.

⁴⁴¹ See Tool #36 on *The implementation plan*.

⁴⁴² Examples: [Guidance](#) for the directive on unfair commercial practices, [guidance](#) for better transposition and application of the Citizens' Free Movement Directive; [Guidelines](#) on the application of Council

Services should assess on a case-by-case basis and on the basis of the content of the document whether it contains interpretation of EU law and whether interpretation goes beyond the Commission's normal administrative operations. The Legal Service and or the Secretariat-General may assist in identifying whether this is the case.

The following documents are not considered guidance documents containing legal interpretation going beyond the Commission's normal administrative operations:

- Guidelines used only internally;
- Documents of a factual nature illustrating best practices;
- Documents that contain only factual information on the existence of EU law provisions or merely paraphrase their contents (such as basic explanation given in a simplified, citizen-friendly way) or on their application (such as implementation reports⁴⁴³).

As part of their normal administrative operations, the Commission services have regular contacts with Member States' administrations and other stakeholders. In this context, the Commission services are frequently requested to provide ad hoc interpretation of legal provisions or technical advice on the practical application of those provisions. In so far as the interaction with the Member States does not take the form of general guidance through which the Commission uses its political discretion that has been given to it by the TFEU or by EU legislation or in which the Commission gives legal interpretation of significant importance that results in new or modified policy developments, or when the interaction remains at a very technical level, the requirement to seek College endorsement does not apply. For example, this may be the case where services are requested to clarify the interpretation of certain legal provisions during expert group meetings, Committees⁴⁴⁴ or in bilateral contacts with a Member State's administration or any other meeting with one or more Member States or stakeholders.⁴⁴⁵

Whenever a formal written reply is provided (for example, in the summary minutes of an expert group meeting, in letters or in e-mails with more than ephemeral significance), the service should mention that the reply reflects the position of the Commission services and does not commit the Commission. In those cases, the following disclaimer could be added:

Directive 2004/113/EC to insurance, in the light of the judgment of the Court of Justice of the European Union in Case C-236/09 (Test-Achats); Commission [Guidance](#) on Implementing the Energy Efficiency Directive

⁴⁴³ A collection of statistical and factual information on, for example, how a certain directive has been implemented so far across the Member States.

⁴⁴⁴ This includes meetings of comitology committees or non-comitology committees (e.g. the European Social Fund Committee).

⁴⁴⁵ This is the case, for instance, for monitoring committee meetings of European Structural and Investment Funds, where the Commission participates in an advisory capacity.

"This [...] was prepared by/ expresses the view of the [Commission services/ DG ...] and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law."

The Legal Service must be consulted on the envisaged interpretation of EU law and will provide assistance, if needed, to determine whether the envisaged action is covered by this note. The Legal Service may also assist in specific cases where submitting general guidance documents to College endorsement raises particular problems.

3. PREPARATION AND FORMAT

In preparing guidance documents, services should check if any of the **better regulation requirements** are to be applied⁴⁴⁶. Guidance documents falling under the scope of Decide should have the appropriate planning entry and political validation before preparatory work begins⁴⁴⁷. Guidance documents are normally subject to an **interservice consultation**⁴⁴⁸.

A guidance document containing an interpretation of EU law to be used by Member States, stakeholders and the general public is to be adopted by the Commission in the form of a Commission interpretative Communication or Notice (with a "C" serial number). It should be adopted in all languages (except Irish) and published in the C series of the Official Journal.

In those cases where the guidance document exclusively concerns inter-institutional relations,⁴⁴⁹ it should be adopted by the Commission as a Commission "Communication" (with a COM serial number) addressed to the other institutions and published on EUR-Lex.⁴⁵⁰ It can be adopted in the three languages, though publication requires translation into all languages (except Irish).

In choosing the format for the guidance document, services are recommended to take into account that Commission Communications (contrary to Commission Notices) may not extend to more than 15 pages (unless agreed with the DGT). Detailed information on the procedures necessary to issue these documents is provided on GoPro⁴⁵¹.

Where documents contain both factual information and interpretation of legislative provisions and the scope and length of the document so justifies, the factual information

⁴⁴⁶ Better regulation Guidelines, SWD(2015) 110 (for example, an impact assessment may be needed)

⁴⁴⁷ See Tool #6 on *Planning and political validation of initiatives*.

⁴⁴⁸ To note that documents which are not adopted by the College (staff working documents) should also be submitted to an interservice consultation, see LS/SG note mentioned above (FN 1)

⁴⁴⁹ For example, Commission Communication of 9 December 2009 - Implementation of Article 290 of the Treaty on the Functioning of the European Union (COM(2009)673 final).

⁴⁵⁰ Is it to be noted that in certain languages, no distinction is made between a Commission interpretative Notice and a Commission interpretative Communication (for example, in French, both documents will be entitled "*communication*").

⁴⁵¹ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Autonomous+acts>

may be set out in a staff working document accompanying the Commission Communication or Commission Notice.

Such Commission guidance documents containing interpretation of EU law should have a disclaimer to clarify that it is ultimately for the Court of Justice to ensure the uniform interpretation of EU law. The following sentence should be added in the document:

"This [...] is intended to assist [citizens and businesses/ national authorities] in the application of this [EU legislation]. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law."

With regard to guidance documents which have already been made public (or released to third parties), services are requested to follow these guidelines once they decide to revise/update the interpretation of EU law in these documents.

TOOL #40. DELEGATED AND IMPLEMENTING ACTS

1. INTRODUCTION

The vast majority of EU legal acts are adopted by the Commission in accordance with powers conferred on it by the legislator in basic legislation, either in accordance with Article 290 (delegated acts) or Article 291 (implementing acts) of the Treaty on the Functioning of the European Union⁴⁵².

Empowerments to adopt delegated acts allow the Commission to adopt legal acts of general application to supplement or amend certain non-essential elements of a legislative act. The Common Understanding between the European Parliament, the Council and the Commission on delegated acts, as annexed to the Interinstitutional Agreement on Better Law-Making⁴⁵³, sets out the practical arrangements and commitments of the institutions on the exercise of these powers.

Empowerments to adopt Implementing acts are used where uniform conditions for implementing legally binding acts are needed. The rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers have been laid down in legislation, i.e. the Comitology Regulation⁴⁵⁴.

Guidelines for the Commission Services⁴⁵⁵ are in place providing detailed explanations on how empowerments for delegated and implementing acts should be included in basic acts, how the empowerments should be used, how delegated and implementing acts should be prepared and how the respective control mechanisms work.

Better regulation principles apply to the preparation of delegated and implementing acts as specified in this Toolbox; the key principles are referenced below.

2. REQUIREMENTS THAT APPLY TO DELEGATED AND IMPLEMENTING ACTS

Standard clauses must be used when including empowerments for delegated and implementing acts in basic acts. For delegated acts these standard clauses have been agreed between the institutions in the appendix to the Interinstitutional Agreement on

⁴⁵² An important number of acts are also still adopted under the regulatory procedure with scrutiny (RPS), set out in Article 5a of Council Decision 1999/468/EC. Better regulation principles apply to these measures as well.

⁴⁵³ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1): https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/IIABL.aspx

⁴⁵⁴ Regulation (EU) 182/2011, OJ L 55, 28.2.2011, page 13.

⁴⁵⁵ <https://myintracomm.ec.europa.eu/sg/comitology/Pages/index.aspx>

Better Law-Making⁴⁵⁶. For implementing acts, templates for the empowerments are set out in the Drafters' Assistance Package (DAP)⁴⁵⁷.

The **use of empowerments must be properly planned**; basic acts often contain several empowerments, sometimes with an obligation for the Commission to act by a specific time, and may contain reporting obligations relating to delegated acts.

Delegated and implementing acts (under committee control and adopted by written or oral procedure) should be entered in **Decide planning**, the latest 12 months before planned adoption date for 'major' initiatives (those with significant impact) and 3 months for 'other' initiatives.⁴⁵⁸

A roadmap or inception impact assessment⁴⁵⁹ should be prepared for all delegated and implementing acts identified as 'major' initiatives. Roadmaps and inception impact assessments are published for feedback for a period of four weeks.⁴⁶⁰

Impact assessments should be prepared for delegated and implementing acts when the expected economic, environmental or social impacts of EU action are likely to be significant and the Commission has a margin of discretion regarding the content of the act.⁴⁶¹ The principle of proportionate analysis applies and the appropriate level and focus of the impact assessment is linked to the type of policy initiative. The impact assessment should be sent to the Regulatory Scrutiny Board for its scrutiny in the usual way⁴⁶². Once the IA report has received a positive opinion from the RSB, it should accompany the draft measure or delegated act as part of the interservice consultation.

Whenever **broader expertise** is needed in the early preparation of delegated and implementing acts the Commission will make use of expert groups, consult targeted stakeholders and carry out public consultation as appropriate.⁴⁶³

Whenever Commission services share early drafts of acts or measures or other preparatory documents with Member State representatives in the relevant committee or experts it must be absolutely clear that these documents are in no way endorsed or adopted by the College. In practice means that:

- The European Commission logo must not appear on the documents;

⁴⁵⁶ OJ L123, 12 May 2016, p1.

⁴⁵⁷ <http://www.cc.cec/wikis/pages/viewpage.action?spaceKey=dap&title=Home>

⁴⁵⁸ See Tool #6 on *Planning and political validation*

⁴⁵⁹ See Tools #6 on *planning and political validation*; #7 on *Drafting of roadmaps, evaluation roadmaps and inception impact assessments*; and Tool # 9 on *When an IA is necessary*.

⁴⁶⁰ See Tool #56 on *Stakeholder feedback mechanisms*.

⁴⁶¹ See Tool #9 on *When an IA is necessary*.

⁴⁶² See Tool #3 on *The role of the Regulatory Scrutiny Board*.

⁴⁶³ See Tools #53, #54 and #55 on stakeholder consultation.

- The documents must not have an official Commission cover page; and
- The following disclaimer must appear on the first (cover) page:

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the member State or entity to which it is addressed for discussion and may contain confidential and/or privileged material.

An **interservice consultation** must be carried out, for delegated acts before adoption by the Commission, for implementing acts under committee control before the draft is submitted to the committee for an opinion.

After the interservice consultation, draft delegated and implementing acts are made public for a **4-week public feedback** with certain exceptions.⁵²⁴

Where applicable **notifications** of drafts under the Agreement on Technical Barriers to Trade (TBT) or the Agreement on the application of Sanitary and Phytosanitary measures (SPS) in the WTO framework need to take place.

Throughout the process of preparation of delegated and implementing acts the **internal political validation and control processes** must be respected. In particular, it is essential that potentially sensitive delegated and implementing acts are flagged as early as possible in Decide and that Commissioners and Vice-Presidents consider whether the issue needs to be discussed in Hebdo or the College before proceeding.⁴⁶⁴

2.1. Delegated Acts

Delegated acts need to be prepared in line with the commitments in the **Common Understanding**, in particular **Member State experts must always be consulted on draft delegated acts** and the **European Parliament and the Council must receive all documents sent to Member State experts** (via a functional mailbox) and can send experts to **participate in expert groups** preparing the delegated acts.⁵¹⁸

Expert groups assisting in the preparation of delegated acts must respect the rules applicable to expert groups.⁴⁶⁵

Delegated acts must include an explanatory memorandum.⁴⁶⁶

⁴⁶⁴ Ares(2016)980167, Ares(2016)1900502, and Ares(2017)1659207

⁴⁶⁵ See new rules on expert groups
<https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Expert%20groups>

⁴⁶⁶ See Tool #38 on *Drafting the explanatory memorandum*.

A basic act may contain several empowerments for delegated acts. On the condition that the Commission provides objective justifications based on the substantive link between two or more empowerments contained in a single legislative act, and unless the legislative act provides otherwise, empowerments may be **bundled**. Consultations in the preparation of delegated acts also serve to indicate which empowerments are considered to be substantively linked (see Interinstitutional Agreement on Better Law-Making, point 31).

After adoption of the delegated act by the Commission, the European Parliament and the Council have the right to object.⁵¹⁸

2.2. Implementing Acts

Implementing acts need to be prepared and submitted to Member State control in the respective committee **in accordance with the Comitology Regulation**.⁵¹⁸

The European Parliament and the Council are informed through the Comitology Register⁴⁶⁷. The European Parliament and the Council have a scrutiny right until adoption.⁵¹⁸

3. FURTHER READING & REFERENCES

- GoPro pages
- Guidelines on Delegated and Implementing Acts
- Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1)
- Regulation (EU) 182/2011, OJ L 55, 28.2.2011, page 13.

⁴⁶⁷ <http://ec.europa.eu/transparency/regcomitology/index.cfm>

Chapter 5

Monitoring the application of an intervention

TOOL #41. MONITORING ARRANGEMENTS AND INDICATORS

1. HOW TO SET UP MONITORING ARRANGEMENTS

How an initiative will be implemented is a key issue that should be assessed in each impact assessment in order that potential problems and monitoring needs can be sketched out. The monitoring needs initially identified will need to be updated to reflect the Commission's proposal and again in light of how the Legislator changes the Commission's proposal.

Monitoring is a continuous and systematic process of data collection about an intervention. It generates factual information for future evaluation and impact assessments and helps identify actual implementation problems.

Monitoring is necessary to allow policy makers and stakeholders to check if policy implementation is 'on track' and to generate information that can be used to evaluate whether it has achieved its objectives. While monitoring looks at "what" changes have occurred since the entry into force of a policy intervention, evaluation looks at "whether" the intervention has been effective in reaching its objectives, and whether the objectives have been met efficiently (i.e. at least cost), as well as the reasons for the success or otherwise of an intervention. In order to do this, an evaluation can and should collect additional data that is too expensive to monitor on a continuous basis or that measures longer-term effects.

New monitoring, and reporting requirements should follow several key principles:

- Collect only what is relevant so as to minimise administrative burden;
- Automate as much as possible with the use of IT tools to shorten data collection and processing time;
- Use common reporting standards to increase interoperability and ease sharing of data in the context of different policy areas;
- Make maximum use of existing data to save time and increase coherence of results;
- Be transparent towards the stakeholders and opt for making data publicly available, preferably as "open data" (c.f. principles of the eGovernment Action plan).

Box 1. Defining monitoring and evaluation arrangements

Monitoring and evaluation arrangements should be provided in the IA report ideally for the preferred option where one is specified (otherwise on the basis of the specific objectives). These should inform the essential monitoring and evaluation elements that ought to be included in the proposal itself and for preparing a detailed plan for monitoring and evaluation once the proposal is adopted by the Legislator.

1.1. What to monitor?

Monitoring is a continuous and systematic process of data collection about an intervention. It helps identify and address any implementation problems and generates factual information for future evaluation and impact assessments. It is important to note,

however, that the data collected will reflect changes due to the EU intervention and those caused by other factors.

The following can be monitored for any type of Commission initiative?⁴⁶⁸

During the life cycle of an initiative, you can monitor its:

- (1) **Implementation** (i.e. transposition of Directives into the national laws of Member States and, more generally, adoption of measures that are necessary to comply with/enable the legislation to be effectively applied. In case of expenditure programmes, spending money allocated to the intervention);
- (2) **Application** (i.e. changes observed in the realisation of the main policy objectives);
- (3) **Compliance and enforcement** (i.e. extent of compliance by businesses, measurements taken, inspections carried out, court cases pursued) can be monitored both during implementation and application stage – and provide useful insight into progress at both stages.
- (4) In addition to monitoring a progress on individual initiative, **contextual information** should be also collected (i.e. developments that are not intentionally related to the policy intervention, although they may be influenced by it, such as the economic growth, break-through technologies, new behavioural patterns etc.).

1.2. Data sources

Many legal measures supporting interventions contain provisions requiring the production of different documents on the performance of an intervention at a given point in time. Member States may have to report on what they have done in accordance with the policy or regulation, or the Commission may conduct its own assessment of its own or Member State actions. Examples include implementation reports, interim evaluations, and reviews of the current state of play in the implementation and application of the EU measure. Different reports contain different kinds of data and information, serving different purposes, particularly depending on the time they are written in the policy cycle.

A wide range of external actors, including the European Parliament, Member States, NGOs, think tanks and consultants, also produce reports on various aspects of EU activities or areas where EU interventions combine with a range of other actions being undertaken. These external contributions can also prove valuable sources of information, confirming or diverging from the findings emerging from the Commission's own work (For further information on data sources please refer to Common tool on "Information (Evidence) gathering").

When collecting data, attention should be paid to International classification. Classification systems are tools which allow for harmonised registration of data. The

⁴⁶⁸ Data collected throughout monitoring will encompass qualitative as well as quantitative variables.

Commission uses these international classifications in order to collect high-quality and harmonised/comparable data.⁴⁶⁹

1.3. Setting up a monitoring System

When defining new monitoring arrangements, you need to assess whether the existing ones (still) serve their purpose, i.e. whether they provide valuable and timely information for the policymaking process⁴⁷⁰. In doing so, you should answer the following questions:

- **What data is collected and how is it used?** How and by whom are data used?⁴⁷¹ Are all the data needed for the purpose for which they were collected? If not, why not? Are they used for other purposes?
- **How is data collected?** To what extent do monitoring structures already exist? By whom is data collected (e.g. the Commission, Member States, intermediaries such as Agencies, operators/beneficiaries, etc.)?

You should always consider a possibility for streamlining the existing reporting requirements (e.g. pooling them across policies, simplifying via web-based electronic collection etc.).

Before proposing new data requirements, you should carefully assess to what extent the existing data reflect the objectives set. If you identify missing key data that will need to be collected, you need to explain in detail what the data will be used for and whether they can be collected via existing monitoring structures. If the additional data collection implies significant administrative burden – be it for businesses, citizens, or public authorities – you need to measure it through the Standard Cost Model and demonstrate that it is proportionate vis-à-vis the identified data (and policy) needs.

In defining your monitoring arrangements, you should:

- Ensure that the monitoring system works from the outset and that adequate (legal) provisions are in place to ensure that data from Member States or from third parties will be collected reliably and smoothly; data and statistics are not always easy to get from the outset; many indicators can only be created and developed when the instrument is implemented, because you need the cooperation and agreement of stakeholders in developing them and in collecting the relevant information.
- Make adequate use of the collected data by ensuring the soundness and reliability of the proposed methods and instruments for collecting, storing and processing follow-up data;
- Design indicators that will allow collection of data relevant for improving the implementation and later evaluation of the policy intervention;

⁴⁶⁹ A good place to find relevant data is the EU's open data portal: <https://open-data.europa.eu/en/data/>

⁴⁷⁰ A first assessment of monitoring systems in place should be provided in the relevant evaluations.

⁴⁷¹ Beware that collected data need to be analysed to make them into useful information.

- Consider the cost of setting up and maintaining a monitoring system over the time life of an intervention should also be taken into account among the cost impacts of options.

2. INDICATORS

An indicator is a quantitative or qualitative measure of how close we are to achieving a set goal (e.g. policy outcome). They help to analyse and compare performance across population groups or geographic areas, and can be useful for determining policy priorities. Indicators should only give one perspective of the performance of a policy intervention, which is highly dependent on the type of indicator selected, data, other influences, etc.. It is important, therefore, to use other complementary approaches to monitoring, such as qualitative analysis or surveys.

When choosing appropriate indicators the following issues should be considered.

- Data should be readily available and of a good quality, ideally at national/regional level if appropriate;
- Indicators should capture the impacts due to the policy intervention within a reasonable length of time but exclude other influences if possible;

The European Commission's Competence Centre on Indicators and Scoreboards (based at JRC) can provide support and advice.

2.1. Setting up indicators

There is no clear-cut rule on the appropriate level of detail for indicators – this will depend on the type of initiative, the complexity of the intervention logic and the hierarchy of objectives constructed for a particular intervention. In principle, however, the "smarter" the policy objective, the easier it is to define a corresponding indicator.

Before you can start monitoring whether your initiative performs as expected, you will need to assess whether and how it has been implemented. At this stage, the spending programmes and regulatory proposals will differ the most:

For a **spending programme**, you will need to know how the money allocated to the intervention has been spent (for example, 20 kilometres of road built).

In the case of a **regulatory proposal**, in addition to its adoption by Council and Parliament, and its transposition into the national laws of the Member States in case of a Directive (both steps are important parameters in monitoring the implementation process), you will need to know which key types of measures have been put in place in order to comply with the regulatory requirements (by the Commission, Member States or other actors).

Table: Examples of monitoring indicators

Stage in the policy cycle	Monitoring	Examples of indicators
Implementation ("outputs")	Indicators relate to results of implementation of an intervention – i.e. deliverables that need to be generated in order to achieve its objective(s).	<i>Kilometres of roads built, scholarships awarded, consultancy services developed, standards developed, databases created, labelling requirements designed and implemented, etc.</i>
Application ("results and impacts")	Indicators aim at monitoring what concretely the policy intervention intends to achieve, i.e. raison d'être of your policy. They represent changes over the short, medium and long term which can be directly linked to the application of the intervention. These indicators should include monitoring both the direct, as well as any significant indirect or unintended impacts of an intervention. They should be closely related to the identified problems and their drivers.	<i>Safety incidents at EU level, tax compliance, innovations/new products generated in the sector, time saved by users of a road, survival rate of businesses, consumption of low fat, low sugar food, mutual recognition of nationally approved products, permissions/derogations granted, bans introduced, e-invoices exchanged cross-border, tax declarations filed, etc.</i>

Table: Examples of links between objectives and indicators

Objectives	Core indicators
Development of organic production ⁴⁷²	• share of organic area in total utilised agricultural area • share of organic livestock in total livestock • number of certified organic operators
Effectiveness in curbing emissions ⁴⁷³	• new vehicle fuel consumption • CO₂ emissions for each heavy-duty vehicle category
Improved balancing in gas transmission systems ⁴⁷⁴	• liquidity on the gas wholesale markets • volumes in trading at the intraday gas market • price convergence between gas markets
Reduction of energy consumption and promotion of energy efficiency ⁴⁷⁵	• energy label rating of units sold • saving on space heating

⁴⁷² http://eur-lex.europa.eu/resource.html?uri=cellar:fbf11871-b33f-11e3-86f9-01aa75ed71a1.0001.01/DOC_1&format=PDF

⁴⁷³ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014SC0160&from=EN>

⁴⁷⁴ http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2014/swd_2014_0114_en.pdf

⁴⁷⁵ http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2014/swd_2014_0222_en.pdf

To the extent possible, all indicators should be ‘RACER’, i.e.:

- (1) **Relevant**, i.e. closely linked to the objectives to be reached. They should not be overambitious and should measure the right thing (e.g. a target indicator for health care could be to reduce waiting times but without jeopardising the quality of care provided).
- (2) **Accepted** (e.g. by staff, stakeholders). The role and responsibilities for the indicator need to be well defined (e.g. if the indicator is the handling time for a grant application and the administrative process is partly controlled by Member States and partly by the EU then both sides would assume only partial responsibility).
- (3) **Credible** for non-experts, unambiguous and easy to interpret. Indicators should be simple and robust as possible. If necessary, composite indicators might need to be used instead – such as country ratings, well-being indicators, but also ratings of financial institutions and instruments. These often consist of aggregated data using predetermined fixed weight values. As they may be difficult to interpret, they should be used to assess broad context only⁴⁷⁶.
- (4) **Easy** to monitor (e.g. data collection should be possible at low cost).
- (5) **Robust** against manipulation (e.g. administrative burden: If the target is to reduce administrative burdens to businesses, the burdens might not be reduced, but just shifted from businesses to public administration).

If necessary, proxy indicators might need to be used to represent a phenomenon in the absence of a direct indicator. They may also help us to monitor things that are difficult to 'measure' in practice such as illegal migration, counterfeits, social inclusion etc. When using proxies, however, you need to understand well the underlying causal links and the limitations of using proxies.

At the end of the process, it would be useful to summarise the system of indicators and monitoring in tabular form:

Operational objective	Indicator	Definition	Unit of measurement	Data source	Frequency of measurement	Baseline	Target

⁴⁷⁶ Various categories of indicators exist, such as qualitative/quantitative, local/global, monetary-non-monetary, etc.

TOOL #42. LEGAL PROVISIONS ON MONITORING AND EVALUATION

1. INTRODUCTION

The evaluation of existing legislation is an integral part of the policy cycle so that an act of Union law should be evaluated and the results used to inform any new initiative to modify it. However, in practice it is often difficult to perform good quality evaluations because implementation of the initiative is not advanced enough to measure or assess its effects. Basic information about the performance of the initiative is also often missing.

In addition, the Legislator often incorporates "review clauses" in Union legislative acts which request the Commission to undertake reviews (e.g. of specific clauses) or prepare new elements (e.g. that could not be agreed in co-decision) often with deadlines that are inconsistent with a rigorous evaluation based on information gained from the practical application of the legislation.

Box 1 sets out the provisions of a new Interinstitutional Agreement on Better Law-Making⁴⁷⁷ which are relevant to the monitoring/review/evaluation of existing legislation. This new agreement sets out the commitment of the European Parliament, Council and Commission to consider establishing monitoring, reporting and evaluation provisions in a systematic way in each basic act.

The aim of this tool is to guide DGs and services on how to draft such provisions when preparing Commission proposals.

Box 1. The 2016 Interinstitutional Agreement on Better Law-Making

- §21: The Commission will inform the European Parliament and the Council of its multiannual planning of evaluations of existing legislation and will, to the extent possible, include in that planning their requests for in-depth evaluation of specific policy areas or legal acts. The Commission's evaluation planning will respect the timing for reports and reviews set out in Union legislation.
- §22: In the context of the legislative cycle, evaluations of existing legislation and policy, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action. To support these processes, the three Institutions agree to, as appropriate, establish reporting, monitoring and evaluation requirements in legislation, while avoiding overregulation and administrative burdens, in particular on Member States. Where appropriate, such requirements can include measurable indicators as a basis on which to collect evidence of the effects of legislation on the ground.
- §23: The three Institutions agree to systematically consider the use of review clauses in legislation and to take account of the time needed for implementation and for gathering evidence on results and impacts.

⁴⁷⁷ OJ L123, 12 May 2016, p1.

2. WHAT IS A MONITORING AND EVALUATION CLAUSE?

Monitoring and evaluation clauses are articles in legislative acts that contain provisions regarding how the changes linked to the EU intervention will be monitored and how the legislation will be evaluated. The aim of evaluation and monitoring clauses is to ensure that appropriate arrangements are put in place early on to track progress and evaluate the performance of EU interventions.

A comprehensive evaluation and monitoring clause would describe who is to collect the necessary information and how and when it is to be collected and, on that basis, when to produce the evaluation of the intervention. There are close links with the assessment of monitoring arrangements that should be an integral part of each impact assessment not least because of the potential impacts associated with data collection.⁴⁷⁸

Currently, the scope of monitoring and evaluation clauses varies greatly depending on the context of the intervention. The simplest cases require reports to be prepared by the Member States or the Commission (or both) by a certain date. While more complex legislation may require information to be collected and reported by private actors, public authorities or both.

3. ISSUES/ELEMENTS TO BE CONSIDERED WHEN PREPARING MONITORING EVALUATION CLAUSES

(1) *The Commission's right of initiative*

It is the Commission's right pursuant to the Treaty to decide if and when to present a proposal to the Legislator to amend existing Union acts. Any review clause proposed by the Commission should not contain any commitment to present any new proposal in the future. In the spirit of better regulation, the Commission's policy should be to evaluate the performance of existing legislation and then assess on the basis of the evidence if any modification is necessary. There may, however, be instances where the Commission needs to act before any evaluation is possible and the Commission should be free to do so in the exercise of its right of initiative.

(2) *Consider how to monitor the new intervention*

The monitoring and evaluation section of the IA report accompanying the Commission proposal should be the starting point for preparing evaluation and monitoring clauses. This section of the IA report describes how the impacts of the EU intervention will be monitored and evaluated relative to the operational objectives of the proposed intervention, what indicators will be used and what data might be needed in addition to that which is already available. Before drafting the proposal, you will also have to consider:

- Which indicators and data are absolutely necessary to monitor the performance of the intervention and what data is already available?;

⁴⁷⁸ See Tool #41 on *Monitoring arrangements and indicators*; and Tool #12 on the *Format of the IA report*.

- Should there be mandatory provisions regarding data collection (by whom, how often, where it will be stored, how it will be transmitted, accessed, etc.)?⁴⁷⁹
- What will be the role of the Member States, the Commission or any relevant EU agencies or bodies?
- Are the new data collection requirements proportionate to the scope and objectives of the intervention? What are the costs and how will they be covered? Only data and information, which is strictly necessary for the assessment of the intervention, should be collected. Existing monitoring and reporting arrangements need to be checked, including those relating to other legislative acts in the same policy area.
- Consider if specific aspects of the intervention are particularly important so that they should be directly referenced to ensure a sufficient focus on the key elements. It is usually good practice to cover all elements of the intervention for monitoring purposes.

(3) *Timing of the evaluation*

An evaluation can only be useful if enough practical experience and performance-related information exists. As a rule of thumb, any future evaluation should have access to a minimum of three years full data relating to the operation of the EU intervention. Equally, when setting the date for an evaluation report, consideration should also be given to the time permitted for transposition, when the key actions will be applied in practice, any time lag in collecting relevant data plus the time needed to evaluate and report.

(4) *Other intermediate reports which can be included.*

Ultimately, an evaluation of the legislation should be prepared that will result in an evaluation SWD being prepared by the lead DG or service possibly together with a formal Commission report to the legislator.

The lead DG should also consider whether it is useful for the Commission (together with inputs from the Member States) to prepare additional reports before the evaluation starts (for example, reports on the state of transposition, and implementation). The table below summarises these intermediate products with an indication of the timing for when such reports should be requested. It should be noted that these intermediate products cannot be considered as a substitute for a comprehensive evaluation as described in the better regulation Guidelines.

Report type	Timing (after application or implementation)	Content
<i>Transposition/ legal compliance reports</i>	6 months +	Factual information on whether and how different provisions of EU directives have been transposed.

⁴⁷⁹ See Tool #41 on *Monitoring arrangements and indicators*

Implementation report	1-3 years	Focus on the Member States' implementation measures; description of the state of play based on limited monitoring data;
Monitoring report	1 +	Information on progress against agreed timetables or objectives; presentation of collected data and information; explanation of <i>what</i> has happened rather than <i>why</i> .

Thought also needs to be given as to how often the different reports should be produced. It is important that the requirements do not impose unnecessary burdens. For example, evaluation reports should not be required more frequently than every 5 to 8 years.

4. EXAMPLES OF MONITORING AND EVALUATION CLAUSES

The Commission's better regulation policy evaluates Union legislation in a uniform way. However, the Legislator often adds to the Commission's proposal requests for monitoring, review or evaluation in an ad-hoc manner. However, the European Parliament, Council and the Commission have now agreed to consider a more systematic approach. This agreement provides an opportunity for the Commission to set out in its proposal what it considers to be appropriate approach for monitoring and evaluation. There is always the risk that the Legislator may amend these proposals but greater consistency across the *acquis* may result in the longer term in the way legislation is evaluated.

There is no single template for the monitoring and evaluation clause that could be applied in every case. The table below contains five examples of articles that refer to issues commonly addressed in evaluation and monitoring clauses. When using these examples, their exact wording may have to be adjusted to reflect the needs of the evaluation and monitoring plan (including the list of data/information, which should be collected). It is important to note that one evaluation clause may mix elements from the different examples. For instance, an evaluation and monitoring clause may require Member States to collect certain data, on the basis of which, the Commission may produce an implementation report (as a first step) that will be followed by an evaluation after the sufficient experience with the performance of the intervention has been gained.

4.1. Model clauses

Examples of evaluation and monitoring clauses	
Evaluation clause	No sooner than [five] years after the date of [application/transposition] of this [Regulation/Directive], the Commission shall carry out an evaluation of this [Regulation/Directive] and present a Report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. The evaluation shall be conducted according to the Commission's better regulation Guidelines*. Member States shall provide the Commission with the information necessary for the preparation of that Report. *SWD(2015) 111 (or most recent version)
Implementation clauses	By [xx/yy/zzzz] at the latest, the Commission should present a Report on the implementation of this Directive to the European Parliament, the Council and the European Economic and Social Committee.

	Member States shall provide the Commission with necessary information for the preparation of that Report.
Monitoring clause – monitoring programme	By [xxx] at the latest, the Commission shall establish a detailed programme for monitoring the outputs, results and impacts of this [Regulation/Directive]. The monitoring programme shall set out the means by which and the intervals at which the data and other necessary evidence will be collected. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence
Monitoring clause-specific requirements	Member States shall regularly monitor the application of the [Regulation/Directive] based on the following indicators: - X, - Y - Z Member States shall organise the production and gathering of the data necessary to measure the change in the indicators described in [paragraph x.x] above, and shall supply that information to the Commission on a [yearly/b-annual/monthly basis].

4.2. Recitals

Reasons will have to be given for any operative clause on monitoring and evaluation will have to be motivated by a corresponding recital in the Commission's proposal: The following examples may be useful:

Issue	Model text:
Evaluation	The Commission should carry out an evaluation of this [Regulation/Directive]. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016*, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU value added and should provide the basis for impact assessments of possible further measures. * OJ L123, 12.5. 2016, p1. [footnote only needed if not previously cited]
Data collection	Information should be collected in order to assess the performance of the legislation against the objectives it pursues and in order to inform an evaluation of the legislation in accordance with paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016*. * OJ L123, 12 May 2016, p1.[footnote needed only if not previously cited]

Chapter 6

Evaluations and fitness checks

Key steps and requirements for evaluations and fitness checks



TOOL #43. WHAT IS AN EVALUATION AND WHEN IS IT REQUIRED?

1. INTRODUCTION

Commission evaluations^{480,481} and fitness checks assess the performance of existing policies, programmes and legislation. This tool provides guidance to Commission officials on the application of the Guidelines, the definition of evaluation and fitness checks and explains the obligations to evaluate.

Box 1. Key definitions

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 uses evidence to judge how well the intervention has performed (or is working), taking account of earlier predictions made in the context of an impact assessment. **Evaluation goes beyond an assessment of *what* has happened; it considers *why* something has occurred (and what links, if any, can be made to the role of the EU intervention) and, if possible, *how much has changed as a consequence. It thus aims (where possible) to draw conclusions about the causal effects of the EU intervention on the desired outcomes***⁴⁸². It should also look at the wider perspective, seeking to identify (and learn from) any unintended/unexpected effects which were not anticipated for example, in the impact assessment or in the act agreed by the Legislators. Evaluation should provide an evidence-based assessment of whether the EU intervention continues to be justified.

Traditionally, evaluations have covered a single EU intervention. Increasingly, evaluations with a wider scope - **fitness checks (FC)** - are undertaken, which evaluate a

⁴⁸⁰ Throughout the Toolbox and Guidelines, the term "evaluation" is used to describe any type of evaluation. For example: fitness checks; evaluations of programmes – often classified as mid-term, final, ex-post; evaluations of policies based on legal instruments or soft law – generally classified as interim because few policies have a set end date); evaluations of agencies conducted by the Commission services; evaluations of other external facing actions. If special consideration is required e.g. for a fitness check, this is mentioned in the text.

⁴⁸¹ Evaluations conducted by decentralised agencies of their own projects etc follow the Evaluation handbook for Agencies, available at http://europa.eu/about-eu/agencies/overhaul/index_en.htm

⁴⁸² As such, evaluation goes further than typical monitoring or audit activities. Monitoring looks at “what” (what has occurred; what has been the output of the intervention), compliance audit looks at “how” (how the internal control systems have functioned and how resources have been used at the implementation level), and performance audit takes a broader look at the overall conduct of the work and its results.

group of interventions which have some relationship to each other (normally a common set of objectives) justifying a joint analysis. There are no set criteria for identifying the scope of a fitness check – rather, the scope should bring together interventions whose evaluation as a group will contribute to a better understanding of the role played by the EU in achieving the related objectives, and reacting to broader policy concerns. Although fitness checks to date have mainly considered groups of related legislative actions, it is in theory possible to include within the scope of a fitness check any type of EU intervention e.g. spending programmes, strategies, agencies etc.

A fitness check should pay particular attention to identifying and trying to quantify 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 measures and help to identify the cumulative impact of the group of 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 via 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.

Box 2. Studies and cumulative costs assessments are important inputs but are NOT evaluations

Not all analysis or evaluative type work can be considered an evaluation which meets the Commission's Guidelines:

- A study is defined as:⁴⁸³ *'a document resulting from intellectual services necessary to support the institutions' own policies or activities. A study is financed through the EU budget. It may be produced inside the institution or commissioned from external experts, generally through procurement procedures'.*
- Based on the above **it is clear that a study on its own is not necessarily an evaluation** because it may not fulfil the definition of evaluation presented earlier (i.e. evidence-based judgement against the five criteria) and the final document of a

⁴⁸³ See Note SG/BUDG Ares (2012) 809202 which describes the Commission's harmonised procedures for studies

study conducted by an external party does not present the evidence-based judgements of the Commission services – this is done in the evaluation SWD.

- Studies generally present important information – but may only cover part of the overall picture. Even where the scope of a study covers the full scope of an evaluation, an evaluation staff working document is required to bring together all the information and present the position of the lead DG.⁴⁸⁴
- Very often DGs commission supporting studies from external contractors to help with certain aspects of an evaluation. The precise content of such outsourced work depends on the evaluation being conducted and the resources available.
- **Cumulative cost assessments (CCA)** are a specific type of study/research intended to assess EU related regulatory costs on an industrial sector. However, given that such work focuses only on costs and does not take into account benefits, "CCAs cannot be the sole basis for policy recommendations"⁴⁸⁵ as they **do not evaluate** the whole performance of such interventions (i.e. they do not assess any of the five criteria used in the definition of evaluation in full). However they can provide an important input to evaluations, helping to inform the efficiency analysis.

2. 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 assessment⁴⁸⁶.

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 economy⁴⁸⁷. In line with the "evaluate first" principle, such evaluation work should generally take place before work on a related initiative is launched (such as an impact assessment), although there may be cases where some overlap is unavoidable⁴⁸⁸.

The conduct and analysis of any evaluation should be proportionate⁴⁸⁹. This means that the resources and time allocated and the work undertaken should reflect i.a.:

- The importance and priority given to the intervention (e.g. Commission Work Programme, Juncker priorities, operational and strategic decision-making needs);

⁴⁸⁴ See Tool #49 on *The staff working document for evaluation*

⁴⁸⁵ Page 15, Regulatory Fitness and Performance: State of Play and Outlook COM (2014) 368 final

⁴⁸⁶ 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>.

⁴⁸⁷ The 2007 Communication on Reinforcing the use of evaluation; http://ec.europa.eu/smart-regulation/evaluation/docs/eval_comm_sec2007_213_en.pdf

⁴⁸⁸ See Tool #52 on *Back-to-back evaluations and impact assessments* for more information on the specific processes to follow.

⁴⁸⁹ See Tool #45 on *How to undertake a proportionate evaluation*

- Requirements for evaluation as set out in the Financial Regulation, as well as any specific requirements set out in the legal basis of the relevant interventions;
- General factors such as the: nature of the policy instrument e.g. Regulation, Directive, Recommendation, communication, strategy, action plan; stage of policy development and associated maturity; magnitude and complexity of the intervention; significance and nature of the expected or observed impacts.

Box 3. Activities which need not necessarily be evaluated in the standard way

It may not be necessary to apply the Guidelines fully when evaluating:

- 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 in the Guidelines. 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 of legal instruments;
- Agencies, where aspects of the agency's performance will be evaluated within the context of the associated programme (executive agencies) or where a wider evaluation of the agency is part of the policy evaluation;
- 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).

Such work, which would not generally constitute an evaluation, should nonetheless broadly follow the concepts and principles of evaluation presented here. In these cases, a more proportionate approach should be applied; in general, a separate Decide planning entry, roadmap and staff working document (SWD) might not be required; the consultation strategy and evaluation criteria applied could cover a lesser 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.⁴⁹⁰

In particular, when planning an evaluation, it is important to make a preliminary assessment of what data is already or likely to be available⁴⁹¹ and how long the EU

⁴⁹⁰ See also Tool #1 on *Principles, procedures and exceptions* and Tool #45 on *How to undertake a proportionate evaluation*.

⁴⁹¹ Section 7 of any associated IA should include indications of monitoring and evaluation arrangements.

intervention has been operating. This will help in designing the evaluation and also allow early signals to be passed relating to what the evaluation will deliver. As a rule of thumb, a minimum of three years full data relating to the operation of the EU intervention should be available. Consideration also needs to be given to the time required to carry out an evaluation (rule of thumb – minimum 9 months) and budget available, with DGs taking a pro-active role in identifying evaluation needs and planning accordingly.⁴⁹²

Many evaluations are imposed by individual (evaluation or assessment) clauses in legislation⁴⁹³. Review clauses are also common – requiring work with backward and forward looking elements. So for example, a review clause may require that by a certain date, the Commission produces an assessment of certain or all elements of an intervention, together with, if appropriate, proposals for change. The assessment in a "Review" clause should only trigger an evaluation according to these Guidelines where sufficient operational / implementation experience has accumulated to permit such analysis and there is already an expectation at that point that a proposal for change will be made. An evaluation may also be necessary due to the application of a sunset clause⁴⁹⁴.

Evaluation or review clauses should be applied by taking into account the requirements set out in the legislation together with the definition of evaluation in the better regulation Guidelines. For example, if there is a clause requiring the Commission to review certain elements (e.g. the effectiveness of the intervention and how it has affected competition) and it has been decided to evaluate the intervention, then the starting point for the scope of the subsequent evaluation should be to consider the usual five criteria (effectiveness, efficiency, relevance, coherence and EU added value) plus competition.

For spending programmes, the **Financial Regulation**⁴⁹⁵ and Rules of Application require an evaluation of all programmes and activities which entail significant overall spending (over €5 million). These rules also apply in full to evaluations of Agencies conducted by the Commission. The evaluation requirements for projects or programmes financed by the (11th) European Development Fund (EDF) budget are laid out in Council Regulation (EU) 2015/323 on the financial regulation.

In addition, for spending programmes financed by the EU budget, an obligation to evaluate is included in **Article 318 of the Treaty on the Functioning of the European Union (TFEU)**⁴⁹⁶, which requires the Commission to establish an annual evaluation report of the Union's finances based on results achieved.

⁴⁹² See Tool #44 on *Planning & the 5-year rolling evaluation plan*; and Tool #46 on *Designing the Evaluation*.

⁴⁹³ See Tool #42 on *Legal provisions on monitoring and evaluation*.

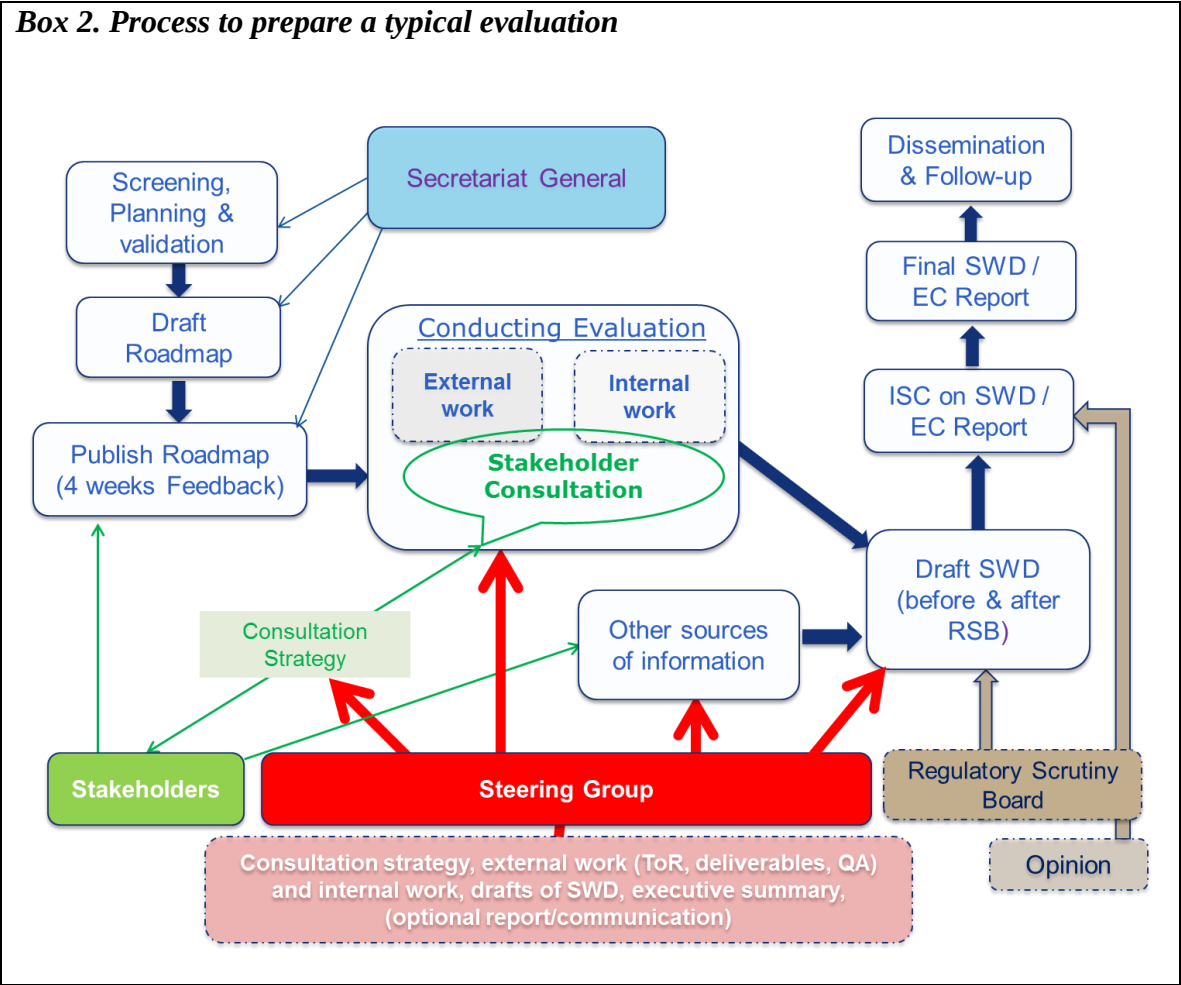
⁴⁹⁴ See for instance the [Joint Statement and Common Approach \(Parliament, Council & Commission\)](#), 2012

⁴⁹⁵ See Commission's financial regulations, particularly Chapter 7, Article 30.4. The Financial regulations are available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:298:0001:0096:EN:PDF>

⁴⁹⁶ Commission's rules of application, in particular Article 18.3. The rules of application are available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:362:FULL:EN:PDF>

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.

Box 2. Process to prepare a typical evaluation



TOOL #44. PLANNING & THE 5 YEAR ROLLING EVALUATION PLAN

1. INTRODUCTION

Good evaluation planning is a critical step to ensure the availability of evaluation results that will feed back into the policy-making cycle. Evaluation activities should be planned in a transparent and consistent way so that the relevant evaluation findings are available in due time for operational and strategic decision-making. They are also an important tool in improving organisational learning, ensuring transparency and demonstrating the accountability of the Commission.

The Commission's organisational framework for evaluation is decentralised, making individual Directorates General responsible for planning and conducting evaluations of all of their activities over time. The choice of structure is at the discretion of each Directorate General, reflecting its needs and requirements.

Each Directorate-General should ensure that:

- A periodic evaluation of all EU interventions under its responsibility. Under the **"evaluate first"** principle, evaluation findings and lessons learned should feed into the decision-making cycle, backing up proposals for change, particularly for items proposed on the Commission Work Programme (CWP). Evaluation findings should, where available, be included in the roadmaps or inception impact assessments drawn up for new initiatives.
- Appropriate monitoring and evaluation activity is planned at the time of adoption of each initiative⁴⁹⁷ to develop or amend EU action (in general such arrangements are first set out in the relevant impact assessments). It is strongly recommended that the associated work is then entered into the evaluation planning, ensuring that deadlines set in legislation are met.
- Relevant evaluation results are available to feed into the Annual Management and Performance Report. From 2016 this combines two former reports: the Evaluation Report produced in accordance with Article 318 of the Treaty on the Functioning of the European Union and the Synthesis Report required by Article 66 (9) of the Financial Regulation. These results are presented in the Annual Activity Reports drawn up by Directorate Generals and in the annual Programme Statements prepared to justify resource allocation in the draft budget, both of which provide a key source of information for the Annual Management and Performance Report.

2. REGULAR SCREENING OF RESPONSIBILITIES

It is recommended that the Director-General screens regularly the legislation falling under its responsibility in order to identify:

⁴⁹⁷ The 2016 inter-institutional agreement on better law making envisages a systematic approach to evaluation and monitoring in basic acts: See Tool #42 on legal provisions on monitoring and evaluation.

- Legal obligations to carry out an evaluation (including under the Commission's financial regulation) or any kind of requirement to review or produce a report, considering whether the time is ripe for a full evaluation⁴⁹⁸.
- When individual interventions were evaluated last and ensure evaluations are available in a timely manner to feed into the next steps in the policymaking cycle.
- The potential to carry out cross cutting fitness checks.
- Other feedback on interventions, including any complaints and/or infringements and/or SOLVIT cases⁴⁹⁹ which might imply problems with implementation, application or performance.

3. ROLLING EVALUATION PLAN

The planning of evaluation activities of individual Directorates-General takes the form of a (minimum) five-year indicative rolling programme, where the plan is broadly fixed for the first two years and stays more indicative for later ones, providing an overview of the structure and coverage of the evaluation policy. The plan needs to be annually updated (but may also be updated throughout the year, if necessary) and confirmed as part of the management plan process of each Directorate-General. The plan is submitted through the interinstitutional studies database and should respect the relevant instructions.

All of a DG's policy areas, including both spending and non-spending interventions, should over time be proportionally covered in the rolling evaluation plan.

The Secretariat-General compiles the evaluation plans of individual DGs into a single Commission evaluation plan which is published on a central website⁵⁰⁰. This ensures transparency, enhancing stakeholder access by publicising what is being and will be evaluated when and thus further enabling their participation.

In addition to the evaluations identified by the screening exercise, other evaluations (e.g. thematic or ad-hoc) may be identified outside of the annual planning process as a result of new strategic decisions or significant (negative) feedback on performance (e.g. implementation problems, indications coming from monitoring results, complaints or infringements, audit reports). It is recommended that such additions are added to the evaluation plan as they occur.

Each Directorate-General should indicate a central evaluation contact point within their plan (for example a functional mailbox address), which is responsible for answering questions from stakeholders on the planning, timing and progress of work on evaluations all year round. The evaluation plan will be a key input to the Regulatory Scrutiny Board's decision on which evaluations it will review.

⁴⁹⁸ The European Parliament produces a rolling check list of review clauses in EU legislation. The latest list was published in [July 2016](#).

⁴⁹⁹ See www.SOLVIT.eu or contact solvit@ec.europa.eu

⁵⁰⁰ See http://ec.europa.eu/smart-regulation/evaluation/index_en.htm

4. TIMING

Whilst the evaluation plan lists all the evaluations planned by a DG during a (minimum) five year period, the "timing" of the evaluation (i.e. when it starts / ends) is a key element of the overall plan. Timing is a crucial factor affecting the use of evaluation in the decision-making process; it should enable the results to be fed into further preparations for the design, renewal, modification or suspension of activities. Both planning and timing need to be aligned with political priorities and while there may always be emergencies, good management of these elements helps to ensure that reasonably up-to-date evaluation material is always available for part of the EU acquis.

Evaluation planning should take into account the life cycle of the intervention, legal obligations and the operational and strategic decision-making needs of the DG. Often, evaluation planning starts by looking at when the findings are required (e.g. to meet a legal obligation). By considering key factors such as resources available, data required/available, desired analysis, overlaps with other on-going work, a first indication of the approach and overall duration can be identified, allowing the probable start date to be estimated. In general, it is good practice to build in some extra time for the evaluation, as projects do not always start on time or can take longer than expected.

Planning for evaluations of **spending initiatives** covered by the multi-annual financial framework (MFF) or the European Development Fund (EDF)⁵⁰¹ is generally defined in the legal basis, predefining the timing of the different evaluations within the seven year funding cycle as well as the nature and number of contributions and reports that are expected. In an attempt to allow the mid-term (or interim) evaluation findings to feed into ex-ante evaluations (or impact assessments)⁵⁰² for the subsequent programming period, the mid-term evaluation results are generally scheduled for delivery around the fourth/fifth year of the programming period. Most ex-post evaluations are expected to take place within two to four years of the end of the programming period.⁵⁰³

Although the timing of the mid-term evaluations might not be ideal (i.e. potentially insufficient time has elapsed since the beginning of the programming period to allow for materialisation of the intervention's results and impacts), carrying out the evaluations later would not allow the evaluation findings to be used in impact assessments for the preparation of the subsequent programming period. Equally there would be insufficient time for any improvements to the current programme to produce significant benefits. To address this, some programmes (where there is little change in objectives between one funding cycle and the next) have brought together the ex-post evaluation of the preceding programme and the mid-term of the ongoing programme, providing a longer data set against which to evaluate performance

It is much harder to apply a uniform timetable to the evaluation of **non-spending activities** which follow a wide range of formats (e.g. regulation, directive, decision,

⁵⁰¹ A different set up applies for the European Structural and Investment Funds.

⁵⁰² See Tool #10 on *Financial programmes and instruments*.

⁵⁰³ In some cases, where the objectives have remained broadly the same between two programming periods, the mid-term evaluations of the current programming period also cover ex-post evaluations of the previous programming period.

recommendation, opinion, action plan, communication, trade agreement etc.). Regulatory activities in particular, have very different cycles. For different reasons Member States can be given relatively long or short periods to complete the transposition of an EU law into national legislation. In other instances, not all the components of the intervention take effect at the same time, with a corresponding delay in the arrival of change etc.

As a rule of thumb, when planning for an evaluation of a non-financial intervention, sufficient time should have passed since its implementation to ensure at least three years' worth of reasonably full data. This makes evaluation planning difficult if a given intervention is revised very frequently, for instance every three years, especially if new objectives are introduced or old ones refined. Even in such cases it is unlikely that the full range of actions are amended each time, so it should still be possible to schedule an evaluation after a given period. However the scope of the evaluation may need to exclude or limit the analysis of certain aspects, reflecting the fact that they have been in place for a shorter duration.

Consideration should also be given during the planning exercise to combining the evaluation of related interventions into a fitness check. Fitness checks of whole policy areas vary in scope but generally provide a broader picture of the extent to which overall policy objectives are being achieved and the extent to which different actions are contributing. Due to their broader scope, fitness checks involve more work during the time that they are running, but produce economies of scale and increase efficiency by combining evaluation actions that would otherwise have been carried out separately.

Note: The vast majority of evaluations are supported by external contractors. The choice of the public procurement award procedure will have a significant impact on the length of the evaluation work and this needs to be taken into account when planning and designing evaluations.⁵⁰⁴ The time needed to meet any translation requirements should also be considered.

Similarly, if the Regulatory Scrutiny Board decides to scrutinise an evaluation⁵⁰⁵, an additional six to ten weeks should be factored in to the timing / duration of that evaluation.

5. RESOURCING

Individual evaluations are run either by the evaluation unit or by the operational unit responsible for a particular intervention depending on the organisational model chosen by a Directorate General.

When considering the timing of an evaluation (when it should start, how long it will take / when it needs to be done by), it is important to reflect on the resources required and how they will be provided. **Whether external contractors are used or not, evaluations also require significant input from Commission staff** – both from the lead Directorate General and also from staff present in the interservice steering group.

⁵⁰⁴ Detailed guidelines to public procurement can be found on the Commission's Internal Financial Website. http://www.cc.cec/budg/imp/procurement/imp-080-020_procproced_en.html

⁵⁰⁵ See Tool #3 on the *Role of the Regulatory Scrutiny Board*.

The vast majority of evaluations are supported by external contractors and this needs to be taken into account in both the planning and design stages. **The (internal and external) resources allocated to an evaluation should be proportional to the perceived importance and expected effects of an intervention, both in terms of its costs and the changes (benefits) it generated.** Ideally, an evaluation should not cost more than its envisaged (expected) effects. However, finding the right balance might be difficult particularly for non-spending interventions where the price of the evaluation cannot be compared to the budget allocated to the intervention.

The overall cost of an evaluation (internal and external elements) can vary a great deal depending on a number of variables linked to the intervention, such as its:

- Scope and complexity;
- Duration and geographical coverage;
- Diversity, size and nature of the stakeholders/target population/beneficiaries;
- Quality of monitoring systems in place and data readily available;
- Methods foreseen for analysis;
- Translation requirements.

The role assigned to contractors should also be carefully considered as this may have significant impact on resources. Typical activities that can be contracted out include: data collection including all or some consultation activities (i.e. including the open public consultation); analysis of data and / or modelling; answering the evaluation questions. Consultants may be asked to do work contributing to analysis for all five of the minimum criteria, or for fewer, or for work relating to an additional evaluation criterion of interest. Generally, the more that is asked from the contractor the higher the costs.

Early consideration of different options for the scope and methodology to be used can help to design the evaluation at a level (financially) proportionate to the intervention and the changes it was expected to generate⁵⁰⁶.

It is recommended that each Directorate General ensures that all resources (including financing and staff) are clearly identified and allocated in a timely manner, allowing the appropriate evaluation activities to be carried out.

⁵⁰⁶ See Tool #45 on *How to undertake a proportionate evaluation*

TOOL #45. HOW TO UNDERTAKE A PROPORTIONATE EVALUATION

The Commission has committed to evaluate in a proportionate way all EU spending and non-spending interventions. The evaluation process should provide the Commission with comprehensive evidence-based answers to the key evaluation questions and hence draw conclusions against the evaluation criteria. However, the scope and depth of the analysis should be proportionate and consistent with the importance/type of intervention, its complexity (number of associated actions, range of actors), maturity (reflecting available operational/implementation experience and hence whether there is sufficient robust data to assess its performance) and the nature of the expected/observed impacts (e.g. legislative/non-legislative, implementing measures, etc.). This relates to all stages of the evaluation process.

1. THE APPROPRIATE SCOPE AND DEPTH OF ANALYSIS

Setting the appropriate depth and scope of the overall analysis implies deciding:

- The *resources and time allocated to the overall evaluation process*, including data collection, stakeholder consultation and conducting external studies;
- The *relative effort required to answer each of the key evaluation questions* (i.e. should more resources be invested in analysing the continued relevance of the intervention or in assessing the associated costs and benefits to evaluate the effectiveness and efficiency of the intervention? At which level of aggregation should impacts be assessed? On which specific issues is it worth drilling down?);
- The *specific purpose and scope of the evaluation* (i.e. is the evaluation triggered due to a clause in legislation, perhaps at an early point in the policy cycle? Should the evaluation feed into the next round of the multi-annual financial framework? Is it the result of complaints and problems notified to the Commission by one or more stakeholder groups? Does it look at a policy area (fitness check) with the expectation of providing broader policy lessons on a group of measures, or at a single EU intervention where more detailed information on what works/does not work should be identified? Does it look at the full EU intervention, or only a sub-set of the associated actions?).

It is the **responsibility of the lead DG, in cooperation with the interservice group**, to determine the level of analysis, taking into account all relevant factors as well as any unsurmountable constraint in the availability of time, resources and data. Setting the level of analysis is likely to be an **iterative process**. First indications should be provided in the evaluation roadmap, which is also the recommended time to request any exceptions. Further discussions should take place as **early** as possible, involving your DG's evaluation support function / unit and the ISG. Proportionality might have to be **adjusted flexibly** as the analysis evolves and as the stakeholder consultation unfolds.

For transparency and accountability, think about how you justify your choices regarding the level of analysis which has been undertaken. In particular, it may be necessary to explain differences between the planned degree of analysis and what was actually possible (often due to expectations on available data not being met). The degree of analysis and any limitations encountered should be described under the dedicated section in the staff working document.

2. FACTORS AFFECTING THE LEVEL OF ANALYSIS

The proportionate level of analysis varies from case to case but is influenced by some general factors and the nature of the particular policy instrument.

<i>The political importance of the intervention under consideration</i>
Does it relate to a Commission priority (promoting growth and jobs, regulatory fitness etc.)? Is there already discussion of a possible impact assessment or inclusion in the Commission Work Programme (evaluate first)? Is it a fitness check of a broad policy area or sector? Have issues been raised related to subsidiarity and proportionality? Are there large numbers of complaints or infringements? Does it have strong stakeholders lobbying for its revision? Is the intervention particularly important in the inter-institutional context or for certain Member States? etc.
Evaluations are undertaken to learn about how well (or otherwise) an EU intervention is performing, providing timely lessons to feed into decision-making. It is important to understand the purpose and scope of an evaluation and to address any issues early on, to prevent miscommunication, manage expectations and ensure appropriate evaluation design. Where political pressures may require a quick Commission proposal, consideration should be given to undertaking a back-to-back evaluation and impact assessment (see tool #52).
In general, evaluations should step back and look at the wider picture. It should not focus only on areas where we know the intervention is working well. It needs to actively seek evidence to address the (five) criteria, drawing on a range of evidence sources. In some instances, an exception can be granted, allowing an evaluation to proceed whilst not covering the required five minimum criteria. Authorisation will depend on a case-by-case justification of why this is not required. There is a growing desire to understand the costs and benefits arising from EU interventions and to have more quantification where possible. It is also important to identify any unnecessary burden or complexity linked to EU interventions.
<i>The stage of policy development</i>
"Evaluate first" - for any existing intervention, an evaluation should be the starting point of any discussions on performance and possible (significant) change ⁵⁰⁷ . The findings of the evaluation should be used to verify whether the legislation is still necessary (relevance criterion) and in line with the subsidiarity principle (EU added value criterion), and to identify which specific provisions should be modified having proven ineffective (effectiveness criterion), excessively costly or over complex (efficiency criterion), incoherent (coherence criterion) or outdated (relevance criterion). On the basis of the findings, a revision or new intervention might be triggered. An evaluation may also be necessary due to the application of a sunset clause ⁵⁰⁸ .
When planning an evaluation, it is important to take into consideration the stage at

⁵⁰⁷ See section "Applying Smart Regulation instruments", Instructions of the Secretary-General implementing the European Commission 2014-2019 Working Methods

⁵⁰⁸ See for instance the Common Approach on EU decentralised Agencies

which the intervention is and to make a preliminary assessment of what data is already or likely to be available. This will help in designing the evaluation and managing expectations with respect to what information the evaluation will provide. In the most extreme case, it may be necessary to consider delaying the evaluation or agreeing that a different kind of analysis is acceptable. The degree of analysis conducted for each evaluation criterion depends on the intervention being evaluated, the timing of the evaluation within its policy cycle and the reliability of the data available. Sometimes this will mean that for some criteria new data need to be collected and analysed, whilst for others a short summary can be presented based on existing reports and information.

As a rule of thumb, a minimum of three years full data relating to the operation of an EU intervention should be available.

The assessment in a "review" clause (i.e. a clause requiring work with backward and forward looking elements) should only trigger an evaluation according to these Guidelines where sufficient operational / implementation experience has accumulated to permit such analysis and / or there is already an expectation at that point that a proposal for change affecting the overall intervention will be made. Often such clauses relate to very specific articles, or to the possibility of introducing new elements (e.g. broadening scope of application). Where sufficient evidence to carry out a meaningful evaluation is not available, services should consider carrying out a different exercise e.g. creating an implementation report instead.

Financial programmes

According to the Financial Regulation, all programmes or activities involving significant expenditure (i.e. in excess of €5 million) should be subject to both ex-ante and retrospective evaluations. This is to ensure conformity with the principle of sound financial management.

The timing and nature of evaluations of financial programmes are set out in the legal basis for the programme. Further guidance is given in the SG guidance: Better regulation requirements for post-2020 MFF proposals (Ares (2016)2349258).

According to the presented planning of evaluations based on the programme-specific legal requirements, some evaluations will not be completed on time to feed into the preparatory work of the next programming cycle.

In those cases where the evaluation will not be ready in time, the IAs will need to be based on all available additional sources of performance information such as evaluations of the previous period, on latest monitoring information and on the outcomes of studies on specific 2014-2020 aspects. This evaluative material can be included as an annex to the IA Report.

The magnitude and complexity of the intervention being evaluated

The more complex the intervention being evaluated and the more pervasive its expected implications for society, the economy and the environment, the greater the need for an in-depth analysis. On the other hand, the smaller and more focussed the intervention, the more the need to discuss on the basis of evidence the opportunity of acting at the EU level in line with the principle of being small on small things and big on big things. The starting point for such an assessment should be any prior impact assessment, complemented with monitoring and feedback collected once implementation started.

<i>The significance of the expected impacts</i>
The evaluation analysis should focus on assessing the impacts that were expected to be significant overall and for specific stakeholders (SME, consumers, specific sectors). The greater the likely impact, the more thorough the assessment should be and the greater the efforts to collect data and quantify impacts (keeping in mind the caveat that some impacts may not be quantifiable). Similarly for the impacts that are likely to be irreversible.
<i>Negative unexpected consequences</i>
Have significant negative unexpected consequences been identified or claimed? If this has happened, the role of the EU intervention in generating such change needs to be analysed and understood. Where there is evidence that such negative consequences really are linked to the EU intervention, rather than to external factors, mitigating actions and possible changes to the intervention might need to be considered.

TOOL #46. DESIGNING THE EVALUATION

1. WHAT IS MEANT BY DESIGN?

Designing the evaluation means identifying the nature and sequence of tasks, assessing data and data collection methods and the range of analytical methods to be used to deliver the evaluation. Good design starts by identifying/agreeing the purpose of an evaluation and identifying what is in scope (e.g. which interventions, which policy objectives and results, over what time period and for what geographical coverage) and what is not⁵⁰⁹. This will influence the evaluation questions set and as a result, the methodology applied and the data and research undertaken to answer robustly these questions. This will then affect who is assigned which tasks within the evaluation.

The evaluation roadmap provides a first description of the evaluation design, communicating the context, purpose and scope of the evaluation and outlining the proposed approach⁵¹⁰. However the level of detail provided in the roadmap simply sets the scene. Further detail will be developed during the course of the evaluation, allowing the appropriate work to be done and enabling the evaluation to meet its purpose.

For fitness checks and evaluations that are selected by the RSB for scrutiny, the RSB can have an early and informal bilateral discussion with the lead DG based on the roadmap.

2. WHY IS DESIGN IMPORTANT?

As with any project, good planning and preparation is necessary to produce a high quality final deliverable. Evaluation requires a critical, evidence-based assessment – using robust and reliable data drawn from a range of sources and analysed in an appropriate manner. Evaluations need to present a clear chain of logic between the data, analysis and conclusions and highlight any particular strengths or weaknesses. This does not happen by accident – but by design.

Other factors which will affect the design include: the political priority of the intervention(s) being evaluated; the timing of the evaluation within the intervention(s)' policy cycle; financial resources and personnel available. It is important to understand how such factors may influence an evaluation – so that expectations are managed and that there is a realistic understanding of what the evaluation will deliver⁵¹¹.

⁵⁰⁹ See Tool #1 on *Principles, procedures and exceptions* and Tool #45 on *How to undertake a proportionate evaluation*

⁵¹⁰ See Tool #6 on *Drafting of roadmaps, evaluation roadmaps and inception IAs*

⁵¹¹ See also Tool #42 on *Legal provisions on monitoring and evaluation*

3. KEY ELEMENTS OF EVALUATION DESIGN

When designing an evaluation it is important to spend time:

- (1) Clarifying the **purpose** of the evaluation: agreeing and clearly describing what the evaluation will deliver and how its findings will be used;
- (2) Defining the **scope**: setting out clearly what will be evaluated. This may be in terms of interventions, measures or legal articles, time period, geographical coverage, particular effects or any other relevant aspect. The reader should understand what will be covered by the evaluation and what will not (with any associated explanation for including or excluding something);

It is important to present the purpose and scope of an evaluation clearly in the evaluation roadmap – this is the first communication with many interested parties who may later provide evidence to the evaluation and/or wish to use the evaluation findings. They may also provide feedback on the roadmap which could, in some instances affect design. Issues relating to the purpose or scope of an evaluation (for example concerns raised by stakeholders, input from other DGs or the RSB, lack of data, timetable) must be addressed by the lead DG early on, to prevent miscommunication and to ensure appropriate evaluation design. In the most extreme case, it may be necessary to consider delaying the evaluation or agreeing that a different kind of analysis is acceptable.

- (3) Explaining the **intervention logic**: summarising how the intervention was (originally) expected to work (i.e. at the time of adoption / implementation), including identifying the underlying assumptions;
- (4) Drafting good **evaluation questions**: clarifying the questions the evaluation will answer;
- (5) Identifying the **appropriate points of comparison / baseline**: the different evaluation questions may be answered / assessed against different expected achievements – for example, comparisons may be drawn against the (IA) baseline, the changes expected under the preferred option, or changes since measurements made at the start of an intervention. Before doing such analysis, it may be necessary to update the original points of comparison to take on-board changes made between the Commission's IA and the adoption of an intervention.
- (6) Considering **appropriate data collection and analytical methods**: it is very important that the evaluation is set up to collect and analyse a range of different data, using the appropriate data and methodologies to fill existing data gaps and to answer robustly the evaluation questions;
- (7) Early consideration as to how findings will be disseminated and possible follow-up actions.

3.1. Purpose

It is important to be clear from the start and state in the roadmap the purpose of an evaluation - to explain why the evaluation is being carried out, the sort of findings it is expected to provide and how these findings may be used.

Many evaluations are required to serve a particular purpose. Examples of such reasons include:

- To meet the 'evaluate first' principle and assess the role of existing EU interventions before bringing forward possible changes. Particular attention is paid to meeting this principle for priority actions (e.g. ones on the Commission's work programme);
- Compliance with an article in the legal base. This applies to many policies and is mandatory for programmes carried out under the Multi-annual Financial Framework (MFF);
- Compliance with the Commission's financial regulation;

3.2. Scope

The scope of an evaluation also has a significant impact on the design and subsequent conduct of the evaluation. **It is important to know from an early stage what will be in the scope of the evaluation and what will not.** Any limitations to the scope must be clearly justified and might need to be formally exempted⁵¹².

Key factors affecting the scope relate to coverage of:

- **An individual intervention or group of interventions:** the scope should be defined in terms of the EU intervention – the legislative act(s) and/or related programme(s), associated implementing and delegated acts, policy(ies), soft law, action plans, strategies, communications etc. covered. Usually, all aspects of a given piece of legislation or an intervention will fall within the scope of an evaluation. There may be circumstances when particular aspects are excluded e.g. due to lack of experience, something not having been tested perhaps due to a later than expected start date or because a given article is conditional on other activities that are not yet complete. Any significant constraints to the scope should be explained in the roadmap and reflected in the design. In the most extreme case, factors affecting scope may raise questions about whether the evaluation should be delayed or a different analysis undertaken.
- **Geography:** all Member States, a subset, the wider EEA, etc.;
- **Period of time:** this could be the full period since the intervention started or a shorter period such as from the end of last evaluation to the current day;
- **Particular effects anticipated:** this may be affected by the time period covered as some effects may not have been expected to materialise at the time of the evaluation. It could also reflect the significance of the different effects expected and availability of data or the particular political and/or policy context.

Scope will be also influenced by any existing feedback on the (perceived) performance of EU action e.g. from stakeholders or monitoring. This may lead to the inclusion of action(s) where there is evidence of synergies (e.g. interventions working together to

⁵¹² See Tool #1 on *Principles, procedures and exceptions*.

complement each other or where data is re-used, simplifying demands on stakeholders) and / or of problems (e.g. targets not being met; low transposition or compliance; complaints). However it is also interesting to include in scope action(s) where there is a theoretical or expected link but no apparent evidence indicating problems or successes. This is because "all is quiet" does not necessarily mean "all is working as expected"; it may, for example, in the worst case mean that the intervention is irrelevant or that there are significant loopholes.

When considering the scope of an evaluation, due attention should be paid to both the political and policy context of the intervention(s).

- Political aspects relating to context may reflect for example a particular emergency or a "hot topic" which could significantly reduce the time available to conduct the evaluation and/or the depth of analysis.
- Policy considerations may refer to the role of the intervention being evaluated within the logic of the wider relevant policy framework and / or any relationship to other actions. Sometimes related actions will be considered under coherence - for example, an evaluation of an EU environmental action relating to water may consider coherence with another EU environmental action relating to waste, or with a particular EU business related action. At other times the interactions and their coherence will be so important and integral to the policy that a fitness check is needed e.g. the Freshwater fitness check looked at six EU environmental actions in the area of fresh water, with further consideration under coherence of wider environmental issues such as waste and emissions controls, but also the common agricultural policy and regional policy.

There is a clear link between the purpose of an evaluation and its scope. If the scope of an evaluation is limited in some way, then it might not be able to fulfil its purpose and meet the expectations of decision makers and stakeholders.

Box 1. Considerations affecting the decision to do a fitness check

- There are no set criteria for defining the scope of a fitness check –consideration should be given to a range of factors including its purpose, context, timing, maturity of actions being considered for inclusion, data availability and resources.
- Setting an acceptable/appropriate scope early is critical. The EU interventions which fall within the scope of a fitness check should be ones that interact together and/or have common objectives. Where this is not the case, it is likely that the work undertaken will deliver several evaluations of the separate interventions, rather than the desired joined up evaluation of the EU policy and its framework.
- When considering which EU actions to include in scope, careful consideration needs to be given to:
 - The interaction between purpose and scope. Increasing the scope by adding more EU actions might increase the time required, but could deliver synergies, providing more useful findings and a more comprehensive overview of the EU's role in that policy area. However expanding the scope and including more loosely connected actions may not provide much additional or important information. For example in the chemicals area, there is certain key central EU legislation (REACH, CLP) relating to chemicals, but EU actions on chemicals also includes legislation on pesticides, nanomaterials, paints, medical equipment

and many others.

- How long the various EU actions have existed and hence operated / not operated together.
- The depth of analysis required – whether the interventions need to be assessed together (a fitness check) against all (five) criteria or whether certain of them could be sufficiently analysed under the criterion of coherence.
- Sectoral fitness checks look at how EU interventions affect a specific sector. They look at the same five criteria, but from the sectoral perspective.
- Many of the legal acts assessed in a sectoral fitness check apply to a wide range of sectors, not just the specific sector identified for a given sectoral fitness check. Although it is beyond the scope of a sectoral fitness check to perform a full evaluation of those acts, some qualitative data of the wider performance of those acts should generally be considered, to provide the appropriate context for the sectoral fitness check. Often a certain sector bears a higher proportion of the overall costs, whilst the benefits are to the wider society.
- Due to their sectoral perspective the follow-up actions of sectoral fitness checks are more limited by definition. Before considering changes to any of the EU interventions falling within the scope of the sectoral fitness check, further evaluation work would generally be required to assess the performance of the evaluated intervention(s) as a whole.

3.3. The intervention logic

The intervention logic provides a (narrative) description and / or diagram summarising how the intervention was expected to work (or put another way, it describes the expected logic of the intervention or chain of events that should lead to the intended change). An intervention is often a solution to a problem or challenge – the intervention logic is a tool which helps to explain (and often visualise) the different steps and actors involved in the intervention, and their dependencies – thus presenting the expected "cause and effect" relationships. This means the intervention logic is useful both as:

- A communication tool – facilitating discussion of the intervention with different parties, helping to identify differences in understanding or to clarify particular details;
- An analytical tool – identifying relationships / dependencies that were expected based on certain assumptions. For example were certain activities expected to occur in parallel or sequentially? Do all activities generate outputs or just some? Do all results feed in to all impacts? Who was expected to do something? Was the "output" from one person/entity an "input" for someone else?

Constructing the intervention logic means considering how different actors were expected to react, what actions were expected to be triggered by the EU intervention, how both actors and actions were expected to interact to deliver the promised changes over time and ultimately achieve the objectives of the EU intervention being evaluated. Given that an evaluation delivers a judgement on why and how the EU intervention has actually worked, compared to what was expected (and in particular what was predicted in any prior impact assessment), it is important to have this understanding from the start.

There are many possible formats or approaches to describe the logic of the intervention (see Box 2) and the better regulation Guidelines do not mandate a particular approach. The approach adopted may reflect individual preferences, or be decided on a case-by-case basis to reflect issues particular to the intervention being evaluated.

A traditional starting point is to consider the categories presented in Figure 1 below (needs, objectives, inputs, activities, outputs, results, impacts, external factors, other EU policies). In this figure, the arrows represent the causal assumption/relationships between the boxes. Using these categories is also helpful when trying to explain or define the five different evaluation categories (effectiveness, efficiency, relevance, coherence, EU added value) which are then used to develop the wider evaluation design.

An alternative starting point could be to consider the intervention from the point of view of different stakeholders –what were they expected to do (which might have associated costs or benefits)? When were they expected to do it – right at the start of the intervention, or later, after other stakeholders had done something? Another approach is to think about the different articles within the legislation and their practical consequences over time.

Whatever starting point is used, thought should be given to:

- What was the rationale for the intervention? What were the "needs" that triggered the EU intervention? What problems was the intervention meant to solve? (this may be a subset of the identified needs). Look at relevant background documents to understand the context – these may include a previous impact assessment, studies, legal text (particularly the recitals) and associated explanatory memorandum. These may also be helpful in identifying key deadlines, milestones, and deliverables.
- What was the situation at the time the intervention was designed? How was it expected to develop without EU intervention (baseline)? How was it expected to develop under different possible EU options?
- How were the objectives expected to be achieved? What was the "positive desired situation"? What were the expected changes that the EU wanted to achieve?
- How were these changes to be achieved? What inputs were expected to be used? Inputs can be a very wide term, covering for example resources such as staff, time, and equipment. Which events (activities) were expected to happen? What obligations were set or what provisions were expected to be put in place? For the evaluation of legislative actions, many of the required actions are identified in the articles of the legal act. These physical "inputs" are often translated into monetary values, leading to a broader consideration of what has been needed to achieve objectives and possibly to considerations of costs / benefits. For example costs / benefits related to changes in employment practices made by an employer to comply with an EU law, or costs incurred by a Member State due to new reporting obligations may start with a consideration of training needs, time taken to train, new systems bought, etc..
- Who was expected to be involved? How were they expected to be involved – were they going to be affected by the intervention (positive or negative)? Were

they responsible for taking a particular action? Activities are often more tangible or visible.

- When was something supposed to happen? What was the expected order of activities or events? What was expected to happen at the same time (in parallel)? What was supposed to happen before or after something else (sequentially)? What changes were expected to be positive (benefits) / negative (costs) and for whom? This consideration of changes over time (outputs/results/impacts) may then be linked to the hierarchy of objectives in the impact assessment⁵¹³.
- Can any external factors be identified which may influence the performance of the EU intervention, or generate the same type of effects? Reality is complex and many other players and factors can intervene and influence a situation.
- For all of the above, what were the underlying assumptions?

It is important to check the draft logic, to see whether it "flows" and is truly "logical", describing the appropriate causal pathways. It is also important to check whether appropriate attention has been given to all the elements which influenced the design of the intervention, including changes made during the adoption process.

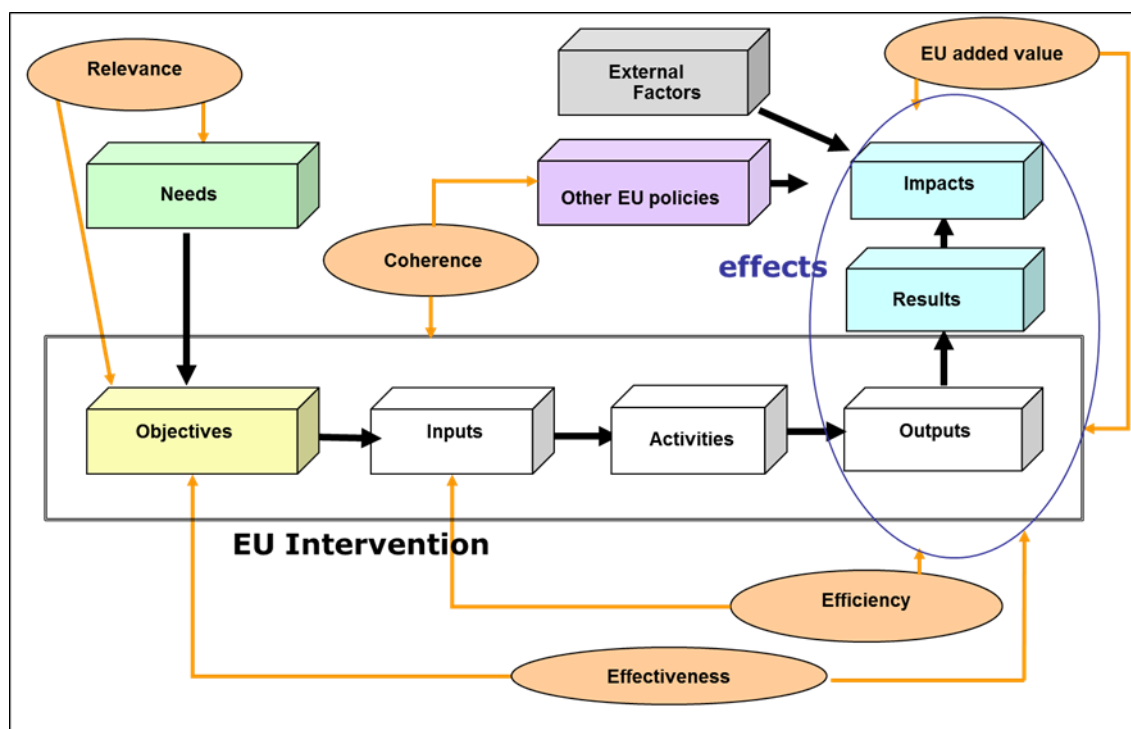


Figure 1: Simplified view of the intervention and the 5 key evaluation criteria

The initial intervention logic should be developed by the lead DG and discussed with the ISG (ideally at the 1st ISG meeting). The intervention logic should be discussed with the interservice group, but it can also be useful to test it out both with colleagues who understand the intervention, and also with people who have little familiarity with the subject.

⁵¹³ See Tool #16 on *How to set objectives*

Some examples of intervention logics developed for the evaluation of EU interventions are provided on the collaborative workspace⁵¹⁴. However these should be considered as starting points only – they can provide inspiration but, they do not provide templates or formulas that should be followed. **Anyone developing an intervention logic is free to produce a diagram or text in a format and at a level of detail which suits the purpose and scope of the evaluation they are conducting.**

The intervention logic is a dynamic tool and can develop further during the evaluation project as understanding develops. In particular, some relevant external factors may only become clear during the course of the evaluation. Sometimes a first (rough) draft intervention logic is included in the terms of reference for external work, and contractors are asked to demonstrate their understanding and evaluation skills by providing a more advanced version. The final intervention logic may look quite different to the initial starting point, providing key input to the evaluation on how actual behaviours and performance differed from original expectations.

The intervention logic can be very helpful in identifying the evaluation questions as it can point to relationships or assumptions that the evaluation might wish to investigate further. It is good practice to develop the intervention logic early on and to identify the appropriate level of detail which will feed into the evaluation questions, sub-questions and their related success criteria/judgement criteria, indicators and information sources (see evaluation matrix below).

Box 2. Describing causal pathways

- The concept of intervention logic combines elements of similar methodologies. Among others, it involves ideas from the Logframe approach and the Theory of Change. Both approaches are used to describe causal pathways in interventions and the mechanisms that enable them.
- Theory of Change is usually oriented towards the objectives that are intended to be achieved under specific conditions. This concept is employed to show the ways and mechanisms that connect activities, objectives and outcomes.
- Theories of Change are often used in early stages of an intervention and serve as a tool to engage stakeholders and the persons who will implement the intervention. They usually try to capture as many factors in the environment of the (potential) programme as possible that might facilitate or hinder the intended change.
- The Logframe approach is an analytical tool to reconstruct the causal pathways between needs, overall and specific objectives, resources, activities, output, outcomes, and the impact of a specific intervention. External factors beyond the control of the intervention are included in the model in case they influence its effects.
- The differences between the Logframe approach and the Theory of Change are not clear-cut and often overlap in practice.

⁵¹⁴ See https://myintracomm-collab.ec.europa.eu/networks/IAWG/eval_network/SitePages/Home.aspx

3.4. Drafting robust evaluation questions

Robust evaluation questions encourage critical analysis. By defining and sharing the questions early in the process, the Commission services clarify what they intend to analyse and invite interested parties to provide relevant contributions. If the evaluation questions are not set at the time that the roadmap is published, it is important that they are discussed with the interservice group at the first meeting and ideally fixed shortly thereafter. These questions will then influence the design and conduct of the subsequent steps, and be answered in the staff working document.

Questions should be worded in a way that forces the evaluator to provide a complete, evidence-based answer that improves understanding of the performance of the EU intervention against the (minimum five⁵¹⁵) evaluation criteria. Answers should go beyond providing a yes/no answer based on simple description and to look at what the links were between the changes observed and the EU intervention(s). This tends to mean that evaluation questions are "causal" or "normative" – "predictive" and "critical" questions are generally more appropriate for impact assessment.

Generally, there is a need to balance broad, generic questions based on the criteria themselves - such as *How effective has the EU action been?* with a number of more detailed, specific questions e.g. *What factors linked to the Directives have most influenced progress? To what extent have the arrangements set out in Article 7 been able to influence progress towards the objectives of the Directive?* General questions are important as they allow the analysis to follow the evidence collected which can often unearth unexpected or unintended changes.

Specific questions allow issues raised during adoption / implementation to be further investigated e.g. in relation to modalities that caused strong debate and a compromise solution to be adopted, or based on feedback from stakeholders that a given article is problematic or a procedure is difficult. It is important that such questions reflect the level of progress / performance expected at the time of the evaluation. For example, if at the time of the evaluation no businesses have completed a certification process specified in the EU legislation, there should be no evaluation questions about how well the specified process has worked.⁵¹⁶

When considering the questions to ask it is also important to think about the usefulness of an answer, and the feasibility of obtaining an answer. This again links back to considerations of scope and purpose.

3.5. Points of comparison / baseline

One aim of evaluation is to capture the change that an intervention has brought over time. Another key aim is to compare actual performance against one or more pre-defined scenarios.

⁵¹⁵ In certain cases exceptions may be granted where the lead DG can justify why it is not appropriate to analyse against all five criteria.

⁵¹⁶ See Tool #47 on *Evaluation criteria and questions*.

The evaluation baseline:

Where there is a prior impact assessment, the impact assessment baseline is the preferred comparison point. In most cases, the (IA) baseline is a "no policy change" scenario which includes all relevant EU-level and national policies and measures which are assumed to continue in force⁵¹⁷. This (IA) baseline may need to be adapted to create an (evaluation) baseline, reflecting any relevant changes since the IA was published e.g. changes during the legislative process, changes to key assumptions such as expected socio-economic developments (aging, GDP growth, etc.) or important technological/societal developments, international context etc. Ideally, such a baseline can be quantified (e.g. expected level over time of pollution or emission of certain substances; level of employment) but as a minimum a qualitative description of what might have happened should be given (e.g. description of expected trends in nature, levels of education in society etc.).

Where no prior impact assessment exists, the evaluation will usually have to build its own evaluation baseline from scratch. Where there is no existing data measuring the situation at or around the time the EU action started, this may have to be a qualitative description.

In some instances, although there might not be a baseline, there may be one or more numbers which do provide some information relevant to the situation (e.g. level of a certain chemical before EU intervention; level of employment). In this instance, a reasonable starting point for constructing an evaluation baseline would be to take this information (number) and reflect on how it might have continued over the period being evaluated, if there had been no policy change. For example, is it realistic to assume a constant level of performance over this period (number does not change)? Or was some level of increase / decrease more likely? How big an increase / decrease? This might allow a reasonable baseline to be created. In doing this, it will be important to state clearly the assumptions being made (e.g. constant performance, decline of 10% a year in line with global trend, etc).

The two figures below illustrate these different points of comparison. The first reflects a situation where the EU intervention is intended to reduce the level of a "bad" or "undesirable" factor e.g. pollution, unemployment, some type of cost. In the second figure, the EU intervention is intended to improve performance e.g. increase education levels, increase levels of safety or protection.

⁵¹⁷ See Tool #17 on *How to identify policy options*

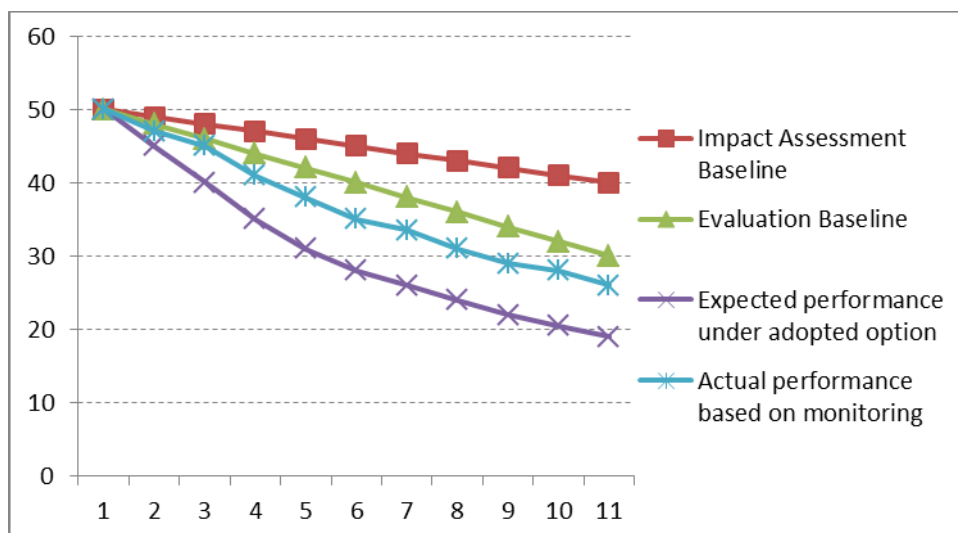


Figure 2: Illustration of different points of comparison – EU policy aims at decreasing a "bad"

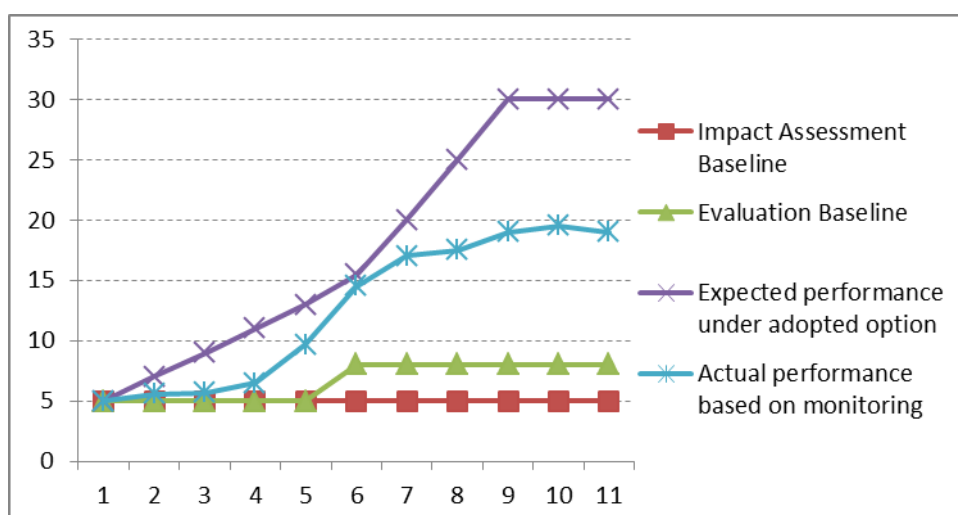


Figure 3: Illustration of different points of comparison – EU policy aims at increasing a "good"

Other useful points of comparison include:

- The predictions from the IA for the adopted option. These are generally the estimated costs and benefits. This will provide an insight into how actual developments compare to what was expected at the time. Again, the original IA predictions need to be updated – most commonly to address changes introduced during the discussions with the co-legislators.
- Different performance ("policy-on") or counterfactual ("policy-off") scenarios may be used, based on clearly stated assumptions. For instance, a common counterfactual scenario would be to consider the situation where the Union does not act. (See section below on Causality and section on EU Added Value).
- Other benchmarks may also be identified or exist for the policy context. They may be used for comparison, to provide additional context or as an aid to interpreting the change identified. For example, there may be benchmarks for certain types of cost, durations of processes etc. which can be drawn from industry or from other countries. Often benchmarks are concrete, actual figures or levels of performance which have been achieved – rather than aspirations or predictions.

After identifying the appropriate point(s) of comparison it is necessary to consider what type of analysis is possible. At the very least, comparison should enable the evaluator to judge whether change has occurred and to decide whether it is change in the desired direction (e.g. to increase or decrease).

A second level of sophistication allows analysis of the magnitude of the change – how much has changed and how that matches expectations.

To a certain extent, comparing against benchmarks is another approach / degree of sophistication, allowing a judgement of whether performance has been good or bad compared to an (external) standard.

When deciding on the appropriate point of comparison and degree of analysis possible, consideration should be given to:

- **Availability of data:** Does the IA contain a projected baseline? Does the IA contain information reflecting the adopted intervention? Is data available to judge if these projections need to be updated? Are there other "benchmarks" from EU/Non-EU MS or organisations that can be used to assess performance? Are other relevant data available that can describe the situation before the intervention? Is it feasible to collect them? Has monitoring been conducted since the intervention started (allowing a robust assessment of actual change over time)?
- **Relevance of the points of comparison:** different comparison points may be more useful, depending on the different evaluation criteria and/or the exact evaluation question posed. For more information, see Tool #47 on Evaluation criteria and questions.

3.6. Methods and data

The methodology of an evaluation should consist of a combination of tools and techniques assembled in order to provide answers to its evaluation questions.

Data availability and the quality of the data will play a key role in deciding which analytical methods can reliably be applied; at the extreme, it may also influence the scope of an evaluation. It will also influence consideration of who will be assigned which tasks – what will be done by Commission staff and what will be contracted out to externals.

The time and budget allocated to the evaluation will have a significant influence on both the methods chosen and the data collected. The lead DG may also wish to contact the JRC, who can advise on both existing and possible data sources that might be used during the evaluation. In particular, the JRC is developing knowledge-management services bringing together data collected during earlier evaluations, impact assessments and studies. It can also offer assistance in reviewing existing evidence in international specialised literature (see end of this tool for further references and reading).

It is also important that evaluations clearly state the challenges that have been encountered and resulting limitations in the certainty or accuracy of the findings, particularly as these vary greatly from case to case.

Desk officers in the Commission involved in evaluation are not expected to become experts in the many tools and techniques used in evaluation. Such expertise is generally available in the DG's evaluation function, from the JRC or from external contractors. However, it is still necessary to have a general understanding of various approaches to data collection and analytical methods, in order to:

- Estimate whether a contractors' offer to use a certain set of methodologies in an evaluation is realistic in view of the reliable data, time and budget available;
- Recognise the strengths and limitations of the methods proposed.
- Get a feel for which methods can be combined, to ensure that the data is based on several sources of information and that the analysis is drawn from several perspectives (triangulation).

When performing an evaluation not supported by any external (contracted out) work, it is equally important to have a reasonable overview of such aspects, before acquiring a deeper understanding of the methods selected for use.

It is important to consider ways to **design the evaluation so that it is possible to triangulate data and modelling results from different sources**. When thinking about the data needed for an evaluation, it is necessary to look first at what is already available – for example, from existing monitoring and reporting arrangements or studies which have been conducted, including any prior impact assessment. A key source of information, which is often overlooked, is to check what complaints (if any) have been received from stakeholders and interested parties. For evaluations involving legislative interventions, it is also important to check whether any infringements have been detected and to look into the underlying reasons for the alleged violation. Both these sources of information can provide significant insight into the actual and perceived performance of the intervention being evaluated. Equally, in policy areas related to the four freedoms of the Single Market, the SOLVIT database might provide additional information.

Once this stock-take of existing data has been carried out, it will be easier to identify new data which will need to be collected and to consider the mix of objective and subjective data. Objective data often comes from statistical reports, monitoring or modelling (although the degree of objectivity will be affected by the assumptions underpinning the model), whilst subjective data is generally opinion based. All evaluations require a consultation strategy presenting consultation scope and objectives, identification of stakeholders, envisaged consultation activities (including a mandatory open public consultation unless duly exempted), their timing and language⁵¹⁸.

Efforts should be made to improve the degree and quality of quantification provided in evaluations and to put a number (or a range) on the costs, benefits and value delivered by the EU intervention.⁵¹⁹ Whether evidence is quantitative or qualitative, every evaluation should include an assessment of the limits encountered (e.g. due to poor data availability

⁵¹⁸ See Chapter 7 on Stakeholder consultation

⁵¹⁹ See Tool #59 on *Methods to assess costs and benefits*.

or modelling issues). This should whenever possible include a measure of the uncertainty or of the “strength of evidence”.

It is good practice to bring together this information on data collection and analytical approach in an "evaluation matrix". This identifies for each evaluation question:

- The "success" or "judgement" criteria against which the answer to the question can be assessed.
- Associated indicators and / or targets, which may be both quantitative and qualitative.
- Data necessary to fill the indicators and provide information for the success/judgement criteria – this should consider not just the type of data, but which stakeholders it involves, whether it is already available or needs to be collected (and how this might happen), time required / feasibility to collect. Where questions have the same sources of data, this may suggest a way to cluster them; where questions require specialised data, the resource implications should be considered.
- Analytical methods for turning data into necessary indicators or information – again considering how this can be done, who will do it, time required / feasibility to do etc. This may then lead to consideration of data collection and analysis methods (and can also be used to inform decisions on the work to be contracted out and its possible value).

Example of an evaluation matrix:

To what extent do the provisions of Directive 92/83/EEC ensure proper functioning of the internal market?

Question	Sub-question	Judgement criteria	Indicator	Data sources
1.1 To what extent does the Directive ensure legal certainty and clarity with regards to the classification of alcohol and alcoholic beverages for excise purposes?	1.1a Which products are difficult to classify (e.g. because they could, arguably fall within several excise categories)?	The applicable rules result in difficult and/or unclear classifications of alcoholic beverages	Classification of alcoholic products that do not fall into one clear category, such as mixtures of fermented beverages and spirits, alcopops containing cleaned-up alcohol, cream liqueurs, mead, etc. by the Member States Other reported instances of alcoholic products whose excise classification was difficult	Survey to national tax authorities Survey to economic operators Reported statistics Studies /papers
	1.1b Do the ambiguities post Siebrand (C-150/08) still cause problems in this area?	Degree to which classification of concerned products follows the criteria laid down in the judgement	Classification of products containing a mixture of fermented and distilled alcohol products by the Member States The interpretation of "essential character" or particular products	Survey to national tax authorities Survey to economic operators Reports and studies

3.7. Causality analysis

Causality, in the context of evaluation, checks the plausibility of the expected chain of events whereby the EU intervention was expected to alter behaviours and create the expected changes (e.g. as identified in a preceding IA) or any other unintended or unexpected changes. It seeks to establish a relationship between an intervention and the observed changes in the issues which the intervention addressed.

It can be difficult to identify a robust counterfactual situation (i.e. what the situation would have been if EU laws had not been adopted) as EU policies operate in a complex environment influenced by a wide range of factors falling outside the scope of the EU intervention. The starting point should be the analysis of the baseline presented in a prior impact assessment.

The increasing availability of data (big data) and developments of new methods increase the scope for proving such "cause and effect" relationships. Counterfactual impact evaluation methods can sometimes be applied to evaluate the value-added or causal effects of an EU intervention.

When causal evaluation is not possible or only at disproportionate costs in terms of data collection and resources, 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. There is growing pressure to find ways to reliably quantify the impacts of EU interventions and efforts should be made to aim for high quality causal evidence.

4. FURTHER READING & REFERENCES

Tools in Chapter 8 of the present toolkit provide a high-level overview of some of the most commonly used tools for structuring an evaluation, collecting and analysing data, and assisting in the formulation of value judgements. The list of methods discussed is by no means exhaustive. Evaluation techniques and approaches are constantly changing, as researchers develop new analytical techniques and learn from their experiences and as new technologies allow for new methods of data collection.

A detailed review of methods is provided in the 'Evalsed' Sourcebook available at: http://ec.europa.eu/regional_policy/en/newsroom/news/2013/11/evaluation-guidance-evalsed-guide-and-sourcebook-updates.

The European Commission's Competence Centre on Microeconomic Evaluation can provide advice on evaluation methods and data, supports the development of appropriate monitoring and evaluation designs and in some cases performs counterfactual impact evaluations in close collaboration with policy DGs. More information can be found at:

- <https://ec.europa.eu/jrc/en/microeconomic-evaluation>
- or by contacting the functional mailbox: cc-me@jrc.ec.europa.eu

Good practice examples of the different elements of evaluation design will be made available via the evaluation collaborative space.⁵²⁰

Other sources (non-exhaustive):

- OECD: <http://www.oecd.org/derec/guidelines.htm>
- World Bank: <http://ieg.worldbankgroup.org/evaluations>

For more theoretical information on impact evaluation see: <https://openknowledge.worldbank.org/handle/10986/2693>

For more practical information see: <http://www.worldbank.org/en/programs/sief-trust-fund/publication/impact-evaluation-in-practice>

- European Evaluation Society: <https://www.europeanevaluation.org/>
- Better Evaluation: <http://www.betterevaluation.org/>
- UK (HMT) The Magenta Book (2011): <https://www.gov.uk/government/publications/the-magenta-book>
- World Bank (2005): The Logframe Handbook - A Logical Framework Approach to Project Cycle Management, Washington, D.C.
- UNDP (2009): Handbook on Planning, Monitoring and Evaluating for Development Results, New York.
- Funnell, Sue C.; Patricia J. Rogers (2011): Purposeful Program Theory: Effective Use of Theories of Change and Logic Models, San Francisco: Jossey-Bass.

⁵²⁰ See https://myintracomm-collab.ec.europa.eu/networks/IAWG/eval_network/SitePages/Home.aspx

TOOL #47. EVALUATION CRITERIA AND QUESTIONS

1. INTRODUCTION

All evaluations and fitness checks should assess the evaluation criteria of **effectiveness, efficiency, coherence, relevance and EU added value of the intervention**, or provide due justification why this is not the case⁵²¹. Additional criteria beyond these five can be added.

Evaluations and fitness checks should also always assess the economic, social and environmental impacts of EU interventions (expected or unexpected) with, where relevant, particular emphasis on those impacts identified in a previous impact assessment.

Projects which do not cover **all** the five evaluation criteria may usefully contribute to a later evaluation (possibly with some updating or confirmation as part of the final process) but are not necessarily considered as "evaluations" unless a prior exception has been authorised.⁵²²

The degree of analysis conducted for each criterion will depend on the intervention being evaluated, the timing of the evaluation and the reliability of the data (proportionality). Often this will mean that for some criteria new data will need to be collected, analysed and compared with other findings; whilst for others, a short summary can be presented based on existing reports and information.

For example, at an "early" stage in the intervention's lifecycle, it may not be necessary to judge the relevance criterion in any depth. If it is only a few years since the intervention has been made, it may be fair to assume the continued relevance of the action and hence simply restating previous arguments should suffice; alternatively, stakeholder feedback may be the only indicator of whether needs have changed and some summary presentation of their (unchanged) opinions may also be sufficient. Equally, EU-added value may be difficult to judge in the early years, particularly if the early changes are related to setting up new organisations or putting in place a framework; in this instance confirming the validity of the (theoretical) EU added value may be as much as is reasonably possible at that time.

Establishing the intervention logic can be helpful in identifying specific evaluation questions. As mentioned in the tool on designing the evaluation, there is a need to balance generic and specific evaluation questions and to ensure that all questions focus on providing useful information such as information on the changes the intervention sought to achieve, investigating particular intervention characteristics or factors which have / have not worked. It is also advisable not to have too long a list of evaluation questions at the start of an evaluation as it may be too constricting and prevent the analysis from "going where the data leads". Whilst evaluation sub-questions can be developed early in

⁵²¹ The evaluation of a single intervention may on an exceptional basis omit one or two of the five evaluation criteria. An exception must be granted, and clear justification for such omission must then be provided in the evaluation roadmap and repeated in the final evaluation report. Fitness checks always consider the five criteria.

⁵²² See Tool #1 on *Principles, procedures and exceptions*.

the evaluation process e.g. to help define a particular question, or drill down on specific areas, this may also happen at a later stage in response to evidence collected.

Depending on the specific evaluation, there may also be overlaps between the criteria and questions asked – for example, in terms of relevance versus EU added value or effectiveness versus impact (sometimes defined as a separate criterion, but given the use within IA of a hierarchy of objectives, considered in the EU context as part of effectiveness). It is generally more important to identify a good set of evaluation questions, than to be too concerned about how to categorise the question, so long as the different criteria are addressed.

It is important to discuss and fix the evaluation questions with the interservice group. Since the evaluation questions do not need to be set at the time that the roadmap is published, they should be discussed at the first meeting and ideally fixed shortly thereafter. These questions will then influence the further design and conduct of the subsequent steps, and be answered in the staff working document.

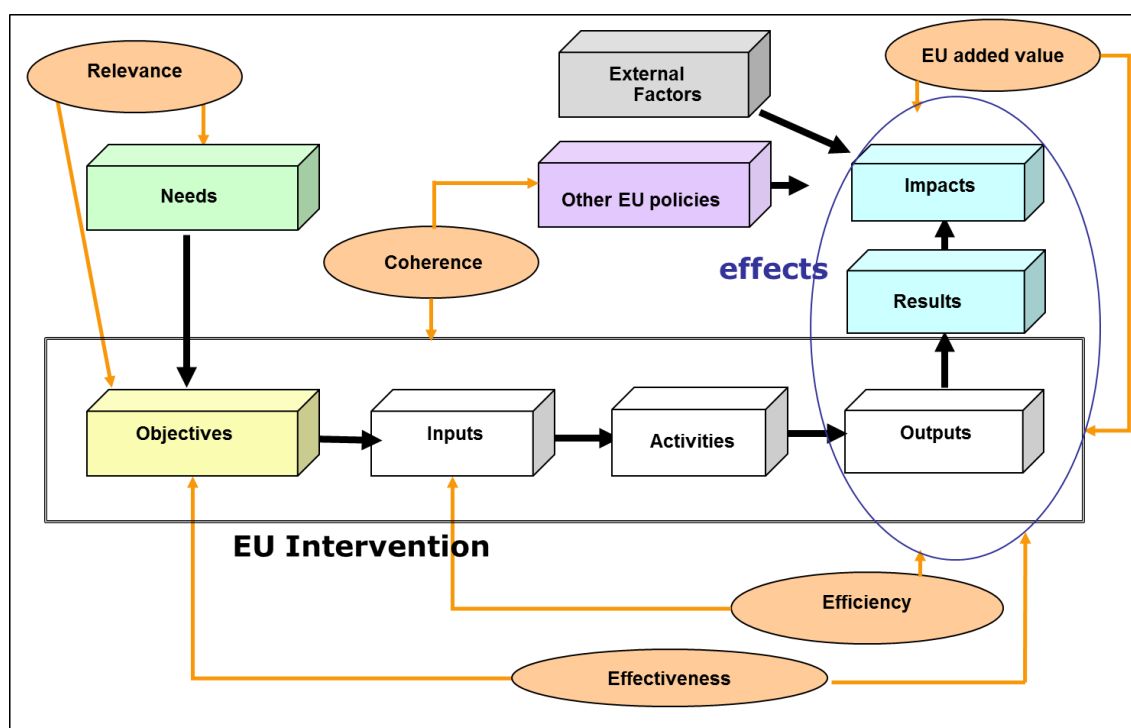


Figure 1: Simplified view of the intervention and the 5 key evaluation criteria

2. EFFECTIVENESS

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives. The evaluation should form an opinion on the progress made to date and the role of the EU action in delivering the observed changes. If the objectives 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 hasn't been successful or *why* it has not yet been achieved. To this end, effectiveness analysis should seek to identify the factors driving or hindering progress and how they are linked (or not) to the EU intervention.

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. Again, it is important to keep in mind that the evaluation is assessing the role played by the EU intervention – so analysis also needs to consider how the observed changes may be linked to the actions triggered by the EU intervention.

Box 1: 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?

In many cases, performance can be identified from monitoring data covering the relevant period. This can then be compared to relevant points of comparison⁵²³ such as:

- The (evaluation) baseline.
- Expectations based on what was expected to have happened at this point (the adopted proposal, drawing on the appropriate information from a prior impact assessment or other relevant documents). This may include comparison with the stated specific / operational objectives.
- Another scenario or benchmark.

3. EFFICIENCY

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

It is important to note that **efficiency analysis should always look closely at both the costs and benefits of the EU intervention as they accrue to different stakeholders**⁵²⁴. As a general rule, the benefits of EU interventions are expected to justify the costs they generate, although those who bear the costs do not always reap the benefits. This is often the case for safety, health, environment or consumer protection policies. Again, it is

⁵²³ See Tool #46 on *Designing the evaluation*.

⁵²⁴ See also Chapter 8 Methods, models and costs and benefits

important to identify what factors are driving these costs/benefits and how these factors relate to the EU intervention.

Typical efficiency analysis will include analysis of administrative and regulatory burden and look at aspects of simplification – which is important for ALL evaluations. Where appropriate, **evaluation findings should pin-point areas where there is potential to reduce inefficiencies, particularly unnecessary regulatory costs, and simplify the intervention.** The full efforts to support and perform an intervention can be broken into different categories such as: staff, purchases made, time and/or money spent, fixed costs, running costs, etc⁵²⁵. These costs can be associated to different aspects of an intervention and judged against the benefits achieved.

Better regulation and particularly the REFIT programme place a strong emphasis on identifying and where possible measuring (i.e. if possible, quantifying and / or monetising) the costs and benefits of EU interventions.⁵²⁶

Sectoral fitness checks pose a specific challenge, because costs corresponding to the examined interventions normally remain with the sector (if not passed on downstream in the form of higher prices), whereas diffuse benefits are enjoyed by society at large. When evaluating the costs/benefits to the sector, it may not be enough to just look at the net position of the sector and see if that is in line with expectations. Although it is beyond the scope of the sectoral fitness check to perform a full evaluation of those acts, some qualitative data on their wider performance have to be considered in order to provide the appropriate context. This is important, because to a certain extent it was this wider context that was used to justify the EU intervention.

A cumulative cost assessment (CCA)⁵²⁷, although providing important inputs into the evaluation process, is not sufficient on its own to provide the required full picture in terms of the efficiency of the EU intervention. As such, it cannot be "the sole basis for policy recommendations"⁵²⁸. To serve as an instrument for the policymakers, CCAs need to be put in the context and CCAs need to be supplemented by the analysis of the corresponding benefits arising from the EU legislation.⁵²⁹

⁵²⁵ See Tool #58 on *Typology of costs and benefits*

⁵²⁶ See Tool #2 on *The Regulatory Fitness programme and the REFIT platform*; and Tool #59 on *Methods to assess costs and benefits*.

⁵²⁷ CCA are studies that aim to estimate the overall regulatory burden on a particular sector. In the EU context, the CCAs will look at the costs arising from the EU regulations.

⁵²⁸ Page 15, *Regulatory Fitness and Performance: State of Play and Outlook* COM (2014) 368 final

⁵²⁹ Further discussion on costs and benefits analysis in the context of CCA is provided in the Tool #59 on *Methods to assess costs and benefits*.

Table 1: Approach towards efficiency analysis in specific cases

	Costs				Benefits					Benefits and costs have same scope and are directly comparable?
	Specific to the sector	To all affected sectors	General welfare/ Costs to society	Overall cost of a policy	Specific to the sector	To all affected sectors	General welfare / Benefits to society	Of a specific policy	Overall benefit of a policy	
Evaluation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fitness check	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sectoral fitness check	Yes	No	No	No	Yes	No	No	Partial	Partial	Possibly
Cumulative cost assessment	Yes	Possibly	Possibly	Possibly	No	No	No	No	No	No

Assessing costs and benefits may be (methodologically) easier for spending programmes which have well defined stakeholders, systems etc. Doing this with precision at EU level can be difficult since obtaining robust, good quality data to use in the evaluation of costs and benefits may be challenging, particularly across all Member States which may have implemented legislation in a variety of different ways and at different points in time. However, sufficient efforts should be dedicated to this task, given its importance.

Box 2. 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 associated benefits?
- 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?](#)

Points of comparison⁵³⁰ to consider include:

- The (evaluation) baseline.

⁵³⁰ See Tool #46 on *Designing the evaluation*

- What was expected to have happened at this point (the adopted proposal, drawing on the appropriate information from a prior impact assessment or other relevant documents).
- The previous system (e.g. an earlier programme).
- Other similar situations which can be used as benchmarks (e.g. standard IT costs; training or performance benchmarks from private sector, performance management systems in other countries, growth rates, education rates, CO2 levels etc.).

4. RELEVANCE

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. Relevance analysis also requires a consideration of how the objectives of an EU intervention (legislative or spending measure) correspond to wider EU policy goals and priorities. Analysis should identify if there is any mismatch between the objectives of the intervention and the (current) needs or problems. For example, the wrong "problem drivers" may have been identified during the impact assessment; incorrect assumptions may have been made about the cause and effect relationships; circumstances may have changed and the needs/problems now are not the same as the ones looked at when the intervention was designed.

Relevance analysis is very important – because if an intervention does not help to address present needs or problems then it does not matter how effective, efficient or coherent it is – it is no longer appropriate (this is why relevance is sometimes called the "kill" criterion!). This is key information that will assist policy makers in deciding whether to continue, change or stop an intervention and also explains the strong link between relevance and the criterion of EU added value – which assesses whether action continues to be justified at the EU level.

In areas of EU exclusive competence (e.g. trade agreements), the analysis of the relevance and efficiency of the intervention may form a large part of the analysis of EU added value (see EU added value below).

Box 3. 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? (N.B. Could include issues related to the specify policy here e.g. social, environmental or to implementation, reporting and compliance)
- How relevant is the EU intervention to EU citizens?

Points of comparison⁵³¹ for relevance are usually more qualitative. In terms of the evaluation baseline, it is necessary to think about what were the needs and objectives behind the EU intervention and compare them to the current situation. There may also be grounds to consider how something is expected to be in the near future (based on anticipated or upcoming technological/social/economic changes). For example, in the telecommunications market, discussions about 5G standardisation are well advanced, even if such technology is not in common use at this point.

5. COHERENCE

The evaluation of coherence involves looking at how well or not different actions work together. It may highlight areas where there are synergies which improve overall performance or which were perhaps not possible if introduced at national level; or it may point to tensions e.g. objectives which are potentially contradictory, or approaches which are causing inefficiencies.

Checking "internal" coherence means looking at how the various components of the same EU intervention operate together to achieve its objectives e.g. the different articles of a piece of legislation, different actions under an action plan. Similar checks can be conducted in relation to other ("external") interventions, 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 national policies or international agreements/declarations (for example EU labour market interventions 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.

When assessing coherence, comparison with other scenarios is again likely to be predominantly qualitative. Suitable points of comparison⁵³² could include looking at changes in coherence between the start and end of the period being evaluated or information from the impact assessment. They might also include looking at existing or new national or international actions. The level of coherence being evaluated (e.g. internal to a given EU action, within a given policy field, wider EU policy or wider global context) could also affect the comparison point and degree of analysis possible.

Box 4. Typical examples of coherence questions

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

⁵³¹ See Tool #46 on *Designing the evaluation*.

⁵³² See Tool #46 on *Designing the evaluation*.

- 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?

6. EU-ADDED VALUE

EU-added value⁵³³ looks for changes which it can reasonably be argued are due to the EU intervention, over and above what could reasonably have been expected from national actions by the 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.

Under the principle of subsidiarity (Article 5 Treaty on European Union), and in areas of non-exclusive competence, the EU should only act when the objectives can be better achieved by Union action rather than action by the Member States. It requires consideration of the added value of EU action compared to that of other actors (see also Tool #5 on Legal basis, subsidiarity and proportionality). EU added value analysis should, where applicable, respond 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 European added value of an EU 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, European 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 the measurement of EU added value is challenging.

In areas where the EU has exclusive competence, the appropriate answer to the question of EU added value may simply involve re-stating the reasons why the EU has exclusive competence or may already be answered by the efficiency and effectiveness analysis.⁵³⁴

In the context of the EU budget, the Commission staff working documents SEC(2011) 867 final and SWD(2015) 124 final recommend that the EU added value test is performed on the basis of the following 3 criteria:

Effectiveness: where EU action is the only way to get results to create missing links, avoid fragmentation, and realise the potential of a border-free Europe.

Efficiency: where the EU offers better value for money, because externalities can be addressed, resources or expertise can be pooled, an action can be better coordinated.

Synergy: where EU action is necessary to complement, stimulate, and leverage action to reduce disparities, raise standards, and create synergies.

⁵³³ For further information see SEC(2011) 867 final "The added value of the EU budget".

⁵³⁴ See Tool #5 on *Legal basis, subsidiarity and proportionality*.

As (big) data becomes easier to collect, possibilities grow to apply new methods to analyse the EU added value (e.g. counterfactual impact evaluation). Where there are difficulties identifying a robust counterfactual, the analysis of EU added value should as a minimum provide qualitative, reasoned arguments about the likely role / contribution of the EU intervention, backed by appropriate quantitative and qualitative evidence. It is also important that evaluations clearly state the challenges that have been encountered and resulting limitations in the certainty or accuracy of such findings, which can vary greatly from case to case.

Box 5. Typical questions on EU added value

- 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?⁵³⁵
- What would be the most likely consequences of stopping or withdrawing the existing EU intervention?

When assessing the EU added value, the comparison⁵³⁶ is likely to involve consideration of performance against both the (evaluation) baseline and, if available a projection of how the situation was expected to evolve without the EU intervention (a defined counterfactual, or some estimate of the cost of the Union not acting - "the cost of non-Europe"). Often such analysis is qualitative, analysing whether the subsidiarity arguments put forward before the intervention (as presented in a prior impact assessment, or other accompanying documents) were valid and whether the expected changes resulting from EU action were delivered. It may also be appropriate to analyse whether any contextual change, or other factors affected the assumption that such change could only be generated by EU level action.

7. OTHER EVALUATION CRITERIA

There are also several further evaluation criteria which it may be appropriate to consider, depending on the type of intervention and the timing of the evaluation. The most common additional criteria evaluated by the Commission are shown below.

Utility: To what extent do the changes/effects of an intervention satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?

Complementarity: To what extent do EU policies and interventions support and usefully supplement other policies (in particular those pursued by the Member States)?

⁵³⁵ In answering this question, it may be interesting to consider the question for each criteria. For example, How efficient has the EU intervention been in comparison to what could reasonably have been expected from Member States acting at national and/or regional levels?

⁵³⁶ See Tool #46 on *Designing the evaluation*.

Coordination: To what extent are **interventions** organised to maximise their joint effects, e.g. by mobilising resources combined with harmonising measures?

Equity: how fairly are the different effects distributed across the different stakeholders / regions? / genders? / Social groups?

Sustainability: *How likely are the effects to last after the intervention ends?* It is often hoped that the changes caused by an intervention are permanent. It can be important to test this expectation for interventions which have a finite duration, such as particular programmes.

Acceptability: To what extent can we observe changes in the perception of the intervention (positive or negative) by the targeted stakeholders and/or by the general public?

8. GOOD PRACTICE TIPS

- Evaluation questions should be worded in a way that forces the evaluator to go beyond an answer based on simple description. Questions that start with How, Why, To what extent are more likely to ensure that the answer provided looks at what the links were between the changes observed and the EU intervention(s). Questions that start with verbs such as "Do" the directives...? "Are" the directives providing...? "Should" be avoided as they tend to provoke yes/no answers.
- Try not to have too many evaluation questions. Sometimes it is necessary to have very specific questions, other times it is better to have a more generic set and see where the data/analysis leads. There is always a trade-off between the number of questions that are set and the depth of analysis that can be conducted, especially across all Member States.
- For spending programmes, it may be necessary to assess to what extent has it been possible to prevent and detect fraud.
- Check any prior impact assessment to see what issues were addressed and what expectations were presented. Where necessary compare the proposal accompanying the impact assessment to the final actions adopted/introduced and try to identify where amendments to the Commission's proposal may have changed the intervention logic described in the impact assessment.
- Encourage consideration of the "end-user" perspective. End-users are most affected by actions triggered due to EU interventions – they have practical experience of what has happened on the ground and may have a different perspective from policy makers, governments, NGOs etc.
- Evaluation questions are often worded in a technical way, using terminology that makes sense within the Commission but which requires further explanation (simplification) to many stakeholders. "Translate" the criteria into more manageable / understandable concepts, particularly for consultation and data gathering exercises. For example:
 - Rather than referring in an abstract manner to the "objectives of the policy" describe the objective in more common terms – so ask "What progress has been

made towards increasing the availability of funding to small and medium sized businesses?"

- If there is a problem with the timetable and it becomes clear that any deadlines set for the final evaluation will be missed, it makes sense to let interested parties know. This is particularly true where an evaluation is set in a legal act and the evaluation findings should be communicated to Parliament and Council.
- The exact scope has significant impacts on the final design. If there are issues about what EU actions to include in scope (this is of particular relevance for fitness checks), consider doing a short "scoping" exercise first.

TOOL #48. CONDUCTING THE EVALUATION

1. INTRODUCTION

When the planning and design is over, the actual evaluation work starts. Conduct is the actual "doing" of the evaluation.

Unless an exception is requested / granted⁵³⁷, an evaluation staff working document (SWD) should be written by the lead DG for all evaluations and fitness checks⁵³⁸. This brings together all work⁵³⁹ carried out for the evaluation. Where no external work is involved, the approach is described as "internal". Where external contractors provide some support to the evaluation, the approach is described as "mixed", because it involves both external work and internal work (as a minimum, the drafting of the SWD).

The vast majority of evaluations involve external contractors in some way. They can be commissioned for all or some tasks such as:

- Collecting and analysing the relevant evidence (including consultation work);
- Developing analytical models and running them;
- Providing "first" answers to some/all evaluation questions;
- Presenting evidence-based conclusions.

Work that a contractor is required to do is set out in the associated ***terms of reference (ToR)***⁵⁴⁰ written by the Commission services.

For all work conducted as part of the evaluation, the evaluation manager and the interservice group (ISG) have a particular role to steer the project and improve its quality at all key steps. Where there is external work, this includes advising contractors, supervising their work (and hence its quality) and enforcing the timetable.

2. WHY IS "GOOD CONDUCT" IMPORTANT?

It is important to constantly check the quality of the work being undertaken, ensuring that it is evidence-based and free from bias. Thorough, robust and reliable research, data

⁵³⁷ See Tool #2 on *Principles, procedures & exceptions*.

⁵³⁸ See Tool #49 on *The staff working document for evaluation*.

⁵³⁹ The support work for an evaluation can be outsourced to external contractors and / or draw on the (internal) work of Commission services including services offered by the JRC. External support work may involve one or several contracts (studies).

⁵⁴⁰ The level of detail and specificity of a terms of reference can depend on the different procurement procedures. Detailed guidelines to public procurement can be found at http://www.cc.cec/budg/imp/procurement/imp-080-020_procproced_en.html

collection and analysis are core activities to conducting a high-quality evaluation and drawing appropriate evaluation findings and conclusions. Robust and reliable results can be delivered only by objective evaluations.

Every effort should be made to ensure the transparency of the evaluation – both in terms of how it progresses (e.g. involvement of ISG, working group, stakeholders) and when reporting (e.g. in terms of collection and use of data, analysis and results). Any limitations to the method applied or the data collected should be clearly discussed over the course of the evaluation, addressed where possible and reported in the final SWD.

Equally, care should be taken to spot weaknesses in both:

- The data: e.g. do they come from a reliable source? Have enough respondents replied?; and
- The analysis: e.g. are the survey questions clear and simple? Do they cover a sufficient time period and identify any trends? Can the modelling be repeated?

Box 1. Conducting an evaluation

- The ISG plays a key role in assuring the quality of the overall evaluation. As this is best ensured by building quality checking into the conduct of the evaluation, the ISG must be involved in all key stages of design and conduct after the publication of the roadmap up until the launch of the interservice consultation on the staff working document (SWD) for and if appropriate any associated report/communication to the European Parliament and Council.
- A 12 week open public consultation is required for every evaluation; additional consultation activities may also be carried out. The timing of the open public consultation, however, is at the discretion of the DG⁵⁴¹.
- Ethics and Integrity concepts should be respected. Any conflicts of interest should be reported to the appropriate actor in the Directorate General and Secretariat General.
- Any attempts to influence the evaluators should be reported to and recorded by independent senior management in the Directorate General and the Secretariat General.
- The evaluation methodology should follow that identified in the design phase (including any commitments in associated ToR) or explain why this has not been possible.
- All evaluations should take into account the evidence base built up over earlier parts of the policy cycle and where appropriate, any prior impact assessment.
- All evaluations should make credible efforts to obtain data from a wide range of qualitative and quantitative sources and distinguish between the opinion of, or data from, vested interests and independent sources. Where possible, it is recommended that the supporting data for an evaluation is made generally available in an easily accessible format.
- Particular effort should be made to access and (re) use data that is already collected,

⁵⁴¹ See Chapter 7 on Stakeholder consultation

for instance by ESTAT, or by public services in Member States for administrative purposes (Admin data).

- Proportionate effort should be made quantify costs and benefits, reflecting the role of the intervention being evaluated and external expectations or discussions (e.g. where there has been significant debate or disagreement between stakeholders in relation to actual costs or benefits delivered). Where this is not possible, a clear explanation of the efforts made and the restrictions encountered should be given.

3. THE ROLE OF THE EVALUATION INTERSERVICE GROUP

Interservice Group (ISG)	
The ISG must be involved in all key steps of the evaluation after the publication of the roadmap ⁵⁴² up until the launch of the interservice consultation on the staff working document (SWD) for interservice consultation and if applicable, the associated executive summary. It may be consulted on any associated report/communication to the European Parliament and Council. The group should discuss the full draft evaluation SWD before it is submitted to the Regulatory Scrutiny Board (RSB) and its revised version (and underlying policy proposal) before the launch of ISC.	
Who?	The group is led by the relevant DG or service. A representative of their evaluation function or unit must also be included in the ISG.
	DGs with policies linked to the subject of the evaluation or likely to be affected by the evaluation should be invited to participate. A representative from the Secretariat-General (generally the evaluation unit) must be invited to the ISG.
	By definition, the ISG is an internal Commission group, made up of representatives from DGs. However this does not prevent consultation with other groups which include non-Commission staff (e.g. from agencies, Member States, academia etc.) which could also provide advice and information. This is particularly relevant when a DG is evaluating an agency. In such a case, it is important to involve representatives of the agency in the evaluation process but they will not be a member of the ISG. One way to do this would be to create an ISG as normal, but to discuss relevant aspects of the work in an additional, wider group (identified at the discretion of the lead DG), which includes both the ISG members and agency representatives. Further examples of such groups include Member State advisory committees, academic or reference panels.
	In addition, DGs with core expertise in specific areas such as economic analysis (e.g. ECFIN), scientific research and analytical models (e.g. JRC), social impacts (e.g. EMPL), SMEs, competitiveness (e.g. GROW), environment (e.g. ENV), fundamental rights (JUST), innovation (RTD), digital/ICT (CNECT) etc. should also participate where appropriate to ensure that the evaluation calls upon all relevant expertise in the Commission

⁵⁴² For information on the activities which precede the work of the ISG, see tool #6 on Planning and validation of initiatives and tool #7 on Drafting of Roadmaps, evaluation roadmaps and inception impact assessments.

	services. Existing ISGs can be used to steer the evaluation work particularly where such a group has been used to conduct a prior impact assessment or to provide advice to policy development. Consultants may be invited to make presentations regarding supporting studies or contracts but should leave the meeting when substantive discussions take place between ISG members. The lead DG should make sure the confidential nature of internal ISG discussion remains protected.
Why?	An effective ISG can significantly increase the credibility of an evaluation. By ensuring that different perspectives are discussed, analysed and reported it improves the quality of the evaluation, helps to ensure coherence with other policies and demonstrates an open and transparent approach to critically analysing performance and delivery. Involving other services should also anticipate (and solve) problems that could emerge later in the process (e.g. during interservice consultation). Colleagues from other areas are a good test of whether your arguments are clear and easy to follow. The ISG encourages a pooling of knowledge and brings together a range of different perspectives. The mix of policy/operational experience and evaluation expertise should prevent particular biases from taking over the evaluation and encourage critical judgements to be made. The ISG is the best way to ensure that a DG's views are taken into account by the lead DG. It is important, therefore, to plan participation well in advance and participate pro-actively. As far as possible, make sure the position expressed in an ISG is representative of the position your DG is likely to take during ISC.
When?	An ISG can be established / convened as soon as the evaluation has been validated and accepted for inclusion in Decide⁵⁴³. The ISG plays a key role in assuring the quality of the overall evaluation. Hence the ISG should meet as many times as needed to cover the important elements of the evaluation. Where applicable, the ISG should also discuss the final draft of the evaluation SWD before it is submitted to the Board. It will also comment on subsequent changes to the evaluation SWD to take on board RSB comments.
	More meetings (and/or email consultations in between meetings) can also be envisaged, particularly in the case of complex evaluations running over a long period. Meetings may also follow the timing of other miles-stones such as an external study or a stakeholder consultation.
How?	The exact process of setting up the steering group differs between DGs, so the lead desk officer should check internal procedures. Often the invitation takes the form of a note from the Director-General of the lead DG to those of the identified DGs asking for a representative to be nominated. The first meeting of the ISG should discuss the intervention logic, evaluation questions and other elements affecting the design/conduct of the evaluation including the consultation strategy. Ideally the evaluation questions will be fixed shortly after this meeting. It is good practice to share information and record decisions on these key elements in written format.

⁵⁴³ See Tool #6 on Planning and validation of initiatives.

	Whilst there is no requirement for the ISG to endorse the draft evaluation roadmap, it may be appropriate to consult interested DG's where relevant. The ISG must steer the evaluation through subsequent key phases (e.g. design / conduct including consultation, studies and SWD), providing input and information and ensuring the quality, impartiality and usefulness of the final product.
	The ISG is also involved in the preparation of terms of reference for external studies and drawing up the scope of possible modelling work. The ISG <u>should agree</u> the design of stakeholder consultation strategy and any consultation documents. It should discuss any feedback received from stakeholders on the evaluation roadmap. It should always discuss intermediate findings e.g. deliverables and quality of modelling work or supporting studies and drafts of the evaluation SWD.
	Meetings should be well prepared with <u>invitations and documents being circulated at least one week in advance</u>. Similarly, ISG members should be given <u>at least one week</u> to provide written comments on drafts of the evaluation SWD. Minutes of meetings should be prepared which record transparently and accurately the views of the ISG members. The minutes of the last ISG meeting should be attached to the covering note if the evaluation SWD is submitted to the RSB.
	The lead DG is recommended to establish a collaborative work space for sharing documents which facilitates more flexible participation by DGs.

TOOL #49. THE STAFF WORKING DOCUMENT FOR EVALUATION

1. WHAT IS THE STAFF WORKING DOCUMENT FOR EVALUATION?

The staff working document for evaluation or fitness check (SWD) is the key deliverable of the evaluation process, presenting the lead DG's evidence-based judgements and answers to the evaluation questions. The lead DG should present its conclusions to the evaluation in a way that is useful to policymakers and that can be used as a basis for future policy development.

The SWD summarises the evaluation and presents in a transparent manner the process and methodology used for the evaluation and any associated limitations to the robustness of the process and findings. All evidence should be clearly presented or referenced. DGs must use the standard format described below for the SWD which will ensure consistency across the Commission.

Where evaluations are based exclusively on the work of external contractors (e.g. by supporting studies), the SWD should not undermine the objectivity and independence of the evaluation process. Instead, the SWD draws on this work and allows the lead DG to take ownership of the findings and conclusions of the evaluation. However, if there are reasons why the lead DG thinks there are different answers or draws different conclusions to those of the external contractor, this can be brought out in the SWD, together with the necessary supporting justification – either by showing why they interpret the evidence differently, or by bringing in additional information.

Where evaluations have limited or no support from external contractors, the SWD should provide a transparent record of the work done by the Commission services together with any information drawn from supporting sources.

The evaluation SWD template and executive summary cover page can be downloaded from GoPro. This template must be used, with a standard cover page created in Legiswrite and be transmitted to at least one of the institutions (in order to receive an SWD serial number).

2. WHY IS THE SWD IMPORTANT?

The SWD is the key document that will inform stakeholders and policy makers on the outcome of the evaluation, presenting the judgements and lessons learned. It should be written by the lead DG irrespective of whether there has or has not been an external supporting study. It is the response to the issues raised in the roadmap and answers the evaluation questions (section 5). It is also the basis for the follow-up plans. It can (via the synopsis report provided in annex⁵⁴⁴) provide an indirect feedback mechanism acknowledging the contributions that stakeholders and experts have made throughout the process.

The SWD should be a self-standing document which follows the standard structure set out below, to ensure consistency across Commission services. It should be written using

⁵⁴⁴ See Tool #55 on *Informing policymaking - the synopsis report*

non-technical language with non-expert readers in mind and should provide the reader with a complete picture of the key steps performed, the main issues and findings. More detailed information or explanations should be provided in the annexes. In most cases, a short executive summary of two DGT standard pages available in FR, DE and EN should also be drafted, although this may be omitted where there is also a requirement to provide a report to the European Parliament and Council.⁵⁴⁵

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 report, the evaluation SWD must provide sufficient detail, enabling the reader to follow the evidence and logic and understand the answers and conclusions without having to read any supporting materials. .

Underlying data, statistics, information, expert contributions and stakeholder views should all be referenced, particularly where choices are made or conclusions are drawn based on them. Whenever possible, direct hypertext internet links should be provided.

Stakeholder views should be integrated throughout the text of the evaluation SWD. A description of the views of the different stakeholder groups should be included and any differences within or across such groups should be highlighted.

3. THE SWD AND ANY ASSOCIATED REPORT / COMMUNICATION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

The evaluation of legislation may be based on a reporting/review clause in a legal act which obliges the Commission to review or evaluate the legislation after a certain time and to provide the European Parliament and Council with a report (or communication – hereafter, just "report").⁵⁴⁶

In cases where the legislation requires such a Commission report (i.e. one adopted by the College), the SWD should be linked to and support the main Commission report. This should help keep the main text of the report concise. Where the Commission reports formally to the Legislator, it is not necessary to provide a separate executive summary of the SWD. This decision is at the discretion of the lead DG, but consideration should be given to the dissemination value and use made by many stakeholders of such documents.

Where there is no legal obligation for the Commission to report formally to the Legislator this can still be done if appropriate. It is sufficient to organise one single interservice consultation covering both the report and the SWD.

The SWD describes the Commission Services' approach, analysis and conclusions to the evaluation. A SWD is an analytical document, drawing conclusions underpinned by factual information and analysis.

⁵⁴⁵ See also GoPro : <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Commission+staff+working+documents>

⁵⁴⁶ See Tool #42 on *Legal provisions on monitoring and evaluation*.

In contrast to the SWD, a formal report to the Legislator can also set out any political message about the evaluation and indications of next steps. This report can be a shorter self-standing document, referring to more detailed indications in the SWD. It should provide clear indications on all key aspects of the evaluation including, if appropriate, (indicative) responses to the conclusions of the evaluation.. The report is not submitted to the RSB (the RSB provides an objective assessment of the quality of the work of the Commission services in relation to the evaluation, and hence is based on the Commission services evaluation or fitness check SWD).

Box 1. The SWD for evaluation

- The evaluation SWD should contain:
 - Judgement/answers, based on a range of data, to the evaluation questions which the evaluation intended to address;
 - A clear summary of the methodology followed and a final assessment of the limitations of the approach taken, any insufficiencies in the data used to support the conclusions and the robustness of the findings;
 - A clear chain of logic between the analysis and findings, the answers to the evaluation questions and the conclusions drawn.
 - Clear conclusions based on the evidence drawing on the lessons learned and providing necessary information for future policy decisions.
 - A summary of the changes requested/introduced by the Regulatory Scrutiny Board (RSB) if they have been consulted. Where the procedural annex contains a summary of the main changes made due to the Quality Assessment (QA) of any external work and confirmation of the involvement of the ISG in that QA, this fulfils the requirement to publish the QA of associated external work. It may also be appropriate (but is not mandatory) to summarise changes introduced during interservice consultation.
- An executive summary of no more than two DGT standard pages available in EN, FR and DE should be issued as a stand-alone document except for cases when a report to the Council and European Parliament is provided and the lead DG has decided not to provide such a summary.
- All contractors' final reports (plus other relevant interim deliverables from external work) and SWDs for evaluation should follow the appropriate corporate publication requirements.
- It is considered good practice to publish non-confidential data used in the evaluation or supporting studies.
- The main text of the SWD (section 4) and the annex presenting procedural information should explain how the opinion of the ISG was sought (process) and be reflected in the SWD (content).

4. THE SWD IN BACK-TO-BACK EVALUATIONS AND IMPACT ASSESSMENTS

For all fitness checks and evaluations selected for scrutiny by the RSB, the results of the evaluation must be presented in a stand-alone SWD, irrespective of the degree of overlap in the back-to-back process.

For other back-to-back evaluations/impact assessments the results of evaluation can be presented as an annex to the IA report. This new annex will follow the structure of an evaluation SWD, reporting as far as possible under each section. It should also explain why a back-to-back approach was taken and identify any limits or issues caused by overlaps in conducting the evaluation and impact assessment.

5. DETAILED STRUCTURE AND CONTENT OF THE EVALUATION SWD AND THE EXECUTIVE SUMMARY

The SWD should follow the structure below. Each section provides further guidance on the text/issues to be covered. This guidance summarises elements of various evaluation tools which provide the complete picture of issues to address under each section.

Executive Summary

An executive summary should be provided. The executive summary should be a reader-friendly (for the unfamiliar reader) **stand-alone document**. Thus, a non-technical style should be applied, providing the full picture of the evaluation and any technical terminology and jargon should either be adapted or explained. The executive summary should be provided in English, French and German.

The executive summary should not be longer than two (DGT) pages.

An executive summary is not necessary when the Commission provides a report to the Council and the European Parliament.

The template is available on GoPro.

Section 1 Introduction

Purpose and scope of the evaluation

- *Set out the purpose of this evaluation/FC, what it will deliver and how its results may be used (e.g. to fulfil a legal obligation, provide the basis for a possible future IA, to improve application etc.)*
- *What are the main issues the evaluation addresses?*
- *What evaluation criteria are applied (noting that all evaluations should cover effectiveness, efficiency, relevance, coherence and EU added value)?*
- *Which time period the evaluation covers (from the start of the intervention until now, or different time period, when covering a different time period explain why)?*
- *Which Member States and other countries the evaluation covers? (if not all Member States and if other countries explain why)*
- *Which related implementing / delegated acts are covered as part of the evaluation? If they are not covered, explain why.*

Indicative length: 2 pages

Section 2 Background to the intervention

Description of the intervention and its objectives

Provide a brief description of the intervention and how it fits in the wider policy framework. Also describe its different components, its objectives and the problems it was intended to solve.

If possible, summarise this information in an intervention logic diagram or text, bringing showing the intended logic from the EU intervention to the expected changes (thus delivering on the objectives).. It is generally helpful to present some sort of picture illustrating how the different components were expected to fit together.⁵⁴⁷

Discuss/show the timing of the different components, their expected outputs and how these actions were ultimately expected to deliver the objectives.

Baseline and / or points of comparison

Either in this section, or in Section 3, describe the points of comparison against which you will assess your intervention. This can be for example the situation before the intervention started (T_0), the no change scenario in the impact assessment (baseline) or the situation you expected to have achieved at this point in time (preferred option). You may need to use different points of comparison for assessing the different evaluation criteria and should clearly explain the choice made⁵⁴⁸.

This section should draw on the prior impact assessment if available (but updated to reflect changes during the adoption process). It should cover in particular the situation linked to the problems / needs the intervention was intended to solve (a quantitative description should be provided as far as possible). This should facilitate a comparison with the current situation and should therefore cover as far as possible the same parameters/indicators that are used to describe the state of play in Section 4.

Use tables/graphs/pictures as necessary.

Indicative length: 3-5 pages.

Section 3 Implementation / state of play

Descriptive section, summarising the current situation.

Explain:

⁵⁴⁷ See Tool #46 on *Designing the evaluation*.

⁵⁴⁸ See Tool #46 on *Designing the evaluation*.

- How the intervention has been implemented, summarising which Member States have done what and what problems/infringements have been identified ;
- What the current situation is in quantitative and qualitative terms (paying particular attention to any information relating to existing costs and benefits). In particular, explain the monitoring arrangements put in place and report back on the different indicators. Concentrate on those aspects of the situation which result from the intervention and which are relevant for this evaluation ;
- Whether any unexpected or unintended changes have been identified, including whether there have been "knock-ons" in other areas due to this intervention.

It is not necessary to repeat in this section all the evidence collected, but clear references should be provided, signposting where further detail/information can be found.

Use tables/graphs/pictures as necessary to illustrate the current situation.

Be aware that there is a need to balance the data presented here in a descriptive format, with later analysis under one or more criteria. Cross-referencing may assist in avoiding unnecessary repetition.

Indicative length: 3 – 5 pages

Section 4 Method

Summarise how the evaluation has been carried out and over what time period. This should be described with reference to the evaluation criteria and questions, available data, analysis etc.

Provide a transparent account of what has been done, by whom (external contractor, Commission), any changes from the original plan (set out in the roadmap) and any mitigating measures taken.

List any known limitations e.g. data, timing, etc. and explain the mitigating measures taken. Provide an overall analysis of the reliability of the available data.

Provide a critical assessment of the work carried out by the external contractor, which allows an understanding why you agreed or disagreed with their conclusions.

Keep detail for the Annex (see 5.2 below): a more elaborate description of the process as well as details relating to the methodologies applied (e.g. studies carried out/used; sources of data; models; stakeholder consultation etc.) should be included in the Annexes to the report.

Indicative length: 2 pages.

By the time readers reach the end of this section, they should all have a common understanding of what the intervention was expected to achieve; how that was expected to happen; and what the situation is now. They should also understand the approach taken for the evaluation and any limits that have been identified,

providing them with a context for the subsequent analysis and managing their expectations about the level of detail and sophistication that will be provided.

Section 5 Analysis and answers to the evaluation questions

Present the evaluation question and provide the answer

Answer ALL evaluation questions that were fixed after the 1st meeting of the ISG in a clear and concise manner that is understandable to the non-expert reader. If there is insufficient data or evidence to answer one or more questions, this should be clearly stated and linked to the limitations under Section 3 above.

Compare the current situation (section 3) with the points of comparison (section 2 or 3). Use the information collected to analyse how far the outputs and outcomes observed match the expectations stated when the intervention was adopted, referencing the intervention logic as appropriate and showing whether it the logic has been followed as expected or not. Consider the impact of delays in implementation. Bring together different sources of data (clearly referenced so that the reader can investigate further if they wish) and provide unbiased and critical judgements of what has/has not been achieved. Ensure triangulation of data.

This section should be analytical, using tables/graphs/pictures to illustrate the analysis.

All the evaluation criteria – Effectiveness, Efficiency, Relevance, Coherence and EU Added Value – should be addressed in the final report, unless an exemption has previously been granted. It is recommended that this is done as a specific sub-section for each criterion. The coverage (written text) allocated to each criterion will vary depending on its importance and the evidence / analysis available.

In particular, under the efficiency criterion, efforts should be made to address in qualitative and quantitative terms cost, benefits and burdens arising from the intervention or explain why this has not been possible.

Indicative length: 10-25 pages.

Section 6 Conclusions

Summarise the main conclusions of the evaluation, usually by evaluation criteria.

The conclusions should be written in such a way that policy makers can use them as a basis for future policy development but respecting the limits of an SWD, **they should not make any commitment for future action or direction of action.** It is important to present the lessons learned and include a systematic screening of the evidence, indicating which findings match expectations, which findings are too preliminary to conclude (wait and see) and what does not work.

It should be clear:

- what elements of the EU intervention are working or not and why;

- the lessons learned (good or bad);
- if actual performance matches the expectations (with appropriate reference to a prior impact assessment);
- if issues need to be addressed by action or will resolve over time.

Where appropriate, clear reference should be made to lessons relating to (REFIT) issues such as regulatory or unnecessary burden, simplicity/complexity, identification of efficiencies/inefficiencies, achievement of objectives at low / high (appropriate / reasonable) costs.

There should be a clear and logical progression between the description of implementation/state of play presented in Section 3, the answers to the evaluation questions provided in Section 5 and the conclusions being drawn. There is no need to repeat here the answers to the individual evaluation questions - these should be provided in section 5.

The conclusions should summarise and qualify the performance of the intervention against the criteria used for the evaluation. As the conclusions text is often read independently of the preceding text, there should be a short recap of the scope and limitations of the evaluation.

No new detail or issue should present in the conclusions section– such information should always be presented in the analysis section first. Related to this, avoid confusion by taking care to use consistent terminology throughout (new wording could give the impression that something is new is being concluded, when it has been mentioned earlier, just with different phrasing).

Indicative length: 2 - 4 pages

5.1. Annexes to the final report

Annexes to be included in the final report

Annexes can be used to present additional technical material particularly to support the information presented in the main body of the report (e.g. a more detailed description of the concerned market or monitoring indicators). Annexes should not be excessively long, be restricted to information which is relevant and pertinent and contain references and hypertext links to external information sources wherever possible (rather than reproducing the material in the report itself).

The following annexes are required:

Annex Procedural information concerning the process to prepare the evaluation or fitness check.

- Identify the lead DG; any Decide /Work Programme references;
- Describe any exceptions from the usual procedural requirements of the better regulation Guidelines together with an appropriate justification;

- Organisation and timing: provide the general chronology of the evaluation or Fitness Check and specify which DGs participated in the Steering Group and how many meetings of the group were held;
- **Consultation of the Regulatory Scrutiny Board (if relevant).** Briefly explain how the Board's recommendations have led to changes compared to the earlier draft. This should be presented in tabular format – the first column identifying the Board's recommendation and the second column how the Report has been modified in response;
- Explain which **evidence** has been used in the evaluation or fitness check together with sources and any issues regarding its robustness (i.e. has the information been quality assured?);
- **External expertise.** Describe how expert advice has been used in the process, including scientific expertise and/or use of Commission expert groups. Describe any studies/work carried out by external contractors, with references and internet links where available. The requirement to publish the QA of a supporting study (ies) can be fulfilled by the inclusion in the procedural annex of the evaluation SWD of summary text relating to the changes introduced following the QA, together with statements confirming the involvement of the ISG in the QA process.

Annex: Synopsis report of the Stakeholder consultation⁵⁴⁹

Annex. Methods and Analytical models used in preparing the evaluation/fitness check

A dedicated annex presenting the following information should be included:

- A description of the methods and approaches which have been deployed during the evaluation or fitness check. This should include as a minimum the evaluation matrix applied. Any differences between the actual evaluation matrix used and the one created at the start of the evaluation should be used to inform the section on limitations.
- Where appropriate, include a brief description of any models used which addresses:
- Model structure and modelling approach with any key assumptions, limitations and simplifications;
- Intended field of application and appropriateness for the specific impact assessment study presented;
- Model validation and peer review with relevant references;
- Citation of input data following good practices for data citation for maximum transparency;

⁵⁴⁹ For detail and content: see Tool #55 on *Informing policymaking – the synopsis report*

- The extent to which the content of the model and input data have been discussed with external experts;
- Explanation of the likely uncertainty in the model results and the likely robustness of model results to changes in underlying assumptions or data inputs;
- Explanation as to how uncertainty has been addressed or minimised in the modelling exercise with respect to the policy conclusions;
- The steps taken to assure the quality of the modelling results presented in the report;
- A concise description of the baseline(s) used in any modelling exercise in terms of the key assumptions, key sources of macroeconomic and socio-economic data, the policies and measures the baseline contains and any assumptions about these policies and measures (such as the extent to which they are deemed implemented by the Member States, or their estimated impact following implementation). Where the baseline deviates from the one identified in a prior impact assessment, the reasons for this should be clearly explained, including any related to changes introduced during the adoption process.

6. GOOD PRACTICE TIPS

- Given the importance of providing a good evidence base, all data and analysis should be clearly sourced and where necessary further detail provided in an annex.
- To be credible, evaluations need to state the findings clearly and not avoid being critical where relevant. The evaluation is a backward looking exercise. Therefore findings and conclusions have to be phrased so that it is clear what has been achieved and what is lacking. Avoid replacing this backward looking angle by forward looking recommendation for future inclusion e.g. writing that there is room for improvement when a lack of something has been observed. Care needs to be taken so that the phrasing of conclusions does not go beyond the limits of a SWD.
- The executive summary and the conclusions section of the SWD should both contain clear statements on the robustness and reliability of the data and analysis which form the basis of the evaluation, in order to reflect the common practice of reading either of them first.
- Compare what is being delivered in the final evaluation to what was agreed in the roadmap. It is easy to promise everything at the start of an evaluation and then find that it is not possible to deliver. Such limitations or variances from the plan should be clearly written up in the SWD.
- In cases where several evaluations of a repetitive nature with very similar content and structure are carried out (e.g. in case of certain funding instruments) it may be possible to cover them in a single SWD. This approach would need to be agreed in advance with the SG on a case-by-case basis.

TOOL #50. DISSEMINATING THE EVALUATION FINDINGS

1. WHAT IS DISSEMINATION?

Dissemination relates to the practice of communicating and promoting the active use of the evaluation and its findings to the widest possible audience. This is often done by drawing up a dissemination plan, which lists the different interested audiences and identifies where different summaries need to be written, tailored to the needs of the different groups.

2. WHY IS DISSEMINATION IMPORTANT?

The purpose of evaluations, namely to promote inputs to decision-making, organisational learning, accountability/transparency and efficient resource allocation, can only be achieved if the resultant information reaches all interested parties.

All relevant supporting deliverables from any external work and SWDs should therefore be disseminated in a manner suited to the potentially different audiences. Active discussion and debate on the evaluation and its eventual findings should be encouraged from an early stage. It is best practice to solicit feedback from stakeholders which can be taken forward in subsequent work such as an impact assessment.

To maximise transparency and access:

- The following files related to the evaluation must be published centrally (eventually in the Better Regulation Portal):
 - (1) The evaluation roadmap;
 - (2) (if applicable) terms of reference (or technical specification), final deliverables from contractors;
 - (3) The staff working document and (if applicable) its executive summary (in French, German and English);
 - (4) (if applicable) The Regulatory Scrutiny Board opinion.
- DGs may wish to consider establishing a dedicated webpage for each evaluation or fitness check within their associated general policy pages. Such pages can act as a dynamic communication tool, bringing together information and providing an update of progress both during the evaluation and after..
- All contractors' final reports (plus other relevant interim deliverables from external work) and staff working documents for evaluation should be published in a manner compliant with corporate guidelines⁵⁵⁰.
- Where appropriate, summary information from the evaluation should be included in the REFIT scoreboard.

⁵⁵⁰ https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/studies.aspx

3. GOOD PRACTICE TIPS

- Consideration should be given to the creation of a written dissemination plan which can be shared internally with interested parties;
- Don't wait till the end of the project to think about dissemination – it should be considered from the early stages of design;
- Where contractors are involved, it may be desirable to ask them to provide findings in different formats (e.g. PowerPoint presentations or videos, leaflets, different documents, using social media etc.);
- Contractors can be asked to give a presentation of their findings – sometimes they will even do this outside of the contract as it promotes their work.
- The final SWD, any relevant contractors' reports and data collected for the evaluation should be sent to the JRC which is creating a knowledge management tool that will maximise future use of the work done.

TOOL #51. FOLLOW-UP ACTION PLANS

1. WHAT IS A FOLLOW-UP ACTION?

Evaluation is not the end of the process. At the end of an evaluation, appropriate follow up actions must be identified and fed into the decision-making cycle.

Completing the SWD and disseminating findings should stimulate discussion of the evaluation findings. In turn, this should help identify 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 and recommendations should feed into the Annual Activity Reports and related follow-up actions should be identified in the Annual Management Plans of the Commission Services.

2. WHY IS FOLLOW-UP ACTION IMPORTANT?

Identifying what follow-up actions will take place is an important part of better regulation, often bridging the gap between retrospective evaluation and prospective actions, such as decisions to undertake an impact assessment, improve guidance etc. Identifying and sharing planned follow-up actions is part of accepting responsibility and accountability for EU actions and ensures transparency; it should also mean that evaluation findings are used and not simply filed on a shelf.

A good way to do this is to write a follow-up action plan, identifying the actions which the Directorate General has decided to take as a result of the evaluation and an indicative timetable. It is equally important to be clear where no action is foreseen and explain why that is the case.

In many instances, the Commission is requested in legislation to send its findings to the European Parliament and Council. Such a document, usually in the form of a Commission report to the Council and Parliament⁵⁵¹, should:

- Summarise the findings of the evaluation;
- Present the Directorate General's opinion on the quality and strength of the evaluation;
- Provide an outlook on the next steps.

3. GOOD PRACTICE TIPS

- It is recommended that within 6 months of the completion of the SWD, the Directorate(s) General concerned should agree any appropriate and more specific follow-up actions with senior management. The unit in charge of the evaluation should provide an (annual) progress update against the follow up actions identified and if necessary updated in the REFIT Scoreboard.

⁵⁵¹ See Tool #49 on *The staff working document for evaluation*.

- To ensure better ownership of the follow up actions, they should be drafted by the operational unit in charge of the policy. The evaluation function is likely to play a role in ensuring that it is implemented.
- Make sure evaluation fulfils its purpose – feed the results of an evaluation into the decision-making process, ensure lessons are learned and communicated.
- The degree of commitment presented in the follow up document will depend on several factors including the timing of its publication in respect to the Commission's strategic planning and programming cycle (e.g. commitments made in management plans, Commission Work Programme). It should in no case pre-empt results of a possible IA.
- The format of the follow up document is important – for example, if it is a staff working document, it cannot make any commitments for the Commission. For more information on the different types of documents and their roles see GOPRO.⁵⁵²
- Where a report to other EU institutions is required by the legislation, the document (report, communication) always has to be adopted by the Commission.
- Often the follow-up actions cannot be completely decided at service level because major policy changes require Commissioner/College endorsement. It may therefore be necessary to distinguish between policy follow-up and administrative-organisational follow-up, where the administrative part can be published more quickly.
- Each follow-up action should be assigned to a particular unit/individual and a target completion date agreed. There is no set format for such a plan – for example, it can be set up as a simple Excel table or Word document.

⁵⁵² <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Acts%20and%20documents>

TOOL #52. "BACK-TO-BACK" EVALUATIONS AND IMPACT ASSESSMENTS

1. INTRODUCTION

Ideally, evaluations and impact assessments should be conducted sequentially so that the results of the evaluation can be fully used in the subsequent impact assessment. This requires appropriate advance planning and may not always be possible. They may be carried out in parallel (in a so-called "back-to-back" manner) as a single process.

Ideally, the intention to conduct a back-to-back evaluation/IA should be clearly specified when the is presented for political validation.⁵⁵³

The text below describes the "back-to-back" process:

(1) Roadmap & inception impact assessment

One combined roadmap/inception impact assessment can be published. This is based primarily on the inception impact assessment but also incorporates elements of the evaluation roadmap⁵⁵⁴. The template is available from GoPro.

(2) Interservice group

A single interservice group (ISG) should be set up. This may be chaired by the Secretariat-General for important or sensitive initiatives or more usually by the lead DG or service.

(3) Conduct

The evaluation and impact assessment work will follow the usual steps. Any external work conducted to support the evaluation will remain subject to a Quality Assessment, discussed with the ISG.

(4) Stakeholder consultation

A single consultation strategy⁵⁵⁵ can be prepared. This strategy should be revised and adapted throughout the process to ensure that the necessary work is conducted to gather information from all the identified stakeholder groups to meet the evaluation and impact assessment requirements.

As usual, the consultation strategy should include a range of appropriate consultation activities. One single open public consultation can be used to support the back-to-back evaluation/IA and the scope of the open public consultation will necessarily reflect the stage reached in the (joint) process. There should, however, be a good mix of backward-looking and forward looking questions that address existing performance and the design of the new initiative.

⁵⁵³ See Tool #6 on *Planning and political validation*.

⁵⁵⁴ See Tool #7 on *Drafting roadmaps, evaluation roadmaps and inception impact assessments*

⁵⁵⁵ See Tool #53 on *The consultation strategy*

- In cases with limited overlap, it should be timed so that stakeholder views can be sought on the (validity of) emerging evaluation findings, together with views on the problems, objectives and possible options.

Only a single Synopsis Report⁵⁵⁶ needs to be drafted as part of the IA report unless the Regulatory Scrutiny Board has selected the evaluation for scrutiny.

(5) Evaluation SWD and the IA Report

For all fitness checks and evaluations selected for scrutiny by the RSB, the results of the evaluation must be presented in a stand-alone SWD, irrespective of the degree of overlap in the back-to-back process.

For other back-to-back evaluations/impact assessments the results of evaluation can be presented as an annex to the IA report. This new annex will follow the structure of an evaluation SWD, reporting as far as possible under each section. It should also explain why a back-to-back approach was taken and identify any limits or issues caused by overlaps in conducting the evaluation and impact assessment.

(6) Regulatory Scrutiny Board

When an evaluation is selected for scrutiny by the RSB, the Board will normally issue a separate opinion on it irrespective of whether it has been prepared "back-to-back" with the impact assessment. A separate evaluation SWD is always required in such cases as well as a separate slot in the Board's rolling activity (meetings) plan. If there are imperative and well-justified timing constraints, the RSB may consider the evaluation SWD and the IA report at the same meeting but in two separate slots. In those cases, the Board will usually still issue a separate opinion on the evaluation SWD.

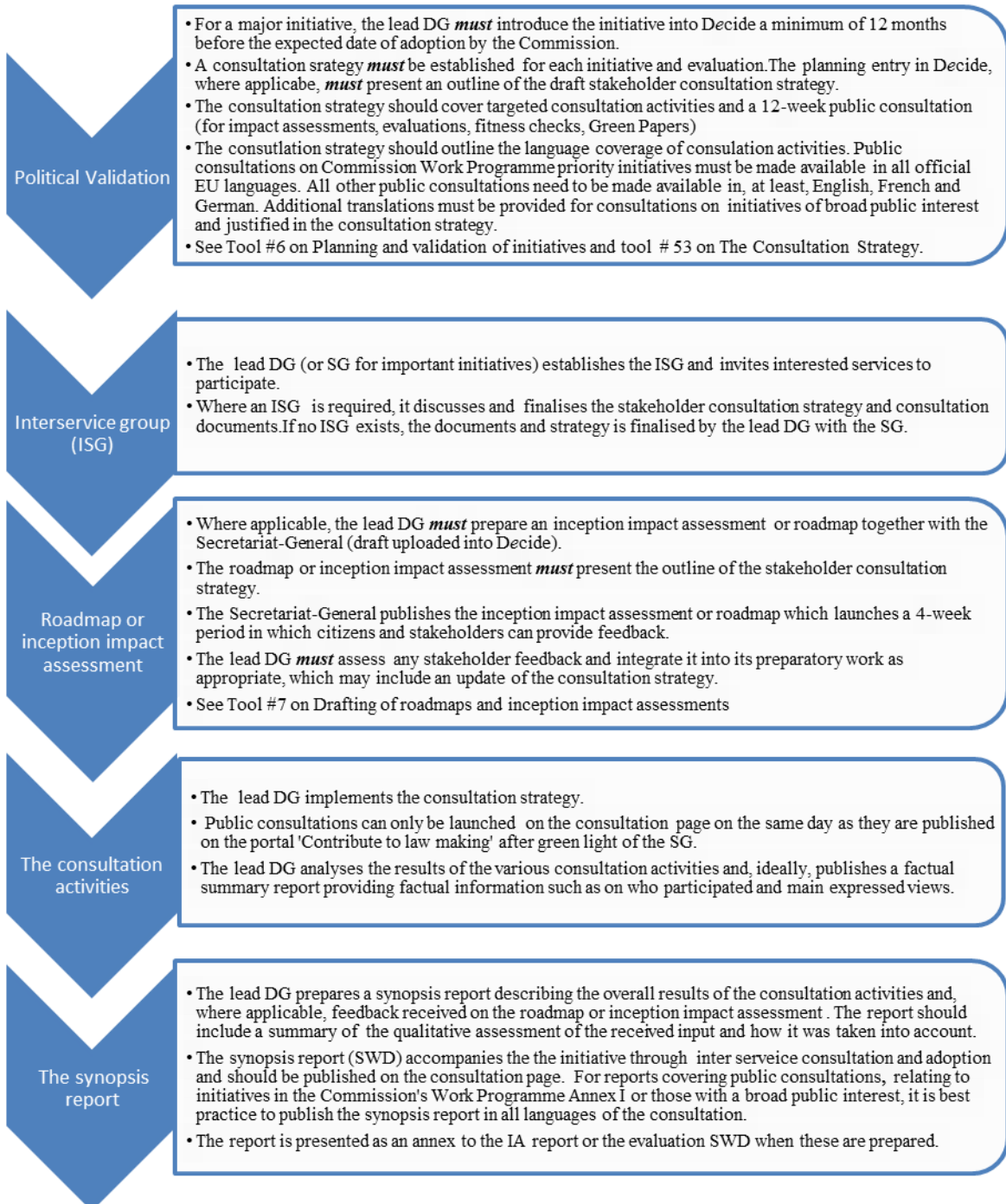
For back-to-back evaluations not selected for scrutiny by the RSB, the findings of the evaluation may be presented in a self-standing SWD or annexed to the IA report. In either case, the findings will be scrutinised by the RSB as part of its scrutiny of the IA report.

⁵⁵⁶ See Tool #55 on *Informing policymaking – the synopsis report*.

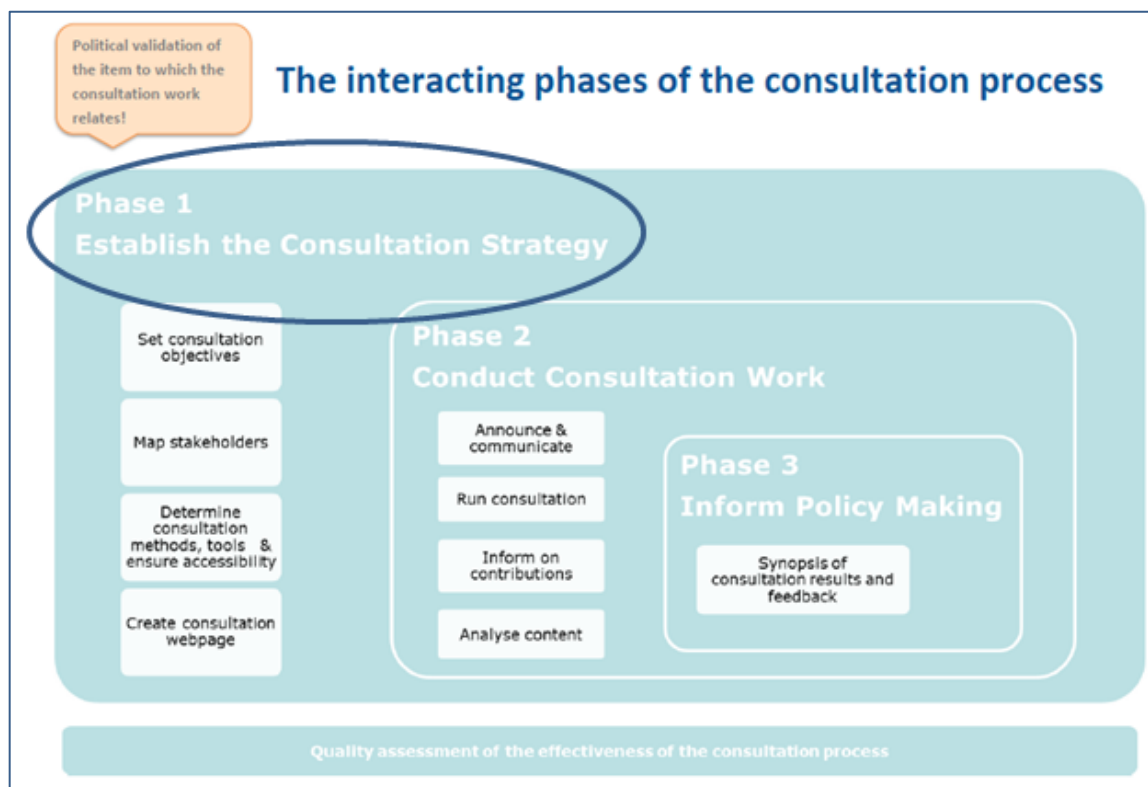
Chapter 7

Stakeholder consultation

Key steps and requirements for stakeholder consultation



TOOL #53. THE CONSULTATION STRATEGY



Box 1. The consultation strategy – Key elements

- A consultation strategy is a key requirement for each initiative, including those accompanied by an impact assessment (IA), evaluation and fitness check and should build on the overall mapping of available evidence and identified gaps.
- The consultation strategy should cover the following key elements: consultation scope and objectives, identification of stakeholders, envisaged consultation activities, their timing and language regime.
- A draft consultation strategy should already be prepared when requesting political validation as the political validation covers required better regulation instruments.
- After political validation, the consultation strategy should be finalised and endorsed by the interservice group, or if no interservice group is established or if no roadmap/inception impact assessment is needed by the Secretariat-General and, where relevant, associated DG's.
- The key elements of the draft consultation strategy should be outlined in the roadmap/inception impact assessment in order to inform stakeholders and to invite them for feedback.
- When the 4-weeks feedback period on the roadmap/inception impact assessment has ended, where relevant, the consultation strategy should be updated based on received

feedback.

- In case of a "back-to-back"⁵⁵⁷ approach a single consultation strategy for the evaluation and IA work is sufficient.
- The consultation strategy should be published or described on the consultation website of the related initiative, evaluation or fitness check.
- When designing the consultation strategy, human and financial resource planning for preparing, conducting and processing the consultation should be considered.
- Planned consultation activities need to be included into the planning module of Decide and the consultation planning calendar.

1. INTRODUCTION⁵⁵⁸

Consulting stakeholders is an important instrument to collect information for evidence-based policymaking. Their views, practical experience and data will help deliver higher quality and more credible policy initiatives, evaluations and fitness checks. It also ensures greater transparency and legitimacy of the policy development process and contributes to a more successful policy implementation.

The purpose of the consultation strategy is to design an effective and efficient consultation approach. It should build on the overall mapping of *available* and *needed* information for a specific initiative, evaluation or fitness check and be fed by a thorough and structured desk review of relevant sources.⁵⁵⁹ The consultation strategy should aim to ensure that all relevant evidence is taken into account, including data about costs, about societal impact, and about the potential benefits of the initiative. Evidence collected from stakeholders should complement evidence obtained from other sources.

Designing a consultation strategy is a key requirement for each initiative, evaluation and fitness check. Already when requesting the political validation⁵⁶⁰ the political level should be informed about the intended better regulation instruments⁵⁶¹ to be used including planned data collection and consultation activities.

This means that the key elements of the draft consultation strategy should already be outlined at the time political validation is requested and be included in the Roadmap or IIA. This is particularly important as through the Roadmap/IIA stakeholders are informed at an early stage about the initiative and planned consultation activities. This allows them to plan ahead and prepare their participation in subsequent consultation activities. In addition, stakeholders have the opportunity to comment through the feedback mechanism on the appropriateness of the data collection and consultation approach.

⁵⁵⁷ See Tool #52 "*Back-to-back*" evaluation and impact assessment.

⁵⁵⁸ See conceptual background in the Guidelines chapter VII paragraph 6.1.

⁵⁵⁹ See Tool #4 on *Evidence-based better regulation*.

⁵⁶⁰ See Tool #6 on *Planning and validation of initiatives*.

⁵⁶¹ See part I of the Guidelines: better regulation essentials

The consultation strategy should be developed in parallel with the roadmap or inception impact assessment (where applicable) and be endorsed by the interservice group. If no interservice group is established or no roadmap/inception impact assessment is required this is done by the Secretariat General and, where relevant, interested DG's.

When the 4-weeks feedback period⁵⁶² for the roadmap or inception impact assessment has ended, the consultation strategy should be updated by considering provided feedback. .

This tool provides methodological guidance on the systematic conception and identification of the key elements to be covered in the consultation strategy: the consultation scope and objectives, the stakeholder groups, the envisaged consultation activities and their timing and language regime. **It is recommended to use the consultation strategy template available on GoPro.** The better regulation support functions in the DGs, as well as SG-C.4⁵⁶³ can provide support to the drafting of the consultation strategy.

The consultation strategy⁵⁶⁴ should be published or described on the consultation website of the relevant initiative, evaluation or fitness check. The consultation strategy may need to be updated in the course of the preparatory process of an initiative, evaluation or fitness check.

Planned consultation activities need to be included in the planning module of Decide and the consultation planning calendar. As soon as the planning of a consultation is known, the key information should be provided to SG.C4 via the [EU survey tool](#)⁵⁶⁵ or via Decide as soon as the 'consultation tab' in the Planning section becomes available.

2. SETTING CONSULTATION SCOPE AND OBJECTIVES⁵⁶⁶

Box 3. Consultation scope and objectives – key elements⁵⁶⁷

- Be clear from the outset about what is 'in-scope' and 'off-scope' due to legal or political limits.
- Map the available sources and information in a concrete and topic related way. This

⁵⁶² See Tool #56 on *Stakeholder feedback mechanisms*.

⁵⁶³ To be contacted via the functional mailbox: SG STAKEHOLDER CONSULTATION

⁵⁶⁴ Either the strategy document or the content of the strategy as information embedded in the website

⁵⁶⁵ https://ec.europa.eu/eusurvey/runner/Planning_Calendar

Note: By end 2017 the information on planned consultation activities will be automatized by means of the Better Regulation Portal. Relevant information will need to be submitted via Decide.

⁵⁶⁶ See conceptual background in the BR-Guidelines chapter VII.

⁵⁶⁷ Practical examples for systematic scoping is available on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

includes also a check of past, but still valid stakeholder consultation work.

- Identify information gaps and the type of information needed for each topic: quantitative data or qualitative data.
- Decide which sources should be used to obtain the missing information.
- Define the concrete and topic related scope of stakeholder involvement.
- Pay attention to sensitive, controversial or highly uncertain issues.
- Be aware of potential blind spots that consultation work should detect.
- Depending on the type of initiative, consider the following:
 - If an **impact assessment** supports the preparatory work the consultation work, including the public consultation, should cover the four key elements of an impact assessment: the problem to be tackled, subsidiarity and the EU dimension to the problem, the policy options and their likely impacts. In addition it should address as well the scope for regulatory cost reduction and simplification measures not affecting the achievement of objectives.
 - If an **evaluation** or **fitness check** is carried out the consultation work should contribute to the subsequent analysis of the five evaluation criteria: effectiveness, efficiency, EU added value, relevance and coherence.
 - In case of the "**back-to-back**"⁵⁶⁸ approach the stakeholder consultation work should cover the five evaluation criteria and the four key elements of an IA.
 - For **initiatives** not supported by an IA nor related to an evaluation or fitness check the consultation work can focus on any element/issue identified in the consultation strategy on which stakeholders should be consulted. It is recommended to follow a similar approach as for consultation activities supporting IAs.

2.1. Introduction

The consultation scope and objectives should be determined based on the scope and content of the new initiative or evaluation.

Depending on the stage in the policymaking process, different aspects should be considered.

For each aspect, concrete themes or topics should be identified that are subject of the policy preparation or evaluation work. Decide for each topic if views and information should be collected, or rather already existing analysis and evidence be tested and

⁵⁶⁸ See Tool #52 on "*Back-to-back*" evaluation and impact assessments.

validated. Clarify if quantitative and/or qualitative data⁵⁶⁹ are needed as this is necessary, at a later stage, for the selection of the appropriate consultation methods and tools⁵⁷⁰.

Check also if there are sensitive or controversial issues, potential diverging views or high uncertainties which need special attention. Don't ignore the 'elephant in the room' Consider and address any relevant input. Ignoring issues entails the risk that they re-appear at a later stage.

Consider that there may be issues/blind spots that you might not be aware of (e.g. due to unintended consequences), but which the consultation work can unveil. The strategy should offer stakeholders the opportunity to raise these issues (e.g. through open questions in a questionnaire or the possibility to upload further material).

Be clear about the topics that are 'off-scope', either due to lack of EU competencies or legal limits (e.g. Treaty provisions) or due to the limited scope set at political level.⁵⁷¹

2.2. Stakeholder consultation in the context of an Impact Assessment

Consultation activities in the context of an IA, including public consultation, should cover the key elements to be addressed in the impact assessment: the problem definition, the subsidiarity and the EU dimension to the problem, possible policy options and their likely impacts. When modifying existing interventions, the scope for efficiency improvement (regulatory cost reduction) and simplification measures not affecting the achievement of objectives should also be covered.

The consultation is usually based on consultation documents rather than the draft legal text, which comes only late in the policymaking process. These consultation documents may include background information, existing evidence and ideas related to the key elements to be addressed in the IA and a questionnaire aiming to collect views and information of stakeholders on these key elements or to test/validate already existing analysis. The stakeholder contributions feed into the IA and help shaping of the draft legal text.

Given the variety of Commission initiatives accompanied by an IA, there is no one-size-fits-all solution on how to consult, in what time sequence and at which stage of the IA process. However, the consultation strategy should include a wide-ranging, open internet based consultation for all IAs as it ensures transparency and accountability and gives any interested party the possibility to contribute. This can be complemented with more

⁵⁶⁹ See Tool #4 on *Evidence-based better regulation*.

⁵⁷⁰ See information on consultation tools and their appropriateness for collecting quantitative information on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁵⁷¹ If the decision to establish a specific EU instrument has been taken by the political level (e.g. Commission decision) – consulting on the type of instrument is thus 'off-scope'. Consultation work should be focussed on the content. Or, if the Commission announced in a Communication a mandatory approach, consultation work should not check stakeholder opinion on the mandatory nature of the approach, but focus on the content. The pure announcement of an intention of an individual Commissioner without College endorsement may not be seen as political limit.

targeted or specialised consultations of particular stakeholder groups or experts, which can be more relevant to gather specific technical input in relation to the IA questions⁵⁷².

Box 4. Type of questions for key IA elements

Objective/ element	Problem	Subsidiarity	Options	Impacts
Testing preliminary analysis	Magnitude/importance of the problem for the groups of affected stakeholders? Identification of risk, uncertainty?	EU dimension of problem? International engagements?	Coverage of options? Implementation arrangements and roles of actors?	Magnitude of impacts, disproportionate impacts? Indirect impacts?
Collection of views/information	Nature of problem and its drivers? Sources of diverging views? Lessons learned?	National intentions or objectives? Solutions at national, regional or local level?	Mitigating measures? Alternative solutions? Feasibility of options?	Unintended consequences? Impacts (positive and negative) that have not been accounted for?

2.3. Stakeholder consultation in the context of an evaluation or fitness check

Consultation activities in the context of an evaluation or fitness check should contribute to the subsequent analysis of the five evaluation criteria: effectiveness, efficiency, EU added value, relevance and coherence.

A consultation is usually based on consultation documents which may include background information and existing evidence related to the evaluation criteria and a questionnaire aiming to collect views and information of stakeholders or to test/validate already existing analysis. The stakeholder contributions feed into the evaluation staff working document.

Given the variety of evaluations, there is no one-size-fits-all solution on how to consult and at which stage of the evaluation process. However, the consultation strategy should include a wide-ranging, open internet based consultation for all evaluations and fitness checks as it ensures transparency and accountability and gives any interested party the possibility to contribute. It is important to note that the overall consultation exercise should always address both the costs and benefits of the legislation subject to the evaluation or fitness check.

In practice, the consultation strategy for the evaluation or fitness check will include a combination of consultation methods (i.e. open/targeted) and tools (i.e. questionnaire, document, meeting, hearing, and workshop)⁵⁷³.

⁵⁷² For more detail see paragraph 4 'Determine the Consultation Methods, Tools & ensure Accessibility'

⁵⁷³ For more detail see paragraph 4 'Determine the Consultation Methods, Tools & ensure Accessibility'

3. STAKEHOLDER MAPPING

Box 5. Stakeholder mapping – key elements

- Identify all stakeholder categories relevant for or interested in the policy area concerned.
- Sort stakeholder groups according to the level of interest in and level of influence on the initiative to be consulted upon.
- Do not limit mapping to the 'obvious' stakeholders, identify target groups that run the risk of being excluded –underserved groups–.
- Make use of existing stakeholder lists gathered during previous consultation or in the context of networks, expert groups, stakeholders listed in the Transparency Register, etc.

3.1. Introduction

Knowing **who** the stakeholders are that should be consulted is an essential prerequisite for successfully collecting necessary information and providing appropriate opportunities for stakeholders to contribute to the EU's policymaking and evaluation work.

While the "obvious" stakeholders of a policy or sector may be well known, it is important to fine-tune and tailor the stakeholder mapping to the concrete initiative or evaluation: While different initiatives in the same sector may have similar/common key stakeholders, concrete impacts and implementing issues may concern additional stakeholders that also need to be addressed.

Thus, it is essential to:

- Find out if there are other stakeholders affected besides the 'obvious' stakeholders.
- Specify who they are.

This can be done in two successive steps:

- (1) **Identification** of stakeholders;
- (2) **Sorting** of the identified stakeholders according to their level of interest and influence.

The following guidance is of purely methodological nature and not exhaustive. Other methods may be more suitable, depending on the specific needs for a certain policy sector.

3.2. Identification of Stakeholder Groups

The stakeholder mapping stage should purely focus on the 'who', and not yet look at 'how' to address them, which is the next step.

The identification of the concrete stakeholders to be consulted can be done in an unstructured and/or structured way.⁵⁷⁴ The table in box 6 gives an overview of the main stakeholder categories of the Commission.

⁵⁷⁴ The JRC Policy LAB can provide support: <http://blogs.ec.europa.eu/eupolicylab/>

Box 6: Stakeholders categories⁵⁷⁵ (non-exhaustive list):	
Citizens	• Individual persons responding on their own behalf
Businesses⁵⁷⁶	• Large-sized enterprises • SMEs • Microenterprises • Self-employed
Trade, business and professional associations	• Chambers of commerce • Business organisations • Trade Unions • Representatives of professions or crafts
Non-governmental organisations	• Non-governmental organisations • Platforms • Networks • Similar associations
Consultancy	• Professional consultancies • Law firms • Self-employed consultants
Research and academia	• Think tanks • Research institutions • Academic institutions
Organisations representing regional, local and municipal authorities, other public or mixed sub-national entities	• Regional, local or municipal structures • Other sub-national public authorities • Transnational associations and networks of public sub-national authorities • Other public or mixed entities, created by law whose purpose is to act in the public interest
National and international public authorities	• National governments • National Parliaments • National public authorities or agencies • EU institutions, bodies or agencies • Intergovernmental organisations⁵⁷⁷

It might be useful to start with a brainstorming: just list those people, businesses or organizations who may be affected by the policy, who have influence on or an interest in its conclusion or revision. Discuss who has relevant information and expertise and who is responsible for implementation or application of a policy.

The brainstorming should be complemented by a more structured approach:

⁵⁷⁵ Organisations and businesses eligible to register in the Transparency Register that choose not to register should be considered as a separate category "non-registered organisations/businesses"⁵⁷⁵ unless they are recognised as representative stakeholders via relevant Treaty provisions⁵⁷⁵.

⁵⁷⁶ For the identification of the business size please consult the [User guide to SME identification](#)

⁵⁷⁷ Definition of [Intergovernmental organisations](#)

- Use available contact information gathered during previous consultation work or in the context of, networks, expert groups, newsletter subscriptions, stakeholders registered in the Transparency Register ⁵⁷⁸ etc.
- Analyse social media⁵⁷⁹ ('Social listening') to identify stakeholders: who discusses the issue, where are they, what are their concerns, how big is their influence⁵⁸⁰ and outreach. Apart from the identification of stakeholders, this may already provide information on expected campaigns, are welcomed but may need special attention.
- Stakeholders can also be assessed systematically according to guiding questions as e.g. suggested in the 'Six tests', or by certain criteria like the level of interest (see mapping matrix below).

3.2.1. The 'Six tests for Stakeholder Identification'

This stakeholder identification tool consists of six questions with a set of sub-questions, which can be used for a structured approach to identify stakeholders (see box 8).

It helps to list those that are impacted, needed for implementation and having expertise and/or interest in the subject⁵⁸¹.

Box 7: The Six Tests for Stakeholder Identification⁵⁸²
Test 1 Who is directly impacted?
• Whose daily/weekly lives will change as a result of this policy? • Who cannot easily take steps to avoid being affected by this policy? • Who will have to change their behaviour as a result of this policy?
Test 2 Who is indirectly impacted?
• Whose daily lives will change because others have been directly impacted by the policy? • Who will gain or lose because of changes resulting from this policy?
Test 3 Who is potentially impacted?
• In particular circumstances, who will have a different experience as a result of this decision? • Are there individuals or groups who will have to adjust their behaviour if particular conditions apply?

⁵⁷⁸ <http://ec.europa.eu/transparencyregister/public/homePage.do>

⁵⁷⁹ Social media analysis tools can be used. Some examples: <http://www.socialbakers.com/>; <https://twitter.com/search-advanced?lang=en>; <http://www.sentiment140.com/>; <http://buzzsumo.com/>; <https://moz.com/followerwonk/>; <https://crowdcontrolhq.com/>

⁵⁸⁰ The identification of the level of influence of somebody and of their followers is beside the identification of linked interested persons or groups also important for the later outreach of the concrete consultation activities, e.g. <https://klout.com/corp/about>; <http://www.marketingcloud.com/products/social-media-marketing/radian6/>

⁵⁸¹ It can be complemented by the 'Circles of Stakeholder Interest' which allows to better fine-tune the level by which certain stakeholders are concerned, more info on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁵⁸² Source: The Consultation Institute, London (Bedfordshire)

Test 4 Whose help is needed to make it work?
• Are there vital individuals or groups in the delivery chain? • Who will have the ability to obstruct implementation unless co-operating? • Who understands the likely impact of this decision on other stakeholders?
Test 5 Who thinks they know about the subject?
• Who has studied the subject and published views on it? • Who has detailed know-how that those implementing the policy should also understand? • Are there individuals or groups that will be perceived as knowledgeable on the subject?
Test 6 Who will show an interest in the subject?
• Are there organisations or individuals who think they have an interest? • Has anyone been campaigning about the issue? • Is there anyone publishing or broadcasting views on this subject?

3.3. Sorting of stakeholders

The second step of stakeholder mapping is the sorting of the identified stakeholder categories:

- **Distinguish stakeholders groups** which **may be affected** by the concrete initiative (both directly and indirectly) in a significantly different way and **determine the level of interest** of these groups;
- **Differentiate the potential different ways stakeholders are affected within a specific stakeholder group** e.g. depending on the size, location, type of activity, or other characteristics.
- **Determine the level of influence** of the identified stakeholders to show the relative influence that different stakeholders have over policymaking and its evaluation.

3.3.1. Stakeholder Mapping Matrix⁵⁸³

Establishing a stakeholder mapping matrix combines insights on the level of influence and the level of interest on the issue consulted on.

To identify **the level of interest** the following guiding questions could be used:

- How close is the issue to the main purpose/role of the stakeholder (proximity test)?
- If a meeting were held tonight, how prominently would it feature on the stakeholders' agenda (agenda test)?
- What is the history of the stakeholder's involvement with this issue?
- How many of the stakeholder's active members are directly affected?

⁵⁸³ Source: Consultation Institute

- At 'worst case' how affected might the stakeholder be?

To identify **the level of influence** the following guiding questions could be used:⁵⁸⁴

- Does the status of the stakeholder confer upon any particular legitimacy or relevance (status test)?
- Is the stakeholder's leadership regarded as personally influential (VIP test)?
- Is there evidence this stakeholder has wide popular following?
- How effective is the stakeholder in using press relations or new technology to publish views?
- What is the stakeholder's track record?
- Has the stakeholder successfully persuaded decision-makers in the past?

Building on e.g. the abovementioned 'Six-tests' the various stakeholders can be attributed to four groups based on the identified influence stakeholders have on policymaking and the interest of stakeholders in the policy matter (see figure 1):

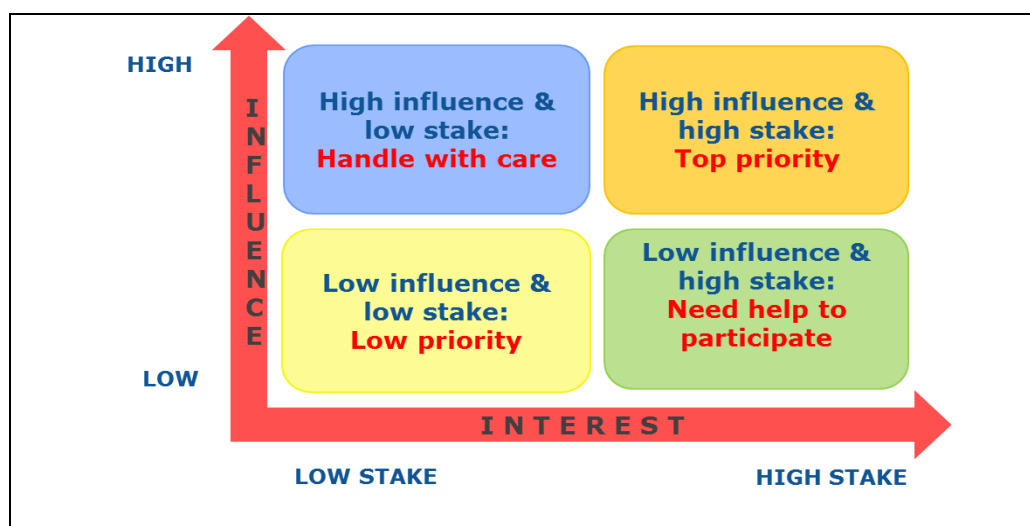


Figure 1: Stakeholder Mapping Matrix

The level of interest combined with the level of influence is important for selecting the appropriate consultation approach. For each stakeholder type, the following issues should be considered:

High influence and low stake:

- Relationship is paramount;
- Use high visibility methods;
- Watch out for increased interest.

High influence and high stake:

⁵⁸⁴ It can be complemented by the 'Pyramid of stakeholder influence' which allows to better fine-tune the level of influence of stakeholder groups, more info on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

- Use well informed communicators;
- Use high-capacity methods;
- Ensure transparency.

Low influence and low stake

- Acknowledge right to participate;
- Easily accessible methods;
- No discrimination.

Low influence and high stake

- Find them and understand them;
- Choose stakeholder specific methods;
- Positive discrimination.

The stakeholder mapping provides important information for the next step: the selection of the appropriate consultation activities.

4. DETERMINE THE CONSULTATION METHODS & TOOLS AND ENSURE ACCESSIBILITY

Box 8. Key elements for the selection of consultation activities & accessibility:

- The most appropriate consultation activities depend on the nature of the initiative, the scope of the consultation, the identified stakeholders, as well as on time and resources required and available.
- If you do an IA, an evaluation or a fitness check, it is mandatory to include a 12-week internet-based public consultation in your consultation strategy as it ensures transparency and accountability and gives any stakeholder the possibility to contribute. This should be complemented, where appropriate, by other consultation activities in order to engage all relevant stakeholders and to target potential information gaps.
- In case of a "back-to-back"⁵⁸⁵ approach to evaluation and IA a single 12-week internet based public consultation is sufficient which should be complemented by appropriate other targeted consultation activities.
- Plan early ahead and consider the timing and sequencing of the proposed consultation work and operational arrangements (i.e. internal and external resources, translations⁵⁸⁶ etc.).
- All consultation work, including any activity outsourced to contractors, should follow the Commission's better regulation Guidelines.
- Ensure adequate language coverage for consultation activities according to the scope

⁵⁸⁵ See Tool #52 on "Back-to-back" evaluation and impact assessment.

⁵⁸⁶ DGT should be contacted as early as possible so that language needs of the target audience(s), length of documents, timing and available translation resources can be properly assessed and taken into account

and outreach of the activity⁵⁸⁷.

- Ensure that persons with disabilities can participate in consultations on an equal basis
- Determine a communication plan as part of the consultation strategy in order to ensure that relevant target groups are reached in the most effective way. It should identify adequate communication actions in function of the identified consultation objectives, targeted stakeholders and consultation activities. (possible action: social media, web, face-to-face, press, publications, etc.)

4.1. Selection of consultation method and activities

4.1.1. Public consultation versus targeted consultation

Public and targeted consultations are generally the two methods for carrying out consultations.

Box 9. Open public consultation and targeted consultations

Public consultation

- Gives unlimited ("self-selected") access to everybody who wishes to contribute.
- The most common tool is a web based consultation (questionnaire).

Targeted consultation

- A targeted consultation activity addresses specific well-defined stakeholder groups and invites them to participate.
- A targeted consultation can be embedded in a web-based public consultation containing specific parts addressed to particular stakeholder groups.
- In a restricted targeted consultation activity, stakeholders are pre-selected and only the explicitly invited stakeholder groups or individuals can participate in the consultation activity (e.g. focus group or workshop). If an internet based activity is carried out, the identification part could only allow the targeted groups to participate. Access rights can be managed with EU login.

In case of a restricted targeted consultation the criteria of selecting the stakeholders as well as information on who has been selected and to what stakeholder group they belong should be transparent and mentioned on the consultation page.

4.1.2. Exploratory consultations

Box 10. Exploratory consultations – key elements

- Exploratory consultations may be needed in those rare cases where essential information is missing that prevent the Commission from making basic conceptual

⁵⁸⁷ See table 4 of Tool # 53 'The Consultation Strategy' and Better Regulation Guidelines, Chapter VII box 'key requirements'

choices.

- The SG is available to help assessing if an intended consultation could be of exploratory nature.
- Exploratory consultations need to be part of the DG work plan and validated at DG level.
- The DG takes full responsibility for the preparation, organisation and follow-up of the consultation activity. This includes its announcement on the policy website, the publication of contributions or a narrative of them, and information on the way forward and next steps.
- Where relevant, associated DGs should be informed or consulted on consultation documents (background papers, questionnaires, etc.) and be kept informed on the outcome of the consultation.
- Exploratory consultations do not waive formal consultation requirements in case they trigger the preparation of a concrete Commission initiative. Information on the exploratory consultation should be incorporated in the scoping part of the consultation strategy of the new initiative.

Usually, formal stakeholder consultation takes place in view of informing the concrete preparation of an initiative or an evaluation or Fitness Check. This type of formal stakeholder consultation is *linked* to a Commission initiative under preparation or in case of an evaluation to an existing policy. In these cases, the establishment of a consultation strategy is necessary and the procedural and methodological requirements of the better regulation Guidelines apply.

However, in rare cases it may be necessary to enter into a formal dialogue with stakeholders to explore a subject for which very limited information is available. Such "exploratory consultations" can provide further information, which may be necessary to take basic conceptual decisions.

"Exploratory consultations" are thus of preliminary nature, do not yet address the broad public, but are targeted to those that 'have the information'. They may provide insights to determine if any problem exists and could be addressed by EU action, or sketch the potential scope of a genuinely new policy. It thus may contribute to the agenda setting of the Commission. They can help identifying how far the Commission should invest in further studies and consultation work on a specific topic and are carried out before validation for a concrete new initiative is sought and before stakeholder consultation *linked* to a concrete initiative takes place – e.g. they may feed the design of a Green Paper.⁵⁸⁸

On the other hand, a consultation is not of exploratory nature simply because it is carried out very early in a policy preparation process or because targeted consultations are complemented by public consultation work.

⁵⁸⁸ Green Papers are documents published to stimulate discussion on given topics at European level. They invite the relevant stakeholders to participate in a consultation process and debate on the basis of the proposals they put forward. Green Papers may give rise to legislative developments that are then outlined in White Papers

"Exploratory consultations" for evaluations and Fitness Check do not exist by definition, i.e. due to their preliminary character described above.

4.1.3. Consultation activities

Based on the scoping and stakeholder mapping for the concrete policy initiative, evaluation or Fitness Check the most appropriate consultation activities should be identified.

There is no one-size-fits-all solution regarding the type of consultation activities and moment in the policy preparation or evaluation process when they should take place. Also, not all identified stakeholders need to be addressed in every consultation activity, but all stakeholders should have the opportunity to contribute somehow.

However, following the scoping and stakeholder mapping steps, information should be available which allows identifying the most appropriate:

- Mix of public and targeted consultations
- Sequence of consultation activities
- Degree of interactivity for the various stakeholder groups – see table below
- Level of effort needed to stimulate contribution of stakeholders with low influence - this includes accessibility⁵⁸⁹ considerations like language regime and participation of citizens with disabilities

An external service provider or a facilitator⁵⁹⁰ (who should comply with the minimum standards for stakeholder consultation and follow the Guidelines) might be considered for certain consultation work. It should be carefully checked that the contractors involved have no interest in the policy area which is subject to consultation and can operate in an independent way on behalf of the Commission.

If you do an IA, an evaluation or a fitness check, it is mandatory to include a 12-week internet-based public consultation in your consultation strategy as it ensures transparency and accountability and gives any stakeholder the possibility to contribute. This should be complemented, where appropriate, by other consultation activities in order to engage all relevant stakeholders and to target potential information gaps. Where the initiative concerns an evaluation of an activity conducted outside the EU or where the internet is not a the most appropriate support tool, an exemption to the mandatory public consultation may be justified as long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. In this case, an exemption should be requested to the SG⁵⁹¹.

⁵⁸⁹ See paragraph on accessibility further down in this tool.

⁵⁹⁰ The JRC.I.2 Policy lab and the 'Community of participatory management' is available to facilitate participatory stakeholder consultation activities like workshops, conferences, policy labs.

⁵⁹¹ For the exemption procedure see Tool # 1: *Principles, procedures and exceptions*

Table 1 below shows the degree of interactivity of certain consultation activities and feedback mechanisms and indicates how they respond to certain consultation objectives at the various stages of the policy cycle.

Table 1: Degree of interactivity with stakeholders regarding objectives and stages of the policy cycle

			
	INFORM and ENABLE FEEDBACK	CONSULT (written)	CONSULT and INVOLVE (based on direct interactions)
Objectives	Provide information to interested parties on Commission plans: • Give a first indication on the issues at stake, why the EU should address them • Keep interested parties informed on when their input will be expected	Obtain input from interested parties on issues at stake, possible solutions and impacts: • Collect views, new ideas, evidence, data • Validate analysis, test hypotheses	Obtain input from interested parties on issues at stake, possible solutions and impacts: • Discuss directly with stakeholders to make sure their points are fully understood • Allow for exchange of views between different stakeholder groups • Facilitate consensus seeking or deliberation
Instruments & activities	• Roadmap/ Inception IA • Calendar of planned public consultations on • Alerts sent by Transparency Register or "Commission at work" notifications	• Public consultation • Consultation tools targeted at specific consultation groups	• Stakeholder meetings, workshops, seminars • Stakeholder conferences, public hearings, broad events • Expert/focus groups
		 Consultation documents and questionnaires	
	Early stages of policy preparation & planning	Policy preparation (development and revision of policies) Policy application (evaluation of policies)	

4.2. Frequently used consultation activities

Table 2 presents frequently used consultation activities and their use. Table 3 gives indications on the potential of consultation activities to collect different types of information: the collection of factual data, the validation of analysis, gathering expertise or information, understanding views and opinions and validating information.

Table 3 also indicates how far they cover characteristics like the level of interactivity, accessibility, transparency and statistical representativeness.

Note that when stakeholder consultation is used for **collecting information** (i.e. evidence such as data, expertise etc.), it should be *verified* if the method used is appropriate for collecting the required type of information in view of its reliability, accuracy etc.⁵⁹².

⁵⁹² See Tool # 4 on *Evidence-based better regulation*.

Tailored information on most frequently used consultation activities is provided by means of overview fiches available on GoPro⁵⁹³.

Table 2: Use of consultation activities (in alphabetical order)

Activity	Used to:
Conferences, public hearings & events	Gather input from a larger number of targeted stakeholders through direct interaction.
Eurobarometer Surveys	Gather views of European citizens through representative samples of targeted populations. Can also target professional stakeholders (e.g. in-depth studies).
Expert groups of the Commission	Gather inputs and advice from experts on a well-defined mandate.
Focus groups	Gather information through group discussion of citizens/stakeholders with similar features.
Interviews	Collect information via in-depth, more or less structured conversations with individuals.
Public consultations	Gather inputs from a broad range of stakeholders through different instruments. Mandatory for impact assessments, evaluations, fitness checks, Commission Communications launching a consultation process and Green Papers.
Consultations targeting SME's - SME panel	Gather information directly from SMEs via the Enterprise Europe Network, managed by DG GROW.
Workshops, meetings and seminars	Collect specific information from targeted stakeholders through direct interaction.

Table 3: Consultation activities: their information potential and characteristics

Consultation activity	Information potential ⁵⁹⁴						Characteristics			
	Collect factual data	Validate analysis	Gather expertise	Gather information	Understand views and opinions	Validate information	Level interactivity	Access ibility	Transpa rency	Statistical representa tiveness
Conferences, Public hearings, Events	○	●	○	●	○	○	●	○	○	○
Eurobarometer Surveys	○	○	○	○	○	○	○	○	○	●
Expert Groups	●	●	●	●	○	●	●	○	●	○
Focus Groups	●	●	○	●	●	●	●	○	○	○
Interviews	●	●	○	●	○	○	●	○	○	○
Public Consultations	●	○	●	●	●	○	○	●	●	○
SME Panel	○	○	○	●	○	●	○	○	●	○
Workshops, Meetings & Seminars	●	●	○	●	●	●	●	○	○	○

Level of information potential/impact on characteristic: ●=high ○=medium ○=low

⁵⁹³ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁵⁹⁴ When stakeholder consultation is used for collecting evidence (e.g. factual data, expertise etc.), there is a need to verify that the method used is correct and appropriate for collecting the required type of evidence.

4.3. The SME dimension in a public consultation

Public consultations can target SMEs either directly or through their representative organisations. These two channels have different characteristics and needs. While the latter usually have experience in participating in Public Consultations, individual SMEs will probably reply only if they are made aware of the launch of a specific OPC and if the subject is particularly relevant for their business. It is advisable therefore:

- To devise different questionnaires for these two types of respondents (as two different questionnaire web links on the OPC main page).
- Not to mix the two channels when analysing the OPC replies.

Detailed guidance on preparing consultations targeting SME's is provided in the specific fiche available on GoPro⁵⁹⁵.

4.4. Accessibility of consultations including language regime

Consultations should be planned and conducted in such a way that all stakeholder groups can participate easily and effectively. A key aspect for accessibility relates to the language regime of consultation activities. **It is essential to ensure adequate language coverage of the consultation activity.** The table below provides information on linguistic accessibility, accessibility of activities and consultation channels, and timing and consultation periods.

Table 4. Accessibility of consultations	
1. Linguistic accessibility	
Language regime	• In general, ensure that consultation documents are translated into as many languages as feasible and appropriate in accordance with the scope and outreach of a consultation. While highly technical consultations could be conducted in English or a few languages only, especially consultations reaching out to non-expert stakeholders or citizens in general should be translated into all EU languages. Equally, ensure that consultation events are interpreted, whenever necessary. • The language regime for consultation activities should be explained and justified in the consultation strategy, to be endorsed by the interservice Group (ISG) or Secretariat-General (SG) and interested DGs, in case no ISG is established. The language regime should be referred to in the consultation section of the roadmap or inception impact assessment. SG will consistently screen consultation strategies to identify consultation activities, in particular those with a broad public interest, which should be translated into all or several languages. • Consultation documents related to public consultations for initiatives included in the Commission Work Programme, Annex I, need to be translated into all official EU languages⁵⁹⁶. Together with the questionnaire, the consultation web page (or at least a summary thereof) and any additional consultation/background documents should be translated.

⁵⁹⁵ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁵⁹⁶ Until the capacity to translate into Irish has been fully built up, translation of public consultations into Irish should be assessed on a case-by-case basis.

	• The questionnaires and any accompanying documents of all other public consultations need to be made available in, at least, the Commission's three working languages: English, French and German. Consultation documents need to be made available in additional languages if the consultation is of broad public interest or if relevant for the underlying initiative. • To allow citizens and stakeholders to easily identify public consultations of interest, for all public consultations, the consultation webpage, or a summary thereof explaining the scope and aim of the consultation⁵⁹⁷, need to be available in all official EU languages. • Exceptions to language requirements, to be duly justified, should be requested to the SG⁵⁹⁸. • All language versions of the consultation documents should be available at the launch of the consultation. If that is <u>exceptionally</u> not possible, stakeholders should be informed that missing translations will be made available shortly. • The Secretariat-General can help in identifying the appropriate language coverage. The Commission translation service (DGT) can advise on timelines for translation of consultation documents. Please contact⁵⁹⁹ DGT as early as possible when planning a consultation so that length of documents, timing and available translation resources can be properly assessed and taken into account⁶⁰⁰. • Stakeholders should be informed that they can always reply to a consultation in any official EU language regardless of the translation of the consultation documents.
Stakeholder friendly language	• Communicate in a manner that is easily understood by diverse audiences including persons of limited linguistic proficiency. • Ensure that consultation documents (strategy, questionnaire, background documents) are explicit, clear and understandable. It is recommended to have them proof-read by non-experts. • Avoid bureaucratic or too technical language. Abbreviations should be avoided too. Necessary specialist terms should be explained. • Make use of plain language guidance when drafting consultation documents. The Commission has issued a guide called "How to write clearly"⁶⁰¹, available in all official EU languages, and also offers trainings on clear writing. The

⁵⁹⁷ Template available:
<https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁵⁹⁸ In accordance with the procedure for exceptions set out in Tool # 1: Principles, procedures & exceptions

⁵⁹⁹ Please go to <https://myintracomm.ec.europa.eu/serv/en/dgt/Pages/index.aspx> or contact the functional mailbox "DGT-ALL-SERVICES".

⁶⁰⁰ DGT can provide translations of consultation documents of up to 10 pages into all requested EU official languages. Details and information about other services offered by DGT in the context of translations of consultations is provided in the internal note Ares (2013)2752242. More info is available on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁶⁰¹ http://www.cc.cec/translation/clear_writing/index_en.htm and service of DGT-EDIT can help to transform technical language to plain and accessible language

	European Court of Auditors' list of "Misused English words and Expressions in EU publications" ⁶⁰² can also help improve clarity.
Participation of persons with disabilities	• Ensure that persons with disabilities can participate in consultations, on an equal basis with others and in line with the UN Convention on the Rights of Persons with Disabilities⁶⁰³ and the European Disability Strategy 2010-2020⁶⁰⁴. • Use a variety of communication means and accessible formats. The Commission has, for example, already used a sign-language video for a consultation and made simplified, easy-to-read questionnaires available. • Ensure that the consultation page complies with the international Web content accessibility guidelines (WCAG)⁶⁰⁵ (version 2.0), level AA. This means that texts, images, forms, sounds, etc. should be accessible and understandable by as many people as possible without discrimination. • As of May 2016, the EU Survey tool allows respondents to switch to a WCAG-compliant view. It is not anymore necessary to manually activate this option when designing the questionnaire. Contact the EU Survey team should there be any problems with the tool.⁶⁰⁶ • Keep questionnaires as simple as possible, using simple question types like free text, single/multiple-choice, and matrixes. Try to avoid tables and file uploads. Also avoid "visual" elements and try not to use formulations like "in the question below" or "in the next section". Refer to the name of the section or question instead. When adding images to your questionnaire make sure to provide a meaningful descriptive text.
2. Accessibility of activities and consultation channels	
Selection of activities and communication channels	• Ensure that relevant target groups are reached and invited to participate in the most effective way. Usually, a combination of different communication channels (e. g. press release, networks, multipliers, events, social media, Commission delegations and representations in Member States) works best. Public consultations should also be included in the planning calendar well in advance.⁶⁰⁷ • Target groups in remote and rural areas, with lower access rates to internet, may need to be addressed by other consultation tools and communication channels than target groups in more densely populated areas with higher access rates to internet. EC Representations and Europe Direct could be engaged in identifying appropriate tools and channels. • For specific target groups (e.g. SMEs), it might be more effective to fine-tune communication actions and limit the scope on social media, press or other

⁶⁰²

http://www.eca.europa.eu/Other%20publications/EN_TERMINOLOGY_PUBLICATION/EN_TERMINOLOGY_PUBLICATION.pdf

⁶⁰³ Council Decision 2010/48/EC of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities

⁶⁰⁴ <http://ec.europa.eu/social/main.jsp?catId=1137>

⁶⁰⁵ <http://www.w3.org/TR/WCAG20/>

⁶⁰⁶ Please contact the EU Survey team via EC-HELPDESK-IT@ec.europa.eu.

⁶⁰⁷ Published on [the 'Consultation Portal': https://ec.europa.eu/info/consultations_en](https://ec.europa.eu/info/consultations_en)

	communication means. • The Secretariat-General⁶⁰⁸ is available for guidance on the design and implementation of a communication plan.
3. Timing and consultation period	
Timely consultation	• Identify the stages of policy preparation where stakeholder input will be needed and define the appropriate moment for each consultation activity as well as their sequence accordingly. • Spread information early and widely.
Timeframe for contributions	• Allow sufficient time for replying to consultations to increase participation. • The consultation period should strike a reasonable balance between the need for adequate input and the need for swift decision-making. • The minimum period for replies to public consultations is 12 weeks. It is strongly recommended to prolong this period if it overlaps with holiday periods. • For meetings, hearings, conferences or other consultation events, relevant documents should be disseminated 20-working-days ahead of the meeting.⁶⁰⁹

4.5. Communicate the Consultation Strategy

The content of the Consultation Strategy should ideally be communicated to the public on the consultation website related to the policy preparation or the evaluation or fitness check. Providing all relevant information on the consultation activities (both planned and concluded), contributes to transparency and accountability of the consultation process. At the same time, it informs stakeholders on their possibilities to contribute.

The website should at least include the following:

- a brief background;
- explain the approach of the consultation, in particular in case of a "back-to-back"⁶¹⁰ approach;
- the consultation strategy;⁶¹¹
- a link to the Roadmap or IIA and its feedback, where applicable
- a description of the consultation activities that are planned or that have already been completed;

⁶⁰⁸ Via the functional mailbox SG-COMMUNICATION@ec.europa.eu

⁶⁰⁹ See the 2002 General principles and minimum standards for consultation of interested parties by the Commission http://ec.europa.eu/governance/docs/comm_standards_en.pdf.

⁶¹⁰ See Tool #52 on "Back-to-back" evaluations and impact assessments.

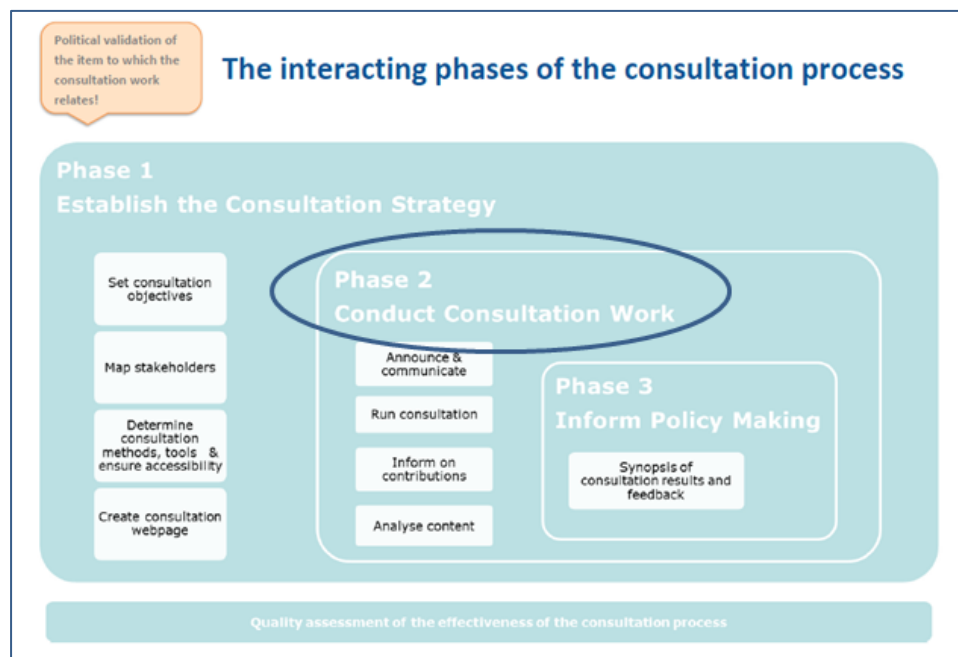
⁶¹¹ Either the strategy document or the content of the strategy as information embedded in the website

- the preliminary timing for upcoming consultation activities;
- the actual consultation activities and documents or links to them;
- where relevant a link to the contributions received in the context of consultation activities;
- A factual summary (recommended) about the main issues raised in a consultation activity and providing a first statistical overview on the number, categories and geographic distribution of participating stakeholders;
- after the conclusion of the last consultation activity: the Synopsis Report
- in case of delegated or implementing acts: information about and a link to the feedback received, and
- in case of legislative proposals: information about and a link to the post-adoption feedback received and a link to the document summarising it.

The web page should be regularly updated. In order to ensure consistency and user-friendly access, a specific template is available for public online consultations, to be cross-linked on the general webpage for the initiative. For the template as well as further guidance on the design of the web pages and **a list of good practice examples**, please see GoPro.⁶¹²

⁶¹² <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

TOOL #54. CONDUCTING THE CONSULTATION ACTIVITIES AND DATA ANALYSIS



While Phases 1 and 3 of the consultation process are carried out only once – at the beginning and at the end – the four elements of Phase 2 have to be considered for each individual consultation activity linked to the specific policy initiative, evaluation or fitness check.

Box 1. Conducting consultation activities – key elements:

- Consultation activities should be conducted in line with the stakeholder consultation strategy.
- Ensure that consultation documents are explicit, clear and understandable, including for non-experts. Avoid use of technical and EU jargon.
- Questions in questionnaires should be relevant, short and simple and be designed in a neutral manner and contain the right balance between open and closed questions.
- Contributions to consultations, both public and targeted, should be published, either with personal information or anonymously, according to the option chosen of the respondent.
- Proper reference need to be made to data protection rules.
- Organisations should be urged to register in the Transparency Register. Contributions received from organisations that choose not to register will be processed as a separate category "non-registered organisations/businesses"⁶¹³ unless they are recognised as representative stakeholders via relevant Treaty provisions⁶¹⁴. A public consultations

⁶¹³ See section on stakeholder categories

⁶¹⁴ European Social Dialogue, Art. 154-155 TFEU.

should be publicised on the relevant Europa policy webpage the same day as it is publicised on the Europa 'Consultation Portal'⁶¹⁵

- Consider sufficient resources for data analysis.
- Reflect well on the questionnaire design: it determines the type of analysis that can be performed on contributions.
- Consider the target audience when deciding on type of graphs and output resulting from the analysis.
- A basic analysis should go beyond the collective results (78% of all respondents agreed that...) and should consider the responses by stakeholder group, country, area of activity etc.
- It is recommended to publish a factual summary report shortly after closing the consultation activity. This report should remain factual and neutral and therefore not contain a qualitative interpretative assessment of contributions, which should be done in the synopsis report later in the process (*see tool #55 on 'informing policymaking-the Synopsis Report'*)

1. ANNOUNCEMENT AND COMMUNICATION OF A SPECIFIC CONSULTATION ACTIVITY

Consultation activities should be prepared as early as possible, and the public - especially the targeted stakeholders – should be adequately informed about the foreseen launch of a consultation activity:

- Update the information on the specific upcoming consultation activity on the policy consultation website⁶¹⁶. Add concrete dates, agenda and other relevant information. Where useful, e.g. for public internet-based consultations, create a separate subpage.
- In case of a targeted consultation activity, ensure balanced stakeholder participation, use clear and transparent criteria for selection of participants and provide information about these criteria on the policy website.
- Reach out to and invite relevant stakeholder groups to participate in the most effective way. Announce the upcoming event through various communication channels (e.g. press releases, social media⁶¹⁷), and use networks and other multipliers.⁶¹⁸

⁶¹⁵ https://ec.europa.eu/info/consultations_en

⁶¹⁶ See Tool #53 *The consultation strategy* (paragraph 5 on communication).

⁶¹⁷ Advert e.g. on Twitter or Facebook account of the DG; teaser question to wake interest and link directly to a consultation activity.

⁶¹⁸ Contact e.g. the 500 Europe Direct Centres in the Member States, Representations of the EU in Member States, umbrella organisations of stakeholder groups, SME-Panel or Network of local SMEs.

2. RUNNING A CONSULTATION ACTIVITY

2.1. How to prepare high quality consultation documents and questionnaires

When consulting stakeholders, it is essential to ensure that the documents and questionnaires used in the consultation activities are of highest quality.

There are different conceptual approaches to consulting stakeholders.

- First, one can opt for a **clearly defined and structured list of questions**. This can, for example, take the form of an (online) questionnaire or questions to be asked in person / over the phone.
- Second, one can opt for **more generic approaches**, either by simply requesting general input/views on a topic or by having stakeholders comment on a specific document such as a Commission Communication launching a consultation process or a Green Paper.
- Thirdly, it is also possible to **combine both approaches**, e.g. a generic Green Paper open for general input including embedded structured questions.

While this distinction between structured and generic approach appears similar to the distinction between closed and open questions, there is in fact only a partial overlap. While more generic approaches most often use open questions, structured approaches (from now on "questionnaires") should feature an appropriate mix of both open and closed questions.

This tool aims to provide methodological and practical support for designing both structured and generic consultation approaches. It does not describe or assess different consultation activities in detail.

2.2. Methodological and practical guidance on questionnaires

There is no 'right' answer on how to design a questionnaire. Whether a questionnaire is suitable – meaning likely to deliver the information needed – depends on a range of factors. After having decided to use a questionnaire, this implies choosing an appropriate structure for the questionnaire, designing the questions as clearly and simply as possible, and finding the most appropriate means to administer the questionnaire.

Developing a good questionnaire takes time and preparations should therefore start as early as possible. A good questionnaire increases the quality of answers and, in turn, leads to more impactful input to policymaking. The Better Regulation coordination desks can provide methodological support and procedural information. Further information can be found on GoPro⁶¹⁹.

2.2.1. When to use a questionnaire?

Given the many consultation activities they can be used for, questionnaires can almost always be helpful when consulting stakeholders. Much depends on *how* they are used: If little prior knowledge is available, a questionnaire consisting of mostly open questions

⁶¹⁹ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

can help to get a better understanding of the issue. If the existing body of knowledge is substantial, closed questions can be used to rank potential solutions and open questions can be used to collect good practices or detailed information. Furthermore, the use of a clearly structured questionnaire often makes it easier to subsequently analyse the answers received.

It is worth considering whether other, more flexible approaches, or approaches that combine questionnaires with policy documents might not produce better results.

Box 2. Strengths and limitations of questionnaires	
Strengths	• Allow collecting information in a structured manner. • Facilitate the analysis of responses (e. g. descriptive statistics provided by EU Survey tool). • May be perceived as less time consuming for respondents, resulting in a high(er) number of contributions.
Limitations	• Do not allow for more detailed input from respondents, as replies to most of the questions are pre-defined. • For open questions –the number of open questions and the length of free text for replies is usually limited. • Depending on the design of the questionnaire, respondents might be pushed into a certain direction and some answers might be excluded in the first place (especially if limited range of responses is offered). • Unless Eurobarometer consultations, results from consultations are not statistically representative: Mainly the active stakeholders will contribute.

2.2.2. Questionnaire design

When designing a questionnaire, start with the **scope** of the questionnaire, as identified in the consultation strategy. What is it that you really need to know from the targeted stakeholders? Only ask those questions that are likely to provide you with the necessary information. Otherwise, try to reformulate or remove the question.

Consider how to meaningfully structure the questionnaire. Only use **sections** that are clear from the perspective of stakeholders. For example, a division into sub-themes is much more meaningful than a division into questions for an evaluation and questions for an impact assessment (in the case of a back-to-back consultation). Such a themed section could, for example, consist of several closed questions and an associated text box for further thoughts and explanations.

When targeting both **expert and non-expert stakeholders**, it might make sense to divide the questionnaire in two parts: the first part would consist of easier, more general questions to be answered by a general public, whereas the second, more detailed part would be addressed to experts. However, even if parts of the questionnaire or specific questions are particularly relevant for certain stakeholder groups, other stakeholders might have relevant input. All questions in public consultations should therefore be open to all stakeholders – also for transparency reasons. Alternatively, consider opting for two different questionnaires.

Every questionnaire should contain an **introduction** which explains – in simple terms – the background and context: What is the initiative about? What is the aim of the initiative? What is the aim and scope of this consultation? In addition, consider beginning

each section with a brief explanatory paragraph, especially when the questionnaire is addressed to non-experts.

As the Commission does not accept anonymous contributions, all questionnaires need to include a **stakeholder identification section**. This section asks for relevant information about the respondent (e. g. which stakeholder category he or she belongs to; contact details for follow-up questions). As many of these questions are used invariably for all questionnaires, the Secretariat-General has prepared a template that can be accessed via GoPro.⁶²⁰ It is strongly recommended to adapt this template, as appropriate, but to use the same stakeholder identification questions for all consultation activities foreseen for an initiative. This allows comparing results.

A questionnaire is usually a **combination of closed questions** (with pre-defined answers from which the respondent has to choose) **and open-ended questions** (leaving the possibility to the respondent to formulate his/her own answer). The right balance between these closed and open questions depends on the aim of the respective questionnaire.

Closed questions are easier to answer and analyse. They should be mainly used to gather quantitative data. When used to collect opinions, the questions and range of answers should be carefully reflected upon to avoid bias. Open questions should mainly be used to gather qualitative data. They offer stakeholders the possibility to explain their view, to add individual information/concerns, and to refer to issues not yet addressed in the questionnaire. Open questions thus help to get a broader and potentially deeper picture, substantiation of responses and will improve the qualitative assessment of the contributions. A good compromise could consist of using open questions when particularly interested in the views of stakeholders on a particular issue and to cap the length of replies (character limit).

Box 3. Closed versus open questions

	Strengths	Limitations
Closed questions	• Suitable to collect quantitative data. • Quick to answer & analyse • Data can be reported statistically, and answers to various questions cross-tabulated	• Force respondents to choose pre-set answer options (usually tick/circle answers) => Can exclude useful points
Open Questions	• Suitable to collect qualitative data • Allow respondents to give the answers they want in the way they want (open space). • Useful for obtaining insights into the reasons behind the responses to closed questions	• Less suitable to collect quantitative data • Difficult to carry out statistical analysis. • Can be time consuming to code and interpret, particularly if there are many responses in numerous languages.

It is usually **recommended to start a questionnaire and each individual section with simpler, more general questions**. These often take the form of closed questions. They

⁶²⁰ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

can then be followed up with more detailed or complex questions. These often take the form of open questions or tables containing a series of closed questions.

It is recommended to **always offer the possibility to submit separate documents** (position papers, background documents) in which the respondent can further clarify positions or views expressed in the responses to the questionnaire.

It is recommended to provide **an indication of the estimated time required to fill in the questionnaire**. It may also be useful to measure the actual time it takes to reply to the questionnaire. The longer it takes, the less likely are contributions from non-experts. In that case, try to reduce the number of questions, simplify the questionnaire or reserve one part of the questionnaire for experts.

It is equally recommended to **pilot** draft questionnaires, i.e. "test" them with selected stakeholders. Asking a few stakeholders to reply to the draft questionnaire and to identify problems – either technical or methodological – can help improving the quality and thus usefulness of the questionnaire.

2.2.3. *Question design*

In addition to focussing on the design of the overall questionnaire, it is important to ensure that its building blocks – the individual questions – are equally well chosen and designed.

Questions and their answer options should be **relevant, short and simple**. Note that short questions and answer options will also make it easier to present the results in tables and figures in the subsequent analysis.

The **language used should be adequate and adapted** to the stakeholders. If non-experts are targeted, abbreviations should not be used, and jargon should be avoided or, at least, explained. Ambiguous words or questions (e.g. double negative) should be avoided in any case. Language should be used consistently throughout the questionnaire. For example, if several questions relate to "the period 2014-2016", all questions should use the same formulation. Deviating from formulation by referring to "the last three years" would, at best, unnecessarily confuse the respondents and might even have a slightly different meaning, thus resulting in different answers.

Questions need to be designed in a neutral manner, meaning that they should not "push" respondents to answer in any particular way. This includes using a balanced answer scale, such as a five-point scale with two positive answer options, two negative answer options and a neutral option.

Answer scales need not only to be balanced, they also need to reply to the question at hand, and need to ensure that respondents can always appropriately answer the question. The latter point is particularly important for mandatory questions as it might otherwise result in a misleading answer. If not all possible answer choices can be foreseen, respondents should be given the possibility to select "other". In addition, it is often useful to allow for an "I do not know" and/or "Not applicable" option as well as providing respondents the possibility to add further comments or explain their answers in a text box. In addition, respondents should always be given the opportunity to upload documents, to accompany the responses to the questionnaire.

2.2.4. *Online questionnaire tools*

While questionnaires can be used for a variety of consultation activities, many are used for internet-based stakeholder consultations. The Commission has therefore developed an online tool, EU Survey⁶²¹. The functionalities of this tool are constantly being improved; an up-to-date overview is available online.⁶²²

Given that EU Survey has been developed with the needs of the Commission in mind (e. g. its interface is available in all official EU languages; it fulfils high standards of data protection; it complies with international accessibility standards) and given that the EU Survey team can be contacted to prevent or solve technical problems⁶²³, it is recommended – though not obligatory – to use this tool. There are many commercial alternatives which offer similar functionalities⁶²⁴.

2.3. **Methodological and Practical guidance on generic consultation approaches**

2.3.1. *When to use generic approaches?*

In some situations, relying on questionnaires might not produce the necessary results. More general approaches can – sometimes in combination with a short list of guiding questions – be useful alternatives. Requesting general comments from stakeholders or having stakeholders comment on a policy document such as a Green Paper or a Communication launching a consultation process might help to avoid/mitigate the bias inherent in questionnaires. They can also be useful for starting a comprehensive debate in a policy area.

2.3.2. *Green Papers*

Green Papers are documents published by the European Commission to stimulate discussion on given topics at European level. They invite all stakeholders to participate in a consultation process and debate on the basis of the ideas and suggestions they put forward. They are published on the Europa 'Consultation Portal'⁶²⁵ and open for stakeholder input for at least 12 weeks.

2.3.3. *Commission Communications launching a consultation process*

A Communication launching a consultation process is a consultation document in the form of a Communication adopted by the College. The same rules apply as to Green Papers.

⁶²¹ <https://ec.europa.eu/eusurvey/>

⁶²² <https://ec.europa.eu/eusurvey/home/about>

⁶²³ Commission staff can also send questions to EC-HELPDESK-IT@ec.europa.eu

⁶²⁴ See, for example, <http://survey-software-review.toptenreviews.com/>

⁶²⁵ https://ec.europa.eu/info/consultations_en

Examples of such Communications include the Communication from the Commission to the EP and Council concerning a consultation on fishing opportunities for 2016 under the Common Fisheries Policy⁶²⁶ or the Commission Communication to the Council, EP, CoR and EESC launching a public consultation on the EU Urban Agenda⁶²⁷.

2.4. Further reading & references

Useful resources are available at the Commission's library and online - a brief selection:

- Creasy, Barry (2008), *Effective Surveys and Questionnaires*, The Consultation Institute, Biggleswade.
- Fowler, Floyd J. (2014), *Survey Research Methods*, Sage, Thousand Oaks.
- Fowler, Floyd J. (1995), *Improving Survey Questions. Design and Evaluation*, Sage, Thousand Oaks.
- Hague, Paul (1993), *Questionnaire Design*, Kogan, London.
- OECD (2012), *Measuring Regulatory Performance. A Practitioner's Guide to Perception Surveys*, OECD, Paris.⁶²⁸

3. PUBLICATION OF RESPONSES, DATA PROTECTION, ACCESS TO DOCUMENTS AND TRANSPARENCY REGISTER

3.5. Publication of responses

The Commission is committed to be open and transparent throughout the policy cycle, including in the way it consults its stakeholders. Therefore, it is strongly recommended that contributions⁶²⁹ submitted in the context of the various consultation activities, public or targeted, are published on the relevant policy webpages.⁶³⁰

For all consultation activities, public or targeted, respondents should be offered the option to have their contributions published either with their personal data or anonymously. Regardless the option chosen, respondents should be required to identify themselves or the organisation on which behalf they respond. Anonymous contributions to consultations should not be accepted. The option for respondents not to have their contribution published is no longer offered by default.

For activities that collect input in writing, the options for publishing the contributions with or without personal data should be clearly mentioned in the consultation document

⁶²⁶ http://ec.europa.eu/dgs/maritimeaffairs_fisheries/consultations/fishing-opportunities-2016/doc/com_2015_239_en.pdf

⁶²⁷ http://ec.europa.eu/regional_policy/sources/consultation/urb_agenda/pdf/comm_act_urb_agenda_en.pdf.

⁶²⁸ Available online at www.oecd.org/gov/regulatory-policy/perception-surveys.htm.

⁶²⁹ Contributions include responses to questionnaires, position papers, background material, etc.

⁶³⁰ See Tool #53 on *The consultation strategy*.

(e.g. questionnaire). For oral input, such as interviews, the way the contributions⁶³¹ will be published must be made clear beforehand (e.g. for interviews, before the start of the interview)

Publication of the contribution with personal information

Contributions are published together with key personal information, including the name of the respondent and the country in which the respondent resides. In case the respondent replies on behalf of an organisation or company, only the name of the organisation/company and country of residence of the organisation/company is published together with the contribution. Any other personal data which may be collected (e-mail, phone number, address, gender, etc.) should not be made public, unless relevant.

Anonymous publication

Contributions are published without any personal data provided in the context of the consultation. However, for practical reasons, documents submitted by stakeholders in the context of a consultation, such as position papers or background documents, can be published in the way they are received. Removing personal data from such documents can be cumbersome and time consuming. Therefore, **it should be clearly mentioned on the consultation webpage or in the questionnaire or feedback form that respondents should not include personal data in documents submitted in the context of consultation if they opt for anonymous publication.**

Publication of ad hoc contributions

If stakeholders provide ad hoc contributions at any point during the policy preparation or evaluation work, these contributions should also be published on the policy web page. If no information on the preferred format of publication is available, by default it should be published with the key personal information (see above).

If manageable, DGs could for courtesy reasons get back to stakeholders and ask them about their preferred form of publication (with or without personal information).

3.6. Data protection

Under EU law, personal data can only be gathered under strict conditions and for a legitimate purpose. Furthermore, persons or organisations, including the EU institutions, which collect and manage personal information, must protect it from misuse and must respect certain rights of the data owners which are guaranteed by EU law, in particular,

Regulation (EC) No 45/2001. Both apply to the processing of personal data by EU institutions and bodies within the scope of Union law.

What is understood by personal data?

According to Article 2 (a) of Regulation (EC) No 45/2001 personal data is defined as follows: "Any information relating to an identified or identifiable natural person, referred

⁶³¹ Information should also clarify how the provided responses will be published (summary or complete responses)

to as "data subject" - an identifiable person is someone who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity.

Privacy statement

By means of the privacy statement, respondents should be informed in a clear way on how data is collected and processed. This document describes the objective of the personal data gathering and processing, the kind of data collected, technical information on the tools or platforms used to store and process data, to whom the data can be disclosed, the way data is protected, the period data is kept as well as contact information. In practice, a specific privacy statement needs to be prepared for each consultation activity involving collection of personal data and should be published on the consultation webpage related to the initiative. Furthermore, a link to the 'protection of personal data' page needs to be provided on the consultation page. The template to be used for the privacy statement for consultations is available on GoPro⁶³²

Data retention Period

Personal data should be kept only for as long as follow-up actions to the Consultation are necessary with regards to the purpose(s) of the processing of personal data. All personal data should be deleted from databases 5 years after the last action in relation to the Consultation. Where necessary, personal data could be kept for a longer period as long as this is foreseen in the Privacy Statement. Consultation Reports containing personal data should be archived according to the Commission's legal framework (e.g.: SEC(2012)713 - Common Commission-Level Retention List for European Commission Files (CRL) of December 2012). Participants must be informed of the fact that they can request their personal data to be deleted."

3.7. Access to Documents

Contributions, including personal data provided, may be subject to a request for access to documents under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents ('Regulation 1049/2001')⁶³³. Regulation 1049/2001 provides any EU citizen and any natural or legal person residing or having its registered office in a Member State the right of access to documents of the EU institutions, subject to principles, conditions and limits defined in the Regulation. If access is requested, the request is subject to a case-by-case analysis based on Regulation 1049/2001 in order to assess the applicability of the exceptions defined in its Article 4, taking into account the legitimate interests and the justifications of non-disclosure in case provided by the author of the contribution. Where disclosure of the contribution, or parts thereof, would undermine the protection of commercial interests of a natural or legal person, the institutions shall refuse access in accordance with Article 4(2), first indent of Regulation 1049/2001.

⁶³² <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁶³³ Official Journal L 345 of 29.12.2001.

3.8. Transparency Register

Organisations and businesses that wish to participate in consultation activities are asked to provide the Commission and the public at large, with information about which interests they represent and how inclusive their representation is, by subscribing to the Transparency Register. Contributions from organisations and businesses that choose not to register will be processed as a separate category "non-registered organisations/businesses"⁶³⁴ unless they are recognised as representative stakeholders via relevant Treaty provisions⁶³⁵.

Publishing a public consultation on the Europa 'Consultation Portal'⁶³⁶ or a roadmap or inception impact assessment on the dedicated webpage⁶³⁷ will trigger an e-mail alert to registered organisations.

More info on the Transparency Register can be found on Europa.⁶³⁸

4. FACTUAL SUMMARY REPORT

For each consultation activity, it is good practice to publish factual information on the input received from stakeholders to ensure transparency. Apart from the publication of meeting agendas, consultation documents and any written contribution, this also includes a factual summary of the issues raised. This information can take different formats, e.g. workshop summary, meeting minutes, conference report, presentation of key issues. Basic statistical information on participating stakeholder groups, number of participants, geographical distribution and other basic figures relevant for an activity should be provided.

The purpose of this information on the stakeholder input is to give an overview on 'what has been said'. It should be neutral as it precedes the analysis and interpretation of consultation results. As these factual summaries may contain views and positions from stakeholders not necessarily shared by the Commission, or may refer to issues on which a decision has not yet been taken, an appropriate disclaimer⁶³⁹ should be added.

It is recommended to publish this factual information soon after the closure of a consultation activity on the consultation page. No specific formal requirements apply.

⁶³⁴ See section on stakeholder categories

⁶³⁵ European Social Dialogue, Art. 154-155 TFEU.

⁶³⁶ https://ec.europa.eu/info/consultations_en

⁶³⁷ <http://ec.europa.eu/info/law/better-regulation/initiatives>

⁶³⁸ <http://ec.europa.eu/transparencyregister/public/homePage.do>

⁶³⁹ Disclaimer: "This document should be regarded solely as a summary of the contributions made by stakeholders [add consultation activity] on the [add title of policy initiative or evaluation or fitness check]. It cannot in any circumstances be regarded as the official position of the Commission or its services.

The factual summary should not be confused with the synopsis report, to be drafted at the end of the consultation process⁶⁴⁰ (see tool #55 Informing policymaking - the synopsis report)

Box 4. Factual summary report	
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? • 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.

5. DATA ANALYSIS OF CONTRIBUTIONS TO QUESTIONNAIRES USED IN CONSULTATIONS⁶⁴¹

5.1. Overview

There is no ‘right’ answer to the question how to best analyse data input for questionnaires, which often consists of a mix between ‘open’ and ‘closed’ questions⁶⁴². Rather, there is a wide a range of factors to consider in order to ensure that a reasonably robust analysis can be performed within the constraints of available time and resources, and considering that the number of responses may be higher than expected.

The most efficient method is likely to involve transferring the data to a ‘master’ Excel spreadsheet containing responses to both ‘closed’ and ‘open’ text questions. With this in mind, it becomes obvious that a consultation which invites broad ranging submissions (including position papers) in the form of pdf documents will be difficult to process.

⁶⁴⁰ See Tool #55 on *Informing policymaking - the synopsis report*.

⁶⁴¹ For further detail see also Commission study [Consultation Support and Development of Advice (Specific Contract No SG/2015/10 under Framework Contract ENTR/172/PP/20-12-FC Lot 3) : <https://bookshop.europa.eu/en/consultation-support-and-development-of-advice-pbKA0217018/?CatalogCategoryID=YR4KABstrdKAAAEjLocY4e5K>

⁶⁴² See paragraph 2 of this tool on questionnaire design.

For the purposes of this tool, it will be primarily focused on two levels of analysis:

Basic analysis, which can be undertaken by those with a reasonably proficient knowledge of Excel.

Advanced analysis, which can be undertaken by those with specific skills to use specialised software aimed at assisting with the analysis of data and campaigns and with computer-aided analysis of open text responses.

In certain cases, it may be desirable to outsource the entire package (questionnaire design, analysis and reporting) to a **professional** contractor (polling or market research company.)

Note that when reporting back on the outcome of the consultation the methodologies and tools should be explained for transparency reasons.

Box 5: Overview different levels of analysis		
Approach	Advantages	Disadvantages
Basic	• Only basic spreadsheet skills required • Good for analysis of closed questions • Can be done in-house by most Commission Policy Officers with/without support from consultants	• Not efficient for high number of responses (several hundred or more), particularly when analysing campaigns and open text responses
Advanced	• Efficient means to analyse campaigns and open text responses where there are hundreds (or thousands) of responses	• Requires use of specialised software. • As such requires suitable Commission in-house staff with/without support from consultants
Professional	• Professional questionnaire design • Independent analysis • High quality presentation of results	• Potential for limited interaction with Commission Policy Officers • Approach may have to conform to a standardised 'template' with limited open text responses

5.2. Data preparation in view of the analysis

5.2.1. Data familiarisation

Once the data is on a master spreadsheet, there are two considerations to be taken into account:

- time and resources for analysis of **closed questions** do not depend on the number of responses
- time and resources for analysis of **open questions** depend on the number of responses and, to a lesser extent, to the diversity of languages in which they were submitted

Before proceeding further with the analysis, it is important to note that the **data represents the views of those that responded**. The **respondents** are self-selecting and **are not a statistical sample of the EU population**⁶⁴³.

However, in some cases the respondents may represent a very high percentage of the population of particular stakeholder groups that are directly impacted by the subject of the consultation. By way of example, potential changes affecting particular industry groups may trigger responses from all the relevant manufacturers.

5.2.2. *Data cleaning and duplicates*

Once processed and organized, the data may be incomplete, contain duplicates, or contain errors. The need for data cleaning will arise from problems in the way that data is entered and stored. Data cleaning is the process of preventing and correcting these errors. Common tasks include record matching, identifying inaccuracy of data, overall quality of existing data, deduplication, and column segmentation. Such data problems can also be identified through a variety of analytical techniques. For example, with financial information, the totals for particular variables may be compared against separately published numbers believed to be reliable. Unusual amounts above or below pre-determined thresholds may also be reviewed. There are several types of data cleaning that depend on the type of data such as phone numbers, e-mail addresses, employers etc. Quantitative data methods for outlier detection can be used to get rid of likely incorrectly entered data. Textual data spellcheckers can be used to lessen the amount of mistyped words, but it is harder to tell if the words themselves are correct

The first step of the data analysis is to simply check the validity of the data on the master Excel sheet. Responses received before the consultation started should be deleted – as these will most likely be associated with final testing and checking of the questionnaire. Responses received a few hours after the formal closure time could be accepted if there may have been valid reasons for the delay. Clearly, responses received days/weeks after the consultation has closed can be deleted.

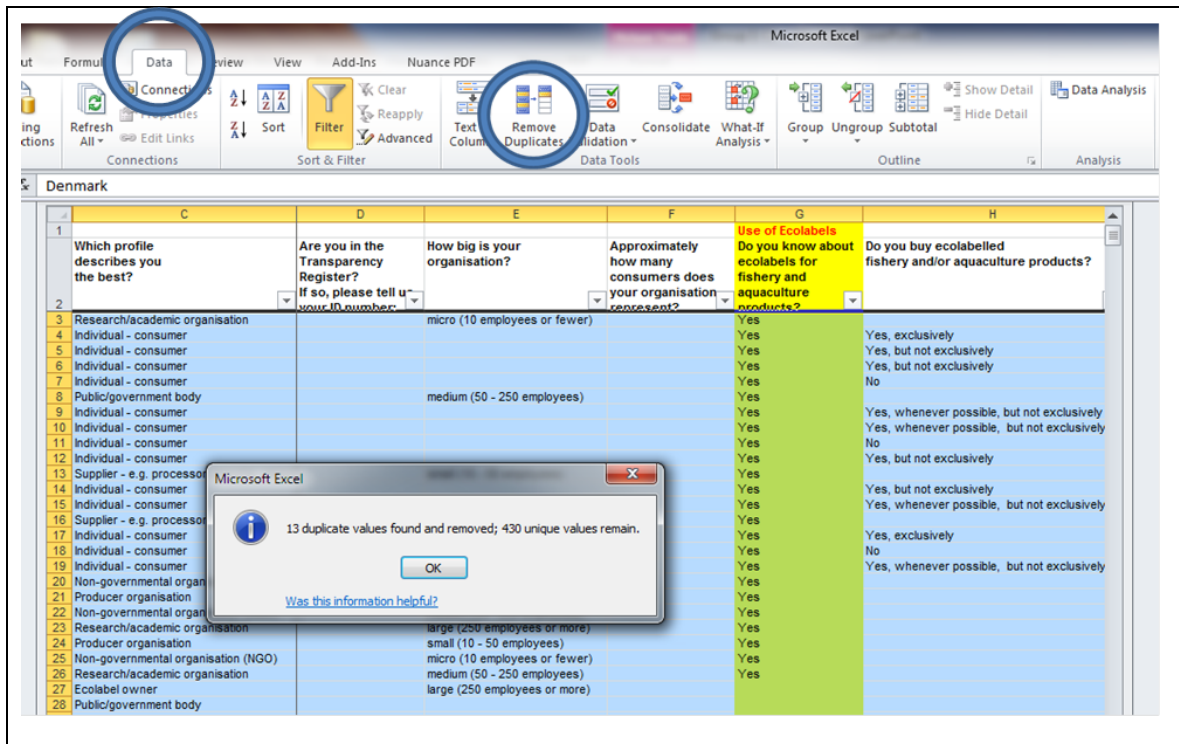
At this point, every response should be given a unique identifier (which could just be simple numbering 1, 2,...435).

Mischievous (or mistaken) entries can be checked and validated if considered necessary (for example, individuals claiming to represent a national Government). However it is not possible to readily validate every response – particularly if there are thousands of responses to consider.

Duplicates are identical entries across all the questions (including name and location). Such entries may be entered deliberately or accidentally. The first step is to determine how many duplicates there are.

Excel has a ‘remove duplicates’ data tool - see example below (using Excel 2010):

⁶⁴³ See also paragraph 5.3.1, sub para: *Interpretation of data - Weighting and representativeness of respondents and replies*



In this example, Excel found 13 duplicates in 443 submissions. Note that the Excel tool is not case sensitive (so that DAVID BROWN = David Brown) and there is a chance that more than one David Brown completed the questionnaire in the same way. Therefore, identifying the duplicates requires manual checking of the Excel sheets before/after the removal of duplicates.

A more advanced approach is to use [STATA](#) (a statistical software package used for more ‘advanced analysis’ – see below which readily groups the duplicates allowing you to determine quickly whether duplicate entries may be a range of common names or whether it is an obvious deliberate multiple entry as illustrated by the example below.

Box 6. Use of STATA (statistical analysis)

```
. duplicates report

Duplicates in terms of all variables
```

copies	observations	surplus
1	1631	0
2	264	132
4	4	3
14	14	13
31	31	30

```
. duplicates drop

Duplicates in terms of all variables

(178 observations deleted)
```

In this example, there were 1,631 unique entries within the dataset and 178 duplicate ('surplus') responses representing 10% all responses. Notably, there was one response that was repeated 30 times (i.e. one 'master' and 30 copies leading to a 'surplus' of 30 entries) and another repeated 13 times. These can safely be deleted as obvious duplicates. There were also 132 pairs of identical answers as well as one with four identical entries. In this example, these duplicates were highlighted (within STATA) and the names reviewed (manually) to see if there was any possibility that these were cases of genuine duplicates (i.e. people with the same name). In this particular case, it was immediately apparent that these were duplicate entries and could be safely deleted. Removing all 178 duplicates, using STATA's *duplicates drop* command, yielded a cleaned dataset with 1,766 individual responses.

Box 7: Summary procedure for considering duplicates

- Identify the level of duplicate responses (anything over 1% is probably indicative of duplicates);
- Remove 'obvious' duplicates;
- Review and perhaps remove remaining duplicates;
- If in doubt, leave duplicate entries in place (as their overall impact on the results will be low).

5.2.3. Campaigns

Overview

Where respondents have responded to a public consultation with the same answers this may be coincidence or it may part of a co-ordinated campaign. **Campaigns are very effective in order to generate interest amongst stakeholders and to highlight key messages for policy makers. At the same time, they present a challenge for those**

analysing the responses to an public consultation. It is therefore essential to well identify campaigns, analyse them separately and present results adequately.

It is therefore necessary to consider the possible presence of campaigns, the means to identify them and how to present the results.

Presence of campaigns

Once a public consultation is launched, it should be continuously monitored. As such, occasional searches on the internet and social media may reveal the presence of organised campaigns which are suggesting answers to the questionnaire.

Once the consultation has finished, identifying campaigns through this method will become less effective as the information is changed/removed or simply overtaken by new events.

Identifying campaigns – basic analysis

Where there are only 100 or less responses to an public consultation, it is possible to sort the Excel data set by responses to successive questions and then check them by scrolling through the responses to identify rows of identical entries. Where these are the **same across all closed questions**, this suggests a campaign – particularly if the respondents represent a particular sub-group of stakeholders (by activity and/or interest and/or location).

As a rule of thumb, the minimum threshold should be 10 or more identical responses (across all the closed questions) to count as a ‘campaign’. On the other hand, if there were 10 identical responses from very diverse groups of respondents to a short questionnaire with a total of 10,000 responses, this would rather be a coincidence.

Identifying campaigns – advanced analysis for closed questions

Although Excel can be used to assist with the identification of campaigns, it is more efficient to use professional statistical software such as [STATA](#)⁶⁴⁴. Professional software is more complex, compared to Excel, and does require someone with training or prior knowledge of the programme in order to use it. The output tables usually also require some explanation/basic understanding of statistics in order to understand the results. Furthermore, it may not be possible to easily export the outputs from this statistical software into Excel or any other programme.

Available statistical software at the Commission can be consulted on the webpage of [DIGIT](#)⁶⁴⁵.

The analysis may also be outsourced to a contractor that may have access to similar software.

⁶⁴⁴ There are various other well-known statistical packages which can provide additional functionality beyond that provided by Excel, including: R, MiniTab, SAS, SPSS, etc. A brief introduction to the ‘top five’ may be found here: <http://www.prostatservices.com/statistical-consulting/articles-of-interest/a-review-of-the-top-five-statistical-software-systems>

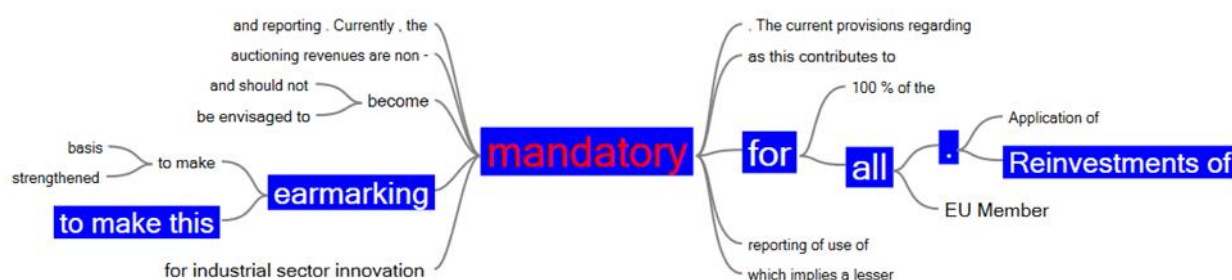
⁶⁴⁵ https://myintracomm.ec.europa.eu/dg/dgt/it_support/software/Pages/index.aspx

Identifying campaigns – advanced analysis for open questions

While some campaigns suggest a series of responses to closed questions, other campaigns may recommend that their supporters should adopt some standard text in their response. As such, the responses may not be exactly the same but some key messages will be repeated.

The most efficient way to identify the presence of campaigns in responses to open questions is to use software designed for qualitative data analysis such as the Commission tool 'Doris' or the commercial tool [NVivo](#), but there are also other similar tools available⁶⁴⁶.

An example of a 'word tree' around the word 'mandatory'



It is immediately apparent that is a campaign, as indicated by the larger font (reflecting greater frequency of occurrence) which includes the suggested word sequence “...to make this earmarking mandatory for all. Reinvestments of...”. Perhaps the easiest way to identify responses from this campaign would be to search the (cleaned) dataset for “earmarking mandatory” and then segregate these responses.

Identifying campaigns – advanced analysis for all questions

Although professional software may be used to look for duplicates across all fields, this may not be efficient. For instance, analysis across closed questions may yield a campaign supported by a particular stakeholder. However, the wording used in the supporting comment boxes may vary slightly due to differences in use of capital letters, mistyping, etc. As such, if the search for campaigns would extend across both closed and open questions, many campaign responses may be missed.

Segregating campaigns and reporting

It is recommended to look for campaigns in both ‘closed’ and ‘open’ questions. Once campaigns have been identified, the associated responses should be segregated and analysed separately from the non-campaign responses.

If campaigns are identified, they should be referred to in the synopsis report. Reporting on campaigns should include the number of respondents supporting the campaign as well as a summary of their points of view – either in text or tabular form

⁶⁴⁶ <http://www.predictiveanalyticstoday.com/top-qualitative-data-analysis-software/>

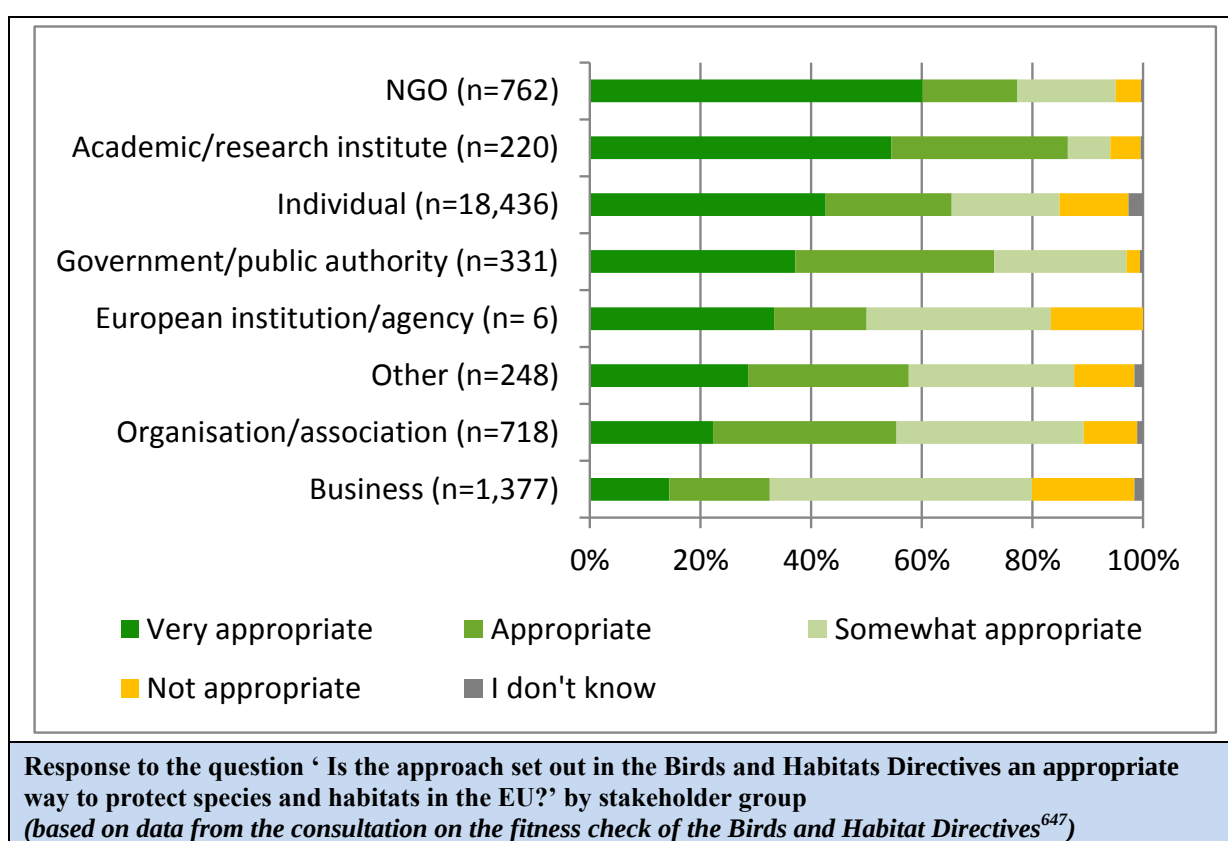
5.3. Analysis of data

5.3.1. Analysis of closed questions

Basic analysis

Basic analysis of closed questions generates information such as: "67% of respondents considered that the legislative framework was delivering benefits." Such information is not so helpful to policy makers unless qualified by the perspective of the stakeholder, for example: "Although 74% of industry respondents considered that the legislative framework was delivering benefits, only 32% of citizens agreed with this view."; or "Less than 30% of Danish respondents considered that the legislative framework was delivering benefits, while 67% of Estonian respondents agreed with this view." Even this information is of limited value if there were only 6 respondents from Estonia while there were 240 from Denmark.

Such quantitative information can be conveyed graphically by including the numbers of respondents as illustrated below.



Basic statistical terms include:

- Mean: the total of a distribution of values divided by the number of values
- Median: the mid-point in a distribution of values

⁶⁴⁷ http://ec.europa.eu/environment/nature/legislation/fitness_check/index_en.htm

- **Mode:** The value that occurs most frequently in a distribution
- **Standard Deviation:** a measure of dispersion around the mean
- **Percentages:** A rate, number, or amount in each hundred to express any proportion or share in relation to a whole
 - When to report percentages: When values are high enough for them to mean something. It is generally bad practice to report percentages if the total number of values is lower than 100, as a percentage point bigger than > 1
 - When reporting changes over time, the difference between percent and percentage points (p.p.):
 - *Percent* is used for a measure of changes in values
 - *Percentage point* is used for a measure of change in percentages

e.g.:

- Last year, in a workforce of 300, 30 people (10%) were smokers.
- This year, in the same workforce of 300, 15 people (5%) are smokers
- The number of smokers has fallen by 50% or the percentage of smokers has fallen by 5 percentage points
- It is **good practice to calculate and report percentages and valid percentages** (percentages of those who answered the question) so that readers can see response rate on questions.
- **Avoid using only percentages in the presentation of results**, make always the link with the amount of responses they correspond to.
 - Example: Q: Do you receive a disability benefit of any kind? Yes: 83
No : 256; => out of a total of 460 who returned a questionnaire (=N)

(N=460)	N	%	Valid
Yes	83	18.04	24.50
No	256	55.65	75.50
Not answered	121	26.31	-

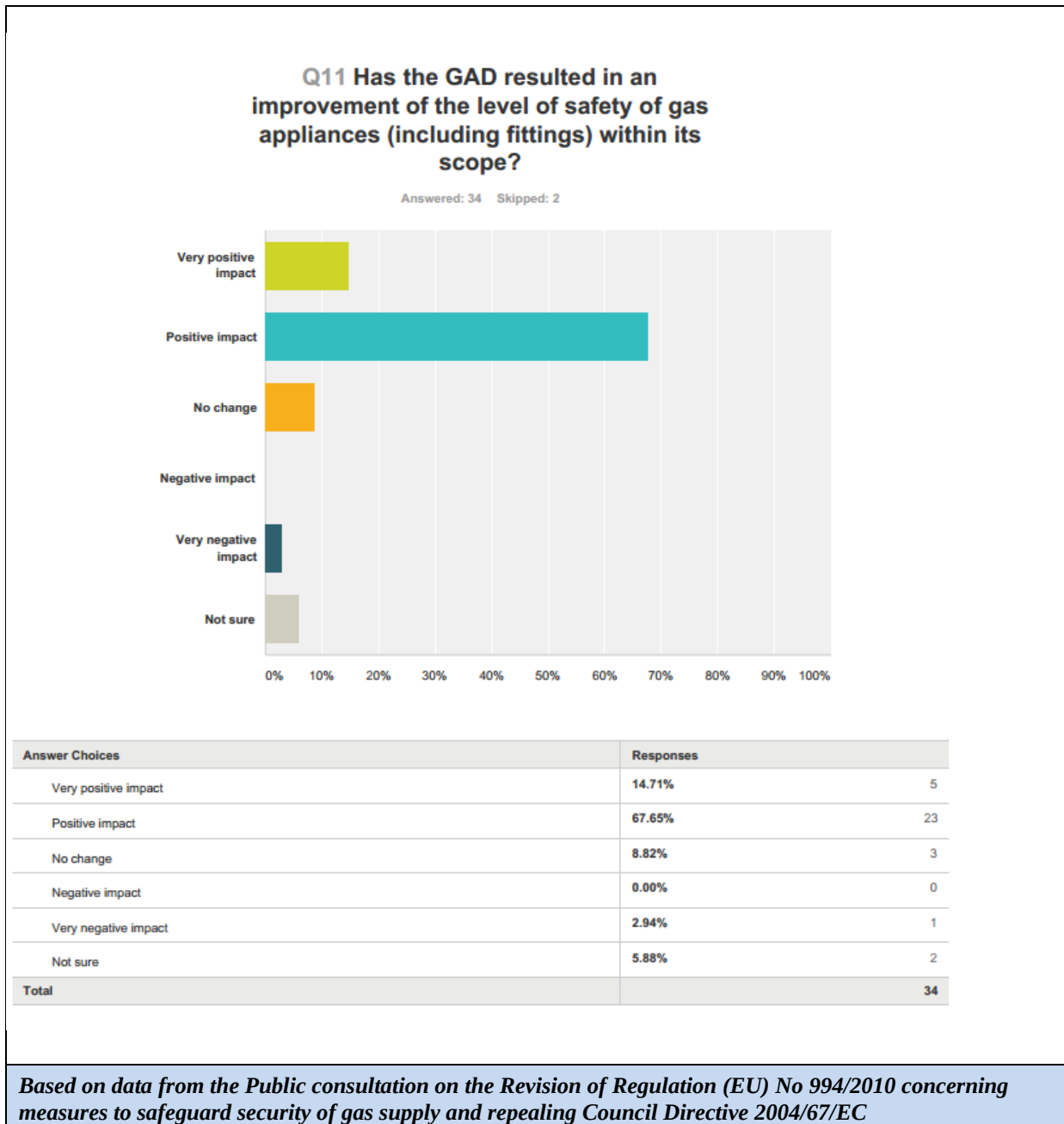
Level of analysis

The analysis of closed questions is relatively straightforward, with Excel able to generate relevant data tables and graphs. However, transferring the results into a report can be time-consuming.

If there are 20 closed questions, then there will be a minimum of 20 tables/graphs representing the answers against another variable – usually stakeholder group (such as authorities, citizens, industry, etc.) and the related comment. There will then be further

tables/graphs if the closed questions incorporate a number of sub-questions and/or more than one possible answer.

If the analysis is to be repeated from another perspective (such as geographical location), another set of tables/graphs would be required. Through specific software (such as EU survey or SurveyMonkey) pre-filtered graphs and tables can be generated as illustrated in the example below, which represents the views of ‘manufacturers’.

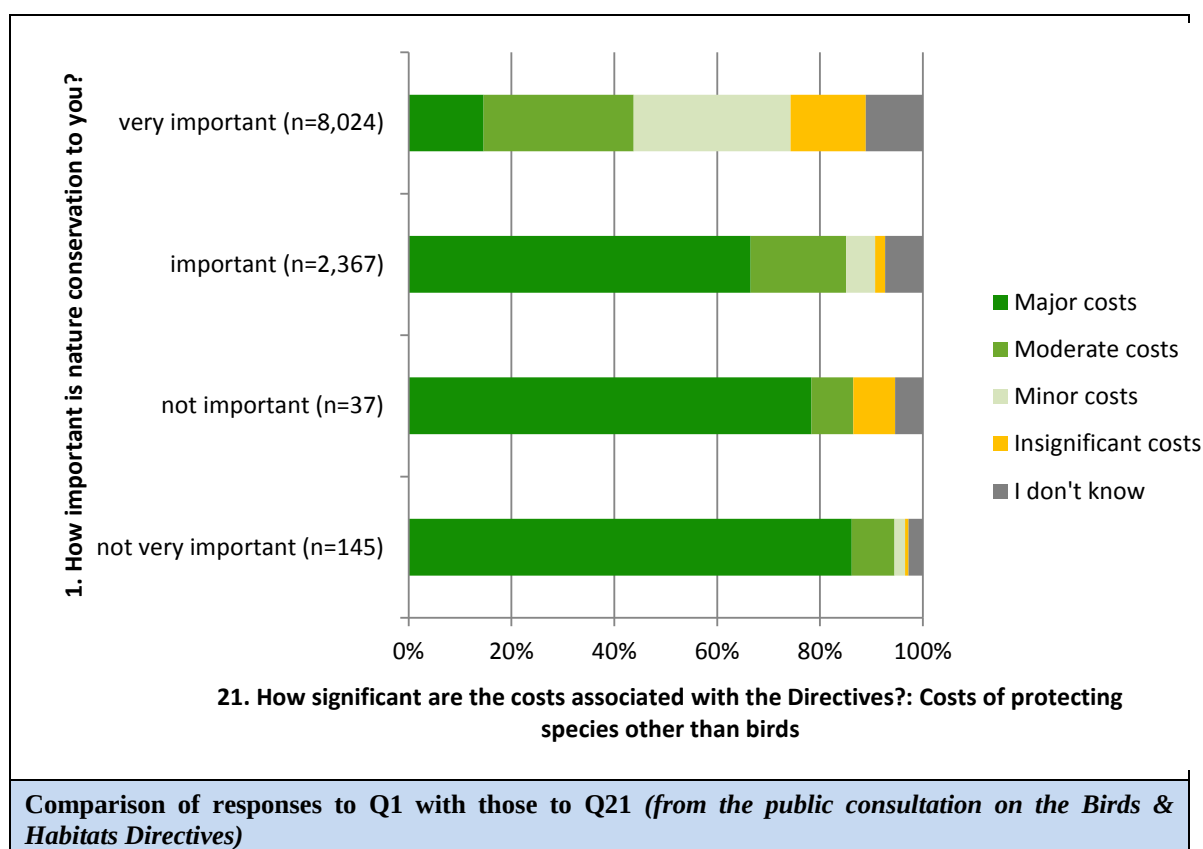


More advanced analysis

Professional polling companies as well as **Eurobarometer**⁶⁴⁸ surveys are specialised in presenting the views of the general population on a great variety of issues. Where the **responses** to particular questions or survey respondents **are drawn from a representative sample**, it may be possible to apply additional analysis of the responses in order to determine the statistical significance of the conclusions – particularly if the responses are inferred to apply to a much wider population (such as that of a particular country or the EU as a whole).

This situation does not apply to the results of a **public consultation** due to the self-selection of respondents, which means that **the responses are not drawn for a representative sample**. While it is accepted that advanced statistical analysis has an important role for some types of analysis, such statistics provide limited added value to results from a self-selecting (i.e. non-randomly selected) sample and can potentially be misleading. In other words, statistics provide little additional information (of use to the policy maker) beyond that obtained by the analysis presented here.

However, this should not suggest that further analysis beyond the ‘basic’ analysis cannot be undertaken. By way of example, it may be useful to analyse the relationships between different questions as illustrated below.



⁶⁴⁸ <http://ec.europa.eu/COMFrontOffice/PublicOpinion/>

Interpretation of data - Weighting and representativeness of respondents and replies

There is a fundamental difference between a survey, such as Eurobarometer⁶⁴⁹, and public consultation (see former paragraph). **Data gathered through public consultation does not provide a representative view of the EU population.**

Weighting of data is a statistical technique of making answers count for more or less to ensure they are representative of the population. You can only use this technique if you have an understanding of the demographic make-up of the population and returns. It is generally very difficult to get this understanding and therefore **it is not recommended** to apply weighting techniques **for the analysis of data from public consultations**. If you need to have representative views, other tools, such as Eurobarometer, should be considered.

Note that when reporting back on the outcome of the consultation the methodologies and tools should be explained for transparency reasons, including if weighting techniques have been applied.

Box 7. Interpretation of data – key aspects

Consultations aim to gather evidence, which is used as input for policy preparation and contributes to informed decision-making. It is therefore **essential to provide the right context of the consultation when presenting the outcome**, including information on who participated and whom respondents represent:

- When analysing⁶⁵⁰ and presenting the results, **distinction should be made between the different stakeholder categories** that contributed to the consultation. A short description should be provided about the different stakeholders (background, whom they represent, etc.)
- Do, preferably, the '**Stakeholder Credibility test**' and consider its outcome in the analysis:
 - *Longevity*: Has the stakeholder organisation been established long enough to acquire the wisdom in the policy field?
 - *Expertise*: How well does it know the subject matter?
 - *Representativeness*: Who exactly does it represent and how well does it do so?
 - *Track record*: How useful/credible has its contribution been in the past?
 - *Reputation*: How seriously do other people take this organisation?
- Contributions from **citizens** should be analysed as a separate stakeholder category
- **Campaigns should be identified** and the relevant responses should be segregated, analysed and presented separately from the non-campaign responses (see para 2.4)
- **Avoid using only percentages** when presenting results; they should be linked to the corresponding amount of responses (see para 3.1.1).

⁶⁴⁹ <http://ec.europa.eu/COMMFrontOffice/publicopinion/index.cfm>

⁶⁵⁰ See also better regulation Guidelines, chapter VII

5.3.2. Analysis of open questions

Overview

Textual input to open questions is considered as qualitative data, which is, compared to quantitative data rich and complex and therefore it cannot be treated statistically. However, this does not mean that systematic and rigorous analysis techniques cannot be applied. Qualitative data, more than quantitative, is extremely prone to bias, and systematic analysis helps prevent this.

Basic Analysis

Under the approach to basic analysis, responses would most commonly be grouped into broad stakeholder groups (typically citizens/NGOs, authorities, industry, others). Under the simplest approach, responses from a particular group for a particular question could then be quickly read to get an overview of the two or three most recurrent points being made.

Coding of qualitative information
Coding is a technique that allows qualitative information to be categorised/sorted/interpreted • A coding frame is constructed from the first 50 or so responses, and subsequently modified as more responses come in • A coding frame is a set of headings under which comments/texts may be placed to categorise it; the headings may be free-standing or 'nested' (with different levels, e.g. car driver -> driver of a motor vehicle -> road user • Text responses are then read and each piece of text is assigned ('coded') to one or more headings • Code frames may apply to individual questions, but (more often) apply across a whole submission

Depending on the nature of the question, one might expect **the analysis to typically yield five to ten themes from the first 20 to 50 responses**. These themes should be noted and the frequency of occurrence in subsequent response should be recorded. Thereafter, experience suggests that fewer themes will be found and, indeed, the rate of reading of responses may increase as the reader becomes familiar with the range of points being made.

This needs to be preferably done in the languages in which the responses have been provided. In some cases, it may be easiest to translate all responses into a single language and then analyse the sample. In other cases, it may be desirable to review the responses in their native language and extract key themes. In this approach, it is preferable to run languages sequentially to avoid similar but different themes emerging for each language which can lead to confusion. In practice, the precise approach adopted will depend on the number and nature of responses and the relevant language skills.

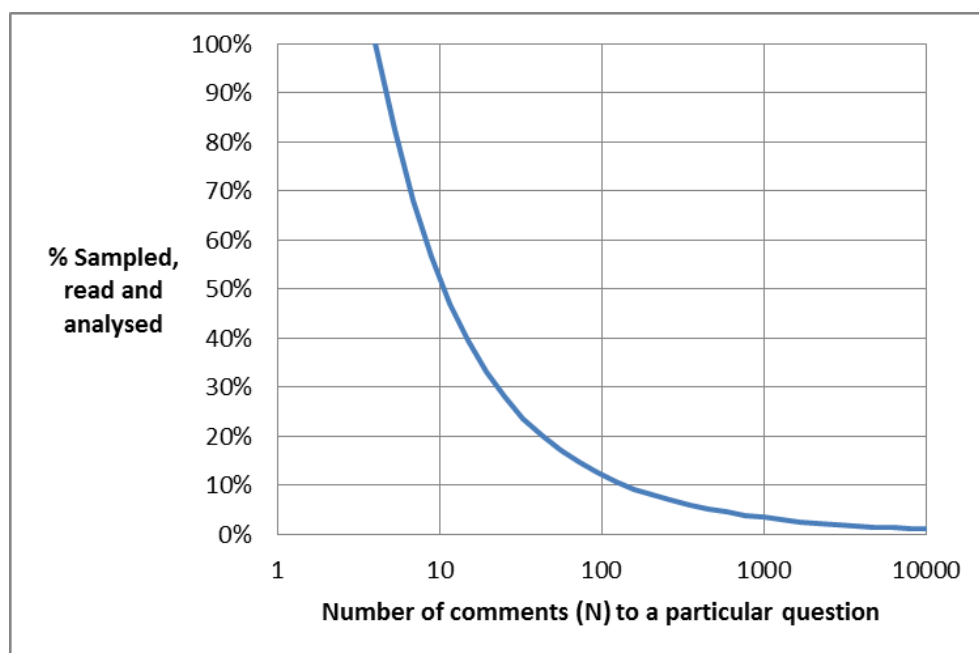
However, as a guide, **once there are more than 500 answers to consider** (e.g. 100 responses x 5 comment boxes or 50 responses x 10 comment boxes), **it may be necessary to use a more resource-efficient method** as outlined below in the advanced analysis.

Resource estimate for consideration of open text contributions

Experience suggests that **detailed consideration of significant contributions⁶⁵¹ takes time – about five answers per hour**. For 50 responses each with 5 significant comment boxes completed will require $(50 \times 5)/5 = 50$ hours, i.e. more than one person/ week.

Sampling for the Advanced Analysis

The more resource-efficient method involves **a combination of reading** a sample of responses **and** then using **advanced software** to analyse all responses. In developing this guidance, consideration was given to the results of sampling responses to 11 different Commission public consultation from which it appeared that **a sample size of $\sqrt{N}+2$ ⁶⁵²** (i.e. the square root of the number of responses, N, plus two) **would typically yield five to ten themes**. In some cases, the computer analysis would reveal a further theme. This seems a reasonable balance between the resources required for the sampling and the associated results. As illustrated in the chart below, where the number of comments being considered is relatively small, a significant percentage will be sampled, read and analysed. For 100 comments, 12 (12%) will be sampled and for 1,000 comments 34 (3.4%) will be sampled.



Sample size ($\sqrt{N} + 2$) as a % of comments read vs number of comments (N)

⁶⁵¹ A 'significant contribution' has been taken to mean, typically, half a page of typed text (in any EU language) from which key themes will be identified and recorded.

⁶⁵² Empiric determined formula; See Commission study [Consultation Support and Development of Advice (Specific Contract No SG/2015/10 under Framework Contract ENTR/172/PP/20-12-FC Lot 3) : <https://bookshop.europa.eu/en/consultation-support-and-development-of-advice-pbKA0217018/?CatalogCategoryID=YR4KABstrdkAAAEjLocY4e5K>

Procedure for computer-aided analysis

The approach for this analysis includes the following steps:

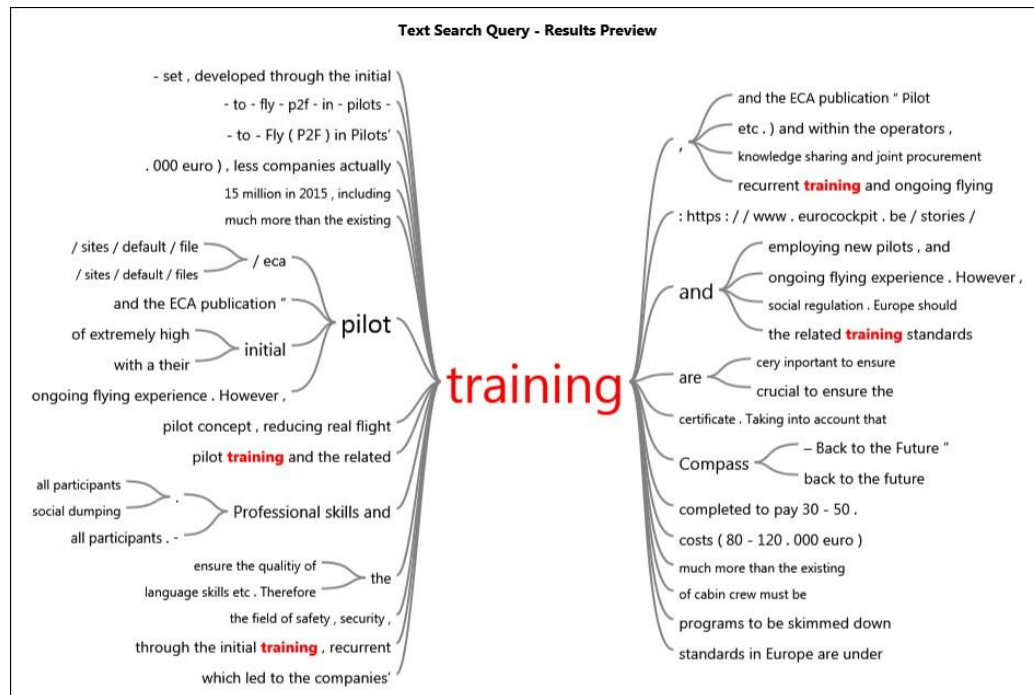
1. **Assigning language markers.** To assist with the analysis, it is important that all responses are given a language marker. This, in turn, leads to the suggestion that if the questionnaire(s) contains comment boxes – it is recommended **to include a final question asking which language has been used for the text boxes** as this makes a significant difference to the time for subsequent analysis (particularly if there are thousands of responses)
2. **Review a sample.** For a particular question – read a sample of $\sqrt{N}+2$ responses and extract key ‘themes’. By way of example, if there were 68 responses, a sample of $\sqrt{68} = 8 + 2 = 10$ would be read and analysed.
3. **Word frequency search:** Using qualitative data analysis software⁶⁵³ enables word frequency searches to be rapidly undertaken to identify the top five most frequently used words in the responses. To be useful, common words (*the, and, it*, etc.) are excluded as are words from the title of the consultation. This should be done for each language for which there are more than 30 responses in multiple languages⁶⁵⁴.
4. **Word cloud:** The ‘word cloud’ function of the software used could be useful to establish for instance the top 100 most frequently used words and to present the results graphically. This could help in identifying themes, particularly when combined with the ‘word tree’ (see below)



⁶⁵³ Such as Doris (Commission tool) or NVivo (commercial)

⁶⁵⁴ NVivo also has the capabilities to perform such searches using synonyms when working with some of the more common languages (EN, FR, DE, ES and PT).

5. **Word tree:** For any words identified in the above word frequency/word cloud approach, which indicated that some themes may have been missed, a ‘text search’ can be carried out and the results of this search displayed in a word tree⁶⁵⁵ (see below) to quickly determine the context in which these words were used, and consequently to identify any themes missing from the sample.



Word tree showing the context of the word ‘training’ for question 1

5.4. ALLOCATING RESOURCES

5.4.1. Introduction

There are essentially two constraints related to the analysis of stakeholder contributions - time and availability of resources. If sufficient time and resources are available, then each and every response can be read and analysed in detail. Similarly, if the questionnaire consists entirely of closed questions, then such constraints are unlikely to pose a serious problem – irrespective of the number of responses. However, **the presence of numerous open text comment boxes can greatly increase the time and resources required.**

⁶⁵⁵ Depending on the software used

5.4.2. *Time*

The figure overleaf illustrates the estimated time required for one person on a full time basis to carry out the analysis of an example consultation with a mix of open and closed questions and with a few hundred responses.

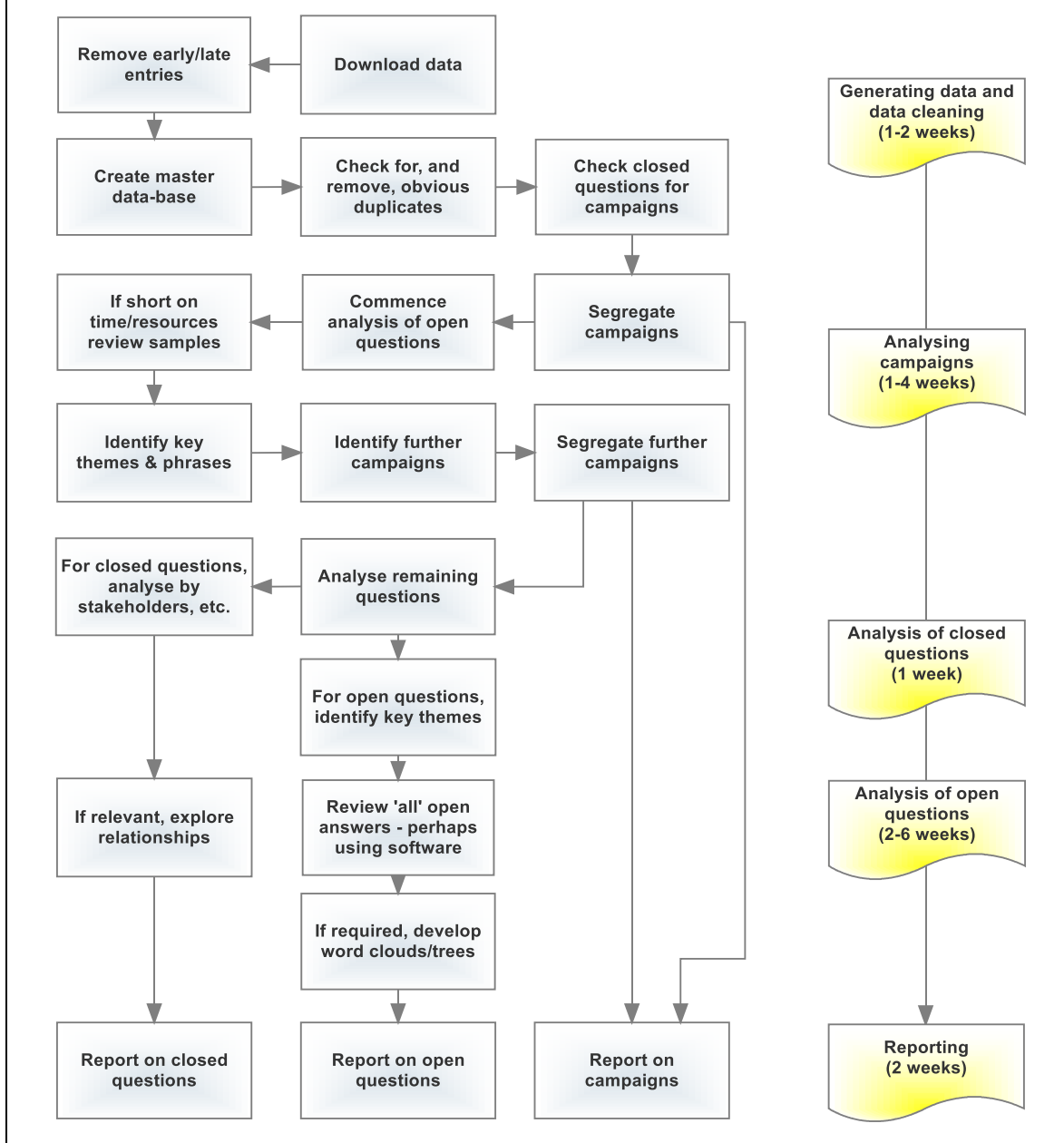
5.4.3. *Resources*

Based on the time taken to analyse responses to a range of public consultations, it is possible to provide indicative guidance as to the resources required (in person-days) for a thorough analysis of a public consultation which attracts a degree of interest from stakeholders.

Clearly, the resources required will increase with:

- The number of closed questions (little impact)
- The number of open questions (big impact)
- The number of responses (mainly for open questions)
- The number of stakeholder groups to be analysed

The estimated time required to analyse a consultation



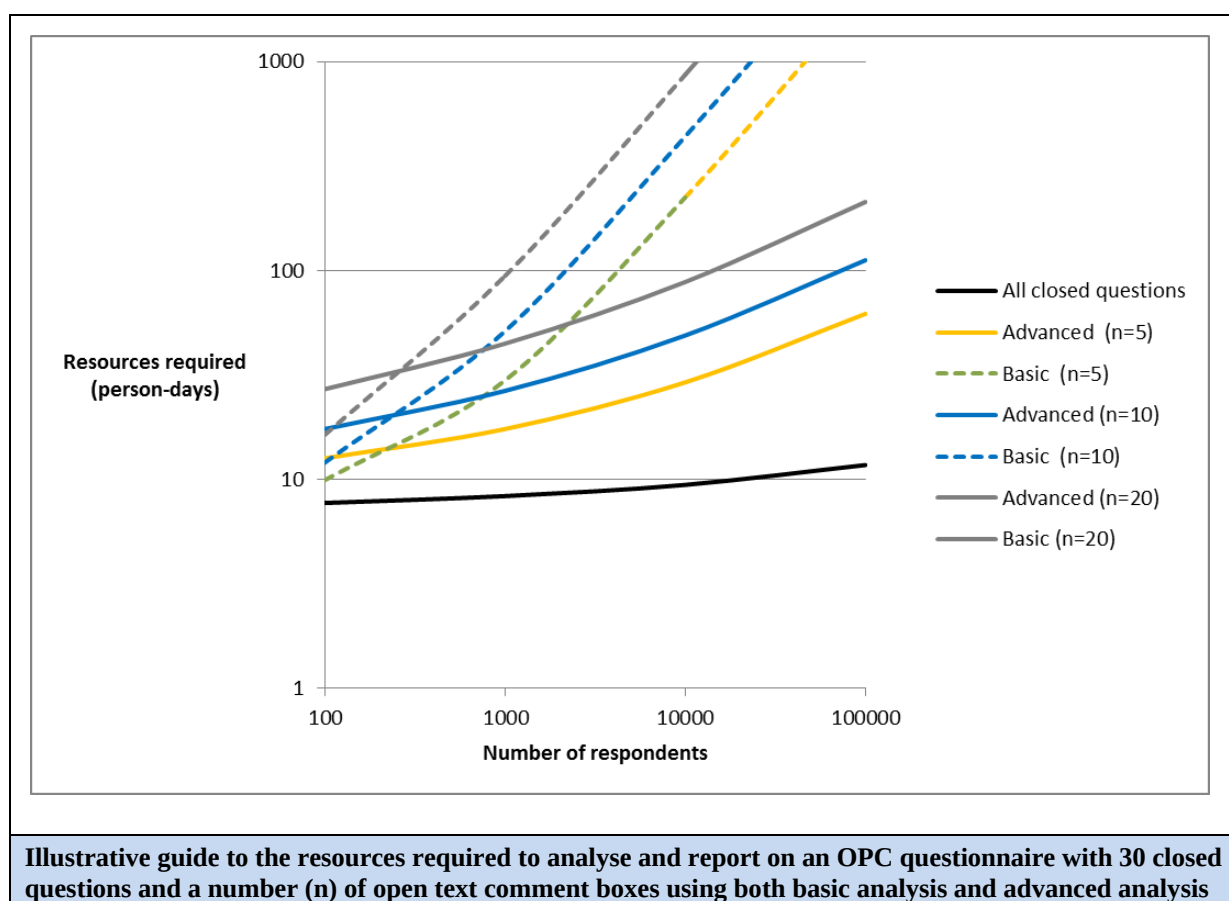
The illustrative example below shows the resources required to analyse the data and provide a summary report based on a mid-sized questionnaire with 30 substantive closed questions divided into five themes and one open comment for each section (five in total). The table below illustrates how the resources required will vary depending on whether the questionnaire elicits 200 or 2000 responses. For this example, two further assumptions have been made:

- The analysis of open and closed questions will focus on three broad stakeholder groups
- The response rate to the open questions is 30% (i.e. they are not mandatory)

Parameter	200 responses	2000 responses
Download data to Excel and analysis of	8 days	9 days

closed questions (including reporting) (Note advanced analysis using STATA for campaigns does not add extra time)		
Basic analysis of open questions (i.e. all comments read and analysed at a rate of 10/hour)	4 days	43 days
Advanced analysis of open questions	6 days (3 days for sampling (@ 5/hour) and 3 days for computer aided analysis)	11 days (7 days for sampling (@ 5/hour) and 4 days for computer aided analysis)
Total (basic analysis of open questions)	12 man days	52 man days
Total (advanced analysis of open questions)	14 man days	20 man days

Further examples are provided in the figure below:

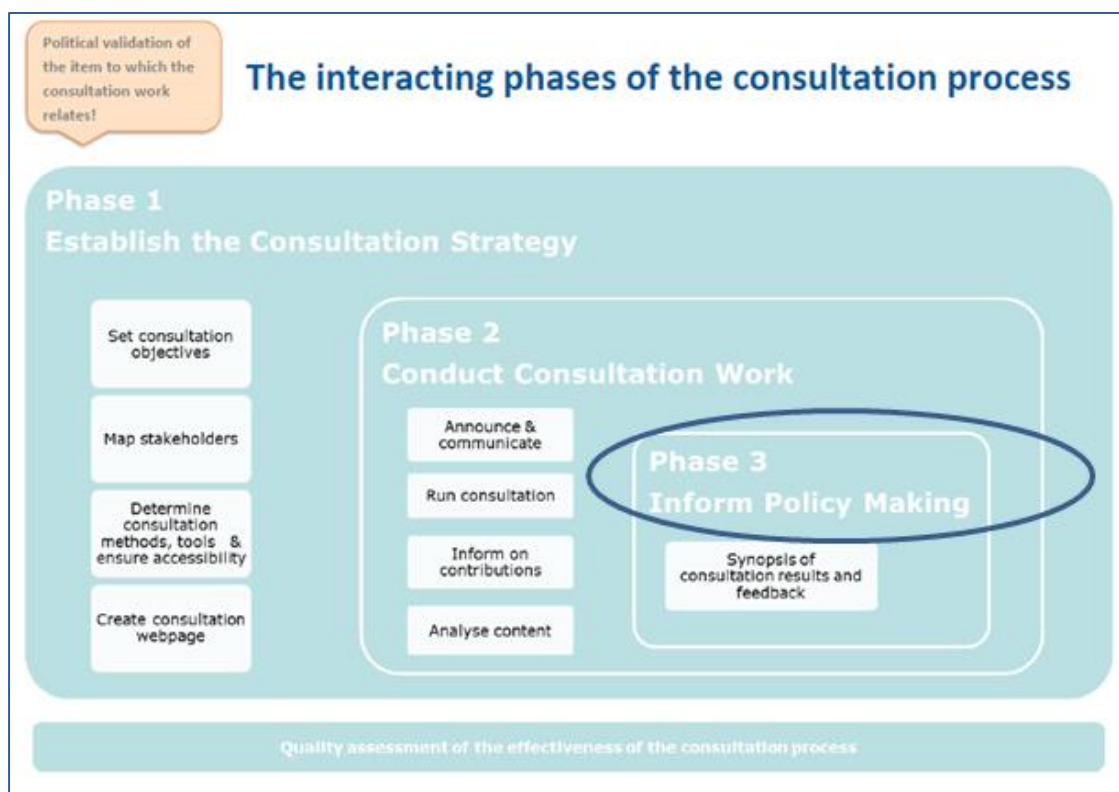


5.5. FURTHER READING & REFERENCES

- Commission Study 'Consultation Support and Development of Advice' (RPA, 2016): <https://bookshop.europa.eu/en/consultation-support-and-development-of-advice-pbKA0217018/?CatalogCategoryID=YR4KABstrdkAAAEjLocY4e5K>

- The Consultation Institute: <https://www.consultationinstitute.org/>
- Commission data analysis tool Doris: <http://doris.cnect.cec.eu.int/dorisBoard>
- Available data analysis software, including request procedure: https://myintracomm.ec.europa.eu/dg/dgt/it_support/software/Pages/index.aspx

TOOL #55. INFORMING POLICYMAKING - THE SYNOPSIS REPORT



1. INTRODUCTION

At the end of the consultation process it is essential to present a concise overview and conclusions of the consultation work carried out to substantiate or a policy initiative under preparation, an evaluation or fitness check.

It is the responsibility of the competent services to ensure transparent and comprehensive information on the overall consultation work, its outcome, the conclusions that may result and any other related issues.

The outcome of the consultation activities should be presented either in the impact assessment report (IA), the evaluation staff working document (SWD) or the fitness check report or in a self-standing synopsis report where none of these is prepared. Consultation activities should also be reported in the explanatory memorandum where relevant.

The synopsis report covers formal consultation work, ad hoc contributions directly linked to the preparation of the policy, evaluation or fitness check and information on the input received through the feedback mechanisms⁶⁵⁶ for roadmaps and inception impact assessments (IIA).

⁶⁵⁶ See Tool #56 on *Stakeholder feedback mechanisms*

2. SYNOPSIS REPORT

The self-standing synopsis report (or the synopsis that is annexed to the IA report, Evaluation SWD or fitness check report) summarises the results of all the consultation activities in relation to a particular initiative, and gives a qualitative analytical overview of these results. Its aim is twofold:

- To inform policymaking on the outcome of all consultation activities.
- To inform stakeholders on how their input has been taken into account and to explain why certain suggestions could not be taken up.

The Synopsis should be prepared as soon as possible after the last consultation activity has taken place and be discussed and endorsed by the Interservice Group, where applicable. The adopted **report⁶⁵⁷ accompanies the initiative through interservice consultation up until adoption and must be published on the consultation webpage of the initiative.**

2.1. Content of the Synopsis report

Whether in a self-standing report or integrated into the IA report, evaluation or fitness check SWD, the synopsis should comprise the following general elements:

- A key outline of the consultation strategy, referring to the consultation objectives as defined, identified stakeholders and selected consultation methods and tools;
- Documentation of each formal consultation activity, including, if applicable, an explanation as to how and why the initial consultation strategy was modified;
- Information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached;
- Short description of the methodology and tools used to process the data.
- Description of the results of each consultation activity, including qualitative and interpretative analysis; if different consultation activities have been undertaken in the context of the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions in relation to contributions and main stakeholder categories;
- Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses). The information should include the share of contributions and their viewpoint.
- For ad hoc contributions received outside the formal consultation context, a separate paragraph should be added describing the origin of the contributions

⁶⁵⁷ See paragraph 2.2 'Format'

received including identification of the type of stakeholder and their represented interests,

- Where applicable, a paragraph summarising the feedback⁶⁵⁸ received on the roadmap or inception impact assessment.
- Explanation on how the information gathered in the context of the consultation work as well as feedback received has been taken into account into the further work on the initiative, evaluation or fitness check. Where relevant, this should include explanation on why certain widely supported views were not or not entirely considered.
- If national Parliaments have contributed, it is recommended to inform in a separate paragraph which national Parliaments contributed (Member State and chamber) and what issues they addressed.

2.2. Format

The self-standing synopsis report should take the **form of a staff working document (SWD)**. In case the report refers to an initiative accompanied by an IA or an evaluation or fitness check, the report should be part of the annex of the IA or evaluation SWD. In case of "Back-to-back" evaluation and IA please consult Tool #52. Note that the synopsis report as part of the annex of an IA or evaluation report should read as a stand-alone document that contains the elements set out in the former paragraph. The main part of the SWD should make reference to key conclusions of the synopsis where relevant.

IA reports, evaluation SWDs or fitness check reports are also presented as SWDs and can only be finalised following an interservice consultation.

The synopsis report should **not exceed ten pages** (using DGT counting of characters).⁶⁵⁹

2.3. Language coverage

The synopsis report is a SWD. Usually, SWDs are not translated. However, if the report covers public consultations relating to initiatives in the Commission's Work Programme Annex I or those with a broad public interest, it is best practice to publish the synopsis report (or the relevant annex in the IA report, evaluation SWD or fitness check report) in all languages of the consultation. The lead DG should contact DGT to plan these translations, for which the maximum length is 10 DGT pages.

⁶⁵⁸ See Tool #56 on Stakeholder feedback mechanisms

⁶⁵⁹ Not exceeding ten DGT pages (15 000 characters without spaces) will ensure that DGT is able to translate the report in 11 working days. For more information, please see <http://www.cc.cec/Ares/ext/documentInfoDetails.do?documentId=080166e591c3f619> or check directly with the translation service. Info as well available on GoPro: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

3. EXPLANATORY MEMORANDUM

For legislative proposals, the explanatory memorandum should explain how far the main contributions have been taken into account in the draft policy initiative, or why they could not (all) be taken into account.

- Report why certain options were discarded (in particular when those were widely supported by respondents)
- Highlight the link between respondents'/participants' input, IA or any other element that justifies and explains the options proposed by the Commission.

4. FURTHER READING & REFERENCES

Good practice examples of synopsis reports and explanatory memoranda will be made available on GoPro.⁶⁶⁰

⁶⁶⁰ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

TOOL #56. STAKEHOLDER FEEDBACK MECHANISMS

1. INTRODUCTION

Citizens and stakeholders can provide feedback on each roadmap (including for evaluations) or inception impact assessment (inception IA), on legislative proposals adopted by the College and on draft conferred legislation, namely draft implementing and delegated acts of a general application as well as on draft measures subject to regulatory procedure with scrutiny (*RPS/PRAC measures*). The tool 'Lighten the Load' offers the opportunity to provide feedback on how to improve existing legislation.

The IT tools allowing for the collection and processing of feedback are integrated in the Commission Europa webpages and accessible via the portal '[Share your views](#)'⁶⁶¹. Technical guidance on their operation and features can be found on GoPro⁶⁶².

*Please note that in the context of the Commission's Better regulation agenda **collecting feedback under the feedback mechanisms differs from collecting input under consultation**:*

<i>Collection of feedback versus Consultation</i>
• The collection of feedback offers an opportunity for stakeholders to express general views on a specific document (roadmap, inception impact assessment, draft secondary legislation, legislative proposals and accompanying impact assessments, established legislation), not based on specific questions or consultation background documents. • Consultation is a formal process of collecting input and views from 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.

2. FEEDBACK ON ROADMAPS FOR NEW INITIATIVES OR EVALUATIONS AND INCEPTION IMPACT ASSESSMENTS

2.1. Introduction⁶⁶³

Roadmaps and inception impact assessments aim to inform citizens and stakeholders about planned Commission initiatives as well as about evaluations and fitness checks. Comments received on a roadmap or inception impact assessment feed into the early stage of policy preparation.

⁶⁶¹ http://ec.europa.eu/info/law/better-regulation/share-your-views_en

⁶⁶² <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁶⁶³ For more detail, see Tool #6 on Planning and validation of initiatives

Roadmaps for new major initiatives describe the problem to be tackled and the objectives to be achieved, explain why EU action is needed and its added value and outline alternative policy options.

Roadmaps for evaluations and fitness checks⁶⁶⁴ specify the scope of the evaluation and the issues to be examined in the context of an evaluation.

If an impact assessment is planned, the roadmap is replaced by an **inception impact assessment** which sets out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.

All roadmaps and inception impact assessments contain information on **planned stakeholder consultations** and outline when and how stakeholders will have the opportunity to provide input.

The feedback period for roadmaps and inception impact assessments is limited to **four weeks**, which allows comments to usefully feed into the further preparatory work of the initiative, including the preparation of external studies and contracts as well as the finalisation of the stakeholder consultation strategy⁶⁶⁵. Consequently, **consultation activities, including public consultations should not be launched and, ideally, studies and contracts should not be put out to tender until the feedback period is closed.**

Overview workflow

<i>Workflow for feedback on Roadmaps and Inception Impact Assessments</i>
• As soon as the underlying initiative is validated in <i>Decide</i>⁶⁶⁶, the roadmap/inception impact assessment⁶⁶⁷ should be finalised between the lead DG and SG and must be uploaded in Decide Planning⁶⁶⁸. It is then published by the SG. • Publication can be done only once per draft act and is irreversible. It is therefore compulsory, before triggering the publication, that the appropriate hierarchical validation is given; the required hierarchical level for validation is decided by the Director-General of the responsible DG. • Feedback can be provided for a period of 4 weeks after publication. • The roadmap/inception impact assessment and all feedback is published on the 'Share your view'⁶⁶⁹ page on Commission Europa. Respondents have the possibility to opt

⁶⁶⁴ Including roadmaps for an ex-ante evaluation required by the Financial Regulation.

⁶⁶⁵ See Tools #53, #54 and #55 on stakeholder consultation

⁶⁶⁶ https://intragate.ec.europa.eu/decide/sep/entrance?Lizard_v3.0.25.9553-2016-09-30T16:13:51.428+02:00#/searchResult/

⁶⁶⁷ See Tool #7 on Drafting of roadmaps, evaluation roadmaps and inception impact assessments.

⁶⁶⁸ For detailed workflow see GoPro:
<https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁶⁶⁹ http://ec.europa.eu/info/law/better-regulation/share-your-views_en

for publication of their contribution with their personal information or anonymous publication of their contribution⁶⁷⁰.

- DG's should ensure that the feedback is taken into account in the further process of policy preparation or evaluation. No formal translation of the feedback is required and no specific replies are expected from the Commission in response to individual feedback.
- **Feedback should be summarised** and referred to **in the 'synopsis report'**⁶⁷¹. It should also **be explained how and to which extent the feedback has been taken into account** in the final initiative/evaluation. For legislative proposals and for delegated acts, information on stakeholder input in general, including feedback, should in addition be referred to in the '**explanatory memorandum**'⁶⁷².

3. FEEDBACK ON LEGISLATIVE PROPOSALS ADOPTED BY THE COLLEGE AND ACCOMPANYING IMPACT ASSESSMENTS

3.1. Introduction

After a legislative proposal is adopted by the College, citizens and stakeholders are able to provide feedback on the proposal and, where relevant, on the accompanying IA.

Feedback can be provided for a period of **eight weeks**, in parallel with the period during which national parliaments have the opportunity to provide reasoned opinions on subsidiarity grounds.

According to The Inter-institutional Agreement on Better Law-making "the three Institutions will keep each other regularly informed throughout the legislative process about their work, about on-going negotiations among them and about any stakeholder feed-back they may receive, via appropriate procedures, including dialogue between them". Following this agreement, the post-adoption feed-back mechanism is a means for the Commission to transparently inform on the views of different stakeholders on its final proposal (and Impact Assessment).

Therefore, the collected feedback will be summarised by the Commission and presented to the European Parliament and Council, with the aim to feed these views into the legislative debate.

3.2. Overview workflow

Workflow for feedback on legislative proposals and accompanying Impact Assessments

⁶⁷⁰ See paragraph 4

⁶⁷¹ See Tool #55 on *Informing policymaking – the synopsis report*.

⁶⁷² See better regulation Guidelines - Chapter VII, paragraph 6.3.1 *explanatory memorandum*

- After adoption by the College, the legislative proposal and, where relevant, the accompanying impact assessment is published automatically on the '[Share your view](http://ec.europa.eu/info/law/better-regulation/share-your-views_en)'⁶⁷³ page of Commission Europa.
- Feedback can be provided **until 8 weeks after the last language version is published.**
- All feedback is published on the '[Share your view](http://ec.europa.eu/info/law/better-regulation/share-your-views_en)'⁶⁷⁴ page on Commission Europa. Respondents have the possibility to opt for publication of their contribution with their personal information or anonymous publication of their contribution⁶⁷⁵.
- No formal translation of the feedback is required and no specific replies are expected from the Commission in response to individual feedback.
- The **responses must be summarised and sent to the European Parliament and the Council by means of a letter from the Director-General** of the Directorate General in charge for the file. This letter should be sent as soon as possible after closure of the feedback period to inform the work of the respective Committees and Working Groups in Parliament and Council. **A copy of the letters must be sent to the office of the Secretary-General.** In case no feedback has been received, no letter should be sent to the European Parliament and Council.
- For the **European Parliament**, the letter should be addressed to the **chair(s) of the Committee(s) to which the proposal is attributed.** Normally, by the time the feedback mechanism is closed, the corresponding proposal should have been attributed to one or more Committees. In case the file is not yet attributed to a lead committee, the letter should be sent to the Chair of the Conference of Committee Chairs.
- For the **Council**, the letter should be addressed to the **Ambassador of the Presidency with copy to the chair of the Council Working Group** in charge of the file. In case the file is not yet attributed the letter should only be addressed to the Ambassador of the Presidency.
- The letter should provide **a factual summary of the feedback received**, without any further qualitative assessment or reference to the Commission's viewpoint on provided views. The letter should include as well **a reference to the '[Share your view](http://ec.europa.eu/info/law/better-regulation/share-your-views_en)'**⁶⁷⁶ page on Commission Europa **where all feedback responses are published.** No formal interservice consultation is required, however, where relevant, **associated DGs should be consulted on the draft.**

⁶⁷³ http://ec.europa.eu/info/law/better-regulation/share-your-views_en

⁶⁷⁴ http://ec.europa.eu/info/law/better-regulation/share-your-views_en

⁶⁷⁵ See paragraph 4

⁶⁷⁶ http://ec.europa.eu/info/law/better-regulation/share-your-views_en

4. FEEDBACK MECHANISM FOR DRAFT DELEGATED AND IMPLEMENTING ACTS AND DRAFT MEASURES SUBJECT TO REGULATORY PROCEDURE WITH SCRUTINY (RPS/PRAC MEASURES)

4.1. Introduction

Delegated act empowerments allow the Commission to adopt legal acts of general application to supplement or amend certain non-essential elements of a legislative act. Implementing act empowerments are used where uniform conditions for implementing legally binding acts are needed.⁶⁷⁷

In the better regulation package of 19 May 2015, the Commission committed to giving stakeholders the possibility to provide feedback on the draft texts of delegated and implementing acts and regulatory procedure with scrutiny (RPS) measures, with exceptions (see below). This feedback period lasts for 4 weeks.

In practice, this means that DGs need to consider, already at the planning stage, whether an upcoming act qualifies for the feedback mechanism and flag this in the Decide planning module. The list of upcoming delegated and implementing acts and RPS measures that will be published for feedback is made available at regular intervals on the '[Contribute to law making](http://ec.europa.eu/info/law/contribute-law-making_en#draft)'⁶⁷⁸ webpage on Commission Europa, in order to allow stakeholders to plan ahead and prepare. Also, DGs need to factor in the additional time needed for feedback and for analysis of the feedback received.

4.2. Overview workflow draft Delegated Acts

Workflow for feedback on Draft Delegated Acts

- All delegated acts need to be **included in the Decide planning module**, those that will be subject to feedback need to be flagged (Feedback Yes/No).
- The planning of upcoming delegated acts subject to feedback is published at regular intervals on the '[Contribute to law making](http://ec.europa.eu/info/law/contribute-law-making_en#draft)'⁶⁷⁹ webpage on Commission Europa
- The draft delegated act can only be published **after the interservice consultation** has taken place. When launching the interservice consultation DGs need to indicate whether the feedback is foreseen and if not which exception applies.
- **Publication** can be done **only once per draft act and is irreversible**. It is therefore compulsory, before triggering the publication, that the **appropriate hierarchical validation** is given; the required hierarchical level for validation is decided by the Director-General of the responsible DG.
- Feedback can be provided **for a period of 4 weeks** after publication.
- All feedback is published on the 'Share your views' page⁶⁸⁰ of Commission Europa. Respondents have the possibility to opt for publication of their contribution with their

⁶⁷⁷ See Tool #40 on *Delegated acts and implementing acts* for more information

⁶⁷⁸ http://ec.europa.eu/info/law/contribute-law-making_en#draft

⁶⁷⁹ http://ec.europa.eu/info/law/contribute-law-making_en#draft

personal information or anonymous publication of their contribution⁶⁸¹.

- No formal translation of the feedback is required and no specific replies are expected from the Commission in response to individual feedback.
- Following the 4 weeks, the lead DG assesses the feedback received and explains how it took it into account in the explanatory memorandum accompanying the delegated act.
- Discussions in the expert group⁶⁸² can precede, run in parallel or come after the feedback period, depending on the nature of the act and the amount of technical expertise required for its preparation. In any case, **Member State experts shall be given the opportunity to see the last version of the draft** (i.e. the one incorporating the feedback), prior to the launch of the adoption procedure by the College

4.3. Overview workflow draft Implementing Acts and RPS measures

Workflow for feedback on Implementing Acts and RSP measures

- All **implementing acts** with committee control that are due to be adopted via oral or written procedure need to be **included in the Decide planning tool**; out of those, the ones that will be subject to feedback need to be flagged (Feedback Yes/No).
- All **RPS measures** need to **be included in planning tool**; out of those, the ones that will be subject to the 4-week feedback period need to be flagged (Feedback Yes/No).
- The planning of upcoming implementing acts and RPS measures that will be subject to the feedback period is published at regular intervals on the '[Contribute to law making](https://ec.europa.eu/info/law/better-regulation/initiatives)'⁶⁸³ webpage on Commission Europa.
- **Publication** can be done **only once per draft act and is irreversible**. It is therefore compulsory, before triggering the publication, that the **appropriate hierarchical validation** is given; the required hierarchical level for validation is decided by the Director-General of the responsible DG.
- When launching the interservice consultation DGs need to indicate in the cover note whether the feedback is foreseen and, if not, which exception applies.
- Feedback can be provided **for a period of 4 weeks** after publication
- **All feedback is published** on 'Share your views' page⁶⁸⁴. Respondents have the possibility to opt for publication of their contribution with their personal information or anonymous publication of their contribution.
- No formal translation of the feedback is required and no specific replies are expected

⁶⁸⁰ <https://ec.europa.eu/info/law/better-regulation/initiatives>

⁶⁸¹ See paragraph 4

⁶⁸² C(2016) 3301 <http://ec.europa.eu/transparency/regexpert/index.cfm>

⁶⁸³ http://ec.europa.eu/info/law/contribute-law-making_en#draft

⁶⁸⁴ <https://ec.europa.eu/info/law/better-regulation/initiatives>

from the Commission in response to individual feedback.

- Following the 4 weeks, the lead DG assesses the feedback received and explains in the committee meeting how it took it into account. This explanation is included in the **summary record of the meeting**, that is then made public in the Comitology Register⁶⁸⁵.

4.4. Scope of the feedback

Publication of draft acts for stakeholder feedback is a measure aimed at improving transparency of the Commission's work. **The feedback mechanism should aim to capture all such acts therefore.** However, there will be situations where publication of the draft act would bring little added value, duplicate previous consultations or would not be possible. The reasons for not publishing are explained in the table below and these must be interpreted restrictively.

The DG makes a first assessment, at the planning and at the interservice consultation stage. This is then scrutinised during the interservice consultation. In case of doubt over the whether to subject a draft act to feedback, the Secretariat-General is ready to provide guidance (SG COMITOLOGIE). It is, however, the responsibility of the DGs to apply the rules on publication so as not to undermine the objective of improving transparency.

	Type	Reason	Examples ⁶⁸⁶
1	No (or limited) margin of discretion	Lack of policy alternatives	Acts implementing an international standards into EU law without any (or limited) discretion. Corrigenda
2	Drafts have been prepared by an EU agency or body and have been subject to full public consultation before being submitted to the Commission and for which the Commission does not have the intention to significantly modify them	Extensive consultation on the draft text has already taken place in a dedicated framework	Acts based on regulatory technical standards submitted by the European Banking Authority or by European Securities and Markets Authority
3	Urgency / emergency measures	Time limitations do not allow additional consultation period	Acts under the urgency procedure or other urgent acts, e.g. temporary exceptional support measures in the agricultural field, urgent/emergency measures addressing threats to public, animal or plant health.
4	Budgetary procedures and measures, programme management decisions	Lack of policy alternatives / implementation of	Decisions on work programmes and selection and award decisions

⁶⁸⁵ <http://ec.europa.eu/transparency/regcomitology/index.cfm>

⁶⁸⁶ Concrete examples are available on GoPro:
<https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

		agreements already decided on	
5	Individual authorisation decisions / acts / decisions based on the assessment of compliance with legal requirements	Lack of significant impact, routine acts	Marketing authorisations in the pharmaceutical field or comparable authorisations, inclusions,
6	Temporary risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors	Temporary food safety measures
7	Based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency findings	Extensive consultation on the substance has already taken place in a dedicated framework	Areas in which agencies such as EFSA have given a scientific advice
8	Other duly justified reasons, e.g.: • Involving business secrets or security threats • Influence on markets	Public consultation not possible or not appropriate, e.g. due to legal restrictions or practical constraints.	Acts with confidential content (such as in the aviation safety or space area, Galileo) Acts relating to the common organisation of the markets in agricultural products, measures relating to aid to certain Member States Authorisations to Member States relating to own resource calculations

4.5. General principles governing publication of draft acts

- **Feedback is the default**

The default is that delegated and implementing acts and RPS measures go out for the 4-week feedback. Exceptions to this rule have to be applied in a restrictive manner.

- **Targeted or public stakeholder consultation does not replace the feedback**

Many DGs carry out extensive targeted stakeholder consultations in the preparatory phase, both for implementing and delegated acts. Such early targeted consultations do not replace the feedback, which gives the public at large the possibility to react on the actual draft act. In some cases, e.g. when an impact assessment is required, a public consultation is carried out in the preparatory stages, which, similarly to targeted consultations, does not replace the feedback mechanisms (given that the purpose of the latter is to allow stakeholders to comment on the actual draft text).

- **Urgency cannot be the result of insufficient planning**

Urgency is justified in those cases in which strict deadlines are provided for in the legal basis. It cannot be used to make good for insufficient planning in the earlier stages but may be used in truly exceptional circumstances of political urgency.

- **Feedback also applies to very technical acts**

The majority of delegated and implementing acts are very technical and may in reality only trigger comments from a specialised group of stakeholders. The feedback applies nevertheless and gives the public at large the possibility to react on the actual draft act.

- **Feedback can also be sought if an exception would apply**

DGs may still decide to use the feedback mechanism even though it may be justified not to publish the draft act.

- **Limited margin to act**

This is meant to cover cases in which the Commission's margin is limited due to prior commitments, notably in the context of international agreements or existing legislation. Obviously discretion in relation to delegated and implementing acts is always circumscribed and limited by the empowerment itself but this is not enough to justify relying on the exception.

- **Procedures with set deadlines**

In some cases the basic act foresees a specific procedure for the Commission with set deadlines. Here it may not be possible to add a four-week public feedback period.

- **Technical Barriers to Trade (TBT) notifications**

The TBT notification does not replace the need for feedback. In practice, the two processes can happen in parallel, with the 4-week feedback running together with the 60 to 90 day TBT notification.

- **Risk management measures**

Depending on the legal framework risk management measures can be **individual measures** (e.g. a decision addressed to a company allowing it to place a specific substance on the market, this is for example the case for medicinal products and GMOs) or **general measures** (e.g. an amendment of an annex or a list allowing for the use of a substance up to a certain concentration limit, e.g. cosmetics). **All individual authorisation decisions are exempted** from the feedback mechanism.

Risk management **measures of general application can also be exempted from the feedback** under exception 7 provided that they are:

- (1) Based on a scientific opinion from an agency or scientific committee (not a consultant);
- (2) On which a public consultation has already taken place on the scientific opinion, (not on the draft measure) and the recommendations concerning the risk management should have been clearly spelled out); and
- (3) Where the Commission follows the agency findings (i.e. the recommendation is essentially translated in legal text and all that is added is the entry into force/applicability/transitional measures for products on the market, not if new elements are added).

5. FEEDBACK OPPORTUNITY UNDER 'LIGHTEN THE LOAD'

At any time citizens and stakeholders can provide feedback on how to improve existing legislation. 'Lighten the load'⁶⁸⁷ has been established under the REFIT platform⁶⁸⁸.

Received feedback and any accompanying document are published instantly on the 'Lighten the load' webpage as well as the Commission/REFIT Platform feedback on contributions from stakeholders.

Received suggestions are reviewed by the REFIT Platform, and may be reflected in its opinions to the Commission.

If the Platform decides not to follow up a suggestion, an explanation will be sent to the person or organisation who submitted it.

The EU helpdesk Europe Direct provides an explanation to anyone who has submitted a suggestion that falls outside the mandate of the REFIT Platform.

6. PUBLICATION OF RESPONSES, DATA PROTECTION, ACCESS TO DOCUMENTS AND TRANSPARENCY REGISTER

6.1. Publication of responses

The Commission is committed to be open and transparent throughout the policy cycle, including in the way it consults its stakeholders. Therefore, contributions⁶⁸⁹ submitted in the context of the various feedback mechanisms should be published on the relevant policy webpages.⁶⁹⁰

Respondents have the option to have their contributions published either with their personal information or anonymously. Regardless the option chosen, respondents are required to fill in the personal identification data fields. Anonymous contributions to the feedback mechanisms are not possible. The option for respondents not to have their contribution published is not possible.

6.1.1. Publication of the contribution with personal information

Contributions are published together with key personal information, including the name of the respondent and the country in which the respondent resides. In case the respondent replies on behalf of an organisation or company, only the name of the organisation/company and country of residence of the organisation/company is published together with the contribution. Any other personal data which may be collected should not be made public, unless relevant. (e-mail, phone number, address, gender, etc.).

⁶⁸⁷ http://ec.europa.eu/info/law/better-regulation/lighten-load_en

⁶⁸⁸ https://ec.europa.eu/info/law/law-making-process/overview-law-making-process/evaluating-and-improving-existing-laws/reducing-burdens-and-simplifying-law/refit-platform_en

⁶⁸⁹ Contributions include responses to questionnaires, position papers, background material, etc.

⁶⁹⁰ See Tool #53 on *The consultation strategy*.

6.1.2. Anonymous publication

Contributions are published without any personal data provided in the context of the consultation. However, for practical reasons, documents submitted by stakeholders in the context of the feedback mechanisms, such as position papers or background documents, can be published in the way they are received. Removing personal data from such documents can be cumbersome and time consuming. Therefore, it should be clearly mentioned on the feedback form that **respondents should not include personal data in documents submitted in the context of consultation if they opt for anonymous publication.**

6.2. Data protection

Under EU law, personal data can only be gathered under strict conditions and for a legitimate purpose. Furthermore, persons or organisations, including the EU institutions, which collect and manage personal information, should protect it from misuse and should respect certain rights of the data owners which are guaranteed by EU law. In particular, Regulation (EC) No 45/2001 applies to the processing of personal data by EU institutions and bodies within the scope of Union law.

6.2.1. What is understood by personal data?

According to Article 2 (a) of Regulation (EC) No 45/2001 personal data is defined as follows: "Any information relating to an identified or identifiable natural person, referred to as "data subject" - an identifiable person is someone who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity.

6.2.2. Privacy statement

By means of the privacy statement, respondents should be informed in a clear way on how data is collected and processed. This document describes the objective of the personal data gathering and processing, the kind of data collected, technical information on the tools or platforms used to store and process data, to whom the data can be disclosed, the way data is protected, the period data is kept as well as contact information. In practice, a specific privacy statement is published on the Europa page that gives access to the feedback tool, including a link to the Europa page providing general information on 'protection of personal data'.

6.2.3. Data retention Period

Personal data should be kept only for as long as follow-up actions to the feedback contributions are necessary with regards to the purpose(s) of the processing of personal data. All personal data should be deleted from databases 5 year after the last action in relation to the feedback follow-up. Where necessary, personal data could be kept for a longer period as long as this is foreseen in the Privacy Statement. Reports containing personal data should be archived according to the Commission's legal framework (e.g.: SEC(2012)713 - Common Commission-Level Retention List for European Commission Files (CRL) of December 2012). Participants must be informed of the fact that they can request their personal data to be deleted."

6.3. Access to Documents

Contributions, including personal data provided, may be subject to a request for access to documents under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents ('Regulation 1049/2001')⁶⁹¹. Regulation 1049/2001 provides any EU citizen and any natural or legal person residing or having its registered office in a Member State the right of access to documents of the EU institutions, subject to principles, conditions and limits defined in the Regulation. If access is requested, the request is subject to a case-by-case analysis based on Regulation 1049/2001 in order to assess the applicability of the exceptions defined in its Article 4, taking into account the legitimate interests and the justifications of non-disclosure in case provided by the author of the contribution. Where disclosure of the contribution, or parts thereof, would undermine the protection of commercial interests of a natural or legal person, the institutions shall refuse access in accordance with Article 4(2), first indent of Regulation 1049/2001.

6.4. Transparency Register

Organisations and businesses that wish to participate in consultation activities are asked to provide the Commission and the public at large, with information about which interests they represent and how inclusive their representation is, by subscribing to the Transparency Register. Contributions from organisations and businesses that choose not to register will be processed as a separate category "non-registered organisations/businesses"⁶⁹² unless they are recognised as representative stakeholders via relevant Treaty provisions⁶⁹³.

Publishing a document subject to one of the feedback mechanisms on the dedicated webpage will trigger an e-mail alert to registered organisations.

More info on the Transparency Register can be found on Europa.⁶⁹⁴

7. FREQUENTLY ASKED QUESTIONS

The list of FAQ is regularly updated and published on GoPro⁶⁹⁵.

8. FURTHER READING & REFERENCES

- GoPro pages;⁶⁹⁶

⁶⁹¹ Official Journal L 345 of 29.12.2001.

⁶⁹² See section on stakeholder categories

⁶⁹³ European Social Dialogue, Art. 154-155 TFEU.

⁶⁹⁴ <http://ec.europa.eu/transparencyregister/public/homePage.do>

⁶⁹⁵ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Stakeholders%20consultation>

⁶⁹⁶ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Delegated+acts;>
<https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Comitology>

- Updated Guidelines on Delegated and Implementing Acts.⁶⁹⁷

⁶⁹⁷ <https://myintracomm.ec.europa.eu/sg/comitology/Pages/index.aspx>

Chapter 8

Methods, models and costs and benefits

This chapter brings together a number of methods and tools that can be used to carry out analyses involving costs and benefits of EU interventions ex ante (in IA) or ex post (in retrospective evaluation/fitness check).

In particular, this section addresses:

- How to identify and assess costs associated with policy options/interventions including compliance costs, implementation and enforcement costs, administrative burden (standard cost model) and cumulative costs;
- Methods to identify and assess benefits (including non-market benefits);
- The role of discount rates when expressing future costs and benefits at today's prices and when performing economy-wide modelling;
- Explanations on how to use the multi-criteria analysis (MCA) and life cycle Analysis (LCA) techniques;
- Tips on how to present information visually in evaluation and impact assessment reports.

TOOL #57. ANALYTICAL METHODS TO COMPARE OPTIONS OR ASSESS PERFORMANCE

1. INTRODUCTION

A crucial part of any retrospective evaluation is the assessment of the performance of the existing policy intervention. Similarly, when a new initiative is being considered, the impact assessment should compare and rank the policy options. This tool presents the various ways/methods in which both can be done. In addition, the tool presents complementary procedural guides on how to perform a multi-criteria analysis and cost-benefit analysis which draw on the content of the separate tools describing methods which can be used to assess costs and benefits and the study prepared by the Centre of European Policy Studies on the assessing the costs and benefits of regulation⁶⁹⁸.

Every evaluation and impact assessment is different and the degree to which quantified information is available will also be different. As such, impact assessments and evaluations will have to employ one or more of the approaches according to the particular circumstances. They will still have to assess the economic, social and environmental impacts in an integrated way and to quantify them as far as is possible.

2. POSSIBLE METHODS

The key methods which are available to inform the assessments are presented below.

2.1. Cost Benefit Analysis

Cost-benefit analysis (CBA) entails the monetization of all (or the most important) costs and benefits related to existing public intervention or all viable alternatives at hand. A step by step guide to undertake a CBA is given in appendix.

CBA is mostly used during the appraisal stage of a new intervention. In its most recurrent form, it disregards distributional impacts and only focuses on the selection of the regulatory alternative that exhibits the highest net benefit. Accordingly, the most common methodology in cost-benefit analysis is the “net benefits” calculation, which differs from the “benefit/cost ratio” method that is typically used in cost-effectiveness analysis (being benefit minus costs, rather than benefits divided by costs).

There are pros and cons of choosing CBA as the method to be used in comparing policy proposals. The principal advantage is the ability of CBA to use an objective unit of measurement (monetised values) to compare alternative options and choose the one that maximizes the “size of the pie”, i.e. societal welfare as described in mainstream economics. The shortcomings, however, are often quite critical for CBA, and mostly refer to the assumption that income can be a proxy for happiness or satisfaction, the fact that it willingly ignores distributional effects (despite some attempts to adjust the methodology to reflect them), and its lack of objectivity when it comes to the selection of certain parameters (e.g. the inter-temporal discount rate), which can tilt the balance in favour of certain regulatory options over others.

⁶⁹⁸ http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

In the evaluation context, CBA can help to determine the overall impact of an intervention and whether it has been worth undertaking. It also provides evidence on the validity and appropriateness of the assumptions and projections used in the impact assessment for the examined intervention. A major advantage of using CBA in retrospective evaluations lies in ensuring that costs and benefits of an intervention are considered in a structured and explicit way. CBA promotes fiscal accountability and can be used to demonstrate added value of EU interventions.

CBA can be, and has been applied, within the EU system. However, it is typically less applied, and more difficult to apply, than in other regulatory systems for various reasons. For example, putting a monetary value on non-monetary costs and benefits can be sometimes difficult and will rely on a number assumptions. As a result, there is a risk that intangible values or outcomes may be under/overestimated or even overlooked. Accordingly, multi-criteria analysis tends to be used more frequently.

2.2. Multi criteria Analysis (MCA)

Multi-criteria analysis is a technique to reach a judgement based on an explicit set of objectives and associated criteria⁶⁹⁹. It is particularly useful in case of complex interventions with diverse quantified impacts measured in different units and/or qualitative impacts (in particular factors which cannot be expressed in monetary terms).

Typically, MCA will be used to *assess and rank alternative options in an impact assessment, or to assess the extent to which a variety of objectives have or not been met, in a retrospective evaluation or fitness check*. For example, the criteria chosen could include the impact on SMEs, the degree of protection of fundamental rights, consumer protection, etc. Multi-Criteria Analysis is particularly useful when impact assessment has to be reconciled with specific policy objectives, and as such is used as an instrument of ensuring the simultaneous assessment of effectiveness, efficiency and coherence of policies. This method allows the capture of distributional impacts (e.g. in terms of stakeholder types, EU regions/countries or time) and trade-offs between dimensions (such as between some economic, social or environmental impacts, or between some families of criteria). A separate tool provides more detail on how to use multi-criteria analysis.

2.3. Least Cost Analysis

Least cost analysis is primarily used in the impact assessment context. It only looks at costs, in order to select the alternative option that entails the lowest net cost. You should choose this method whenever benefits are fixed, and you only need to choose how to achieve them. Costs do not need to be precisely monetised or even quantified but their relative magnitude across options should be determined.

2.4. Cost-effectiveness Analysis

Cost-effectiveness analysis (CEA) entails that you quantify (not monetise) the benefits that would be generated by one Euro of costs imposed on society. While CEA is closely

⁶⁹⁹ See Tool #63 on *Multi-criteria analysis*.

related to CBA, instead of monetised benefits it uses other measures such as increased life expectancy, educational attainment, emissions abated etc.

In impact assessment, the typical method used to compare options is thus the so-called benefit-cost ratio, which means dividing the benefits by costs. This method is normally used for all expenditure programs, as it leads to identifying the “value for money” of various expenditure programs. A typical question that can be answered through cost-effectiveness analysis is “how many jobs will be created for every Euro invested?”, or, “how many lives are saved by every Euro spent?”⁷⁰⁰

CEA is less easily applicable to interventions with more than one main objective. If the intervention aims to achieve a number of objectives (e.g. job creation and environmental protection), or have indirect impacts, the results of CEA may be misleading or irrelevant.

In the evaluation context, the cost-effectiveness analysis will very often be used to compare the evaluated intervention against best practice or other interventions that aim to achieve similar objectives. It can also be used to assess the effectiveness of the implementation process where different implementation approaches have been pursued

2.5. Counterfactual Analysis

Counterfactual analysis is a statistical method devoted to quantifying whether a given intervention produces the desired effects on some pre-established dimension of interest.

The challenge for quantifying effect is finding a credible approximation to what would have occurred in *the absence* of the intervention, and to compare it with what actually happened. Different types of counterfactual analysis exist: Randomized Controlled Trials, Difference in Difference; Propensity Score Matching; Discontinuity Design and Instrumental Variables.

More precisely, a counterfactual analysis consists in comparing the outcomes of interest of the beneficiaries of a policy (the “treatment group”) with those of a group similar in all respects to the treatment group (the “comparison group”), except that it has not been subject to the policy. The comparison group informs us on what would have happened to the members of the treated group, had they not been exposed to the policy under scrutiny. This is the counterfactual.

Strengths: The observed differences (over time, across individuals) in the outcomes between the treated group and the counterfactual (over time, across individuals) provide estimates of the causal effect of the policy.

Limitations: Counterfactual Analysis requires extensive data sets on policy outcomes, collected before and after the intervention. There is also a need of pre-intervention outcome data which can represent an insurmountable obstacle. Finally, the challenge facing the evaluator is to avoid giving a causal interpretation to differences that are due to other factors, not to the intervention. It is necessary to identify the possible sources of bias arising in each specific situation and indicate which methods can overcome these biases, under which assumptions

⁷⁰⁰ See Tool #10 on *Financial programmes and instruments*.

The European Commission Competence Centre on Microeconomic Evaluation has expertise in designing counterfactual evaluations and can provide policy DGs with advice on possibilities and limitations.

2.6. SWOT Analysis

A SWOT analysis is used to identify the Strengths, Weaknesses, Opportunities and Threats in relation to a project/organisation and how such an assessment will change over time.

In the context of evaluation, this method can be used for e.g. when assessing the services provided by a project/programme.

A group needs to be convened to discuss different options and categorise them into a SWOT matrix.

SWOT can take past weaknesses and transform them into a constructive learning process. SWOT is not an analytical tool per se; instead it is a way to synthesize preceding analyses and use them for developing a strategy.

3. WHICH METHOD IS MOST APPROPRIATE?

Cost-benefit analysis is one of many methodologies that can be used in evaluations and impact assessments. The other methods described above may prove more appropriate depending on the case at hand.

Cost-benefit analysis as the method to formulate the judgment if:

- At least all direct benefits and direct costs can be monetised, covering where possible the economic, social and environmental impacts of the proposal at hand (if benefits can be quantified, but not monetised, consider cost-effectiveness analysis): this requires an assessment of data availability in order to understand whether CBA will be feasible within a reasonable time frame.
- The magnitude of impacts justifies the effort and time needed to perform CBA (as a full-fledged CBA is normally more time-consuming than other, more qualitative techniques).
- Distributional impacts are unlikely to be substantial (otherwise, consider multi-criteria analysis, or break down CBA by affected stakeholder without aggregating costs and benefits into a net benefits analysis).

Cost-benefit analysis has a significant potential to identify and inspire efficient regulatory choices, but is subject to several weaknesses, related to its relative ignorance of distributional impacts, its reliance on income as a proxy for utility and happiness, and a number of other underlying assumptions, which can prove detrimental for the accuracy of the whole exercise. Cost-benefit analysis is also more challenging when assessing initiatives at the EU level, for the following reasons:

The Commission requires an integrated assessment of economic, social and environmental impacts. However, monetizing some of the impacts, such as respect for

fundamental rights, would be a meaningless exercise, and as such should not be undertaken. Rather, multi-criteria analysis should be used in order to provide policymakers with a basis for informed decisions.

The multi-institution, multi-level nature of EU policymaking makes it difficult to reach a sufficient level of accuracy in the analysis of certain costs and benefits. In particular, predicting the mode of enforcement and the related costs for public administrations at the national level is almost impossible at the *ex-ante* stage, unless rather extreme assumptions are formulated. This also means that compliance costs will be more difficult to predict and measure, as they partly depend on enforcement patterns.

A related problem is the greater difficulty to perform cost-benefit analysis due to problems of data availability. The need to collect data from all Member States or, alternatively, to extrapolate data collected for some Member States to the EU28 makes the performance of cost-benefit analysis much more difficult at the EU level.

In the EU impact assessment system, CBA is also more challenging as impact assessments are carried out for a wide variety of legislative and non-legislative initiatives, including white papers and communications for which policy options might not be fully detailed and as such difficult to analyse in terms of costs and benefits. CBA should be used as the method to compare alternative policy options if both benefits and costs vary according to the chosen alternative (if not, consider least-cost analysis). In addition, cross-cutting legislative initiatives which feature significant distributional impacts may be better analysed through multi-criteria analysis.

In the evaluation context, the choice of the most appropriate method will vary for every evaluation. This will for example depend on the type of intervention being evaluated (e.g. spending, non-spending), scope of the evaluation (e.g. EU wide, pilot project), evaluation timing (e.g. interim, ex-post evaluation) and the availability and measurability of outcomes (e.g. what data already exist, key indicators).

4. UNCERTAINTY/SENSITIVITY

The uncertainty which is inherent in the various estimates of costs and benefits should be explicitly recognised and quantified as far as possible as it may have an important bearing on the judgment as regards both the performance of public intervention and ranking of policy options in impact assessments.

The influence of the key variables should be investigated by a sensitivity analysis. These variables should be allowed to vary in order to test the robustness of the final and should be linked to the drivers of the problem identified in the problem definition.

Possible ways to approach the problem of sensitivity analysis are:

- *Worst/best case scenario analysis*: this requires adopting all the most conservative and all the least conservative values for variables used in the calculation of the Net Present Values, costs and benefits, and cost-effectiveness etc.
- Partial sensitivity analysis (i.e. changing only some of the assumptions, but not others) should be selectively used, for those key risk factors and underlying assumptions that are expected to tilt the balance in favour of one policy option. This

is often the case of variables such as the compliance rate, the evolution of consumer demand, etc.

- Monte Carlo sensitivity analysis is a more sophisticated technique that entails the creation of a distribution of net benefits by drawing key assumptions or parameter values from a probability distribution. While this is a more robust approach to sensitivity analysis, care needs to be taken in adopting reasonable and justified assumptions about the probability distributions which have been assumed. This type of analysis normally takes the form of a random sampling process to approximate the expected values and the variability inherent in the assumptions which are expressed as probability distributions for the most sensitive and uncertain parameters (risk variables). It is a computer-aided methodology through which many possible project scenarios are generated through a random selection of input values from the specified probability distributions. An example of this technique is provided in the tool on the use of analytical models⁷⁰¹.

If the robustness of the basic assumptions cannot be examined numerically, a qualitative discussion on the appropriateness of each assumption can help readers to gauge the reliability of the results.

5. FURTHER INFORMATION

Study prepared by the Centre of European Policy Studies on [the assessing the costs and benefits of regulation](#).

[OECD Regulatory Compliance Cost Assessment Guidance](#).

Unit C2 of the Secretariat General can provide advice on the content of this tool via its functional mailbox SG-C-2@ec.europa.eu

⁷⁰¹ See Tool #62 on *The use of analytical models*

Appendix

10 steps to complete a Cost Benefit Analysis

The following steps should be followed when completing a cost-benefit analysis. More detail can be found in chapter 3 of the CEPS study⁷⁰² and the Tool #59 on Methods to assess costs and benefits.

Step	Description
1	<i>Decide whether CBA is the most appropriate approach</i> to formulate a judgment. The advantages and disadvantages described in the main body of this tool should guide this decision.
2	<i>Identify the full range of Costs and Benefits</i> to be measured. Failure to identify significant impacts may skew the final judgment.
3	<i>Partial or general equilibrium analysis.</i> The choice will depend on the extent of the impacts and is important to help prevent the use of excessively costly and time-consuming methods (e.g. stated preference methods, or ex novo CGE modelling) for narrowly defined initiatives or for certain policy initiatives with non-binding effects. In this respect, you have to answer the following questions. – Does the problem at hand affect several markets and present significant cascading and cumulative effects? – Are there very significant impacts on the economy? If the answer is “yes” to both questions then you should opt for a general equilibrium approach. In this case, if you have no specific expertise in how to use general equilibrium models, you should refer to the impact assessment or evaluation unit of your DG and possibly seek the help of expert staff or external consultants. In all other cases, i.e. if the problem: – Affects a limited number of markets/economic sectors, and/or – Produces mostly direct effects on stakeholders, and/or – Generates limited indirect, macroeconomic effects, Then you can address the problem and the related assessment of impacts through a partial equilibrium analysis.
4	<i>Monetise direct costs for the public intervention in question or for all policy alternatives and calculate total direct costs.</i> • Are direct charges imposed on particular stakeholders/societal group? • Are compliance costs increased including administrative burdens? • What are the enforcement costs?
5	<i>Monetise direct benefits.</i> The following issues are relevant:

⁷⁰² See Chapter 3 pp156 of the 2013 CEPS Study on [Assessing the Costs and benefits of Regulation](#).

	• Are there cost reductions in regulatory charges, compliance costs and enforcement costs? • Improvements in market efficiency should be monetised as far as possible (consumer surplus, producer surplus, and deadweight loss). • Monetization of non-market benefits (health, safety, environment etc.)
6	<i>Assess indirect impacts.</i> • Are there significant indirect costs? • Are there significant indirect benefits? • Are there other non-monetisable benefits (protection of fundamental rights, legal certainty, reduced infringement of legal rules etc.)
7	<i>Determine when costs and benefits occur in the life of the initiative and apply social discounting to determine net present values⁷⁰³.</i>
8	<i>Present impacts and formulate the judgement on the performance of existing public intervention or the comparison of the policy options.</i> • Present the different types of costs and benefits which have been monetised • Present qualitative information on non-monetised costs and benefits • Comparison should be performed in terms of the various cost/benefit categories, net benefits and net present value, distributional impacts on stakeholders.
9	<i>Check the robustness of the results</i> • Sensitivity cases to assess influence of key variable/assumptions on uncertainty and on conclusions • Check methods (no double counting, baseline versus policy option, consistent base currency used, spurious accuracy in results) • Recognise any behavioural biases • Assess interaction/interdependency between the categories of costs and benefits (e.g. enforcement costs rising as compliance costs decline)
10	<i>Consider distributional and cumulative impacts</i> • On Member States if proportionate • On future generations • Richer and poorer sections of society • SMEs

⁷⁰³ See Tool #58 on the *Typology of costs and benefits*.

TOOL #58. TYPOLOGY OF COSTS AND BENEFITS

1. INTRODUCTION

A sound analysis of initiatives requires careful assessment of the costs and benefits. Societal costs and benefits are the most relevant to consider when assessing the impact of a policy from the point of view of society as a whole. However, the net impact on total welfare and the net impacts on specific groups (i.e. winners and losers) as well as overall affordability is important to inform policymaking.

It is important to bear in mind that costs and benefits are simply terms used to describe impacts which affect social (and private) welfare in different directions. A cost is any item that makes someone worse-off, or reduces a person's well-being. A benefit is any item that makes someone better-off, or increases a person's well-being. Depending upon the nature of the impact generating the change in well-being, costs and benefits can be direct or indirect. The different types of costs and benefits are **illustrated in Box 2** and described below⁷⁰⁴.

Costs often arise immediately following a new regulation, are concentrated on a specific group of stakeholders and are in general more easily measurable in monetary terms. Benefits, on the other hand, tend to emerge over a longer time frame.

Costs and benefits should usually be based on market prices (reflecting the opportunity cost of action). However, these are not always available and so other methods may be needed to express impacts in monetary terms or indeed sometimes impacts cannot be expressed in monetary terms (e.g. what is the value of an increased protection of fundamental rights? or the loss of biodiversity?).

Unsurprisingly, costs and benefits are often mirror images. The cost savings brought about by many regulatory interventions aim at simplifying legislation, reducing regulatory burden, or harmonizing requirements for companies operating across the single market, are an important category of benefits.

At times, what is a cost to a party may be a benefit to another and these symmetrical changes in private welfare will normally cancel out at the aggregate level. In addition, Investments which are needed to comply with legislation generate at the same time economic activity and income and may enable cost savings later. It is therefore very important to distinguish between costs and benefits that represent net additions or reductions of total welfare, as opposed to costs and benefits that arise for specific categories of stakeholders as a result of a transfer of resources.

2. DIFFERENT TYPES OF COSTS

The total cost arising from a given initiative or regulation is the sum of (1) Direct Costs; (2) Enforcement Costs; and (3) Indirect costs:

⁷⁰⁴ [Assessing the Costs and Benefits of Regulation; CEPS \(2013\)](#) a study prepared for the European Commission; Chapter 1.

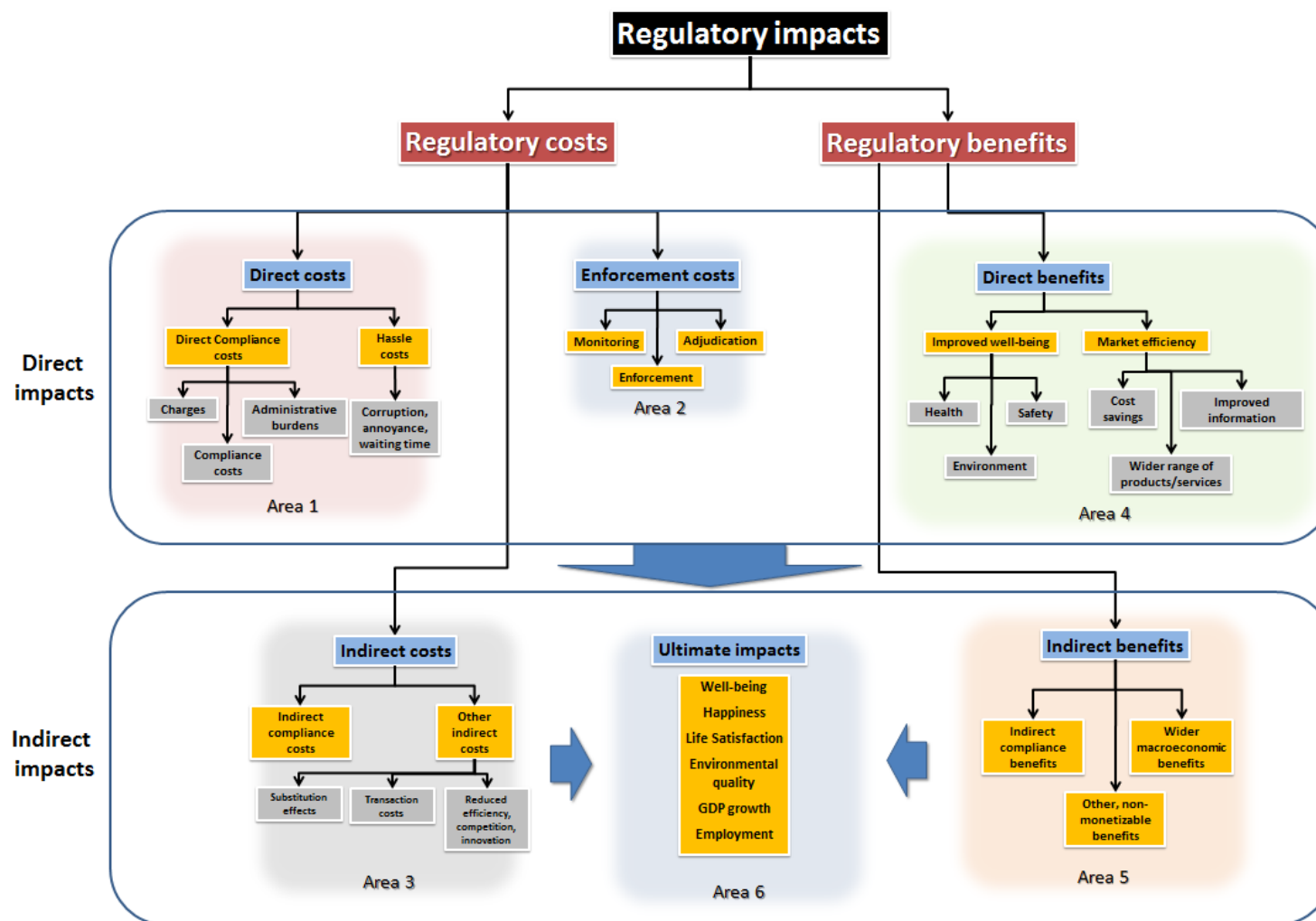
Direct costs from regulation include direct compliance costs and hassle/irritation burdens:

- Regulatory charges, which include fees, levies, taxes, etc.
- Substantive compliance costs, which encompass those investments and expenses that are faced by businesses and citizens in order to comply with substantive obligations or requirements contained in a legal rule; and
- Administrative burdens are those costs borne by businesses, citizens, civil society organizations and public authorities as a result of administrative activities performed to comply with information obligations included in legal rules.
- Hassle costs are often associated with businesses, but they apply equally well to consumers: they include costs associated with waiting time and delays, redundant legal provisions, corruption etc.

Box 1. Policy types and associated recurrent costs

Type of regulatory alternative	Recurrent costs
Self-regulation	• Monitoring costs • Transaction costs • Direct compliance cost
Co-regulation	• Monitoring costs • Enforcement costs • Transaction costs • Direct compliance cost
Market-based instruments	• Transaction costs • Charges • Direct compliance costs • Indirect compliance costs
Performance-based standards	• Monitoring costs • Direct compliance costs • Indirect compliance costs
Command and control	• Charges • Administrative burdens • Direct compliance costs • Indirect compliance costs • Monitoring costs • Enforcement costs • Adjudication

Box 2. A map of regulatory costs and benefits (CEPS report page 21)



Enforcement costs. These costs are associated with activities linked to the implementation of an initiative such as monitoring, enforcement and adjudication.

Indirect regulatory costs. These costs are incurred in related markets or experienced by consumers, government agencies or other stakeholders that are not directly targeted by the initiative/regulation. These costs are usually transmitted through changes in the prices and/or availability and /or quality of the goods or services produced in the regulated sector. Changes in these prices then ripple through the rest of the economy changing prices in other sectors and ultimately affecting the welfare of consumers. The category also includes so-called “indirect compliance costs” (i.e. cost related to the fact that other stakeholders have to comply with legislation) and costs related to substitution (e.g. reliance on alternative sources of supply), transaction costs and negative impacts on market functioning such as reduced competition or market access, or reduced innovation or investment.

3. THE IMPACT OF REGULATORY COSTS ON DIFFERENT STAKEHOLDERS

It is possible to categorise costs in terms of the stakeholder affected i.e. business, citizens and consumers and public administrations.

<i>Impact of regulatory costs on different stakeholders</i>					
Type of cost		Citizens	Consumers	Business	Administrations
Direct costs	Charges		•	•	
	Administrative burdens	•		•	•
	Substantive compliance costs	•		•	•
	Hassle costs	•		•	•
Indirect costs	Indirect compliance costs		•	•	
	Offsetting		•	•	
	Reduced competition		•	•	
	Reduced market access		•	•	
	Reduced investment/innovation		•	•	
Enforcement costs	Information & monitoring	•		•	•
	Inspections and sanctions			•	•
	Complaint handling	•		•	•
	Adjudication/litigation	•		•	•

Citizens: means citizens and society as a whole and refers to impacts that are widespread and do not affect a particular sub-group in a specific way;

Consumers refers to a specific product or service. Consumers do not necessarily overlap with citizens but may be a sub-group e.g. a group of citizens targeted by a given regulation;

Business includes all types of businesses including SMEs;

Public administrations are EU, national, regional or local administrations.

4. DIFFERENT TYPES OF BENEFITS

There is no commonly agreed taxonomy of regulatory benefits although the comprehensive study undertaken for the Commission recommends a convenient classification into three categories which are shown in the figure in Box 2.:

(1) Direct regulatory benefits (Area 4 in the figure in Box 2).

The improvement of the well-being of individuals, which in turn encompasses health, environmental and safety improvements; and

Efficiency improvements, which include, notably, cost savings but also information availability and enhanced product and service variety and quality for end consumers.

(2) Indirect regulatory benefits (Area 5 in the figure in Box 2):

- Spill-over effects related to third-party compliance with legal rules (so-called “indirect compliance benefits”);
- Wider macroeconomic benefits, including GDP improvements, productivity enhancements, greater employment rates, improved job quality etc.; and
- Other non-monetisable benefits, such as protection of fundamental rights, social cohesion, reduced gender discrimination, international and national stability, etc.

Box 3 Important issues in respect of costs and benefits

When assessing costs or benefits it is important to:

- Distinguish between private or social costs / benefits.
- Avoid double-counting costs and benefits of regulation by recognising that the gains of one category and the losses of another may be flip sides of the same coin⁷⁰⁵.
- Recall that all costs (and benefits) generated by a new legal provision are by definition incremental costs, i.e. they are additional with respect to the existing situation, as well as additional to the costs (and benefits) that would emerge absent legislative intervention. This means that all costs (and benefits) considered for the purposes of an impact assessment should exclude those costs (and benefits) that would materialize anyway even in absence of a new policy measure ("BAU").
- Regardless of the relevance of incremental changes in social costs and benefits, it is the private costs and benefits, and the overall cumulative costs and benefits, that are the most familiar and relevant concepts for non-experts and different stakeholder groups.

⁷⁰⁵ For example, assume that a new technical standard will impose an additional €1 billion of direct costs to car manufacturers, and that half of these are passed-on to consumers. Counting both the €1 billion of additional direct costs for manufacturers and the half billion that will fall on consumers would lead to an incorrect overestimation of the costs of the regulation. However, the opportunity cost borne by those consumers that, as a result of the price increase, will decide not to buy a car should be counted separately, as a net loss for society.

(3) *The “ultimate impacts” of regulation (Area 6 of the figure in Box 2),*

All regulations usually aim, as an ultimate impact, to achieve some advancement in social welfare, which can be described in terms of efficiency or in others terms. These ultimate impacts encompass well-being, happiness and life satisfaction, environmental quality, and more economic goals such as GDP growth and employment. They may overlap with certain direct benefits which a specific initiative aims to achieve.

TOOL #59. METHODS TO ASSESS COSTS AND BENEFITS

Different methodological approaches can be used to estimate costs and benefits ex ante (within impact assessment work) or ex post (in retrospective evaluation/fitness check work). The most appropriate choice will depend on several factors including the nature of the initiative and the availability of data. The calculation of costs and benefits is an important element of impact assessments and evaluations which allows the merits of different policy options to be compared or the efficiency of existing interventions to be evaluated.⁷⁰⁶

Costs

1. HOW TO ASSESS COMPLIANCE COSTS

Direct costs are those costs linked to the needs to divert resources to carry out the direct consequences of a regulatory option⁷⁰⁷. **An important category of direct costs are the so-called compliance costs**, i.e. those costs incurred by businesses and other parties in undertaking the actions necessary to comply with the new regulatory requirements.⁷⁰⁸

Compliance costs are often the aggregate of all direct costs generated by legislation: over time, they have become the subject of specific assessment methods in various countries. However, it is often useful to analyse (and estimate) compliance costs on the basis of their individual components.

Compliance cost components
Charges
Regulation often affects businesses and consumers by imposing the payment of fees, levies, or taxes on certain stakeholders. These costs are often easy to calculate, as their extent is by definition known. What is sometimes more difficult to assess is who will bear those costs, as this might depend on the extent to which these costs are passed-on to entities other than those targeted by the legal rule. For example, copyright levies might be passed-on downstream on end consumers in the form of higher prices for certain hardware devices.
Administrative costs
That is the costs of complying with information obligations stemming from policy option under consideration.
Substantive compliance costs
These are the incremental (i.e. non-business as usual) costs to the target group of complying with regulation other than fees and administrative costs.

⁷⁰⁶ See Tool #57 on *Analytical methods to compare options or assess performance*.

⁷⁰⁷ [Assessing the Costs and Benefits of Regulation; CEPS \(2013\)](#) a study prepared for the European Commission.

⁷⁰⁸ [OECD \(2014\), OECD Regulatory Compliance Cost Assessment Guidance](#). See page 62 for a list of regulatory compliance activities

They can be one-off or recurrent and <i>can be broken down in further sub-categories</i> ⁷⁰⁹ :	
<i>Implementation costs</i>	The costs regulated entities incur in familiarising themselves with new or amended regulatory compliance obligations, developing compliance strategies and allocating responsibilities for completing compliance-related tasks. In large part, therefore, they are short-term one-off costs.
<i>Direct labour costs</i>	The costs of staff time devoted to completing the activities required to achieve regulatory compliance. Only the costs of staff directly involved in undertaking these activities should be included: the costs of staff supervision/management are included in the overhead cost category (see below). Direct labour costs include two main elements the cost of wages paid non-wage labour costs.
<i>Overheads</i>	The costs of rent, office equipment, utilities and other inputs used by staff engaged in regulatory compliance activities, as well as corporate overheads, such as management inputs, that are attributable to compliance activities
<i>Equipment costs</i>	Those costs incurred by businesses whenever they need to purchase items of capital equipment to comply with a regulation. This can include both machinery (e.g. equipment to treat the emissions from a production facility to conform to new emissions standards) and software (e.g. programs required to undertake real-time monitoring of actual emissions).
<i>Material costs</i>	The incremental costs incurred in changing some of the material inputs used in the production process in order to ensure regulatory compliance (thus, they are sometimes called “input costs”). They are therefore ongoing costs.
<i>Cost of external services</i>	The cash cost of payments made to external suppliers providing assistance in achieving regulatory compliance. For example, faced with more stringent emissions controls, a firm may hire consulting engineers to advise on the available means of reaching compliance and their relative costs and benefits.
An alternative, more aggregate, subdivision of compliance costs would differentiate among capital / fixed costs (CAPEX), operating and maintenance costs (OPEX) and financial costs ⁷¹⁰ .	

Generally speaking, **different methodological approaches can be used to estimate different types of compliance costs**. All have limits. **You should pick the one that is most appropriate, given:**

⁷⁰⁹ The categorization proposed in the OECD Regulatory Compliance Cost Assessment Guidance is presented below

⁷¹⁰ CEPS (2013), p.25-26.

- The expected magnitude of compliance costs: the higher the expected cost or the more the scope of the analysis to yield different outcomes in terms of comparison of options, the more resources should be invested in estimating compliance costs
- The availability of data: the greater the availability of data, the more compliance costs should be quantitatively estimated.
- The nature of the initiative: when compliance can be broken down to a relative precise set of activities to be carried out, compliance costs can more easily be estimated adding up the various costs of these activities for a typical party. Conversely, the more qualitative or a top down, rather than a bottom up, estimating approach may be more appropriate in the case of complex policy proposals, where the range of starting positions across regulated entities is wide and/or there are potentially numerous different ways to achieve compliance.

When making methodological choices, you will frequently have to accept compromises, focussing on major cost drivers and relying on simplifying assumptions (extrapolating data from some economic actors or member states to others etc.). You should, however, always start by aiming, as far as possible, for a comprehensive and precise estimation and be ready to justify transparently all key methodological choices. Perhaps more importantly, you should always flag the limitations of any estimated result and take them into due account when using the results to compare options. When appropriate, you should subject your results to sensitivity analysis⁷¹¹.

Methods to estimate compliance cost components	
CEPS (2013) and OECD (2013) both provide useful references to existing methods which extend the standard cost model from administrative cost to compliance costs more generally. The following provides a short summary.	
Charges	
(1)	Estimate the population of stakeholders that will have to comply with the obligation to pay charges.
(2)	Estimate the frequency of the payment (1 = once a year; 2 = twice a year; 0.5 = once every two years, etc.).
(3)	Estimate the unit cost (cost of the fee, license, and permit).
(4)	Multiply the three parameters.
For example, if you expect that 2,500 enterprises will have to pay a licence fee of €500 twice a year, your total on a yearly basis will be $(2,500 \times 500 \times 2) = \text{€}2.5 \text{ million}$.	
Administrative costs	
See later section on the Standard Cost Model	
Substantive compliance costs	
(1)	<i>Identify substantive duties (SDs)</i>
These are all the activities necessary to comply but for those linked to the provision of	

⁷¹¹ See Tool #57 on *Analytical methods to compare options or assess performance*.

information (dealt with above). Please distinguish between one-off and recurrent duties.	
(2)	<i>Estimate the population of stakeholders that have to comply with each SDs for each of the alternative options.</i>
(3)	<i>Estimate the mode of compliance with each SD by a “normally efficient business”, an “ordinary citizen” or a “normally efficient administration”.</i> This might change depending on the regulatory alternative at hand, and will certainly change according to the different segment of the population you have identified. The concept of “normal efficiency” is needed in order not to factor into the analysis the inefficiency of some of the targeted companies: in order to assess <i>ex ante</i> how long would it take for businesses to comply. This means that you will have to assess the “reasonable” amount of time that it will take for businesses or citizens to comply with the obligations stemming from legal rules: this implies the assumption that regulated entities handle their administrative and substantive tasks neither better nor worse than may be reasonably expected.
(1)	<i>Estimate the “BAU” factor for each SD and each of the alternatives, based on direct assessment or empirical data.</i> The business-as-usual (BAU) factor is often obtained by consulting targeted stakeholders or experts: its estimation is often the result of assumptions as regards the share of costs that would not be avoided if the legislative measure containing the obligation were repealed. In some cases, the BAU factor can be estimated directly by looking at the share of costs associated with a substantive obligation that are borne by similar entities that are not targeted by specific legislative provisions: when this is the case, you can observe the level of compliance costs for the “regulated” entities and the “unregulated” ones, and take the difference as the relevant portion of compliance costs to be considered in your estimate. You should be aware of the fact that the BAU factor might differ depending on the territory and the segments of the population you have identified.
(1)	<i>Consider segmenting the population by creating “case groups” differentiated according to size (micro, small, medium, large enterprises) or other dimensions (level of government for public administrations, availability of Internet connection for citizens, etc.).</i> If different case groups can be established, you might consider adopting different notions of “normal efficiency” and BAU for each of the groups.
(2)	<i>Estimate the compliance cost associated with each SD for each segment and each alternative.</i> Useful guidance on this can be found in chapter 3 of the OECD (2013)
(3)	<i>Assess whether compliance costs are likely to change over the life of the proposed legislation.</i> In particular, you should assess whether, as a result of entry/exit of businesses, technological innovation, “learning by doing” or any other relevant factor, the impact of the costs identified is likely to change over time. For example, assume your analysis today leads to establishing two case groups depending on whether a SD is complied with through a digital solution (20% of the population) or through a more traditional solution (80%). The percentage of businesses that rely on the digital solutions is likely to change over time, such that the percentages in 5 years from now might even be reversed. This should be taken into account in a prospective analysis or regulatory costs,

and – if possible – coupled with sensitivity analysis on the assumptions behind the evolution of costs over time.

(1) *Sum up and extrapolate all compliance costs to reach a total estimate for each of the alternative options considered.*

The accuracy of these methods depends significantly on the extent to which resources are devoted to data collection. **Without significant data availability, results can only be considered broadly indicative.⁷¹² They can be useful indicators of the relative magnitude of compliance costs across different alternative options but cannot be considered reliable estimates of actual cost.**

2. ASSESSING ADMINISTRATIVE COSTS (THE STANDARD COST MODEL)

Administrative costs are defined as the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be construed in a broad sense, i.e. including labelling, reporting, registration, monitoring and assessment needed to provide the information. In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supply on request.

Whenever a measure is likely to impose significant administrative costs on business, the voluntary sector or public authorities, the EU Standard Cost Model presented in Appendix 2 should be applied. The main aim of the model is to assess the net cost of information obligations imposed by EU legislation (net costs = costs introduced by a proposal if adopted, minus the costs it would eliminate at EU and/or national level). You are also invited to apply the model on a tentative basis for assessing costs imposed on citizens. The possibility and need for monetisation in this case is left to your discretion. A separate tool describes the how the standard cost model should be applied in practice.

In principle it is sufficient to measure the administrative burden only for the preferred option. However, if information obligations are at the core of the proposal (e.g. changing labelling or reporting requirements) then the administrative burden should be assessed for all policy options considered.

3. HOW TO ASSESS IMPLEMENTATION AND ENFORCEMENT COSTS

Implementation and enforcement costs are those costs direct borne by public authorities in implementing, administering and enforcing regulatory requirements.

⁷¹² This is because of the extreme nature of some of the methodological assumptions required, even when adapted on the basis of survey results. This applies to the “normally efficient business” concept, the assessment of the BAU factor, the importance of learning curves suggesting compliance costs are likely to decrease with time and the various methodological decisions such as the level of overhead, the specific allocation of given personnel and human resources to specific substantive obligations, the allocation of fixed and common costs etc.

They can include the cost of publicising new requirements, establishing licencing or permit systems, dealing with queries and applications, implementing inspections and audits to verify compliance and sanctioning non-compliance⁷¹³.

These costs can vary significantly from option to option and from Member State to Member State. Measuring methodologies are less developed and less commonly used than for other direct costs.

In principle, implementation and enforcement costs can be estimated following a similar bottom up approach to the one described in for compliance costs: first defining the activities required to implement and enforce legislation, then estimating their frequency and their cost taking into consideration the BAU factor and possibly distinguishing between different case groups as appropriate. Implementing and enforcement authorities may be in a position to provide good unit cost estimates for different types of activities.

In reality, however, estimating these costs ex ante at the stage of Commission policy design may be particularly complex. First, data are rarely available. Second, implementation and enforcement activities often cannot be defined (and thus costed) since they are to be decided by Member States at a later stage.

When this is the case, you should still aim to provide a qualitative assessment. This would help avoiding any significant underestimation of direct costs and taking into account any trade-offs between business (or citizens) compliance costs and implementation and enforcement costs⁷¹⁴. To this end, it is suggested to:

- Assess whether some or all of the related policy options would require the creation of new enforcement mechanisms, or whether they would rely on existing enforcement mechanisms.
- Describe whether enforcement costs are likely to vary significantly across different policy options.
- Assess whether the magnitude of enforcement costs is so significant that it might tilt the balance in favour of one policy option over other alternatives.
- If this is the case, assess what factors would be essential in determining the magnitude of enforcement costs (e.g. monitoring costs, inspection costs, etc.) and provide comments on the critical nature of enforcement costs in the choice of the preferred alternative. These comments would be useful for policymakers in making an informed choice.

⁷¹³ For a list of possible implementation and enforcement activities, see p. 63 in OECD (2013).

⁷¹⁴ Thus, an option that provides greater flexibility in the ways in which business can comply with the regulatory requirements may minimise costs to firms, but may increase the costs of administering the regulation, since verifying compliance will be more complex and involve a higher degree of professional judgement. Total direct costs may well be higher than under a less flexible regulatory option. Total costs would of course also depend on indirect impacts such as impacts on business competitiveness, innovation, the ultimate goal of the regulation etc.

4. HOW TO ASSESS CUMULATIVE COSTS

Every policy proposal should be assessed on its own merits. For this reason, impacts are assessed against a baseline, meaning that only incremental costs and benefits need to be estimated. When standard cost-benefit analysis is the methodology of choice, it is the sign of the net change in costs and benefits that matters for policy decision, not the aggregate (or cumulative) level of regulatory costs and benefits.

Consideration of costs from the point of view of a particular economic sector, typically undertaken in a Cumulative Cost Assessment, is a backward-looking exercise which can be useful when defining a baseline scenario. This is a partial approach which does not by definition look at benefits. The costs are the regulatory costs that affect the sector only stemming from different regulations. For example, unlike in an impact assessment or evaluation, investment costs would be included by estimating the costs of financing (which depends on the approach for financing them) and at the time when those financing arrangements were made.

It is advisable to take into consideration cumulative impacts to the extent that this may be possible and proportionate

Assessing Cumulative Impacts	
Why?	Because it helps avoiding redundant requirements (for instance, reporting ones) and/or highlights opportunities to simplify legislation. Cumulative assessments can also help in defining better the baseline scenario.
	Because a good assessment of indirect impacts may depend upon a good understanding of cumulative impacts.
	Thus, for instance, the impacts on sectoral competitiveness of an increase in regulatory cost depend upon the sector overall cost structure vis-à-vis international competitors. Cumulative regulatory costs may be an important component of aggregate cost for the industry. Assessing costs resulting from sector-relevant EU legislation including direct ⁷¹⁵ and indirect costs and administrative burdens.
How and when?	<u>During the process of public consultation</u> when stakeholders could usefully be invited to discuss interactions between a proposed initiative and the existing body of legislation.
	<u>When designing policy options</u> when the lead services and the IAWG should check the proposed measures and the existing body of legislation (across the sector and policy areas) for possible redundant requirements, overlaps etc. In doing so, the results of existing retrospective evaluation should provide a useful source of information.
	<u>When assessing impacts and, notably indirect impacts and impacts on micro and small enterprises⁷¹⁶</u> . No generally recognised standard methodology

⁷¹⁵ Direct costs stem from substantive obligations under the legislation; investments costs to finance the required investments (e.g. pollution control equipment), financial costs (interest charged), and operational costs.

	exists for the consideration of cumulative impacts. However, a growing number of studies are generating data by sector and type of enterprise. The methodologies used can also provide useful models for new specific estimations.

A prominent tool for making CCAs is the Dutch Compliance Cost Assessment tool ("CAR model") which was conceived essentially for retrospective analyses of existing legislation⁷¹⁷.

Benefits

5. APPROACHES TO QUANTIFY BENEFITS

The classification of benefits is not as well-developed as for costs not least because they are often the objective of the initiative, are initiative specific and are difficult to classify. They can, however, be direct or indirect in nature meaning that they can affect the same stakeholders targeted by the initiative or go beyond the target group and even become diffuse societal benefits.

Direct benefits can be expressed in terms of:

(1) *Improved market efficiency*

This might include improved allocation of resources, removal of regulatory or market failures or cost savings generated by new initiatives/regulation. Within this category, cost savings can be mapped using the same classification as for costs (e.g. reductions in administrative burden or compliance costs);

(2) *Additional citizens' utility, welfare or satisfaction.*

Such non-market benefits are often valued using techniques which capture the sum of individual preferences which are themselves modelled using techniques such as willingness to pay or, alternatively, via simulated experiments observing what people would actually do in different future situations as opposed to what people think they will do⁷¹⁸;

Indirect benefits include:

(3) *Spill over effects related to third party compliance with new legal rules ("indirect compliance benefits").*

⁷¹⁶ See Tool #22 on *The SME test*.

⁷¹⁷ See The Study on Assessing the costs and benefits of Regulation prepared by the Centre for European Policy Studies (December 2013); pp 70 for description of the model and its strengths and weaknesses in relation to impact assessments and evaluations.

⁷¹⁸ See Tool #31 on the *Health impacts*, Tool #32 on *Consumers*, Tool #35 on *Resource efficiency*, Tool #29 on *Employment working conditions income distribution social protection & inclusion*, Tool #30 *Education and training culture and youth* etc. which cover a wide range of social and environmental benefits (impacts).

These are benefits which accrue to individuals or business that are not the direct addressees of the initiative but who enjoy positive effects due to the compliance of others who are directly addressed (e.g. societal health care costs due to strategies to reduce obesity or tobacco smoking);

- (4) ***Wider macroeconomic benefits such as an increase in GDP, improved competitiveness or productivity (e.g. programmes to reduce administrative burdens may increase GDP);***
- (5) ***Other non-monetisable benefits such as the protection of fundamental rights, social cohesion, international stability etc.***

There are specific tools in this chapter which provide much more information on the identification of benefits such as those in the social, consumer, employment and environment fields.

6. HOW TO ASSESS COST SAVINGS

Not all regulatory proposals lead to direct cost increases. At times, the very aim of a regulatory proposal is to reduce existing regulatory costs either by simplifying existing EU legislation or by harmonizing regulations across Member States and thus generally reducing compliance costs for businesses operating across the single market.

7. SIMPLIFICATION PROPOSALS

Methods to estimate direct cost savings
Whenever a policy option leads to a reduction in regulatory charges , you could follow the same approach as suggested in chapter 4 of this Tool to estimate the value of the reduction.
Whenever a policy option leads to a reduction in compliance costs (both substantive compliance costs and administrative burdens), you should follow the same approach as in chapter 4 of this Tool and in chapter 5 on administrative burdens to estimate the value of the reduction.
Whenever a policy option leads to a reduction in implementation and enforcement costs you should follow the same approach as in chapter 6 of this Tool to estimate the value of the reduction (or at least assess its relevance qualitatively).

All the usual caveats applying to bottom up estimation approaches apply to the above. In particular, it is very important to complement any such estimation with an assessment of indirect costs and of direct and indirect benefits. This is to make sure that cost savings do not reduce regulatory benefits (or at least do not reduce them in a manner which worsens both the effectiveness and the efficiency of an existing policy). It is also necessary to take into account possible trade-offs among different categories of costs. The following offers a checklist of such possible trade-offs using administrative obligations as an example.

Verifying the effective nature of cost savings
<i>A reduction proposal may lead to lower administrative burdens, but at the same time increase other compliance costs for the same targeted businesses. Administrative burdens (Abs) constitute only a subset of costs imposed on businesses by legislative</i>

acts. For example, the implementation of an e-government or any other IT-enabled solution can reduce the amount of time related to compliance with the information obligation. At the same time, however, it may require a degree of investment in upgraded IT equipment and training of employees, which would not be considered as ABs, but fall generally in the category of compliance costs. Similarly, a proposal that reduces ABs may increase public expenditure in monitoring and enforcement (see below): these costs may be recovered by the government through higher tax burdens, thus increasing direct charges. Finally, a proposal may reduce burdens by requiring structural changes in the production process, which would guarantee a certain level of product safety without any need for burdensome certifications: in this case too, burdens are reduced, but costs may increase.

A reduction proposal may reduce administrative burdens, but at the same time increase administrative burdens of a different origin. In the context of multi-level governance, the reduction of ABs achieved by eliminating some information obligations at a certain level of government – say, at the EU level – may require the introduction of new information obligations at the lower level – say, at the national or regional level.

A reduction proposal may reduce administrative burdens, but at the same time increase costs for other private actors (businesses and/or citizens, workers). For example, reducing labelling obligations for products may increase information costs borne by consumers, who would need to collect their information from other sources in order to make an informed choice of what products are most likely to fit their preferences

A reduction proposal may lead to lower administrative burdens, but at the same time increase monitoring and enforcement costs for public authorities. This is often the case whenever the information obligations eliminated involve the keeping and reporting of information available to businesses, but not to public authorities. For example, the provision of information on the respect of hygiene standards or the reporting of large exposures by banks is typical instances of highly burdensome activities for businesses that comply with these requirements. These information obligations are vital for public authorities, as they ensure that more informed businesses provide information that would otherwise not be readily available to public authorities. Absent the provision of this information, public authorities would have to deploy more resources to obtain the information, which is likely to lead to more inspections and enforcement costs – in our two examples, more hygiene inspections and more investigations into the riskiness of banks' exposure *vis à vis* certain clients.

8. SINGLE MARKET JUSTIFICATION

A specific case of savings can occur whenever you are dealing with options that have an impact on the Single Market, especially when such options entail the harmonization of national legislation. Savings might emerge whenever national legislation is fragmented and inconsistent and EU legislation is adopted to harmonise it. This is due to the fact that when legislation in Member States is fragmented, companies wishing to engage in cross-border trade have to incur “adaptation costs”, such as:

- ***Having to change contracts or other practices to comply with differing national legislation.*** Monetizing these costs is normally possible. One way of doing it is to collect data directly from companies and validate them with experts. For example, in the case of

national rules that are stricter than Article 102 TFEU⁷¹⁹, legal costs were estimated by some companies in the range between €12,000 and €20,000.

- ***Having to modify standards or equipment, or train personnel to deal with differing national legislative requirements.*** These costs are easily monetised by referring to market prices, and (in the case of equipment) depreciating these assets over time (for example, over five years).
- ***Incur additional administrative burdens due to the fact that national legislation contains different information obligations,*** which have to be complied with and which would not be incurred if the company refrained from entering the national market. In this case, you have to estimate the time that would be spent complying with the additional information obligations, and convert this into a monetary value by using data on labour costs for the specific country you are looking at (normally available at Eurostat), for the job profile of the person that would have to perform the relevant administrative activities.

A number of *caveats* should be kept in mind when performing these calculations. First, adaptation costs might not be incurred by companies if they keep internal compliance programs that apply to one or more countries: for example, if a company adopts an internal antitrust compliance program that is tailored to the most restrictive country, this will automatically mean that the company also complies with legislation in less strict countries. Also, the magnitude of administrative burdens should be gauged against the so-called “BAU” factor, *i.e.* the extent to which the activities performed to comply with national legislation would be performed anyway even if they would not be required by law.

Finally, cost savings are only one category of benefits one has to deal with when looking at harmonization of legislation. Indirect benefits may emerge due to market efficiency impacts. Estimating these benefits is normally not prohibitively difficult but for accurate monetization you need data on demand and supply functions and demand elasticity⁷²⁰. It is suggested to seek expert guidance for this type of estimation⁷²¹. For further guidance see the tool on impacts in the internal market.

9. NON-MARKET BENEFITS

Social Cost Benefit Analysis seeks to assess the net value of a policy or project to society as a whole (see related Appendix 3 on the use of discount rates). Monetisation of non-market benefits is easiest when the values can be linked to market prices. For example, air pollution damage to crops might reduce crop yields, thus allowing for relatively straight forward monetisation. However, the full value of many goods (benefits) such as health, the

⁷¹⁹ http://ec.europa.eu/internal_market/retail/docs/140711-study-utp-legal-framework_en.pdf

⁷²⁰ In the US, dedicated databases are available, which make it easier to estimate the response of supply and demand curves to a given change in price or in the quality of products. See, for example, <http://www.ers.usda.gov/data-products.aspx#.UnUkoZTk-Es> and in particular the section on commodities and food elasticity's. In the economics literature, several estimates of elasticity are available, which could be collected into a single dataset made available to the desk officers wishing to perform CBA. See for example in relation to air transport, http://www.iata.org/whatwedo/Documents/economics/Intervistas_Elasticity_Study_2007.pdf

⁷²¹ For a general presentation see CEPS (2013), p. 178-182.

environment, or educational success cannot readily be inferred from market prices but this does not mean that these important social impacts can be ignored in policymaking. The valuation of non-market impacts is challenging but should be undertaken wherever possible.

Alternative or complementary tools exist to compare the merits of policy options where quantitative/monetary information may be limited (such as multi-criteria analysis)⁷²².

Economists try to determine a monetary value for non-market goods by looking at their impact on utility i.e. the satisfaction a person derives from consuming a particular good or the change in welfare or well-being. Utility is difficult to observe directly and is generally inferred by observing the choices people make within related or hypothetical markets.

9.1. Market based approaches: Stated preference and Revealed preference

The preferred method of estimating the change in utility is to simulate the market in order to estimate people's willingness to pay (WTP) or willingness to accept (WTA) a policy's impacts. WTP is the maximum amount of money an individual is willing to give up in order to receive a good. WTA is the minimum amount of money they would need to be compensated to forego or give up a good. The amount consumers are willing to pay depends on the levels of income available to them so valuations are usually obtained by averaging across income groups. The market based approaches to determine utility changes comprise "Revealed Preference" and "Stated Preference" methods⁷²³.

Box 4. "Revealed Preference" vs "Stated Preferences" vs "Experiments"

- Revealed Preference techniques involve inferring the implicit price placed on a good by consumers by examining their behaviour in a similar or related market. For example the value of house prices and its relationship to ambient noise or the travel costs incurred by individuals who wish to enjoy the amenity offered by a forest or other recreational site.
- Stated Preference techniques use specially constructed questionnaires to describe a hypothetical choice within a hypothetical market in order to elicit estimates of the willingness to pay or willingness to accept. When using stated preferences, the main choice is between contingent valuation and choice modelling. The former elicit WTP or WTA via direct questions on the amounts they would be prepared to pay to receive a particular good while the latter present respondents with a series of alternatives and asking for their preference.
- Experiments are different to revealed or stated preference surveys, as subjects in experiments make incentivised choices, and may accrue benefits and incur losses. In revealed and stated preference surveys, these types of incentives are not present.

Revealed preference methods are generally perceived to be more reliable and should be used where the information can be inferred. However, such techniques cannot estimate the value placed on an asset by people who make no use of it and stated preference techniques should then be used. In any event, consistency of results can be checked by using both techniques.

⁷²² See Tool #57 on *Analytical methods to compare options or assess performance*.

⁷²³ See overview in Table 29 of the CEPS 2013 study on Assessing the Costs and Benefits of Regulation, pp. 185. http://ec.europa.eu/smartregulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

The approaches described above can be used to estimate the value of improved health outcomes⁷²⁴ (such as from reduced air pollution), reduced road congestion, reduced road fatalities and injuries, disamenity (e.g. from waste disposal and quarrying) and recreational amenity (e.g. forests).

It may be difficult to judge the reliability of estimates emerging from a single study using a single method. Responses to questionnaires may be unreliable, inconsistent or biased or studies may not adequately take into account budget constraints. Robustness may be better from using different methods or aggregating results of different studies from different researchers. In any event, a range of values should be used to indicate the sensitivity of the ultimate decision to a particular valuation of benefits.

In the absence of an existing reliable and accurate monetary valuation of an impact, a decision should be made whether to commission a study, and if so, how much resource to allocate to the project. Factors to consider include (i) whether further research is likely to yield a robust valuation; (ii) whether the results will be useful for future IAs; (iii) how accurate does the valuation need to be in relation to the assessment at hand; (iv) the political importance/magnitude of the policy initiative and the expected impacts.

The technique of benefit or cost transfer (usually just called ‘benefits transfer’) can also be used to estimate values of impacts that do not have market prices. In this technique, values obtained in one study are transferred to a different study. For example, estimates of the costs of preventing a motorway accident in one Member State might be used to estimate the costs in other Member States. Using this technique increases the uncertainty of the estimated values, but can be helpful to give an order of magnitude of likely impacts, or if there are time and money constraints. Databases of valuation studies have been developed to make the technique of benefits transfer easier. You can find an evaluation of the possibility of adapting one such database for use in the EU on the Europa website.

When valuing impacts, the proportionality principle applies, as in all parts of Impact Assessment: don’t devote a lot of energy to putting a value on non-marketed impacts if they are a very small part of the overall impacts. In addition, there may always be significant impacts that cannot sensibly be monetised and these should be presented in non-monetary units (e.g. weighted emissions of greenhouse gases) or in more qualitative terms. Where material costs cannot be valued in monetary terms they should still be clearly taken into account in the impact assessment. Alternative techniques such as multi-criteria analysis may be helpful (see below). It is suggested that you consult your impact assessment support unit for further guidance.

9.1.1. Illustrative examples

(a) Revealed preference: the value of life or avoided injury

Suppose that a particular safety feature of a car (such as an airbag) reduces the risk of fatal injury by 50% in the case of an otherwise fatal accident and that the likelihood of having such an accident is 0.1 % for the average driver (meaning that statistically one out of 1,000 drivers will have such an accident). If the price for an airbag is 500 Euros and 70% of the cars are equipped voluntarily with an airbag, this means that 70% of the drivers are willing to pay 500

⁷²⁴ See Tool #31 on *Health impacts*.

Euros for a 0.05% reduction of the likelihood of having a fatal accident. This in turn means that the value the drivers of these cars attach to a life is at least $2,000 * 500 = 1$ million Euros on average. This illustrative example also shows that the valuation of risk differs between individuals. While 30% of the drivers (those not fitting the car with an airbag) implicitly attach a lower value (given their budget constraint), some of the drivers buying the additional safety feature may attach a substantially higher value to their life but still only have to pay 500 Euros for the airbag.

(b) Stated preference: Disamenity impacts

An example from the UK illustrates how activities including the transport and disposal of waste and the quarrying of minerals and aggregates (for road building) can give rise to undesirable impacts on the public's enjoyment of a an area used for recreation⁷²⁵.

Box 5. WTP and a tax on the quarrying of aggregates in the UK

- A study was conducted to see how much people valued avoiding adverse environmental impacts associated with quarrying for aggregates used by the construction industry (crushed rock, sand and gravel) both in their locality and in landscapes of national importance;
- Ten thousand randomly selected persons who lived nearby to 21 sample quarries were asked how much they would be willing to pay (in the form of taxes over five years) for the local quarry to be shut down and restored in line with the surrounding landscape and with no loss in employment.
- A further 1000 respondents (randomly selected from areas not in proximity to quarrying activities) were asked what they would be willing to pay to close a quarry in a national park.
- People were asked to consider environmental effects such as nature conservation (loss of biodiversity), noise due to transport and blasting, dust levels and visual intrusion.
- The willingness to pay for early closure of quarries were as follows:

Case study site	£/tonne of aggregates
Hard rock	0.34
Sand and gravel	1.96
Quarries in national parks	10.52
National average amount which individuals were willing to pay for the early closure of all types of quarry sites weighted by type was calculated as £1.80 per tonne.	

(c) Market and non-market benefits: Air pollution

The analysis supporting the updated strategy for air pollution was able to estimate direct benefits in terms of reduced economic costs to society arising from reduced use of medicines, visits to hospitals, lost work days from air-pollution and reduced yields of agricultural crops

⁷²⁵ ["The Green Book – Appraisal and Evaluation in Central Government"](#), HM Treasury, pp.67

as well as estimated benefits associated with reduced incidences of acute and chronic mortality due to exposure to air pollution (fine particles)⁷²⁶.

Box 6. Monetised impacts of air pollution

- Concentrations of individual air pollutants across the EU are measured and can be predicted based upon emissions inventories and complex atmospheric models.
- Research over many years has allowed exposure-response relationships to be derived for many health end points (short-term/long term mortality, and sickness) as well as for the damage on crop yields and buildings.
- Direct benefits have been determined for the improvements in air pollutant emissions by calculating the changes in air pollutant concentrations and changes in health endpoints and crop/buildings damage. This also allows indirect benefits to be calculated such as lost production due to employment incapacity etc.
- For non-market impacts such as premature mortality, willingness to pay studies have provided financial values for each of year of life lost given from the exposure response relationship.
- In 2010, air pollution was estimated to be responsible for 400,000 annual premature deaths with health-related external costs of between € 330-940bn per year, including direct economic damages of €15bn from lost workdays, €4bn healthcare costs, €3bn crop yield loss and €1bn damage to buildings.

10. OTHER METHODS USED WHEN ESTIMATING COSTS AND BENEFITS

Economic models are often used in the preparation of impact assessments but these are generally complex models which are unlikely to have been developed by DGs or services. The JRC has established a competence centre on modelling which can provide information about the available models and help and assistance in using such models. A separate tool exists in relation to the use of analytical models and methods and covers issues such as data quality, sensitivity analysis etc.

10.1. Partial equilibrium analysis

In many policy proposals, the impact of the policy proposal goes beyond a single sector and actually results in interaction across many sectors or even economy wide. Such analysis of costs and benefits can usually not be done based on a bottom up analysis or spreadsheet calculations but requires specific tools such as economic models which cover core interactions between several elements, sectors and actors and try to represent real world behaviour. Depending on their scope, economic models can also be able to assess several cost and benefit dimensions simultaneously. For instance a partial equilibrium model that looks at the functioning of the energy system at large can look simultaneously at issues such as investment costs, operational and fuel savings, emissions fluctuation and implications for energy security.

The use of partial equilibrium analysis assumes that the effects of the regulation on all other markets will be minimal and can either be ignored or estimated without employing a model of

⁷²⁶ [SWD\(2013\) 531](#):

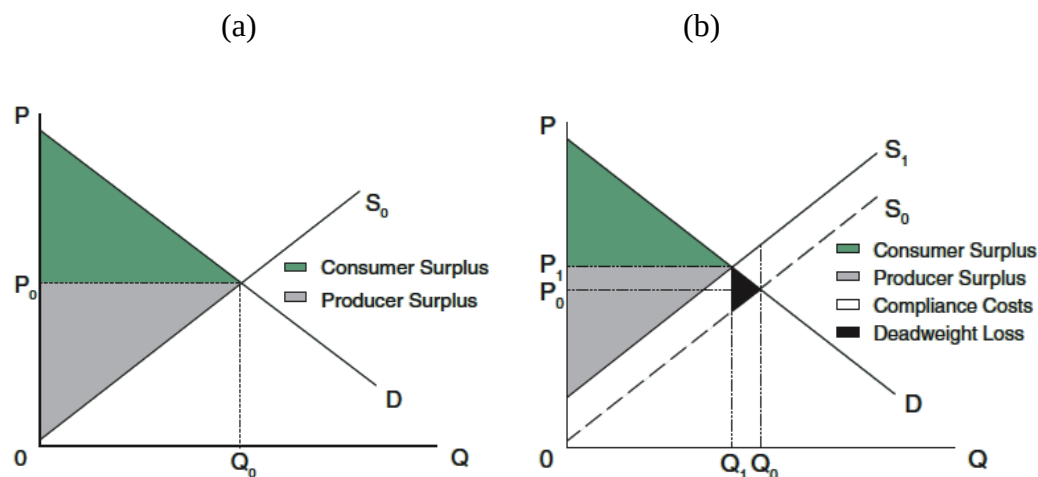
the entire economy. This means, in most cases, that indirect impacts will be less significant than direct impacts, and will be confined to the passing-on of certain costs and benefits to downstream markets. This section presents some simple diagrams to show how social cost can be defined in a partial equilibrium framework. For the sake of simplicity, we refer to a market context: however, the problem of whether to focus on the sector directly affected by the regulation or also to a number of other more indirectly affected sectors or domains can also occur in cases where there is no market context to refer to.

Figure 1(a) shows a competitive market before the imposition of an environmental regulation. The intersection of the supply (S_0) and demand (D) curves determines the equilibrium price (P_0) and quantity (Q_0). The shaded area below the demand curve and above the equilibrium price line is the consumer surplus. The area above the supply curve and below the price line is producer surplus. The sum of these two areas defines the total welfare generated in this market: the net benefits to society from producing and consuming the good or service. In this market, assume that the imposition of a new environmental regulation raises firms' production costs. Each unit of output is now more costly to produce because of expenditures incurred to comply with the regulation. As a result, firms will respond by reducing their level of output. For the industry, this will appear as an upward shift in the supply curve. This is shown in Figure 1(b) as a movement from S_0 to S_1 . The effect on the market of the shift in the supply curve is to increase the equilibrium price to P and to decrease the equilibrium output to Q_1 , holding all else constant.

As seen by comparing Figures 1(a) and 1(b), the overall effect on welfare is a decline in both producer and consumer surplus. Compliance costs in this market are equal to the area between the old and new supply curves, bounded by the new equilibrium output, Q_1 . Noting this, a number of useful insights about the total costs of the regulation can be derived from Figures 1a and 1b. First, when consumers are price sensitive — as reflected in the fact that the demand curve is downward sloping — a higher price causes them to reduce consumption of the good. If only direct costs are estimated and this price sensitive behaviour is not taken into account (i.e., the estimate is based on the original level of output (Q_0)) compliance costs will be overstated.

A second insight derived from Figures 1a and 1b is that compliance costs are usually only part of the total costs of a regulation. The “deadweight loss” (DWL) shown in Figure 6b is an additional, real cost arising from the regulation. It reflects the foregone net benefit due to the reduction in output. Moreover, unlike many one-time compliance costs, DWL will be a component of social cost in future periods. Under the assumption that impacts outside this market are not significant, then the social cost of the regulation is equal to the sum of the compliance costs and the deadweight loss (shown in Figure 1b). This is exactly equal to the reduction in producer and consumer surplus from the pre-regulation equilibrium (shown in Figure 1a). This estimate of social cost would be the appropriate measure to use in an impact assessment of the regulation.

Figure 1 – Partial equilibrium analysis



Source: EPA (2010)

Third, Figure 1(b) above also shows that, depending on the elasticity of the demand and supply curves, legal rules can also produce unintended effects on stakeholders that are not those who are through to be directly affected by the rule. This is typically the case whenever firms that are subject to regulation through, say, the introduction of a stricter environmental or product standard are able to pass-on (and thus recover) part of the corresponding “compliance cost” on downstream actors or end consumers. Estimating the degree of passing-on is not always easy, and requires that those that carry out impact assessment are aware of the likely elasticity of demand and supply. However, while performing an *ex ante* impact assessment the degree of precision required may not always be extreme: in some circumstances, awareness of the possibility that a minimal, significant or very substantial part of the increased cost might be passed on downstream or upstream can in any event lead to a better understanding of the consequences of adopting a given regulatory measure.

The preceding discussion describes the use of partial equilibrium analysis when the regulated market is perfectly competitive. In many cases, however, some form of imperfect competition, such as monopolistic competition, oligopoly, or monopoly, may better characterize the regulated market. Firms in imperfectly competitive markets will adjust differently to the imposition of a new regulation and this can alter the estimate of social cost. If the regulated market is imperfectly competitive, the market structure can and should be reflected in the analysis.

10.2. Multi-market analysis

In certain situations, **when the effects of a regulation are expected to impact a limited number of markets beyond the regulated sector**, it still may be possible to use a partial equilibrium framework to estimate social cost. Multi-market analysis extends a single-market, partial equilibrium analysis of the directly regulated sector to include closely related markets. These may include the upstream suppliers of major inputs to the regulated sector, downstream producers who use the regulated sector’s output as an input, and producers of substitute or complementary products. Vertically or horizontally related markets will be affected by changes in the equilibrium price and quantity in the regulated sector. As a consequence, they will experience equilibrium adjustments of their own that can be analysed in a similar fashion.

10.3. General equilibrium analysis

In some cases, the adoption of a new legislative measure might bear significant effects in many markets, including markets that are far from those that are directly subject to the regulation. As the number of affected markets grows, it becomes less and less likely that partial equilibrium analysis can provide an accurate estimate of costs and benefits. Similarly, it may not be possible to accurately model a large change in a single regulated market using partial equilibrium analysis. In such cases, a general equilibrium framework, which captures linkages between markets across the entire economy, may be a more appropriate choice for the analysis. These models are appropriate in particular when indirect impacts are likely to be the most significant ones in terms of magnitude of expected impacts. For example, a significant increase in energy prices due to the introduction of some new environmental regulation can have widespread impacts across the whole economy (e.g. increased energy poverty of households due to higher energy prices).

General equilibrium models are able to simulate the shifts in supply curves and corresponding demand changes that can result from any change in the economy, from a price shock in raw materials to a new form of price regulation. Accordingly, they are able to model the links between connected markets in a way that shows the ultimate impact on outputs and consumption of goods and services in the new market equilibrium; and they can also determine a new set of prices and demands for various production factors (labour, capital, land). As a final result, they can also provide indications and estimates as regards macroeconomic changes, such as GDP, overall demand, etc.

11. FURTHER INFORMATION

- Study prepared by the Centre of European Policy Studies on [the assessing the costs and benefits of regulation](#).
- [OECD Regulatory Compliance Cost Assessment Guidance](#).
- Unit C2 of the Secretariat General can provide advice on the content of this tool via its functional mailbox SG-C-2@ec.europa.eu.

Appendix

Illustrative examples on how to quantify costs and benefits

All relevant impacts should be assessed quantitatively if possible as well as qualitatively when preparing impact assessments, fitness checks and evaluations. Similarly, impacts should be monetised whenever possible. However, whether quantification can be undertaken depends on whether a sound methodology exists and if the required data exist and can be collected without disproportionate cost.

In particular, quantification should accompany REFIT initiatives in order to meet the commitment of the May 2015 Better Regulation Communication.

In case of any significant amendments introduced by the co-legislators to the original Commission proposal, the Commission should also consider working with the European Parliament and Council to update estimations presented in the initial impact assessment.

Example 1: Annual material costs of a new obligation requiring the use of winter tyres in certain weather conditions (snow and ice).⁷²⁷

In practice vehicle owners do not just change to winter tyres once, but revert to summer tyres in spring. The costs for this second change are directly related to the provision and must therefore be taken into account when identifying and presenting the compliance costs.

There are 56 million registered vehicles and it is assumed that:

- Vehicles owned by public authorities are already fitted with winter tyres.
- 70% (39.2 million vehicles) have their tyres changed in autumn and spring due to different reasons (recommendations by driving organizations and economic considerations such as wear and tear, fuel consumption).
- A further 20% (11.2 million vehicles) are driven all-year round with all-weather tyres or are not driven at all during wintry road conditions.
- The remaining 5.6 million vehicles, which have only used summer tyres to date, therefore represent the calculation basis. Their owners will have to purchase winter tyres for the first time and change them regularly in the following years (frequency 2 per annum, number of vehicles: 5.6 million, number of cases = 11.2 million vehicles).

Cost type	Annual material costs	
	Segment 1 (40% of cars)	Segment 2 (60% of cars)
3.36 million private cars which change tyres twice per year with a unit price per change of a set of tyres of €20 at a garage [3.36 x 2 x 20]		€134.4 m
2.24 million private cars where the owner changes the tyres twice per year	€0	

⁷²⁷ Guidelines on the identification and presentation of Compliance costs in legislative proposals by the Federal Government, The German Federal Government, Nationaler Normenkontrollrat & Federal Statistical Office, October 2012.

himself/herself at zero material cost.		
3.36 m. private cars changing tyres every 6 years (frequency 0.17 per annum) with an additional cost relative to summer tyres of €100. [3.36 x 0.17 x 100]		€ 57.1
2.24 million private cars changing tyres every 6 years (frequency 0.17 per annum) with an additional cost relative to summer tyres of €100. [2.24 x 0.17 x 100]	€38.1	

Example 2: Material costs incurred by a company due to the introduction of an IT-process (fictitious), here: identification of the average annual material costs per company.⁷²⁸

Average material cost per company	Annual	One-time
4000 companies need to buy new software licences and IT support at unit cost of €800 [4000 x €800 euro]	€3.2 m	
4,000 companies purchase new hardware and incur costs for its installation of €2500 [4,000 x €2,500]		€10 m
Total:	€3.2 m	€10 m

Example 3: Employees must be trained to operate new equipment that is required by a new law.

The new proposal leads to one-time costs for the first ‘wave’ of training courses and ongoing costs for annually required training courses. The following are assumed:

- 19 euro per hour are taken as basis for the labour costs of the employees to be trained,
- The training takes 12 hours.
- The hourly wage rate is €19.
- 45,000 employees are trained during the first year.
- It is assumed that 4,500 new employees, i.e. 10% of staff, are newly recruited and trained every year.

	Personnel costs (in euro)	
	Annual	One-time
<i>Ongoing costs per case</i> Number of new employees per annum x (frequency of training) x (hourly wage rate) x (duration of training) [4500 x 1 x 19 x 12]	€1.0 m	€10.3m
<i>One-time costs per case</i> Number of existing employees to receive one-off training x (hourly wage rate) x (duration of training) [45,000 x 19 x 12] = 10,260,000		

⁷²⁸ Guidelines on the identification and presentation of Compliance costs in legislative proposals by the Federal Government, The German Federal Government, Nationaler Normenkontrollrat & Federal Statistical Office, October 2012.

euro		
Compliance costs	€1.0 m	€10.3

Example 4: Modernising VAT obligations for cross-border eCommerce

As part of the Digital Single Market initiative and the Action Plan for the modernisation of VAT, the Commission adopted a proposal for a reform of VAT on cross-border eCommerce. This is a REFIT initiative with simplifications brought by the application of the 'destination principle' and the mini one stop shop (MOSS). The impact assessment⁷²⁹ used a systematic approach for the quantification of impacts by covering both economic costs and benefits and administrative burden for businesses and public authorities. The impact assessment estimated that the preferred option would generate an annual increase in VAT revenues of €7 billion and reduce annual compliance costs for businesses by 55% (i.e. an annual saving of €1.9 billion). It would also increase eCommerce by 0.3% with negligible eCommerce price increases of the order of 0.7%. The table below illustrates the combination of qualitative and quantitative tools used for these calculations of impacts.

Impact	Approach used	Analytical tools	Key assumptions	Key sources
<i>Impacts for Member States' revenues, costs and benefits for Member States to implement the Option</i>	Quantitative analysis Qualitative analysis	Standard Cost model (SCM)	Costs similar to the MOSS Different scenarios for e-Commerce growth Compliance monitoring based on risk profiling	Member States' interviews and questionnaires) Stakeholder workshops Desk research Member States' interviews
<i>Impacts on administrative burden for businesses</i>	Quantitative analysis	SCM	Impacts of OSS similar to those of MOSS Number of businesses Number and behaviour of micro-businesses engaged in cross-border e-Commerce	Businesses interviews Stakeholder workshops Business online survey
<i>Impacts on competition and growth</i>	Quantitative analysis	CGE model	Different scenarios for e-Commerce growth Number of businesses Number and behaviour of micro-businesses engaged in cross-border e-Commerce	Consumer survey SCM Desk research
<i>Impacts on compliance</i>	Quantitative analysis Qualitative analysis	Projections	Different scenarios for e-Commerce growth	Member States' interviews and questionnaires Stakeholder workshops Desk research Mock purchases

⁷²⁹ Insert reference and link to IA

Example 5. New emissions controls on medium sized combustion plants package [SWD(2013) 531 Annex 12 on air pollution]

The emissions abatement compliance costs, emissions monitoring costs and administrative costs were estimated for the large number of medium-sized combustion installations in the EU to meet stricter emissions limits.

The approach involved the compilation of a detailed inventory of combustion plants compiled by size category, fuel and combustion technology. To this, the impacts of imposing new emissions limits (control technologies) were estimated.

Example 6. The impacts of a Standard VAT return [SWD(2013) 427]

Some 30 million companies file 150 million VAT returns annually at a cost of €30 bn annually. 0.2% of these are from big businesses; 6.6% from SME and 12.2% micro-SME (130 million). 13% of companies must submit such a VAT return in more than 1 Member State.

Detailed studies from Deloitte and PWC allowed data to be collected on the different VAT declarations used across the EU, the different types of information required to be filled-in and to make informed assumptions about the time needed to fill out returns, average wage levels and the use of consultants (in a limited number of Member States).

Example 7. Proposal for a Regulation on binding annual greenhouse gas emission reductions by Member States from 2021 to 2030 [SWD(2016) 247 and 248].

A suite of models was used to assess the impacts in the EU's energy system and key economic sectors including transport and the land using sector (LULUCF⁷³⁰). These models include PRIMES, GAINS and GLOBIOM-G4M-CAPRI. Key aspects of the modelling approach include:

- **Emissions:** CO₂ emissions from energy and processes (PRIMES), CH₄, N₂O, fluorinated greenhouse gases (GAINS), CO₂ emissions from LULUCF (GLOBIOM-G4M), air pollution SO₂, NO_x, PM_{2.5}-PM₁₀, ground level ozone, VOC, NH₃ (GAINS).
- **Emission reduction and removals:** structural changes and technologies in the energy system and industrial processes (PRIMES), technological non-CO₂ emission reduction measures (GAINS), changes in land use (GLOBIOM-G4M-CAPRI).
- **Time horizon:** 1990 to 2050 (5-year time steps).
- **Geography:** individually all EU Member States, EU candidate countries and, where relevant Norway, Switzerland and Bosnia and Herzegovina
- **Impacts:** on energy, transport and industry (PRIMES), agriculture, forestry and land use (GLOBIOM-G4M), atmospheric dispersion, health and ecosystems (acidification, eutrophication) (GAINS), macro-economy with multiple sectors, employment and social welfare.

⁷³⁰ Land Use, Land Use Change and Forestry.

TOOL #60. THE STANDARD COST MODEL FOR ESTIMATING ADMINISTRATIVE COSTS

1. ADMINISTRATIVE COSTS AND THE "STANDARD COST MODEL"

Administrative costs are costs incurred by enterprises, the voluntary sector, public authorities and citizens **in meeting legal obligations to provide information** on their activities, either to public authorities or to private parties. This captures a broad range of information including labelling, reporting, registration data as well as monitoring and assessments needed to generate the information. In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supplied on request.

Box 1. Example of administrative costs versus compliance costs

- A regulation on air quality sets an obligation to keep a register of pollutant emissions and an obligation to meet an air quality threshold.
- Keeping a register of pollutant emissions is an administrative cost, while action taken to meet an air quality threshold is not. That type of compliance cost is sometimes referred to as 'substantive compliance cost' because the obligation affects the core industrial activity.
- Keeping a register does not entail in itself any obligation to change the production process, the nature of the end-products or the treatment of emissions. Meeting the pollution threshold will require a substantive change to the industrial activity (for instance the installation of new filters).

Whenever a measure is likely to impose significant administrative costs on business, the voluntary sector or public authorities, the **EU Standard Cost Model** presented below⁷³¹ should be applied. The main aim of the model is to assess the **net cost of information obligations** imposed by EU legislation.⁷³² Commission services are also invited to apply the model on a tentative basis for assessing costs imposed on citizens. The possibility and need for monetisation in this case is left to their discretion.

2. OUTLINE OF THE MODEL

2.1. Definition of administrative costs and administrative burden

Recurring administrative costs and, where significant, **one-off administrative costs** have to be taken into account.

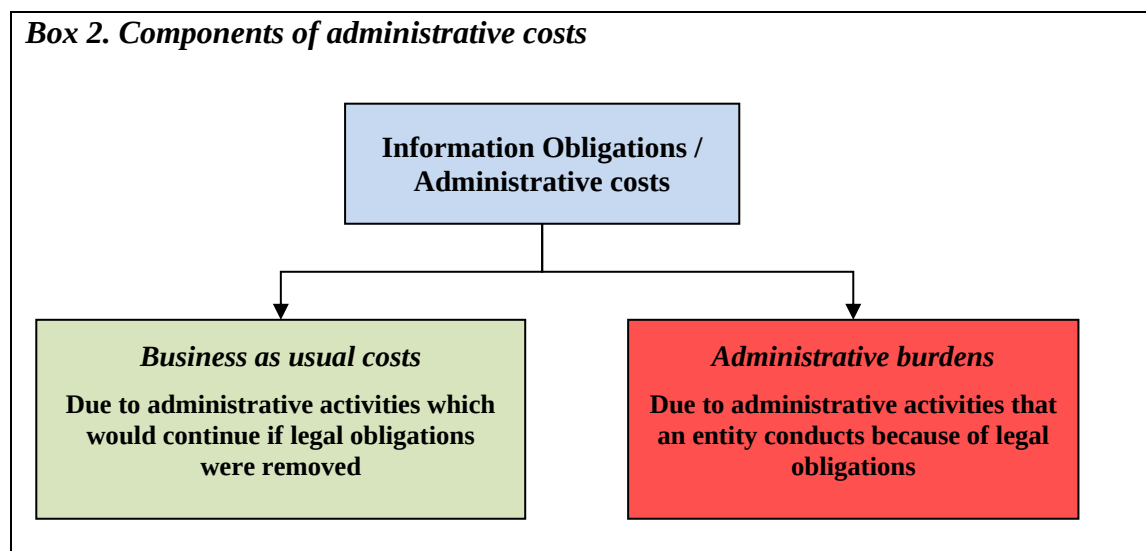
The administrative costs consist of two different cost components: the **business-as-usual costs** and **administrative burdens**. While the business-as-usual costs correspond to the costs resulting from collecting and processing information which would be done by an entity even

⁷³¹ https://myintracomm.ec.europa.eu/sg/better_regulation/Documents/eu_cost_model_report_sheet_June_2016.xls

⁷³² net costs = costs introduced by a proposal if adopted, minus the costs it would eliminate at EU and/or national level.

in the absence of the legislation, **the administrative burdens stem from the part of the process which is done solely because of a legal obligation**⁷³³.

Box 2. Components of administrative costs



This distinction is particularly important for policymaking. New legal obligations codifying (business) good practices are by definition less burdensome for targeted entities than those requiring tasks never performed before. Conversely, the suppression of a ‘pure’ obligation will provide greater cost relief than the suppression of an obligation that is to a large extent part of business as usual activities.

Although determining what an entity would ‘normally’ do may be open to interpretation, reduction efforts focus on the way to minimise or reduce ‘real’ administrative burdens.

2.2. Core equation of the cost model

Administrative costs should be assessed on the basis of the **average cost of the required administrative activity** (Price) multiplied by the **total number of activities performed per year** (Quantity).

The average cost per activity will be generally estimated by multiplying a tariff (based on average labour cost per hour including pro-rated overheads) and the time required per action. Where appropriate, other types of costs such as outsourcing, equipment or supplies’ costs should be taken into account⁷³⁴.

The quantity will be calculated as the frequency of required actions multiplied by the number of entities concerned. In case of multiple relevant administrative activities per information obligation these need to be summed up to calculate the administrative cost per information obligation. The core equation of the SCM is as follows:

⁷³³ Most businesses would for instance have an accounting system, even in the absence of legal bookkeeping, but would not necessarily provide caloric value information for all their products

⁷³⁴ Many small businesses for instance use external accountants to fulfil certain information obligations set by Company Law. Chambers of commerce and sectoral professional associations also provide form filling services.

Box 3: Core equation of the Standard Cost Model

$$\text{Administrative cost} = \sum P \times Q$$

where **P** (for Price) = Tariff x Time; and

where **Q** (for Quantity) = Number of businesses x Frequency

2.3. Scope of application of the model and expected level of accuracy

The effort of assessment should remain proportionate to the scale of the administrative costs imposed by the legislation and should be determined according to the principle of proportionate analysis (see chapter 3 of the main text). There is therefore no need to cost obligations requiring for instance **little equipment, if the amount of time per action is small and the frequency low as these are bound to be insignificant**. Such decisions (i.e. no costing) will be taken on a case-by-case basis and should be documented. In order to keep assessment of costs at a reasonable level and ensure compatibility with national methodologies, **estimates will be based on working assumptions** simplifying the complex reality of the Union. These assumptions are presented together with **step specific guidelines below**.

3. STEP BY STEP GUIDE

The assessment of positive or negative effects on administrative burden on businesses, citizens or public administrations resulting from EU legislation should begin with a **full mapping of the introduction of new or suppression of existing information obligations** for each of the options under review. This mapping should show clearly how policy options differ in terms of information obligations. In a tabular form, such comparative mapping will usually indicate the type of information obligation, the data requirements, the target group and the obligation's frequency.

That table should also indicate which obligations are likely to impose **significant administrative burdens**. The significance (high – medium – low) is usually determined by a qualitative assessment of the likely number of entities concerned as well as the frequency and complexity of the required data.

Significant burdens will then be roughly quantified (monetary estimates) on the basis of the EU 'Standard Cost Model' (see core equation above).

A greater level of detail is expected for the monetary assessment of administrative burdens stemming from the preferred option. This detailed application can be divided in a number of steps. The entire workflow is summarised in Table 1 below, followed by a description of each step⁷³⁵. Following these steps will also allow you to fill in the Standard Reporting Sheet (see step 11).

⁷³⁵ Assessment is an iterative process, where earlier steps may need to be revisited in the light of work undertaken later in the process. This is of course also true here.

Table 1: Step by step application of the model

Phase I: Preparatory analysis	
Step 1:	Identification and classification of information obligations (e.g. certification of products) & data requirements (e.g. the certificate must provide the date of production and composition of the product)
Step 2:	Identification of required actions (e.g. training members and employees about the information obligations, filling forms)
Step 3:	Classification by regulatory origin (e.g. EU rule on certification is the transposition of an agreement of the World Trade Organisation)
Step 4	Identification of target group(s), also called segmentation (e.g. large enterprises that have to fulfil obligation ‘A’ and small enterprises that have to fulfil obligation ‘B’, the size of the enterprise being defined by its turnover)
Step 5	Identification of the frequency of required actions (e.g. small enterprises have to fill a form once a year)
Step 6	Identification of relevant cost parameters (e.g. particular relevance of external costs – using accounting firms – and equipment) Qualitative assessment of significant burdens (i.e. applying de minimis threshold test to determine which information obligations need to be quantified)
Step 7	Choice of data sources and, if necessary, development of data capture tool(s) (e.g. deciding that the number of entities concerned will be extrapolated on the basis of data available on Eurostat, but that the number of hours each need to perform required actions will be based on the results of interviews of enterprises; for the latter task, preparation of an interview guide and selection of a representative sample of entities including organisations representing citizens)
Phase II: Data capture and standardisation	
Step 8	Assessment of the number of entities concerned (e.g. 100.000 SMEs)
Step 9	Assessment of the performance of a ‘normally efficient entity’ in each target group, taking into account cost parameters identified in step 6 (e.g. enterprises have once a year to spend, on average, 25 hours of work by an engineer to gather information and 5 hours of work by a clerk to fill the annual form)
Phase III: Calculation and reporting	
Step 10	Extrapolation of validated data to EU level
Step 11	Final reporting and transfer to the database

3.1. Step 1: Identification and classification of information obligations

In order to facilitate the assessment of administrative costs by analogy and to improve data analysis (identification and comparison of the most burdensome types of obligation across various sectors), services are asked to use the following typology on the nature of the administrative information obligations (Box 4) when inserting relevant information obligations in the Standard Excel Report Sheet (an example is provided at the end of step 11).

Box 4: Types of obligation

- Notification of (specific) activities or events (e.g. for transportation of dangerous cargoes; when an accident affects the environment)
- Submission of (recurring) reports (e.g. annual accounts)
- Information labelling for third parties (e.g. energy labelling of domestic appliances; price labelling)
- Non labelling information for third parties (e.g. financial prospectus; disclosure obligation of employers towards employees)
- Application for individual authorisation or exemption i.e. obligation to fulfil each time a particular task has to be carried out; (e.g. building permits; road transporters applying to be exempted from Sunday driving ban)
- Application for general authorisation or exemption (e.g. license granting permission to engage in an activity such as banking or liquor selling)
- Registration (e.g. entry in a business register or a professional list)
- Certification of products or processes, i.e. obligation to deliver a certificate (e.g. treatment facilities having to issue a certificate of destruction of a vehicle) or to get a certificate (e.g. aeronautical products and organisations involved in their design, production and maintenance must get the certification of the European Aviation Safety Agency – EASA)
- Inspection on behalf of public authorities (e.g. businesses having to monitor conditions for employees)
- Cooperation with audits & inspection by public authorities or their appointees (e.g. obligation to cooperate with workplace inspection), including maintenance of appropriate records (e.g. obligation for treatment facilities to keep records about waste electronic equipment entering and leaving the treatment facility; obligation for hotels to keep a visitor log; these records must be presented during the inspection)
- Application for subsidy or grant (e.g. to structural or cohesion funds)
- Other

Distinguishing an obligation to provide information from other regulatory obligations is normally straight forward. There could however be a number of **borderline cases** where it is difficult to decide whether a rule falls within the scope of the model or not. It is important to ensure that such borderline cases are discussed and evaluated in the light of decisions taken in other similar areas so as to ensure consistency.

Box 5: Examples of borderline information obligations

- Costs induced by exercising a right to complain. These costs are not considered as an administrative cost by Member States quantifying administrative costs using the Standard

Cost Model because there is no ‘obligation’ to complain.

- Costs induced by inspection. The usual purpose of an inspection is to collect the information needed to verify compliance with legal obligations (review of corporate books, etc.). Ensuing costs are clearly administrative costs. However inspections are sometimes used to collect information unrelated to legal obligations (level of satisfaction of businesses, etc.). Submitting to such inspection is by definition voluntary and ensuing costs therefore fall outside the definition of administrative costs imposed by legislation.
- Costs induced by policy assessment. Some EU programmes require Member States to draw up national reform programmes. Designing a reform programme is of course quite different from an obligation to provide information. However designing monitoring schemes, collecting data on the implementation of the policy, filling tables and submitting them to the Commission are clearly linked to information obligations. So policy design should not be considered as administrative cost, with the sole exception of policy assessment design.
- Costs induced by the obligation of drawing safety plans. Some EU acts require businesses to design staged evacuation strategies, conduct exercises to verify that everyone knows what to do and when, etc. (cf. plans for so-called Seveso establishments, airports,). This is of course quite different from an obligation to provide information; resulting costs should therefore not be considered as administrative burden. The only eligible costs here basically are those linked to the obligation to collect information about impending risks (safety plans must often be based on a risk assessment) and the obligation to file and/or send the safety plan.
- Testing costs. When business have to submit their products & processes to the test in order to get an authorisation or a certificate, these testing costs are not considered as administrative costs.

Some EU legislative acts and proposals also mention the possibility for Member States to ask for additional information (i.e. ‘...Member States may ... require the inclusion of other statements in the annual accounts in addition to the documents referred to in the first subparagraph ...’). Such possibilities are not to be understood as EU IOs, insofar as Member States are not obliged to ask that information. Nevertheless such possibilities will be documented as they often pave the way for Member States' additions ("gold-plating").

3.2. Step 2. Identification of required action

The services are asked to use the following typology on the type of required action (inserted in the excel report sheet).

Box 6. Types of required action

- Familiarising with the information obligation
- Training members and employees about the information obligations
- Retrieving relevant information from existing data
- Adjusting existing data and Producing new data
- Designing information material (e.g. leaflet conception)
- Filling forms and tables (including recordkeeping)
- Holding meetings (internal/external with an auditor, lawyer etc.)

- Inspecting and checking (including assistance to inspection by public authorities)
- Copying (reproducing reports, producing labels or leaflets)
- Submitting the information to the relevant authority (e.g. sending it to the relevant authority)
- Filing the information
- Buying (IT) equipment & supplies (e.g. labelling machines) to specifically used to fulfil information obligations
- Other

3.3. Step 3. Classification by regulatory origin

In order to enhance transparency on who is responsible for what, the **regulatory origin of information obligations** needs to be identified. Three simple rules should be used for this:

If the obligation arises entirely from an authority that specifically states the way in which the obligation must be met, attribute 100% of costs induced by the obligation to that authority.

If the obligation set by an authority requires transposition by another authority and if the transposing authority limits itself to what is needed to meet the obligation, attribute 100% of the costs to the authority which set the obligation.

if the obligation set by an authority requires transposition by another authority and if the transposing authority goes beyond what is needed to meet the obligation, attribute the % resulting from 'gold plating' to the transposing authority.

Gold plating in the case of administrative obligations refers, among other things, to increasing the reporting frequency, to add 'data requirements' or to widen the target groups.

In the context of the impact assessment, services are only requested to determine costs originating from the international and EU levels, not those that may originate at national or lower levels. The reporting sheet (see [step 11 – Report](#)) has been conceived to be used by EU institutions and Member State authorities, for (ex-ante) assessment of proposed measures and (ex post) evaluation of existing legislation. If a national government decides to evaluate the administrative costs put on a sector in its country, it needs to account for purely national and regional obligations in addition to obligations of international and EU origins. By contrast, when the Commission assesses a possible measure, there is no point guessing what level of "gold-plating" transposing authorities in each Member State might introduce. The Commission only has to account for proposals transposing international obligations in the EU and those resulting from its own initiative. There is by definition no obligation of national or regional origin applying to the entire Union.

Example: The World Health Organisation has adopted a framework convention on tobacco control. The Community and the Member States, as signatories to the Convention, are bound by these international rules. Article 11 provides that information on emissions of tobacco products must appear on each package of tobacco products. It also provides that labels may include warnings in the form of pictures. Supposing that the Commission envisages a measure obliging manufacturers to provide information on tobacco emissions as well as to print cancer pictures on each package, 100% of the costs induced by the first obligation will be attributed to the 'international' level, while 100% of the costs induced by the second obligation will be

attributed to the ‘EU’ level. By imposing the inclusion of pictures, the EU would indeed go beyond what is needed to meet WHO obligations.

Attention should be paid to the **references of the act at the origin of the obligation**. In order to ensure optimal addition and comparison of data, all parties using the EU common methodology (Commission, European Parliament, and Council) or contributing data (Member States at different levels of authority) have been asked to use the EU-Lex format for existing EU legislation. The enumeration order varies with the type of act⁷³⁶ and it is therefore easier to make a ‘cut and paste’ of the reference given by the search engine (use <http://eur-lex.europa.eu/homepage.html>) than list referencing rules.

For **Commission proposals**, EU-Lex will normally use the following format: ‘Proposal for a Directive of the European Parliament and of the Council on the exercise of voting rights by shareholders of companies having their registered office in a Member State and whose shares are admitted to trading on a regulated market and amending Directive 2004/109/EC, COM/2005/0685 final.’

For an **EU act transposing an international act**, services will also provide the name and reference of that international act, as well as information on the transposition. They will fill the simple concordance table included in the report sheet. The table is made of two columns: the first column gives the reference of the article detailing the obligation assessed; the second column gives the reference of the ‘original’ obligation, i.e. the article of the act laying down the obligation transposed by the act being assessed.

3.4. Step 4. Identification of target groups

As for the target groups, it may be useful to distinguish between groups on the basis of their size, type or location. Size may be particularly pertinent for enterprises. It is indeed often the case that an obligation is more burdensome for small enterprises than for large ones benefitting from economies of scale. Regulation often adjusts the type of information obligations according to a number of objective criteria (number of employees, turnover level, financial capacity of the citizens, etc.).

3.5. Step 5. Identification of the frequency of required actions

The frequency indicates how many times per year an action is required⁷³⁷. If, for instance, an information has to be submitted once a year, the frequency = 1; if it is every 6 months, the frequency = 2; if it is every three years, the frequency = 0.33; etc.

In some cases, the frequency may vary in time. For instance, in a number of statistics regulations such as Intrastat, enterprises have to report if their dispatches are above a set

⁷³⁶ Regulation (EC) No 2560/2001 of the European Parliament and of the Council of 19 December 2001 on cross-border payments in euro, Official Journal L 344 , 28/12/2001 P. 0013 – 0016’; but ‘Council Regulation (EC) No 2580/2001 of 27 December 2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism.

⁷³⁷ By definition that notion does not apply to one-off costs such as ‘familiarising with the information obligation’. These costs will therefore not be included in the standard report sheet allowing monitoring the level of recurring costs.

threshold. Their level of intra-EU sales will therefore determine if they have to report or not. Here again, the advice is to keep things simple. If such fluctuations concern a limited number of enterprises, they should not be taken into account.

3.6. Step 6 Identification of relevant cost parameters

The relevant cost parameters are of course deduced from the core equation (see [core equation of the cost model](#)). It is assumed that the main costs induced by information obligations are **labour costs**. Where appropriate, **equipment or supplies' costs** or costs per action should be taken into account or used as the basis for analysis (rather than taking time as the basis unit).

The cost parameters for the *price per action* (administrative action carried by the targeted entity itself) are the (i) **number of minutes spent on a specific action**, (ii) the **hourly pay** of those performing the action. This hourly pay should correspond to the gross salary plus overheads costs (25% by default). In order to ensure overall consistency, services are asked to use the overall tariff (all Member States & 9 qualification segments) used for the EU baseline measurement.

The cost parameters for *equipment & supplies* (i.e. acquired by the targeted entity to comply with the information obligation and solely used for that purpose) are the **acquisition price** and the **depreciation period** (service life of 'x' years).⁷³⁸

The cost parameters for the *outsourcing costs* (administrative action contracted out) is what the service provider charges on average per information obligation, per entity and per year .

3.7. Step 7. Choice of data sources and, if necessary, development of data capture tool(s)

Data collection methods to be chosen according to the individual case include: focus groups, consultation of stakeholders, field trials, consultancy studies, and expert assessment. Irrespective of the source and mode of collection, services need to verify and interpret collected data (see Annex 11.1 approximating numbers).

In standard cases, it will be sufficient to produce overall estimates based on 'EU Administrative Burdens Calculator as well as available EU statistics (provided, among others, by [Eurostat](#) and the Small and Medium-Sized Enterprises Observatory);

In exceptional cases, field work limited to a sample of Member States and/or questionnaires sent to a standard sample of the business community or organisations representing individuals (for example, consumers), and simulation may have to be used. Key templates are provided in the 'Starter kit for measuring and reducing administrative burdens'⁷³⁹. Even if data are not collected by these means, it is always useful to talk to the future addressees, insofar as they are well placed to identify hidden costs.

⁷³⁸ For instance, barcode printer and scanner.

⁷³⁹ http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm

Member States have agreed to assist the Commission to collect data where standard sources do not suffice⁷⁴⁰.

3.8. Step 8. Assessment of the number of entities concerned

In order to ensure comparability of estimates made by different DGs and ensure compatibility with estimates conducted by a large number of Member States, services will base their assessment of administrative costs on the basis of an **assumption of full compliance by all entities concerned**. All the assumptions concerning population size (e.g. SMEs), in particular for proposals with long time horizon, should be clearly explained.

3.9. Step 9. Assessment of the performance of a ‘normally efficient entity’

In order to keep assessment of costs at a reasonable level and ensure compatibility with national methodologies, the **assessment will be based on ideal types** (typical firms, typical public service, etc.). National databases don’t work with ranges of estimates, but with discrete figures corresponding to standardised costs.

To start with, services will make a critical review of available data, identify and remove obvious outliers (entities whose performance is clearly eccentric, i.e. greatly below or above the other performances). In many cases, calculating the median or the average of remaining data might be sufficient. The standard deviation and variance (measuring how spread validated data are) will help deciding on the most appropriate method for identifying the performance of the ‘normally efficient entity’. The following example in Box 7 (borrowed from the ‘International SCM Manual’) shows how to proceed with simple cases.

In addition to the **number of minutes**, services will have to determine ‘normal’ level of qualification required by the main actions linked to information obligations and the **‘normal’ labour cost per hour** including prorated overheads (expenses for premises, telephone, heating, electricity, IT equipment, etc.).

⁷⁴⁰ The Council ... reiterates its October 2004 commitment to assist the Commission in implementing the methodology. In this context Ministers agree: to provide, on request and in a proportionate manner, the information needed to carry out assessments of EU administrative burdens and; that the methodology proposed by the Commission provides a common basis for the collection and exchange of data’ (The Council (ECOFIN) 2688th meeting, 8 November 2005). ‘The European Council recognises the importance for Member States to provide, on request and in a proportionate manner, the information needed to assess administrative costs imposed by EU legislation’ (Conclusions of the European Council, 15/16 December 2005).

Box 8: Identifying typical business

Required action A			
Company 1	10 min.	}	10 min.
Company 2	10 min.		
Company 3	10 min.		
Company 4	10 min.		
Company 5	30 min.		
Required action B			
Company 1	10 min.	}	15 min.
Company 2	20 min.		
Company 3	10 min.		
Company 4	20 min.		
Company 5	15 min.		
Required action C			
Company 1	10 min.	}	More research
Company 2	20 min.		
Company 3	50 min.		
Company 4	2 min.		
Company 5	5 min.		
Required action D			
Company 1	10 min.	}	20 min.
Company 2	20 min.		
Company 3	25 min.		
Expert 1	20 min.		
Expert 2	15 min.		

Explanation: As far as action A is concerned, Company 5 is clearly different from the others and should therefore not be taken into account to determine the performance of a typical (or normally efficient) business. The convergence of the other data is sufficient to choose 10 minutes as a basis for the calculation of the cost imposed on a 'normally efficient entity'. In the case of action B, there are no obvious outliers. The standard performance could be assessed on the basis of the average (13 min.) or the median value (15 min.). The difference being negligible (2 min.) any method would do. No estimate can be made on the basis of data concerning action C because the latter vary too much. More research needs to be done. Consideration should first be given to whether companies selected are not representative or whether specific circumstances can explain this wide variation of performance. The segmentation should be reconsidered and, if necessary, more interviews done. In the case of action D, only three companies answered the questionnaire. An expert assessment was seen as necessary. The combination of the two data sets leads to opt for 20 minutes.

3.10. Step 10 Extrapolation of validated data to EU level

There is **no need to provide specific estimates for each Member State** or administrative body concerned, unless to do so would be proportionate. In most cases, services will estimate EU costs by extrapolating available data at national or EU level. When data are available for only a very limited number of Member States, extrapolation could be done on the basis of the country distribution of administrative costs in a similar sector or for a similar event. The 'EU database on administrative burdens' provides approx. 340 of these (see step 6). Benchmarking projects as well as national baseline measurements⁷⁴¹ conducted by several Member States and the most advanced Commission Impact Assessments are a prime source of information on country distributions.

⁷⁴¹ For details see SCM network website <http://www.administrative-burdens.com/>

3.11. Step 11. Report

Estimates need to be reported in a standardised manner to allow for their comparison and addition. The report sheet downloadable on the SG IA website should therefore be used⁷⁴². Calculation is automatically done by the Excel report sheet.

For strategic proposals, **the common report sheet will often act as a summary of more detailed analyses**. It does not prevent services from presenting more detailed data (such as ranges of costs or key uncertainties) in separate tables and texts.

Encoding instructions: Put the equipment yearly cost based on the depreciation period in the corresponding column. When a measure amends existing provisions and if it removes administrative obligations, the sheet will include negative figures corresponding to the burden reduction. Detailed instructions are included in the standard spread sheet (see link above and example below).

Methodological caveats: When reporting on their assessment, particular care should be taken to indicate, succinctly but clearly, the working assumptions and methodological limitations. This will include assumptions concerning compliance rate and a warning about the nature of the data presented (estimates and not exact measures).

Please note that it is sufficient to present the results of the EU SCM calculations in the main text. The reporting sheet, major assumptions, costs parameters, etc. should be placed in an annex.

4. A CAPTURE TOOL

This section provides an example of a questionnaire designed to capture data needed to apply the model on administrative costs. The questionnaire is targeting a representative sample of the business community.

Some questions are meant to collect quantitative data needed to assess the monetary cost of the regulation (number of hours ...). Others are meant to collect qualitative information useful for caveats (e.g. putting into perspective the very notion of ‘burden’ by indicating that some obligations will correspond to business’ good practices) or useful for policy design. For instance, knowing which types of obligations are a major irritant is an important element for setting simplification priorities, improving perception of the regulatory environment and improving compliance.

⁷⁴² https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/index.aspx
http://ec.europa.eu/governance/impact/docs/eu_cost_model_report_sheet_v2.xls.

Example Questionnaire for collecting data on a statistical regulation

European survey on the administrative costs of producing statistics on intra-EU trade in goods (European Business Test Panel)⁷⁴³	
In recent years the issue of better regulation and in particular, the issue of administrative costs on enterprises has gained increasing attention internationally, at EU level and in the Member States. The European Commission and its statistical office, Eurostat, are therefore increasing their efforts to measure and better manage the administrative costs caused by European legislation. The system known as Intrastat was devised to collect statistics on intra-Community trade. Developed by Eurostat and operational since 1 January 1993, Intrastat involves collecting information directly from businesses on a monthly basis. Companies exceeding a certain amount of trade in goods within the European Union are liable for Intrastat declarations. To improve our knowledge on administrative costs caused by this specific legislation, we invite you to fill in and submit this short questionnaire.	
1	Does your company have to provide Intrastat declarations to your competent national administration (CNA)? (Usually the national statistical office or the national bank.) - YES / - NO (if NO, please go to question 9).
2	Does this information concern: - Dispatches & shipments only / - Arrivals & receipts only / - Both arrivals & receipts and dispatches & shipments?
3	How many hours are spent each month, on average, for collecting the information required for the Intrastat declaration? What is the average labour cost per hour (including prorated overheads)? (Please do not use currency symbols, spaces or dots between thousands)
4	How many hours are spent each month, on average, for drawing up the Intrastat declaration? What is the average labour cost per hour (including prorated overheads)? (Please do not use currency symbols, spaces or dots between thousands.)
5	How does your company transmit the data to the CNA? – Electronically / - On paper
6	Do you think that the preparation/transmission of your Intrastat declaration today takes less time than when it was initially introduced some 10 years ago? - YES / - NO / - DON'T KNOW. If YES, could you express the change in %:
7	Do you expect the time required by Intrastat to evolve in the future, for instance because of organisational or technological adaptations? - YES / - NO / - DON'T KNOW. If yes, will it - DECLINE / - INCREASE - Could you express the change in %:
8	Do you consider Intrastat reporting to be (on a scale of 1 to 5) not at all burdensome (1) to very burdensome (5)?
9	Does your company make use of the statistics on Intra-EU trade in goods as they are published at national level and/or by Eurostat? - YES, please specify the use: / - NO

⁷⁴³ The European Business Test Panel is a representative group of around 3600 European companies that can be directly consulted on the development of important initiatives. The actual survey took place in August and September 2005.

Comments on the adaptation of the data capture tool to the regulation assessed

There was no need to ask questions on external costs, because very few enterprises outsource the management of their shipments and arrivals.

In the present case (sending a table of figures), expert judgment was sufficient to assess transmission costs. The cost of electronic transmission is negligible because it requires very little time and no specific equipment (enterprises use IT equipment and connection they need for their professional work). The time and level of qualification needed for paper transmission is fairly standard and the cost of national mail is easy to determine. It was therefore enough to assess the proportion of enterprises using paper transmission. This contributed to keep the questionnaire as short as possible and ensure higher response rate.

On the contrary, because of the specific reporting frequency and overall costs of the regulation, it was important to collect information on the enterprises' learning curve (see questions 6 & 7) and to have a rather precise idea of routine costs to avoid overestimation. That information also helps assessing indirectly one off costs.

Example of Report Sheet filled out

Note that information obligations and figures presented in the report sheet below are **purely illustrative**. They are not based on actual estimates.

Actions 1, 2 and 10 should not have been fully assessed and reported. With a very low frequency, very limited time required and no specific acquisition required, their total cost was bound to be insignificantly low. The analysis should have been stopped after the assessment of the required number of hours. There was no need to assess other parameters such as hourly pay or overhead, and produce a monetised estimate of these information obligations (see 10.1 Scope of application of the model and expected level of accuracy).

Regulation (EC) No 2580/2001 of the European Parliament and of the Council of 19 December 2001 on cross-border payments in euro, Official Journal L 344 . 28/12/2001 P. 0013 - 0016																	
No.	Anc. Art.	Type of obligation	Description of required action(s)	Target group	Tariff (€ per hour)	Time (minutes)	Price (per action)	Freq. (per year)	Nbr of entities	Total number of actions	Equipment (per entity & per year)	Outsourcing (per entity & per year)	Total Administrative Costs	Business Disruption Costs (% of AC)	Total Administrative Burdens (AC - BAU)	Regulators origin (%)	
1	4§1	Non labelling information for third parties	P familiarizing with the information obligation	Banking sector	30	60.00	30	1	500	500			15.000	0%	15.000	EU	Nat
2	4§1	Non labelling information for third parties	Retrieving relevant information from existing data	Banking sector	25	30.00	13	1	500	500			6.250	20%	5.000		
3	4§1	Non labelling information for third parties	Designing information material (leaflet conception,...)	Banking sector			0	1	500	500		400	200.000	0%	200.000		
4	4§1	Non labelling information for third parties	Copying (reproducing reports, producing labels or leaflets)	Banking sector			0	1	500	500		3.000	1.500.000	50%	750.000		
5	4§1	Non labelling information for third parties	Submitting the information (sending it to the designated recipient)	Banking sector			0	300	500	150.000	500		75.000.000	0%	75.000.000		
6	5§1	Non labelling information for third parties	Retrieving relevant information from existing data	Banking sector	25	6.00	3	3	500	1.500			3.750	0%	3.750		
7	5§1	Non labelling information for third parties	Submitting the information (sending it to the designated recipient)	Banking sector			0	3	500	1.500		1	1.500	0%	1.500		
8	6§1	Submission of (recurring) reports	Retrieving relevant information from existing data	Banking sector	25	-10.00	-4	1	-500	-500	50	300	-172.917	0%	-172.917		
9	6§1	Submission of (recurring) reports	Filling forms and tables	Banking sector	50	-5.00	-4	1	500	500			-2.083	30%	-1.458		
10	6§1	Submission of (recurring) reports	Submitting the information (sending it to the designated recipient)	Banking sector			0	1	500	500	-80		-40.000	0%	-40.000		
No. = gives a number for each action.																	
Anc.= article and § detailing the obligation assessed on that line.																	
Orig. Art. = if the act assessed is the transposition of an act adopted at another level, insert here the article and § of the 'original' act corresponding to the obligation assessed on that line (for ex., article of the EC directive at the origin of one specific obligation imposed by national law)																	
Total administrative costs (I) 76.511.500																	
Price per action (P)= Tariff * Time, Total Nbr of actions (Q)= Frequency *Number of entities. Total cost per action = P/Q, Equipment + Outsourcing. Total administrative burden (II) Administrative costs by origin (Ic)																	
For equipment, yearly cost is calculated on the basis of the depreciation period.																	
When the act amends existing provisions and reduce the value of a parameter (lower frequency, lower number of entities concerned, etc), negative figures corresponding to that reduction should be typed in the relevant columns																	
Regulatory act refers to legislative and statutory acts																	
For the reference of the proposal /act, use EU-Lex format ('cut and paste' of the reference given by http://europa.eu.int/eur-lex/lex/RECH_menu.do?initlang=en).																	
No. = gives a number for each action.																	
Art.= article and § detailing the obligation assessed on that line.																	
Orig. Art. = if the act assessed is the transposition of an act adopted at another level, insert here the article and § of the 'original' act corresponding to the obligation assessed on that line (for ex., article of the EC directive at the origin of one specific obligation imposed by national law)																	
Price per action (P) = Tariff * Time, Total Nbr of actions (Q) = Frequency * Number of entities, Total cost per action = P/Q + Equipment + Outsourcing.																	
For equipment, yearly cost is calculated on the basis of the depreciation period.																	
When the act amends existing provisions and reduce the value of a parameter (lower frequency, lower number of entities concerned, etc), negative figures corresponding to that reduction should be typed in the relevant columns																	

TOOL #61. THE USE OF DISCOUNT RATES

1. INTRODUCTION

Most new policies or projects result in costs and benefits that arise at different times. For example, building a new railway line has an immediate cost but provides benefits for many years in the future. The social discount rate is used to compare costs and benefits that occur in different time periods from the point of view of society. It is based on different arguments, one is the principle that people prefer to receive goods and services now rather than later, another one on the shadow costs of risk-free capital.

As well as the social discount rate, there is also the question of what discount rates are used by business and households.

2. SOCIAL DISCOUNT RATES AND PRESENT VALUES

A social discount rate is used to convert all costs and benefits to "present values" so that they can be compared. This discount rate is a correction factor applied to costs and benefits expressed in constant prices. Costs and benefits should be based on market prices in the year at which they occur. For example, the capital cost of an investment should be recorded as a cost when the action is undertaken, with any associated operating costs taking place in later years recorded in those years. This approach is in line with the economic principle of opportunity costs where market prices reflect the best alternative uses for goods or services.

The social discount rate is the rate most used in Impact Assessments, as these normally consider costs and benefits together from the point of view of society as a whole (rather than from the point of view of a single stakeholder group). **The recommended social discount rate is 4%.** This 4% rate is in real terms and is applied to costs and benefits expressed in constant prices. It can be easily adjusted for inflation: if instead you are dealing with nominal prices, and inflation is, say, 3% per annum then a 7 % nominal social discount rate (4% rate plus 3% to account for inflation) would be used.

Box 1. Example on the determination of present values using a social discount rate of 4%

- The mathematical expression used to calculate discounted present values is given below where r is the discount rate and n is a future year:

$$\text{Discount factor in a future year } n = \frac{1}{(1 + r)^n}$$

- As an example, the present value of €1000 in future years is shown below:

	Year					
	0	1	2	3	4	5
Present Value	€1000	€962	€925	€889	€855	€822

- The above example assumes that €1000 is in today's prices so stripped of inflation.

2.1. Net Present Values (NPV)

Calculating the present value of the difference between the costs and the benefits provides the **Net Present Value (NPV)** of a policy option. Where such a policy or project generates a positive NPV there would be no obvious reason to prevent it from proceeding so long as the distribution of costs and benefits among different social groups is deemed to be acceptable and all costs and benefits are included in the computation (which is often methodologically challenging).

Box 2. Formula for the determination of Net Present Value

$$NPV = \sum_{i=0}^{i=n} \frac{B_i}{(1+r)^i} - \sum_{i=0}^{i=n} \frac{C_i}{(1+r)^i}$$

Where the Costs and Benefits in a given year i are C_i and B_i respectively over the policy/project lifetime of n years (starting in year 0).

The Net Present Value can be used to distinguish between two competing policy options as shown below.

Box 3. Example to show the calculation of NPV for two competing policy options

Alternative projects A and B are both expected to improve the functioning of an organisation.

Option A: requires €10 million in capital costs initially in order to realise benefits of €2.5 million per annum in the following 4 years.

Option B: requires €5 million in capital costs initially to realise benefits of €1.5 million per annum in the following 4 years.

Year	0	1	2	3	4	NPV
Discount factor	1.0000	0.9615	0.9246	0.8890	0.8548	
Option A						
<i>Costs(€ m)</i>	10	0	0	0	0	
<i>Benefits(€ m)</i>	0	2.5	2.5	2.5	2.5	
<i>Benefits less costs(€ m)</i>	-10	2.5	2.5	2.5	2.5	
<i>Present value (€ m)</i>	-10.00	2.40	2.31	2.22	2.14	-0.93
Option B						
<i>Costs(€ m)</i>	5	0	0	0	0	
<i>Benefits(€ m)</i>	0	1.5	1.5	1.5	1.5	
<i>Benefits less costs(€ m)</i>	-5	1.5	1.5	1.5	1.5	
<i>Present value (€ m)</i>	-5.00	1.44	1.39	1.33	1.28	0.44

Project B realises a positive NPV of €0.44 million whereas Option A has a negative NPV of -€0.93 million. Project B is preferable therefore.

2.2. Annualised costs and benefits

Care needs to be exercised when comparing policies with different time horizons as the use of the net present value criterion is no longer appropriate. To make valid comparisons in such circumstances, it is often useful to calculate the annualised values of costs and benefits of alternative policies. This is defined as the fixed annual stream of income that would be paid by a fixed-interest annuity with the same net present value as the policy. Social discount rates could be applied for this approach as well if the societal perspective is relevant.

3. SENSITIVITY ANALYSIS USING LONG-TERM DISCOUNT RATES

In general, it is not appropriate to use alternative social discount rates, as using the 4% rate consistently in Impact Assessments and an evaluation ensures coherence and comparability. However, it may be appropriate to undertake sensitivity analysis of the social discount rate when it is applied over long time frames. This is because discounting at even modest rates (i.e. 4%) reduces the value of costs and benefits effectively to zero over very long time periods. This can be criticised because it excludes future generations from consideration in today's decisions.

For example, in assessments with very long time frames, an alternative lower social discount rate which decreases with time should be considered in addition to the fixed rate of 4%. Such a reducing rate better reflects individuals' perceptions, uncertainties about the economy in the future and the concerns that constant-rate discounting shifts unfair burdens of social cost onto future generations⁷⁴⁴.

Such sensitivity analysis can have significant impacts on the present value of benefits for some projects/policies with long lifetimes:

The long term benefits of new road infrastructure would be emphasised with a declining discount rate which makes road infrastructure investment more attractive;

The long term social cost of biodiversity loss increases with a declining discount rate as damage much further into the future is given a greater weight.

4. COSTS FROM THE PERSPECTIVE OF PRIVATE CAPITAL AND ECONOMY WIDE MODELLING

There is widespread consensus that the social discount rate is usually lower than the discount rate that should be used for individual companies or households, who are unable to diversify risk as effectively as society as a whole. The social discount rate is only used, therefore, when looking at issues from the societal point of view. For example, a higher discount rate should be used when trying to assess the behaviour of a company in respect of an investment decision. This would essentially be the internal rate of return required to trigger an investment. For a business, a good proxy is the Capital Asset Pricing Method, which takes account of both the costs of capital and the riskiness of the investment. In some cases, the

⁷⁴⁴ For example, in the IPCC WG3 report 2014 "a consensus favours using declining risk-free discount rates over longer time horizon." The UK Government utilises a 3.5% discount rate for periods up to 50 years which declines to 1.0% where the time horizon exceeds 300 years.

Weighted Average Cost of Capital could also be used⁷⁴⁵. Higher discount rates may also apply for households when deciding on whether to make an investment due to a range of factors: such as finance costs and other behavioural constraints like split incentives (e.g. landlord/tenant), short time horizons, risk averseness, information asymmetries or other obstacles or barriers.

4.1. **Assessment of costs from the point of view of a regulated sector**

An alternative approach is the consideration of costs from the point of view of a particular economic sector, typically undertaken in a **Cumulative Cost Assessment**. This is a partial approach which does not look at benefits. The costs are the regulatory costs that affect the sector. For example, investment costs would be estimated by the costs of financing (which depends on the approach for financing them) and at the time when those financing payments are made.

When looking at the affordability impacts from the point of view of a regulated sector, it may be necessary to present the capital investment costs annuitized over time, so that they can be compared to other cash flows (e.g. income). In such a case, a discount rate representing the financing costs for the relevant sector should be used.⁷⁴⁶ This approach can be used in addition to an analysis from the social point of view, as it can provide additional relevant information.

4.2. **Economy wide modelling**

Economy wide modelling provides a complementary approach to assessments made from the point of view of society or from a regulated sector. This is useful when the policy options have significant impacts for multiple sectors and for the economy as a whole. The approach allows monetary flows and constraints across the whole economy to be examined as well as the indirect impacts of measures across sectors. It also allows information on the affordability of a given policy for economic actors to be identified which can be used in addition to or, in certain cases where it is a cross sectoral policy, instead of the usual determination of societal costs.

Models can, therefore, be used to simulate 'real world' behaviour including its limitations and barriers as well as society-wide limitations regarding the use of scarce resources reflected in opportunity costs and risk averseness. This can be explicitly done through macroeconomic modelling that takes into account scarcity of financial resources within the model but also through partial equilibrium modelling tools that look at the economy wide measures but use exogenously determined private discount rates that reflect risk aversion, opportunity cost and other barriers. A common example is energy system modelling where sector-specific discount rates can be much higher than the 4% social discount rate. If private discount rates are adapted according to different policy options, the links between the market failures targeted by the

⁷⁴⁵ The Weighted Average Cost of Capital consists broadly of a risk free rate plus the Beta for the sector times the equity risk premium. Its value is not affected by a firm's choice between chosen equity and debt funding to fund investment.

⁷⁴⁶ The discount rate used when deciding whether to invest may be different to the actual cost of financing as it includes other factors, barriers or risks. For a firm, the cost of financing would be the Weighted Average Cost of Capital. However, "hassle" or transaction costs are a valid cost category and so can be included as such in an analysis.

policy option and the impact on the sector-specific discount rate should be clearly demonstrated and documented. Lower discount rates should only be used if it can be shown that a policy option can indeed address the relevant market failures, and care should be taken that costs comparisons across scenarios are still possible in a relevant and meaningful way.

Economy-wide modelling to assess affordability for sectors or cost-effectiveness (or the economy for economy wide modelling) is best achieved using a sector-specific discount rate for annuitizing capital costs.

TOOL #62. THE USE OF ANALYTICAL MODELS AND METHODS

1. INTRODUCTION

Models provide a framework to analyse and investigate the impacts of policy options ex ante (IA), or also ex post (retrospective evaluations). Their purpose is to provide information to support decision makers. All models are simplifications but good models provide insights and understanding if used correctly. It is important, therefore, to ensure that the right model is selected and used in a manner to deliver policy relevant results of the requisite quality.

Box 1. Simplified description of economic model types typically used in IA and evaluation studies (N.B. models often span the arbitrary boundaries presented below)

General Equilibrium Models: Allow for consistent comparative analysis by ensuring that the economic system and individual markets remain in general equilibrium in the long term. They are typically used to capture one-off and long-term effects from policy "shocks". They are able to produce disaggregated results as such models only require one (base) year of data. They provide detailed information on the policy impact of a particular variable of interest. Many CGE models suffer from a lack of historical validation. Some types of CGE are also used for forecasting and scenario building.

Econometric Models: These models are typically used to capture medium/long-term effects from shocks and for forecasting. Modelled relationships are econometrically estimated using historical detailed time-series data rather than economic theory. Models can capture the process of dynamic adjustment and structural changes if these are not too substantial. Such models are not generally suitable for short-term analysis (but can in some cases span different time frames). They are also premised on the assumption that historical relations will still be valid in the future.

Partial equilibrium models: Single Sector Models or System Models typically used in the detailed analysis of a specific economic sector (such as energy supply) or a combination of related economic sectors (such as the interaction of energy supply, and a number of energy demand sectors) over short/medium/long term. They can provide a high degree of disaggregation within the sector(s) covered. Models are unable to capture the interactions with other sectors and the effects in other markets but remain in equilibrium within the sectors in question. Factors related to issues outside of the sectors in question must be supplied exogenously and interaction/feedback to the rest of the economy is ignored.

Micro-simulation Models: Typically used for analyses at a detailed disaggregated level over the short term these usually focus on individuals, households or firms (e.g. tax effect on income distribution) although they can provide insights at a higher level of aggregation. Models require very detailed disaggregated data and may not therefore be able to cover all actors of interest or all resource flows nor important general equilibrium feedback effects.

Input-Output models offer an alternative approach to large-scale economic modelling. This is typically used for short-term analysis of supply chains and how industries are related. The models are based around economic input-output tables which indicate the values of purchases between economic sectors in a particular year. Input-output tables are usually available at the national level though they can be aggregated to regional and European levels. Results are easy to interpret and few resources are necessary but the models are simple, rely heavily on assumptions and can only be used for static analysis as the model doesn't take into account changes over time.

Integrated modelling approaches combine other relevant models or modules together. The resultant integrated model can be applied to assess impacts in several policy areas simultaneously (e.g. combined analysis of air pollution emissions, atmospheric transport, ecosystem sensitivity and economic abatement costs can be used to develop cost-effective abatement strategies). Despite its strengths, an integrated model requires a great deal of resources to construct. The difficulties lie in both theoretical approaches, with models that may be based on different assumptions, and the practicalities of linking different sets of computer code, model classifications, etc.

Modelling is a complex and technical activity that requires specific expertise. The JRC⁷⁴⁷ can provide advice and support related to IA modelling activities. The JRC has established an on-line inventory⁷⁴⁸ of all the models that are currently in use in the Commissions called MIDAS. This inventory has an export function that automatically generates a model description that can be used when preparing Annex 4 to the IA report which describes the models used in the IA.

The rest of this tool addresses key aspects of modelling in relation to preparing an impact assessment.

2. GENERAL PRINCIPLES ABOUT THE USE OF MODELS

Successful modelling requires communicating to decision makers how a model works and the strengths and limitations of a chosen modelling approach. As for all impact assessment methods, communicating and understanding uncertainty in model outputs is also vital. Quality Assurance processes and where relevant uncertainty analysis can ensure that decision makers receive this key information.

3. QUALITY ASSURANCE (QA)

In any modelling exercise, time and resources should be allocated to quality assurance processes. The level of quality assurance should be proportionate to the impact and complexity of the model. Models are also developed and used by external organisations on behalf of the Commission but QA procedures should nonetheless be an integral part of the work such contractors undertake for the Commission services and this may have to be included in appropriate terms of reference. QA will include:

- Testing by the model developer before a new model version is released. This might include checking the consistency of results from previous model exercises using earlier versions of the model;
- Validation that a model can reproduce historical/statistical data. This gives confidence that the model can be used to assess policy scenarios;
- A periodic review (of relevant parts of the model) by internal or external reviewers particularly for complex models which may be the sole basis for evaluating policy options.
- A critical assessment of the assumptions used in the construction of the model to determine whether they are realistic and relevant to the problem at hand.

This type of quality assurance does not have to be undertaken as part of each individual impact assessment particularly if a model and modelling team are involved in preparing

⁷⁴⁷ Unit JRC-I.1; JRC-I1-SEC@ec.europa.eu

⁷⁴⁸ The modelling inventory and knowledge management system (MIDAS) is an inventory of models that are in used by the Commission services to support policy preparation. It describes the relationships between models, data, policies and people. <http://midas.jrc.it> (internal site of the Commission)

several such assessments in a short period of time. What counts is the reliability of the results used in each impact assessment.

A key element of risk management is ensuring that models are developed, managed and maintained by appropriately skilled and experienced staff. Furthermore, the model user should be fully capable of using the model and understanding model risks, limitations, major assumptions and outputs.

Transparency regarding models and modelling approaches can enhance the quality of models and their outputs. Publication of all or some relevant details of a model or its outputs can be a useful QA tool because it facilitates effective scrutiny by engaging external experts.

The Commission may receive evidence for an impact assessment from external sources. In such cases it is important to exercise a quality control process or ensure that it has been performed by the external contractor and that the results are available for examination.

4. SENSITIVITY AND UNCERTAINTY ANALYSES

A transparent and high-quality impact assessment should acknowledge and, to the extent relevant or possible, attempt to quantify the uncertainty in model results because the uncertainty could change the ranking and conclusions about the policy options.

Sensitivity analysis is about understanding how the uncertainty in the output of a mathematical model or system (numerical or otherwise) can be attributed to the different sources of uncertainty in the model inputs which allows identification of those inputs that have the greatest effect on model results. The quantification of uncertainty in a model output using the propagation of uncertainty in the input variables is known as uncertainty analysis. Such analysis can give an estimate of the *variance* of the output.

Undertaking sensitivity analyses is likely to require extra computational, human or financial resources to be deployed during the impact assessment. These resources may not be routinely available to undertake the necessary sensitivity analysis for particularly complex models. Nonetheless, those undertaking modelling studies should attempt, at least periodically and not necessarily for each and every impact assessment, to understand the influence of key model parameters on model results. The JRC can provide support on sensitivity and uncertainty analyses in impact assessments.⁷⁴⁹

There are two ways to quantify uncertainty. The first "one at a time" approach is more common and less complex than the second "global" approach. However, the one at a time approach provides unrealistically small estimates of model uncertainty in most cases. The choice will necessarily be determined by the complexity of the model, the available resources (including computing, time and personnel resources) and the importance of the policy intervention.

The first approach examines the variation in the model output as each input variable is changed one at a time, usually to the minimum and maximum plausible values. This "one-at-a-time" (OAT) approach is most commonly used in Commission IAs.

⁷⁴⁹ JRC I.01/SAMO

Box 2. A simple example of sensitivity analysis

A model is built to estimate the potential economic cost of a chemical accident at a proposed plant in a European region, including trans-boundary effects. It examines the number of people and businesses living within a certain radius and estimates the total value of lost property and life corresponding to different classes of explosion or fire.

Applying sensitivity analysis, the output variable of interest is the total cost of the damage. Uncertain inputs include medical costs per individual, total population within the impact radius, the size of the impact radius, and the assumed proportion of people and businesses affected, among others.

Using expert opinion and available statistics, probability distributions are assigned to each variable, and a sample is constructed consisting of some thousand runs of the accident model. The sample is used to run the model, and the resulting output vector is used to estimate sensitivity.

It is found that, with 95% confidence, the estimated cost is within €2Bn to €20Bn. Furthermore, the most influential input variable is the stock of flammable material, causing 38% of the variance in the cost, followed by engineering variables accounting for 15% of the variance, with a set of meteorological parameters (wind speed and direction) accounting for most of the remaining variance.

A “global” approach for quantifying uncertainty allows for the simultaneous exploration of all sources of known uncertainty and which can capture nonlinearities and interactions between model inputs. In global uncertainty and sensitivity analysis (GSA), probability distributions are assigned to uncertain model inputs. This uncertainty is then propagated through the model by running it repeatedly with different input values, which provides probability distributions of the model outputs. In particular, the variance of each model output is used as a measure of uncertainty, and the contribution of each input to the output variance is a measure of sensitivity. Software is available to simplify such analyses. Sensitivity analysis can also be designed to address higher level model uncertainty, such as the impact of different model specifications or model selections which can be propagated through the analysis via model-averaging procedures.

The basic steps to performing GSA are as follows:

- (1) Define a variable of interest for the analysis. This variable should be the main model output of interest to the impact assessment, and can be the result of a suitable aggregation of spatially distributed or time-dependent model outputs. An examples might be the net monetary benefit;
- (2) Identify all model variables which are affected by uncertainty in consultation with experts and stakeholders as appropriate. Inputs can be of various natures, i.e. scalar variables, time series or spatially distributed maps.
- (3) Characterise the uncertainty for each selected input by assigning a probability distribution using all available information such as experiments, estimations, physical bounds considerations and expert opinion. This is also a particularly important step which may require significant resources. Extended peer-review should be considered to ensure quality in the treatment of uncertainty.
- (4) Generate a sample from the previously defined probability distributions. The sample is a matrix which specifies the input values to use for each model run (of a large number

of such model runs) and is designed to allow the calculation of sensitivity. The sample is generated so as to explore the full extent of uncertainty and is based on the input distributions specified in the previous step. Such samples can be generated from a number of software packages.

- (5) The model is run many times using the sampled input variables for each model run as identified in the previous step. For each run, record the value of the output variable of interest is recorded. This process is usually accomplished automatically using computer software.
- (6) The results of the model runs are then used to estimate sensitivity, as well as the uncertainty in the model output. The suggested software will yield the fractional contribution of each input to the output variance.

Box 3. IA on biofuels and indirect land use change (SEC(2012) 343): Monte Carlo analysis to illustrate the range of uncertainty of ILUC GHG factors.

The IFPRI-MIRAGE-BioF model was used to model the consumption of biofuels used in the EU and to estimate the emissions of greenhouse gases associated with indirect land-use change for a range of biofuel feedstocks. The model is a general equilibrium model, which encompasses all economic sectors and markets and their inter-actions at a global scale. The figure below shows the estimated indirect land-use change emissions in gCO₂/MJ for a range of different biofuel feedstocks. The model was combined with a Monte Carlo simulation, to provide a better description of the probability distribution of the uncertainty associated with the key model variables. More information on this analysis can be found (see Annex XI of SEC(2012) 343).

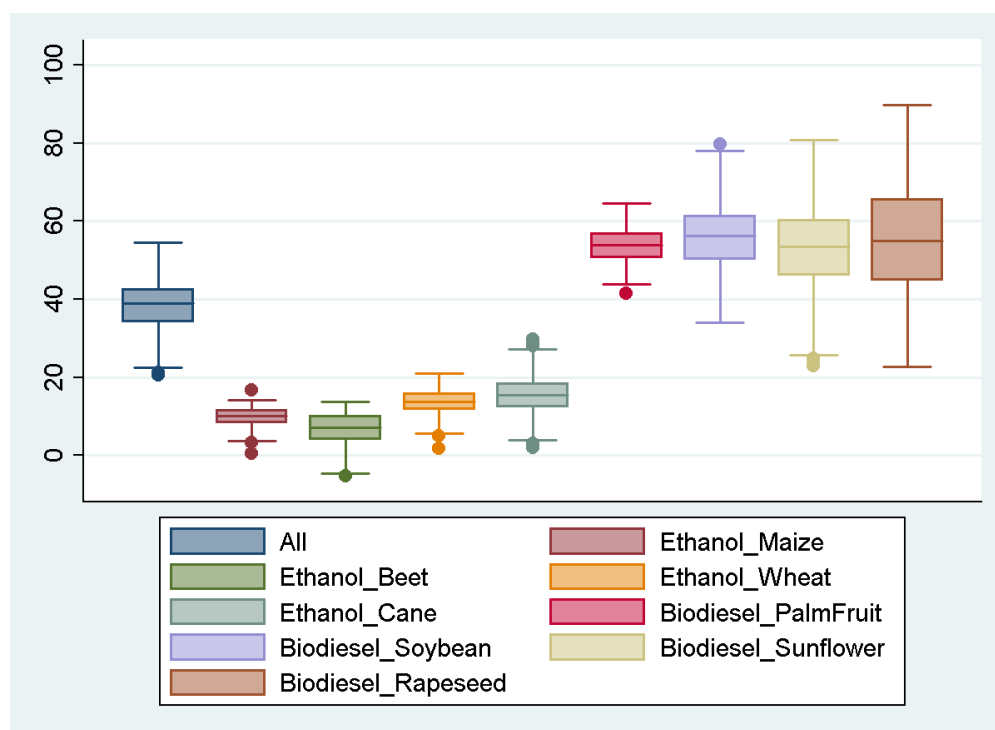


Figure 6: Results of the Monte-Carlo analysis: estimated indirect land-use change emissions (gCO₂/MJ)-under scenario of current trade policy. The bars indicate 1st and 99th percentile, while the boxes are 25th and 75th percentiles.

Sensitivity analysis following the above steps can be complicated, impractical or infeasible. For example, large computer models require sufficient computing power and may take a long time to run. There may also be large numbers of uncertain model inputs, and correlations

between input variables. Techniques exist to deal with these problems for which the JRC can provide assistance.

Sensitivity analysis can only address uncertainties for which there is quantitative information characterising that uncertainty. When this information is missing, or when a deeper assessment of the framing of the analysis is needed, or where there is a major disagreement among stakeholders about the nature of the problem, or when there is a lack of time/computational resources, then sensitivity auditing is more suitable but sensitivity analysis is still advisable as one of the steps of sensitivity auditing.

Sensitivity analysis measures how uncertainty in model input variables contributes to the uncertainty in the model output, and is therefore a numerical analysis which requires uncertainties to be quantified. Sensitivity auditing, on the other hand, is a wider consideration of the effect of all types of uncertainty, including structural assumptions embedded in the model, and subjective decisions taken in the framing of the problem. Sensitivity auditing includes sensitivity analysis as part of its procedure.

The ultimate aim is to communicate openly and honestly the extent to which particular models can be used to support policy decisions and what their limitations are.

Modellers could usefully consider the following principles:

- Before entering into contractual arrangements with third party consultants, consider the full spectrum of available models in the available literature to tackle the problem, and whether the complexity of the model is justified by the quality of information used to calibrate it, i.e. that a large model is not being used rhetorically to convey a spurious impression of accuracy.
- Critically examine all model assumptions. Are there implicit or hidden assumptions which a third party might point to? Would it be possible to evaluate the impact of taking a different approach to tackle the issue?
- Be careful not to over or under-estimate uncertainties in model input parameters. In some cases, uncertainty assigned to parameters can be cross-checked against values in published research, or given second opinions by experts. Where uncertainty is particularly difficult to quantify, it may be better to discuss it in qualitative terms rather than give a spurious impression of accuracy.
- Aim for transparency – when relevant and possible the model calculations should be checked by third parties.

In general, sensitivity auditing stresses the idea of honestly communicating the extent to which model results can be trusted, taking into account as much as possible all forms of potential uncertainty, and to anticipate criticism by third parties. In particular, one should avoid giving the impression of false confidence by “quantification at all costs”. In some cases there is simply not enough data, or the process is too complex, to give a meaningful quantitative prediction.

5. TRANSPARENCY

When IA analysis relies on modelling or the use of analytical methods, the model should be documented in the corporate modelling inventory MIDAS and the IA report should include a dedicated annex presenting the following information:

- A brief description of the main model/method which addresses:
 - The model developer and nature (public/private/open source) of the model;
 - Model structure and modelling approach with any key assumptions, limitations and simplifications (where these are not explained in the description of the baseline in the IA Report);
 - Intended field of application and appropriateness for the specific impact assessment study presented;
 - Model validation and peer review with relevant references;
 - The extent to which the content of the model and input data have been discussed with external experts.
- Explanation of the likely uncertainty in the model results and the likely robustness of model results to changes in underlying assumptions or data inputs. Where this is not possible at least a qualitative indication of the uncertainty and its relevance in relation to the analysis and comparison of policy options should be provided.
- The steps taken to assure the quality of the modelling results presented in the IA.
- A concise description of the baseline used in the modelling exercise in terms of the key assumptions, key sources of macroeconomic and socio-economic data, the policies and measures the baseline contains and any assumptions about these policies and measures (such as the extent to which they are deemed implemented by the Member States, or their estimated impact following implementation).

6. USE OF CONSISTENT HORIZONTAL ASSUMPTIONS AND FORECASTS

The impact assessment process requires a baseline scenario to be constructed which incorporates all existing policies and measures and shows how a particular problem will evolve in the future without further policy intervention. In addition, the impacts associated with each policy option should be compared against this baseline. Developing a model baseline implies:

- Deciding upon the assumptions on how to represent the existing policy framework for the relevant sector at Union and Member State level;
- Making assumptions over a defined future time horizon on the evolution of important macroeconomic and socio-economic variable such as GDP, demographic structure, energy prices etc.

Many different models are used in the Commission covering a wide range of different policy areas. Discussion in the IA Steering Group will help ensure that the most appropriate information sources and assumptions are used in constructing model baselines. For example,

population projections (EUROPOP)⁷⁵⁰ and GDP projections⁷⁵¹ are regularly produced by ESTAT and DG ECFIN. Projections on energy, transport and GHG emissions are regularly prepared by DGs ENER, CLIMA and MOVE.

⁷⁵⁰ <https://open-data.europa.eu/en/data/>

⁷⁵¹ http://ec.europa.eu/economy_finance/publications/european_economy/2012/2012-ageing-report_en.htm

TOOL #63. MULTI-CRITERIA ANALYSIS

1. INTRODUCTION

Multi-criteria analysis (MCA) can be a useful complement or alternative to cost benefit analysis, and is particularly relevant at the two following stages of an Impact Assessment (as both are multi-criteria in nature), either independently or in combination:

- at the stage of assessing the economic, social and environmental dimensions (wherever relevant) of each option including possible trade-offs between some of these dimensions (or sub-criteria used in each);
- at the stage of comparing the policy options: against the 3 main criteria of Effectiveness, Efficiency and Coherence with other EU policies (wherever relevant). MCA also allows the distribution of costs and benefits across different types of stakeholders (where it is uneven) – in order to also take into account some equity concerns, where relevant.

2. MULTI-CRITERIA ANALYSIS OPERATIONAL GUIDES

MCA proceeds on the basis of defining four concepts, namely: objectives, evaluation criterion, goals and attributes. Objectives indicate the direction of change desired, e.g. growth has to be maximised, social exclusion has to be minimised, carbon dioxide emissions have to be reduced. An evaluation criterion is the basis for evaluation in relation to a given objective (any objective may imply a number of different criteria). It is a function that associates alternative actions with a variable indicating its desirability according to expected consequences related to the same objective, a classical example in economics might be national income, savings and inflation rates under the objective of economic growth maximisation. A goal is synonymous with a target and is something that can be either achieved or missed, e.g. reducing nitrogen pollution in a lake by at least 10%. If a goal cannot, or is unlikely to, be achieved, it may be converted to an objective. An attribute is a measure that indicates whether goals have been met or not, on the basis that a particular decision will provide the means of evaluating various objectives.

Historically the first stage of the development of MCA is characterised by the so-called methodological principle of multi-criteria decision-making (MCDM). The main aim of this is to elicit clear subjective preferences from a “mythical” decision-maker, and then try to solve a well-structured mathematical decision problem by means of a, more or less, sophisticated algorithm. The limitations of the classical concept of an optimum solution and the consequential importance of the decision process were emphasised later on. All aspects of the evaluation process which leads to a given decision also contribute to its quality and success.

Under the concept of a Multiple-Criteria Decision Aid (MCDA), the principal aim is not to discover a solution, but to construct or create something which is viewed as liable to help an actor taking part in a decision process either to shape, argue, and/or transform her/his preferences, or to make a decision in conformity with his/her goals. The need for public participation has been increasingly recognised in the most recent developments of MCA. In particular, Social Multi-Criteria Evaluation (SMCE) recognises the need to extend MCDA by incorporating the notion of the social actor. Thus, a SMCE process

should be as participative and as transparent as possible; although, participation is a necessary but not a sufficient condition for successful evaluation.

3. A VARIETY OF MULTI-CRITERIA ANALYSIS METHODS

A multi-criteria method is an aggregate of all objectives (or goals), criteria (or attributes) and criterion scores. This implies that what formally defines a multi-criteria method is the set of properties underlying the convention it uses for mathematical aggregation of these different aspects. There is no perfect aggregation procedure, thus only reasonable mathematical procedures can be developed; in this framework, reasonable means that algorithms can be evaluated not only according to the formal properties they respect, but, overall, according to the empirical consequences implied by their use.

There are a whole variety of different MCA methods and supporting tools, responding to various a variety of problems (e.g. choice, ranking, classification) arising in impact assessment or evaluations: some are aggregative, others not (or only partially so); compensatory or not (or partially so); some are easier to understand/nearer to the human reasoning than others, have richer properties (e.g. in taking into account uncertainty or incomparability), based on different sets of assumptions/use context/or methods for eliciting stakeholders views/values/preferences or experts judgement - or for deriving weights, when they are used, from these very preferences/judgments rather than out of the blue. Most importantly, many have been proven to work in practice as an operational aid to handling complexity in multi-criteria multi-stakeholders problems/decisions or negotiations – including in the context of EU policies.

Among this interesting mix of MCA methods and tools which could be possible candidates some of the steps necessary in IAs (whether for assessing or for ranking options) or evaluations (e.g. for assessing a policy or programme based on a variety of dimensions (such as economic, social and environmental - or at a lower level, various families of (qualitative or quantitative) criteria in a given field, the following may be worth particular consideration:

QuickScan (among recent excellent methods/tools developed under the ESPON programme - initially developed by DG REGIO), NAIADE (developed at JRC already in the nineties), Promethee, D-SIGHT, Macbeth, Electre methods as well as the Decision Deck open source components approach.

In addition, the most recent of these tools include a variety of presentational options, facilitating the automated display of complementary types of views (e.g. options ranking not just overall, but as viewed by different types of stakeholders without manual intervention). They also frequently include tools to facilitate the elicitation of values/judgements/preferences (within processes to facilitate group discussion and convergence/dynamics), to facilitate robustness and sensitivity analyses and other types of simulations.

In the following section, one type of MCA method is described in detail (as JRC has previous experience in supporting its use), nevertheless JRC is also available to provide

further advice/support regarding other existing MCA methods/tools which DGs may wish to consider.

4. A NON-LINEAR/NON-COMPENSATORY APPROACH

One reasonable method for performing an MCA in the impact assessment context consists in the 3 following steps - note that a similar approach can be followed in the ex post evaluation context, by replacing different policy options with different categories of impacts (though the problem will no more be one of overall ranking/choice, but one of scoring/comparing with objectives):

(1) For each of N policy options (or alternatives in general) a number of indicators (or criteria) should be established which are important in determining an overall ranking of policy options. Three pieces of information are needed:

- *Performance* of given policy option with respect to each criterion (i.e. the numerical value of the pertinent indicator);
- *Weight (importance)* attached to each criterion;
- *Direction* of each criterion with respect to overall objective. That is, whether higher values of a *criterion* correspond to better (denoted by +1) or worse (denoted by -1) performance of the option.

Multiplication of the *Performance*, *Weighting* and *Direction* gives a composite quantity which allows each policy option to be compared and ranked in respect to each criterion.

(2) The second step is to build a square $N \times N$ matrix, called the outranking matrix, which summarises how one option compares against another for all possible pairs of policy options.

For a given pair of options (say Option A and Option B), the weightings for each criterion are summed but only for those criteria where the first option is determined to be better than the second. This sum provides an element (A-B) of the outranking matrix. Only the weightings are added. It makes no difference how much better each option is in respect of each of the criteria. (See Box 1 for a worked example).

(3) The aim is to select a final ranking of all the possible policy options which maximizes pair-wise agreement (and minimize disagreement). There are $N!$ (factorial) different ways to rank the policy options which should be "scored" using the outranking matrix prepared in step 2. For example, in the case of three policy options A, B, and C, there are $3!$ (i.e. 6) different possible rankings (ABC, ACB, BAC, BCA, CAB, and CBA). These are scored by summing the elements from the outranking matrix for each policy pair which make up a given ranking of the policy options (i.e. for the ranking ABC, the policy pairs are AB, AC and BC). The optimal ranking is the one with the highest score.

An illustrative computation is shown in Box 1.

Box 1. Comparison of three policy options through a non-compensatory MCA

The following example assumes that there are three distinct policy options (A, B, and C) and five criteria/indicators which will be used to assess the options.

Step 1. The weightings, direction and performance of the three options need to be determined for each of the five criteria. The importance of the criteria is reflected in the respective weights.

Input matrix			Policy Options					
			A		B		C	
Criteria	Weight	Direction	Performance	Weighted performance	Performance	Weighted performance	Performance	Weighted performance
Criterion 1	0.1	1	50	5	70	7	90	9
Criterion 2	0.2	1	0.6	0.12	0.3	0.06	0.4	0.08
Criterion 3	0.1	-1	400	-40	500	-50	600	-60
Criterion 4	0.3	1	0.6	0.18	0.7	0.21	0.4	0.12
Criterion 5	0.3	1	4000	1200	5000	1500	3000	900

Step 2. An "outranking matrix" is prepared. Options are compared pairwise. For each comparison (e.g. option A versus option B) all the weights are summed for the criteria where Option A is favoured over Option B (abbreviated as AB) as indicated by the weighted performance of each criterion. In this case, AB receives the weights of Criteria 2 and 3 ($0.2+0.1=0.3$). The comparison BA gets the sum of the weights of the remaining criteria: 1, 4, 5 ($0.1+0.3+0.3=0.7$). For n options, there are $n(n-1)/2$ comparisons. All the values from the pairwise comparisons are entered in a so called outranking matrix.

Outranking matrix	Option A	Option B	Option C
Option A	0	0.3	0.9
Option B	0.7	0	0.7
Option C	0.1	0.3	0

Step .3 – The policy options can be ranked in $3! (=6)$ different ways but the aim is to find the permutation with the maximum likelihood score. To give an example, the score for the ranking ABC is simply the support of AB plus those of AC and BC (e.g. all the available ordered pairs from left to right). This gives $0.3+0.9+0.7=1.9$. The optimal ranking is the one with the maximum likelihood score: i.e. Option B followed by Option A followed by Option C (**BAC**).

Policy ranking permutation	Policy parings	Coefficients of policy pairings	Final score
ABC	AB + AC + BC	$0.3 + 0.9 + 0.7$	1.9
ACB	AC + CB + AB	$0.9 + 0.3 + 0.3$	1.5
BAC	BA + AC + BC	$0.7 + 0.9 + 0.7$	2.3
BCA	BC + CA + CB	$0.7 + 0.7 + 0.1$	1.5
CAB	CA + AB + CB	$0.1 + 0.3 + 0.3$	0.7
CBA	CB + CA + BA	$0.3 + 0.1 + 0.7$	1.1

A general recommendation is to complement this type of MCA with sensitivity analysis to determine the robustness of the final ranking to the assumption about the weights given to each criterion.

When many policy options need to be compared, enumerating all possible rankings becomes computationally intractable. In such cases, more sophisticated techniques are needed to identify the optimal ranking or, if that is not possible, provide a provably-good approximation of it.

A drawback of MCA performed using best practice such as the illustrated above (also known as Kemeny's rule) may be more difficult to communicate because stakeholders may find it difficult to understand how the rule works. In these instances, it may be an idea to complement the Kemeny-based ordering of the options with a simple impact matrix – which would in this case play the role of a simplified scoreboard informing the reader of the strength of the various options according to the weighted performance against the different criteria.

An additional practical shortcoming of MCA using Kemeny's rule that policy makers should be aware of is that it may at times lead to inconclusive policy rankings, as nothing precludes the existence of multiple optimal orderings.

5. FURTHER INFORMATION

For an exhaustive recent overview of the state of the art on MCA, see Figueira, J., Greco, S. and Ehrgott, M. (eds.) (2016) *Multiple-criteria decision analysis. State of the art surveys*. Springer International Series in Operations Research and Management Science, New York.

Further operational guidance on the various types of existing MCA methods and tools available is given in the following publications:

- Multi-criteria analysis: a Manual, Department for Communities and Local Government, London, 2009 (as published on-line on the UK government's web site)
- Ishizaka Alessio, Nemery Philippe, *Multicriteria Decision Aid: Methods and software*, Wiley, Chichester, 2013 (ISBN: 978-1-1199-7407-9) – available for loan from DG DIGIT's library
- Munda, Giuseppe, *Social Multi-Criteria Evaluation for a Sustainable Economy*, Springer, Heidelberg, 2008 – also available from the Commission libraries.

TOOL #64. LIFE CYCLE ANALYSIS

1. INTRODUCTION

Impacts should be considered as far as possible in a holistic and integrated manner. This is fundamental to avoid shifting burdens between environmental or socioeconomic impacts. Additionally, when impacts are associated with production processes and/or to consumption, there is the need to avoid shifting the burden from one part of the product life cycle to another (e.g. from production to consumption). Burden shifting can similarly be considered in terms of spatial and temporal resolution; such as shifting problems from within the EU to the outside or from current generations to future ones. Concepts and supporting methodologies that implement these concepts are therefore needed.

2. WHAT IS LIFE CYCLE ASSESSMENT?

Life Cycle Thinking is a broad concept that facilitates an integrated assessment of the benefits and the burdens in terms of environmental, social, and economic aspects, for specific products and regions, etc. The application of Life Cycle Thinking requires specific methodologies. Life Cycle Assessment (LCA) is a systemic approach which supports the integration of sustainability into design, innovation and evaluation of products and services and related policies in the EU^{752,753,754,755} and internationally^{756,757}. Life Cycle Assessment is now a mature environmental management methodology, developed from the 1970's, internationally standardised (ISO14040 and ISO14044- ISO, 2006).

LCA aims to make an integrated environmental assessment of products (goods and services) along their supply chain, through multi-criteria assessment, covering a wide variety of pressures and impacts associated with human health, ecosystem health, and resources. By applying a life-cycle approach, priorities and trade-offs can be identified more transparently resulting in potentially more effective policies.

In an LCA, the resources consumed and emissions into air, water and soil are quantified, and related burdens assessed, using various indicators of impacts. These are then evaluated in relation to overarching issues, termed Areas-of-Protection, such as Human Health, Ecosystem Health and Resources. The evaluations are made using a range of

⁷⁵² Integrated Product Policy - Building on Environmental Life-Cycle Thinking. Communication from the Commission; COM(2003) 302

⁷⁵³ Stimulating technologies for sustainable development: an environmental technologies action plan for the European Union. Communication from the Commission; COM (2004) 38.

⁷⁵⁴ Thematic Strategy on the Prevention and Recycling of Waste. Communication from the Commission; COM(2005) 666.

⁷⁵⁵ Building the Single Market for Green Products. Communication from the Commission; COM (2013) 196 final

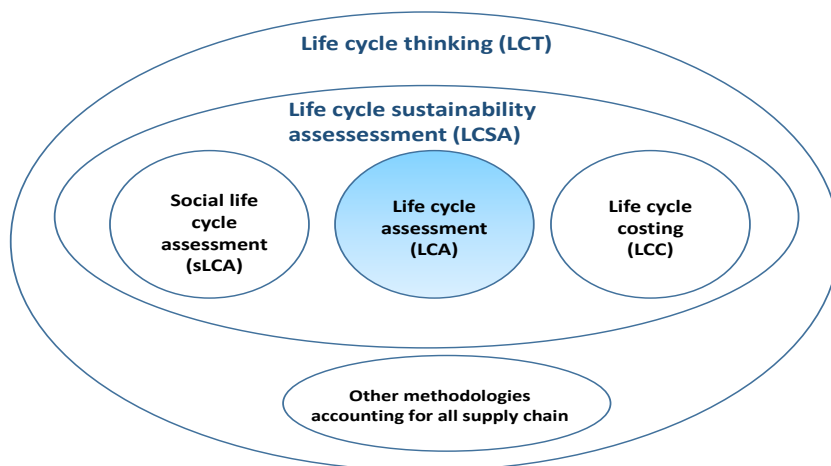
⁷⁵⁶ Why take a life cycle approach? UNEP, Paris, p 28

⁷⁵⁷ UNEP-SETAC life cycle initiative; <http://www.lifecycleinitiative.org/>

models resulting in impact indicators for each Area of Protection (e.g. indicators for climate change, acidification, ecotoxicity, human toxicity, resource scarcity etc.).

More recent methodological development have aimed at extending life cycle thinking also to evaluate social issues (Social Life Cycle Assessment-sLCA) and economic issues (Life Cycle Costing - LCC) towards a complete and comprehensive Life Cycle Sustainability Assessment (LCSA) (Box 1). This document focuses on LCA.

Box 1. Life cycle thinking concept and related methodologies



Life Cycle Thinking (LCT) is the basic concept referring to the need of assessing burden of products adopting a holistic perspective, from raw material extraction to end of life. To make LCT operational, several methodologies exist, namely: Life cycle assessment (LCA), Life cycle costing (LCC), social life cycle assessment (sLCA) and other methodologies designed for a supply chain approach (e.g. material flow accounting, MFA).

3. RESOURCES INSIDE OF THE COMMISSION TO HELP WITH LCA

The Commission has established the European Platform on Life Cycle Assessment (EPLCA)⁷⁵⁸. The EPLCA Platform developed by the JRC, together with DG-Environment, represents the reference point for data and methods essential to implementing Life Cycle based approaches. Through the European Platform, the International Reference Life Cycle Data System (ILCD) Handbook was launched. The Handbook provides a series of guidance documents for different types of LCA applications⁷⁵⁹. More recently, this has been complemented for example by the launch of the Life Cycle Data Network (LCDN), which aims to provide an international basis for inter-operable, quality assured life cycle inventory data. It equally supports the European Reference Life Cycle Database (ELCD).

Since 2013, the Commission has recommended the use of common methods to measure and communicate the life cycle environmental performance of products and

⁷⁵⁸ <http://eplca.jrc.ec.europa.eu/>

⁷⁵⁹ The ILCD handbooks are a series of operational guidance for LCA and could be downloaded from <http://eplca.jrc.ec.europa.eu>. These guidance include:

organisations⁷⁶⁰. This established a harmonised method for multi-criteria environmental LCAs of products and organisations (the "Product Environmental Footprint" and the "Organisation Environmental Footprint"). The two guidelines on Product EF (PEF) and Organisation EF (OEF) provide practical guidance for a more robust and consistent environmental assessment of products and organisations. To further support comparisons within product groups and sectors, Product Environmental Footprint Category Rules (PEFCRs) and Organisation Environmental Footprint Sector Rules (OEFSRs) are developed by the European Commission.

The ILCD handbook builds on the ISO standards, introducing further specifications including:

- A clear definition of the impact categories (with corresponding assessment models and environmental indicators) to be considered in order to perform a more comprehensive LCA and avoid potential burden shifting to other impact categories (e.g. by reducing global warming more chemicals are used that may induce cancer effects);
- Specified minimum quality requirements for life cycle inventory data to improve quality of results ;
- Detailed technical instructions for addressing some critical aspects of LCA studies (such as system boundary definition, to improve consistency and reproducibility).

For example, regarding the impact assessment phase, current EU recommendations⁷⁶¹ identified 14 impact categories (Box 2) and recommended specific models for assessing those impacts (see Annex 1 for the list of impact categories and models). This list of models and indicators will be updated from time to time and the latest developments, supporting Environmental Footprint applications are available in the EPLCA website.⁷⁶²

The JRC can provide training on LCA and may be able to support DGs when conducting specific LCA studies at micro (product) and meso/macro scale as well as helping review existing studies developed by third parties.

4. PROCEDURAL STEPS OF LIFE CYCLE ASSESSMENT

According to the ISO standard (ISO 14040), Life Cycle Assessment consists of four phases (*see Box 2*):

- Goal and scope definition phase: definition of the aims of the LCA and description of the central assumptions and system choices in the assessment are described;

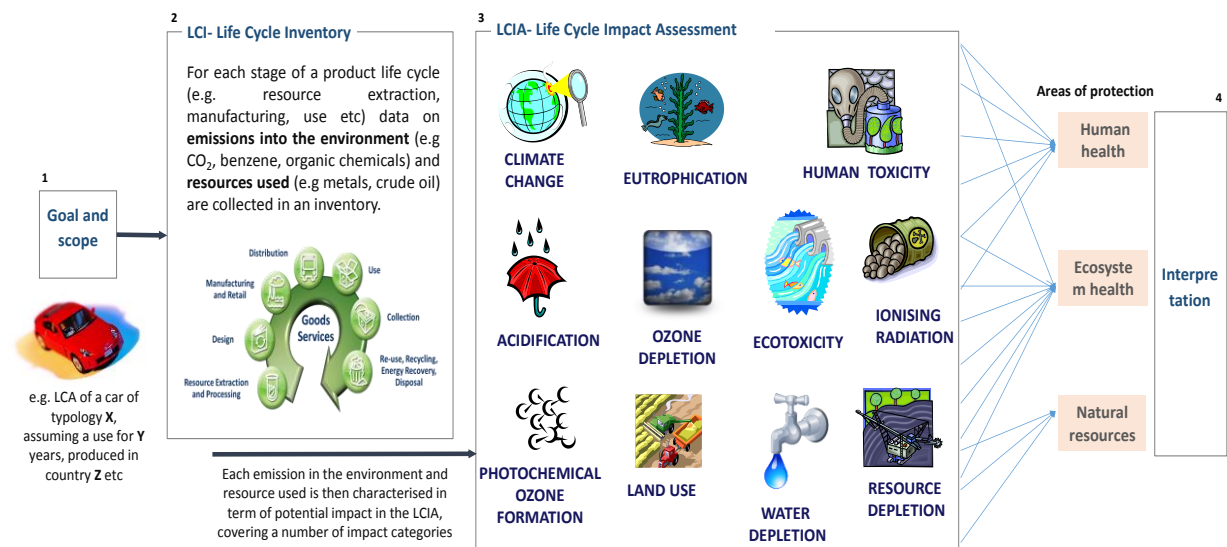
⁷⁶⁰ Recommendation 2013/179/EU.

⁷⁶¹ JRC (2011) Recommendations based on existing environmental impact assessment models and factors for life cycle assessment in European context. First edition EUR24571EN. ISBN 978-92-79- 17451-3. Available at <http://eplca.jrc.ec.europa.eu/>

⁷⁶² <http://eplca.jrc.ec.europa.eu>

- Life Cycle Inventory (LCI): collection of data on the emissions and resources related to the chosen products/services for each life cycle stage (from extraction of raw material to end of life);
- Life Cycle Impact Assessment (LCIA): emissions and resource data collected in LCI are translated into indicators that reflect ecosystem and human health impacts as well as considerations associated with resources availability, covering different impact categories. This calculation is based on factors, which represent the predicted contribution to a pressure or burden per unit emission or resource consumption. These factors are calculated using specific models (see Annex 1);
- Interpretation: the outcome of the LCA calculation is interpreted in accordance with the aim defined in the goal and scope of the study.

Box 2. Procedural steps of LCA



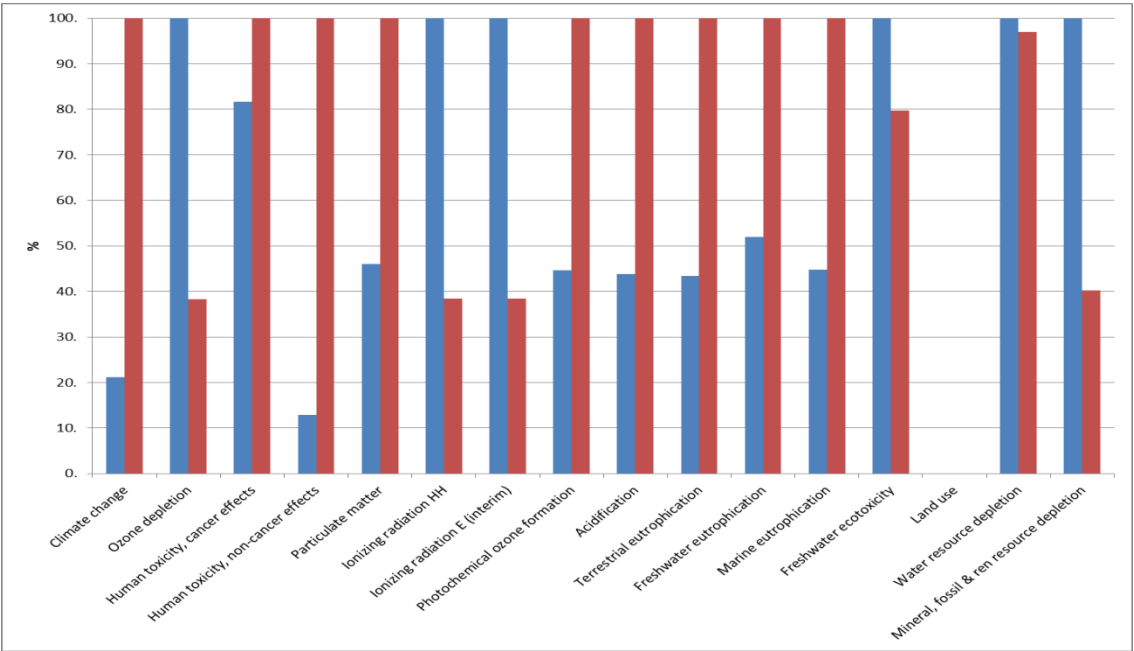
The basic scheme of a Life Cycle Assessment. After having set the goal and scope of the study, data on all the emission and resources used for a product are reported in the life cycle inventory (LCI). These emissions and resources are evaluated against a number of different impact categories (such as climate change, acidification, ecotoxicity etc.) in the life cycle assessment. The impact on different impact categories may then, be associated with three Area of Protections (AoP): human health, ecosystem health, natural resources. A last phase is the interpretation of the results (4).

LCA studies are usually performed through commercial software which calculates the environmental impact associated to the elements of the supply chains being assessed (see the EPLCA Resource directory for a list of software). The environmental impact refers to a functional unit (e.g. a car, a litre of milk etc.) set as a reference quantity for the study, reflecting a specific product and its function. Inventory data on processes (e.g. emission to air, water, soil associated to the production of 1 kg of steel) are available through commercial databases and, increasingly, are made available through the European Platform on Life Cycle Assessment, in the ILCD Data Network. It should be noted that this methodology is less suitable for innovative products as they are not included in commercial databases. The software associates each inventory data with specific indicators of impacts, calculating through specific models the burden associated to the functional unit. This is the life cycle impact assessment phase in which the impacts/burdens associated with a product, a life cycle stage or even a specific process

are estimated. Additionally, a sensitivity analysis can be conducted, for example by applying different models, to help understand the uncertainty in the results.

Box 3. Examples of LCA results

Typical results of comparison of two products may be presented by highlighting the relative performance in each impact category. For example, if we compare the environmental impacts of two electricity mix in two countries (1 MJ 'Electricity mix, at consumer, 1kV - 60kV -country A in red) and (1 MJ 'Electricity mix, AC, consumption mix, at consumer, 1kV - 60kV -country B in blue)⁷⁶³ we obtain the figure below. This is calculated using as



The analysis could be done on products/sectors for assessing hotspots of impacts. In this case, summary results may be presented, highlighting which kind of impacts occur and in which life cycle stage. Below is an example of a hotspot analysis for one product

PRODUCT A	LIFE CYCLE STAGES			
	Raw material	Manufacturing	Use	End of life
Climate change				
Ozone depletion				
Human toxicity, cancer effects				
Human toxicity, non-cancer effects				
Respiratory inorganics				
Ionising radiation				
Photochemical ozone formation				
Acidification				
Eutrophication, terrestrial				
Eutrophication, aquatic				
Ecotoxicity (freshwater/terrestrial/marine)				
pesticide				
Heavy metals				
POP's				
others				
Land use				
Resource depletion, water				
Resource depletion, mineral, fossil and renewable				
Waste				
XXXX				
XXXX				

very relevant impact

relevant impact

slightly relevant

not relevant

⁷⁶³ Method: ILCD 2011 Midpoint+ (for use in PEF/OEF pilots) V1.04 / EU27 2010, equal weighting

Some results of life-cycle based assessments are already being used in a number of EU policies, such as the Ecolabel Regulation, Green Product Procurement and Ecodesign Directive. Further development of LCA and adaptation to policy needs is aiming at increasing consideration of life cycle aspects in policymaking. Additionally, some examples where LCA is or has been used in EU policy development and in impact assessment are reported below and in a JRC report on LCA for supporting policies⁷⁶⁴:

Box 4. Examples of use of LCA in EU policies and impact assessment

- LCA used to define emerging problems, especially related to products and product supply chains, and new technologies: e.g. (i) the repeal of waste oil directive based also on a study reporting LCA evidences; (ii) the problem definition of the impact assessment of the communication Building single market for green product ; (iii) Communication on Resource Efficiency Opportunities in the Building sector
- LCA used to identify policy options: e.g.(i) in the impact assessment of plastic bags directive where policy options has been based on tackling issue coming from a convergence of different LCA which were supporting prevention policy options; (ii) in the waste framework directive where LCA is cited for justifying possible changes in the waste hierarchy, due to environmental concerns; (iii) in the directive on renewable resources, there is an LCA based requirement on GHG reduction for Biofuels; (iv) in the communication “Building single market for green product” where LCA is the reference methodology for product and organisation assessment.

⁷⁶⁴ JRC(2016). Life cycle assessment for the impact assessment of policies. Luxembourg. Publications Office of the European Union: ISBN 97892-79-64813-7

Annex 1: LCIA impact categories and recommended models and indicators

The International Reference Life Cycle Data System (ILCD)⁷⁶⁵ Handbook is a series of technical guidance documents for LCA that complement the International Standards to provide the basis for greater consistency and quality of life cycle data, methods and assessments. A specific handbook is devoted to Life Cycle Impact Assessment, recommending models and indicators for 14 impact categories at midpoint.

Table 1 Recommended methods and their classification at midpoint

Impact category	Recommended default LCIA method	Indicator
Climate change	Baseline model of 100 years of the IPCC	Radiative forcing as Global Warming Potential (GWP100)
Ozone depletion	Steady-state ODPs 1999 as in WMO assessment	Ozone Depletion Potential (ODP)
Human toxicity, cancer effects	USEtox model (Rosenbaum et al, 2008)	Comparative Toxic Unit for humans (CTU _h)
Human toxicity, non- cancer effects	USEtox model (Rosenbaum et al, 2008)	Comparative Toxic Unit for humans (CTU _h)
Particulate matter/Respiratory inorganics	RiskPoll model (Rabl and Spadaro, 2004) and Greco et al 2007	Intake fraction for fine particles (kg PM2.5-eq/kg)
Ionising radiation, human health	Human health effect model as developed by Dreicer et al. 1995 (Frischknecht et al, 2000)	Human exposure efficiency relative to U ²³⁵
Ionising radiation, ecosystems	No methods recommended	
Photochemical ozone formation	LOTOS-EUROS (Van Zelm et al, 2008) as applied in ReCiPe	Tropospheric ozone concentration increase
Acidification	Accumulated Exceedance (Seppälä et al. 2006, Posch et al, 2008)	Accumulated Exceedance (AE)
Eutrophication, terrestrial	Accumulated Exceedance (Seppälä et al. 2006, Posch et al, 2008)	Accumulated Exceedance (AE)
Eutrophication, aquatic	EUTREND model (Struijs et al, 2009b) as implemented in ReCiPe	Fraction of nutrients reaching freshwater end compartment (P) or marine end compartment (N)
Ecotoxicity	USEtox model, (Rosenbaum et al,	Comparative Toxic Unit

⁷⁶⁵ http://eplca.jrc.ec.europa.eu/?page_id=86

Impact category	Recommended default LCIA method	Indicator
(freshwater)	2008)	for ecosystems (CTU _e)
Ecotoxicity (terrestrial and marine)	No methods recommended	
Land use	Model based on Soil Organic Matter (SOM) (Milà i Canals et al, 2007b)	Soil Organic Matter
Resource depletion, water	Model for water consumption as in Swiss Ecoscarcity (Frischknecht et al, 2008)	Water use related to local scarcity of water
Resource depletion, mineral, fossil and renewable	CML 2002 (Guinée et al., 2002)	Scarcity

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TOOL #65. HOW TO USE VISUAL AIDS AND PRESENT QUANTITATIVE DATA

1. INTRODUCTION

Many interventions deal with a complex range of issues and highly technical subject matter. Illustrations and visual aids can provide both expert and non-expert readers with a clear overview of the problems and their drivers, policy objectives and solutions, as well as the different steps in the analytical process.

This tool presents three visual aids which are particularly relevant for policy interventions: problem trees, objective trees and intervention logic diagrams. These tools can help illustrate complex ideas and facilitate common understanding and better communication both inside the Commission and with external stakeholders. The text below also presents tips on how to present quantitative data clearly.

2. PROBLEM TREES

2.1. What are problem trees?

A problem tree is a highly effective communication tool that helps to demonstrate the need for intervention. It is used to visualise the identified problems, the interactions between these problems, their underlying drivers and likely consequences. The output is a graphical presentation of problems arranged according to ‘causes’ and ‘effects,’ joined by a core, or focal, problem. The problem tree should provide a simplified but robust representation of the reality. It also encourages a logical, comprehensive and coherent narrative and structure to the analytical process and report.

2.2. How to create problem trees

The graphs can be created in MS Word, Excel, equivalent open-source tools or specialised software such as [DoView](#), [MS Visio](#), [Smart Draw](#) or [Lucidchart](#).

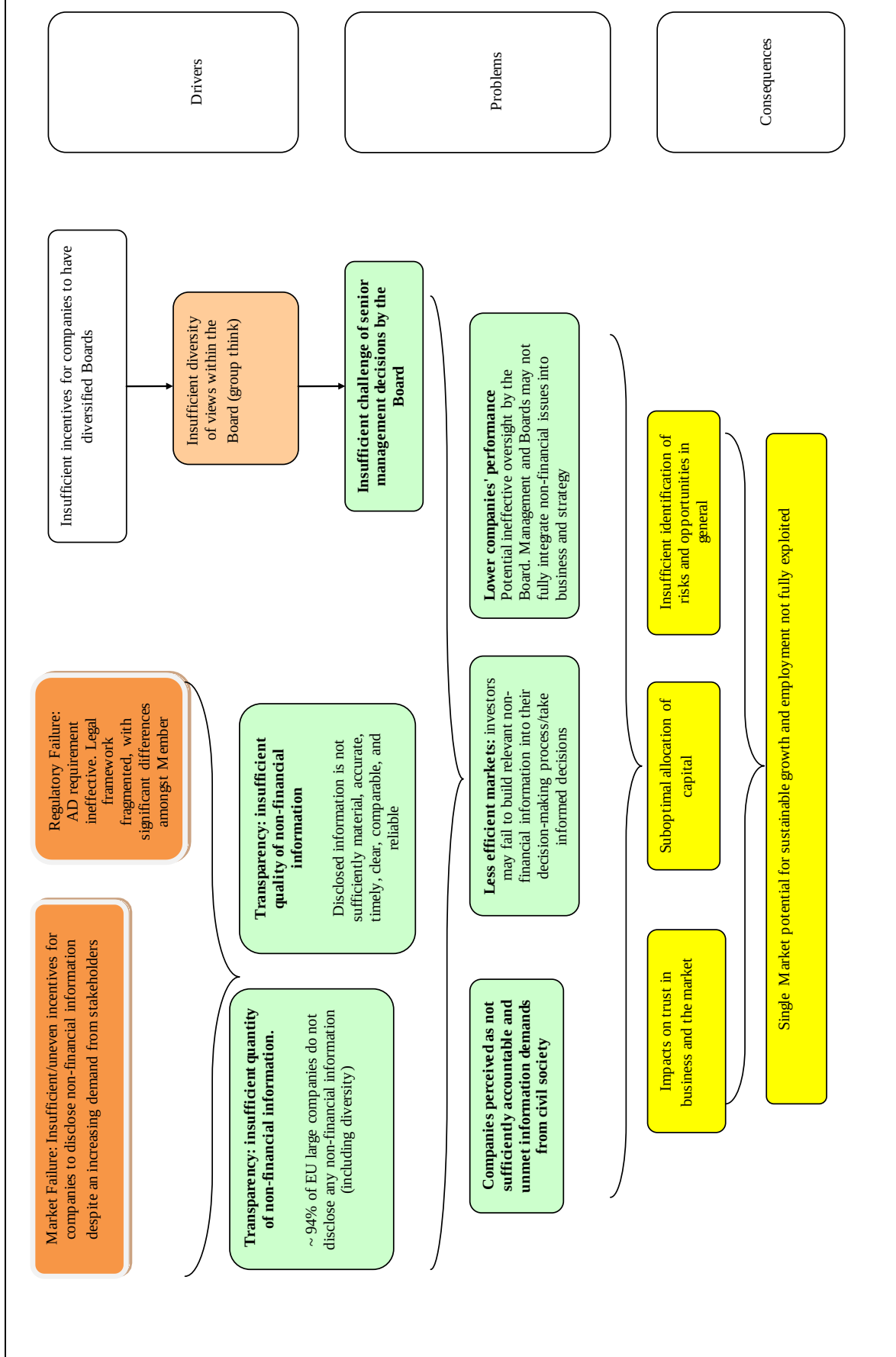
Box 1 shows an example on disclosure of non-financial and diversity information by certain large companies and groups (amending Council Directives 78/660/EEC and 83/349/EEC)⁷⁶⁶. The links between the problems, their drivers and the consequences can be clearly seen. For example, poor quality financial information is a problem that is caused, *inter-alia*, by a lack of incentive for companies to disclose such information.

Problem trees can also usefully illustrate what is outside the scope of the EU intervention; for instance because not all of the problem(s) can or should be addressed by EU level action. The example in Box 2 on the initiative on e-invoicing in public procurement⁷⁶⁷ illustrates this:

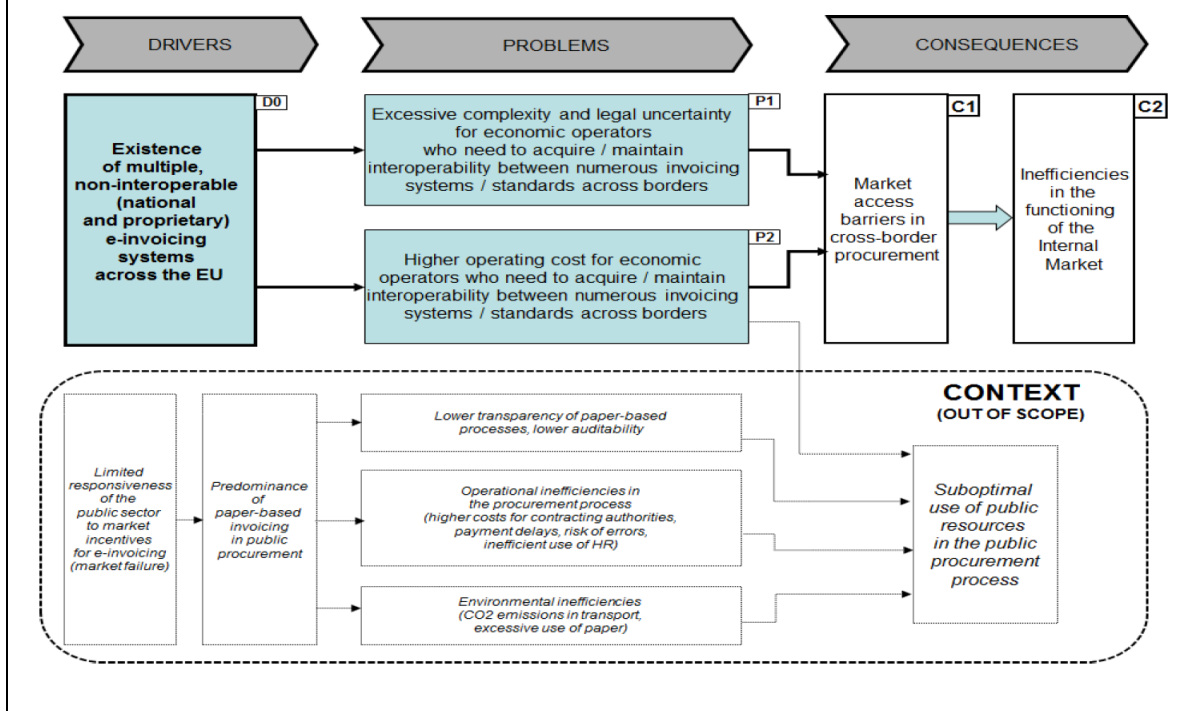
⁷⁶⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0127&from=EN>

⁷⁶⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0222&from=EN>

Box 1. Problem tree on the disclosure of nonfinancial and diversity information by certain large companies and groups



Box 2. Problem tree on e-invoicing



3. OBJECTIVE TREES

The "**objectives tree**" is a graphical illustration of the different layers of objectives. Box 3 illustrates how the different levels of objectives can be represented graphically. It is an example of the Directive 2009/142/EC relating to appliances burning gaseous fuels (GAD)⁷⁶⁸.

Box 3. Objective tree concerning appliances burning gaseous fuels.

General objective	Specific objective
Better protect health and safety of users of gas appliances and fittings as well as to ensure their appropriate performance	Ensure that economic operators have adequate safety and performance relevant data available on the framework conditions
	Ensure clarity of the requirements
Improve the fair playing field for economic operators in the gas appliance sector	Ensure legal clarity regarding the application of more specific EU product harmonisation legislation
Simplify the European regulation environment in the field of gas appliances and fittings	Ensure that legislation is up to date
	Ensure clarity of the scope

⁷⁶⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014SC0151&from=EN>

4. INTERVENTION LOGIC DIAGRAMS

Intervention logic diagrams/result-chains are synthetic and diagrammatic representations of the different steps of the analytical process. They can help to improve the coherence of the report, by making the links between problems, objectives and options more explicit. Box 4 shows how a diagram can be used to map the problems and objectives and relates to the initiative laying down maximum authorized weights and dimensions for certain road vehicles circulating within the Community⁷⁶⁹.

Box 4. Intervention logic diagram: authorized weights of road vehicles

Problem/Driver	Objective
<u><i>Problem (Part 1)</i></u> Certain limits on weights and dimensions set by the Directive constitute obstacles to energy efficiency improvements of road vehicles and to intermodal transport operations	<u><i>General objective (Part 1)</i></u> To facilitate energy efficiency of road transport and intermodal transport by revising certain limits on weights and dimensions of vehicles while maintaining the balance with the requirements of infrastructure maintenance, road safety and the protection of the environment.
<u><i>Root cause 1</i></u> Certain maximum weights and dimensions prevent the market uptake of more aerodynamic electric hybrid trucks and reduce the attractiveness of certain coach services.	<u><i>Specific objective 1</i></u> To enable the market uptake of more aerodynamic electric hybrid trucks and to increase the attractiveness of certain coach services.
<u><i>Root cause 2</i></u> Certain maximum weights and dimensions have not kept pace with the technical development of intermodal transport and containerisation.	<u><i>Specific objective 2</i></u> To enhance the development of intermodal/combined transport
<u><i>Problem (Part 2)</i></u> The Directive is not applied in an effective manner.	<u><i>General objective (Part 2)</i></u> To improve the internal market for road transport by providing a fairer playing field for hauliers.
<u><i>Root cause 3</i></u> Lack of common and dissuasive enforcement methods.	<u><i>Specific objective 3</i></u> To ensure better enforcement of the maximum weights and dimensions across the EU.

It is also possible to map objectives with policy options (in the IA context) or implemented measures (in the context of retrospective evaluation) – Box 5 contains an example from the IA accompanying the initiative laying down maximum authorized weights and dimensions for certain road vehicles circulating within the Community. To address the problem and its drivers, and given the substantial list of possible measures

⁷⁶⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0108&from=EN>

needed, it was proposed to form policy packages (PP) of measures for further assessment. This example shows an overview of measures proposed in three policy packages.

Box 5. Intervention logic mapping objectives to policy options (packages).

	PP1	PP2	PP3
<i>Specific Objective SO1: To enable the market uptake of more aerodynamic, electric and hybrid trucks and to increase the attractiveness of certain coach services.</i>			
1. Rear flaps	X	X	X
2. Longer cabins		X	X
3. Mandatory rear flaps for all vehicles			X
4. Higher weight limits for electric/hybrid trucks	X	X	X
5. Max. 19 t for two-axle coaches	X	X	X
<i>SO2: To enhance the development of intermodal/combined transport</i>			
6. Allow for 45' containers in <i>combined</i> transport	X/Ø	X/Ø	X/Ø
7. Allow for 45' containers in <i>intermodal</i> transport	X/Ø	X/Ø	X/Ø
8. Facilitations for larger containers			X
<i>SO3: To ensure better enforcement of the maximum weights and dimensions across the EU</i>			
9. Guidelines on enforcement	X	X	X
10. Common categorisation of infringement		X	X
11. Mandatory preselection of vehicles targeted for manual checks		X	X
12. Co-liability of the shipper/forwarder		X	X
13. Standards for on-board weighing devices		X	X
14. Compulsory on-board weighing devices			X
15. Minimum level of manual checks			X

In evaluation, the intervention logic provides a description or diagram summarising how the intervention was expected to work. Usually this shows how different inputs/activities/outputs triggered by the EU intervention were expected to interact to deliver the promised changes over time and ultimately achieve the objectives. The intervention logic should also consider external factors which may influence both the performance of the EU intervention, or generate the same type of effects.

The evaluation intervention logic is a dynamic tool and it is quite normal for it to develop further during the evaluation project as assumptions are tested. The final intervention logic may look quite different to the initial starting point, providing key input to the evaluation on how actual behaviours and performance differed from original expectations.

Box 6. Describing causal pathways

In evaluation, the concept of intervention logic combines elements of similar methodologies. Among others, it involves ideas from the Logframe approach and the Theory of Change. Both approaches are used to describe causal pathways in interventions and the mechanisms that enable them.

Theory of Change is usually oriented towards the objectives that are intended to be achieved under specific conditions. This concept is employed to show how activities towards the objectives on the one hand and outcomes on the other can be connected in various ways and through different mechanisms. Theories of Change are often used in early stages of an intervention and serve as a tool to engage stakeholders and the persons who will implement the intervention. They usually try to capture as many factors in the

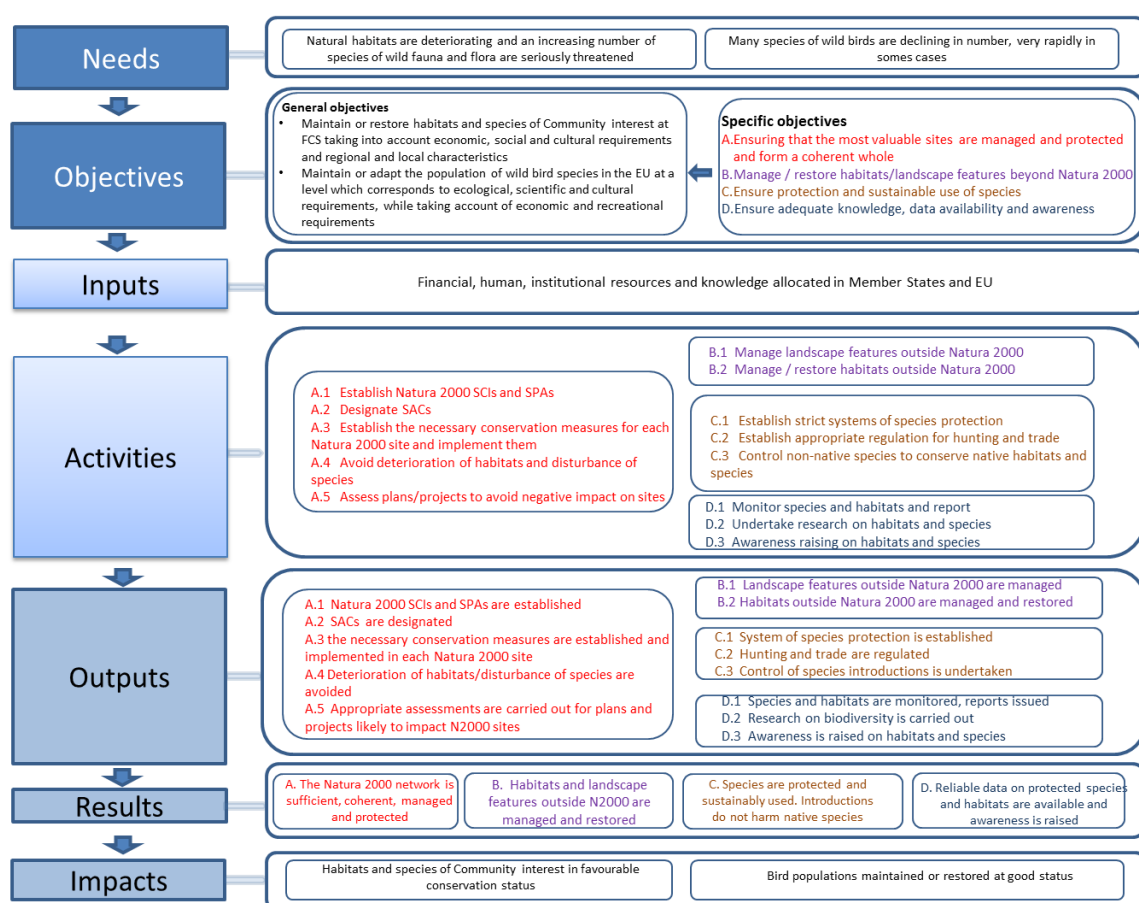
environment of the (potential) programme as possible that might facilitate or hinder the intended change.

The Logframe approach is an analytical tool to reconstruct the causal pathways between needs, overall and specific objectives, resources, activities, output, outcomes, and the impact of a specific intervention. External factors beyond the control of the intervention are included in the model in case they influence its effects.

The differences between the Logframe approach and the Theory of Change are not clear-cut and they are used in various definitions. In application, their meaning often overlaps.

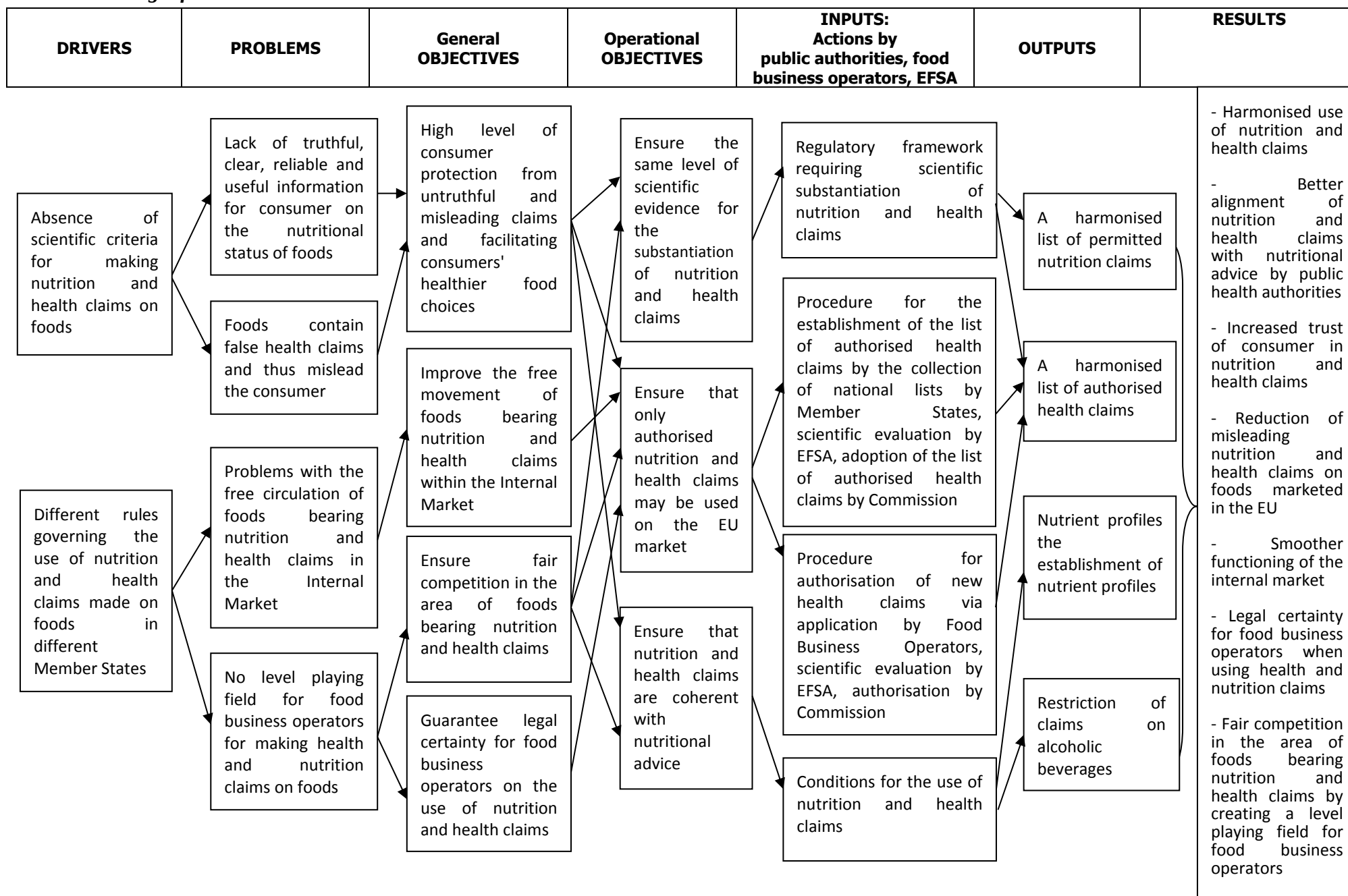
Some examples of intervention logics used in evaluation are presented below. Others can be found on the evaluation collaborative space⁷⁷⁰.

Intervention logic for the Birds and Habitats directives:



⁷⁷⁰ https://myintracomm-collab.ec.europa.eu/networks/IAWG/eval_network/SitePages/Home.aspx

Intervention logic for health and nutrition claims



5. PRESENTING QUANTITATIVE DATA

5.1. How to present quantitative data?

Data can be presented in the text, in a table, or **pictorially** as a chart, diagram or graph. Any of these may be appropriate for demonstration. Detailed tables should be put in an annex, with a summary in the main text for demonstration purposes. In general the following is a guide to presenting numerical data:

Text alone should not be used to convey more than three or four numbers.

Sets of numerical results should usually be presented as tables or graphs: (a) well-presented tables and graphs can concisely summarise information which would be difficult to describe in words alone; (b) on the other hand, poorly presented tables and graphs can be confusing or irrelevant.

The text should always include mention of the key points in a table or graph. If it does not warrant discussion it should not be there. You should ensure the message in the text is consistent with that in the table.

There are two main types of **graph**:

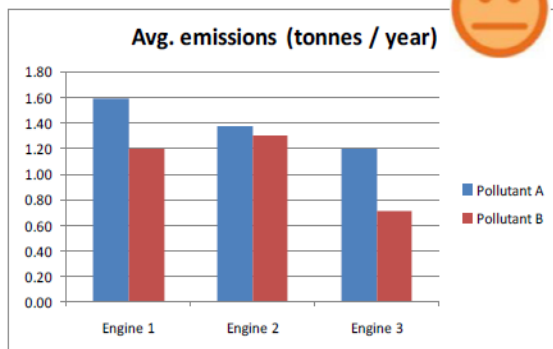
- **Line graphs** can show more detail than bar charts. They should be used when the horizontal axis represents a continuous quantity (such as time).
- When the horizontal axis is a qualitative factor - such as countries, products, etc. - **bar charts** are natural.

Tables used for demonstration purpose are intended to be assimilated quickly by the reader. They should be clear and well-presented and reduce numbers to relatively few significant digits.

It is preferable not to use overly large tables: (a) if the information is all necessary, split it into manageable components; (b) omit any column which can be readily calculated from data in other columns. Less relevant categories can be combined.

Box 7. Tables versus graphs

In general, tables are better than graphs for giving structured numeric information. For instance:



	Avg. emissions (tonnes/year)	
	Pollutant A	Pollutant B
Engine 1	1.59	1.20
Engine 2	1.38	1.30
Engine 3	1.20	0.71
Average	1.39	1.07

In general, graphs are better than tables for indicating trends, making comparisons, or showing relationships.

Good practice

Tables and graphs should be self-explanatory: the reader should be able to understand them without detailed reference to the text; users may well pick things up from tables or graphs without reading the whole text.

The titles of the tables/graphs should be informative

Rows and columns of tables or axes of graphs should be clearly labelled: what is measured, where, units, timeframe, source (as relevant)

Box 8. Clear tables

A first version sent to the IAB:

IAB: "Total emissions, not change"

IAB: "Thousand tons, not tons"

IAB: "Carbon monoxide should be covered"

IAB: Source?

IAB: Decimals

IAB: Clear title?

Table 4: Total emissions change measured in tons per year

	HC+NOx (tons/year)	PT (tons/year)
Option 1 - No change	40 907	539
Option 2 - Stage II	30 061	296
Sub-option 3.1 - Stage II + Flexibility scheme	31 105	387

Table 5: Average percentage reduction / year compared to Option 2 - Stage II

	HC + NOx	PT
Option 2 - Stage II	-26,5%	-45%
Sub-option 3.1 - Stage II + Flexibility scheme	-23,9%	-28,2%

Revised version:

Table 8: Total emissions measured in tons per year

	HC+NOx (tons/year)	PM (tons/year)	CO (tons/year)
Option 1 - No change of the limits	40 907	539	153 142
Option 2 - Stage II	30 061	296	184 634
Sub-option 3.1 - Stage II + Flexibility scheme	31 105	387	180 698

Source: ARCADIS Complementary Impact Assessment Study July 2008, p.57

Table 9: Average emission change / year compared to the Option 1

	HC + NOx	PM	CO
Option 2 - Stage II	-26,51%	-45,08%	+20,56%
Sub-option 3.1 - Stage II + Flexibility scheme	-23,96%	-28,20%	+17,99%

5.2. Comparing options in the IA report

In order to be an effective aid to decision-making, the IA reports need to present a credible set of alternative policy options, and their comparison **should clearly outline the advantages and disadvantages of each option**. Visual aids can be helpful in this regard.

A variety of presentational options are frequently included in multi-criteria analysis which can reduce efforts for presenting the comparison of options (in particular these tools frequently offer useful complementary views such as ranking by type of stakeholder).

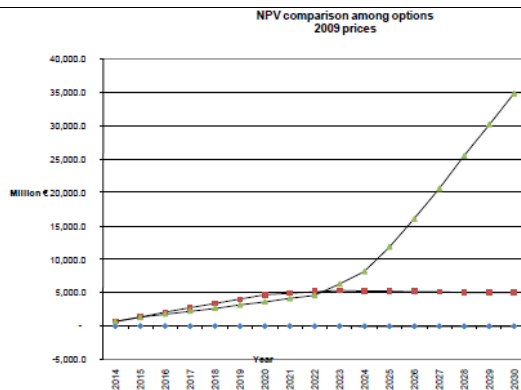
5.3. Radar charts

Radar charts can be used to compare options. They are particularly well-suited to show outliers and commonalities or when one option outranks another; they are less well-suited to show trade-offs. To make any sense, you need at least 5 quantifiable criteria. The order of criteria is important to convey meaning.

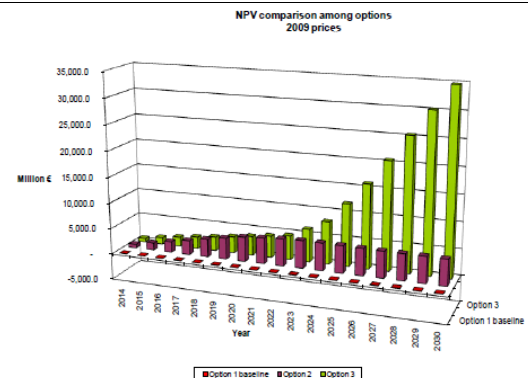
Box 9. Example of visual aids used to compare options

Example 1: IA on communication analysing the specific challenges for the space components of GMES (Global monitoring for environment and security). “In quantitative terms, the options can be compared most easily on the basis of their generated NPV in the period under consideration.”

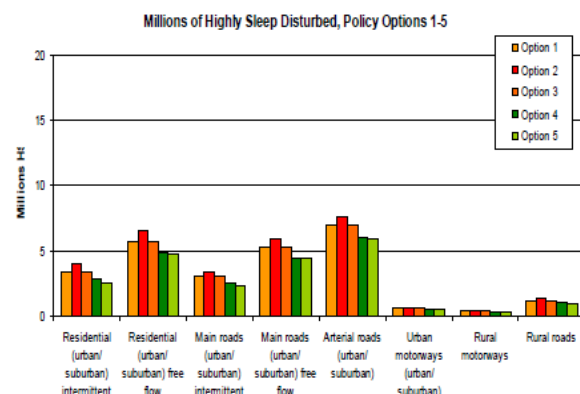
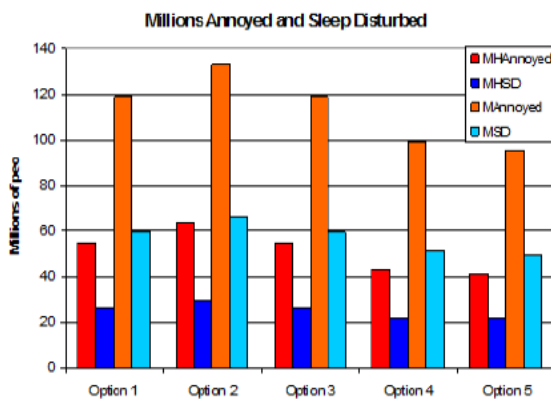
Is this the most appropriate kind of graph?



The IA report presents the graph below instead: different styles of graphs can enhance clarity and generate interest



Example 2:



Box 10. Example of radar charts

