



EUROPEAN COMMISSION

***Better Regulation "Toolbox"***

*This Toolbox complements the Better Regulation Guideline presented in in SWD(2015) 111*

*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-tools which are downloadable from the Commission's Better Regulation web site. [http://ec.europa.eu/smart-regulation/index\\_en.htm](http://ec.europa.eu/smart-regulation/index_en.htm)*

The Toolbox presents a comprehensive array of additional guidance to assist practitioners in the application of Better Regulation. Users are not expected to read and apply each individual tool but to use the toolbox selectively and with common sense.

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.

## Better Regulation Toolbox

This Tool Box complements the main guidelines on Better Regulation in SWD (2015) 111. It provides more specific and operational guidance to those involved with the various Better Regulation instruments.

The Tool Box 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 IA 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 are comprehensive and are expected to cover the relevant aspects of all initiatives and policy interventions. They are advisory in nature and following them is not compulsory except in a few cases (such as the format of documents submitted to the Regulatory Scrutiny Board) which have been identified in the main Better Regulation Guideline.

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**Chapter 1**  
**General Principles of Better Regulation**

## TOOL #1: PRINCIPLES OF BETTER REGULATION

### 1. COMMON BETTER REGULATION PRINCIPLES

Through its Better Regulation agenda, the European Commission has committed to design, deliver and support the implementation of interventions of the highest possible quality. It 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.

All Better Regulation activities within the Commission are governed by a set of common principles. These are expressed as a set of guiding principles which 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 consultation<sup>1</sup> and evaluation<sup>2</sup>. The application of these principles 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.

<b>Better Regulation instruments should:</b>	
<i>Embedded in the planning and policy cycle</i>	Be well-planned and timely. All the preparatory and analytical work, including stakeholder consultations, must be done in time to feed into the policy development process. Lessons from implementation and retrospective evaluations must be taken into account as part of the “evaluate first” approach to policy development. Possible implementation challenges should always be considered in impact assessments and future monitoring needs should also be sketched out.
<i>Of high quality</i>	Be of the highest quality. The basis of any stakeholder consultation should be clear, concise and include all necessary information to facilitate responses. The Commission's impact assessments, fitness checks and evaluations should conform to the requirements of the relevant guidelines as judged by the independent Regulatory Scrutiny Board.
<i>Evidence-based</i>	Be based on the best available evidence including scientific advice, or a transparent explanation of why some evidence is not available and why it is still considered appropriate to act.
<i>Participatory/ Open to stakeholders' views</i>	Ensure wide participation throughout the policy cycle. Every effort should be made to ensure that the Commission has sought and considered a wide and balanced range of views

<sup>1</sup> COM(2002)704 final

<sup>2</sup> SEC(2007)213

	and 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 or impact assessment. Stakeholders must be given sufficient time to respond (12 weeks for consultation) or prepare responses (4 working weeks for meetings).
<b><i>Respect for subsidiarity and proportionality</i></b>	Explain how these two principles are respected. EU action must 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.
<b><i>Comprehensive</i></b>	Be comprehensive. They must consider relevant economic, social, and environmental impacts of alternative policy solutions. Stakeholders' views must be collected on all key issues.
<b><i>Coherent/ Conducted collectively</i></b>	Be coherent across different policy domains; and instruments coherent within policy areas. New initiatives, impact assessments, consultations and evaluations must be prepared collectively by all relevant services in the framework of interservice groups.
<b><i>Proportionate</i></b>	Be proportionate to the type of intervention or initiative, the importance of the problem or objective, and the magnitude of the expected or observed impacts.
<b><i>Transparent</i></b>	Be clearly visible to the outside world if they 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 must be explained.
<b><i>Unbiased</i></b>	Be objective and balanced. They should inform political choices with evidence - not the other way around.
<b><i>Appropriately resourced and organised</i></b>	Be underpinned by sufficient human and financial resources to enable each evaluation, impact assessment or consultation to deliver a timely high quality result. DGs should establish centres of expertise (or functions) to support “Better Regulation activities throughout the policy cycle.

## 2. EMBEDDED IN THE PLANNING AND POLICY CYCLE

Commission initiatives and related Better Regulation instruments should be well-planned and timely. A new initiative must receive political validation *before* concrete work can start and resources are allocated. Policy planning and implementation are always steered

by the political level. The political validation must be understood as giving the green light to proceed with further technical work. The necessary level of political validation as well as the inclusion into Agenda Planning (AP) depends on the scope, type and magnitude of an initiative.

DGs are asked to determine, if an initiative falls under the category 'major', 'other' or 'DG internal work planning'.<sup>3</sup> Further guidance to services can be found on the IntraComm website of Agenda Planning<sup>4</sup> as well as GoPro.

## **2.1. Key planning and validation steps for major initiatives**

If a planned initiative falls into the category 'major', at the latest 12 months before the adoption date, an Agenda Planning entry should be created, which initiates the screening and political validation by the responsible Commissioner, Vice President and First Vice-President. Once obtained, the preparatory work can start and an Inter-service Steering Group set up.

The preparation of a Roadmap (RM) is mandatory for all major initiatives and evaluations and Fitness Checks. For initiatives that will undergo Impact Assessment (IA), the Roadmap shall be developed and presented in the form of an Inception IA. The Roadmaps/Inception IAs will systematically be discussed and finalised in the Inter-service Steering Group, if one has been established. Stakeholders can provide feedback on Roadmaps/Inception IAs directly via the webpage on *EUROPA*.

The following key planning and validation steps for major initiatives have to be followed. The specific procedures will vary across DGs and you should check with the planning unit of your DG on how to proceed.

<b>Major Initiatives</b>
<p><b>1. DG 'internal' preparation and pre-validation by Commissioner(s) and Vice-President(s)</b></p> <ul style="list-style-type: none"><li>– DG Policy desk prepares a RM or Inception IA<sup>5</sup> and requests initiative to be included into Agenda Planning by completing the pro-forma template;<sup>6</sup></li><li>– DG Planning unit seeks approval by the DG's management;</li><li>– DG seeks validation by the responsible Commissioner(s) and Vice-President(s)</li><li>– DG Planning unit creates a new Agenda Planning entry and uploads the drafted RM or Inception IA; Initiative = "Pending validation" by the First Vice-President;</li></ul> <p><b>2. SG screening of the initiative and the draft RM/Inception IA</b></p>

<sup>3</sup> See Chapter II on Planning in the main BR Guideline guidelines (Section 4).

<sup>4</sup> <https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

<sup>5</sup> If co-chefs may be responsible for the initiative, the RM needs to be co-drafted.

<sup>6</sup> RM/Inception IA and AP-entry template:  
<https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

- SG PLANNING launches the screening of the initiative and dispatches the RM/Inception IA to SG policy desks for review
- SG policy desks responsible for policy coordination, evaluation, impact assessment and implementation provide screening comments on the initiative, confirm better regulation requirements and comment on the content and quality of the RM/Inception IA.

### **3. Validation by the First Vice-President**

- On the basis of the screening comments, SG PLANNING submits the new initiative to the First Vice-President for validation
- The First Vice-President confirms if preparatory work for an initiative should be pursued.
- SG PLANNING informs the DG on the result of the validation by the First Vice-President.
- If the initiative is validated, SG PLANNING sends the SG's comments on the RM/Inception IA back to the DG.

### **4. Finalisation and publication of the RM/Inception IA**

- The DG Planner sends the SG comments to the policy desk
- If an ISG is established, it finalises the RM.
- If no ISG is established, the policy desk finalises the RM.
- An ISG has to be established for all initiatives undergoing IA. It finalises the Inception IA.
- The DG Planner up-loads the final RM/Inception IA for publication in AP.
- SG PLANNING publishes the RM/Inception IA on the EUROPA website.

## **2.2. Key planning and validation steps for 'other' initiatives**

DGs should not start work without having political validation by the responsible Commissioner. At the latest 3 months before the planned adoption, the initiative has to be introduced in Agenda Planning. For delegated acts and implementing acts an appropriate justification why they do not have significant impacts and are thus 'not major' has to be provided.

### **"Other initiatives" in Agenda Planning**

#### **DG 'internal' preparation and validation by Commissioner(s)**

- DG Policy desk prepares template requesting the insertion of an initiative into Agenda Planning<sup>7</sup>
- DG Planning unit seeks approval by the DG's management

<sup>7</sup> RM and AP-entry template: <https://myintracomm.ec.europa.eu/sg/planning/Pages/index.aspx>

- DG seeks validation by the responsible Commissioner(s)
- DG Planning unit creates a new Agenda Planning entry and provides justification why this initiative does not need to be considered as a "major" initiative.

### **2.3. Key planning and validation steps for Commission work Planning outside Agenda Planning**

There are initiatives which do not need to be listed in Agenda Planning. Each DG establishes its proper workflows and procedures for the programming and validation of such initiatives. Policy desks should verify the concrete planning and the timeline of their initiative with those responsible for Agenda Planning and/or DECIDE-Coordination in their respective DG.

## **3. HIGH QUALITY**

### **3.1. The Regulatory Scrutiny Board**

The mission of the Regulatory Scrutiny Board (RSB) is to improve the quality of the Commission's Impact Assessments, major retrospective evaluations and fitness checks through quality control. The RSB will scrutinise all impact assessments and *major* retrospective evaluations and fitness checks.

Once the preparatory work has been completed, the appropriate Staff working document which summarises the impact assessment process, major evaluation or Fitness Check must be submitted to the RSB for its quality check (*see Box*).

#### ***Box 1. Submission of the draft SWDs to the Regulatory Scrutiny Board***

- The draft IA Report (SWD) or the SWDs summarising the major evaluation or Fitness Check must be submitted at least 4 weeks before the RSB's meeting where it will be discussed. It should be transmitted with a note addressed to the chair of the RSB from the Director General and circulated via Ares. The minutes of the last ISG meeting should be attached.
- The RSB meets in principle twice a month. The author service should contact the RSB secretariat (SG.C2) well in advance to book a slot for the Board's examination (at least 2-3 months before the preferred meeting date). Subsequent changes of foreseen date should be avoided as far as possible.
- In the Board meeting, the SWD will be discussed on the basis of a Quality Checklist which will be submitted to the author service in advance. The Checklist outlines the RSB's preliminary view on the quality of the report relative to the requirements of the relevant guidelines and identifies priority issues for discussion at the meeting.
- In certain cases, the RSB may treat the draft SWD in written procedure. In such cases, the author service has to respond in writing to the issues raised in the Quality Checklist. The RSB delivers its opinion within 2-3 days following its meeting.

### 3.2. Opinions of the Regulatory Scrutiny Board

For **impact assessments**, the RSB's opinions can be positive or negative. A positive opinion is required before the inter-service consultation (ISC) on the related proposal can be launched.

**Positive opinion:** In the case of a positive opinion, the author service is still obliged to revise the Report to take account of the recommendations of the RSB before seeking approval for launching the ISC. The ISG should have the opportunity to consider the revised version of the IA report together with a draft of the underlying initiative/proposal before the launch of ISC. In any event, during the ISC the SG pays special attention to the way reports have been revised to reflect the Board's opinion and the way in which the 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 substantial improvements are needed on a number of significant issues. In such cases the author service must 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 the RSB may call for a second resubmission. Albeit rare, a third negative opinion may be issued.

For major **evaluations and Fitness Checks**, the RSB provides an opinion on the quality of the draft staff working document and recommends any necessary improvements. These recommendations must be addressed in the revised report, which will be checked by the Secretariat-General during the formal ISC or when finalising the SWD. The opinion of the Regulatory Scrutiny Board should be published on the Europa web site.

For **impact assessments**, the opinion is published once the related initiative has been decided by the College. Similarly, 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 or Fitness Check Staff Working Document has been cleared for publication by the services following a formal interservice consultation.

### 3.3. Participatory and open to stakeholder views

Stakeholder consultation helps EU law making to be transparent, well-targeted and coherent and increases credibility and acceptance.

The general rules and minimum standards on how the Commission services should consult are specified in the main BR Guideline which builds upon earlier Commission Communications<sup>8</sup>. Additional information can be found in the dedicated tool on stakeholder consultation as well as the tools which cover stakeholder consultation in the context of evaluation and impact assessment.

The running of stakeholder consultations is decentralised to the Commission service responsible for the respective initiative. In some cases, external consultants can support or even conduct the consultation work, but the lead service remains responsible for the

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<sup>8</sup> COM(2002)704 final as complemented by COM(2012)746 and accompanying SWD(2012)422 and by COM(2014)368.

scope and objectives of the consultation, its process, outcome, and the fulfilment of the Minimum Standard requirements.

The stakeholders concerned and the key elements of the consultation strategy, like tools and timing, should be explained in the roadmap.

Consultation strategies and documents are discussed and endorsed by the interservice (steering) group (ISG). If no ISG is set up for a given initiative, SG and any other associated service needs to be consulted.

For public consultations a minimum consultation period of 12 weeks has to be foreseen, while for stakeholder meetings 20 working days' notice is required.

### **3.4. Appropriately resourced and organised**

The conduct of stakeholder consultations, impact assessments, evaluations, Fitness Checks and implementation checks require substantial human and financial resources and time to complete satisfactorily.

While each DG is responsible for the conduct and oversight of these Better Regulation activities, the resource requirements need to be planned in advance so that resources are available and the public procurement processes in place to deliver the necessary inputs.

In addition, DGs should consider providing centralised expertise in the fields of impact assessment, evaluation, stakeholder consultation and implementation in order to support those charged with delivering specific aspects of Better Regulation.

Central support is provided by **the Secretariat General**, including provision of general guidance and training on all aspects of Better regulation.

## TOOL #2: EVIDENCE BASED BETTER REGULATION

### 1. INTRODUCTION

Compiling a robust information or evidence base is an essential component of better policy making. 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 that any 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

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

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 sources such as previous reports (e.g. research, foresight, monitoring, evaluation or impact assessment reports), studies, statistical publications, newspaper, magazine and journal content. The Commission library<sup>9</sup> 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 the proportionality of investing additional resources to obtain the missing information if not done and provide reasons in the roadmap. 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 identifying targets and new ways for policy interventions in a more systemic manner. It contributes to connect research and science activities to societal

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<sup>9</sup> <https://myintracomm.ec.europa.eu/corp/cl/EN/Pages/index.aspx>

challenges by strengthening the engagement of stakeholders and citizens in policy-making. 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 policy making cycle. Foresight tools and methods will enable to: analyse the problem with a systems approach, facilitate inter-service collaboration; consider 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 Commission<sup>10</sup> and the European Parliament<sup>11</sup>.

An important source of anticipatory intelligence is the review of existing forward looking material produced by specialized 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 policy making 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 policy-making** 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
<b>Informing policy</b>	Understanding of change Visions of change	Long term orientation Additional source for information (based on a broad variety of views) Awareness of future challenges
<b>Facilitating policy implementation</b>	Networks, shared visions	Better receptivity of actors for policy objectives due to ownership of results therefore easier implementation

<sup>10</sup> L 347/974 [http://ec.europa.eu/research/participants/data/ref/h2020/legal\\_basis/sp/h2020-sp\\_en.pdf](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](http://ec.europa.eu/research/innovation-union/pdf/expert-groups/effla-reports/effla_pb_14_-_towards_a_foresight_standard.pdf)

<sup>11</sup> 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.

<b>Embedding participation in policy-making</b>	Transparency of policy making process	Better identification of citizens with policy (legitimacy)
<b>Supporting policy definition</b>	Generation of strategic options together with policy makers	Direct support in strategy development and implementation

#### 4. TRANSPARENCY AND ROBUSTNESS

The author service and inter service 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 to 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 be biased, incomplete or suffer from other imperfections – all of which need to be taken into account when drawing conclusions. *Prima facie*, data which has come 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, evaluation 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 the experts or 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 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 in the BR context and the need to consider quality assurance and uncertainty<sup>12</sup> 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.

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<sup>12</sup> See tool on the use of analytical models.

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.<sup>13</sup> The assembled expertise sufficiently covers the topics to be addressed, both mainstream and divergent views are included and that any direct or indirect interest in the issue at stake has been declared and addressed.

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. There is a need to always make a careful analysis of stakeholders' arguments and 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 thought 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 acquire such information must be particularly robust and comprehensive.

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 policy makers to make well informed decisions.

In addition, the emergence of Big Data<sup>14</sup> 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

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

<i>Evaluations</i>
The Commission is committed to the " <i>evaluate first</i> " 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 checks" <sup>15</sup> ) where interactions between instruments can be explored and assessed. Information used in evaluations may come from monitoring systems,

<sup>13</sup> COM(2002) 713 final

<sup>14</sup> 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.

<sup>15</sup> [http://ec.europa.eu/smart-regulation/evaluation/docs/fitness\\_checks\\_2012\\_en.pdf](http://ec.europa.eu/smart-regulation/evaluation/docs/fitness_checks_2012_en.pdf)

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 reliability) for their specific area of responsibility. The specific impact tools in this guidance provide links to data sources relevant for their specific types of impacts.

**Eurostat**<sup>16</sup> is the statistical office of the European Union and provides statistics at European level (from data collected by statistical authorities of Member States) using harmonized methodologies that enable comparisons between countries and regions. Eurostat provides free access to an online statistics Database and publications.

**Eurobarometer**<sup>17</sup> 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 programming<sup>18</sup> 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 re-use of public sector produced information. The **EU Open Data Portal**<sup>19</sup> 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 public data portals. In addition, the EU strategy of Open Access<sup>20</sup> provides free access to EU-funded research results, including scientific publications and research data.

Studies managed inside the European Commission<sup>21</sup>. Information on studies planned or conducted by EU institutions will be available in the future Inter-institutional database of studies managed by the Publications Office (to be operational by mid-2015).

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

<sup>16</sup> <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>

<sup>17</sup> [http://ec.europa.eu/public\\_opinion/index\\_en.htm](http://ec.europa.eu/public_opinion/index_en.htm)

<sup>18</sup> <https://myintracomm.ec.europa.eu/corp/comm/AtAGlance/Pages/Eurobarometer.aspx> .

<sup>19</sup> <http://open-data.europa.eu/en/data/>

<sup>20</sup> <https://www.openaire.eu/search/find>

<sup>21</sup> <https://myintracomm.ec.europa.eu/corp/sg/en/edomec/studies/Pages/studies.aspx>

below:

- United Nations: <http://data.un.org>
- Organisation for Economic Co-operation and Development: <http://stats.oecd.org/>
- International Energy Agency: [www.iea.org](http://www.iea.org)
- World Trade Organization: [www.wto.org](http://www.wto.org)
- World Bank: <http://data.worldbank.org>
- International Monetary Fund: [www.imf.org](http://www.imf.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](http://www.fuelseurope.eu)
- European car manufacturers (ACEA): [www.acea.be](http://www.acea.be)
- European Steel Association (EUROFER): [www.eurofer.org](http://www.eurofer.org)
- Farming/agri-business (COPA COGECA): <http://www.copa-cogeca.be>
- Commercial data banks can be consulted against a fee and must 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 groups**<sup>22</sup> composed of individuals appointed in their personal capacity are a prime source of expertise in the evidence gathering context. 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 needs 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 Register<sup>23</sup> which ensures transparency about group composition and interests. When creating and operating an expert group (or similar entities) you should follow the dedicated guidance<sup>24</sup>. More widely, a set of principles and guidelines<sup>25</sup> 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,

<sup>22</sup> <http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2>

<sup>23</sup> <http://ec.europa.eu/transparency/regexpert/>

<sup>24</sup> C(2010) 7649 final, SEC(2010) 1360 final

<sup>25</sup> C(2002) 713

prevention of conflicts of interest and transparency, including as regards any persisting uncertainty and divergent views.<sup>26</sup>

You may also use available Commission online tools for the collection of expertise such as **SINAPSE**<sup>27</sup> 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.

### *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 method you use is correct and appropriate for collecting the required type of information<sup>28</sup>. When using evidence gathered through consultation in your IA, evaluation or fitness check report, 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 can significantly enhance the quality of such information.

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<sup>26</sup> For more information on expertise in the context of risk assessment, please see the tool on risk assessment and management.

<sup>27</sup> <http://europa.eu/sinapse/>

<sup>28</sup> See tool on stakeholder consultation.

## TOOL #3: LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

### 1. INTRODUCTION & LEGAL BASIS

The Union can only act in areas where competence has been conferred on it by the Treaties (principle of conferral). In addition, all Union actions are governed by the overarching principles of subsidiarity and proportionality<sup>29</sup>. These principles are important. The Union should only act where the principle of subsidiarity is respected and actions should restrict themselves to what is strictly necessary to achieve the objectives defined in the Treaties.

The IA Report must 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 (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 but 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 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 infringements of fundamental freedoms or distortion of competition are not sufficient. Action may also be justified to prevent the likely emergence of such obstacles<sup>30</sup>;
- 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?

### 2. SUBSIDIARITY

The principles of subsidiarity and proportionality may be used to challenge the lawfulness of Union acts before the Union courts. In addition, national Parliaments have a specific role in scrutinising the Commission's respect of the subsidiarity principle.

A subsidiarity analysis is important when considering a new initiative but also when evaluating the relevance and EU added value of existing interventions. In relation to evaluation, it is often difficult to identify what the situation would be like in the absence

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<sup>29</sup> Article 5(1) of the Treaty on European Union.

<sup>30</sup> Case C-376/98 Federal Republic of Germany v European Parliament and the Council of the European Union, para 84.

of the EU intervention, although useful reference may be made to the baseline scenario from the impact assessment. 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 Member States.

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).<sup>31</sup>

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); and
- Where the objective can 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 be a key consideration of the problem definition where the "EU relevance" of the problem (for an IA) or the intervention (for an evaluation) must be described and quantified as far as possible.

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 relevant Treaty objective; second, whether Union action would have an added-value with regard to action by the Member States.

The following steps can help when assessing subsidiarity:

<b>I. Verify whether the Union has exclusive competences or not</b>	
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 Art.3 of the Treaty on the Functioning of the European Union)?
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").

<sup>31</sup> 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.

If no	move to step II and III below
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<b>II. Perform the necessity/relevance test</b>	
Question	Can/have the objectives of the (proposed) action be(en) achieved sufficiently by Member States acting alone?
Relevant issues	<p>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 considerations should be:</p> <ul style="list-style-type: none"> <li>• To describe and, as far as possible, quantify the geographical scope, the numbers of businesses/actors affected the number of Member States implicated and the level of economic damage.</li> <li>• To establish, qualitatively and as far as possible quantitatively, whether there is a significant cross-border problem (e.g. how much of an environmental problem like air pollution is due to the activities of other Member States?).</li> </ul>
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	<p>Illustrate the specific limits of Member States' action, their underlying drivers, and why they would/have not be(en) "sufficient".</p> <p>Move to next step.</p>
Examples	Relevant situations could involve cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital.

<b>III. Perform the EU added value test</b>	
Question	Can/have the objectives of the proposed action be(en) better achieved at Union level?
If yes	<p>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.</p> <p>The principle of subsidiarity is complied with.</p>
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.
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**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 evidence<sup>32</sup>.

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.

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 countries 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.....

### 3. PROPORTIONALITY

The content and form of Union action must not go beyond what is necessary to meet the objectives of the Treaties<sup>33</sup>. 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 IA<sup>34</sup>, evaluation or Fitness Check.

<sup>32</sup> To be referred to rather than repeated if already presented in the problem analysis.

<sup>33</sup> Article 5(4) of the Treaty on European Union.

<sup>34</sup> In the context of IA, proportionality is a key criterion to consider in the comparison of the policy options.

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?

<b>Case law examples of disproportionate/proportionate measures</b>	
<i>Fedesa</i> <sup>35</sup>	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> <sup>36</sup>	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> <sup>37</sup>	An EU Decision to ban the import of Japanese fish into the EU was

<sup>35</sup> [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.](#)

<sup>36</sup> [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;](#)

<sup>37</sup> C-183/95 *Affish BV v Rijksdienst voor de Keuring van Vee en Vlees* [1997] ECR I-4315

	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> <sup>38</sup>	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> <sup>39</sup>	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> <sup>40</sup>	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.

<sup>38</sup> [C-210/03 Swedish Match AB and Swedish Match UK Ltd \[2004\] ECR I-11893](#)

<sup>39</sup> [C-310/04 Spain v Council \(Cotton support scheme\) \[2006\] ECR I-7285](#)

<sup>40</sup> [Joined Cases C-402/05 and C-415/05 Yassin Kadi and Al Barakaat International Foundation v Council and Commission \[2008\] ECR I-6351](#)

## **Chapter 2**

### **How to carry out an Impact Assessment**

## TOOL #4: 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 (from 1.5-2 years) or shorter (8-10 months) 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, 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 evaluation<sup>41</sup> 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 proposal<sup>42</sup>. This assessment takes place within the more general process of policy planning and the preparation of Roadmaps/Inception IAs.

### 3. THE DETAILED STEPS IN PREPARING THE IA

The IA process should be conducted in accordance with the new structure and working methods of the European Commission<sup>43</sup> as well as the more detailed working instructions<sup>44</sup>. More information on the policy preparation and adoption process can be found at the [Go-Pro](#) site on Intracomm.

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

The creation of an Inter-service Group (ISG) which will steer the IA process and collectively prepare the IA report;

- (1) The finalisation (by the ISG) and publication of an **inception impact assessment** which 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. Any feedback from stakeholders on the inception IA should be assessed and changes made as appropriate to the next steps in the IA process.

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<sup>41</sup> An evaluation or fitness check will only be necessary where there is an existing policy or legislative framework in place.

<sup>42</sup> See tool on assessing whether an IA is necessary.

<sup>43</sup> [C\(2014\) 9004](#); Communication from the President to the Commission on the working methods of the European Commission 2014-2019.

<sup>44</sup> <https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx>

- (2) The collection and analysis of relevant data and expertise, foresight and consultation of stakeholders. Data needs can already be identified in the inception IA;
- (3) Drafting of the impact assessment report together with members of the ISG;
- (4) A quality review of the draft IA report by the Regulatory Scrutiny Board;
- (5) Adaptation of the draft IA report to respond to the opinions of the Regulatory Scrutiny Board prior to the launching of a formal interservice consultation on the associated initiative/proposal (together with the IA Report);
- (6) Adaptation of the draft IA report to take on board comments made during the ISC.

Specific tools have been prepared to assist in the process of gathering evidence, conducting a stakeholder consultation and analysing impacts<sup>45</sup> as well as in relation to the content of the IA report<sup>46</sup>. Details are provided below for the other aspects.

<b>Inter-service Group (ISG)</b>	
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. In each case, support should be provided by a member of the relevant DG's IA support function /unit.
	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 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) 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 inter-service groups can be used to steer the IA work particularly where an inter-service group has been used to conduct a related evaluation or fitness check. The inter-service group should also be used to prepare and discuss the related policy proposal.
	Consultants may be invited to make presentations regarding supporting

<sup>45</sup> See tools on evidence gathering, stakeholder consultation during an IA, the use of analytical models.

<sup>46</sup> See tool on the format of the IA report.

	<p>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.</p>
Why?	<p>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.</p> <p>By mobilizing 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.</p> <p>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 inter-services 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.</p>
	<p>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.</p> <p>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.</p> <p>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.</p>
When?	<p>An ISG is established as soon as the initiative has been politically validated and accepted for inclusion in Agenda Planning (i.e. according the internal working methods of the Commission and instructions for the services and with the agreement of the lead Commissioner, Vice-President and 1<sup>st</sup> Vice-President).</p>
	<p>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 ISC, the group will discuss the legislative proposal in parallel to its IA.</p> <p>More meetings (and/or email consultations in between meetings) can also be envisaged, particularly in the case of complex initiatives developed over a long period. Meetings may also follow the timing of other miles-stones such as an external study or a stakeholder consultation.</p>
How?	<p>The ISG should be involved in all IA work phases. It should always discuss intermediate results and IA report drafts. It must also be involved in finalising the Inception IA, 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</p>

	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. <b>The minutes of the last ISG meeting should be attached to the covering note when the IA Report is submitted to the RSB.</b>

#### 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)<sup>47</sup>.

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 with the subsidiarity, proportionality and Better Regulation principles, including the results of 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 SG 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.

When the final proposal adopted by the Commission deviates significantly from the options assessed in the impact assessment, the explanatory memorandum<sup>48</sup> should clarify the likely impacts of this change.

<sup>47</sup> See tool on the IA Report format.

<sup>48</sup> See tool on drafting the explanatory memorandum

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 GREFFE<sup>49</sup>.

## 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 agreements<sup>50,51</sup>. Within this framework, the other Institutions have made a commitment to assess the impact of substantial amendments they make to Commission proposals. In duly justified cases, the Commission may, on its own initiative or at the invitation of the European Parliament and/or the Council, decide to complement its original IA. 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 all cases where the Commission is asked to provide additional information, you should consult SG.C.2 as early as possible.**

In any event, the European Parliament and the Council take an increasing interest in the Commission's impact assessments and you may be contacted to present your IA work 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 Interinstitutionnels (GRI). You can contact the IA unit of the Secretariat General (SG.C.2) to get advice on how to proceed. The Commission is responsible for presenting its impact assessments to the Council and **under no circumstances should the Commission's contractors be involved** in such presentations.

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<sup>49</sup> <https://myintracomm.ec.europa.eu/corp/sg/en/egrefe/Pages/contacts.aspx>

<sup>50</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2003:321:0001:0005:EN:PDF>

<sup>51</sup> [http://ec.europa.eu/smart-regulation/impact/ia\\_in\\_other/docs/ii\\_common\\_approach\\_to\\_ia\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_in_other/docs/ii_common_approach_to_ia_en.pdf)

## TOOL #5: WHEN IS AN IA 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 sector, societal group or geographical area.

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 or Inception IA. Detailed guidance is available describing the procedural steps for carrying out such an assessment<sup>52</sup>.

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, 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)<sup>53</sup>.

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.

<b>A. Initiatives for which the need for an IA must be assessed<sup>54</sup></b>
New legal acts
Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts <sup>55</sup>

<sup>52</sup> See tool on steps to be followed to conduct an Impact Assessment.

<sup>53</sup> 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.

<sup>54</sup> This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

<sup>55</sup> 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 REFIT annex of the Commission

Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law <sup>56</sup>
White papers
Policy communications
Action Plans
Commission and Council Recommendations
Recommendations for the negotiation of international agreements.
Social partner agreements pursuant to Articles 154-155 TFEU <sup>57</sup> .
Financial programmes (i.e. all basic acts for spending programmes and financial instruments) <sup>58</sup>

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 policy making.

In the case of Recommendations, the need for an IA 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.

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 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, must clearly signal that an IA would accompany any follow up initiative with directly identifiable significant impacts.

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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 a REFIT evaluation).

<sup>56</sup> A key determining factor will be whether the Commission has any policy discretion over the content of its transposing measures.

<sup>57</sup> See tool on IA requirements for social partner agreements.

<sup>58</sup> See tool on Impact Assessment for spending programmes.

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

<b>Type<sup>59</sup></b>	<b>Reason</b>
Administrative decisions	Lack of significant impact
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, Finance Decisions and programme management decisions	Lack of policy alternatives / ex-ante evaluation not required
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
Risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors
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

<b><i>EU agencies and IAs</i></b>
<ul style="list-style-type: none"> <li>• 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</li> </ul>

<sup>59</sup> This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

a priori.

- However, the lead service must ensure that the agency analysis broadly meets the Commission's consultation and IA standards and takes responsibility/ownership for the quality of the assessment otherwise a complementary IA may be necessary.
- The lead service should (in consultation with the SG) 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.
- During policy preparations, services can ask the lead service to supplement the agency analysis if duly justified and/or – in consultation with the SG – to undergo scrutiny by the Regulatory Scrutiny Board.

## TOOL #6: IAS FOR SPENDING PROGRAMMES & FINANCIAL INSTRUMENTS

### 1. INTRODUCTION

The requirements for carrying out ex-ante evaluation are based on Articles 30 and 140 of the Financial Regulation<sup>60</sup>. These requirements cover the principles of sound financial management which are also embedded in the impact assessment process<sup>61</sup> (e.g. demonstrating the **EU added value** and assessing the **cost-effectiveness (efficiency) of a proposal**). It is, therefore, not necessary to carry out both processes and where an ex-ante evaluation is required, services should prepare only an IA which should include all of the necessary ex-ante evaluation elements<sup>62</sup> (see below).

#### ***Box 1. Requirements of the Financial Regulation***

##### *Article 30 of the Financial Regulation:*

4. In order to improve decision-making, institutions shall undertake both ex ante and ex post evaluations in line with guidance provided by the Commission. Such evaluations shall be applied to all **programmes and activities which entail significant spending** and evaluation results shall be disseminated to the European Parliament, the Council and spending administrative authorities.

##### *Article 140 of the Financial Regulation:*

2.(f) **Financial instruments** shall be established on the basis of an ex ante evaluation, including an evaluation of the possible reuse of additional resources referred to in point (f) of paragraph 8.

### 2. HOW TO CARRY OUT IMPACT ASSESSMENT OF SPENDING PROGRAMMES AND FINANCIAL INSTRUMENTS?

You need to follow the IA guidelines both as regards the content and standards of an impact assessment process. 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 Statement<sup>63</sup>.

#### 2.1. Spending programmes

An IA for a spending programme should:

- (1) Use the financing available under the existing Financial Framework as the baseline scenario for programmes that already exist (including absorption levels,

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<sup>60</sup> [http://ec.europa.eu/budget/biblio/documents/regulations/regulations\\_en.cfm](http://ec.europa.eu/budget/biblio/documents/regulations/regulations_en.cfm)

<sup>61</sup> The IA guidelines therefore replace the 2001 specific guidance on ex-ante evaluation (i.e. "A practical guide for preparing proposals for expenditure programmes")

<sup>62</sup> Note that in practice, ex-ante evaluations for pilot projects and preparatory actions are not carried out as they usually do not entail "significant spending" and are by definition preparing eventual spending programmes.

<sup>63</sup> 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

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).

- (2) Focus the options for implementation on issues such as:
  - Programming (priority setting, allocation of resources, adjustments during the programme duration);
  - Management provisions and requirements regarding the prevention of errors, irregularities or fraud (audit, controls), 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)<sup>64</sup>.
- (3) Consider the different types of budgetary cost:
  - Direct financial outlays (to beneficiaries or third parties) from the EU budget;
  - Financial outlays from Member State budget 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;
  - Other administrative expenditure for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc.).
- (4) Assess (financial and operational) risks associated with the identified options, for which you may need to seek additional expertise (e.g. from your internal audit and/or financial unit and OLAF).
- (5) 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) TFEU<sup>65</sup>; 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;<sup>66</sup>

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<sup>64</sup> See e.g. Guidelines for the establishment and operation of executive agencies

<sup>65</sup> DG COMP can assist in this assessment

- (6) 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;
- (7) 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.

## **2.2. Financial instruments<sup>67</sup>**

When preparing a proposal for financial instrument, you will need to pay particular attention in your IA to the elements listed Article 224 of the Rules of Application<sup>68</sup>, namely:

- 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.
- 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 CSF Funds.
  - 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.

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<sup>66</sup> DG TRADE can assist in this assessment

<sup>67</sup> 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 of, for example, debt and equity instruments under Horizon 2020.

<sup>68</sup> [http://ec.europa.eu/budget/biblio/documents/regulations/regulations\\_en.cfm](http://ec.europa.eu/budget/biblio/documents/regulations/regulations_en.cfm)

- 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 #7: IA REQUIREMENTS FOR 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 partners<sup>69</sup> 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 consultation<sup>70</sup>.
- 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;

<sup>69</sup> Social partners' include employers' organizations 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.

<sup>70</sup> 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.

(k) the modernisation of social protection systems without prejudice to point (c).

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.

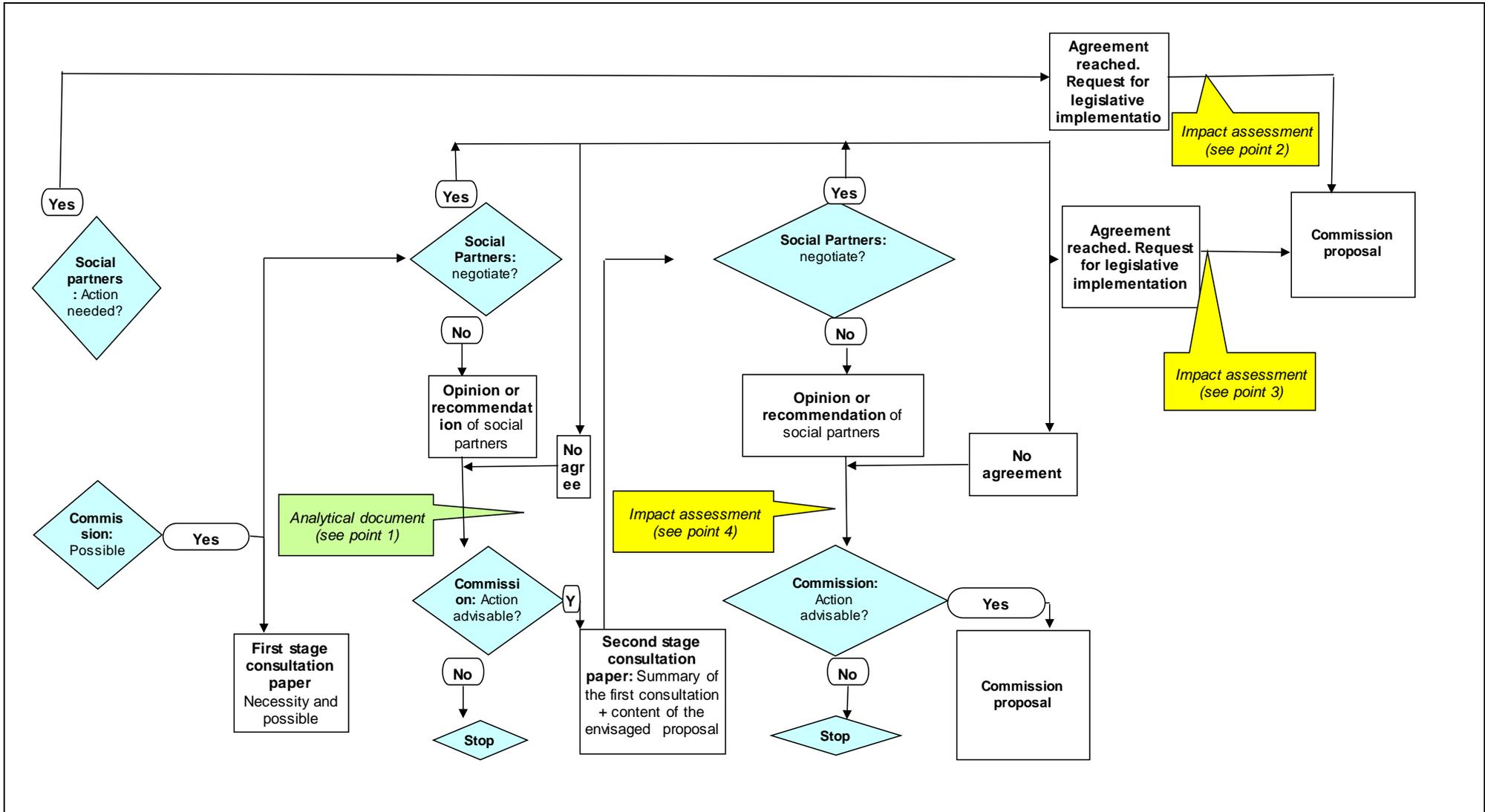
Whenever the impacts of the agreement are likely to be significant, before taking its decision, the Commission will carry out a proportionate impact assessment which will focus in particular on the representativeness of the signatories, the legality of the agreement vis-à-vis the EU legal framework and 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 policy-making process and the outlines the scope and/or depth of the required impact assessments.

<b>I. For the social partners' consultations prescribed by Art. 154</b>
<b><i>(1) Before the second stage of consultation</i></b>
<p>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 '<b>analytical document</b>'.</p> <p>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.</p> <p>The analytical document shall be based on necessary analysis and information and shall take into account the results of the first stage social partners' consultation<sup>71</sup>.</p>
<b>II. For social partners' agreements as provided for in Art. 155</b>
<b><i>(2) When considering an agreement concluded at the social partners' own initiative</i></b>
<p>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.</p> <p>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.</p>

<sup>71</sup> Stakeholder consultation guidelines and the minimum consultation standards do not apply at this stage.

<b><i>(3) When considering an agreement by the social partners after Art. 154 consultation</i></b>
<p>At this stage, the impact assessment should inform the Commission decision 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.</p> <p>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.</p>
<b>III. For Commission initiatives in social policy fields under Art. 153</b>
<b><i>(4) When considering a proposal in the absence of a social partners' agreement</i></b>
<p>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.</p>



## TOOL #8: 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.

DGs must 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 must also be clear who will be affected by the initiative and how.

The main IA report must be complemented by an **executive summary sheet** not exceeding 2 DGT standard pages. This summary sheet must be presented as a separate Staff Working Document and be translated into all EU languages. It should follow the format in Appendix 1.

### 2. GENERAL REQUIREMENTS FOR THE MAIN IA REPORT

The following general requirements must be respected:

- The main 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 but including tables and figures). If DGs believe there is a need to go beyond this, they must signal and discuss this with the impact assessment unit of the Secretariat-General (SG.C2) before the impact assessment is submitted to the Impact Assessment Board<sup>72</sup>;
- The main 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 annexes<sup>73</sup>;
- The IA report should be created in Microsoft word using the Eurolook "report" template;

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<sup>72</sup> Requests to be sent to the functional mailbox [SG-C-2@ec.europa.eu](mailto:SG-C-2@ec.europa.eu)

<sup>73</sup> 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 report must have a standard cover page created in legiswrite<sup>74</sup>;
- The report must contain a table of contents;
- Underlying data, statistics, information, expert contributions and stakeholder views must all be referenced particularly where choices are made or conclusions are made 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.

### 3. DETAILED STRUCTURE AND CONTENT OF THE MAIN IA REPORT

The report must 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 Guideline and how to structure the relevant sub-sections of the IA report. However, some issues should be reported in all IA Reports.

#### Section 1. 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 of the problem?
- Why is it a problem? What are the main drivers?
- Who is affected by the problem, in what ways, and to what extent? Whose behaviour would have to change to improve the situation?
- What is the EU dimension of the problem?
- How would the problem evolve, all things being equal?
- Has any fitness check/retrospective evaluation been carried out of the existing policy framework? What was concluded from the evaluation/fitness check?

#### Section 2. Why should the EU act?

*Issues to cover:*

- Does the EU have the right to act?

<sup>74</sup> [Legiswrite template CP-025\(SG-050\) – SWD linked;](#)

- Why could Member States not achieve the objectives of the proposed action sufficiently by themselves?
- What would be the added-value of action at EU-level?

### Section 3. What should be achieved?

#### Issues to cover:

- What are the general policy objectives? What are the more specific objectives?
- How do they link to the problem? How do the objectives relate to each other, i.e. are there any synergies or trade-offs?
- Are these objectives consistent with other EU policies and with the Charter for fundamental rights?

### Section 4. What are the various options to achieve the objectives?

#### Issues to cover:

- What are the possible options for meeting the objectives and tackling the problem? N.B. the option of changing nothing should always be considered (also known as the baseline) 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.
- 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.
- Who would be targeted by the different policy options? Has different digital solutions been considered?
- 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.

### Section 5. 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 should be covered unless one or two are clearly not relevant. Whenever this is the case, the IA report should explicitly say so.
- List positive and negative impacts, direct and indirect, intended and unintended, including those outside the EU;

- **Impact on SMEs:** The IA Report should 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 should 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.** Which actions/measures would those affected by the measure need to take to comply with the requirements (see also Annex 3). 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;
- 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 6. 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.

## Section 7. 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. In particular:
- Identify core monitoring indicators for the main policy objectives and the corresponding benchmarks against which progress will be evaluated;
- Verify that monitoring arrangements are in place from the outset and evaluations are designed and scheduled<sup>75</sup> 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 and evaluated, by whom and how the results will be used.

### **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 Inter-service Steering 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 – 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**

- A brief summary should be provided of the consultation strategy/process. You should provide details of how, who and on what you consulted. You should explain how you ensured that all relevant stakeholders have had an opportunity to provide an opinion on all key IA elements. In particular;

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<sup>75</sup> In both terms of having data already available and the right moment in the SPP cycle.

- Indicate if the Commission’s minimum standards have all been met, and, if not, why not.
- Indicate which groups of stakeholders have been consulted, at what stage in the IA process and how (public or targeted consultations);
- You should also include a more detailed summary of all relevant consultations and their results. This text should be factual and avoid drawing any conclusions based on the overall share of respondents favouring or opposing a measure.
  - The results should preferably be presented for each key IA element and differentiated across stakeholder groups.
  - 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.

### ***Annex 4. Analytical models used in preparing the impact assessment.***

When IA analysis relies on modelling, a dedicated annex presenting the following information must be included:

- A brief description of the model 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;
  - 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;

- Explanation as to how uncertainty has been addressed or minimised in the modelling exercise with respect to the policy conclusions; and
- The steps taken to assure the quality of the modelling results presented in the IA;
- A concise description of the baseline(s) 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).

### **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).

<b>Executive Summary Sheet (Max 2 pages)</b>
Impact assessment on [ <i>insert title: ...</i> ]
<b>A. Need for action</b>
<b>What is the problem and why is it a problem at EU level?</b>
<i>[Problems' size, probability of occurrence and expected evolution. Main drivers. Most affected stakeholders. EU-dimension. Reference to relevant fitness checks/ex-post evaluations.]</i>
<b>What should be achieved?</b>
<i>[Specify the main policy objectives.]</i>
<b>What is the value added of action at the EU level (subsidiarity)?</b>
<i>[Transnational aspects. Limits of Member States action. Why need to act at EU level.]</i>
<b>B. Solutions</b>
<b>What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?</b>
<b>What are different stakeholders' views? Who supports which option?</b>
<b>C. Impacts of the preferred option</b>
<b>What are the benefits of the preferred option (if any, otherwise of main ones)?</b>
<i>Provide summary of expected positive economic, social and environment impacts indicating quantitative estimates to the extent possible and referring to main beneficiary groups (incl. consumers, businesses, etc.).</i>
<i>Whenever the case, include a justification for lack of quantification.</i>
<b>What are the costs of the preferred option (if any, otherwise of main ones)?</b>

*Provide summary of expected negative economic, social and environment impacts providing quantitative estimates to the maximum extent possible and referring to main groups affected.*

*Please clarify magnitude and type of compliance costs and their sources.*

*Whenever the case, include a justification for lack of quantification.*

**What are the impacts on SMEs and competitiveness?**

*Confirm exemptions for micro-enterprises or lighter regimes for SMEs or clarify and explain reasons for different arrangements - Describe likely impacts on SMEs, including quantitative estimates as far as possible (e.g. of administrative and compliance costs) – Describe the impact on the most affected business sectors and their competitiveness – (Or state that there are none expected)*

**Will there be significant impacts on national budgets and administrations?**

*Also refer to any potential difficulties to transpose or implement this initiative for certain Member States.*

**Will there be other significant impacts?**

*No (why) / Yes [identify impact and provide reference to section in IA report]*

*Reference impacts are those outlined in IA guidelines and not already covered above. For instance, fundamental rights, international (third countries, trade and investment flows), regional, simplification, competition, digital, etc.*

**Proportionality?**

*Does the preferred option exceed what is necessary to solve the original problem and meet the objectives of the initiative?*

**D. Follow up**

**When will the policy be reviewed?**

*Refer to retrospective evaluation plans, foreseen policy reviews*

## TOOL #9: HOW TO UNDERTAKE A PROPORTIONATE IA

The IA process should provide the Commission with comprehensive evidence-based answers to the key IA questions. However, it should also avoid unnecessary effort that would not lead to further relevant insights. **The analysis should, in other words, be proportionate** i.e. of an appropriate scope and depth. 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 service, in cooperation with the inter-service 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.

#### 2.1. General factors

##### *The political importance of the initiative under consideration*

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 polarized views on the best policy option? Is the initiative particularly important in the inter-institutional context or for certain Member States? etc.

<p>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 inter-institutional decision-making process.</p>
<p><b><i>The stage of policy development</i></b></p>
<p>If an initiative <b>breaks new ground</b>, 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.</p>
<p>When <b>reviewing existing legislation</b>, a retrospective 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.</p>
<p>When preparing the IA for a <b>delegated act</b> or an <b>implementing measure</b>, 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 <b>transposing an international agreement</b> into EU law should focus on whatever margin of discretion exists for the Commission.</p>
<p><b><i>The magnitude and complexity of the problem being addressed</i></b></p>
<p>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.</p>
<p><b><i>The significance of the expected impacts</i></b></p>
<p>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 the caveat that some impacts may not be quantifiable). Similarly for the impacts that are likely to be irreversible.</p>
<p><b><i>The risk of negative unexpected consequences</i></b></p>
<p>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.</p>

## 2.2. Nature of the policy instrument

**The appropriate level and focus of the analysis is also linked to the type of policy initiative**, in particular by looking at how stringent requirements it would impose on Member States, citizens, businesses or any other economic/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 all<sup>76</sup>.

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.***

**IA should focus on:**

- Relevant problems and drivers, where relevant building on retrospective evaluation of existing policy framework;
- 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.

**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.

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<sup>76</sup> See tool 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/simplification initiatives**: clearly spell out the simplification benefits and quantify these as far as possible;
- Clear identification of who will be affected and how; measurement of compliance costs and administrative burden;

#### **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 compliance costs and administrative burden;
- 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 instruments<sup>77</sup> and initiatives in the social policy field pursuant Articles 154-155 TFEU<sup>78</sup>.

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<sup>77</sup> See tool on IA requirements for spending programmes.

<sup>78</sup> See tool on IA requirements for social partner agreements.

## TOOL #10: STAKEHOLDER CONSULTATION IN THE CONTEXT OF AN IA

### 1. INTRODUCTION

Consulting interested parties is an obligation for every IA and it must follow the minimum standards and guidelines described in the Stakeholder Consultation chapter V of the Better Regulation guide. The objective is to consult those who will be affected by a new policy initiative and those who will implement it. Their views, practical experience and data will help deliver higher quality and more credible proposals. It also gives greater transparency and legitimacy to the policy development process and will contribute to a more successful policy implementation.

#### *Box 1. Key principles of stakeholder consultation in the context of an IA*

- Plan your consultation strategy early. The Inception IA should already set out the key elements of the strategy including any specific evidence needs or gaps;
- Your consultation strategy should include a 12-week internet-based public consultation but should be complemented by other approaches and tools in order to engage all relevant stakeholders and to target potential information gaps. Consultation documents should be agreed in the ISG.
- Ensure that stakeholders can provide comments on all IA elements, i.e. the problem, the question of subsidiarity, the policy options and their impacts;
- Make information available about the contributions received for each consultation undertaken.
- Analyse stakeholders' contributions for the decision-making process and inform on stakeholder views throughout the IA report. A synopsis report outlining the overall results of the consultation work and providing feedback must be published on the consultation website and added as an annex to the IA Report.

### 2. WHAT SHOULD THE CONSULTATION IN THE IA CONTEXT COVER?

**Stakeholders must be consulted on all IA elements in the IA process.** The key issues which must be addressed are therefore:

- The problem to be tackled;
- The issue of subsidiarity and the EU dimension to the problem;
- The available policy options; and
- The impacts of those policy options.

Given the variety of Commission initiatives accompanied by IA, there is no one-size-fits-all solution on how this should be done and at which stage of your IA process. A wide-ranging, open internet based consultation is, however, necessary for all impact assessments as it ensures transparency and accountability and gives any interested party the possibility to contribute. This can be complemented with more 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 questions.

The Inception IA is published on the Commission's web site and sets out the basic elements of the impact assessment including the problem definition, subsidiarity issues, policy objectives, policy options and a preliminary assessment of the impacts associated with these policy options. Stakeholders will be able to provide feedback on the Inception IA which should be considered by the ISG in taking the IA process forwards.

### 3. HOW TO CONSULT IN THE IA PROCESS

Depending on each case, you may choose to use the stakeholder consultation either to collect views and information in relation to the IA questions, or to test/validate already existing analysis/evidence. Before deciding on how to consult in the IA process, you should therefore answer the following key questions:

- Have stakeholders already been consulted on the Commission's assessment/definition of the problem, its relevance for the EU, possible solutions and their impacts (e.g. in a preceding evaluation)?
- Are there sensitive or controversial issues, diverging views or high uncertainty?
- Are there issues that we may not be aware of (for example, due to unintended consequences)?

**Box 2. Type of questions for key IA elements**

Objective/element	Problem	Subsidiarity	Options	Impacts
<b>Testing preliminary analysis</b>	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?
<b>Collection of views/information</b>	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?

In practice, your consultation strategy for the IA will include a combination of consultation methods (i.e. open/targeted) and tools (i.e. questionnaire, document, meeting, hearing, workshop), depending on the type of your initiative, its stage of preparation and the replies to the questions above.

When stakeholder consultation is used for **collecting information** (i.e. evidence such as data, expertise etc.), you need to *verify* that the method you use is appropriate for collecting the required type of information in view of its reliability, accuracy etc.<sup>79,80</sup>.

#### 4. PLANNING YOUR CONSULTATIONS

In order to optimise your impact assessment process, you need to plan your consultations early – key elements of your consultation strategy should be described in the Inception IA and be closely interlinked with the timing of the key IA steps and your strategy for collecting evidence. Following the Inception IA's publication on the Europa website, stakeholders have the opportunity to provide feedback on the outlined elements (including a first description of the problem, subsidiarity, possible policy options and their impacts). You should be therefore prepared to assess this initial feed-back and feed it into your IA work.

**The consultation strategy and draft consultation documents should be discussed and agreed with the members of the Inter-service Group (ISG) before the consultation is launched.** In sensitive cases where views are difficult to reconcile, a formal inter-service consultation may be needed. Your consultation strategy should include information on:

- the relevant stakeholders (i.e. general public, a specific category of stakeholders or designated individuals/organisations - SMEs, regions, MS authorities, NGOs, consumer organisations) and results of consultations carried out so far;
- the objectives for each individual consultation steps, i.e. on the analysis of problem, subsidiarity, description of options and impacts - be it collecting information, views or testing existing analysis/evidence;
- The foreseen consultation methods and tools for engaging with the affected stakeholders (i.e. open consultation, seminars/workshops, surveys, open hearings etc.);
- Timing of the proposed consultation work and operational arrangements (i.e. internal and external resources, translations<sup>81</sup>, deadlines, etc.);

For general guidance on how to do stakeholder consultations, please see the main Guidelines in relation to stakeholder consultation.

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<sup>79</sup> See tool on consultation methods.

<sup>80</sup> See tool on evidence gathering.

<sup>81</sup> 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. See also the table on "Accessibility of consultations" in the Guidelines on stakeholder consultation.

## **5. CONSULTATION RESULTS AND REPORTING**

Irrespective of the chosen mix of consultation methods and tools, the consultation results should feed into and inform your impact analysis. You should avoid, therefore, organising your consultations too late in the IA process.

To best integrate the consultation results into your IA process, you should:

- Take stock of the contributions or consultation results received with the ISG and discuss how they should be taken into account in the IA;
- Adapt your IA and consultation plan as relevant (for example as regards further consultation needs).

Apart from being a key part of your IA work, stakeholder consultations also require significant time and effort on the part of stakeholders. It is essential, therefore, that you present clearly the results of the consultation in your IA report<sup>82</sup>.

## **6. CONSULTATION OF SPECIFIC GROUPS OF STAKEHOLDERS**

Besides respecting specific consultation frameworks, you should keep in mind that not all interest groups are equally able to take part in consultations or express their views with the same force. You may need, therefore, to make specific efforts to ensure that all relevant stakeholders are both aware of, and able to contribute to, the consultation. To make sure all relevant stakeholders are consulted across the economic, social and environmental areas, you should consult the ISG members.

### **6.1. Social partners**

Social partners need to be specifically consulted in case of initiatives in the field of social policy or with social implications. A distinction should be made between initiatives in the field of social policy and initiatives with social implications for a specific sector:

### **6.2. Social policy measures**

There are specific Treaty provisions for consulting social partners (management and labour), regarding initiatives in the field of social policy e.g. health and safety in the workplace, working conditions, social security and social protection of workers, and information and consultation (see Treaty Articles 153-155 TFEU, and particularly Article 153 TFEU on the policy fields concerned). This consultation process includes two stages: first, social partners are consulted on the general direction of an initiative; then, in a second stage, on its actual content. Therefore, minimum standards for consultation do not apply to social dialogue, but they do apply to other types of stakeholder consultations in the employment and social affairs field.

### **6.3. Initiatives with social implications for a specific sector**

Sectoral social dialogue committees, for the sector of activity for which they are established, should be consulted on developments at Union level having social

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<sup>82</sup> See tool on IA report format.

implications. You should therefore verify whether your initiatives will create social implications for a sector for which a sectoral social dialogue committee exists<sup>83</sup>. If that is the case, a consultation of the committee should be organised with the assistance of DG EMPL.

#### **6.4. Consumers/consumer organizations/patient groups**

A consumer consultation toolbox is available for proposals with an impact on consumers<sup>84</sup>. The Consumer consultation toolbox includes:

- Consultation of the European Consumer Consultative Group (ECCG)<sup>85</sup> which is composed of European and national consumer organisations;
- Direct consultation of consumers through other tools such as Eurobarometers<sup>86</sup>, Focus groups<sup>87</sup>, Citizens juries<sup>88</sup>, public hearings, town meetings<sup>89</sup>.
- Whenever health impacts are identified, it is advised to consult the Health Policy Forum to get input from public health actors including patients groups<sup>90</sup>.

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<sup>83</sup> See also tool on IA requirements for Social Partner Agreements.

<sup>84</sup> <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=tools>

<sup>85</sup> The European Consumer Consultative Group is a consultative group of the Commission, established by Commission Decision 2003/709/EC of 9 October 2003.

<sup>86</sup> Standard and Special Eurobarometer: (example: EB on Consumer protection in the Internal Market). It is used by DG COMM for its general set of questions on EU-related issues. This instrument is well suited for in-depth cross analysis and for relatively long questionnaires. It uses face-to-face interviewing techniques, interviewing a sample of around 1000 respondents per Member State (depending of the population of the country). Flash Eurobarometer: (example - Businesses attitudes on Cross-border sales and consumer protection). It is well adapted to short and simple questionnaires, for which results are needed relatively rapidly. Flash surveys allow the targeting of specific groups (SME managers, farmers, teachers, etc.).

<sup>87</sup> This tool is efficient to make an in-depth study of the attitudes of a selected social group towards a given subject (example: focus group on consumers' opinions on Services of General Interest). However, results cannot generally be extrapolated to the whole population. The methodology uses focus groups of 8 to 10 persons or individual interviews. The discussion guide is non-directive, and leaves some room for spontaneous expression.

<sup>88</sup> Small panel of non-specialists. Similar to a criminal jury, carefully examine an issue of public significance and deliver a verdict. Good for developing creative and innovative solutions to difficult problems.

<sup>89</sup> The aim of these meetings is to directly involve "citizens" in the decision-making process. In these meetings a representative group of citizens is invited to comment and suggest policy options for a specific legislative initiative or a project. This tool is notably used in the US. Since 1997, America Speaks has organized Town Meetings in 31 US States. Meetings have addressed local, state and national decisions on a broad range of issues.

<sup>90</sup> See at: [http://ec.europa.eu/health/ph\\_overview/health\\_forum/policy\\_forum\\_en.htm](http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm)

## 6.5. SMEs

SME consultations may be conducted through the Enterprise Europe Network.<sup>91</sup> The tool is constructed in a way that allows the Commission services to reach SMEs in a targeted way, given that Network partners are well placed in their regions to identify companies that will be the most affected by the subject of the consultation. It's an optional tool for sectoral and targeted SME consultation. Thanks to the broad geographic coverage and the high number of Network partners, this tool has a potential to provide substantial results compared to other ways of consultation. Questionnaires are translated and the advantage of the Network is that the Network Partners run the SME panel consultation in their regions, collect the questionnaire and encode them in EU Survey in English.

There are some formal requirements for a questionnaire for an SME panel consultation: the questionnaire should be short (max 15 questions) and should be written in a clear plain language (to make it easy to translate for the national partners).<sup>92</sup>

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<sup>91</sup> Managed by DG GROW

<sup>92</sup> See tool on the SME test.

## TOOL #11: HOW TO ANALYSE PROBLEMS

### 1. INTRODUCTION

The first step of an IA is to verify the existence of a problem 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. Key inputs to this assessment will be retrospective evaluations, fitness checks, implementation reports and infringements of existing Union legislation.

The answer to these questions should give decision makers the information necessary to decide whether a policy response is warranted.

While inefficient regulations, market failures, etc., can all be targeted by policy initiatives, it is important that the problem analysis identifies the drawbacks for citizens and enterprises and the behaviour (i.e. of enterprises, consumers, workers, citizens, public authorities, etc.) that would need to change.

### 2. THE FIVE KEY ISSUES TO ASSESS

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

<b>A. Establish what the problem is and why it is problematic (i.e. its negative consequences).</b>	
Why?	To identify the issues that might have to be addressed.
How?	Clearly but succinctly describe the current situation (the "status quo").
	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 (for instance, international competitiveness disadvantages, lack of coherence with EU development objectives etc.)

<b>B. Assess the magnitude and EU dimension of the problem</b>	
Why?	To show whether a problem is relevant or not.
How?	The extent to which a problem can be "quantified" or even "monetized" 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. <sup>93</sup>
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### C. Establish the causes ("drivers") and assess their relative importance.

Why?	To help identifying policy options which address the problem.
How?	Map the main underlying causes (drivers) of the problem. 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.
	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.
	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), 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 <b>no-policy change</b> , or <b>baseline, scenario</b> against which the impacts of policy options will be measured and compared.
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.

<sup>93</sup> See tool on subsidiarity and proportionality

	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 <sup>94</sup> .
	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) should also be taken into account. The same applies to EU proposals put forward by the Commission but not yet approved by the co-legislators.
	The hypotheses underlying the analysis must 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**") must 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 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.

<sup>94</sup> See tool on impacts on ICT, the digital economy and Society for more detailed guidance.

### 3.1. Market failures

<b>A. Externalities</b>	
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 <sup>95</sup>	Either aim to ensure prices better reflect ("internalize") 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>B. Public goods</b>	
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

<sup>95</sup> This is a non-exhaustive list providing examples of policies that have been used to target specific drivers.

	supplied, a public good is available to be consumed by everybody in society. It is difficult, therefore, and/or undesirable from a societal perspective to charge individuals directly for consuming the good or service in question and consumers can take a "free ride" without having to pay for the good or service.
Examples	National defence is a public good as all people in a nation "consume" the same amount of national defence (provided by the government) and the benefits for each person do not depend on how much a person contributes towards providing it. Other examples are public health and welfare programmes, 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 Treaty on the Functioning of the European Union requires the Member States and the Union to conduct their economic policies in accordance with the principle of an open market economy with free competition that favours an efficient allocation of resources. If firms face no, or only weak competition, then the quantity and quality of goods and services they produce may fall short of the socially efficient level.
Examples	<p>Signs of insufficient competition are unusually high profits, or prices which are much higher than marginal cost, or signs of collusion between firms to fix prices as may be possible when there is only one enterprise (monopoly) or a limited number of firms supplying the market from either within the EU or globally.</p> <p>Where technology is such that it is efficient for a single firm to supply the entire market, we talk of economies of scale and a resulting "natural" monopoly. 'Network' industries – transport, energy, and telecommunications – may exhibit some features of natural monopolies (cf. retail energy suppliers, residential telephone cables).</p>
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

	<p>charges would be insufficient.</p> <p>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.</p>
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.

<b>E. Split markets – Principal-Agent</b>	
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	<p>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.</p> <p>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.</p>
Possible policies	Financial incentives such as taxes can change/encourage different behaviour and/or the take-up of different products. Regulation can re-define 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.

<b>F. Imperfect information</b>	
Issue?	Market players may have imperfect information leading to sub-optimal societal outcomes.
Relevance?	<p>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.</p> <p>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).</p>
Examples	<p>As information on the energy consumption of different models of household appliances, or passenger cars, or the nutritional content of foodstuffs is costly to acquire, consumers' choices may not take these factors into account when buying.</p> <p>Since lenders cannot easily / cheaply distinguish between good and bad</p>

	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 a retrospective **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. Examples could include, tackling discrimination based on race, gender, sex, sexual orientation, age or disability. Protection and fulfilment of fundamental rights afforded to citizens of the Union may also provide grounds for intervention.

### 3.4. Behavioural bias

Markets forces will deliver an efficient outcome as long as there are no market failures (see above) 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.

Four key issues identified by behavioural economics are particularly relevant for both the justification of a policy and its design<sup>96</sup>. First, choices are influenced by the simplicity of information and of 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.

#### *Box 1. 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.

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<sup>96</sup> "Behavioural Economics and Regulatory Policy", Dr Peter Lunn; GOV/RPC(2013) 15, 22 October 2013, Organisation for Economic Co-operation and Development.

## TOOL #12: RISK ASSESSMENT AND MANAGEMENT

### 1. INTRODUCTION

Assessing risks<sup>97</sup> 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 Commission<sup>98</sup>, either on a stand-alone basis or by feeding into the IA process. A large number of these decisions do not necessitate an IA as they are taken on a case-by-case (e.g. substance by substance) basis, implementing risk management approaches determined in the basic legislation<sup>99</sup>.

However, in cases where impacts are likely to be significant, sufficient discretion exists and/or the decision deviates from the advice of risk assessors, an impact assessment may be required<sup>100</sup>. 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 principle<sup>101</sup>. In such cases, the results of the risk assessment are fed into the IA process.

### 2. WHAT IS 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.

#### ***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

<sup>97</sup> 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 IA tool on modelling and uncertainty analysis (see IA tool on modelling and uncertainty analysis).

<sup>98</sup> Note that EASA can also take risk management decisions.

<sup>99</sup> In areas such as food/feed safety, animal health, plant health, animal welfare, medicinal products, medical devices, cosmetics, biocides, chemicals.

<sup>100</sup> Emergency measures (to prevent contagion/spread of a disease etc.) would generally be exempt.

<sup>101</sup> COM(2000) ; Communication on the precautionary principle

expresses the combination of the level of hazard and the likelihood of its occurrence.

*Risk = Hazard (expressed in terms of its negative impact)\*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 must be expressed as a functional relationship rather than a simple multiplication of both variables<sup>102</sup>.

In today's society, where potential risks are numerous and inter-related, **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.

### 3. HOW TO ASSESS RISK?

In conjunction with the in-house expertise of the Commission services<sup>103</sup>, 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, EASA<sup>104</sup>);
- Scientific Committees set up by the Commission<sup>105</sup> (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

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<sup>102</sup> For more details, see for example SEC(2010)1360.

<sup>103</sup> With the exception of JRC that is referred to later on as a dedicated scientific body

<sup>104</sup> European Food Safety Authority, European Chemicals Agency, European Medicines Agency, European Centre for Disease Prevention and Control, European Aviation Safety Agency.

<sup>105</sup> 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 occur<sup>106</sup>.
- (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 them<sup>107</sup>.

**Uncertainty** is inherent in every stage of risk assessment. Irrespective of the different definitions and classifications of uncertainty<sup>108</sup>, 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 evaluated<sup>97</sup> 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).

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<sup>106</sup> 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.

<sup>107</sup> See tool on methods to assess costs and benefits (including non-market impacts).

<sup>108</sup> 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 comprehensive risk assessment (because of the lack of knowledge), or to (b) determine the risk with sufficient certainty (as the sensitivity analysis may conclude<sup>109</sup>). 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 protection<sup>110</sup>. Proportionate risk management measures may then be based on the precautionary principle together with collection of additional evidence and review<sup>111</sup>.

#### 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 possible as they are less restrictive and lead to an internalisation of negative effects (and thus an efficient outcome)<sup>112</sup>.

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<sup>109</sup> See tool on the use of analytical models.

<sup>110</sup> 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.

<sup>111</sup> 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.

<sup>112</sup> See tool on the choice of policy instrument.

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.

## 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.](#)

### 7.2. 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.

### **7.3. 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 #13: HOW TO SET OBJECTIVES

### 1. INTRODUCTION

Objectives link the analysis of the problem 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.<sup>113</sup>

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

Objectives setting	
<i>After the analysis of the problem</i>	
<b>General</b>	These are the Treaty-based goals which the policy aims to contribute to.
<b>Specific</b>	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>After identifying the preferred option</i>	
<b>Operational</b>	These are defined in terms of the deliverables of policy actions. As such, they are typically option-specific. These should not, therefore, be reported in the same place in the IA Report <sup>114</sup> as the general and specific objectives but reported in the section referring to the preferred policy option and in relation to monitoring and evaluation.

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

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

What are S.M.A.R.T. objectives?	
<b>Specific</b>	Objectives should be precise and concrete enough not to be open to varying interpretations by different people.
<b>Measurable</b>	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.
<b>Achievable</b>	Policy aims must be set at a level which is ambitious but at the same time realistically achievable.
<b>Relevant</b>	The objectives should be directly linked to the problem and its root causes.
<b>Time-Bound</b>	Objectives should be related to a fixed date or precise time period to allow an evaluation of their achievement.

<sup>113</sup> See tool on monitoring and evaluation.

<sup>114</sup> See tool on the format of the IA Report.

When objectives are multiple and inter-related, it is important to highlight the links between them, particularly any possible trade-offs. When problems are complex and have many underlying drivers, numerous objectives are often identified, be they general, specific or operational. In these cases, an "objectives tree" can be used to depict graphically the relations among different goals<sup>115</sup>.

### Example of a hierarchy of policy objectives

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

Source: SWD(2014) 118 final

<sup>115</sup> See tool on the use of visual aids.

## TOOL #14: 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 4 STEPS TO FOLLOW

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

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

<b>I. Consider a wide variety of policy options (content and tools/instruments).</b>	
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.
	Policy options must 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 <sup>116</sup> .
	Do not forget to ask for stakeholders' ideas and opinions.
	Make sure to consider those options that can count on considerable support among stakeholders, experts, policy-makers, Member States and other EU institutions.  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>The "No policy change" baseline scenario<sup>117</sup></i>

<sup>116</sup> See Chapter III of the Main BR Guidelines and the tool on ICT assessment, the digital economy and society.

	<p>A good baseline scenario should have a strong factual basis and, as far as possible, be expressed in quantitative terms. It should also factor in as far as possible important technological/societal developments such as the pervasive nature of the internet and social media which by themselves are bringing about large changes.</p> <p>It should also be set for an appropriate time horizon. The length of the latter depends on the likely life-time of any individual option and on the need to allow for impacts to be realised.</p>
	<i>Alternative policy responses</i>
	<p>Consider alternative types of policy responses to reach the objective as regards the content/design of the measure. For instance:</p> <p>Could the objectives be reached through alternative basic policy approaches? If there are clear arguments in favour of a particular general policy approach, are there different options for the more detailed parameters of the initiative?</p> <p>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)?</p> <p>Whenever EU policy already exists, could the objective be reached by improving implementation and/or enforcement of existing legislation? Ways to facilitate better policy-making by Member States could also be considered.</p> <p>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.</p> <p>Consider non-regulatory alternatives (such as self- or co-regulation<sup>118</sup>), market-based solutions which should respect the best-practice principles developed by the Commission services<sup>119</sup>.</p> <p>When revising an existing intervention, you should always consider ways to achieve the existing objectives <b>more simply and cheaply and to limit the administrative burdens</b> of those affected by the policy.</p>

II. 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.
	The key <b><u>criteria for screening</u></b> the viability of your options are:

<sup>117</sup> See tool on how to analyse problems.

<sup>118</sup> See the principles for better self- and co-regulation at <http://ec.europa.eu/digital-agenda/en/principles-better-self-and-co-regulation-1>.

<sup>119</sup> <http://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>.

	<i>Legal feasibility</i>
	Options must 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 uncontrovertibly 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.

<b>III. Check the suitability of the set of retained options</b>	
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.).

	<p>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.</p> <p>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.</p> <p>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 IAR when significant impacts depend upon it. Otherwise, considering a different level of aggregation may be more appropriate for the main text of the IAR.</p>
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<b>IV. Outline the retained options in greater depth</b>	
Why?	<p>To allow the identification of the impacts of alternative options.</p> <p>For transparency.</p>
How?	<p>Options should be sufficiently well developed to allow you to differentiate them on the basis of their performance in achieving the identified objectives.</p> <p>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-co-regulatory nature). Enough detail on their actual content should be provided for the analysis of impacts to provide insights on the key elements for political choice (e.g. level of benefits and costs, distributional impacts, impact on SMEs, citizens, EU competitiveness, sustainability, etc.).</p> <p>Similarly, remember that you will have to finalize the analysis of compliance with the subsidiarity principle as well as show the proportionality of any preferred option.</p>

## TOOL #15: 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 strictly 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 particular<sup>120</sup>;

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.

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 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

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<sup>120</sup> See tool on subsidiarity and proportionality.

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 of the Treaty on the Functioning of the EU (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 Directive<sup>121</sup> sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.
- The working time directive<sup>122</sup> 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 Biocides Regulation sets out the detailed rules concerning the making available on the market and the use of biocidal products<sup>123</sup>;
- The Effort Sharing Decision<sup>124</sup> 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,

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<sup>121</sup> Directive 2010/75/EC

<sup>122</sup> Directive 2003/88/EC

<sup>123</sup> Regulation (EC) No 528/2012

<sup>124</sup> Decision No 406/2009/EC

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 recognized in the field (such as economic operators, social partners, non-governmental organizations, or associations). 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 can foster innovation. Co-regulation can remove barriers to the single market, simplify rules and can be implemented flexibly and quickly. The New Legislative Approach type of legislation (see box 4) falls within this category.

#### ***Box 2. Examples of self & co-regulation***

##### ***Reduction of CO<sub>2</sub> emissions from cars***

The Commission previously recognised voluntary agreements with the European, Japanese and Korean car manufacturers to reduce the CO<sub>2</sub> 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 CO<sub>2</sub> 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 140 g CO<sub>2</sub>/km by 2008/2009, but that the Community objective of 120 g CO<sub>2</sub>/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 120 g CO<sub>2</sub>/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 CO<sub>2</sub> to reach an objective of 130 g CO<sub>2</sub>/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"<sup>125</sup>, 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 anymore to follow up on the implementation although DG CNECT continues to monitor the initiative, yet without concrete milestones/actions planned.

The success of self- and co-regulation depends in essence on several key factors which include: representativeness, transparency, legal compliance and effective implementation and monitoring.<sup>126</sup> The Commission services have prepared a set of best practice principles which should be reflected in all self and co-regulation initiatives<sup>127</sup>. These are divided into two phases: the inception phase and the implementation phase. In the inception phase every self-/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-/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/co-regulation initiatives cannot a priori be excluded from any policy area. However, based on the information available in the monitoring database run by the EESC<sup>128</sup>, 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.

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<sup>125</sup> <http://ec.europa.eu/digital-agenda/en/self-regulation-better-internet-kids>

<sup>126</sup> Based on EESC SMO report "European Self- and Co-Regulation" ([http://www.eesc.europa.eu/resources/docs/auto\\_coregulation\\_en--2.pdf](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>.

<sup>127</sup> <http://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>

<sup>128</sup> <http://www.eesc.europa.eu/?i=portal.en.smo-database>

### ***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; 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.)

### **3.2. Technical standards**

Standards are 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 Organisation standardisation organisations (ESOs). European standardisation is a key instrument for consolidating the Single Market, supporting competitiveness of European industry at global market, harmonising conflicting national standards and facilitating cross-border trade in a less intrusive manner than technical regulations. The Commission has an active standardisation policy<sup>129</sup> and co-operation agreements<sup>130</sup> with the ESOs.

Regulation (EU) No 1025/2012<sup>131</sup> 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 any regulating or they (like “harmonised standards”) enable legislation which may concentrate only to essential requirements and

<sup>129</sup> [http://ec.europa.eu/growth/single-market/european-standards/policy/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/policy/index_en.htm)

<sup>130</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52003XC0416%2803%29>

<sup>131</sup> OJ L 316, 14.11.2012, p. 12–33

where technical details can be given in voluntary standards. The Regulation sets also requirements to the ESOs for the transparency of their standardisation work programmes and standards, requirements on the 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 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 recognized<sup>132</sup> European standardisation organisations (ESOs): the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) or the European Telecommunications Standards Institute (ETSI).
- The ESOs are private organisations and they bring together industry, other stakeholders and the National standardisation bodies of EU/EEA and of some neighbouring countries. Once a European standard is developed and agreed, the National standardisation bodies, who are members of the ESOs, must 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'<sup>133</sup> which support application of Union's harmonisation legislation for products (**New Legislative Framework**<sup>134</sup>). 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, provides tools, databases and guidance<sup>135</sup> how to use voluntary European standardisation in support Union legislation and policies and co-ordinates the preparation of standardisation requests<sup>136</sup> to the ESOs.

<sup>132</sup> Annex I of Regulation (EU) No 1025/2012 on European standardisation

<sup>133</sup> [http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm)

<sup>134</sup> [http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm)

<sup>135</sup> [http://ec.europa.eu/growth/single-market/european-standards/vademecum/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/vademecum/index_en.htm)

<sup>136</sup> [http://ec.europa.eu/growth/single-market/european-standards/requests/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/requests/index_en.htm)

### 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 citizens<sup>137</sup>. 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 5. Example of Recommendations:***

- **Commission Recommendation** on access to a basic payment account – this IA assesses several instruments<sup>138</sup>
- **Council Recommendation** on the validation of non-formal and informal learning<sup>139</sup>

### 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.

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

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<sup>137</sup> E.g. [Recommendation 2002/236/EC](#)

<sup>138</sup> [http://ec.europa.eu/governance/impact/ia\\_carried\\_out/docs/ia\\_2011/sec\\_2011\\_0906\\_en.pdf](http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2011/sec_2011_0906_en.pdf)

<sup>139</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0252:FIN:EN:PDF>

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. INFORMATION**

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

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

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

A good example of an effective consumer information scheme is the energy labelling of energy using products<sup>140</sup>.

#### **5. ECONOMIC INSTRUMENTS**

Market-based instruments (MBIs) include taxes, charges, 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”<sup>141</sup>. 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-

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<sup>140</sup> Directive 2010/30/EC; [http://ec.europa.eu/energy/efficiency/labelling/labelling\\_en.htm](http://ec.europa.eu/energy/efficiency/labelling/labelling_en.htm)

<sup>141</sup> Organisation for Economic Co-operation and Development (OECD). 1994. *Managing the environment: the role of economic instruments*. OECD, Paris.

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 disadvantages are 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 System<sup>142</sup>.

**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 proposal to overhaul the outdated rules on the taxation of energy products in the European Union and take into account both their CO<sub>2</sub> emissions and energy content<sup>143</sup>.

## 6. COMBINATIONS OF INSTRUMENTS AND BEHAVIOURAL ECONOMICS

Some combinations of instruments are naturally complementary. For example, information strategies are unlikely to be wholly effective on their own but they will nonetheless be important as complements to other instruments. Monitoring information 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 theory and empirical studies are available. Assumptions about the behaviour of individuals and businesses based on classical rational choice theory are not necessarily observed in practice. Behavioural biases can influence these more classical policy

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<sup>142</sup> Directive 2003/87/EC, 13 October 2003, OJ L 275, 25.10.2003, p.32

<sup>143</sup> [http://ec.europa.eu/taxation\\_customs/taxation/excise\\_duties/energy\\_products/legislation/index\\_en.htm](http://ec.europa.eu/taxation_customs/taxation/excise_duties/energy_products/legislation/index_en.htm)

analyses. The IA tool on problem drivers provides several examples where the design or the intensity of the instrument is affected by behavioural insights<sup>144</sup>.

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<sup>144</sup> See tool on how to analyse problems

**Chapter 3**  
**How to identify impacts in Impact Assessments, evaluations**  
**and Fitness Checks**

## TOOL #16: 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 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:  <b>Citizens</b> – Whenever changes are widespread and do not affect any particular sub-group.  <b>Consumers</b> – Whenever users of a particular product / service are affected.  <b>Workers</b> – Whenever employees in general or in a specific industry are affected.  <b>Enterprises</b> – Again, 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.  <b>Public authorities</b> – Distinguish between EU, national and sub-national levels as appropriate.  <b>Third countries</b> – Whenever they are directly affected. Relevant sub-groups 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 <b>comply</b> 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 <b>implement, monitor and enforce</b> a new legislative requirement?
	Is <b>any other action</b> 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 ("second-order") changes and so on. These can be as important as first round 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 first-round 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 maximizing societal welfare.
	Specifically relevant objectives will vary from initiative to initiative and from option to option.
	An indicative table is provided in the Appendix below. Specific IA tools or indicative lists of issues are provided for most. 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. STEP1: 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 impacts<sup>145</sup> follows at the end of this section.

<i>Overview of key impacts to be screened</i>		
<b>Economic</b>	<b>Social</b>	<b>Environmental</b>
Growth and investment	Employment	Fighting climate change
Sectoral competitiveness	Working Conditions	Fostering the efficient use of resources (renewable & non-renewable)

<sup>145</sup> The obligation to screen these impacts is the consequence of the Treaty on the Functioning of the European Union (Articles 8-14).

Facilitating SMEs growth	Income distribution and social inclusion	Preserving the quality of natural resources / fighting pollution (water, soil, air etc.)
Achievement of the Single Market	Health & safety	Protecting biodiversity, flora, fauna and landscapes
Increased innovation and research	Social protection	Reducing and managing waste
Technological development / Digital economy	Education	Minimizing environmental risks
Increased international trade and investment	Security	Protecting animal welfare
Competition	Governance & good administration	
Energy independence	Preserving the cultural heritage / multi-linguism	
Deeper and fairer economic and monetary union	Crime, Terrorism and Security	
	Social protection, health and educational systems	
	Cultural heritage	
Economic and social cohesion		
Impacts in developing countries		
Sustainable development		
<b>Fundamental Rights</b> <ul style="list-style-type: none"> <li>• General impacts</li> <li>• Dignity</li> <li>• Individuals, private and family life, freedom of conscience and expression</li> <li>• Personal data</li> <li>• Asylum and protection of removal, expulsion or extradition</li> <li>• Property rights and the right to conduct a business.</li> <li>• Gender equality, equality treatment and opportunities, non –discrimination, rights of persons with disabilities.</li> <li>• Rights of the child</li> <li>• Good administration / Effective remedy/ Justice</li> </ul>		

### 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.**

<b><i>The relevance of the impact within the intervention logic</i></b>
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.
<b><i>The absolute magnitude of the expected impacts</i></b>
The analysis should also focus on those impacts with the greatest magnitude.
<b><i>The relative size of expected impacts for specific stakeholders</i></b>
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.
<b><i>The importance of impacts for Commission horizontal objectives and policies</i></b>
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 Inter-service Steering 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 SG) 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<sup>146</sup> and costs and benefits<sup>147</sup> 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.

<b>Economic impacts</b>	<b>Key impacts</b>
<b>Operating costs and conduct of business</b>	<ul style="list-style-type: none"> <li>• Will it impose additional adjustment, compliance or transaction costs on businesses?</li> <li>• How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)?</li> <li>• Does it affect access to finance?</li> <li>• Does it impact on the investment cycle?</li> <li>• Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited?</li> <li>• Will it entail stricter regulation of the conduct of a particular business?</li> <li>• Will it lead to new or the closing down of businesses?</li> <li>• Are some products or businesses treated differently from others in a comparable situation?</li> </ul>
<b>Administrative burdens on businesses</b>	<ul style="list-style-type: none"> <li>• 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)?</li> </ul>
<b>Trade and investment flows</b>	<ul style="list-style-type: none"> <li>• How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods?</li> <li>• How will investment flows be affected and the trade in services?</li> <li>• Will the option give rise to trade, customs or other non-trade barriers?</li> <li>• Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered?</li> </ul>
<b>Competitiveness of business</b>	<ul style="list-style-type: none"> <li>• 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?</li> <li>• What impact does the option have on business' capacity to innovate i.e. its ability to produce more/higher quality products and services that meet customers' expectations?</li> <li>• What impact does the policy option have on business' market share and comparative advantages in an international context (e.g. imports, exports, investment flows, trade barriers, regulatory convergence, etc.)?</li> </ul>
<b>Position of SMEs</b>	<ul style="list-style-type: none"> <li>• What is the impact of identified additional costs and burdens on the operation and competitiveness of SMEs and micro SMEs in particular?</li> </ul>

<sup>146</sup> Chapter 3 of the tool box

<sup>147</sup> See Chapter 8 of the toolbox.

<b>Economic impacts</b>	<b>Key impacts</b>
<b>Functioning of the internal market and competition</b>	<ul style="list-style-type: none"> <li>• What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers?</li> <li>• 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.?</li> </ul>
<b>Innovation and research</b>	<ul style="list-style-type: none"> <li>• Does the option stimulate or hinder research and development?</li> <li>• Does it facilitate the introduction and dissemination of new production methods, technologies and products?</li> <li>• Does it affect the protection and enforcement of intellectual property rights (patents, trademarks, copyright, other know-how rights)?</li> <li>• Does it promote or limit academic or industrial research?</li> <li>• Does it promote greater productivity/resource efficiency?</li> </ul>
<b>Public authorities</b>	<ul style="list-style-type: none"> <li>• 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?</li> <li>• Does it bring additional governmental administrative burden?</li> <li>• Does the option require the creation of new or restructuring of existing public authorities?</li> </ul>
<b>Consumers and households</b>	<ul style="list-style-type: none"> <li>• Does it impact consumers' ability to benefit from the internal market and international competition?</li> <li>• Does the option affect the prices consumers pay for goods and services?</li> <li>• Does it have an impact on the quality or safety of the goods/services consumers receive?</li> <li>• Does it affect consumer choice, trust or protection?</li> <li>• Does it affect the level of consumer information?</li> <li>• Does it have an impact on the availability or sustainability of consumer goods and services?</li> </ul>
<b>Specific regions or sectors</b>	<ul style="list-style-type: none"> <li>• Does the option have significant effects on certain sectors?</li> <li>• Will it have a specific impact on certain regions, for instance in terms of jobs created or lost?</li> <li>• Is there a single Member State, region or sector which is disproportionately affected (so-called “outlier” impact)?</li> </ul>
<b>Third countries and international relations</b>	<ul style="list-style-type: none"> <li>• Is the option compliant with the 's legal commitments such as WTO Agreements and Free Trade Agreements, Economic Partnership Agreements, investment protection agreements and other preferential trade arrangements?</li> <li>• Does it affect EU foreign policy and EU/EC development policy? Does it comply with the obligation of Policy Coherence for Development?</li> <li>• What are the impacts on third countries with which the EU has</li> </ul>

<b>Economic impacts</b>	<b>Key impacts</b>
	<p>preferential trade arrangements? Does it affect the interest of the ACP group of states party to the Cotonou Partnership Agreement?</p> <ul style="list-style-type: none"> <li>• Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner?</li> <li>• Does the option impose adjustment costs on developing countries?</li> <li>• Does the option affect goods or services that are produced or consumed by developing countries?</li> </ul>
<b>Macroeconomic environment</b>	<ul style="list-style-type: none"> <li>• Does it have overall consequences of the option for economic growth and employment?</li> <li>• How does the option contribute to improving the conditions for investment and the proper functioning of markets?</li> <li>• Does the option have direct impacts on macro-economic stabilisation?</li> </ul>

<b>Social impacts</b>	<b>Key questions</b>
<b>Employment and labour markets</b>	<ul style="list-style-type: none"> <li>• To what extent are new jobs created or lost?</li> <li>• Are jobs created or lost in specific sectors, professions, regions or countries or specific social and or age groups?</li> <li>• Are there significant indirect effects which might employment levels?</li> <li>• Are there factors that would further prevent or enhance the potential to create jobs or prevent job losses?</li> <li>• To what extent does the option influence the supply of labour of specific groups through labour market participation or mobility?</li> </ul>
<b>Working Conditions</b>	<ul style="list-style-type: none"> <li>• Does the option affect wages or wage setting mechanisms or labour costs?</li> <li>• Does the option affect employment protection particularly the quality of work contracts, risk of undeclared work or false self-employment?</li> <li>• Does the option affect work organisation?</li> <li>• Does the option affect occupational health and safety, working conditions or the effective exercise of labour standards?</li> <li>• Does the option affect social dialogue?</li> <li>• Does the option affect access to vocational training and career development advice?</li> </ul>
<b>Effects on income, distribution and social inclusion</b>	<ul style="list-style-type: none"> <li>• Will the option have an impact on inequalities and the distribution of incomes and wealth in the Union as a whole or in specific regions?</li> <li>• Will the option change the number of workers with insufficient income?</li> <li>• Does the option impact on poverty rates, severe material deprivation and access/quality of social protection schemes?</li> <li>• Will the affordability of basic goods and services be affected,</li> </ul>

Social impacts	Key questions
	particularly for those subject to social exclusion?
<b>Governance, participation and good administration</b>	<ul style="list-style-type: none"> <li>• Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach?</li> <li>• 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?</li> <li>• 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?</li> <li>• Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities?</li> <li>• Does the option make the public better informed about a particular issue? Does it affect the public's access to information?</li> <li>• Does the option affect political parties or civic organisations?</li> </ul>
<b>Public health and safety</b>	<ul style="list-style-type: none"> <li>• 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)?</li> <li>• Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment?</li> <li>• Does it affect health due to changes in the amount of noise, air, water or soil quality?</li> <li>• Will it affect health due to changes energy use and/or waste disposal?</li> <li>• Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs?</li> <li>• Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?</li> </ul>
<b>Crime, Terrorism and Security</b>	<ul style="list-style-type: none"> <li>• Does the option improve or hinder security, or impact on crime or terrorism risks?</li> <li>• Does the option affect the criminal's chances of detection or his/her potential gain from the crime?</li> <li>• 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?</li> <li>• Does it affect law enforcement capacity to address criminal activity?</li> <li>• Will it have an impact on security interests?</li> <li>• Does it affect the victims of crime and witnesses or their rights?</li> </ul>
<b>Access to and effects on</b>	<ul style="list-style-type: none"> <li>• Does the option have an impact on services in terms of quality/access for</li> </ul>

Social impacts	Key questions
<b>social protection, health and educational systems</b>	<p>all?</p> <ul style="list-style-type: none"> <li>• Does it have an effect on the education and mobility of workers (health, education, etc.)?</li> <li>• Does the option affect the access of individuals to public/private education or vocational and continuing training?</li> <li>• Does the option affect the level of education and training outcomes?</li> <li>• Does it affect the cross-border provision of services, referrals across borders and co-operation in border regions?</li> <li>• Does the option affect the financing / organisation / access to social, health and care services?</li> <li>• Does it affect universities and academic freedom / self-governance?</li> </ul>
<b>Culture</b>	<ul style="list-style-type: none"> <li>• Does the proposal have an impact on the preservation of cultural heritage?</li> <li>• Does the proposal have an impact on cultural diversity?</li> <li>• Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?</li> </ul>
<b>Social impacts in third countries</b>	<ul style="list-style-type: none"> <li>• Does the option alter the recognition of ILO 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?</li> <li>• Are there employment, social protection and poverty impacts in non-Member States (including developing countries)?</li> </ul>

Environmental Impacts	Key questions
<b>Climate</b>	<ul style="list-style-type: none"> <li>• Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane, nitrous oxide, etc.) into the atmosphere?</li> <li>• 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 ETS)</li> <li>• Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs etc.)?</li> <li>• Does the option affect our ability to adapt to climate change?</li> </ul>
<b>Air quality</b>	<ul style="list-style-type: none"> <li>• 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.)?</li> </ul>
<b>Water quality and resources</b>	<ul style="list-style-type: none"> <li>• Does the option decrease or increase the quality or quantity of freshwater and groundwater?</li> <li>• 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)?</li> </ul>

<b>Environmental Impacts</b>	<b>Key questions</b>
	<ul style="list-style-type: none"> <li>• Does it affect drinking water resources?</li> </ul>
<b>Biodiversity, flora, fauna and landscapes</b>	<ul style="list-style-type: none"> <li>• 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)?</li> <li>• Does it affect protected or endangered species or their habitats or ecologically sensitive areas?</li> <li>• Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones?</li> <li>• Does the option affect the scenic value of protected landscape?</li> </ul>
<b>Soil quality or resources</b>	<ul style="list-style-type: none"> <li>• Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates?</li> <li>• 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)?</li> </ul>
<b>Waste production / generation / recycling</b>	<ul style="list-style-type: none"> <li>• Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?</li> </ul>
<b>Efficient use of resources (renewable &amp; non-renewable)</b>	<ul style="list-style-type: none"> <li>• Does the option affect the use of renewable resources (fish etc.) and lead to their use being faster than they can regenerate?</li> <li>• Does it reduce or increase use of non-renewable resources (groundwater, minerals etc.)?</li> </ul>
<b>Sustainable consumption and production</b>	<ul style="list-style-type: none"> <li>• Does the option lead to more sustainable production and consumption?</li> <li>• Does the option change the relative prices of environmental friendly and unfriendly products?</li> <li>• Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc.?</li> <li>• Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?</li> </ul>
<b>International environmental impacts</b>	<ul style="list-style-type: none"> <li>• Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?</li> </ul>
<b>Transport and the use of energy</b>	<ul style="list-style-type: none"> <li>• Does the option affect the energy intensity of the economy?</li> <li>• Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc.) used in energy production?</li> <li>• Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split?</li> <li>• Does it increase or decrease vehicle emissions?</li> </ul>

<b>Environmental Impacts</b>	<b>Key questions</b>
	<ul style="list-style-type: none"> <li>• Will the option increase/decrease energy and fuel needs/consumption?</li> </ul>
<b>Animal welfare</b>	<ul style="list-style-type: none"> <li>• Does the option have an impact on health of animals?</li> <li>• Does the option affect animal welfare (i.e. humane treatment of animals)?</li> <li>• Does the option affect the safety of food and feed?</li> </ul>
<b>The likelihood or scale of environmental risks</b>	<ul style="list-style-type: none"> <li>• Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions?</li> <li>• Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms?</li> </ul>
<b>Land use</b>	<ul style="list-style-type: none"> <li>• Does the option have the effect of bringing new areas of land ('Greenfields') into use for the first time?</li> <li>• 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)?</li> </ul>

<b>Fundamental rights Impacts</b>	<b>Key questions</b>
<b>General</b>	<ul style="list-style-type: none"> <li>• What fundamental rights are affected?</li> <li>• Are the rights in question absolute rights (which may not be subject to limitations, examples being human dignity and the ban on torture)?</li> <li>• 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)?</li> </ul>
<b>Dignity</b>	<ul style="list-style-type: none"> <li>• Does the option affect human dignity, the right to life or to the integrity of the person?</li> <li>• Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)?</li> <li>• Would it entail risks in terms of torture and inhuman or degrading treatment or punishment?</li> <li>• Would it have an impact in terms of forced labour or trafficking in human beings?</li> </ul>
<b>Individuals, private and family life, freedom of conscience and expression</b>	<ul style="list-style-type: none"> <li>• Does it affect the right to liberty of individuals?</li> <li>• Does the option affect the right to private life privacy (including their home and communications)?</li> <li>• Does it affect an individual's right to move freely within the EU?</li> <li>• Does it affect the right to marry and to found a family or the legal, economic or social protection of the family?</li> <li>• Does the option affect freedom of thought, conscience and religion?</li> </ul>

<b>Fundamental rights Impacts</b>	<b>Key questions</b>
	<ul style="list-style-type: none"> <li>• Does it affect freedom of expression and information?</li> <li>• Does it affect freedom of assembly and of association?</li> <li>• Does it affect the freedom of the arts and science?</li> </ul>
<b>Personal data</b>	<ul style="list-style-type: none"> <li>• Does the option involve the processing of personal data?</li> <li>• Who processes personal data and for which purpose?</li> <li>• Are the individual's right to access, rectification and objection guaranteed?</li> <li>• Was the data processing activity notified to the competent authority?</li> <li>• 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?</li> <li>• Is the security of the data processing activities provided for from a technical and organisational point of view?</li> <li>• Are any safeguards which render the interference into the right of data protection proportionate and necessary provided for?</li> <li>• Are appropriate/specific review and oversight mechanisms in place?</li> </ul>
<b>Asylum and protection of removal, expulsion or extradition</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Property rights and the right to conduct a business.</b>	<ul style="list-style-type: none"> <li>• Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited?</li> <li>• If yes, will there be a complete loss of property? If so what are the justifications and compensation mechanisms?</li> <li>• Does the option affect the freedom to conduct a business or impose additional requirements increasing the transaction costs for the economic operators concerned?</li> </ul>
<b>Gender equality, equality treatment and opportunities, non – discrimination, and rights of persons with disabilities</b>	<ul style="list-style-type: none"> <li>• 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?</li> <li>• Does the option have (directly or indirectly) a different impact on women and men?</li> <li>• How does the option promote equality between women and men?</li> <li>• 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?</li> <li>• 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 <a href="http://eur-lex.europa.eu/legal-">http://eur-lex.europa.eu/legal-</a></li> </ul>

<b>Fundamental rights Impacts</b>	<b>Key questions</b>
	<a href="content/EN/TXT/?uri=CELEX:32010D0048">content/EN/TXT/?uri=CELEX:32010D0048</a> )
<b>Rights of the child</b>	<ul style="list-style-type: none"> <li>• Does it strengthen or restrict the rights of the child (or group)? What is the justification for a possible restriction?</li> <li>• Does the option take into account the principle of the best interests of the child?</li> <li>• 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 CRC? If so, which articles may be concerned?</li> <li>• How are the guiding principles of the UN CRC promoted in the option?</li> <li>• Does the option impede any of the guiding principles of the UNCRC?</li> <li>• What steps have been taken to improve or compensate for any adverse effects of the option?</li> <li>• Has the child's right to be heard on all matters that affect him/her been respected?</li> <li>• Does the option contribute to the promotion of child-friendly justice systems adapted to the needs, age and maturity of a child?</li> </ul>
<b>Good administration / Effective remedy/ Justice</b>	<ul style="list-style-type: none"> <li>• Will the administrative procedures in place become more burdensome?</li> <li>• 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?</li> <li>• Is the individual's access to justice affected?</li> <li>• 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?</li> <li>• 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?</li> </ul>

## TOOL #17: IMPACTS ON 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 initiative 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 competitiveness<sup>148</sup>. It may also be relevant to address how a sector's competitiveness

<sup>148</sup> [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:

<b>Cost and price competitiveness</b>	<b>Positive</b>	<b>Negative</b>
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	
<b>Capacity to innovate</b>		
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
<b>International competitiveness</b>		
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 quantitative estimate 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?<sup>149</sup>

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?
- (5) Does the proposal affect the **cost of energy**?

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<sup>149</sup> See common tool on SME impacts

- (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?<sup>150</sup>
- (8) Until now, you would have identified most of the changes in compliance and operational costs. Now you should consider the cost implications:
- (9) What would be the adjustment costs for enterprises (incl. workforce)?
- (10) Would the sector need a major restructuring such as closing of production lines, substitution of technologies, substitution of skills, etc.?
- (11) Might it lead to closing down of enterprises?
- (12) Would SMEs or microbusinesses be able to meet the cost of restructuring?

#### **Step 6. What is the effect on the enterprises' capacity to innovate?<sup>151</sup>**

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; and
  - 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 organizational skills and talents; and
- (4) The ability to access risk capital.

#### **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

<sup>150</sup> See tool on impacts on competition

<sup>151</sup> See tool on impacts on innovation

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 on assessment of impacts on 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 organizations.

#### **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 sector<sup>152</sup>.

#### **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 Scoreboard<sup>153</sup> and the Eurostat Community Innovation Survey<sup>154</sup> 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 issue<sup>151</sup>.

#### **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.

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<sup>152</sup> See tools on the typology of costs and benefits and methods to assess costs and benefits

<sup>153</sup> <http://iri.jrc.ec.europa.eu/reports.htm>;

<sup>154</sup> [http://epp.eurostat.ec.europa.eu/portal/page/portal/science\\_technology\\_innovation/data/database](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>

- 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 sub-sectors. This might include less onerous compliance requirements or deeming a certain subset of rules not applicable to certain sectors (Example: 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 Eco-design 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 CO<sub>2</sub> 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 sectors<sup>155</sup>.

### 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 sub-sectors based on NACE; time series of nearly 20 years; 95 items, including assets, liabilities and the profit & 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, m<sup>2</sup>, m<sup>3</sup>, 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 SITC 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)<sup>156</sup> based innovation statistics are part of the EU science and technology statistics. Surveys are carried out with two years' frequency by EU member states and number of ESS member countries. 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

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<sup>155</sup> <https://bookshop.europa.eu/en/home/>; <http://ec.europa.eu/enterprise/sectors/>

<sup>156</sup> <http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/cis>

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, m<sup>2</sup>, 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, through number of enterprises, number of persons employed; turnover; value-added; investment; productivity; SME share of added-value& 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](#) / UN database on International Merchandise Trade Statistics. More than 1.75 billion trade records starting from 1962 + analytical tables 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](#): OECD members "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); "Productivity Levels and GDP per capita". Contains data on main EU competitors to assess the evolution of EU international competitiveness.

- [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: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 #18: IMPACTS ON RESEARCH & INNOVATION

### 1. FACTORS AFFECTING RESEARCH & INNOVATION

The overall impact on research and innovation depends on a range of factors, including regulation design, implementation and enforcement. The table below lists some of these factors, which will help you understand (i) the potential impact of your proposals on research and innovation behaviours and outcomes, (ii) the potential to mitigate negative impacts on research and innovation, and (iii) how to stimulate investment and incentives for R&I.

Regulatory factors	Impact on innovation
<b>Process-related vs outcome-related</b>	Prescriptive regulations set out in detail the means by which outcomes are to be achieved, including the inputs and technologies to be used and the types of business processes, practices and models permitted. They can discourage innovation since firms have limited freedom to try out new technologies, business process, practices and models. On the other hand, performance or outcome-based regulations grant greater flexibility to businesses in how they achieve the desired outcome, stipulating only at a relatively high-level what they can and cannot do. For their success, business activities must be appropriately incentivised and enforced.
<b>Setting stringent outcomes</b>	A regulation is judged to be stringent if firms need to significantly change their behaviour or develop new technologies, processes or business models in order to comply with it. Although the evidence of the impact of stringency of regulation on innovation is ambivalent, it appears that more stringent regulations are likely to induce radical innovations <sup>157</sup> , provided that the distance between regulatory requirements and the status quo is not excessive and that the outcome is specified in a technology-neutral manner. <sup>158</sup>
<b>Timing</b>	The time given to firms to comply with a new regulation can play an important role in determining the overall impact on innovation. There is a trade-off between the benefits of innovation and the benefits of compliance. If operators are given too little time to adjust to a specific regulatory framework, this may result in an inferior technological, economic and social outcome. On the other hand, while granting firms longer (but definitive) time frames to comply may encourage them to develop more innovative technological and non-technological solutions, they may also delay the benefits of regulation.
<b>Compliance costs</b>	The opportunity cost of allocating limited resources to complying with regulation can imply 'lost' innovation. The amount of innovation which may be lost as a result of regulation depend in part

<sup>157</sup> See, for example, Blind (2012)

<sup>158</sup> Pelkmans, Renda (2014)

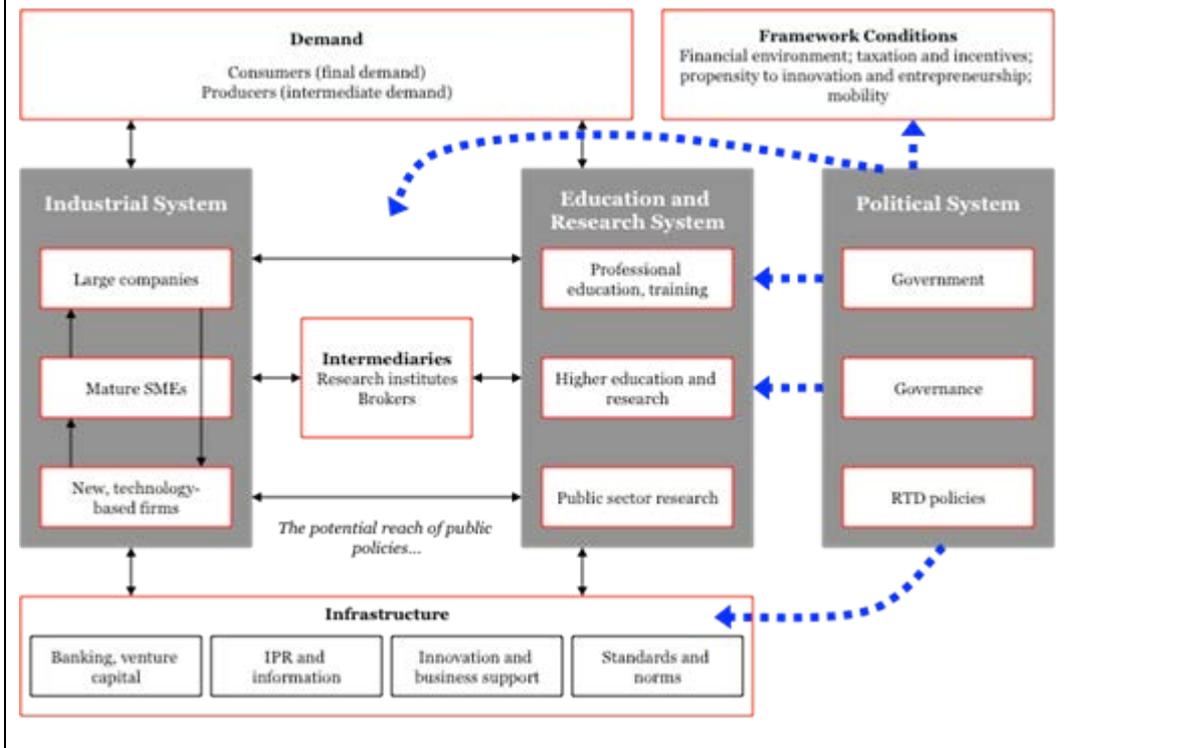
	on whether compliance costs are one-off or recurring, and also how quickly firms can rebuild their finances to fund further innovation activity. It may also depend on the size of firms. Lost innovation may be greater for smaller firms than larger companies because the cost of complying with regulation is disproportionately greater. An important element of compliance cost is spending on defensive R&D (in order to assure safety of existing substances), which may divert R&D from innovation, lock-in old technology or reduce product availability (see example in Box 2).
<b>Regulatory uncertainty</b>	Although there are examples where anticipation of future regulation has encouraged innovation, uncertainty about the regulatory approach, its actual shape or form is likely to hamper innovation. Developing new products and improved processes is a risky and costly process and regulatory delay and uncertainty can add to this.
<b>Interactions with other policies</b>	Regulatory intervention may encourage innovation if it strengthens other government policies aimed at reducing barriers to innovation (e.g. competition policy, education and skills development, procurement). On the other hand, regulatory intervention may work against other government policies by reducing the incentives to innovate or introducing distortions in the allocation of resources in the innovation system.

Research and innovation activities are not pursued in isolation. They tend to be the outcome of the interplay of various actors such as businesses, including start-ups and SMEs; research organisations, financial institutes and regulators (see figure 1 below). Therefore they are affected not only by policies targeting R&I activities directly, but also they are impacted by the existing regulatory frameworks and major complementary policies being pursued in parallel.

How the **broader context** may affect research and innovation is key to designing mutually reinforcing interventions. The following questions should be considered:

- What are the main research and innovation needs in the sector? Which of those needs might be affected by the proposed intervention?
- What are the drivers and barriers to innovation in the targeted sector?
- How does the regulatory landscape in the sector impact the innovation system? How is the existing regulation or policy implemented? How does that support or hinder innovation activities?

**Figure 1. Stakeholder mapping in research and innovation processes**



## 2. HOW DOES THE PROPOSED POLICY OPTION/INTERVENTION AFFECT THE INNOVATION CAPACITY OF COMPANIES, NOTABLY SMEs?

Innovation activities are costly and long-term processes which involve high risks but they create new value and new markets. Regulation may alter **incentives and choices** for investment in R&I. This should be considered using the following questions:

- Would the intervention privilege or prohibit characteristics a new type of good or service could have? Could this even lead in the extreme to preventing a product group or, conversely, leading the market to a single technological solution?
- Would the proposed intervention level the market conditions between incumbent and new offers, e.g. by abolishing privileges to the former or granting incentives to purchase the latter?
- Does the implementation of the intervention put an administrative burden specifically on introducing new goods, services and production plants on a market or on their demonstration prior to market introduction?
- Does the intervention alter the rewards from innovation (e.g. the length of patent protection)?
- What is the impact on product development and is there a possibility that some products would be taken from the market (i.e. de-selected) or technologies lost?
- What is the impact on market confidence, consumer acceptance or demand for new products or technologies?

- Are there indirect effects in other sectors or policy areas such as health, employment or consumer protection?

Regulation can affect **resources** (human as well as financial means) available for innovative activities:

- Does it impinge on the price, quantity or mobility of human resources with skills appropriate to new technologies and work methods, be it vocationally trained workers or experienced managers?
- Would public or private sources (internal, credit, early stage venture capital et al.) of financing be affected? This could regard not only R&D and other innovation activities such as a first production plant, but also the first buyers of innovations or the distribution of risk and revenue in public private partnerships, for instance.
- May the intervention indirectly influence a company owners' preference for keeping a firm size below a certain limit and hence R&D capacity, e.g., because of labour, tax or administrative rules?

Innovation is a dynamic and evolutionary process with constant interaction and feedback between the different stages, with ideas and knowledge often being developed and exchanged. Regulation can impact on the **creation and diffusion of knowledge**:

- Does the proposed intervention impact the generation of new ideas, their adaptation and application, including from the knowledge base to industry?
- Does it affect the co-operation (e.g. circulation of data, research results or researchers) among public researchers and between public and corporate R&D and with intermediaries that provide advice and support to R&I activities, e.g., the openness to co-operate or the distribution of benefits?
- Does the proposed intervention potentially affect the establishment of, access to and functioning of research and innovation infrastructures?

### **3. HOW TO MINIMISE NEGATIVE IMPACTS ON RESEARCH AND INNOVATION**

Measures that can minimise any adverse effect on research and innovation while attaining the policy objective of the measure should be considered.

Appropriate mitigating measures could be temporary or permanent. Regulatory uncertainty is known to be detrimental to innovation and so, to the extent possible, any interventions should be designed to promote regulatory certainty and stability over time (e.g. by limiting follow-up acts). Examples of possible mitigating measures include:

- Prefer laying down (technology-neutral) performance levels in a legal act rather than technologies, products or production means that could reach such a performance (i.e. let market forces operate to find the most efficient (and innovative) solution).
- Higher administrative cost from regulation on any R&D factor (staff, infrastructure etc.) or on the placing of new goods or services on a market may be alleviated with lighter regimes or exemptions for SMEs.

- Advantages given by public policy to incumbent products may be abolished or reduced to attain a more level market situation. Should this not be feasible, the advantages may be offset by granting new financial support to the acquisition of the innovations.
- If doubts exist about innovation capacity and the availability of a particular technical solution to meet a given regulatory requirement then a transitional period may be defined with advantages for the early movers.
- An awareness raising campaign, delivered by, e.g. public institutions or trade associations, and a new public support service to innovation may be proposed.
- To the extent possible, the intervention should be designed to avoid creating expectations of damaging regulatory uncertainty (e.g. limiting follow-up acts).

***Box 2: Example: veterinary products – innovation stifled by the regulatory regime to such an extent that there is a lack of medicines to treat animals***

- The aim: To free resources from the pharmaceutical industry for re-investment in new product development, therefore indirectly having a positive effect on the availability of novel medicines for companion and farmed animals.
- ***Measures suggested in the IA:*** Introducing a level of flexibility to the authorisation system, simplifying the requirements regarding packaging and labelling, variations procedures, and pharmacovigilance; extending the period of data protection for veterinary medicines to a maximum of 20 years, to better protect developments efforts leading to new products; removing an inconsistency within the legislation to allow the protection period for safety data to cover environmental data to potentially encourage applications for generics. Enable companies to join efforts to carry out studies to generate safety data.

#### **4. INFORMATION SOURCES AND BACKGROUND MATERIAL**

- To assess whether regulation is stimulating or hindering R&I: Regulatory screening [A short guide on the innovation effects of regulation](#), DG RTD 2014,
- To assess the impact on the innovation capacity of enterprises, see the sections on innovation capacity in: European Commission, "**Operational guidance for assessing sectoral competitiveness within the Commission impact assessment system: A 'competitiveness proofing' toolkit for use in impact assessments**", SEC(2012) 91, 21/01/2001.
- To determine the scale of innovation activities, the characteristics of innovation firms and the internal and systemic factors that can influence innovation, [Measurement of Scientific and Technological Activities](#), Oslo Manual – Guidelines for Collecting and Interpreting Innovation Data, OECD/Eurostat, 2005
- The impact of regulation on innovation. K Blind. 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.
- **Innovation Union Scoreboard**, DG Internal Market, Industry, Entrepreneurship and SMEs, European Commission.
- **Community Innovation Survey**, Eurostat.

## TOOL #19: 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. At the same time SMEs find it more difficult to access capital and their cost of capital is often higher than for larger businesses.

Businesses can be characterised as Small and Medium Enterprises (SMEs) by looking at the number of employees: micro companies have 0-9 employees, small companies have 10-49 employees, medium-sized companies have 50-249 employees while large companies have 250 or more employees.

The Commission has adopted the 'Small Business Act'. It aims to improve the overall approach to entrepreneurship, permanently anchor the 'Think Small First' principle in policy making and to promote SMEs' growth by helping them tackle the remaining problems which hamper their development. 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 policy making in order to make legislation more SME friendly.

#### ***Box 1. SME policy: The "Think Small First principle"***

- The 'Small Business Act' sets out 10 principles to guide the conception and implementation of policies for SMEs both at EU and Member State level:
- Create an environment in which entrepreneurs and family businesses can thrive and entrepreneurship is rewarded;
- Ensure that honest entrepreneurs who have faced bankruptcy quickly get a second chance;
- Design rules according to the "Think Small First" principle;
- Make public administrations responsive to SMEs' needs;
- Adapt public policy tools to SME needs: facilitate SMEs' participation in public procurement and better use State Aid possibilities for SMEs;
- Facilitate SMEs' access to finance and develop a legal and business environment supportive to timely payments in commercial transactions;
- Help SMEs to benefit more from the opportunities offered by the Single Market;
- Promote the upgrading of skills in SMEs and all forms of innovation;
- Enable SMEs to turn environmental challenges into opportunities;
- Encourage and support SMEs to benefit from the growth of markets.

In addition, it is Commission policy<sup>159</sup> to exempt micro-enterprises from EU legislation wherever possible or introduce special regimes so as to minimise the regulatory burden

<sup>159</sup> COM(2011) 803

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.

## 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 policy making.**

An 'SME test' has been developed and comprises four steps:

- (1) Consultation of SME stakeholders;
- (2) Identification of affected businesses;
- (3) Measurement of the impact on SMEs;
- (4) Assessment of alternative mechanisms and mitigating measures.

### Step (1) Consultation that captures the SMEs angle

The SME dimension should be a central element of the consultation strategy (for which separate guidance exists<sup>160</sup>) and, in addition to an open public consultation, may involve specific consultation actions such as round table discussions, focus group meetings, hearings targeting SME representatives, SME Panels – questionnaire surveys carried out with the assistance of the Enterprise Europe Network aimed at providing inputs into the SME Test section of the Impact Assessment, etc.<sup>161</sup>

### Step (2) Identification of affected businesses

During this stage, you should establish whether and which SMEs (e.g. micros) are among the 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 information<sup>162</sup> 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;
- Weight of the different kinds of SMEs in the sector(s) (micro, small and medium ones);

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<sup>160</sup> See tool on stakeholder consultation in the context of IA

<sup>161</sup> DG GROW [unit D.4] coordinates the preparation of these panels

<sup>162</sup> A useful starting point to find this information are the Structural Business Statistics produced by Eurostat, see [http://epp.eurostat.ec.europa.eu/portal/page/portal/european\\_business/introduction](http://epp.eurostat.ec.europa.eu/portal/page/portal/european_business/introduction)

- Links with other sectors and possible effect on subcontracting; for instance, there may be may have an impact not only on the targeted sector but also on its suppliers or customers; such indirect impacts should 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.

### 3. HOW TO MEASURE IMPACTS ON SMES

#### Step (3) Measurement of the impact on SMEs

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, quantitatively<sup>163</sup>. 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.

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 organisations<sup>164</sup>.

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 costs<sup>163</sup> 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).

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**<sup>165</sup>. You

<sup>163</sup> See tool on methods to assess costs and benefits

<sup>164</sup> See tool on sectoral competitiveness

<sup>165</sup> It is recommended to use the ranges of the SME definition: 0-9, 10-49, 50-249 and 250+ employees.

could also **compare the costs identified to the total overhead or turnover of the company**<sup>166</sup>.

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;<sup>167</sup>
- Possible impact on innovation.<sup>168</sup>

***Box 2. Examples of good forward-looking assessments of impacts on SMEs***

- A summary of the results of the SME analysis **must** be presented in the IA Report<sup>169</sup>.
- 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 market"<sup>170</sup> (2012) summarizes all 4 steps of the SME test. It gives an overview and evidences that SMEs specific concerns were taken into account
  - Impact Assessment report on the directive on combating late payment in commercial transactions<sup>171</sup> contains an annex dedicated to the SME test.
- It is recommended that the underlying SME Test analysis is structured and laid out in a way facilitating further reference.

#### **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

<sup>166</sup> Representative samples of different size of companies can also be used.

<sup>167</sup> See tool on impacts on the internal market

<sup>168</sup> See tool on impacts on innovation

<sup>169</sup> See tool on the format of the IA Report

<sup>170</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0135&from=EN>

<sup>171</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0315&from=EN>

other Treaty-based goals or fundamental rights, they should be covered but the possibility to apply adapted solutions should be assessed.

A non-exhaustive list of mitigating measures to be considered includes:

- Complete or partial size-related exemptions (Example: businesses below certain thresholds do not have to comply with certain specific obligations when this does not invalidate the original purpose of the legislation);
- 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, 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.

***Box 3. Examples of mitigating measures<sup>172</sup>***

- 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 400m<sup>2</sup>.
- It is proposed in a new general Data Protection Regulation that companies with less than 250 workers need not have a Data Protection Officer and that specific measures must be considered for SMEs in the context of Commission delegated acts aimed at further specifying the criteria for assessing whether a Data Protection Impact

<sup>172</sup> [http://ec.europa.eu/smart-regulation/impact/best\\_practices\\_examples/docs/eu/lighter\\_regimes\\_for\\_smes\\_oct\\_2013.pdf](http://ec.europa.eu/smart-regulation/impact/best_practices_examples/docs/eu/lighter_regimes_for_smes_oct_2013.pdf)

Assessment is necessary.

- 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 a current proposal.
- Member States would be forbidden from charging micro-businesses fees under the Food and Feed Controls proposal.

## 5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- [DG GROW Intranet website:](https://myintracomm.ec.europa.eu/dg/ENTR/dirunits/D/D4/Pages/thesmetest.aspx)  
<https://myintracomm.ec.europa.eu/dg/ENTR/dirunits/D/D4/Pages/thesmetest.aspx>
- EU SME policy framework:
- [Small Business Act \(COM\(2008\)394\)](#)
- [Review of the "Small Business Act" for Europe:](#)
- [Report of the expert group 'Models to reduce the disproportional regulatory burden on SMEs': + Entrepreneurship Action Plan 2013](#)
- [Smart regulation - Responding to the needs of small and medium - sized enterprises:](#)
- [Definition of SMEs in the context of access to financial incentives: Commission Recommendation 2003/361/EC:](#)
- [A guide to the application of the SME definition:](#)
- [Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises: COM\(2011\) 803](#)

- [Structural Business Statistics \(Eurostat\)](#):

## **6. SUPPORT**

SME Test Helpdesk: [ENTR-SME-POL-DEVT-AND-SMALL-BUS-ACT@ec.europa.eu](mailto:ENTR-SME-POL-DEVT-AND-SMALL-BUS-ACT@ec.europa.eu)

Unit D4 of DG GROW will provide advice and support on issues related to impacts on SMEs.

## TOOL #20: IMPACTS ON 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 authorization 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 (recognizing 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 liberalization 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 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 re-couped, 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
<b>Impacts on existing firms?</b>	<p><u>What is the impact on the cost of meeting the regulation?</u></p> <ol style="list-style-type: none"> <li>(1) Is the policy option creating additional costs for existing firms? In case the policy option introduces licences or permits, are additional costs quantifiable?</li> <li>(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.</li> <li>(3) How large are the costs relative to businesses' annual sales revenues?</li> <li>(4) Does the answer in (3) vary by the size of the business? For example, are small businesses more adversely affected?</li> <li>(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?</li> <li>(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?</li> </ol> <p><u>What is the impact on the exit of firms?</u></p> <ol style="list-style-type: none"> <li>(1) Will these costs/requirements lead some businesses to exit the market?</li> <li>(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?</li> </ol> <p>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.</p> <ol style="list-style-type: none"> <li>(1) Does the regulation limit growth opportunities of existing</li> </ol>

Impacts	Key questions
	<p>competitors?</p> <p>(2) Does the regulation favour the incumbent over existing competitors?</p> <p><u>What is the impact on the anti-competitive behaviour of firms?</u></p> <p>(1) Will it increase the incentive for anti-competitive behaviour of firms (collusion, etc.)?</p> <p>(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).</p>
<b>Impacts on entry of new firms?</b>	<p>(1) Does the policy option restrict entry:</p> <p>For all types of entrants<sup>173</sup>? 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.</p> <p>For specific types of firms? Does it affect new firms/new plants more than incumbent businesses? Does it affect small and medium entrant's more than large undertakings? Does it affect foreign firms and not national firms?</p> <p>(2) Does the policy option limit the access to specific resources (e.g. input products, know-how, distribution channels)?</p>
<b>Impacts on prices?</b>	<p>(1) Are prices paid by consumers likely to increase? If yes, what are the likely major factors that will cause prices to rise?</p> <p>An increase in production costs?</p> <p>An increase in market power?</p> <p>Greater information sharing and cooperation among businesses leading to collusion?</p>
<b>"Non-price" impacts on consumers?<sup>174</sup></b>	<p>(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.</p> <p>(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.</p>
<b>Impact on upstream and downstream markets?</b>	<p>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).</p> <p>(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</p>

<sup>173</sup> Provide broad definition in footnote of entrant types.

<sup>174</sup> See tool on consumer impacts

Impacts	Key questions
	<p>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?</p> <p>(2) How will the bargaining power of buyers be affected?</p> <p>(3) How will the bargaining power of suppliers be affected?</p>

## 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 anticompetitive 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.<sup>175</sup>

Regulation of the quantity supplied, price or characteristics of externality-generating products or activities is one possible approach of attempting to correct for these 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

<sup>175</sup> 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.

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. In some cases, adequate information disclosure may be sufficient, allowing consumers to make informed decisions.

*Example:* Setting labelling requirements to disclose unhealthy content in food products, instead of banning certain 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 Toolkit<sup>176</sup> 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](http://ec.europa.eu/competition/index_en.html)

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<sup>176</sup> <http://www.oecd.org/competition/assessment-toolkit.htm>

## TOOL #21: IMPACTS ON THE 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 citizens<sup>177</sup> 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.

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.

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<sup>177</sup> The term citizen is used in this fiche to comprise different relevant (sub-) groups, including consumers, workers and professionals.

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*<sup>178</sup>:**

- 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?;
- 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 do 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 – e.g. different price, different terms and conditions (e.g., ways of payment, delivery options, possibility to return, guarantee, redress, insurance)?;<sup>179</sup>

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<sup>178</sup> See tool on how to analyse problems

<sup>179</sup> 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 MS where the consumer is domiciled. The principle is that consumers should not have lower level of protection than in their home Member States.

- Are there market imposed obstacles to the free movement of capital? (e.g. Stock Exchange Rules on listings, additional requirements for reporting or requirement to use certain standard 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?

(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 harmonized? Do companies/citizens face different rules/requirements in each Member State?
- In case of different national rules, is there a mutual recognition principle<sup>180</sup> 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?<sup>181</sup> 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 local representative, need for 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 harmonized 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? (E.g. selection mechanism of tender winner in public procurement, non-publication of tenders; lack of meaningful information about regulated professions);

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<sup>180</sup> Existing mutual recognition principle cover trade in certain goods as well as recognition of professional qualifications.

<sup>181</sup> See tool on impacts on competition

- 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 cases, etc.)?
- Does the regulated market structure create barriers? (e.g. very long contracts awarded by authorities, that form a barrier to entry to the market – e.g. high way long term concession; 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 MS)? 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 choice, 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.?

IAs 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 establish a level playing field for companies, workers and consumers). It might also look into other policy issues, 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)<sup>182</sup>.

You could further consider using benchmarks to assess the level and effectiveness of market integration, such as e.g. goods market and services markets, trade between Canada and USA, trade between US states or trade between EU/EEA Member States.<sup>183</sup>

<sup>182</sup> See tool on the SME test

<sup>183</sup> See tool on impacts on trade and investment

### 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 consultations<sup>184</sup>.

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 harmonized EU regime or by creating the 29<sup>th</sup> (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.***

- ‘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 MS). Under alternative scenarios e.g. only a subset of Member States and related costs can be considered (e.g. following actual behaviour of companies who choose to protect their patent in a limited number of Member States).
- ‘EU scenario’(harmonized 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

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<sup>184</sup> See tool on evidence gathering

future single EU regime would impose and changes in company behaviour regarding cross-border trade and investment that would follow.<sup>185</sup>

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 harmonized 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 Market Pillar of the European Semester"<sup>186</sup>.

### 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).

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
<b>Trade creation:</b> trade between MS, 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
<b>More competitive markets:</b> 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)

<sup>185</sup> See tool on assessing costs and benefits

<sup>186</sup> For more explanation and detailed examples, [see page 70 of the full report](#).

<b>Gains in efficiency/productivity:</b> 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.
<b>Innovation:</b> 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.
<b>Free movement of people:</b> Job opportunities in other MS, 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).
<b>Free movement of capital:</b> More investing opportunities, diversification	Interest rate convergence, foreign listing, share of foreign assets/liabilities in financial sector
Policy influence and synergies, <b>cooperation and coordination</b>	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 companies and	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 <sup>187</sup>
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 MS.
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 MINIMIZE 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 etc.);
- Promoting transparency and information (preferably in multiple languages) – e.g. setting information points /one stop shops for (e.g. Points of Single Contact);
- Limiting any unnecessary administrative and private obstacles to cross border movement/trade;
- Mutual Recognition, Harmonisation and Best Practice spreading;
- 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;

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<sup>187</sup> See tool on impacts on employment, working conditions, income distribution and inequality

- 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](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 #22: 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 WTO Agreements; but also bilateral and plurilateral 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 must 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 Agreement<sup>188</sup>, 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 protectionism<sup>189</sup>.

***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 technical regulations have to be fair and equitable. The agreement discourages methods that would give domestically produced goods an unfair advantage and

<sup>188</sup> Please refer to [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm)

<sup>189</sup> [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm4\\_e.htm#TRS](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm#TRS)

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)<sup>190</sup> 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 IPR and competition.

## **2.3. Consistency with investment protection provisions/agreements**

Investment protection provisions can be found in Member State agreements<sup>191</sup>, 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 Products<sup>192</sup> (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.

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.

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<sup>190</sup> For further detail, please refer to <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/>

<sup>191</sup> 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>

<sup>192</sup> For more on ACAA, please see [http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/aaa-neighbouring-countries/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/aaa-neighbouring-countries/index_en.htm).

### **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 sub-contractors, 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 context<sup>193</sup>, 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).<sup>194</sup>

#### **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 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

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<sup>193</sup> See tool on stakeholder consultation in the context of IA

<sup>194</sup> See tool on impacts on competitiveness

countries can be found in the UN Broad Economic Categories (BEC) classification (see also [www.wiod.org](http://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.<sup>195</sup> 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.<sup>196</sup>

### **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 co-operation 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.<sup>197</sup> 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?***

The ACP-EU Partnership Agreement<sup>198</sup> 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.

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<sup>195</sup> See tool on impacts on competitiveness

<sup>196</sup> The IA report is available at [http://ec.europa.eu/smart-regulation/impact/ia\\_carried\\_out/docs/ia\\_2013/swd\\_2013\\_0185\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2013/swd_2013_0185_en.pdf)

<sup>197</sup> See tool on impacts on developing countries

<sup>198</sup> 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.

**(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:

- 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](mailto: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](http://www.wto.org/english/docs_e/docs_e.htm)
- For a [list of EU trade agreements](http://ec.europa.eu/trade/policy/countries-and-regions/agreements/#_europe) see [http://ec.europa.eu/trade/policy/countries-and-regions/agreements/#\\_europe](http://ec.europa.eu/trade/policy/countries-and-regions/agreements/#_europe) and for a list of [investment agreements between Member States and third countries](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:131:0002:0098:EN:PDF) see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:131:0002:0098:EN:PDF>
- 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 EU27 imports and exports](#) of goods with all partners and all products disaggregation.
- [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](#) that covers trade in services and FDI by partner country and product.
- 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](http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2012_0091_en.pdf)

## TOOL #23: ICT ASSESSMENT, THE DIGITAL ECONOMY AND SOCIETY

### 1. INTRODUCTION

Digital technologies<sup>199</sup> such as the Internet, social media and mobile devices heavily impact daily life but their pervasive presence and influence is expected to grow yet further. The aim, therefore, should be to prepare "digitally minded" initiatives that support the development of the **Digital Single Market**. This should cover initiatives which address directly Information Communication Technologies (by for example establishing rules for their use and functioning and choosing the most appropriate policy instrument<sup>200</sup>) as well as others, where ICT is a supporting element (e.g. IT systems and services, computer networks, information management systems, etc.).

The implementation of almost any new EU legislation requires the support of ICT systems, e.g. for secure cross-border exchange of information between authorities, for the delivery of online public services to citizens and/or business, information processing and publication through web-based Portals, etc. However, the use of ICT for the implementation of EU legislation has implications for existing information systems. The earlier ICT requirements and associated implications are identified and analysed, the greater the likelihood that appropriate solutions can be prepared which are accepted by stakeholders including Member State administrations.

This tool is relevant for forward-looking impact assessments as well as retrospective evaluations and Fitness Checks.

### 2. WHAT IS THE DIGITAL ASSESSMENT AND WHEN SHOULD DIGITAL ISSUES BE CONSIDERED?

For each initiative, you should consider a digital assessment comprising two key elements:

- Are there relevant ICT or Internet drivers<sup>201</sup> influencing the problem definition?
  - Are there identifiable trends in your policy domain indicating that digital technologies will change the nature of the problem definition?
  - How are ICT and the Internet linked to the problem? Is Internet based activity growing compared to classical activity (face to face; snail mail; broadcast, etc.)? Is amongst the causes of the problem the fact that ICT means are not used, or are insufficient/outdated and not responding to the needs?
  - Whether ICT and Internet factors are properly identified in the **baseline scenario**. How rapidly is the problem changing? To what extent? How stable is

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<sup>199</sup> Note that for explanations on specific Information Technology terms and acronyms, you can refer to the [DG CONNECT Glossary](#) and [List of Acronyms used in DG CONNECT](#).

<sup>200</sup> See tool on policy instruments which discusses the range of available "soft" and "hard" instruments including self and co-regulation, market based instruments as well as traditional legislation.

<sup>201</sup> See appendix for more information on internet drivers.

the baseline scenario you have established with respect to identifiable technology trends?

- Who are the **stakeholders** and how they are linked to the ICT and Internet dimension of the problem?

Policy options should:

- Be "**Internet ready**": The pervasive nature of the Internet means that initiatives should now be prepared from the outset with the **Internet in mind**, given that Internet based mediated commercial and social activities are now prevalent.
- *Not discriminate between digitally (on-line) and physically (off-line) implementations/outcomes* when both types of transactions exist or are being used. Sales channels, whether physical stores or on-line sellers, should be treated 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, including across the value-added chain.
- *Consider ICT as an instrument* to implement policy options. Business automation, information processing particularly when it concerns interconnection of different sources in order to exchange/share information, they all require some sort of underlying ICT solution. Impact may concern both the development of **new or the migration of existing IT systems or services**.

You should consider at an early stage whether ICT implications arise and should be further assessed, i.e. at the time the **Idea** for a new initiative is conceived and initially explored and when the **Roadmap** is prepared. This will signal to concerned stakeholders, DG DIGIT, DG CONNECT and the ICT experts of the line DG on possible ICT implications and enable their further participation.

During the **Impact Assessment** or the **Evaluation**, the initial ICT implications identified in the Roadmap should be further analysed and updated.

A "**digital screening**" to reveal the existence of ICT/Internet based options needing further analysis is recommended to take place at this stage. An easy way to do it is to answer the following questions simply with a "YES" or "NO":

Criterion	YES	NO
<p><b>Is there any need to establish an ICT or Internet based solution?</b></p> <p>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/Internet is in the core of the legislation or simply a supporting driver of it.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• "Energy efficient labelling" on the Internet (ecoSearch Directive<sup>202</sup>), transfers traditional consumers rights and dealers obligations to the Internet sales channel for kitchen appliances and other white goods;</li> <li>• Member States administrations cooperate by making use of the Internal Market Information system<sup>203</sup>;</li> <li>• Member States interconnect their business registers and notify each other about changes to those registers<sup>204</sup>.</li> </ul>		
<p><b>Is any "information processing" involved?</b></p> <p>By this we mean collection, storage, retrieval, consultation, filtering, exchange, reporting, etc. of any kind of meaningful data (text, image or video).</p> <p><i>Examples:</i></p> <ul style="list-style-type: none"> <li>• Industrial installations and aircraft operators have to report on CO<sub>2</sub> emissions under the Emissions Trading System;</li> <li>• Airline companies have to report to law enforcement authorities on passengers' data to prevent terrorism;</li> <li>• National authorities have to exchange information on criminal records.</li> </ul> <p><i>Caution:</i></p> <ul style="list-style-type: none"> <li>• When data-forms have to be designed it is likely that information processing will occur and will be probably supported by an IT system;</li> <li>• When "reporting" is required it is likely that data have to be collected, formatted and transmitted (as information) through IT systems and networks.</li> </ul>		

<sup>202</sup> <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2014%3A029%3A0001%3A0032%3AEN%3APDF>

<sup>203</sup> IMI Regulation (EU) No 1024/2012

<sup>204</sup> BRIS Directive 2012/17/EU

<p><b>Are any "business processes" established or changed?</b></p> <p>By "business process" we mean a sequence of activities to produce a specific result. Today, most of those activities can be automated and executed through workflows.</p> <p><i>Examples:</i></p> <ul style="list-style-type: none"> <li>• In the case of public procurement, a call for interest is published, companies submit their bids, which are evaluated before the winning applicant is awarded;</li> <li>• 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 collected by the organisers and validated by the national competent authorities and the Commission to be informed of the result;</li> <li>• Following inspection of a product in the market (i.e. laboratory control), food inspectors notify national authorities for product's non-compliance. Following verification at national level, the Commission and connected Member States are alerted.</li> </ul> <p><i>Caution:</i></p> <ul style="list-style-type: none"> <li>• Information processing is partly or wholly a business process (e.g. information collection, reporting, etc.). It means that whenever "information is processed", it is likely that some sort of business processes will have to be established or modified;</li> <li>• The existence of business processes does not necessarily require the implementation of an IT solution. It can be that a mixture of automated and non-automated (e.g. paper based) processes exist. It is however probable that over time a full automation will be necessary and this should be considered upfront.</li> </ul>		
<p><b>Are there any "security or data protection" requirements?</b></p> <p>Sensitive data must be treated with care. If any option refer to such a need it is highly possible that special IT measures should be taken to ensure exchange, integrity and confidentiality of this data, such as encryption, secure hosting, limited access, etc.</p> <p><i>Example:</i></p> <ul style="list-style-type: none"> <li>• Competent national authorities wishing to exchange citizens' data, even if it is on paper that has been digitally scanned, must do so in a secure manner.</li> </ul> <p><i>Caution:</i></p> <ul style="list-style-type: none"> <li>• It is highly unlikely that information can be exchanged securely, especially across countries, without electronic means. Whenever such a need arises a secure IT network and system are likely to be required.</li> </ul>		

If the answer to ALL of the above questions is “NO”, then the link with ICT is very likely to be either insignificant or non-existent. No further analysis is required at this

stage. However as the Impact Assessment process evolves, a reappraisal may be necessary.

If the answer to ANY of the above questions is “YES”, then it is highly likely that there is a dependence of the option on ICT and you should move on to the next section of the present tool. It is advised that, ICT experts are called upon to classify with precision the ICT impact and get involved in the rest of the process.

### 3. HOW TO DEVELOP ICT AND/OR INTERNET BASED OPTIONS

At this stage you have identified and broadly shape options that are ICT/Internet based. You should now further analyse and assess their respective impacts along the following lines:

- **Ensure that ICT is integral, well identified, part of the options associated with the high level business processes. An indicative list of those includes:**
  - *Information handling*: it concerns information provision, retrieval or exchange;
  - *Monitoring*: it concerns the retrieval of observed information (text, images, sound, etc.) or status (e.g. to test the availability/continuity of service or correct functioning of some systems);
  - *Decision-making systems or other automated solutions*: concerns the implementation of 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.
- **Take into account interoperability** among concerned actors. Ensure that you refer to the **European Interoperability Framework (EIF)**<sup>205</sup> 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.;
- **Think of reusability**. 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 be extended to existing solutions developed at Member States' level. "Reuse" could also be understood as the maximum use of **open data**. There are various sources of information that will help identifying potential reusable solutions (refer to Appendix 2 for a detailed list).

Deciding between different types of ICT/Internet based options may not be possible immediately. They may require in-depth analysis with stakeholder representatives. Indeed, there are many possible ways in which a given problem may be addressed, through a variety of organisational approaches and supporting digital tools (e.g. centralised versus decentralised approaches, standardisation versus meta-standardisation

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<sup>205</sup> [http://ec.europa.eu/isa/documents/isa\\_annex\\_ii\\_eif\\_en.pdf](http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf)

etc.), and these can entail very different distributions of responsibility/empowerment among stakeholders, different degrees of complexity and sustainability and related costs.

A variety of ICT options and sub-options may need to be retained for further analysis, until the various stakeholders consulted are fully convinced of which can be further explored and which should be discarded.

In addition, in areas of fast technological change (such as in the field of digital policies), it is even more relevant to seek to avoid legislation where lighter means are available to reach a given objective, in particular by exploring any **Self/Co-Regulation** options or sub-options with stakeholders (based on SR/CR best practice) and limit legislation to the level of principles, leaving implementation issues to some later more detailed discussions with stakeholders or within a time-window in keeping with the observed speed of evolution of technologies, innovation and science.

More details on how to introduce ICT in the proposed options can be found in Appendix *I*.

Depending on the level of ICT analysis, it may be that frameworks, methods and services included in Appendix 2 can be used as references.

#### **4. IDENTIFY ICT COSTS AND BENEFITS (IMPACTS)**

At this stage you should have already identified whether ICT is involved and impacts have to be further analysed. It is now time to start setting up the landscape for the assessment of costs and benefits of the chosen options. Steps to go through include:

- (1) Identify the various **costs and benefits**<sup>206</sup>;
- (2) Map the various cost and benefits according to the relevant **stakeholders**: this will help you to better prepare the collection of data from the concerned stakeholders and identify those that bear the greatest impacts.

The following costs should be considered where possible and relevant<sup>207</sup>:

- *Infrastructure* costs provide the total (anticipated) cost of the hardware (e.g. network, servers) and software (e.g. applications, libraries) required to develop, support, operate and maintain the system;
- *Development* costs provide the total (anticipated) cost (human resources and other) for the development of the system (e.g. analysis and process reengineering activity, coding activity, project management activity, test activity, configuration & change management activity, deployment activity);

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<sup>206</sup> See tool on typology of costs and benefits

<sup>207</sup> Total Cost of Ownership (TCO) comprises the sum of infrastructure, development, maintenance and support costs:

- *Maintenance* costs provide the total (anticipated) cost (human resources and other) in person days per year to maintain the system (e.g. activities related to both corrective maintenance and evolving maintenance);
- *Support* costs provide the total (anticipated) cost (human resources) in person days per year to support the system (e.g. helpdesk, operations);
- *Training* costs are not included in the TCO considering that these are not substantial for the online collection system implementation.

Cost estimate may include, whenever possible, the use of methods such as the Function Point Analysis (FAP) and the like.

An ICT based option can produce benefits **directly** related to the policy objectives, e.g.:

- Setting up a new surveillance system gathering seismic information from distributed sensors is expected to help predict better the occurrence of earthquakes which can be translated in terms of costs or lives saved;
- Public administrations making public data openly available, increase the efficiency of the market, by enabling the creation of new commercial services and products through the use of which improved information could be provided to citizens and businesses;
- In an "on-line" environment, cost savings may accrue from an ICT based 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.

An ICT based option can produce benefits **indirectly** related to the policy objectives, e.g.:

- May remedy problems linked to the provision of transparent, timely and precise information on a market in which competition is imperfect. Enhanced competition may in turn boost creativity, innovation and bring further indirect socio-economic benefits;
- The Internet or other IT 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. There may also be 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. These one-off impacts should also be analysed where relevant;
- When putting in place ICT infrastructures that are not only used for the specific legislation but create a digital environment that can either be reused by another legislation or generally establish channels for types of information exchange other than those required by the legislation.

## 5. ASSESSING POLICY OPTIONS

Assessment criteria will allow comparison of the ICT based options. In line with the Impact Assessment/Evaluation guidelines, the main criteria to consider include *effectiveness, efficiency and coherence*<sup>208</sup>. Additional ones, such as the *technical feasibility* of requirements, may be introduced as needed.

Various elements should be checked in relation to the coherence of a particular option:

- *Consistency with existing and on-going legislation to avoid misalignment of regulatory requirements:* alignment with other legislation, especially that of cross sectorial nature should be sought, i.e. eIDAS<sup>209</sup> on electronic identification in the internal market, electronic invoicing in public procurement<sup>210</sup>, Services Directive<sup>211</sup>, the revised Directive on the re-use of public sector information<sup>212</sup>, open data strategy etc., and even larger overall EC strategic agendas such as the Digital Single Market;
- *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 governance<sup>213</sup>, and the recently adopted NetMundial<sup>214</sup> principles for Internet Governance. Where a proposal can have an impacts related to these basic principles, these need to be carefully analysed in the Impact Assessment. In some cases, the *impact on the evolving technical infrastructure of the Internet* should be considered. It could be that legislative proposals imply that there additional compliance costs 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;
- *Consistency with existing Interoperability standards, specifications and guidelines:* the Commission has adopted the European Interoperability Framework (EIF) that elaborates upon the main principles and recommendations needed to achieve interoperability at different levels (legal, organisation, semantic and technical). The ISA<sup>215</sup> Programme, managed by DIGIT, has produced a

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<sup>208</sup> See the main Better Regulation Guideline on impact assessment and evaluation

<sup>209</sup> Regulation (EU) No 910/2014

<sup>210</sup> Directive 2014/55/EU

<sup>211</sup> Directive 2006/123/EC

<sup>212</sup> Directive 2013/37/EU

<sup>213</sup> COM(2014) 72, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2014:0072:FIN:EN:PDF>

<sup>214</sup> <http://netmundial.br/wp-content/uploads/2014/04/NETmundial-Multistakeholder-Document.pdf>

<sup>215</sup> Interoperability Solutions for European Public Administrations, [http://ec.europa.eu/isa/index\\_en.htm](http://ec.europa.eu/isa/index_en.htm)

variety of ready-to-use interoperability solutions based on open and reusable specifications and tools;

- *Consistency with the ICT Governance, methods and tools of the Commission:* in cases where the Commission is involved as a stakeholder, e.g. to develop/host/operate/maintain and support an ICT solution at its premises, it has to be ensured that relevant ICT development practises, frameworks, technical architecture and specifications, hosting arrangements, etc. proposed in the option and used by the Commission are compatible.

**Technical Feasibility** refers to quality criteria (e.g. functional completeness, performance, compatibility, usability, portability, security, etc.) ICT solutions used by the relevant option have to comply with, such as the *IT systems software and quality requirements* derived from ISO/IEC 25010:2011.

## 6. THE IT GOVERNANCE FRAMEWORK OF THE COMMISSION

It is often possible that the Commission itself is also impacted in terms of ICT. This can be extracted already by the Roadmap or be the result of the Impact Assessment or Evaluation report. In case this occurs and regardless of the policy area or budget concerned, the ICT governance bodies<sup>216</sup> 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 system as appropriate.* This will allow streamlining policy and related ICT development in the Commission, will ensure good planning and efficient use of resources.

## 7. FURTHER INFORMATION AND ASSISTANCE

### DG -DIGIT

For **advice on techno-economic issues** linked to the **development or interfacing of ICT systems** (new and/or existing ones) and their implications especially in terms of cost and the possibility of **reusing open solutions** developed (by the Commission services, programmes such as the ISA<sup>217</sup>, and Member States) in such a way that interoperability is assured, please contact DG DIGIT unit B6 via the [DIGIT-ISA-ICT-IMPACT-ASSESSMENT@ec.europa.eu](mailto:DIGIT-ISA-ICT-IMPACT-ASSESSMENT@ec.europa.eu) or [ISA@ec.europa.eu](mailto:ISA@ec.europa.eu) functional mailboxes.

In particular DG DIGIT's contribution includes:

- A **method**<sup>218</sup> the DGs can use either on their own or with the help of DIGIT to perform their assessments;
- A **service**<sup>219</sup> ("Assessment of ICT implications of EU legislation") to the Commission DGs wishing to perform their assessments;

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<sup>216</sup> <http://www.cc.cec/itservices/en/content/corporate-it-governance-coordination-support>

<sup>217</sup> <http://ec.europa.eu/isa/>

<sup>218</sup> [http://ec.europa.eu/isa/actions/03-ict-implications-assessment/3-1action\\_en.htm](http://ec.europa.eu/isa/actions/03-ict-implications-assessment/3-1action_en.htm)

- **Screening of published Roadmaps** to identify cases where ICT assessment is needed.

## **DG -CONNECT**

For **advice on digital economy and society issues** and related opportunities/impacts (in particular those related to assessing options' effectiveness, efficiency and coherence with other policies) and on how to address **Internet Readiness checks** (see later in this section), please contact DG CONNECT helpdesk via the [CNECT-02@ec.europa.eu](mailto:CNECT-02@ec.europa.eu) functional mailbox.

In particular DG CONNECT's contribution includes:

- Advice on matters of **best practice** and modernised methods through state-of-the-art **ICT support tools** which:
  - Help 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 (such as in open policy-making approaches based on the transparency principle and welcoming feedback continuously), of Inter-service Steering Group collaboration;
  - Facilitate the comparison of options across differing impact dimensions (economic, social and environmental) including trade-offs or greatly differing distributions among types of stakeholders/territories or even timelines.
- Support on new mandatory **Internet-readiness checks**, towards adaptive governance and Internet-inclusive legislation policy-making, meaning *legislation that is "fit for purpose" on the Internet as well as in the physical world*<sup>220</sup>. Such checks should clarify whether Internet drivers are sufficiently taken into account in the baseline, whether some ICT based options could address the objectives more effectively, efficiently and with greater coherence with other EU policies (including digital policies), and whether some ICT solution can facilitate future monitoring/evaluation plans (to lower related administrative costs).

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<sup>219</sup> <http://www.cc.cec/itservices/en/content/assess-ict-implications-eu-legislation>

<sup>220</sup> A study carried out in 2014 (Putting the IC into 'Policy' – Strategic analysis for optimising the role of ICT in EU policy delivery: <https://ec.europa.eu/digital-agenda/en/news/strategic-analysis-optimising-role-ict-eu-policy-delivery-smart-20130021-study-report>) has discussed the potential long-term effects of online factors on existing regulatory environments in three policy areas, to ensure that these are Internet-ready.

## How to identify and develop ICT-related problems and options

The digital dimension must be taken into account at a number of essential steps in the IA development process, as further detailed and illustrated below along these main steps:

### 1. IDENTIFYING ICT RELATED PROBLEMS

#### *Box 1. Digital technologies and the problem definition*

- 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 must 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 administrations<sup>221</sup>, 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 scrutinize).

### 2. DIGITAL CHECK – HOW TO DEVELOP ICT RELATED POLICY OPTIONS

#### 2.1. Consider all options on an equal footing

When defining the objectives of a policy proposal and seeking to identify feasible policy options which can help meet these, basic principles are **not to discriminate between on-line and off-line implementations/outcomes** (when both types of transactions exist/are being used), **not to discriminate between the digital and the physical world** and to **think digital first**.

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<sup>221</sup> 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](#)

Sales channels, whether physical stores or on-line sellers, should be treated 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.

It may be useful to distinguish between various types of ICT based options supporting **business functions** considered in the initiative:

- **Information handling** related to:
  - 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;
  - 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;
  - On the **exchange of information** - e.g. booking services.
- **Monitoring** (e.g. through satellite imaging, video monitoring, network monitoring, aerial thermography etc.) – consisting basically of information retrieval - texts or transactions, but also images and sound (using varieties of formats) – or on status check (e.g. to test/check the availability/continuity of service/correct working of some systems).
- **Decision making:** 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).

## 2.2. Think of interoperability

It is essential that **interoperability** (e.g. overcoming national **standards** or extending a service with multilingual interfaces) is considered from the beginning since the lack of it generates obstacles to the free movement of goods/services within the European Union, interoperability/multilingual support solutions can be attained through standardisation/meta-standardisation or semantic/ontological approaches.

### 2.3. Think of reusability

Reusing is a key to achieving cost reduction, timely implementation, good quality due to proven previous application and interoperability as reused solutions tend to be easily interconnected. The Commission has put in place various tools and services that can help to identify ICT reusable solutions (more in appendix 2). Reusability should be sought not only at the level of ICT services and software tools, but also through the use of **open data** that can increase the potential of building solutions of high impact and value.

### 2.4. Developing your options as ICT based business processes

Irrespective of whether an ICT-focused option is the preferred option, all the options analysed should include consideration of ICT/Internet aspects.

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 IT-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 on-board 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 ICT BASED 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 off-line versus on-line 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 2. On-line 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 must 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 on-Line 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 "on-Line" 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.

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.

<i>Sources of reusability</i>		
<b>Source of information</b>	<b>When and how should I use it?</b>	<b>Where to find?</b>
<i>EICart</i>	To search for and discover existing ICT solutions that can be reused by EU public administrations to build up digital services.	<a href="mailto:ISA@ec.europa.eu">ISA@ec.europa.eu</a>
<i>Trans-European Systems Cartography</i>	To identify and reuse trans-European systems or their modules developed to support EU policies.	Please refer to DIGIT.B6
<i>Joinup</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".	<a href="https://joinup.ec.europa.eu/">https://joinup.ec.europa.eu/</a>
<i>Open Data Portal</i>	To locate, use, reuse, link and distribute EU data (research, financial, demographic, etc.) for commercial and non-commercial purposes.	<a href="https://open-data.europa.eu/">https://open-data.europa.eu/</a>
<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 MS, 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>	<a href="https://psx1.psteering.com/EC/Home.page">https://psx1.psteering.com/EC/Home.page</a>
<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.	<a href="http://www.cc.ec/itservices/en">http://www.cc.ec/itservices/en</a>

The table overleaf 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.

<i>Methods, frameworks and services</i>		
<b>Source of information</b>	<b>When and how should I use it?</b>	<b>Where to find?</b>
<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.	<a href="https://joinup.ec.europa.eu/asset/eia/description">https://joinup.ec.europa.eu/asset/eia/description</a>
<i>DIGIT's Reference Architecture for IS development</i>	If the solution is to be implemented by the Commission, the use of this architecture and its implementing framework can guarantee a high degree of reusability, technical quality, interoperability, low cost and short development time.	<a href="http://www.cc.ec/itservices/en/services/65">http://www.cc.ec/itservices/en/services/65</a>
<i>CEAF</i>	If the whole or part of the ICT solution is to be implemented by the Commission, compliance with the framework should be proposed to ensure alignment with the Enterprise Architecture principles of the Commission.	<a href="http://www.cc.ec/itservices/en/content/commission-enterprise-architecture-framework-ceaf">http://www.cc.ec/itservices/en/content/commission-enterprise-architecture-framework-ceaf</a>
<i>PM<sup>2</sup></i>	If the solution is to be implemented by the Commission, this is the de-facto project management method to propose.  If the solution is developed externally to the Commission, it can be proposed that project management principles are defined as per PM <sup>2</sup> or similar methods.	<a href="http://www.cc.ec/itservices/en/content/pm%C2%B2-project-management-methodology">http://www.cc.ec/itservices/en/content/pm%C2%B2-project-management-methodology</a>
<i>RUP@EC</i>	If the solution is to be implemented by the Commission, this is the de-facto software development method to propose.  If the solution is developed externally to the Commission, it can be proposed that software development is based on methods promoting a user-centric and iterative IT development style.	<a href="http://www.cc.ec/itservices/en/content/pm%C2%B2-project-management-methodology">http://www.cc.ec/itservices/en/content/pm%C2%B2-project-management-methodology</a>
<i>BPM@EC</i>	In case business processes can be identified, they could be organised and presented, at the required level of detail, in standard formats to help comprehension and better link them with the underlying ICT solution.	<a href="http://www.cc.ec/itservices/en/content/business-process-management-bpm">http://www.cc.ec/itservices/en/content/business-process-management-bpm</a>
<i>SMP@EC</i>	If the IT solution is going to be designed following the SOA style, SMP@EC is the proposed Commission methodology.  It guides IT architects to identify capabilities to be exposed as SOA services and provides artefacts & tools (architectural blueprints, service contracts & interfaces) to formally specify the SOA solution as a	<a href="http://www.cc.ec/wikis/display/SMPAtEC/What+is+SMP@EC">http://www.cc.ec/wikis/display/SMPAtEC/What+is+SMP@EC</a>

	whole from a logical point of view.	
<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.	<a href="http://www.cc.c ec/itservices/en/services/67">http://www.cc.c ec/itservices/en/services/67</a>
<i>VAST</i>	If you want to measure the value of the option for the EU, the Commission and/or the proposal's stakeholders.	<a href="http://ec.europa.eu/dgs/informati cs/vast/index_en .htm">http://ec.europa. eu/dgs/informati cs/vast/index_en .htm</a>

## TOOL #24: FUNDAMENTAL RIGHTS & HUMAN RIGHTS

### 1. INTRODUCTION

Fundamental rights<sup>222</sup> 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 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 requirement<sup>223</sup>. EU legal acts can be challenged before national courts as well as the European Court of Justice for failing 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 must 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 examples<sup>224</sup>.

When assessing the impacts of initiatives with effect outside of the EU, additional consideration would have to be given to international Human Rights instruments in addition to the requirements of the Fundamental Rights Charter. 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 agreements<sup>225</sup>.

#### ***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

<sup>222</sup> 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.

<sup>223</sup> As expressed in the Charter of Fundamental Rights and other legal documents.

<sup>224</sup> [http://ec.europa.eu/smart-regulation/impact/key\\_docs/docs/sec\\_2011\\_0567\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2011_0567_en.pdf)

<sup>225</sup> See DG TRADE guidance on the analysis of human rights impacts in trade impact assessments

Charter’.

- The Charter rights are of relevance to all EU policies and the Institutions are bound to respect its provisions both in its internal and external action policies.
- 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.’*
- The level of protection offered by the Charter cannot be less than that provided by international agreements to which the Union or all the Member States are a party. The Charter should be interpreted in line with such instruments including the UN Convention on the rights of persons with disabilities (CRPD)<sup>226</sup> to which the EU has been a party since 2011.

## 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.<sup>227</sup>

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 disabilities<sup>228</sup>) who could also be

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<sup>226</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010D0048;>  
[www.ohchr.org/en/hrbodies/crpd/pages/crpdindex.aspx](http://www.ohchr.org/en/hrbodies/crpd/pages/crpdindex.aspx)

<sup>227</sup> See tool on how to analyse problems

<sup>228</sup> EMPL-RIGHTS-DISABILITIES@ec.europa.eu

invited to participate in the IA work of the interservice group. The EU Agency for Fundamental Rights<sup>229</sup> (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.

## 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 must 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 point 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 to protect the rights and freedoms of others (This step should identify which objective of general interest or to protect 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

<sup>229</sup> <http://fra.europa.eu/en>

without going beyond what is necessary to achieve it? Why is no equally effective but less intrusive measure available?);

- 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 a **interference** to one or several fundamental rights, it must 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 Explanations<sup>230</sup> 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*<sup>231</sup> 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*<sup>232</sup> 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-law<sup>233</sup>. 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.<sup>234</sup>

<sup>230</sup> 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>

<sup>231</sup> [http://ec.europa.eu/justice/news/intro/doc/com\\_2010\\_573\\_en.pdf](http://ec.europa.eu/justice/news/intro/doc/com_2010_573_en.pdf)

<sup>232</sup> [http://ec.europa.eu/smart-regulation/impact/key\\_docs/docs/sec\\_2011\\_0567\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2011_0567_en.pdf)

<sup>233</sup> <http://infoportal.fra.europa.eu/InfoPortal/infobaseShowContent.do>.

<sup>234</sup> <http://www.echr.coe.int/Pages/home.aspx?p=home>

## **TOOL #25: EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION AND INEQUALITY**

### **1. INTRODUCTION**

This BR tool aims at introducing the main concepts and questions in assessing some of the key impacts falling within the broad category of social impacts. It covers changes in employment levels and working conditions. A third theme relates to distributional impacts including impacts on perspectives and life-situations of people in, or at risk, of poverty.

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 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. Examining potential negative impacts is needed in order to avoid (unintended) negative consequences.

### **2. ARE IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION AND INEQUALITIES POTENTIALLY SIGNIFICANT?**

The impacts covered by this tool are likely to be the most frequently encountered social impacts (next to health issues) in an Impact Assessment (IA).

These impacts are multi-faceted. Identifying potentially significant impacts relies to some extent on value judgement but should be guided by two key criteria:

- Are there any (potential) social impacts which could significantly affect society or specific social groups and which are likely to be politically sensitive? (e.g. fear of significant job-losses, fear of deteriorating working conditions, or burdens which are considered as unfair or disproportionate);
- Could (potential) social impacts enhance /or undermine other EU initiatives (e.g. job creation, longer working lives, greater social inclusion, or better qualified citizens)?

The aim of the assessment should be to identify those social groups which are likely to be the most affected and for which a thorough assessment will need to be undertaken. As policy options may have different impacts on different parts of society, it is important to identify social groups which are concerned by a particular impact (i.e. including groups located in specific regions or working in specific sectors). It could be that a measure raises the disposable income of certain population groups but reduces other groups to poverty and negatively affects their chances to participate fully in society<sup>235</sup>. In such

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<sup>235</sup> This could be the case of moving from direct taxation (e.g. taxing the income, where normally the ability to pay is taken into consideration) to indirect taxation (e.g. increased VAT or taxation of fuel for heating purposes), which could have – without accommodating measures – problematic effects on low-income households.

cases, calculating the average general impact on the total population could be misleading, and would, therefore, be insufficient.

## **2.1. Impacts on the level of employment**

*Impacts on the level of employment* can be expected whenever demand or supply of a product changes or where relative prices change (e.g. between different producers). The main question is whether there will be more or less jobs or eventually more or less hours worked overall or for specific social groups. It will give you an indication whether a larger workforce will be needed and/or whether redistribution of labour is to be expected.

- To what extent does the option lead to overall (gross and net) job creation or losses?
- Does the option lead to direct job creation or job losses in specific sectors, professions, skill levels, regions, countries – (or a combination thereof) with consequences for specific social and/or age groups? Which ones?

The following questions explore various dimensions to the assessment of employment impacts.

- (1) *Are there any significant indirect effects which might lead to additional changes in employment levels?*

An option can lead to indirect employment effects (e.g. new industrial activity can employ directly or stimulate indirectly job creation through the purchases of goods and services).

- (2) *Are there any factors that would further affect (i.e.: blocking or accelerating) the exploitation of the potential for job creation or the risks for job losses under the option?*

Delays in the acknowledgement and certification of new qualifications or a lack of arrangements to provide for a transition can create significant employment problems without need. While analysis often implies easy adaptation processes, an important aspect of employment related impacts requires explicit consideration for timing and sequencing of the intervention.

- (3) *To what extent does the option influence the supply of labour of specific groups 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, work-life balance policies, work intensity and working conditions, length of working life, the occupational /or geographical mobility of labour.

## **2.2. Impacts on working conditions**

*Impacts on working conditions* are more difficult to capture and cover a broader range of outcomes. The most important factors affecting working conditions to be considered are:

- (1) *Does the option affect wages or wage setting mechanisms and/or labour costs?*

**Wage-level and/or labour costs:** while wages safeguard labour income and are positively correlated with consumption, labour costs are – generally – negatively correlated with the competitiveness of goods produced. The **wage setting mechanism** affects the level or conditions of minimum wages, the coverage of workers by collective agreements, negotiating power of social partners.<sup>236</sup>

(2) *Does the option affect directly or indirectly employment protection, especially the quality of work contracts, risk of undeclared work, or false self-employment?*

**Employment protection:** employer-driven flexibilisation of working hours and reduction of job security makes employee's income less predictable and leads to instable living conditions.<sup>237</sup> 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 the work organisation?*

**Work organisation:** work autonomy, level of teamwork and job rotation, pace of work and work intensity are important elements of work organisation; they 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. Work organisation can change with the introduction of new technologies but also as a consequence of industrial restructuring.

(4) *Does the option affect health and safety at work? (e.g. exposure to potentially harmful substances or situations, and/or tight/unsocial working hours)*

**Health and safety at work:** stress levels, conditions to reconcile work and private life, exposure to potentially harmful substances or situations, insufficient protective equipment – also combinations thereof can be problematic for workers' health; while satisfying work and good working conditions constitute a value in itself, their absence does not only lead to discontent, but can also produce significant negative effects including negative externalities – such as e.g. increased health expenditure, thereby 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.

(5) *Does the option affect the social dialogue?*

**Social partner influence** on working conditions and wage negotiations (trade unions and employer's organisations are an important means to organise a dialogue between employers and employees. It is an important mechanism for conflict resolution and a means to internalise external effects which take place at sectoral level).

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<sup>236</sup> You might want to assess here: 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.

<sup>237</sup> 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, strong competition from undeclared work, forced and false self-employment, very strong involvement of temporary work agencies.

- (6) *Does the option affect access to vocational learning and to career development/advice?*

**Training/lifelong learning opportunities** and returns to it (recognition of skill acquired in other companies, but also in other Member States) can influence career perspectives /security.

- (7) *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, 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.

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 and inequalities

*These impacts* relate to social fairness considerations and in the extreme forms to the probability of poverty. 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 efforts have income distributional impacts. Typical impacts to be analysed:

- (1) *Will the option have an impact on inequalities and the distribution of incomes and wealth in the Union or in one of its parts?*

**Income inequalities:** increasing income inequalities threaten social cohesion and can be linked to a number of factors such as wage dispersion, tax wedge, social protection systems, level of union coverage, etc.

- (2) *Will the option reduce or increase number of workers with insufficient income? Does the option impact directly or indirectly on poverty rates and severe material deprivation?*

**Disposable income:** is an important indicator of social status and of someone's living standard. If it falls below a certain threshold, people will either be poor and/or rely on social assistance. The three dimensions of poverty comprise: low work intensity, material deprivation and relative poverty.

- (3) *Will the option have an impact on access to and quality of social protection schemes?*

Changes related to coverage, level and /or duration of **social protection schemes:** eligibility, duration and level of benefits; type of risks covered; rights to receive benefits when moving to another MS beyond the obligatory rights (mainly unemployment, sickness, maternity/parenthood, old-age; insurance vs. solidarity; tax financed vs. contribution based; range of membership).

(4) *Will availability or affordability of basic goods and services be affected?*

**Access to and quality of basic goods and services** (food, healthcare, education, housing, energy, water, transport, banking services, digital services): it might be important to assess the access and quality of these goods and services especially for people not covered by the regular social protection schemes.

**2.4. How to assess impacts on employment, working conditions, income distribution and inequalities?**

**Impacts:** Some effects, such as number of jobs can be easily counted. Others, such as working conditions can be measured only to some extent by using proxies<sup>238</sup>: 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 causalities). In these areas, the first step is to define reasonable indicators which allow at least 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 invested to collect and process the necessary information.

**Personal characteristics:** Some of the identified groups will be well defined (for instance by gender, age, income, disability, level of education) while others might be more elusive (for instance those affected by a possible action in a specific way or vulnerable). In practice, it is useful to start by examining whether there are any systematic impacts on well-defined groups. 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.

The identification of those for whom there may be positive and negative impacts may also help to foresee resistance and may point to mitigating measures to reduce negative impacts. This also explains the need to consult on possible effects with informed stakeholders or third parties.

**Sectoral effects:** 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. Sectoral dimension implies also a general requirement to consult with social partners regarding 'social impacts'.

**Regional dimension:** Here the question of alignment with the NUTS classification is essential. The regional dimension might actually not have been on the mind of those designing the policy: e.g. reforming the common agricultural policy for wine-growing was expected to have no employment impact in those MS with (almost) no wine-growing, very little impact in those MS where the sector had already undergone significant reforms and significant, impact in those MS where such reforms had not yet taken place. However, depending on the respective structure (age of farmers, size of

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<sup>238</sup> On indicators, see common tool on monitoring, evaluation and indicators

farms), these impacts were expected to differ even in those countries. Being able to draft a nuanced picture of the social impacts is an important element for political debate.

### 3. POSSIBLE METHODS

In selecting methods of social Impact Assessment, a balance needs to be found between sophistication and practicality.

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 3-6 issues (combination of impact and group affected) which are most important from a social perspective.

The qualitative scoping is necessary to decide whether and which (if any) formalised model can be employed. In general, a specific mix of qualitative and quantitative approaches is needed, the latter ranging from relatively simple measurement, mainly based on past observations, up to highly complex formalised (and data consuming) models, like Computable General Equilibrium (CGE) models or econometric models of the (world) economy.<sup>239</sup> Before deciding for a method one should ensure that econometric modelling makes sense in cases where quantitative employment impacts or redistributive impacts prevail.

#### 3.1. Key principles to follow:

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.

Some impacts (e.g. related to social inclusion) might be undisputed but difficult to quantify. The extent to which an impact can be modelled needs to be clarified.

If impacts are concentrated on small groups it will be difficult or impossible to find suitable data or a reasonable model.

If 'qualitative scoping' suggests considerable impact on income distribution or on employment on a large part of society, a model should be used. The decision not to do so needs to be justified in the impact assessment report.

### 4. INFORMATION SOURCES AND BACKGROUND MATERIAL

Below we provide a list of key EU-level data sources:

- **The European Union Labour Force Survey** (EU LFS) is the most important survey for labour market data available on EUROSTAT:

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<sup>239</sup> For further information on how to use models see IA tool on modelling and sensitivity analysis.

[http://epp.eurostat.ec.europa.eu/portal/page/portal/employment\\_unemployment\\_ifs/introduction](http://epp.eurostat.ec.europa.eu/portal/page/portal/employment_unemployment_ifs/introduction)

- The **European Working Conditions Survey** is available on the European Foundation for the Improvement of Living and Working Conditions (Eurofound): <http://www.eurofound.europa.eu/ewco/surveys/index.htm>
- For health and safety, statistical data on accidents at work, occupational diseases and work-related problems are available: **European Statistics on Accidents at Work (ESAW)**, **European Occupational Diseases Statistics (EODS)** and **Statistics on work-related health problems**.
- 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](http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/eu_silc)
- 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](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](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Continuing_vocational_training_statistics)
- 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 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](http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/adult_education_survey)

For further reference, information sources, background material and methodological issues refer to the 3<sup>rd</sup> level operational guidance on employment, working conditions, income distribution and inequalities available prepared by DG EMPL.

## TOOL #26: IMPACTS ON EDUCATION CULTURE AND YOUTH

### 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 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 e.g. in 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**

- Art 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.
- Art 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"
- Art 165 TFEU invites the EU to encourage the **participation of young people** in democratic life in Europe

### 2. ARE IMPACTS ON ECY POTENTIALLY SIGNIFICANT?

In order to identify potential impacts on ECY 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

*Is the initiative/policy designed to make a contribution to the achievement of a high level of education? 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 (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?*

*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 educational settings affected by a policy option?*

Impacts on different educational sectors, incl. pre-school, primary/secondary school, vocational education and training (VET), higher education, adult learning, non-formal learning through youth work as well as effects on levels of and access to knowledge and skills need to be taken into account. These impacts need to be considered in the light of different societal groups/age cohorts, regions and sectors.

Screening should not be restricted to 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 & 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 right<sup>240</sup>. 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

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<sup>240</sup> See Art. 27 of [Universal Declaration of Human Rights](#)

ability to participate in democratic life<sup>241</sup>, 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 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 education impacts with respect to the youth.

*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 ECY**

*Education*

- Changes in expenditure scheme – e.g. re-allocation 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
- Systemic changes – e.g. 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

*Culture*

- 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

<sup>241</sup> For example, participation in social and civic activities and organisations, volunteering, opportunities to express opinions in decision-making processes

cultural objects unlawfully removed from the territory of a MS (recast)<sup>242</sup>

### *Youth*

- Policies impacting education
- Policies impacting labour market
- Policies impacting health

## **3. HOW TO ASSESS IMPACTS ON ECY?**

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**

Assessing impacts on education can be based on different components, with list provided below:

#### *3.1.1. Education 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 marketplace. Significant differences persist in the effectiveness of national education and training systems (young adults with nominally equivalent levels of education 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 education 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 education processes paving the way for smart innovation.

#### *3.1.3. Levels of literacy and numeracy*

Levels of literacy and numeracy significantly affect a population's potential to contribute to developed society. They are one of the most important indicators in terms of education as well as a frequent target of new policies.

<sup>242</sup>

<http://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52013SC0189&from=EN>

#### *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 education participation. 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.

Gathering information on levels of knowledge, skills and competencies 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.

#### *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 period before starting compulsory education. Statistics on these are regularly monitored with 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 educational process 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 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 increasing need for the provision of high quality traineeships, apprenticeships and dual educational 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 & 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.<sup>243</sup>

## **3.3. 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 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, education in terms of formal education, 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

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<sup>243</sup> Eurobarometer on Cultural access and participation  
[http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_399\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_399_en.pdf)

youth development. For detailed list of corresponding impacts on education, please see above.

**Box 3 : Example of cost-benefit assessment in The Youth Guarantee approach<sup>244</sup>**

- 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 respond to young people's expectations.

#### 4. HOW TO MINIMISE NEGATIVE IMPACTS ON ECY

**Box 4: Example of best practices in Open Up Education initiative<sup>245</sup>**

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 Courseware<sup>246</sup> in raising cross border cooperation between geographically close universities of Germany, Luxembourg, France and Belgium.
- Open Education Europa Portal<sup>247</sup> 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 pages<sup>248</sup>.

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<sup>244</sup> <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](http://eurofound.europa.eu/sites/default/files/ef_files/pubdocs/2012/54/en/1/EF1254EN.pdf)

<sup>245</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0341&from=EN>

<sup>246</sup> 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.

<sup>247</sup> <http://openeducationeuropa.eu/>

<sup>248</sup> <https://myintracomm.ec.europa.eu/dg/eac/governance-tools/ensuring-quality/evaluation-and-impact-assessments/impact-assessments/Pages/Impact-Assessments.aspx>

## 5.1. Education

The core quantitative information and data required are described and further annually assessed in the European Education and Training Monitor<sup>249</sup>. 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);
- **OECD**<sup>250</sup> – information on teachers and their professional development (TALIS), annual study on students' performance (PISA), assessment of adults' skills (PIAAC);
- **EURYDICE**<sup>251</sup> – 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**<sup>252</sup> – indicators and annual studies on vocational education and training, thematic secondary comparative analyses and skills forecasts;
- **CRELL**<sup>253</sup> (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**<sup>254</sup> (JRC) - secondary comparative analyses, definition of indicators and prospective analyses on ICT, OER and creativity by delivering;
- **EENEE**<sup>255</sup> – analysis and reports by network of experts in the field of economy of education and training;
- **NESET**<sup>256</sup> - analysis and reports by network of experts in the field of equity in education and training.

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<sup>249</sup> [http://ec.europa.eu/education/tools/et-monitor\\_en.htm](http://ec.europa.eu/education/tools/et-monitor_en.htm)

<sup>250</sup> <http://www.oecd.org/education/>

<sup>251</sup> [http://eacea.ec.europa.eu/education/eurydice/index\\_en.php](http://eacea.ec.europa.eu/education/eurydice/index_en.php)

<sup>252</sup> <http://www.cedefop.europa.eu/EN/publications.aspx>

<sup>253</sup> <https://crell.jrc.ec.europa.eu/>

<sup>254</sup> <https://ec.europa.eu/jrc/en/institutes/ipts>

<sup>255</sup> <http://www.eenee.de/eeneeHome.html>

<sup>256</sup> <http://www.nesetweb.eu/>

## 5.2. Culture

- Cultural diversity: 2005 UNESCO convention on the protection and promotion of the diversity of cultural expressions;<sup>257</sup>
- Participation in culture: 2013 Eurobarometer on cultural access and participation<sup>258</sup>: Household expenditure surveys;
- Public policy in the area of culture, including funding: 2013 EENC report on trends in public funding for culture;<sup>259</sup>

## 5.3. Youth

- The EU Dashboard of Youth Indicators<sup>260</sup> 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"<sup>261</sup>.
- The study on the value of youth work<sup>262</sup> 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).

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<sup>257</sup> <http://www.unesco.org/new/en/culture/themes/cultural-diversity/diversity-of-cultural-expressions/the-convention/convention-text/>

<sup>258</sup> [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_399\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_399_en.pdf)

<sup>259</sup> <http://www.eenc.info/category/eencdocs/reports-documents-and-links/>

<sup>260</sup> [http://epp.eurostat.ec.europa.eu/portal/page/portal/employment\\_social\\_policy\\_equality/youth/indicators](http://epp.eurostat.ec.europa.eu/portal/page/portal/employment_social_policy_equality/youth/indicators)

<sup>261</sup> [http://ec.europa.eu/youth/library/reports/creative-potential\\_en.pdf](http://ec.europa.eu/youth/library/reports/creative-potential_en.pdf)

<sup>262</sup> [http://ec.europa.eu/youth/library/study/youth-work-report\\_en.pdf](http://ec.europa.eu/youth/library/study/youth-work-report_en.pdf)

## TOOL #27: IMPACTS ON HEALTH

### 1. INTRODUCTION

The Treaty (art 168) 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 (art 114 (3)). 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 asbestos<sup>263</sup>. 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 health<sup>264</sup> 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 have an incidence of respiratory conditions.

#### ***Box 1. Questions to help identify whether there might be health-related impacts***

##### ***Direct impacts***

- *Does the option create (or reduces) 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,

<sup>263</sup> Directive 1999/77/EC

<sup>264</sup> 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](https://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](http://www.euro.who.int/document/e81384.pdf))

unsafe consumer products)

- *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, 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 status<sup>265</sup>.

In any case, the identification of significant impacts on health of a proposal/option should be informed by the outcomes of stakeholders' consultation (see section on 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<sup>266</sup>. The identification of the most appropriate methodology to use will depend on the characteristics or nature of the options under assessment<sup>267</sup>. To assess impacts on health it is necessary to have at least a general knowledge of public health<sup>268</sup> policies and

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<sup>265</sup> 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?

<sup>266</sup> See on methodological tools.

<sup>267</sup> 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](http://ec.europa.eu/health/strategy/evaluation/index_en.htm)

<sup>268</sup> 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".

health systems<sup>269</sup> 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, in Member States level or by third parties more generally<sup>270</sup>.

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.

#### Non-monetary approaches<sup>271</sup>

- **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")<sup>272</sup>. Values are generally derived from surveys

<sup>269</sup> 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).

<sup>270</sup> See for instance the “Public health England” website that provides a gateway to Health Impact Assessments ([www.apho.org.uk/default.aspx?RID=44539](http://www.apho.org.uk/default.aspx?RID=44539))

<sup>271</sup> 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> )

<sup>272</sup> 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](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](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2956_en.pdf)

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 disease<sup>273</sup>, 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)**<sup>274</sup> 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 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 worsening<sup>275</sup>. 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)<sup>276, 277</sup>.

<sup>273</sup> See the WHO Global Burden of Disease reports ([www.who.int/topics/global\\_burden\\_of\\_disease/](http://www.who.int/topics/global_burden_of_disease/) and <http://www.healthdata.org/>) including for additional information on weighting and discounting.

<sup>274</sup> For general information on HLY, see ([www.ec.europa.eu/health/indicators/healthy\\_life\\_years/index\\_en.htm](http://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](http://www.ec.europa.eu/eurostat/cache/metadata/en/tsdph100_esmsip.htm))

<sup>275</sup> See tools on methods to estimate costs and benefits

<sup>276</sup> 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](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:

## ***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 policy making. 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 conducted<sup>278</sup>.

### ***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).

- **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

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[http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP\\_CBA\\_corresponding\\_to\\_IIASA11\\_v2.pdf](http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP_CBA_corresponding_to_IIASA11_v2.pdf)

<sup>278</sup> [http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmenthealthandtransportpolicies.htm#Executive\\_Summary](http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmenthealthandtransportpolicies.htm#Executive_Summary)

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 1. 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)<sup>279</sup>. 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 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)

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<sup>279</sup> <http://www.who.int/choice/cost-effectiveness/en/>

works on elaborating methodological guidelines for health economic evaluations (including a reflection on discounting<sup>280</sup>).

## 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** 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**<sup>281</sup> 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**<sup>282</sup> and the Joint Action on HTA<sup>283</sup> can help identifying or gathering relevant Health Technology Assessment (HTA).<sup>284</sup>

### 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 impacts<sup>285</sup>

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<sup>280</sup> <http://www.eunetha.eu/>

<sup>281</sup> Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR).

<sup>282</sup> 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](http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm)

<sup>283</sup> 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>)

<sup>284</sup> 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).

- INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe)<sup>286</sup>
- Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012<sup>287</sup>

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 interventions<sup>288</sup>
- WHO Guide to Cost effectiveness<sup>289</sup>

#### *Health Impact Assessments*

- Health Impact Assessment website of 'Public Health England'<sup>290</sup>
- DYNAMO-HIA (2011) Development of a dynamic modelling tool to assess health impact of policies
- European Policy Health Impact Assessment – EPHIA (2004)<sup>291</sup>
- WHO toolbox on Health Impact Assessment<sup>292</sup>
- Health inequalities in Health Impact Assessments<sup>293</sup>
- EU Health Systems Performance Assessment tool<sup>294</sup>

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<sup>285</sup> <http://www.heimtsa.eu/>

<sup>286</sup> <http://www.intarese.org/about>

<sup>287</sup> [http://www.sdu.dk/en/om\\_sdu/institutter\\_centre/ist\\_sundhedstjenesteforsk/forskning/forskningsenheder/sundhedsfremme/forskningsprojekter/rapid](http://www.sdu.dk/en/om_sdu/institutter_centre/ist_sundhedstjenesteforsk/forskning/forskningsenheder/sundhedsfremme/forskningsprojekter/rapid)

<sup>288</sup> <http://publications.nice.org.uk/how-nice-measures-value-for-money-in-relation-to-public-health-interventions-lgb10b/introduction>

<sup>289</sup> [http://www.who.int/choice/publications/p\\_2003\\_generalised\\_cea.pdf](http://www.who.int/choice/publications/p_2003_generalised_cea.pdf)

<sup>290</sup> [http://www.apho.org.uk/default.aspx?QN=P\\_HIA](http://www.apho.org.uk/default.aspx?QN=P_HIA)

<sup>291</sup> [http://ec.europa.eu/health/ph\\_projects/2001/monitoring/fp\\_monitoring\\_2001\\_a6\\_frep\\_11\\_en.pdf](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](http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_frep_11_en.pdf)

<sup>292</sup> <http://www.who.int/hia/tools/en/>

<sup>293</sup> <http://www.equityaction-project.eu/about/health-inequalities>

<sup>294</sup> [http://ec.europa.eu/health/health\\_policies/impact/assessment\\_tool/index\\_en.htm](http://ec.europa.eu/health/health_policies/impact/assessment_tool/index_en.htm)

### 5.3. Studies

- OECD (2012) Mortality Risk Valuation in Environment, Health and Transport Policies<sup>295</sup>
- EU-OSHA (2014) Estimating the cost of accidents and ill-health at work: A review of methodologies<sup>296</sup>
- European Observatory on Health Systems (2007) study on the effectiveness of HIA<sup>297</sup>
- Marsh et al. (2012) Estimating cost-effectiveness in public health: a summary of modelling and valuation methods<sup>298</sup>
- Roberta Ara, Allan Wailoo (2012) Using Health State Utility Values in Models Exploring the Cost-Effectiveness of Health Technologies<sup>299</sup>
- Divajeva et al (2014) Economics of chronic diseases protocol: cost-effectiveness modelling and the future burden of non-communicable disease in Europe<sup>300</sup>
- CEPS, Economisti Associati (2013) Assessing The Costs And Benefits Of Regulation<sup>301</sup>

### 5.4. Data sources

- EUROSTAT : Including the European Core Health Indicators (ECHI)<sup>302</sup>,
- Health at a glance: Europe – an EU publication, issued once in 2 years in collaboration with the OECD<sup>303</sup>,
- OECD Health Statistics (on Health Expenditure, Health care resources, Health care activities)<sup>304</sup>

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<sup>295</sup> [http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies\\_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01](http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01)

<sup>296</sup> <https://osha.europa.eu/en/publications/reports/estimating-the-costs-of-accidents-and-ill-health-at-work/view>

<sup>297</sup> <http://www.euro.who.int/en/about-us/partners/observatory/studies/effectiveness-of-health-impact-assessment-the>

<sup>298</sup> <http://www.healtheconomicsreview.com/content/2/1/17>

<sup>299</sup> <http://www.sciencedirect.com/science/article/pii/S1098301512016087>

<sup>300</sup> [www.biomedcentral.com/1471-2458/14/456](http://www.biomedcentral.com/1471-2458/14/456)

<sup>301</sup> [www.ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://www.ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

<sup>302</sup> [http://ec.europa.eu/health/indicators/echi/list/index\\_en.htm](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](http://epp.eurostat.ec.europa.eu/portal/page/portal/health/health_care/data/database)

<sup>303</sup> [http://ec.europa.eu/health/reports/european/health\\_glance\\_2012\\_en.htm](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>

- WHO, WHO Regional office for Europe<sup>305</sup>
- European Observatory on Health Systems and Policies<sup>306</sup>
- The Cost-Effectiveness Analysis (CEA) Registry, Boston, MA<sup>307</sup>.
- The Cochrane Collaboration – systematic reviews<sup>308</sup>
- PubMed - the free US resource for research and medical publications<sup>309</sup>

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<sup>304</sup> <http://www.oecd.org/health/health-systems/>

<sup>305</sup> <http://www.who.int/research/en/> and <http://www.euro.who.int/InformationSources>

<sup>306</sup> [http://www.euro.who.int/observatorv/publications/20020522\\_1](http://www.euro.who.int/observatorv/publications/20020522_1)

<sup>307</sup> <http://research.tufts-nemc.org/cear4/Home.aspx>

<sup>308</sup> <http://www.cochrane.org/>

<sup>309</sup> [pubmed.gov](http://pubmed.gov)

## TOOL #28: IMPACTS ON 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.<sup>310</sup> 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. The Charter of Fundamental Rights***

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.<sup>311</sup>

This definition focusses on **end-consumers** rather than intermediate consumers who purchase for re-sale. In some situations, impacts on businesses might serve as a proxy for

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<sup>310</sup> [http://ec.europa.eu/consumers/eu\\_consumer\\_policy/consumer\\_issues\\_in\\_other\\_policies/index\\_en.htm](http://ec.europa.eu/consumers/eu_consumer_policy/consumer_issues_in_other_policies/index_en.htm)

<sup>311</sup> OJ L 149, 11.6.2005, p. 22, art. 2. a; OJ L 304, 22.11.2011, p. 64, art. 2 (1). 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. OJ L 304, 22.11.2011, p. 64, recital (17).

consumer impacts which are ultimately passed through to end-consumers.<sup>312</sup> While in some circumstances consumers might best be thought of as individuals, in other cases **households** may be the more relevant unit to consider.<sup>313</sup> 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?*

Policies ensuring that a consumer is not made subject to discriminatory requirements based on his nationality or place of residence (non-discrimination principle<sup>314</sup>) 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**<sup>315</sup> 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 asymmetries are also at play e.g. in cases of unsubstantiated or misleading environmental

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<sup>312</sup> 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.

<sup>313</sup> E.g. in the case of consumption of goods for children under parental care.

<sup>314</sup> OJ L 376, 27.12.2006, p. 60, art. 20.

<sup>315</sup> 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.

claims<sup>316</sup> 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.<sup>317</sup>

**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.<sup>318</sup> 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.<sup>319</sup> 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 the trader could reasonably be expected to foresee shall be assessed from the perspective of the average member of that group.<sup>320</sup>

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<sup>316</sup> [http://ec.europa.eu/consumers/consumer\\_evidence/market\\_studies/docs/environmental-claims-report-ecs-2013\\_en.pdf](http://ec.europa.eu/consumers/consumer_evidence/market_studies/docs/environmental-claims-report-ecs-2013_en.pdf)

<sup>317</sup> 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

<sup>318</sup> 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).

<sup>319</sup> 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.

<sup>320</sup> OJ L 149, 11.6.2005, p. 27, art. 5(3).

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.<sup>321</sup> 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.<sup>322</sup>

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**.<sup>323</sup>

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;<sup>324</sup> recent advances in behavioural economics have stressed the importance of 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

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<sup>321</sup> For the assessment of consumer health impacts, e.g. related to product safety, the forthcoming IA tool on assessing Health Impacts is the source of choice.

<sup>322</sup> 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>.

<sup>323</sup> 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](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](http://ec.europa.eu/consumers/consumer_evidence/market_studies/internet_services/index_en.htm).

<sup>324</sup> For further information, please consult the forthcoming IA tool on competition.

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.<sup>325</sup>

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**.<sup>326</sup>

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<sup>325</sup> 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.

<sup>326</sup> 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.

### 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 trust<sup>327</sup> 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 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**

<sup>327</sup> E.g. Consumers' **knowledge** of their rights, **awareness** of relevant institutional actors relevant in field and **confidence** in market conditions.

**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.<sup>328</sup> 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 are EU-wide [consumer and retailer surveys](#).
- The **Consumer Markets Scoreboard** tracks the **performance of over 50 consumer markets** across the EU, Iceland and Norway.<sup>329</sup> 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.<sup>330</sup>
- Findings of [in-depth market studies of underperforming sectors](#) and of transversal studies have influenced policy with tangible benefits for EU consumers. Market studies<sup>331</sup> 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

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<sup>328</sup> 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](#).

<sup>329</sup> They are based on the indicators of comparability, trust, problems and complaints, overall satisfaction with respect to expectations, choice and switching.

<sup>330</sup> The Commission adopted a [Recommendation](#) to ensure complaints' data comparability across the EU.

<sup>331</sup> These studies include consumers' opinion surveys, stakeholders' surveys, the collection of prices for goods/services, surveys based on mystery shopping methodology and behavioural experiments.

be carried out through the [Framework Contract for the Provision of Behavioural Economic Studies](#).

The **helpdesk** for assessing consumer impacts provides tailored information and specific guidance.

## TOOL #29: 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 models<sup>332</sup> 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](http://www.espon.eu).

#### **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.

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<sup>332</sup> See the Modelling Inventory Database & Access Services (MIDAS) Portal <http://midas.jrc.it/discovery/midas/>

### **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.<sup>333</sup>

## **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 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.

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<sup>333</sup> Contact the SG-C2 for further information

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 final<sup>334</sup>.
- **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](#).
  - **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 inventory<sup>335</sup> 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/>

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<sup>334</sup> [http://ec.europa.eu/smart-regulation/impact/key\\_docs/docs/cswd\\_ati\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/key_docs/docs/cswd_ati_en.pdf)

<sup>335</sup> 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 #30: 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.<sup>336</sup>

The EU defined five global PCD challenges where policy impacts should be given particular attention.<sup>337</sup> 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 fundamental and human rights in developing countries may also need to be addressed.<sup>338</sup>

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 OECD<sup>339</sup>).

#### ***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

<sup>336</sup> An updated list of Developing Countries and Least Developed Countries can be found, respectively, at the World Bank's and IMF's official websites.

<sup>337</sup> 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>

<sup>338</sup> See tool on fundamental rights.

<sup>339</sup> 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.

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 <sup>340</sup>	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?

<sup>340</sup> See tool on impacts on employment, working conditions, income distribution and inequality

	What is the impact on poverty levels <sup>341</sup> 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 <sup>342</sup> 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 <sup>343</sup>	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 <sup>344</sup> , EITI <sup>345</sup> or Kimberley agreement <sup>346</sup> ?

<sup>341</sup> Those people that stay below the poverty line

<sup>342</sup> See tool on Fundamental Rights

<sup>343</sup> For additional information see tool on Methods to assess costs and benefits and on Resource Efficiency

<sup>344</sup> 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](http://ec.europa.eu/environment/forests/illegal_logging.htm)

<sup>345</sup> 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>

<sup>346</sup> 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/>

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.<sup>347</sup>

## 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 techniques<sup>348</sup>.

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.<sup>349</sup>
- ***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 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.)<sup>348,350</sup>. For examples on how to use modelling in IA see Box 2.

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<sup>347</sup> [http://ec.europa.eu/agriculture/policy-perspectives/impact-assessment/cap-towards-2020/index\\_en.htm](http://ec.europa.eu/agriculture/policy-perspectives/impact-assessment/cap-towards-2020/index_en.htm)  
- Annex 12

<sup>348</sup> For the list of plausible models see tool on the use of analytical models

<sup>349</sup> For more details see, for instance, Joshua D. Angrist & Jörn-Steffen Pischke (2009), "Mostly Harmless Econometrics: An Empiricist's Companion", Princeton University Press.

<sup>350</sup> 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

### ***Box 2. Example of a recent 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.<sup>351</sup> 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 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.

<sup>351</sup> See [http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc\\_150737.pdf](http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf)

#### 4. INFORMATION SOURCES AND BACKGROUND MATERIAL

Box 4 provides examples of sources on information already available and on databases that 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).<sup>352</sup>
- **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 Biological Diversity](#), [Global Climate Change Alliance](#) and the [Forest Law Enforcement, Governance and Trade](#).

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<sup>352</sup> 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.

## TOOL #31: RESOURCE EFFICIENCY

### 1. INTRODUCTION

Resource efficiency means using the Earth's limited resources in a more sustainable manner while supporting economic growth and providing jobs<sup>353</sup>. 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 costs<sup>354</sup>. 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;
- Contribute, even indirectly, to the creation of new demand, markets, skills and business models (e.g. in innovation, telecommunication, education and employment

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<sup>353</sup> COM(2011)571

<sup>354</sup> COM(2014) 440

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? (e.g. bees 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. bees, 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**<sup>355</sup>, 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;

Nature and ecosystems:

- (a) Biodiversity: (i) Common birds index; (ii) Area under organic farming; (iii) Landscape fragmentation;
- (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

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<sup>355</sup> [http://epp.eurostat.ec.europa.eu/cache/REIs/REIs\\_EN\\_banner.html](http://epp.eurostat.ec.europa.eu/cache/REIs/REIs_EN_banner.html)

- (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 2012 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](#)<sup>356</sup> 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 competitiveness<sup>357</sup>.

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:***

- 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);

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<sup>356</sup> <https://ec.europa.eu/eip/raw-materials/en/content/eip-raw-materials-monitoring-and-evaluation-scheme>

<sup>357</sup> See tool on sectoral competitiveness

- Has the "rebound effect" been considered? (i.e. an improvement in resource efficiency is offset by an increase in consumption);
- Is 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, 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 Assessment<sup>358</sup> 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 F.1) 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:](#)

### 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://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](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):

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<sup>358</sup> See tool on methods to estimate costs and benefits

<b>SWD ref</b>	<b>Title of the proposal</b>	<b>Resource Aspect considered</b>	<b>Main Sections</b>
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 <sub>2</sub> 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

## **Chapter 4**

### **Implementation, transposition & preparing proposals**

## TOOL #32: THE IMPLEMENTATION PLAN

Where an implementation plan is required it should follow the format below<sup>359</sup>:

*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 IA 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*<sup>360</sup>:

- 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 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;
- Providing a platform for an exchange of good practice in implementation;

<sup>359</sup> This replaces the model provided in the Annex I of the Note dated 7/01/2013 (Ares(2013) 12012).

<sup>360</sup> 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.

- 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 IA on potential implementation problems related to national legislation;
- Informing the Commission 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).

<b><i>Implementation challenge</i></b>	<b><i>Support action</i></b>	<b><i>Timing</i></b>

## TOOL #33: TRANSPOSITION CHECKS

### 1. COMPLIANCE ASSESSMENT: A TWO-STAGE SYSTEMATIC APPROACH

To ensure the full effectiveness of Article 258 and 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 imposed on the Member States contained in the directive that is to be transposed.

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 falling under partial transposition***

- The concept of completeness of transposition measures in terms of geographic scope is relatively straightforward.<sup>361</sup> 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;<sup>362</sup>
- The concept of completeness of transposition measures in terms of substantive scope means that every obligation of a directive should find a counterpart in the national transposition measures.<sup>363</sup> Therefore, a complete screening of all articles and sub-articles is necessary should fall under the scope of the transposition check as well. For example, if a provision contains an obligation, and the sub articles contain specific derogations therefrom, both should be checked during the transposition check.<sup>364</sup>
- Occasionally, Member States notify transposition measures that merely specify a framework for future implementation. 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

<sup>361</sup> See the guidance in Box 48, SEC(2010)922/3.

<sup>362</sup> For an example, see Case [C-428/04, Commission v. Republic of Austria \[2006\]](#) ECR I-3325.

<sup>363</sup> See the guidance in Box 48, SEC(2010)922/3.

<sup>364</sup> 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.

for individual Member States have been received in advance. All acts need to be checked against transposition deadlines.

## 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. Examples falling under 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 concrete cases should normally be assessed within the conformity check. This holds especially true for so-called 'open norms' that grant significant discretionary power to national administrations.<sup>365</sup>
- 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.<sup>366</sup> 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.<sup>367</sup>

The conformity check starts in principle either once the Commission has completed the transposition check.

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 can propose bringing a case for failure to notify in relation to the parts that are missing<sup>368</sup>.

**Reports on conformity assessment from external contractors** need to be verified by the Commission services.

Given that conformity studies may feed into infringement proceedings, they should not be published or disclosed (ex. Article 4(2), third indent, of Regulation No. 1049/2001).<sup>369</sup>

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<sup>365</sup> 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".

<sup>366</sup> For an example, see provision 11(1) of [Directive 2000/60/EG](#).

<sup>367</sup> For an example, see article 3 of [Directive 2002/21/EG](#).

<sup>368</sup> SEC(2010)923/3 Box 48

<sup>369</sup> 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.

If available, services should use the information contained in implementation plans when they assess the risks regarding correct transposition of the directive.

## **TOOL #34: DRAFTING THE EXPLANATORY MEMORANDUM**

### **1. WHEN IS AN EXPLANATORY MEMORANDUM NECESSARY?**

All Commission proposals and delegated acts should include an explanatory memorandum.

### **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 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 must 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 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 is directly connected with the transparent exercise of the Commission's right of initiative. Given its public function, the explanatory memorandum must be reader-friendly, clearly worded, concise and written with the non-specialist in mind.

The specific content of the explanatory memorandum responds 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 retrospective 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:

#### **(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 PROPORIONALITY***

- 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 several options exist.

- 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? (boundary test);
  - Effectiveness test: What is the most effective solution – that achieved by Union action or that achieved by national means? What specific added value is expected by the planned Union measure and what would the cost be 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:
    - Is the form of Union action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the 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 policy making, 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. 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.

- Ex-post evaluation/fitness check
  - 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.
- 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 "Your Voice in Europe" portal<sup>370</sup>).
- 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.

- Use of expertise

If the Commission has relied on expertise<sup>371</sup>, 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 Impact Assessment Board

A summary presentation of the main elements of the impact assessment (IA) process serves, on the one hand, to strengthen the motivation underlying the proposed policy choice, and, on the other hand, to show that the careful assessment of alternative policy options as well as their 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. In case an IA was not carried out, this section should explain why.

In such cases, the sections below can still be developed 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 Roadmap where the question about the need for a roadmap is addressed and also to the Better regulation Guideline and the tool on when an IA is necessary;
- 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;

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<sup>370</sup> [http://ec.europa.eu/yourvoice/consultations/index\\_en.htm](http://ec.europa.eu/yourvoice/consultations/index_en.htm)

<sup>371</sup> See tool on evidence gathering

- 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. In particular, outline:

- If the proposal is part of the REFIT programme and aims to reduce regulatory burdens, the explanatory memorandum should quantify wherever possible the burden reduction the proposal aims to deliver;
  - 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 generally<sup>372</sup>;
  - 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?<sup>373</sup>
- *Fundamental rights*: Where the proposal has consequences for fundamental rights, explain how the fundamental rights obligations have been met<sup>374</sup>.

#### **(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.

#### **(5) OTHER ELEMENTS**

- *Implementation plans, monitoring, evaluation and reporting arrangements*: Reference should be made to the implementation planning associated with the measure,

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<sup>372</sup> See tool on the SME test for examples of mitigating measures for SMEs

<sup>373</sup> See tool on ICT impacts

<sup>374</sup> See tool on fundamental rights and human rights

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.
- *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. This additional text must 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.

## **Chapter 5**

### **Monitoring the application of an intervention**

## TOOL #35: 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.

#### ***Box 1: Defining monitoring and evaluation arrangements***

A broad outline of the monitoring and evaluation arrangements should be provided in the impact assessment report, with more specific arrangements for the preferred option. 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?<sup>375</sup>

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 enter into application. In case of expenditure programmes, spending money allocated to the intervention);

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<sup>375</sup> Data collected throughout monitoring will encompass qualitative as well as quantitative variables.

- (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 Commission uses these international classifications in order to collect high-quality and harmonised/comparable data.

## 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 policy making process<sup>376</sup>. 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?<sup>377</sup> Are all the data needed for the purpose for which they were collected? If not, why not? Are they used for other purposes?

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<sup>376</sup> A first assessment of monitoring systems in place should be provided in the relevant evaluations.

<sup>377</sup> Beware that collected data need to be analysed to make them into useful information.

- **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;
- 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 us analyse and compare performance across population groups or geographic areas, and can be useful for determining policy priorities.

For instance, an initiative may not deliver exactly what was intended or may do so at higher costs even if adequately implemented, applied and enforced. This may be due to the (policy) design or unexpected developments in the baseline. You need, therefore, to identify indicators that will allow you to monitor the changes in terms of the main objectives.

Indicators must be based on reliable and comparable data collected through sound monitoring systems.

## 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
<b>Implementation ("outputs")</b>	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>
<b>Application ("results and impacts")</b>	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 <sup>378</sup>	<ul style="list-style-type: none"> <li>• share of organic area in total utilised agricultural area</li> <li>• share of organic livestock in total livestock</li> <li>• number of certified organic operators</li> </ul>
Effectiveness in curbing emissions <sup>379</sup>	<ul style="list-style-type: none"> <li>• new vehicle fuel consumption</li> <li>• CO<sub>2</sub> emissions for each heavy-duty vehicle category</li> </ul>
Improved balancing in gas transmission systems <sup>380</sup>	<ul style="list-style-type: none"> <li>• liquidity on the gas wholesale markets</li> <li>• volumes in trading at the intraday gas market</li> <li>• price convergence between gas markets</li> </ul>
Reduction of energy consumption and promotion of energy efficiency <sup>381</sup>	<ul style="list-style-type: none"> <li>• energy label rating of units sold</li> <li>• saving on space heating</li> </ul>

To the extent possible, all indicators should be ‘RACER’, i.e.:

- (5) **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).
- (6) **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).
- (7) **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 only<sup>382</sup>.
- (8) **Easy** to monitor (e.g. data collection should be possible at low cost).

<sup>378</sup> [http://eur-lex.europa.eu/resource.html?uri=cellar:fbf11871-b33f-11e3-86f9-01aa75ed71a1.0001.01/DOC\\_1&format=PDF](http://eur-lex.europa.eu/resource.html?uri=cellar:fbf11871-b33f-11e3-86f9-01aa75ed71a1.0001.01/DOC_1&format=PDF)

<sup>379</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014SC0160&from=EN>

<sup>380</sup> [http://ec.europa.eu/smart-regulation/impact/ia\\_carried\\_out/docs/ia\\_2014/swd\\_2014\\_0114\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2014/swd_2014_0114_en.pdf)

<sup>381</sup> [http://ec.europa.eu/smart-regulation/impact/ia\\_carried\\_out/docs/ia\\_2014/swd\\_2014\\_0222\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2014/swd_2014_0222_en.pdf)

<sup>382</sup> Various categories of indicators exist, such as qualitative/quantitative, local/global, monetary-non-monetary, etc.

- (9) **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.

## **Chapter 6**

### **Evaluations and Fitness Checks**

## TOOL #36: WHAT IS AN EVALUATION AND WHEN IS IT REQUIRED?

### 1. INTRODUCTION

The following chapter provides guidance to Commission officials on the main steps of an evaluation and fitness check. The **requirements**, as set out in the main Better Regulation, are complemented by further explanations on their purpose and importance.

Where appropriate, a distinction is made between Evaluations and Fitness Checks and additional information is provided on the REFIT programme. Throughout the text, **good practice tips** provide further assistance on the different steps of evaluation.

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

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

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

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

### 2. WHAT IS AN EVALUATION

#### ***Box 1. Key definitions***

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

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

Evaluation is a tool to help the Commission services assess the actual performance of EU interventions compared to initial expectations. By evaluating, the Commission services take a critical look at whether EU activities are fit for purpose and deliver, at minimum cost, the desired changes to European businesses and citizens and contribute to the EU's

global role. Evaluation also provides a key opportunity to engage stakeholders and the general public, encouraging feedback on how EU interventions are perceived.

**Evaluation** uses the available 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 is not an assessment of *what* has happened; it considers *why* something has occurred (the role of the EU intervention) and, if possible, *how much has changed as a consequence*.** It should look at the wider perspective, looking to see if there were unintended/unexpected effects which were not anticipated by the impact assessment or the act agreed by the Co-legislators. Evaluation should also draw conclusions on whether the EU intervention continues to be justified.

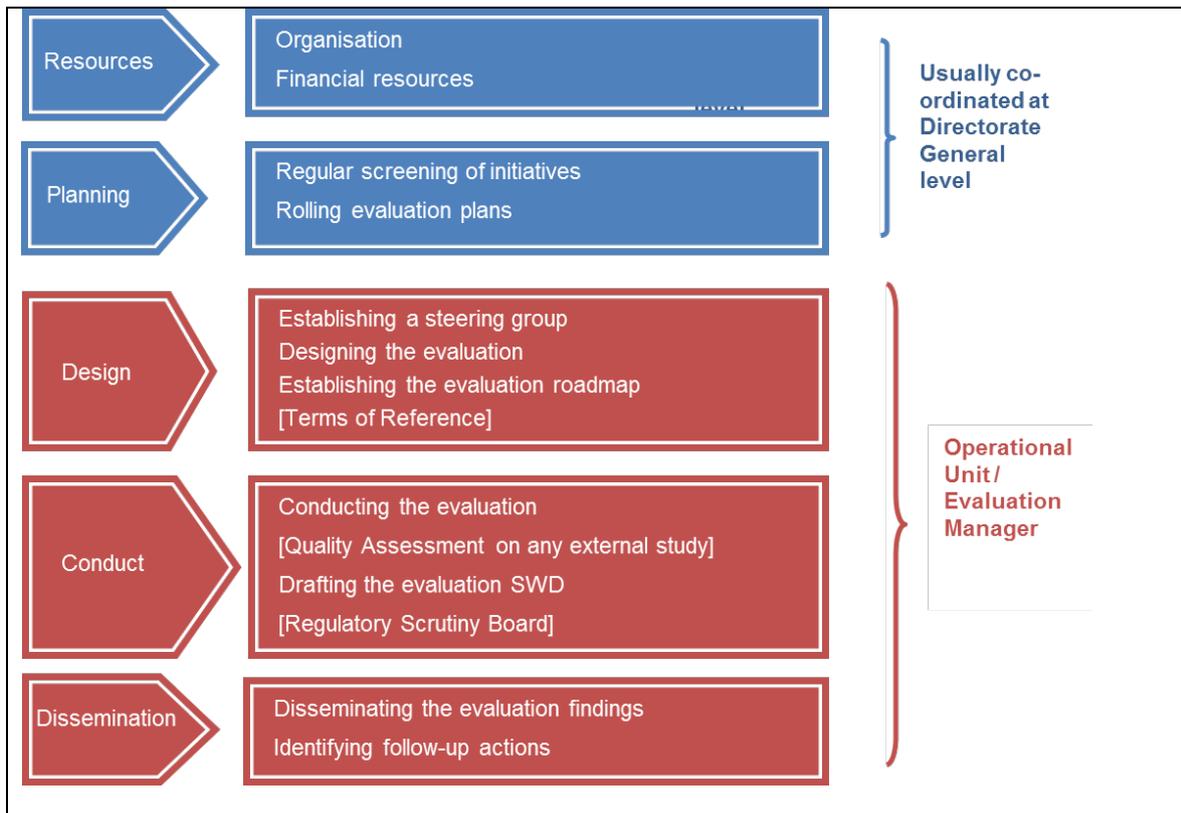
A **Fitness Check (FC)** is like an evaluation of an individual intervention except that it covers a group of measures which have some relationship with each other justifying a joint evaluation (normally a common set of objectives).

A Fitness Check should pay particular attention to identifying any synergies (e.g. improved performance, simplification, lower costs, reduced burdens) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures) within the group of measures and help to identify the cumulative impact of the interventions covered, covering both costs and benefits.

Evaluations and Fitness Checks are tools that are used to implement the **Regulatory Fitness and Performance programme (REFIT)**. REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose', that regulatory burdens are minimised and that all simplification options are identified and applied.

This chapter describes the main steps of an evaluation/Fitness Check, following the chronological order of actions needed to design and conduct an evaluation and then disseminate the findings and identify any follow-up (see Box 2).

***Box 2. The evaluation process***



### 3. WHAT ARE THE REQUIREMENTS TO EVALUATE?

Evaluations are an essential step to manage and revise the existing body of EU legislation and policy and should precede impact assessment<sup>383</sup>.

The Commission is committed to evaluate in a proportionate way all EU spending and non-spending activities intended to have an impact on society or the economy. This should be done on the basis of the life cycle of the intervention, the operational and strategic decision-making needs, general 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<sup>384</sup>.

Many evaluations are triggered by individual clauses in legislation, often formulated as requiring a review<sup>385</sup> which specifies the evaluation or assessment of certain elements and provides the possibility, as appropriate, for the Commission to present by a certain date proposals for change.

The evaluation or review requirements stated in the legal base may be considered as a minimum. The definition of evaluation in these guidelines commits Commission services

<sup>383</sup> 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>.

<sup>384</sup> The 2007 Communication on Reinforcing the use of evaluation; [http://ec.europa.eu/smart-regulation/evaluation/docs/eval\\_comm\\_sec2007\\_213\\_en.pdf](http://ec.europa.eu/smart-regulation/evaluation/docs/eval_comm_sec2007_213_en.pdf)

<sup>385</sup> "Review" clauses can only lead to evaluations where sufficient operational/implementation experience has accumulated to permit evaluation.

to conduct evaluations which go further, assessing the effectiveness, efficiency, relevance, coherence and EU added value of an intervention, or justifying why this has not been possible.

In line with the "evaluate first" principle, such evaluation work will take place before IA work begins, unless justified by political demands on the Commission.

For spending programmes, the **Financial Regulation**<sup>386</sup> and Rules of Application require an evaluation of all programmes and activities which entail significant overall spending (over € million).

In addition, for spending programmes financed by the EU budget, a commitment to evaluation is included in **Article 318 of the Treaty on the Functioning of the European Union (TFEU)**<sup>387</sup>, which requires the Commission to establish an annual evaluation report of the Union's finances based on results achieved.

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.

For projects or programmes financed by the European Development Fund (EDF) budget, the evaluation requirements are laid out in Council Regulation (EU) 2015/323 on the financial regulation applicable to the 11th European Development Fund.

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

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<sup>386</sup> 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>

<sup>387</sup> 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>

## TOOL #37: PREPARING FOR AN EVALUATION

### 1. ORGANISATION

The Commission's organisational framework for evaluation is **decentralised**, making individual Directorates General responsible for the evaluation of their activities. The choice of structure is at the discretion of each Directorate General, reflecting its needs and requirements. In principle, three models can be distinguished across the Commission services: a **centralised model** where the evaluation function is fully centralised in a horizontal unit; a **decentralised model** where the evaluation is fully decentralised to operational units and a **hybrid model** where operational management of evaluations is decentralised, supported by a central evaluation unit.

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.

Central support is provided by **the Secretariat General**, including provision of general guidance and training on evaluation.

There is also a **Commission-wide network** which meets several times a year to discuss evaluation issues and share information.

### 2. FINANCIAL RESOURCES

The costs of an evaluation always have to be seen in the context of the intervention being evaluated. The amount spent on the evaluation project should be proportional to the intervention in terms of its costs and the changes it generated. 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 cost of an evaluation project can vary a great deal depending on a number of variables, such as: size and duration of the intervention, scope and complexity of the intervention, geographical diversity, size and nature of the stakeholders/target population/beneficiaries, quality of monitoring systems in place, data readily available and methods foreseen. Generally, the more is asked from the contractor the higher the costs.

Considering different options for the scope of and methodology to be used for an evaluation can help to design the evaluation at a level (financially) proportional to the intervention.

It is recommended that each Directorate General ensures that financial resources are clearly identified and allocated for evaluation activities to be carried out.

### 3. REGULAR SCREENING OF RESPONSIBILITIES

The **regulatory** acquis screening carried out under the REFIT programme<sup>388</sup> facilitates an assessment of the need for evaluation. The annual review of the mapping<sup>389</sup> provides an overview of the acquis, the stage reached in the policy cycle and the issues identified in the application of the law, which may be used to justify a particular evaluation work and its priority among competing claims. In some instances a DG may wish to supplement this screening of the acquis to include other (non-legislative) actions.

#### ***Box 2: Screening of responsibilities***

It is recommended that the Director General ensures that screening of all initiatives falling within a Directorate General's remit takes place regularly, to identify:

- 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 evaluation.
- When individual initiatives were evaluated last and ensure evaluations are available in a timely manner to feed into the next steps in the policy making cycle.
- The potential to carry out cross cutting Fitness Checks.
- Other feedback on interventions, including any complaints and/or infringements which might imply problems with implementation, application or performance.

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<sup>388</sup> A systematic screening of the regulatory acquis was carried out for the first time in 2012 in the context of the REFIT programme, Communication on Regulatory Fitness, COM(2012) 746.

<sup>389</sup> REFIT maps are available on [https://myintracomm.ec.europa.eu/corp/sg/en/smart\\_regulation/Pages/refit.aspx](https://myintracomm.ec.europa.eu/corp/sg/en/smart_regulation/Pages/refit.aspx)

## TOOL #38: 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 ensuring transparency and demonstrating the accountability of the Commission.

Each Directorate General should ensure that:

- Under the "**evaluate first**" principle, evaluation results are available to feed into the decision making cycle, backing up initiatives for change proposed on the Commission Work Programme (CWP). The availability of evaluation results is normally indicated in the roadmaps drawn up for new initiatives.
- Appropriate monitoring and evaluation activity is planned at the time of adoption of each significant initiative to develop or amend EU action (in principle such arrangements are set out in the relevant impact assessments).
- Relevant evaluation results are available to feed into a report from the Commission to the European Parliament and the Council on the evaluation of the Union's finances based on the results achieved (the so called Article 318 report). These results will in principle be presented in the Annual Activity Reports drawn up by Directorate Generals, which provide a key source of information for the Article 318 report.
- Evaluation results are available to justify resource allocation in Draft Budget programme statements.

### 2. ROLLING EVALUATION PLAN

In practice, the evaluation plans are integrated in the Management Plans<sup>390</sup> of individual Directorates General according to the format specified in the Management Plans standing instructions, issued each year. The Secretariat General compiles the evaluation plans of individual Directorates General into a single Commission evaluation plan which is published on a central website<sup>391</sup>. This ensures transparency of the Commission's evaluation activities, enhancing stakeholder access by publicising what is being and will be evaluated when and thus further enabling their participation.

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 within a given year.

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<sup>390</sup> Management Plan, Annex IV: Planning of studies (evaluations and other studies).

<sup>391</sup> [http://ec.europa.eu/smart-regulation/evaluation/index\\_en.htm](http://ec.europa.eu/smart-regulation/evaluation/index_en.htm)

### ***Box 1: Planning evaluation activities***

- The planning of evaluation activities of individual Directorates General takes the form of a (minimum) 5-year indicative rolling programme, where the plan is broadly fixed for the first 2 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 in year, if necessary) and respect the Management Plan Standing Instructions.
- Periodic evaluation is required for all EU interventions. In line with instructions issued by the Secretary-General to guide services in the practical implementation of the Working Methods, evaluation should precede impact assessment.
- It is recommended that all policy and programme Directorates General conduct at least one evaluation (or Fitness Check) each year. When producing the rolling evaluation plan (and the Commission Work Programme), feedback received from stakeholders, including in the context of the REFIT programme, should be taken into account.

In addition to the evaluations based on the screening of initiatives in a Directorate General's remit, thematic or ad-hoc evaluations may need to be carried out as a result of new strategic decisions, implementation problems, indications coming from monitoring results, feedback on the REFIT programme, complaints from stakeholders, EU Pilot files, infringement procedures, audit reports etc. It is recommended that such additions are added to the evaluation plan as they occur.

All of a Directorate General's policy areas, including both spending and non-spending interventions, should be proportionally covered in the rolling evaluation plan.

### **3. TIMING**

Timing is a crucial factor for fostering 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. Evaluation planning should take into account the life cycle of the intervention and the operational and strategic decision-making needs of the DG.

Planning for evaluations of *spending initiatives* covered by the Multi-annual financial framework or the European Development Fund is generally a relatively straight forward exercise<sup>392</sup>. The legal basis of spending programmes usually predefines the timing of evaluations as well as the nature and number of contributions and reports that are expected. In order to allow the mid-term (or interim) evaluation results to feed into ex-ante evaluations (impact assessments) for the subsequent programming period, the mid-term evaluation results need to be delivered around the fourth/fifth year of the programming period. Most ex-post evaluations are expected to take place within 4 years

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<sup>392</sup> A different set up applies for Structural Funds.

of the end of the programming period.<sup>393</sup> 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 results 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.

It is much harder to apply a uniform timetable to the evaluation of *non-spending activities* which take such a wide range of formats (e.g. regulation, directive, decision, 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 of time to complete the transposition of the EU law into national legislation. In other instances, not all the components of the regulation 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 initiative, sufficient time should have passed since the implementation of the activity to ensure at least 3 years' worth of reasonably full data. This makes evaluation planning difficult if a certain legal act is revised very frequently, for instance every three years, especially if new objectives are introduced or old ones refined.

The Commission has been working on the codification of EU regulation per sector. 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, but produce economies of scale. They can combine evaluation actions that would otherwise have been carried out separately, bringing economies and increasing efficiency.

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.<sup>394</sup>

Similarly, if the Regulatory Scrutiny Board scrutinises an evaluation, an additional 2-3 months should be factored in the planning.

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<sup>393</sup> In some cases, the mid-term evaluations of the current programming period cover also ex-post evaluations of the previous programming period.

<sup>394</sup> 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](http://www.cc.cec/budg/imp/procurement/imp-080-020_procproced_en.html)

## TOOL #39: SETTING UP AN INTER-SERVICE STEERING GROUP

### 1. WHAT IS AN INTER-SERVICE STEERING GROUP?

An inter-service steering group (ISG) consists of people from a range of Directorates General who work in the same or related areas as the subject of the evaluation, plus a representative from the evaluation function of the Directorate General conducting the evaluation. It should be involved in all key aspects of the evaluation, particularly from the set up (roadmap) through to drafting the Staff Working Document and its launch into inter-service consultation.

### 2. WHY IS AN ISG IMPORTANT?

An ISG is established as soon as the initiative has been politically validated and accepted for inclusion in Agenda Planning. Its role is to steer the project at all key phases (roadmap, consultation, studies, Staff Working Document), providing input and information and ensuring the quality, impartiality and usefulness of the final product. It also provides quality control, overseeing all the key steps in the process. 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.

A good 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 would have in any case emerged later in the process (e.g. during inter-services consultation).

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. In addition, DGs with core expertise in specific areas such as economic analysis and models (e.g. ECFIN), scientific research (e.g. JRC), social impacts (e.g. EMPL), SMEs, competitiveness (e.g. GROW), external trade (e.g. TRADE), environment (e.g. ENV), fundamental rights (JUST) etc. should also participate where appropriate to ensure that the evaluation calls upon all relevant expertise in the Commission services.

#### ***Box 1: Inter Service Steering Group***

As stated in the Better Regulation guidelines:

- All evaluations should have an ISG composed of at least three members. At least one member should be from the Directorate General's evaluation function.
- The ISG should be consulted on the evaluation roadmap, terms of reference (where applicable), any associated deliverables from an external contractor, consultation documents and any other draft reports, most importantly the draft evaluation Staff Working Document.
- The ISG should contribute to the quality of all deliverables, including substantive

input from all participants on aspects relevant to the work of their DGs.

- When external contractors are involved in the evaluation, the ISG must discuss the various deliverables provided. The ISG must contribute to the Quality Assessment of the contractors' work.
- If the evaluation is subject to the RSB's scrutiny, the minutes of the last ISG meeting must be attached to the covering note when the Staff Working Document (SWD) is submitted to the RSB. (The other elements of the package include the draft evaluation SWD and executive summary; where applicable the relevant contractors' report and associated Quality Assessment by the ISG.) The ISG will also comment on subsequent changes to the SWD to take on board RSB comments.

#### **Fitness Check and REFIT considerations**

- A member of the Secretariat General's evaluation unit must be included in the ISG of a Fitness Check or of any evaluation/Fitness Check carried out under REFIT.

### **3. GOOD PRACTICE TIPS**

- It is recommended that where the intervention is clearly of interest to other Directorates General, they should be invited to participate in the steering group.
- Existing inter-service groups can be used to steer the work particularly where an inter-service group has been used to conduct a related IA, evaluation or Fitness Check.
- Contractors may be invited to make presentations regarding supporting studies or contracts. It is at the discretion of the DG whether they remain in the meeting when substantive discussions take place between ISG members. In some instances such discussion can be informative to the evaluation. The lead DG should make sure that any internal discussions of confidential nature are protected.
- The ISG should consider ways to improve the involvement of stakeholders and external parties along the evaluation process (see also guidance on consultation strategies). Attention should be paid as to how existing working groups (e.g. Member State committees or expert groups) can provide their input.
- Meetings should be well prepared with invitations and documents being circulated at least one week in advance. Similarly, ISG members should be given at least one week to provide written comments on drafts of the various reports or the Staff Working Document.
- Participation can take different forms – presence by video-conference, contributions in writing or phone conferences. Sometimes members will chose to keep a general overview of what is happening and ask to be copied in on documents etc., providing their inputs as they see fit.
- Minutes of the steering group should be agreed by members. The minutes should record the key points discussed, summarise the input of each member and note the arguments why certain decisions/positions have been taken.
- The ISG should meet as many times as needed to cover the important elements of the process.

## TOOL #40: ESTABLISHING AN EVALUATION ROADMAP

### 1. WHAT IS AN EVALUATION ROADMAP?

Every evaluation should have a project plan with a list of tasks to be performed to keep the evaluation project on track and ensure the quality of deliverables. To maintain consistency in the level of information provided for all evaluations, this detail must be provided in the **evaluation roadmap**.

Stakeholders are invited to provide feedback on the roadmap during a 4 week period and the Commission has the discretion to decide which comments to address.

When an Impact Assessment follows-on directly from an evaluation DGs have the option of producing only one roadmap. This will be decided on a case by case basis, following discussion with the Secretariat General.

The evaluation roadmap is the "project plan" for the evaluation and plays a similar role to the roadmap for a Commission initiative<sup>395</sup>. It sets out the subject of the evaluation and its purpose and provides key information on the scope, timing, data, stakeholder consultation and analysis planned to be used.

### 2. WHY IS AN EVALUATION ROADMAP IMPORTANT?

The draft evaluation roadmap can be commented on by stakeholders before it is finalised. This provides them with an opportunity to contribute to the design itself and/or allows them to prepare and collect data which they can provide to the evaluation.

The final roadmap **will be published** on the central website (together with the evaluation Staff Working Document and RSB opinion where relevant).

#### ***Box 1: The evaluation roadmap***

- For each evaluation, an evaluation roadmap, compliant with the template provided by the Secretariat General must be published centrally. Stakeholders are invited to give feedback that could feed into the further preparatory process, which usually starts 4 weeks following publication (So if stakeholders want their input to be considered, they should ideally provide feedback within this 4 week period).
- The roadmap will indicate:
  - The subject of the evaluation, its purpose and scope (including draft evaluation questions and where relevant other tasks);
  - The background and original objectives of the intervention being evaluated (including a short description of how these were expected to be achieved);
  - The questions covering the five mandatory evaluation criteria (or an explanation about why not all five criteria are addressed);
  - The evidence base for the evaluation, covering both data already available and data which will be collected during the evaluation, including key elements of

<sup>395</sup> See main guidance on Planning

the consultation strategy;

- Key expected dates including, the start of the evaluation, timing of consultation and publication of the final report;
- Contact details allowing stakeholders to provide feedback.
- The final version of the evaluation roadmap will be signed off by the Director General and published on the central website. Where relevant, it may also be published on the related policy pages of the author service.

***Box 2. Fitness Check and REFIT considerations***

- All Directorates General with legislation included in the scope of the roadmap must be allowed sufficient time to comment on the draft roadmap including any potential changes indicated by feedback from external parties.
- The roadmap for a REFIT evaluation should include a reference to the REFIT programme in general and more specifically, the year in which the particular REFIT commitment was made.
- The roadmap for a REFIT items ("major initiatives") must be politically validated by the Commissioner(s), VP(s) and the First VP, in close cooperation with President's Cabinet.
- A REFIT evaluation should place greater emphasis on questions intended to analyse the effectiveness and efficiency of the EU action(s), the clarity and simplicity of the legal measure and any associated regulatory burden.

**3. GOOD PRACTICE TIPS**

- Feedback received after the publication of the roadmap may lead to changes e.g. in scope or approach. Since such changes could also affect any ToR for external support study, it is recommended that the ToR are only finalised after any stakeholder comments are received on the roadmap. To ensure impartiality of the tendering process, feedback received from potential tenders should not be used to modify the Terms of Reference to their advantage.
- When deciding on the scope and depth of analysis of certain aspects, priorities should be based on the proportionality principle<sup>396</sup>. A short explanation of why certain issues have been prioritised should be included in the roadmap.

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<sup>396</sup> Art 5 of the Treaty on the European Union; <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012M/TXT>

## TOOL #41: DESIGNING THE EVALUATION

### 1. WHAT IS MEANT BY DESIGN?

Designing the evaluation means identifying the sequence of tasks to be done and range of methods to be used during an evaluation. Good design starts by identifying/agreeing the purpose of an evaluation and identifying what is in scope (e.g. which interventions, over what time period and for what geographical coverage). This will influence the evaluation questions set and as a result, the methodology applied and the data and research undertaken to robustly answer these questions.

### 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 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 deliver (see also section on monitoring, subsection on evidence building).

### 3. KEY ELEMENTS OF EVALUATION DESIGN

When designing an evaluation it is important to spend time:

- (1) Stating the **purpose** of the evaluation: explaining why the evaluation is being carried out and any particular aspects of analysis that will be conducted;
- (2) Defining the **scope**: setting out clearly what actions, what period and what geographical coverage will be covered by the evaluation and what will not (with any associated explanation);
- (3) Explaining the **intervention logic**: summarising how the intervention was expected to work;
- (4) Drafting good **evaluation questions**: clarifying the questions the evaluation will answer.
- (5) Considering **appropriate methods and required data**: it is very important that the evaluation is set up to collect and analyse a range of different data, using the appropriate methodologies used.

### 3.1. Purpose

Most evaluations are required to serve a particular purpose or to fulfil a particular obligation. It is important to be clear on the purpose of an evaluation and to explain why the evaluation is being carried out. Generally this is for one or more of the following reasons:

- To comply with an evaluation article in the legal base. This applies to many policies and is mandatory for programmes carried out under the Multi-annual Financial Framework (MFF);
- In compliance with the Commission's Financial regulation;
- As part of the Commission's REFIT programme;
- Linked to a future action on the Commission Work Programme (reflecting the 'evaluate first' principle) etc.

### 3.2. Scope

It is important to know from an early stage what measures/initiatives will be in the scope of the evaluation and what will not. The scope should be defined in terms of the legislative act(s) and/or related programme(s), policy(ies), soft law etc. covered. When considering the scope of an evaluation, due attention must be paid to the context of the intervention(s), its role within the logic of the relevant policy framework and any relationship to other actions. Sometimes related actions will be considered under the criterion of coherence, other times they will be so important and integral to the policy that the evaluation needs to consider several interventions (i.e. as a Fitness Check).

Scope may also include consideration of the geographical coverage of the evaluation (28 MS or a subset) and the period of time (since the intervention started or limited to a lesser period e.g. end of last evaluation to current day). The scope of an evaluation will have a significant impact on the design of the evaluative work to be carried out. Clearly communicating the scope of an evaluation is also an important way of managing the expectations of all parties interested in a given area.

Scope will be influenced by any existing feedback e.g. from monitoring, stakeholders on the (perceived) performance of EU action. This may mean that the scope includes action(s) where there is evidence of problems – for example targets not being met; low transposition or compliance; complaints from stakeholders. However it is also interesting include in scope action(s) where there is no such evidence available, or which have not been evaluated for some time as "all is quiet" does not necessarily mean "all is working as expected", as it may for example rather mean that the intervention is irrelevant.

#### ***Box 1 Fitness Check considerations***

- Setting a good/correct scope is even more important when conducting a Fitness Check, which by its very definition is "a comprehensive policy evaluation assessing whether the (regulatory) framework for a policy area is fit for purpose". The EU interventions which fall within the scope of a Fitness Check must be ones that interact together and/or have common objectives. Where this is not the case, it is likely that the project will deliver several evaluations of the separate interventions, rather than

the desired joined up evaluation of the EU policy and its framework.

- Sectoral Fitness Checks look at how the EU actions in scope impact the achievement of objectives set for the sector.

### 3.3. The intervention logic

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. For the evaluation of legislative actions, many of the required actions are identified in the articles of the legal act. Where they exist, the Commission services' impact assessment and/or any further analysis conducted by the European Parliament or the Council can provide key inputs helping to explain the expected causal chain of the intervention.

The 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.

The intervention logic can be very helpful in identifying particular evaluation questions.

### 3.4. Drafting good evaluation questions

Good evaluation questions encourage critical analysis. By defining the questions at the start of the process, the Commission services clarify what they intend to analyse and invite interested parties to provide relevant contributions. The questions should be worded in a way that forces the evaluator to 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).

### 3.5. Methods and data

The methodology of an evaluation is usually composed of a combination of tools and techniques assembled and implemented in order to provide answers to the specific questions posed within that evaluation.

**Data availability and the quality of the data will play a key role in deciding which methods can reliably be applied; at the extreme, it may also influence the scope of an evaluation.** The time and budget allocated to the evaluation will also have a significant influence on both the methods chosen and the data collected.

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 Directorate General's evaluation function or from external contractors. However, it is still necessary to have a general understanding of various methods and approaches to data collection, for several reasons:

- 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;
- To recognise the strengths and limitations of various methods for a particular evaluation.
- To 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 based on several perspectives (triangulation).

If you are asked to perform an internal evaluation, you will need a reasonable overview, before having to acquire a deeper understanding of the particular methods you want to use.

Tools 50 to 58 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 more detailed review of methods is provided in the 'Evalsed' Sourcebook.<sup>397</sup>

It is important to consider ways to **design the evaluation so that it is possible to cross-check 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.

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.

### 3.6. Limits to 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.

Such "cause and effect" relationships are challenging to prove, particularly when evaluating EU policies which operate in a complex environment influenced by a wide

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<sup>397</sup> The Sourcebook is available at: [http://ec.europa.eu/regional\\_policy/sources/docgener/evaluation/guide/evaluation\\_sourcebook.pdf](http://ec.europa.eu/regional_policy/sources/docgener/evaluation/guide/evaluation_sourcebook.pdf)

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

## TOOL #42: IDENTIFYING THE EVALUATION CRITERIA AND QUESTIONS

### 1. INTRODUCTION

All evaluations must 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 case. 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, with – where relevant, particular emphasis on those impacts identified in a previous IA.

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 considered as "evaluations".

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 criteria relevance 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; alternatively, stakeholder feedback may be the only indicator of whether needs have changed. 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.

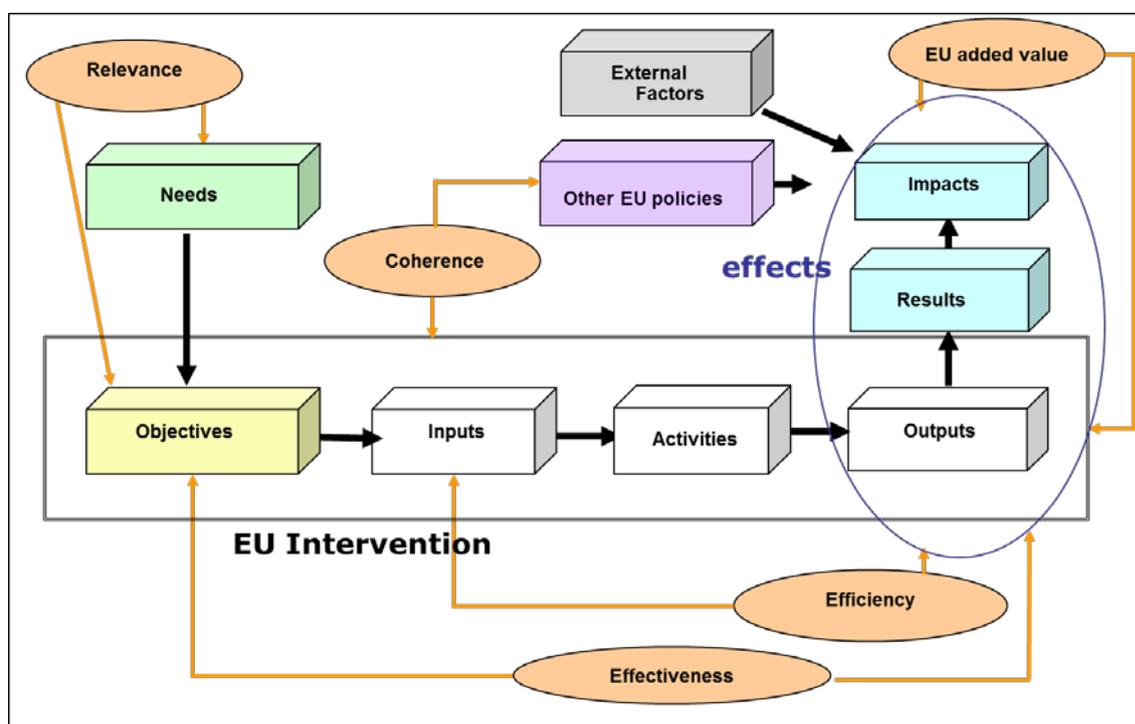


Figure 1: The simplified intervention logic and the 5 key evaluation criteria

## 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, 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.

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.

### ***Box 1: Typical examples of effectiveness questions***

- To what extent have the objectives been achieved?
- What have been the (quantitative and qualitative) effects of the intervention?
- To what extent do the observed effects correspond to the objectives?
- To what extent can these changes/effects be credited to the intervention?
- What factors influenced the achievements observed?
- To what extent did different factors influence the achievements observed?

## 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).

Typical efficiency analysis will include analysis of administrative and regulatory burden and look at aspects of simplification – which is important for ALL evaluations, but particularly those identified under the REFIT programme. **Evaluation findings should pin-point areas where there is potential to reduce inefficiencies particularly regulatory burden and simplify the intervention.** The full efforts to support and perform an intervention can be broken into different categories such as: staff, purchases made, time and/or money spent, fixed costs, running costs, etc. 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 the costs and benefits of EU interventions.

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.** A cumulative cost assessment (CCA)<sup>398</sup>, although providing important inputs into the evaluation analysis, on its own is not enough to address the efficiency aspect and cannot be "the sole basis for policy recommendations"<sup>399</sup>. To provide the full picture, CCAs

<sup>398</sup> 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.

<sup>399</sup> Page 15, Regulatory Fitness and Performance: State of Play and Outlook COM (2014) 368 final

need to be supplemented by the analysis of the corresponding benefits arising from the EU legislation.

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 is a challenge, particularly across 28 Member States which may have implemented legislation in a variety of different manners. However, sufficient efforts should be dedicated to this task, given its importance.

***Box 2. Typical examples of efficiency questions***

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

#### **4. RELEVANCE**

Relevance looks at the relationship between the needs and problems in society and the objectives of the intervention.

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.

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 (still) correspond to the needs within the EU?
- How well adapted is the intervention to subsequent technological or scientific advances? (N.B. Could include issues related to the specify policy here e.g. social, environmental)
- How relevant is the EU intervention to EU citizens?

## 5. COHERENCE

The evaluation of coherence involves looking at how well or not different actions work together.

Checking "internal" coherence means looking at how the various internal components of an EU intervention operate together to achieve its objectives 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 international agreements/declarations (for example EU labour market initiatives might be looking into coherence with ILO conventions).

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

### ***Box 4. Typical examples of coherence questions***

- To what extent is this intervention coherent with other interventions which have similar objectives?
- To what extent is the intervention coherent internally?
- To what extent is the intervention coherent with wider EU policy?
- To what extent is the intervention coherent with international obligations?

## 6. EU-ADDED VALUE

EU-added value<sup>400</sup> looks for changes which it can reasonably be argued are due to EU intervention, rather than any other factors. In many ways, the evaluation of EU added value brings together the findings of the other criteria, presenting the arguments on causality and drawing conclusions, based on the evidence to hand, about the performance of the EU intervention.

Under the principle of subsidiarity (Article 5 Treaty on European Union), the EU should only act when the objectives can be better achieved by Union action rather than by potentially varying action by Member States. It requires consideration of the value and improvements which are caused by the EU rather than another party taking action (see also Tool on Subsidiarity and Proportionality).

The sources and nature of this additional value vary from intervention to intervention. It is, in particular, useful to distinguish the European added value of an EU policy measure in general (like an EU regulation to foster the single market) and that of an EU spending programme per se. In both cases, European added value may be the results of different

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<sup>400</sup> For further information see SEC(2011) 867 final "The added value of the EU budget".

factors: coordination gains, legal certainty, greater effectiveness, complementarities etc. In all cases, measurement is a challenge and the final judgement on whether expected added value would justify an EU intervention is ultimately the result of a political process.

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

The Commission Staff Working Document (SEC(2011) 867 final) recommends 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.

The analysis of EU added value is often limited to the qualitative, given the stated difficulties to identify a counter-factual. It is therefore 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.

***Box 5. Typical questions on EU added value***

- What is the additional value resulting from the EU intervention(s), compared to what could be achieved by Member States at national and/or regional levels?
- To what extent do the issues addressed by the intervention continue to require action at EU level?
- What would be the most likely consequences of stopping or withdrawing the existing EU intervention?

**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)?

**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 28 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.
- 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 must 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 #43: WHAT KEY IMPACTS MUST BE CONSIDERED?

The evaluation must address impacts falling within the economic, environmental and social pillars of sustainable development. Consideration of the evaluation criteria should lead to the evaluation of the same broad categories of impacts analysed in a prior (Commission services) impact assessment. The toolbox describes a wide range of impacts which might need to be considered.

A detailed description of how to assess impacts is provided in dedicated tools of the present toolbox.

How and when these issues will be considered will depend on the design of the intervention – often such analysis will take place when evaluating effectiveness or efficiency.

In all evaluations, it should be remembered that the key evaluation criterion "efficiency" implies a ratio of costs to benefits (or in other words: inputs to intended effects) which in turn requires an assessment of **both** costs and benefits.

But beyond the estimation of actual costs and benefits, every evaluation and Fitness check should seek to identify and report on the potential to reduce administrative burdens and/or regulatory burdens by simplifying or revising the existing intervention(s).

For **administrative burden assessment**, a definition and relatively simple EU Standard Cost Model<sup>401</sup> has been developed by the Commission services and agreed with the Member States. An administrative burden calculator is also available.<sup>402</sup> A considerable amount of data is also available that can inform new evaluations.

Definitions of all aspects of **regulatory burden** can be found in the tools on methods, models and costs and benefits.

For the **SME aspects**, it is important to consider how easy it has been for SMEs to comply with the legislation and whether they incurred disproportionate costs in comparison with their limited staff and turnover. For example, it makes a big difference whether a reporting obligation that creates 5 person-days of work per year needs to be implemented by a multinational enterprise with thousands of employees which may absorb this cost relatively easily, or whether it needs to be implemented by a micro-enterprise that consists only of the entrepreneur plus one employee.

If **micro-enterprises** were already exempted from legislation in the past, or subject to a lighter regime, it needs to be evaluated whether this resulted in clear benefits for them and whether such an exemption or lighter regime should continue.

Depending on the evaluation context, the impact of EU interventions on **competitiveness** can be analysed at the firm, sector and country/EU level. In most cases, the sectoral perspective, i.e. the impact of EU interventions on the performance of a particular industry, will be of the main interest to the evaluators. In particular, when a limited group of sectors bears most of the costs of an intervention, and if these sectors are

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<sup>401</sup> See tool on "Methods to assess costs and benefits"

<sup>402</sup> <http://adminburden.sg.cec.eu.int/default.aspx>

geographically concentrated in a few regions, the social costs can be considerably amplified. The key competitiveness considerations should include impact on costs (e.g. labour, energy), capacity to innovate (e.g. supply of relevant skills, protection of intellectual property rights) and market competition (e.g. removing barriers to trade). In all cases, competitiveness analysis should consider the impacts of EU interventions on the ability of EU firms/industries to compete internationally<sup>403</sup>.

With respect to **gender equality**<sup>404</sup>, evaluations studies have the potential to provide the Commission's policy-makers with strategic and/or practical information on the integration of gender in a specific policy field. The respect and promotion of **fundamental rights**<sup>405</sup> as enshrined in the Charter of Fundamental rights is another core obligation is another core value of the Union that can be assessed in the context of an evaluation<sup>406</sup>. Evaluating Fundamental Rights & Gender Equality requires paying attention to which groups benefit and which groups contribute to the intervention under review.

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<sup>403</sup> See tool on "Impacts on competitiveness"

<sup>404</sup> Gender equality refers to the equal rights, responsibilities and opportunities of women and men, girls and boys.

<sup>405</sup> Fundamental Rights are the civil, cultural, economic, political and social rights inherent to all human beings, regardless of one's nationality, place of residence, sex, sexual orientation, national or ethnic origin, colour, disability, religion, language etc.

<sup>406</sup> See tool on "Fundamental Rights"

## TOOL #44: STAKEHOLDER CONSULTATION IN THE CONTEXT OF EVALUATION

### 1. INTRODUCTION

Consulting interested parties is an obligation for every evaluation. All consultation, including any such activity outsourced to contractors, must follow the Commission's guidelines as described in the Better Regulation guide.

Stakeholder's views, practical experience and supporting evidence can help deliver higher quality and more credible evaluations.

#### ***Box 1. Key principles of stakeholder consultation in the context of evaluation***

- Design the consultation strategy early in the evaluation process;
- The consultation strategy must include a 12-week internet-based public consultation but should be complemented by other approaches and tools in order to engage all relevant stakeholders and to target potential information gaps;
- Maintain contact with stakeholders throughout the process and provide feedback;

### 2. HOW TO CONSULT IN THE EVALUATION PROCESS

Given the variety of evaluations, there is no one-size-fits-all solution on how consultation should be done, or at which stage in the evaluation process it should take place.

The Commission services should allow stakeholders the opportunity to provide feedback on the roadmap for a period of 4 weeks. This Roadmap will also be available during the formal consultations of stakeholders which follow.

A 12-week internet based open public consultation is necessary for all evaluations as it ensures transparency and accountability and gives any interested party the possibility to contribute. This consultation can take place at any time point during the evaluation but must cover the five mandatory evaluation criteria. Where the evaluation is of an activity conducted outside the EU or where the internet is not a practical support tool, this mandatory open public consultation may be waived so long as the consultation strategy envisages appropriate tools to reach the relevant stakeholders. Such derogations should be discussed and agreed with the Secretariat General. The open public consultation can be complemented with more targeted or specialised consultations of particular stakeholder groups or experts.

Depending on each case, stakeholder consultation may be used either to collect evidence in relation to answering the evaluation questions, or to test/validate already existing analysis or evidence coming from different sources.

In practice, the consultation strategy for the evaluation will include a combination of consultation methods (i.e. open/targeted) and tools (i.e. questionnaire, document, meeting, hearing, and workshop). For evaluations outsourced to external contractors, the consultation can be externalised.

When stakeholder consultation is used for **collecting evidence** (i.e. 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<sup>407</sup>.

## **2.1. Planning your consultations**

In order to optimise the evaluation process, consultations should be planned at an early date. Key steps in the consultation strategy should be described in the evaluation roadmap and be closely interlinked with the timing of the key evaluation steps and the strategy for collecting evidence.

Following the roadmap's publication on the Europa website, stakeholders have the opportunity to provide comments on the elements outlined in the Roadmap. The lead DG should be prepared to assess this initial feed-back and feed it into the evaluation work, including the design of any consultation activity.

The main Better Regulation guideline sets out the general requirements for conducting stakeholder consultations which is complemented an overview of the various consultation methods in the toolbox.

## **2.2. Consultation results and reporting**

Irrespective of the chosen mix of consultation tools and methods, the consultation results should feed into and inform the evaluation.

Results of the consultation should be reflected in the contractors' report (if applicable) and the evaluation SWD. A synopsis report covering all consultations launched needs to be annexed to the SWD.

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<sup>407</sup> See tool on "Stakeholder consultation"

## TOOL #45: CONDUCTING THE EVALUATION

### 1. INTRODUCTION

When the planning is over, the actual evaluation work starts. Conduct is the actual "doing" of the evaluation.

Evaluations can be entirely outsourced to external contractors and/or draw on the (internal) work of Commission services.

The vast majority of evaluations are outsourced to external contractors to collect and analyse the relevant evidence, answer a set of evaluation questions, draw conclusions and identify policy implications or recommendations.

The work that the contractor is required to do is set out in the *Terms of Reference (ToR)*<sup>408</sup> written by the Commission services.

### 2. WHY IS GOOD CONDUCT IMPORTANT?

It is important to be constantly checking 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 to conducting an evaluation and drawing the 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 steering group, 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 report.

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?

In outsourced evaluations, the research and analysis is normally done by contractors. The role of the evaluation manager and the steering group is to steer the project and advise contractors, as well as supervise their work, ensure the quality of the work and enforce the timetable.

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<sup>408</sup> 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](http://www.cc.cec/budg/imp/procurement/imp-080-020_procproced_en.html)

***Box 1: Conducting an evaluation***

- A 12 week open public consultation is required for every evaluation. The timing of the consultation, however, is at the discretion of the DG.
- For internal evaluations, where no external contractors are involved, it is recommended that the operational unit should not take the lead in evaluating the EU actions that it manages (conflict of interest).
- 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.
- 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.

**3. DRAFTING THE TERMS OF REFERENCE**

When evaluations are outsourced, the Commission calls upon the services of an external contractor. The work that the contractor is required to do is set out in the Terms of Reference (ToR) written by the Commission services.

Together with the offer submitted by the winning contractor, the ToR becomes part of the contract and is enforceable, leading to penalties if the contract is not performed as required.

The ToR set the legal limits for what the Commission services can ask from the contractor to do under the contract. Therefore it is important to prepare the ToR very carefully in order to ensure that it covers everything that the contractor is required to do.

Practical Guidance on public procurement is provided in the ‘**Public Procurement Vade-mecum**’ drawn up by the Central Financial Service<sup>409</sup>.

***Box 2. Drafting the Terms of reference (ToR)***

- Terms of Reference must be established for all evaluations outsources to contractors.
- The Quality Assessment criteria need to be included as an annex to all Terms of

<sup>409</sup> [http://www.cc.cec/budg/imp/procurement/imp-080-020\\_procproced\\_en.html](http://www.cc.cec/budg/imp/procurement/imp-080-020_procproced_en.html)

Reference.

- The ISG has to be consulted on a draft of the Terms of Reference before it is published.
- All external studies must respect the Commission Visual Identity and be registered in the Inter-institutional database of studies from the planning stage and then, if not confidential, published in EU Bookshop.

#### 4. GOOD PRACTICE TIPS

- Carefully consider the budget and timeline of the evaluation - do not expect contractors to perform tasks that are too expensive for the given budget or too lengthy for the timeline.
- The decision as to whether the ToR leave the choice of methods to external contractors or specify a particular approach should be taken on a case by case basis. However, the ToR should specify that only approved methodologies can be accepted and that triangulation of methods is required. Furthermore, ToR should draw the attention of potential contractors to a range of sources of information and ideas.
- Contractors should be asked to explain in their bid the advantages, limitations and risks involved in using the proposed tools and techniques.
- A contractor should be able to explain even the most complex method to a non-expert. If they are not able to do this (after several requests), there may be good reasons to doubt their ability to properly conduct the evaluation and communicate the findings.
- The ToR can ask contractors to set up a panel of independent academic experts to review the content and quality of their deliverables, or ask the contractors to act on the findings of such a panel already set up by the Directorate General.
- To provide an additional safety net to ensure a high editorial quality of the contractors' final report, consider including the following clause in the ToR: "In view of its publication, the final report by the contractors must be of high editorial quality. In cases where the contractor does not manage to produce a final report of high editorial quality within the timeframe defined by the contract, the contracting authority can decide to have the final report professionally edited at the expense of the contractor (e.g. deduction of these costs from the final payment)." This would be fully in line with Recommendation No. 6 of the Commission's Clear Writing Task Force<sup>410</sup>.
- If one contract combines a retrospective analysis (evaluation) and a prospective analysis (study feeding into an Impact Assessment and revision of legislation), care must be taken to ensure that enough time and budget are allocated to each component. Experience shows that such contracts can save time and money but that contractors tend to allocate a significant proportion of resources to the forward-looking part.

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<sup>410</sup> See page 4 of report available at [http://www.cc.cec/dgintranet/europeaid/resources/infrastructures/translation/documents/clear\\_writing\\_report\\_en.pdf](http://www.cc.cec/dgintranet/europeaid/resources/infrastructures/translation/documents/clear_writing_report_en.pdf)

- Describe how the outcome of the work will be used. Contractors will want to know that their recommendations will be taken seriously and made use of and that this is not just a tick box exercise. The ToR should therefore describe how the results of the project will be used in house.
- ToR should specify that all consultation carried out by contractors must comply with the Commission's minimum standards for Consultation.
- ToR should specify that contracts can be discontinued whenever the quality of the deliverables is insufficient in light of the terms of reference and the quality assessment criteria, and when the contractors have not taken the necessary steps to remedy the insufficiencies.
- The contractor may be requested to further elaborate the evaluation questions presented in the ToR related to effectiveness, efficiency, relevance, coherence and EU added value and to set out a methodology to answer each of those questions. The contractor may suggest additional sub questions and should indicate success criteria, relevant indicators and the sources for the indicators/methodology for gathering necessary evidence. The sub questions break down the overall questions into more manageable issues, and allow for a structured and logical response to the higher level questions.

## 5. MANAGING AN EVALUATION PROJECT AND ITS MEETINGS

Evaluation managers and ISG members are expected to spend time handling logistics, attending project review meetings, handling communications, making information/material available to the contractors and to identify stakeholders. Their most important role, however, is to quality control the deliverables of the evaluation.

In other words, sufficient resources to manage contracts must be allocated, with a nominated staff member as project manager, responsible for the management of the contractors, and the involvement of the appropriate in-house stakeholders.

All contracts must have a **kick off meeting** that will, inter alia, review and confirm the outline project management plan that the contractor was asked to supply as part of their proposal; confirm working procedures (including, if needed, procedures for the approval of payments and confirm the contractor's project team.

The overall objective the kick off meeting is to arrive at a clear shared understanding of what is required by the contracting authority. Ideally, the contracting authority should therefore convene the Steering Group members in advance of the kick-off meeting to ensure a coordinated response towards the contractors.

**Inception/Project review/mid-term review meetings** should be set up to review progress to date against the project plan. They should address the current status of risks / threats to the project and should put in place whatever is necessary to mitigate and manage all risks. Ideally, a matrix table should be set up during the inception phase. All new risks identified in the course of the project and the likelihood of their impact should be assessed and appropriate countermeasures agreed.

The mid-term review meeting should be scheduled when approximately 2/3 the project duration has elapsed.

The purpose of the **final meeting** is to present the results of the evaluation and to allow for an in depth discussion of the draft final evaluation report by the contractors and necessary modifications for completion.

The draft final contractor evaluation report is a key deliverable of the evaluation process, presenting the critical judgements and answers to the evaluation questions. It summarises the evaluation and presents the research, analysis, findings and conclusions/recommendations of the evaluation, providing input to the next round of decision making.

## **6. GOOD PRACTICE TIPS**

- Make the process as transparent as possible and keep communications going between the Steering Group. Consider the use of different information platforms, not just email – for example CIRCA to share relevant information and progress.
- All members of the steering group have an equal right to participate and be heard; to do this they also need sufficient time to consider the various documents.
- Meetings should be well prepared with invitations and documents being circulated at least one week in advance or shared on an EC collaborative workspace (such as SharePoint). The advantage of a collaborative workspace is that all participants can provide their specific redrafting suggestions (using track changes) or further comments directly on a common version of a .docx document shared on SharePoint
- Participation can take different forms – presence by video-conference, contributions in writing or phone conferences. Sometimes members will chose to keep a general overview of what is happening and ask to be copied in on documents (and/or to have access to the shared repository of documents, meeting minutes etc.), so they provide their inputs as they see fit.
- Minutes of the steering group/meetings with contractors should be agreed by participants. The minutes should record the key points discussed, summarise the input of each member and note the arguments why certain decisions/positions have been taken.
- To facilitate independence and transparency, where an external contract exists, staff in at least the operational unit and the evaluation function should be in copy of communications between the Commission services and the contractor.
- Keep track of progress – if a project is scheduled to run for more than a month, it is good practice to require regular feedback from the contractor. This is just part of the ‘no surprises’ approach in which both sides agree to inform the other if things are not going to plan or if they see potential problems. For example, request periodic updates against the agreed timetable. Progress reports do not need to be extensive – traffic light reports every one or two months can be sufficient.
- While work should be carried out in a participatory manner, contractors/Commission services should be aware of the data protection rules and protect the anonymity and confidentiality of individual information and ensure the dignity of those interviewed.

- Make sure to provide any agreed data to contractors/evaluators in a useable format. Often data is provided in a format which requires considerable cleaning/structuring taking resources away from the analysis.
- Contractors can be asked to comment on the quality of data, in particular from monitoring systems, and provide recommendations on how to get better data the next time.
- Encourage wide consideration of unexpected/unintended impacts– this is often an area which is overlooked.

## TOOL #46: COMPLETING THE QUALITY ASSESSMENT

### 1. WHAT IS THE QUALITY ASSESSMENT?

The Quality Assessment (QA) by the ISG judges the external contractor's report and its overall process. It is the final "sign off" by the ISG of the contractor's work and includes a judgement on whether key aspects of the work conducted meet the required standards and provides any related comments.

### 2. WHY IS THE QUALITY ASSESSMENT IMPORTANT?

If evaluations are to increase transparency, accountability and organisational learning, the Commission services need to deliver high quality work, based on robust data and methodologies.

The ISG plays a key role in ensuring that the evaluation is designed and conducted appropriately. It is responsible for supervising the process and assessing the quality of the contractor's report by filling in a QA report, compliant with the template provided by the Secretariat General.

If the evaluation is selected for review by the Regulatory Scrutiny Board, this QA and minutes of the last ISG meeting will form part of the package<sup>411</sup> submitted to the RSB.

The Quality Assessment and (where applicable) the opinion of the Regulatory Scrutiny Board will also be submitted as part of the inter-service consultation required to finalise the Staff Working Document.

#### ***Box 1 The Quality Assessment***

- The Quality Assessment criteria need to be included as an annex to all Terms of Reference for studies to support an evaluation.
- The minutes of the steering group meeting where the quality assessment of the contractors' draft Final Report was discussed are submitted as part of the package accompanying the draft evaluation Staff Working Document to the Regulatory Scrutiny Board (where applicable) and into inter-service consultation.
- A summary of the changes requested/introduced by the ISG's Quality Assessment should be presented in the final report.

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<sup>411</sup> The package is composed of the draft final SWD; the draft final report produced by the consultants; roadmap and minutes of the last SG meeting.

## **TOOL #47: THE STAFF WORKING DOCUMENT FOR EVALUATION**

### **1. WHAT IS THE STAFF WORKING DOCUMENT FOR EVALUATION?**

The Staff Working Document for evaluation (SWD) is the key deliverable of the evaluation process, presenting the critical judgements and answers to the evaluation questions. It summarises the evaluation and presents in a transparent manner the research, analysis, findings and conclusions/recommendations of the evaluation, providing input to the next round of decision making.

Where evaluations are based exclusively on the work of external contractors, the SWD should not undermine the objectivity and independence of the evaluation process. Instead, the SWD should summarise and present the final results of the evaluation, the Commission services response to the findings and conclusions of the evaluation and propose follow up actions.

It is equally important that those evaluations which have limited or no support from external contractors are objective and follow an independent evaluation process. In such cases, the SWD should be based on the work done by the Commission services together with any information drawn from supporting sources.

In all cases the lead DG must clearly present 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 and changes introduced as a result of the various quality control procedures (QA on external contractors' report, RSB opinion, inter-service consultation) should be identified. Disagreements must be clearly stated and insofar as possible explained.

### **2. WHY IS THE SWD IMPORTANT?**

The SWD is the key document that stakeholders will see (and possibly comment upon). It is also the basis for the follow-up plans. Last but not least, it serves as indirect feedback mechanism to acknowledge 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 non-technical language with non-expert readers in mind and should provide the reader with a complete picture of the main issues and findings. More detailed information or explanations should be provided in the annexes. A short executive summary of two pages translated into FR, DE and EN should also be drafted.

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 SWD should be no more than 15-20 pages. For all Fitness Checks and those evaluations which have had either limited or no support from contractors the document is likely to be longer (50 pages maximum) as it will have to present the process, evidence and analysis in more detail.

Underlying data, statistics, information, expert contributions and stakeholder views must all be referenced, particularly where choices are made or conclusions are drawn based on them. Whenever possible, direct hypertext internet links should be provided.

The opinion of the Regulatory Scrutiny Board will be published alongside the SWD.

***Box 1: The SWD for evaluation***

- As indicated in the guidelines, the SWD must contain:
  - An executive summary of no more than two pages, translated into a minimum of EN, FR and DE.
  - 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 results;
  - A summary of the changes requested/introduced by the steering group's Quality Assessment of any external work and/or the Regulatory Scrutiny Board and/or inter-service consultation.
  - A clear chain of logic between the analysis and findings, the answers to the evaluation questions and the conclusions drawn.
- The Staff Working document must be published in the EIMS and centrally, alongside the accompanying roadmap, and where applicable, the opinion of the Regulatory Scrutiny Board and any external contractors' report and associated QA.
- It is considered good practice to publish non-confidential data used in the evaluation or supporting studies.

**REFIT considerations**

- All SWD for REFIT evaluations or Fitness Checks must contain a REFIT reference in their title.
- The SWD must contain a section on REFIT, explaining why the intervention or policy has been included in the REFIT programme of Year X.
- The SWD must contain clear conclusions against the key REFIT objectives – explaining whether the intervention or policy is fit for purpose, minimises associated costs and burdens and maximise the simplification potential.

### 3. DETAILED STRUCTURE AND CONTENT OF THE EVALUATION SWD

The SWD must follow the structure below. Each section indicates the information/issues that should be covered. They do not replace the main evaluation guidance, which provides the complete picture of issues to address under each key question. Generally there is flexibility in how to respond proportionately to the questions in the main Guideline and how to structure the relevant sub-sections of the SWD.

#### Section 1 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 journalistic 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 EN, FR and DE.

The executive summary should not be longer than two pages.

#### Section 2 Introduction

- *Purpose of the evaluation* - Set out purpose of this evaluation, what it will deliver, how its results will be used
- *Scope of the evaluation* - Define the scope of evaluation: explain what is covered, what is not and why.

#### Section 3 Background to the initiative

##### Description of the initiative and its objectives

*Provide a brief description of the initiative and its different components, its objectives and the problems it was intended to solve.*

If possible, summarise this information in an Intervention Logic diagram, bringing together how the different measures were expected to interact. Even if a full Intervention Logic cannot be developed, there should be some sort of picture illustrating how the different components were expected to fit together.

Discuss/show the timing of the different components, their expected outputs and how these actions were ultimately expected to deliver the objectives.

##### Baseline

Describe what the situation was like before this initiative was taken, e.g. baseline.

#### Section 4 Evaluation Questions

Repeat the key evaluation questions that were published in the evaluation mandate. It may not be necessary to repeat all the sub-questions, as the information collected to answer these will be used to answer the main questions.

NOTE: All evaluations should ask questions about the effectiveness, efficiency, relevance and coherence of the initiative. In areas of shared competence, they should address the issue of whether EU level action has provided added value.

## **Section 5 Method**

Explain how the evaluation has been carried out and over what time period. Provide a transparent account of what has been done, any changes from the original plan (set out in the mandate) and any mitigating measures taken.

Detailed information of the process as well as details considering the methodologies (e.g. studies carried out/used; sources of data; models; stakeholder consultation etc.) should be included in the Annexes to the report.

### Limitations – robustness of findings

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 should be included.

## **Section 6 Implementation state of play (Results)**

This section should be descriptive and summarise the current situation, explaining:

- How the initiative has been implemented, summarising which MS have done what and what problems/infringements have been identified ;
- What the current situation is in quantitative and qualitative terms. In particular, explain the monitoring arrangements put in place and report back on the different indicators ;
- Whether any unexpected results have been achieved, including whether there have been "knock-ons" in other areas due to this initiative.

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.

## **Section 7 Answers to the evaluation questions**

Answer ALL evaluation questions set up in the evaluation mandate. If there is insufficient data or evidence to do so, this should be clearly stated.

Use the information collected to analyse how far the outputs and outcomes observed match the expectations stated when the initiative was adopted. 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 – must be addressed in the final report, preferably through specific sections.

Evaluations and Fitness Checks must assess the economic, social and environmental impacts of EU interventions

## Section 8 Conclusions

This section of the document should summarise the main conclusions of the evaluation by evaluation criteria. There should be a clear and logical progression between the results presented, the answers to the evaluation questions provided and the conclusions being drawn.

### 3.1. 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).

Suggested minimum annexes are:

**Annex 1: Procedural information** concerning the process to prepare the evaluation or Fitness Check.

- Identify the lead DG; any Agenda planning/Work Programme references;
- 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.

## **Annex 2: Stakeholder consultation**

- A brief summary should be provided of the consultation strategy/process. Provide details of how, who and on what consultation took place. Explain how it was ensured that all relevant stakeholders had an opportunity to provide inputs. In particular;
  - Indicate if the Commission’s minimum standards have all been met, and, if not, why not.
  - Indicate which groups of stakeholders have been consulted, at what stage in the process and how (public or targeted consultations);
- Include a more detailed summary of all relevant consultations and their results. This text should be factual and avoid drawing any conclusions based on the overall share of respondents favouring or opposing a measure.
  - The results should preferably be presented for each key evaluation/Fitness Check element and differentiated across stakeholder groups.
  - 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. Methods and Analytical models used in preparing the evaluation/Fitness Check**

A dedicated annex presenting the following information must be included:

- A description of the methods and approaches which have been deployed during the evaluation or fitness check.
- A brief description of the 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;
  - 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 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).

#### **4. GOOD PRACTICE TIPS**

- Given the importance of providing a good evidence base, all data and analysis must 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. Sometimes this means saying a negative e.g. there is a lack of something, rather than trying to make a recommendation for its future inclusion and thereby painting things more positively e.g. there is room for improvement.
- To reflect the common practice of reading either the executive summary or the conclusions first, both these sections should contain clear statements on the robustness and reliability of the data and analysis which form the basis of the evaluation.
- 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.

## **TOOL #48: 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 supporting reports and SWD's should therefore be disseminated in a manner suited to the potentially different audiences. Active discussion and debate on these findings should be encouraged.

To maximise transparency and access:

- Any contractors' final report must be published in the EU Bookshop;
- The Staff Working Document and contractors report should be published on the EIMS;
- The evaluation roadmap, SWD, and (if relevant) any contractors' report and associated Quality Assessment, opinion from the RSB should be published centrally in an easily accessible format.
- Where appropriate, summary information from the evaluation must be included in the REFIT scoreboard.

### **3. GOOD PRACTICE TIPS**

- Every evaluation should have 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. Think how you will pass on bad news (to hierarchy) as well as good;
- 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.

## **TOOL #49: FOLLOW UP ACTION PLANS**

### **1. WHAT IS A FOLLOW-UP ACTION?**

Evaluation is not the end of the process. Completing the SWD and disseminating findings should stimulate discussion of the evaluation findings. In turn, this should lead to the identification of appropriate follow-up actions to put into practice the lessons learned and feed the evaluation findings into the next cycle of decision making. The evaluation results and recommendations must feed into the Annual Activity Reports and related follow up actions must 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.

This is often done by writing 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 the legal base of an intervention to send the findings to the European Parliament and Council. Such a document, usually in the form of the Commission report to the Council and Parliament, 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.
- 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.
- The implementation of such follow up depends to a large extent on senior management support. This is one of the reasons why senior management should

already be involved in designing the original evaluation and drafting the evaluation questions - to raise their interest and prepare the ground for ownership of the results and effective follow-up action.

- 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, REFIT). It should in no case pre-empt results of 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.
- Where a report to other EU institutions is requested in the legal base of an intervention, 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.

## **Chapter 7**

### **Stakeholder consultation**

## TOOL #50: STAKEHOLDER CONSULTATION TOOLS

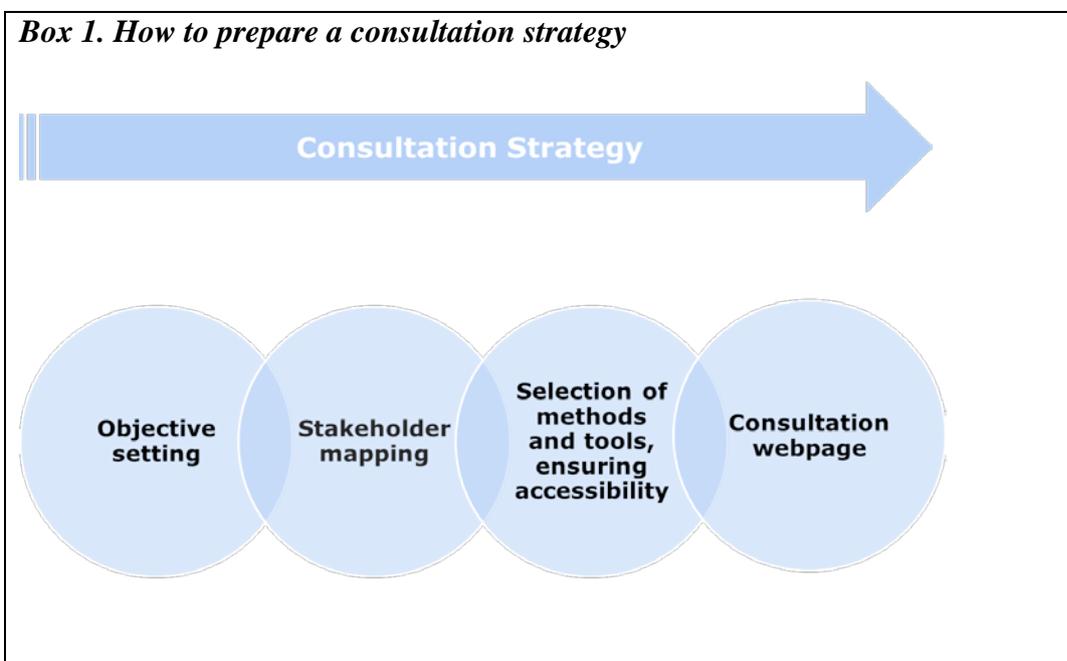
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## 1. CONSULTATION STRATEGY TOOLS

### 1.1. Consultation strategy design

The design of the consultation strategy should be fed by a thorough and structured reflection process.



The consultation strategy can be drawn up as an informal document, which must be endorsed by the ISG or, if no ISG is established, the SG / concerned DGs. It should cover at least the elements listed below:

To the extent possible, the consultation strategy should also include information on human and financial resource planning. An external service provider or a facilitator (who must comply with the minimum standards for stakeholder consultation and follow the guidelines) might be considered for certain consultation work. It should be carefully verified that the contractors involved have no interest in the policy area subject to consultation and can operate in an independent way.

#### ***Step 1: Set consultation objectives***

##### Key elements:

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

##### Consider:

- The context, scope and expected impacts of the initiative and the stage in the policy development process,
- The consultation background of the initiative under preparation,
- The scope of the consultation: What is in the focus, where is it still possible to influence policy preparation?

- The difference between collecting views or opinions (subjective) and collecting data or facts (objective).

### ***Step 2: Map Stakeholders***<sup>412</sup>

#### Key elements:

- *Identification of stakeholder categories relevant for or interested in the concerned policy area(s);*
- *Sorting stakeholder categories according to the level of interest in or influence on the concrete initiative that is to be consulted upon.*

### ***Step 3: Determine consultation methods, tools & ensure accessibility***

#### Key elements:

- *The most appropriate consultation methods and tools<sup>413</sup> depend on the objectives of the consultation, the identified stakeholders, the nature of the initiative as well as required time and resources.*

#### Consider:

- **Consultation method:** Open public consultation or targeted consultation?
- **Consultation tools:** The consultation method determines the consultation tools. The selection of the most appropriate consultation tool should take into account
  - Proportionality;
  - The degree of interactivity needed (e.g. written consultation versus stakeholder events/ online discussion fora/ other internet based tools);
  - Accessibility considerations; and
  - Possible timing requirements;
  - Necessity to provide statistically representative results (use of surveys, e.g. Eurobarometer).
- **Accessibility of consultations:**
  - *Linguistic accessibility:* language regime, stakeholder friendly language, participation of persons with disabilities;
  - *Accessibility of tools and consultation channels:* selection of communication channels;

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<sup>412</sup> See later guidance in this tool on stakeholder mapping.

<sup>413</sup> See later guidance in this tool for an overview of possible consultation methods and tools.

- *Time accessibility*: Timely consultation, timeframe for contributions – mandatory timeframes for consultation and feedback for certain types of initiatives.

#### **Step 4 - Create a consultation webpage<sup>414</sup>**

##### Key elements:

- *Establish a consultation webpage on the DG's website for the policy initiative under preparation*
- *Publish the consultation strategy, including the planned dates of the various consultation activities, as soon as known*

##### Consider:

- Add and up-date all information about the various consultation activities linked to a given initiative.
- It is best practice to create specific sub-pages for the various consultation work (e.g. open public consultation, stakeholder conference etc.).
- Dates for consultations will also be included in the Commissions' Consultation Planning Calendar, compiled by the SG based on information received from the DGs and to be published on 'Your Voice in Europe'.
- Communication relating to a consultation should be clear and concise.

### **1.2. Summary of initiatives or documents on which stakeholders are consulted or can provide feedback**

Initiatives without Impact Assessment	
Roadmap	<ul style="list-style-type: none"> <li>• Prepared in a single language version according to a standard template available in GoPro.</li> <li>• Published on the Commission's web site following political validation of the initiative and agreement of the interservice group if one has been established for the initiative.</li> <li>• Stakeholders should have the <b>opportunity to provide feedback on the Roadmap during a period determined on a case by case basis taking in to account the expected timing of any subsequent consultation.</b> Feedback should be via the relevant website. Stakeholders can comment in any of the official languages of the Union.</li> <li>• The identity of Stakeholders and their comments should be publicly available via the relevant website.</li> <li>• Stakeholder feedback should be assessed by the lead DG in the policy preparation process and changes may be made to the</li> </ul>

<sup>414</sup> See later guidance on constructing a consultation web page

	<p>Roadmap if appropriate. There is no need to acknowledge stakeholder comments or provide feedback on how the Commission has used them.</p>
<p>Consultation documents</p>	<ul style="list-style-type: none"> <li>• The interservice group (if established) should agree upon the consultation strategy and consultation documents. If no interservice group exists, the SG and any other associated service have to be consulted.</li> <li>• A list of upcoming consultations will be published on the Commission's website to give advance notice to stakeholders.</li> <li>• Questionnaires and background information used to support a 12-week internet-based public consultation. Green papers: In addition, ISC and adoption by the College needed.</li> <li>• Other questionnaires/documents used to target relevant stakeholders and evidence.</li> <li>• For stakeholder meetings or conferences, the consultation documents should be made available at the latest 20 working days before the meeting.</li> <li>• The results of the stakeholder consultation should be reported either in the explanatory memorandum of any proposal or in a synopsis report which should be made available to stakeholders.</li> </ul>
<p><b>Initiatives with Impact Assessment</b></p>	
<p>Inception IA</p>	<ul style="list-style-type: none"> <li>• Prepared in a single language version according to a standard template available in GoPro.</li> <li>• Published on the Commission's web site following political validation of the initiative and finalisation and agreement in the interservice group responsible for preparing the IA and the initiative.</li> <li>• Stakeholders should have the opportunity to provide feedback on the Roadmap during a period determined on a case by case basis taking in to account the expected timing of any subsequent consultation. Stakeholder comments should be made public and be assessed by the lead DG. Feedback should be assessed by the lead DG and used in the subsequent policy preparation process; The Inception IA can also be updated if appropriate. There is no need to acknowledge stakeholder comments or provide feedback on how the Commission has used them. Stakeholders can comment in any of the official languages of the Union.</li> <li>• If the timing of the publication of the Inception IA coincides with the launch of the mandatory 12-weeks public consultation, it is sensible and preferable to use the inception IA as one of the supporting documents for the mandatory 12-week internet-based public consultation together with any other consultation documents. In such cases, stakeholder feedback on the inception IA can be provided as part of the public consultation process.</li> <li>• Results of the consultation should be reflected in IA report and the</li> </ul>

	<p>synopsis report annexed to the IA Report.</p>
<p>Consultation documents</p>	<ul style="list-style-type: none"> <li>• A list of upcoming consultations will be published on the Commission's website to give advance notice to stakeholders.</li> <li>• Questionnaires and background information (together with the inception IA) used to support the mandatory 12-week internet-based public consultation.</li> <li>• Other questionnaires/documents used as part of the broader consultation strategy to target relevant stakeholders and evidence.</li> <li>• The interservice group should agree the consultation strategy and consultation documents.</li> <li>• Stakeholders must be consulted on all elements covered in the main IA questions: <ul style="list-style-type: none"> <li>- the problem to be tackled,</li> <li>- the issue of subsidiarity and the EU dimension to the problem,</li> <li>- the available policy options; and</li> <li>- The impacts of the policy options.</li> </ul> </li> <li>• Results of the consultation should be reflected in IA Report (SWD) and the synopsis report annexed to the IA Report.</li> </ul>
<p><b>Evaluations and Fitness Checks</b></p>	
<p>Roadmap</p>	<ul style="list-style-type: none"> <li>• Prepared in a single language version according to a standard template available in GoPro.</li> <li>• Published on the Commission's web site following political validation of the initiative (necessary in case the evaluation/ fitness check is part of the CWP's REFIT annex) and finalisation by the interservice group responsible for preparing the Evaluation/Fitness Check.</li> <li>• Stakeholders should have the opportunity to provide feedback on the Roadmap during a period of 4 weeks via the relevant website Stakeholders can comment in any of the official languages of the Union.</li> <li>• The identity of Stakeholders and their comments should be publicly available via the relevant website. Feedback should be assessed by the lead DG in the subsequent evaluation/Fitness Check and changes may be made to the Roadmap if appropriate. There is no need to acknowledge stakeholder comments or provide feedback on how the Commission has used them.</li> <li>• If it is sensible and preferable, the Roadmap may be used as one of the supporting documents for the mandatory 12-week internet-based public consultation together with any other consultation documents. Thus stakeholder feedback on the Roadmap can be provided as part of the public consultation process.</li> </ul>

<p>Consultation documents</p>	<ul style="list-style-type: none"> <li>• A list of upcoming consultations will be published on the Commission's website to give advance notice to stakeholders.</li> <li>• Questionnaires and background information used to support the mandatory 12-week internet-based public consultation</li> <li>• Other questionnaires/documents used as part of the broader consultation strategy to target relevant stakeholders and evidence.</li> <li>• The interservice group should agree the consultation strategy and consultation documents.</li> <li>• It is essential to consult on the 5 mandatory evaluation criteria, which are: <ul style="list-style-type: none"> <li>- effectiveness of the intervention,</li> <li>- efficiency of the intervention in relation to resources used,</li> <li>- the relevance of the intervention in relation to the identified needs/problem it aims to address,</li> <li>- coherence of the intervention with other interventions which share common objective; and</li> <li>- The EU added value resulting from the intervention compared to what could be achieved by Member State action only.</li> </ul> </li> <li>• Results of the consultation should be reflected in the contractors' study (if applicable) and the evaluation SWD and the synopsis report annexed to the document.</li> </ul>
<p><b>Draft Delegated Acts and Implementing Acts</b></p>	
	<p>See separate tool on stakeholder consultation on draft delegated and implementing acts</p>
<p><b>Post adoption comments</b></p>	
<p>Initiatives and / or, where applicable, related impact assessment reports</p>	<ul style="list-style-type: none"> <li>• The initiative is published by the Commission in all official languages of the Union following adoption. The impact assessment is available in a single language version but a summary will be available in all EU languages.</li> <li>• Stakeholders should have the opportunity to provide feedback on either the initiative or the impact assessment during a period of 8 weeks following their transmission to the other institutions.</li> <li>• The stakeholder comments will be accessible to the public at large including the other institutions and will be taken into account by the Commission in formulating its positions during the legislative procedure.</li> <li>• Lead DGs should prepare a synthesis of these views which will be communicated to the Parliament and the Council in line with usual procedures governing interinstitutional relations (i.e. the GRI).</li> </ul>

### 1.3. Stakeholder consultation on draft delegated and implementing acts

#### *When is the 4-week public consultation on draft delegated and implementing acts required?*

Delegated and implementing acts can have important impacts on a specific sector, or even for the whole society, which creates the need for greater transparency and consultation before they are adopted. Once adopted by the Commission, and unless in the case of delegated acts they are objected by the European Parliament or the Council, they become law. Therefore, consulting on the actual draft legal text is particularly important, in order to make sure that what is going to be adopted is sound both from a technical and policy perspective.

The 4-week consultation is the rule for all delegated acts with only very few exceptions. For implementing acts, a 4-week consultation must be considered for acts adopted under committee control. However, several categories of exemptions may apply. These need to be decided on a case-by-case basis. Delegated and implementing acts are now, as a general rule, included in Agenda Planning. When introducing the Agenda Planning entry, an indication should be given whether the 4-week consultation on the draft text is foreseen. This is in order to facilitate the publication of the planning for upcoming consultations on draft delegated and implementing acts.

<b>Initiatives for which the need for a 4-week public consultation on the final draft text must be assessed</b>
Delegated acts (Art. 290 TFEU)
Implementing acts (Art. 291 TFEU) with committee control under Regulation 182/2011
Measures adopted under the regulatory procedure with scrutiny

#### *Exceptions to the 4-week public consultation on Delegated/Implementing Acts<sup>415</sup>:*

<b>Type</b>	<b>Reason</b>	<b>Examples</b>
No (or limited) margin of discretion	Lack of policy alternatives	Acts implementing international standards into EU law without any discretion. Corrigenda
Drafts have been prepared by an EU agency or body and have been subject to full public consultation before	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

<sup>415</sup> The table refers to delegated and implementing acts. This does not prejudice in any way the choice of instrument; certain types of acts such as those linked to budgetary procedures and programme management or individual authorisation decisions, can, by their nature, only be implementing acts.

Type	Reason	Examples
being submitted to the Commission and for which the Commission does not have the intention to significantly modify them		Securities and Markets Authority
Urgency	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
Budgetary procedures and measures, programme management decisions	Lack of policy alternatives / implementation of agreements already decided on	Decisions on work programmes and selection and award decisions
Individual authorisation decisions	Lack of significant impact, routine acts	Marketing authorisations in the pharmaceutical field or comparable authorisations
Temporary risk management decisions	Lack of policy alternatives / no significant direct impacts / no deviation from the advice of risk assessors	Temporary food safety measures
Based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency findings	Extensive consultation on the substance has already taken place in a dedicated framework	Areas in which agencies such as EFSA have given a scientific advise
Other duly justified reasons, 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 MSs  Authorisations to MS relating to own resource calculations

### ***How is the 4-week public consultation on draft delegated and implementing acts carried out?***

The 4-week consultation takes place on the draft text of the delegated or implementing act itself. No specific consultation document in addition to the draft text needs to be prepared by the service. Links to earlier consultations and any existing supporting documents should be provided.

The scope of the 4-week consultation on the draft is defined by the following elements:

- Delegated and implementing acts must respect the empowerments in the basic legal act. The basic act, its policy choices and the scope of empowerments are outside the scope of these consultations.
- If there have been preceding consultations in the preparation of the delegated or implementing act, be it open public consultations (for example if an impact assessment is being prepared) or targeted stakeholder consultations, issues that were already addressed are not subject of the consultation anymore.
- In many cases the Commission may be acting based on expertise from agencies or scientific committees. If their scientific input has already been subject to a public consultation it does not fall in the scope of the 4-week consultation.

The 4-week consultation on the draft delegated or implementing act is always an open public consultation on the internet. In relation to linguistic accessibility the same rules as for other consultations apply.

The 4-week consultation on the draft takes place via a consultation website of the respective service and is linked to a special section of Your Voice in Europe. In case other targeted consultations have taken place earlier, stakeholders that were addressed in that context should be made aware of the consultation on the draft delegated or implementing act.

The consultation on draft delegated and implementing acts will run for a period of 4-weeks. The shortened timeframe is justified by the limited scope of these consultations and the fact that earlier consultation has often taken case already. The shorter timeframe will be mitigated by making a planning available that allows stakeholders to plan ahead.

The consultation can only be launched after the interservice consultation is concluded. The consultation can run in parallel with the Technical Barriers to Trade notifications. The consultation must be carried out for delegated acts before the adoption by the College and for implementing acts and measures under the regulatory procedure with scrutiny before the submission to the opinion of the Committee.

Contributions to the 4-week consultation can be provided via a dedicated functional mailbox provided on the consultation website. Individual or collective acknowledgments of receipt can be automatically generated at the entry point.

Contributions received will be made public on the consultation website.

In case of delegated acts the key outcomes of the consultation process are reflected in the explanatory memorandum, which should give a short and proportionate summary of the consultation. In case of implementing acts the Committee will be informed about the outcome of the consultation and the discussion will be reflected in the minutes of the meeting.

## 2. STAKEHOLDER MAPPING TOOLS

Identification or mapping of relevant/interested stakeholders involves two steps:

- (1) Identification of stakeholder categories relevant for or interested in the concerned policy area(s),
- (2) Sorting stakeholder categories according to the level of interest in or influence on the concrete initiative that is to be consulted upon.

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

Useful tips:

- Identify the persons and groups with expertise or technical knowledge in a given field
- Member States could be invited to provide a list of interest groups for the concerned policy area within their countries.
- Existing contacts (e.g. in mailing or distribution lists),
- subscriptions in the 'Commission at work notifications' and the 'Transparency register' or the
- Track record of participants in previous consultations
- Advisory or expert groups or standing groups of stakeholders, established by Directorates General around a specific policy area
- Inter-Service Group members could also suggest new contacts.

<b>Stakeholders categories (non-exhaustive list):</b>	
<b>Citizen/individual</b>	
<b>Industry, business or workers' organisations</b>	Multi-national/global National Small and Medium-sized Enterprises Business organisation Trade Union Chamber of commerce
<b>EU platform, network, or association</b>	Representing for-profit interests Representing not-for-profit interests Representing professions/crafts
<b>Organisation or</b>	National organisation representing for-profit interests

<b>association</b>	National organisation representing not-for-profit interests, National organisation representing professions/crafts International/ Inter-governmental organisation
<b>Public authority</b>	EU institution National government National Parliament Regional/ local/municipal authority National competent authorities or Agencies.
<b>Consultancy</b>	Think-tank Professional consultancy Law firm
<b>Research/academia</b>	University School & education establishment Research institute
<b>Other</b>	

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

- **Distinguish between stakeholder categories**, which the concrete initiative may affect (both directly and indirectly) in a significantly different way
- **Differentiation within a specific stakeholder category** which can be affected by the concrete initiative differently, e.g. depending on their size, location, type of activity, whether they are public or private, incumbent operators or new entrants.

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

- Identify target groups that run the risk of being excluded,
- Seek balance and comprehensive coverage,
- Identify if you have the need:
  - **for specific experience**, expertise or technical knowledge or
  - **to involve non-organised interests**, as opposed to organised interested parties at European or Member States level.
- Avoid 'regulatory capture',
- Use clear and transparent criteria for selection of participants.

*Guiding questions to identify the level of influence and level of interest of stakeholders:*

**The Six Tests for Stakeholder Identification<sup>416</sup>**

<sup>416</sup> Source: Consultation Institute

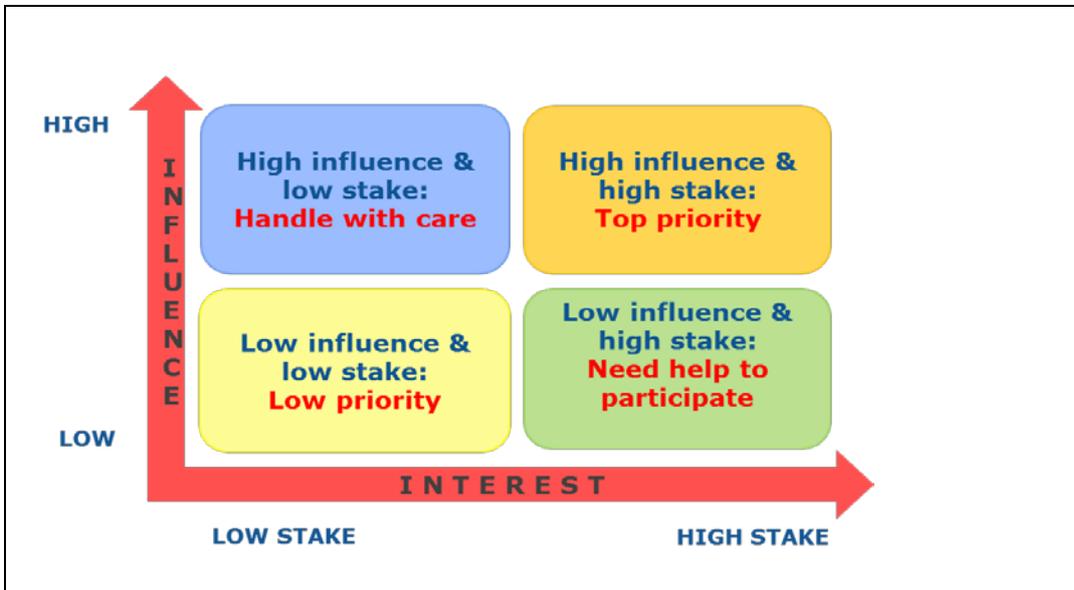
<b><i>Test 1 Who is directly impacted?</i></b>
<ul style="list-style-type: none"> <li>• Whose daily/weekly lives will change as a result of this policy?</li> <li>• Who cannot easily take steps to avoid being affected by this policy?</li> <li>• Who will have to change their behaviour as a result of this policy?</li> </ul>
<b><i>Test 2 Who is indirectly impacted?</i></b>
<ul style="list-style-type: none"> <li>• Whose daily lives will change because others have been directly impacted by the policy?</li> <li>• Who will gain or lose because of changes resulting from this policy?</li> </ul>
<b><i>Test 3 Who is potentially impacted?</i></b>
<ul style="list-style-type: none"> <li>• In particular circumstances, who will have a different experience as a result of this decision?</li> <li>• Are there individuals or groups who will have to adjust their behaviour if particular conditions apply?</li> </ul>
<b><i>Test 4 Whose help is needed to make it work?</i></b>
<ul style="list-style-type: none"> <li>• Are there vital individuals or groups in the delivery chain?</li> <li>• Who will have the ability to frustrate implementation unless co-operating?</li> <li>• Who understands the likely impact of this decision on other stakeholders?</li> </ul>
<b><i>Test 5 Who thinks they know about the subject?</i></b>
<ul style="list-style-type: none"> <li>• Who has studied the subject and published views on it?</li> <li>• Who has detailed know-how that those implementing the policy should also understand?</li> <li>• Are there individuals or groups that will be perceived as knowledgeable on the subject?</li> </ul>
<b><i>Test 6 Who will show an interest in the subject?</i></b>
<ul style="list-style-type: none"> <li>• Are there organisations or individuals who think they have an interest?</li> <li>• Has anyone been campaigning about the issue?</li> <li>• Is there anyone publishing or broadcasting views on this subject?</li> </ul>

***Stakeholder mapping matrix<sup>417</sup>:***

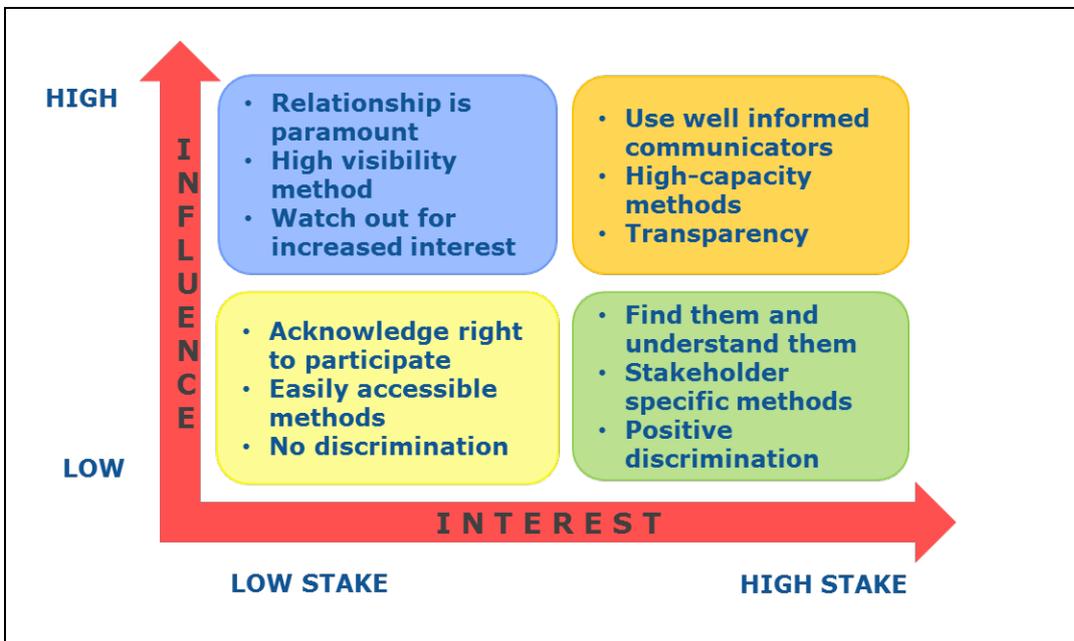
Based on the Six-test or other methodological work, the stakeholders can be attributed to the following four groups:

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<sup>417</sup> Source: Consultation Institute



The level of interest and influence is important for deciding the appropriate consultation methods and tools. For each stakeholder type, the following issues should be considered:



### 3. DATA PROTECTION AND TRANSPARENCY REGISTER

Data protection rules have to be respected. If personal data is collected and processed, the processing has to comply with Regulation (EC) 45/2001 on the protection of personal data. Therefore, when conducting any kind of consultation, **it must be clearly stated that contributions are going to be published on the dedicated website, unless**

**respondents provide a substantial justification for their opposition to the publication of their contribution.** In practice, a specific privacy statement needs to be prepared for each consultation in a separate document. Furthermore, a link to the 'protection of personal data' page needs to be provided on each consultation webpage. Contributions which will not be published for the above-mentioned reasons still need to be considered when analysing the results of the consultation.

Information about the **Transparency Register** has to be provided: Organizations that wish to submit comments on a policy proposal 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 Register. Submissions from organisations that choose not to register will be treated as "individual contributions"<sup>418</sup> unless they are recognised as representative stakeholders via relevant Treaty provisions<sup>419</sup>. Publishing a consultation on 'Your Voice in Europe' and publishing a Roadmap on the dedicated webpage will trigger an information e-mail alert to registered organisations.

#### 4. ACCESSIBILITY OF CONSULTATIONS

The choice of consultation methods and tools should take account of accessibility issues, so that different stakeholder groups have the opportunity to contribute to Commission's policy development.

<b>Accessibility of consultations</b>	
<b>1. Linguistic accessibility</b>	
<b>Language regime</b> <sup>420</sup>	<ul style="list-style-type: none"> <li>• Translation requirements need to be identified according to the scope and outreach of a consultation method.</li> <li>• All language versions of the consultation documents should be available on the date of the consultation event/ the launch of the consultation.</li> <li>• The Commission translation service (DGT) advises on the appropriate language coverage. DGT should be contacted as early as possible when planning a consultation 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<sup>421</sup>.</li> </ul>
<b>Stakeholder friendly language</b> <sup>422</sup>	<ul style="list-style-type: none"> <li>• Communicate effectively and convey information in a manner that is easily understood by diverse audiences including persons</li> </ul>

<sup>418</sup> See section on stakeholder categories

<sup>419</sup> European Social Dialogue, Art. 154-155 TFEU.

<sup>420</sup> There are currently no formal requirements concerning the language coverage of consultation documents. Individual replies to consultations can be provided in any of the EU official languages.

<sup>421</sup> 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.

<sup>422</sup> [http://www.cc.cec/translation/clear\\_writing/index\\_en.htm](http://www.cc.cec/translation/clear_writing/index_en.htm)

	<p>of limited linguistic proficiency.</p> <ul style="list-style-type: none"> <li>• All consultation documents and questionnaires should be explicit, clear and understandable.</li> <li>• Bureaucratic or too technical language should be avoided.</li> <li>• Specialist terms and abbreviations should be explained to ensure common understanding.</li> </ul>
<b>Participation of persons with disabilities</b> <sup>423</sup>	<ul style="list-style-type: none"> <li>• Foresee provisions that allow persons with disabilities to participate effectively in line with the UN Convention on the Rights of Persons with Disabilities<sup>424</sup>.</li> <li>• The use of a variety of communication means and accessible formats to ensure equal access by persons with disabilities can broaden participation.</li> <li>• Ensure the accessibility of websites and facilitate the use of sign language and Braille when dealing with EU institutions and use an accessible format of websites.</li> </ul>
<b>2. Accessibility of tools and consultation channels</b>	
<b>Selection of tools and communication channels</b>	<ul style="list-style-type: none"> <li>• The selection should ensure that relevant target groups are reached and invited to participate in the most effective way.</li> <li>• 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.</li> <li>• Announcements in trade press or specialised publications may be more effective than publication in general press for specific target groups (e.g. SMEs).</li> </ul>
<b>3. Time wise accessibility</b>	
<b>Timely consultation</b>	<ul style="list-style-type: none"> <li>• Stakeholders should have the opportunity to be involved before certain policy decisions have been made. It is therefore crucial to set the appropriate moment for launching each consultation activity as well as their sequence, and to assess the stages of policy preparation where stakeholder input will be needed.</li> <li>• Spread information early and widely by using various channels, networks and multipliers.</li> </ul>
<b>Timeframe for contributions</b>	<ul style="list-style-type: none"> <li>• Sufficient time for responding must be given to ensure greatest possible participation.</li> <li>• The consultation period should strike a reasonable balance between the need for adequate input and the need for swift decision-making.</li> <li>• The minimum period for replies to open public consultations is</li> </ul>

<sup>423</sup> European Disability Strategy 2010-2020: A Renewed Commitment to a Barrier-Free Europe, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0636:FIN:EN:PDF>

<sup>424</sup> 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,

	<p>12 weeks.</p> <ul style="list-style-type: none"> <li>• For meetings, hearings, conferences or other consultation events, the Minimum Standards require that relevant documents are disseminated 20-working-days' ahead of the meeting.</li> </ul>
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## 5. CONSULTATION METHODS AND TOOLS

### 5.1. Overview

The table below provides an overview on key consultation methods and tools which should be considered when developing the consultation strategy. The consultation methods and tools should correspond to the identified consultation scope and objectives and ensure that the identified stakeholder groups are reached and are able to contribute. It shows the degree of interactivity of certain consultation methods and tools and indicates how they respond to certain consultation objectives at the various stages of the policy cycle.



	<b>INFORM and ENABLE FEEDBACK</b>	<b>CONSULT (written)</b>	<b>CONSULT and INVOLVE (based on direct interactions)</b>
<b>Objectives</b>	<p><b>Provide information to interested parties on Commission plans:</b></p> <ul style="list-style-type: none"> <li>• Give a first indication on the issues at stake, why the EU should address them</li> <li>• Keep interested parties informed on when their input will be expected</li> </ul>	<p><b>Obtain input from interested parties on issues at stake, possible solutions and impacts:</b></p> <ul style="list-style-type: none"> <li>• Collect views, new ideas, evidence, data</li> <li>• Validate analysis, test hypotheses</li> </ul>	<p><b>Obtain input from interested parties on issues at stake, possible solutions and impacts:</b></p> <ul style="list-style-type: none"> <li>• Discuss directly with interested parties to make sure their points are fully understood</li> <li>• Allow for exchange of views between different stakeholder groups</li> <li>• Facilitate consensus seeking or deliberation</li> </ul>
<b>Instruments, methods &amp; tools</b>	<ul style="list-style-type: none"> <li>• Roadmap/ Inception IA</li> <li>• Calendar of planned open public consultations on Your Voice in Europe (YViE)</li> <li>• Alerts sent by Transparency Register</li> <li>• Alerts sent by "Commission at work" notifications</li> </ul>	<ul style="list-style-type: none"> <li>• Open public consultation</li> <li>• Consultation tools targeted at specific consultation groups</li> </ul>	<ul style="list-style-type: none"> <li>• Stakeholder meetings, workshops, seminars</li> <li>• Stakeholder conferences, public hearings, broad events</li> <li>• Expert/focus groups</li> <li>• Online discussion fora</li> <li>• Other online tools</li> </ul>
		<p>Consultation questionnaires, consultation documents, surveys and other representative consultations</p>	
	<b>Early stages of policy preparation &amp; planning</b>	<b>Policy preparation (development and revision of policies) Policy application (evaluation of policies)</b>	

## 5.2. Open public online consultation

OPEN PUBLIC ONLINE CONSULTATION	
<b>Overview</b>	<p>An open public consultation is open to all - anyone interested can provide input and so it is able to <b>reach a broad range and large number of stakeholders.</b></p> <ul style="list-style-type: none"> <li>• 'Your Voice in Europe' website to be used.</li> <li>• Other social media not allowed, e.g. as parallel entry point(s).</li> <li>• A specific sub-page to the overall consultation website linked to this initiative should be created. In order to ensure consistency and user-friendly access to information, the standard consultation page template should be used<sup>425</sup>. A vade mecum with explanatory notes on how to prepare the standard consultation page is available on the internal Commission website.</li> <li>• Online-reply as default.</li> </ul> <p>Instruments which can be used:</p> <ul style="list-style-type: none"> <li>• Questionnaires</li> <li>• Surveys</li> <li>• Documents</li> </ul> <p>Consultation document and/or questionnaire published on the 'Your Voice in Europe' website.</p> <p><b>Target audience:</b> General public/all stakeholders.</p>
<b>When to use it?</b>	<p><b>Mandatory for impact assessments, evaluations and Fitness Checks and Green Papers.</b></p> <p>The minimum time limit for replies to open public consultations is 12 weeks. Allowing a longer period than 12 weeks may be appropriate, depending on:</p> <ul style="list-style-type: none"> <li>• Specificity of a proposal e. g. complexity of the issue or the diversity of the interested parties on:</li> <li>• Consultations that overlap with holiday periods or bank holidays</li> </ul>
<b>Procedure</b>	<ul style="list-style-type: none"> <li>• Consultation documents and questionnaires to be endorsed by the ISG if established, otherwise by SG/concerned DGs.</li> <li>• Requests for publication on "Your Voice in Europe" should be sent to the functional mailbox 'SG YOUR VOICE IN EUROPE' (in copy to 'SG STAKEHOLDER CONSULTATION').</li> </ul>

<sup>425</sup> The standard page provides details about the title and policy field of consultation; target groups; period of consultation (and reason why the consultation period is less than 12 weeks for cases in exceptional circumstances); objective of consultation; instructions on how to submit contributions; information about results of consultation and next steps, privacy statement.

	<ul style="list-style-type: none"> <li>• Requests should be sent (at least) <u>two days prior to the desired publication date.</u></li> <li>• Information to be included: <ul style="list-style-type: none"> <li>- Title of the consultation translated into all 24 official EU languages;</li> <li>- Link to the consultation page (url on DG's website on Europa);</li> <li>- Indication of the policy area of the consultation;</li> <li>- Opening and closing dates for the consultation (minimum 12 weeks).</li> </ul> </li> </ul>
<b>Strengths</b>	Reaches a broad range and large number of stakeholders.
<b>Limitations</b>	<p>Might be resource-intensive and is time-intensive.</p> <p>Poor response rates</p> <p>Self-selection bias</p> <p>Lack of representativeness</p> <p>Excludes the 20+% of the population without internet access</p> <p>Not necessarily useful for initiatives of a more technical nature (e.g. linking of existing databases at EU level)</p>

### 5.3. Open public online consultation – consultation website template

In order to ensure consistency and user-friendly access to information, the standard consultation page template should be used. A vademecum with explanatory notes on how to prepare the standard consultation page is available on the internal Commission website<sup>426</sup>.

When preparing your consultation webpage, the following should be considered:

- Information to facilitate and encourage stakeholder input should be included. It is recommended to set up a single functional mailbox for contributions, but also for information purposes related to the consultation concerned. It might be useful to send reminders or re-send information about an ongoing consultation.
- The webpage should indicate the language regime. When the consultation is conducted in several languages, users should be able to navigate in the same language from entering the page to completing the consultation. Regardless of the languages used for consultation documents or questionnaires, it must be made clear to potential respondents that they can send their reply in any EU official language.
- If relevant, a FAQ section should be created.

<sup>426</sup> <https://myintracomm.ec.europa.eu/corp/sg/en/stakeholder/Pages/template.aspx> .

<b>OPEN PUBLIC ONLINE CONSULTATION – CONSULTATION WEBSITE TEMPLATE</b>	
<b>Title</b>	Title of the consultation or consultation document or questionnaire or the title of the meeting or seminar or public hearing to be held.
<b>Policy field(s)</b>	See the list on 'Your Voice in Europe' for the correct terminology for the Commission's policy fields.
<b>Target group(s)</b>	<p>For an open consultation all citizens and organisations can contribute. In this field, a DG could use the following message:</p> <p><i>"All citizens and organisations are welcome to contribute to this consultation. Contributions are particularly sought from..."</i></p> <p>For a targeted consultation, where something specific or highly technical is at stake, a DG can designate the particular groups targeted. All relevant target groups must be allowed to contribute to the consultation. To ensure transparency on this point, the target groups should be listed.</p>
<b>Period of consultation</b>	Opening and closing dates in the format 'dd.mm.yyyy'. The minimum consultation period required is 12 weeks. Efforts should be made, if possible, to allow longer periods depending on the needs of stakeholders as well as the service. It is recommended to make adjustments for European public and summer holidays when calculating the consultation period.
<b>Objective of the consultation</b>	<p>Text that explains the problem and the possible ways to resolve it. Describe the objective of this consultation.</p> <p>You can use existing texts, for example, the objective set out in the Roadmap etc.</p>
<b>How to submit your contribution</b>	<p>Text provided which should be included in all consultations.</p> <ul style="list-style-type: none"> <li>• Inform contributors as to what information they should include with their contribution – name, type of organisation, registration number transparency register, contact details, etc.</li> <li>• ask contributors to read through all the consultation information before</li> <li>• invite contributors to look at the reference or background information</li> <li>• Finally, include the paragraph provided regarding the publication of the contributions.</li> </ul>
<b>View the consultation document*</b>	Link to consultation document.
<b>View the questionnaire*</b>	Link to the questionnaire.
<b>Access the invitation to*</b>	Title, date and place of the meeting, seminar or hearing and the link to its registration page.
<b>Reference documents and</b>	Insert links to any background documents and related consultations already held on the same matter.

<b>other, related consultations</b> ***	
<b>Contact details of responsible service</b>	<p>Name of the service responsible for the consultation.</p> <p>Give the e-mail address where contributions should be sent. This should be a general e-mail address of a service, not of an official (in view of the mobility of Commission staff).</p> <p>Also, provide a postal address in case the contributions cannot be sent electronically.</p>
<b>View the contributions</b> **	<p>In the interests of transparency, organisations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation is not registered, the submission is published separately from the registered organisations.</p> <p>This text provided by SG must always appear in this field. Insert the link to the contributions when they are published. The Commission has committed itself to publishing all contributions to its consultations. To make a clear distinction between contributions from organisations listed in the Register and those from all other organisations (as required by the Commission's communication of 21 March 2007) the contributions should be published at least in the following categories:</p> <ul style="list-style-type: none"> <li>• Contributions from Registered Organisations</li> <li>• Contributions from Public Authorities (European, National, Subnational, National Parliaments)</li> <li>• Individual Contributions <ul style="list-style-type: none"> <li>- • individual citizens</li> <li>- • unregistered organisations</li> </ul> </li> </ul> <p>DGs may add further sub-categories in addition to the above structure. It is recommended that when the consultation template is ready for publication, the webmaster should also be asked to prepare in advance the web page for viewing the contributions.</p>
<b>Results of consultation and next steps</b> **	<p>The Commission is committed to providing feedback on consultations. Use this field to provide this feedback on the results of the consultation and the next steps to be taken. It is an example of good practice to publish a consultation report as soon as the consultation is over.</p>
<b>Protection of personal data</b>	<p>Provide the link to the rules on personal data protection on EUROPA.</p>
<b>Specific privacy statement</b>	<p>Provide a link to the specific privacy statement for this consultation.</p> <p>The specific privacy statement should include the following paragraph:  <i>"Received contributions, together with the identity of the contributor, will be published on the Internet, unless the contributor objects to publication of the personal data on the grounds that such publication would harm his or her legitimate interests. In this case the contribution may be published in anonymous form. Otherwise the contribution will not be published nor will, in principle, its content be taken into</i></p>

	<i>account."</i>
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Notes on certain fields of the template, indicated by asterisks:

\* Fields marked with one asterisk are not necessary for every consultation. Choose the appropriate field depending on your type of consultation.

\*\* Fields marked here by two asterisks will always be visible to the public even in the early stages of the consultation before the contributions have been published.

\*\*\* The fields marked with three asterisks are optional (if there are no reference documents or links to them have been provided elsewhere, for example, in the description of the consultation at "How to submit your contribution").

#### 5.4. Surveys

SURVEYS	
<b>Overview</b>	<p><b>Collect facts and opinions from a group of respondents.</b></p> <p>It consists of a series of written questions. Most surveys will contain both open-ended and closed questions. Different approaches can be applied when conducting a survey:</p> <ul style="list-style-type: none"> <li>• <u>Representative surveys</u> aim to gather information from a representative sample of the population. Typically, they would use some type of sampling to ensure that the survey respondents can be seen as representative of the studied population.</li> <li>• <u>Open surveys</u> are open to all stakeholders and very often take a form of an open public consultation. Open surveys do not use any sampling methods and cannot be assumed to be representative of the wider population. This means the evaluators need to take an extra care when interpreting the results to ensure all potential biases and limitations are identified and accounted for.</li> <li>• <u>Targeted surveys</u> aim at a specific subset of stakeholders. Very often targeted surveys are designed to gather more detailed information, which is relevant only to a specific group of stakeholders (e.g. national authorities, consumers). If sampling methods are applied, targeted surveys can deliver representative results.</li> </ul> <p>More complex evaluations are likely to use a greater range of different survey and questionnaire techniques. In all cases, a successful survey requires a good knowledge of questionnaire and survey design.</p> <p><b>Target audience:</b> all stakeholders</p>
<b>When to use it?</b>	<p>Surveys present a proper tool for almost any type of analysis. As designing a survey questionnaire requires a very good understanding of the main issues, it is recommended to conduct surveys after desk research and initial interviews with key stakeholders.</p>
<b>Resources</b>	<p>Resources required will depend on the type of the survey, its length and scope. The main distinction can be made between representative and</p>

<b>required</b>	non-representative surveys. The former deliver more robust results but are considerably more expensive to run, especially if the survey intends to cover all Member States. The survey type and design will also have an important cost implication. For example, a telephone survey will be more expensive than the online survey questionnaire. Similarly, a survey consisting of only closed questions will produce standardised information, which will be easier to summarise, as compared to a questionnaire with open-ended questions. Finally, the length of the survey and the number of language versions will also impact on the amount of resources required to prepare and analyse the survey.
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Surveys are a good source of quantitative and qualitative data. They are particularly useful in collecting evidence on stakeholders' experiences, perceptions and opinions. Large number of stakeholders can be reached through surveys. Representative surveys provide the most robust results, as the information obtained is statistically representative and can be extrapolated to the entire population.</li> <li>• Targeted surveys are useful when different input is sought from different stakeholders, usually of more detailed, technical nature. When deciding to conduct a targeted survey, it should be ensured that key stakeholder groups not covered by the survey can provide an input into the process through other channels.</li> </ul>
<b>Limitations</b>	Even when open-ended questions are used, there are limits, to which survey questionnaires can examine more complex issues and opinions. Also, unlike interviews, questionnaires do not provide an opportunity to clarify questions or to verify that answers are understood correctly by the respondents. Sometimes, there might be a problem of low response rate, which makes it more difficult to interpret and analyse the results.

## 5.5. Eurobarometer Surveys

<b>EUROBAROMETER SURVEYS</b>	
<b>Overview</b>	<p><b>Gather opinions of European citizens.</b></p> <p>Eurobarometer is the public opinion service. It produces different types of surveys providing results which are representative of the targeted populations:</p> <ul style="list-style-type: none"> <li>• <u>Standard Eurobarometer</u>: surveys consisting of approximately 1000 face-to-face interviews per Member State, with reports published twice yearly. Over time, the evolution of public opinion can be followed on a number of topics.</li> <li>• <u>Special Eurobarometer</u>: surveys based on in-depth thematic studies, requested by the European Commission's own services.</li> <li>• <u>Flash Eurobarometer</u>: ad hoc thematic surveys, conducted by telephone at the request of the European Commission, providing relatively quick results focusing on specific target groups.</li> <li>• <u>Qualitative studies</u>: in-depth investigations of the motivations,</li> </ul>

	<p>feelings and reactions of selected social groups towards a given subject, carried out by listening to and analysing group discussions and interviews.</p> <ul style="list-style-type: none"> <li>You can request a Eurobarometer survey within the context of DG COMM's annual programming, and depending on the Commission's communication priorities.</li> </ul> <p><b>Target audience:</b> Citizens or professional stakeholders</p>
<b>When to use it?</b>	Policy stage: any
<b>Strengths</b>	<ul style="list-style-type: none"> <li>Because Standard, Flash and Special Eurobarometers are based on a random sample selection process, (representative) information on citizens' opinions on an issue can be gathered that can be extrapolated to the whole population.</li> <li>Allows gathering opinions from those that would not take part in a written consultation or in a stakeholder event.</li> <li>Qualitative studies allows for an in-depth analysis of existing circumstances relevant for a policy, for instance from various professional stakeholder groups.</li> <li>The use of DG COMM's framework contracts for Eurobarometers is rather easy in comparison to many other tendering procedures, and the results are very quickly available (field work for citizens survey takes a few days, a few dozen in-depth interviews of 90 minutes with professional stakeholders can take place in 1-2 months).</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>As solitary consultation tool insufficient from a general consultation perspective – does not give the opportunity to everyone that wants to express its opinion to do so.</li> <li>Resource-intensive (relatively expensive).</li> <li>Needs early planning in the previous year and agreement from Cabinet (=administratively burdensome).</li> </ul>

## 5.6. Stakeholder conferences/public hearings/events

<b>STAKEHOLDER CONFERENCES/PUBLIC HEARINGS/EVENTS</b>	
<b>Overview</b>	<p><b>Gather input from a larger number of targeted respondents through direct interaction.</b></p> <ul style="list-style-type: none"> <li>• Stakeholders can take part as <u>participants</u> or as <u>speakers</u>. <u>Several respondents groups</u> should participate. The <u>number of participants is larger</u> than in stakeholder meetings/workshops/seminars.</li> <li>• A stakeholder conference or a public hearing may be organized complementary to a written consultation.</li> <li>• In order for the event to be useful a clear objective needs to be set up.</li> <li>• The event <u>can be web streamed</u> in case of wide interest.</li> <li>• Clear selection <u>criteria</u> for participation are needed.</li> <li>• <b>Target audience:</b> Open to a limited number of participants (those with particular involvement, interest or stake in the policy being prepared or those that are most concerned). However, these events include a larger number of participants than meetings/workshops/seminars</li> </ul>
<b>When to use it?</b>	<ul style="list-style-type: none"> <li>• Stage in policy preparation process: any (sometimes organised together with Green Papers, to launch discussions on new topics. Sometimes at later stages, when there is clarity on options/impacts).</li> <li>• Appropriate for discussion and resolution of issues identified during the written consultation. Often based on input already provided by different stakeholder groups.</li> </ul>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Allows for interactions and direct involvement, different groups affected by an initiative can enter into dialogue.</li> <li>• Responses by stakeholders can be clarified and explored further.</li> <li>• Increases attention to the policy/consultation among stakeholders and general public.</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>• Risk of privileged access and risk of complaints of those not invited.</li> <li>• Not representative, only targets very small proportion of interested parties.</li> <li>• Subject to selection biases.</li> <li>• Resource-intensive.</li> </ul>

## 5.7. Stakeholder meetings/workshops/seminars

<b>STAKEHOLDER MEETINGS/WORKSHOPS/SEMINARS</b>	
<b>Overview</b>	<p><b>Gather focused/specific input from targeted respondents through direct interaction.</b></p> <ul style="list-style-type: none"> <li>Stakeholder events can be done with <u>several stakeholder groups</u> or they can be <u>narrowed down to one particular group</u>. Stakeholders can take part as <u>participants</u> or as <u>speakers</u>. A set of <u>structured questions</u> should be prepared to steer the discussions. A <u>facilitator</u> with knowledge of the topic and skills in steering a debate and resolving conflicts is also required.</li> <li>Clear <u>selection criteria</u> for participation are needed.</li> <li><b>Target audience:</b> Open to a limited number of participants (those with particular involvement, interest or stake in the policy being prepared or those that are most concerned)</li> </ul>
<b>When to use it?</b>	<ul style="list-style-type: none"> <li>Stage in policy preparation process: any (but usually more advanced stages).</li> <li>When more specific details/in-depth responses are needed from those directly affected.</li> <li>To deal with more technical issues.</li> <li>Appropriate for discussion and resolution of issues identified during the written consultation. Can be based on input already provided by different stakeholder groups.</li> </ul>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>Allows collecting detailed input from respondents, including by participatory workshops moderated by colleagues trained in organising such events.</li> <li>Allows tapping expertise.</li> <li>Allows for interactions, different groups affected by an initiative can enter into dialogue.</li> <li>Responses by stakeholders can be clarified and explored further.</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>Risk of privileged access and risk of complaints of those not invited; prevents some groups from participating.</li> <li>Risk of hidden agendas of some groups/individuals passing undetected.</li> <li>Not representative, only targets very small proportion of interested parties.</li> <li>Subject to selection biases.</li> <li>Several meetings might be needed to gather the input - can be resource-intensive and more difficult to manage (also in terms of making sure that all relevant issues are covered).</li> </ul>

## 5.8. Focus groups

<b>FOCUS GROUPS</b>	
<b>Overview</b>	<p><b>Form of a group discussion of people from similar backgrounds or experiences focusing on a specific topic of interest.</b></p> <ul style="list-style-type: none"> <li>• Typically, the focus group will be composed of 6-8 people and will be guided by a moderator who introduces topics and facilitates the discussion.</li> <li>• Focus groups as a research tool to collect information can be applied in a variety of different settings. In the evaluation context, focus groups can be used, for example, to explore different ideas, clarify objectives, and collect information on a topic of interest. The technique is particularly valuable for analysing themes, which give rise to divergent opinions or involve complex issues that need to be explored in depth. It is also a good method to employ prior to designing questionnaires.</li> <li>• <b>Target audience:</b> Citizens or professional stakeholders</li> </ul>
<b>When to use it?</b>	<p>In most cases, focus groups will be conducted during the structuring and data collection stages. However, the technique can also be applied to discuss the collected data and initial findings. Sometimes, focus groups will be combined with other qualitative research methods such as individual interviews, for example, as part of a case study.</p>
<b>Resources required</b>	<p>Similarly to Metaplan discussions, focus groups may require using a trained moderator. Other costs may include covering participants' travel expenses and venue hiring costs.</p>
<b>Strengths</b>	<p>Using focus groups evaluators are able to quickly collect in-depth information on the participants' values and opinions. As the information emerges from discussions within the group, the focus group ensures a certain balance in the answers by judging the pros and cons of each person's arguments and thus avoiding extreme opinions.</p>
<b>Limitations</b>	<p>The small size of focus groups means that it can be difficult to ensure that participants are representative of the larger population and that their views and opinions are consistent with experiences of their peers. In addition, focus group participants may feel pressure to conform to the dominant view, which can skew the results. As with other group techniques, the role of the moderator is very important in ensuring an honest and constructive discussion.</p>

## 5.9. Interviews

<b>INTERVIEWS</b>	
<b>Overview</b>	<p><b>Information collection tool, which has a form of an in-depth conversation with one or several individuals.</b></p> <p>It is mostly used to collect qualitative data. Based on the degree of structuring, interviews can be divided into three categories:</p> <ul style="list-style-type: none"> <li>• <u>Structured interview</u> - this type of interview will have a set of predefined questions that are asked in the same order for all respondents. This standardisation is intended to minimise the effects of the interviewer on the research results. In a sense, structured interviews are similar to surveys, with the exception that structured interviews are conducted in an oral form.</li> <li>• <u>Unstructured interview</u> - these interviews are more conversational and less formal, relying on the spontaneous generation of questions in the natural flow of an interaction.</li> <li>• <u>Semi-structured interviews</u> combine elements of a structured and unstructured interview. The interviewer will still use an interview guide but he will have a certain amount of room to ask new questions based on the context of the interviewee's responses.</li> <li>• <b>Target audience:</b> all stakeholders</li> </ul>
<b>When to use?</b>	Typically, interviews will be conducted at the early stages of the evaluation project. Unstructured interviews can be particularly helpful during the structuring phase, where the main focus is on mapping out the evaluation process and identifying main issues. Structured interviews can be also used later in the project during the data collection stage.
<b>Resources required</b>	Interviews are a relatively resource intensive information collection tool. The main costs will relate to hiring the trained professionals to conduct the interviews and time and resources needed to prepare the interviews and analyse the result. There could be also some extra costs related to travel expenses. The overall costs will depend on the number of the interviews and the interview mode (telephone, face-to-face)
<b>Strengths</b>	Interview is a useful tool to obtain detailed information about personal feelings, perceptions and opinions. As compared to surveys, interviews offer the possibility to clarify any answers that may be ambiguous or incomplete. In addition, unstructured and semi-structured interviews can be used to go into depth on a subject and also to explore new ideas and issues. Furthermore, one-to-one interviews will have the advantage of eliminating the risk that the respondent may be influenced by others in the group.
<b>Limitations</b>	Interviews are a considerably more expensive tool compared to a survey, where a large number of people can be reached easily. Also, the information collected from different interviews may not be comparable, and therefore can be difficult to summarize. In most cases, interviews will only collect qualitative data

## 5.10. Commission Expert Groups / Similar Entities

<b>COMMISSION EXPERT GROUPS/SIMILAR ENTITIES</b>	
<b>Overview</b>	<p><b>Gather specific input/collect expertise.</b></p> <p>The primary function of expert groups is to provide the Commission with advice and expertise in relation to a number of tasks<sup>427</sup>. Gathering expertise from various sources may also include gathering the views from stakeholders. Expert groups are set up by the Commission or its services and can be permanent or temporary. A limited number of similar consultative entities are set up by a third party but administered and financially managed by the Commission. Expert groups provide high-level input from a wide range of sources such as Member States' authorities, individuals – either appointed in a personal capacity or representing a common interest shared by stakeholders - companies, associations, NGOs, the ACP secretariat, EU development NGOs, trade unions, social partner organisations, universities, research institutes and EU bodies in the form of opinions, recommendations and reports. Expert groups do not take binding decisions on the Commission.</p> <p>All expert groups must be published on a dedicated public Register. For each group this register provides a great amount of information, including the mission, tasks, composition and selection procedures.</p> <p><b>Target audience:</b> Open to participants with expertise in the subject at hand.</p>
<b>When to use it?</b>	When in need of specific expertise, in relation to a well-defined mandate.
<b>Strengths</b>	Allows tapping expertise and in specific cases of consultative committees representing the interests at stake in one specific sector it is a fit for purpose tool for consultation of this specific sector.
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>• Risk of privileged access/risk of complaints of those not involved.</li> <li>• Not always representative, when targeting very small proportion of interested parties.</li> <li>• Can be resource-intensive. Expert groups are not set up to be used for consultation purposes. Composition of groups is determined first of all on the basis of quality expertise needed in relation to the defined mandate of any given group. In order to ensure that the Commission obtains the full range of views and expertise on a given</li> </ul>

<sup>427</sup> The preparation of legislative proposals and policy initiatives, the preparation of delegated acts and the implementation of existing EU legislation, programmes and policies.

	matter, it should also use other tools and methods to supplement the work of expert groups <sup>428</sup> .
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### 5.11. SME Panels

SME PANELS	
<b>Overview</b>	<p><b>Gather direct feedback from SMEs</b></p> <ul style="list-style-type: none"> <li>• SME Panel Consultations are conducted through the Enterprise Europe Network. It is managed by DG GROW.</li> <li>• This tool enables services to reach SMEs in a targeted way, as network partners in Member States are well placed in their regions to identify companies that will be most affected by the subject of consultation.</li> <li>• Ahead of the consultation, a draft questionnaire can be sent for comments to a group of Network partners. During the consultation phase network partners translate the questionnaire and run the consultation in their region. They collect the replies and encode them into EU Survey in English.</li> </ul> <p>On consulting SMEs in general:</p> <ul style="list-style-type: none"> <li>• SMEs are willing to be consulted, but they have time and resource constraints. Therefore questionnaires should be short (max 15 questions/4 pages) and written in clear language. The questionnaire should be accompanied by a simply and clearly written note, which explains the background, the issues at stake, and the purpose of the consultation and how the SME's input will be used.</li> <li>• SMEs are very diverse in terms of size, location, type of activity, experience etc. Depending on these factors different issues might be important for them. Therefore it is important to properly target the SMEs that will be consulted and think about how they will be consulted.</li> <li>• Some SMEs are members of industry representative organisations, which can represent interests of both small and large enterprises and therefore will not have an 'SME only' perspective. However, some SMEs are not a member of any representative organisation. That is why it is important to consult not only via representative organisations, but also directly with a number of individual SMEs</li> <li>• <b>Target audience:</b> SMEs</li> </ul>
<b>When to use it?</b>	Whenever an initiative has a potentially significant impact on SMEs
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Broad geographical coverage.</li> <li>• High number of Network partners.</li> <li>• Relatively quick response rate (8-10 weeks from the launch of SME</li> </ul>

<sup>428</sup> For example, studies, European agencies, Green papers and hearings.

	panel consultation).
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>• Subject to self-selection biases.</li> </ul>

### 5.12. Consultation of local / regional authorities (networks of the Committee of the Regions)

<b>CONSULTATION OF LOCAL/REGIONAL AUTHORITIES (NETWORKS OF THE COMMITTEE OF REGIONS)</b>	
<b>Overview</b>	<p><b>Gather input from Local and Regional Authorities.</b></p> <ul style="list-style-type: none"> <li>• The Protocol on Cooperation between the Commission and the Committee of Regions stipulates that the Commission services preparing impact assessments may ask for support from the Committee.</li> <li>• When carrying out a consultation, you can use the assistance of the Committee of Regions (CoR) platforms, networks (e.g. Subsidiarity Monitoring Network, Europe 2020 Monitoring Platform) or regional offices which have a good access point to local and regional authorities.</li> <li>• The consultation questionnaire specifically targeted at the local and regional authorities is prepared together by the Commission service and the CoR. The consultation report is then prepared by the CoR and sent to the Commission together with all the contributions received.</li> <li>• If you consider that such a support would be useful for your consultation, you should contact the Committee of Regions via: <a href="mailto:impact_assessment@cor.europa.eu">impact_assessment@cor.europa.eu</a>.</li> <li>• <b>Target audience:</b> Local and Regional authorities</li> </ul>
<b>When to use it?</b>	Whenever an initiative has potentially significant regional impacts
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Good access to regional and local authorities.</li> <li>• Enables to strengthen the analysis of regional aspects as well as the analysis of subsidiarity and proportionality.</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>• Subject to self-selection biases.</li> </ul>

### 5.13. Questionnaires

QUESTIONNAIRES	
<b>Overview</b>	<p><b>Gather input in a structured manner.</b></p> <p>Tool which can be used for all consultations methods in which written input is expected; design to be adapted to target group and consultation objective.</p>
<b>When to use it?</b>	<ul style="list-style-type: none"> <li>• Stage in policy preparation process: any.</li> <li>• When specific questions with a close set of precise answers can be used to deal with all relevant issues or to collect opinions and views (to strike a balance between a more exploratory use: targeted consultation with few expected answers: open questions are possible and more affirmative use: broad consultation with many expected answers and closed questions are indispensable).</li> <li>• When straightforward responses or responses in terms of rating are expected (yes/no; agree/disagree...).</li> <li>• When responses from a large number of respondents are expected (e.g. consultation on tobacco or shale gas).</li> <li>• <b>Target audience</b> is depending on the selected consultation method:</li> <li>• General public, all stakeholder groups (published on 'Your Voice in Europe', runs for 12 weeks, counts as open public consultation)</li> <li>• Targeted at specific groups (in these cases, the distribution can be done via channels other than 'Your Voice in Europe' – e.g. Member States contact points for SMEs)</li> </ul>
<b>Resources required</b>	<p>It is assumed the questionnaires are available online (same applies to consultation documents). If need be, for particular stakeholder groups, alternative ways of responding should be offered, to increase the accessibility and response rate.</p> <p><u>Practical aspects:</u></p> <ul style="list-style-type: none"> <li>• Consider analysability when formulating questions.</li> <li>• Only ask questions on aspects for which influencing is still possible.</li> <li>• A questionnaire is usually a combination of <u>closed questions</u> (with pre-defined answers from which the respondent has to choose one answer) and <u>open-ended questions</u> (leaving the possibility to the respondent to formulate its own answer) at the end of each section of closed questions.</li> <li>• It includes the possibility to design different <u>sub-sets of questions</u> for the different types of respondents (e.g. different questions to citizens than to public authorities).</li> </ul> <p><u>Formats:</u></p> <ul style="list-style-type: none"> <li>• Hard copies: in conferences or meetings.</li> <li>• Online documents using EU-Survey.</li> </ul>

	<ul style="list-style-type: none"> <li>• EU survey tool' is the Commission's application for creation and management of online surveys and consultations.</li> <li>• It is also possible to create a username and password to ensure the identity of contributors in case of specifically targeted consultations.</li> <li>• E-documents with direct voting possibility: in conferences, meetings, videoconferences.</li> <li>• Direct voting tools in social media.</li> </ul> <p><u>Quality assurance:</u></p> <ul style="list-style-type: none"> <li>• The questionnaire should be endorsed by the ISG or the IASG.</li> </ul>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Allows collecting feedback in a structured manner.</li> <li>• Allows for easier analysis of responses (descriptive statistics provided by EU Survey tool).</li> <li>• May be perceived as less time consuming for respondents, so they may be more willing to take part in consultation.</li> <li>• In accordance with the principle to consult widely.</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Possible lobbying campaigns (leading to multiple identical replies) or individuals filling in the questionnaire several times.</li> <li>• Difficulty when analysing results – if duplicate replies are not identified, analysis of answers will be skewed in favour of these multiple identical responses – this is in particular an issue when anonymous responses are allowed.</li> <li>• Does not allow for more detailed input from respondents, as replies to most of the questions are pre-defined. For open-ended questions – their number and length of free text for replies is usually limited, thus unsuitable tool for an in-depth analysis (but the Commission is free to use more free text questions without limitation of the response in the future).</li> <li>• 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).</li> <li>• Lack of randomized sampling does not allow for any assurance that results are representative of targeted populations.</li> <li>• Generally not statistically representative: Mainly the active stakeholders will contribute.</li> <li>• Used too often and inadequate situations a survey fatigue will arise.</li> </ul>

#### 5.14. Online discussion fora / interactive online tools

ONLINE DISCUSSION FORA/INTERACTIVE ONLINE TOOLS	
<b>Overview</b>	<p><b>Gather feedback and engage in direct interactions with wide range of respondents.</b></p> <ul style="list-style-type: none"> <li>• Facilitator with technical skills, knowledge of the topic and skills in simulating/steering debate, resolving conflicts is needed.</li> <li>• Rules should be set up (on how to deal with spam, frequent messages, messages not related to the topic, defamatory or offensive contributions).</li> <li>• Interactions should be structured around a certain number of issues (ask opinions or submit alternative ideas etc.) otherwise it will not produce useful results.</li> <li>• <b>Target audience:</b> all stakeholders.</li> </ul>
<b>When to use it?</b>	Stage in policy preparation process: any.
<b>Strengths</b>	Allows for interactions, geographically dispersed groups can discuss online.
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Should only be used to complement wider consultation processes - insufficient from a more general consultation perspective.</li> <li>• Not representative, only targets part of interested parties.</li> <li>• Subject to self-selection biases.</li> <li>• Resource-intensive. Issues with languages. Might be difficult to manage it as discussions can get disorganised, dominated by few participants.</li> <li>• Difficult to analyse contributions and to provide feedback.</li> </ul>

#### 5.15. Consultation of specific groups of stakeholders

Besides respecting specific consultation frameworks, you should keep in mind that not all interest groups are equally able to take part in consultations or express their views with the same force. You may need, therefore, to make specific efforts to ensure that all relevant stakeholders are both aware of, and able to contribute to, the consultation. To make sure all relevant stakeholders are consulted across the economic, social and environmental areas, you should consult the ISG members.

##### *Social partners*

Social partners need to be specifically consulted in case of initiatives in the field of social policy or with social implications. A distinction should be made between initiatives in the field of social policy and initiatives with social implications for a specific sector:

## ***Social policy measures***

There are specific Treaty provisions for consulting social partners (management and labour), regarding initiatives in the field of social policy e.g. health and safety in the workplace, working conditions, social security and social protection of workers, and information and consultation (see Treaty Articles 153-155 TFEU on social dialogue, and particularly Article 153 TFEU on the policy fields concerned). This consultation process includes two stages: first, social partners are consulted on the general direction of an initiative; then, in a second stage, on its actual content. Therefore, minimum standards for consultation do not apply to social dialogue, but they do apply to other types of stakeholder consultations in the employment and social affairs field.

### ***Initiatives with social implications for a specific sector***

Sectoral social dialogue committees, for the sector of activity for which they are established, should be consulted on developments at Union level having social implications. You should therefore verify whether your initiatives will create social implications for a sector for which a sectoral social dialogue committee exists<sup>429</sup>. If that is the case, a consultation of the committee should be organised with the assistance of DG EMPL.

### ***Consumers/consumer organizations/patient groups***

A consumer consultation toolbox is available for proposals with an impact on consumers<sup>430</sup>. The Consumer consultation toolbox includes:

- Consultation of the European Consumer Consultative Group (ECCG)<sup>431</sup> which is composed of European and national consumer organisations;
- Direct consultation of consumers through other tools such as Eurobarometers<sup>432</sup>, Focus groups<sup>433</sup>, Citizens juries<sup>434</sup>, public hearings, town meetings<sup>435</sup>.

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<sup>429</sup> The list of sectors covered by European sectoral social dialogue committees can be found at <http://ec.europa.eu/social/main.jsp?catId=480&langId=en>.

<sup>430</sup> <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=tools>

<sup>431</sup> The European Consumer Consultative Group is a consultative group of the Commission, established by Commission Decision 2003/709/EC of 9 October 2003.

<sup>432</sup> Standard and Special Eurobarometer: (example: EB on Consumer protection in the Internal Market). It is used by DG COMM for its general set of questions on EU-related issues. This instrument is well suited for in-depth cross analysis and for relatively long questionnaires. It uses face-to-face interviewing techniques, interviewing a sample of around 1000 respondents per Member State (depending of the population of the country). Flash Eurobarometer: (example - Businesses attitudes on Cross-border sales and consumer protection). It is well adapted to short and simple questionnaires, for which results are needed relatively rapidly. Flash surveys allow the targeting of specific groups (SME managers, farmers, teachers, etc.).

<sup>433</sup> This tool is efficient to make an in-depth study of the attitudes of a selected social group towards a given subject (example: focus group on consumers' opinions on Services of General Interest). However, results cannot generally be extrapolated to the whole population. The methodology uses focus groups of 8 to 10 persons or individual interviews. The discussion guide is non-directive, and leaves some room for spontaneous expression.

- Whenever health impacts are identified, it is advised to consult the Health Policy Forum to get input from public health actors including patients groups<sup>436</sup>.

### *SMEs*

SME consultations may be conducted through the Enterprise Europe Network.<sup>437</sup> The tool is constructed in a way that allows the Commission services to reach SMEs in a targeted way, given that Network partners are well placed in their regions to identify companies that will be the most affected by the subject of the consultation. It's an optional tool for sectoral and targeted SME consultation. Thanks to the broad geographic coverage and the high number of Network partners, this tool has a potential to provide substantial results compared to other ways of consultation. The advantage of the Network is that the Network Partners translate the questionnaire into their respective languages and run the SME panel consultation in their regions. Furthermore they collect the questionnaire and encode them in EU Survey in English.

There are some formal requirements for a questionnaire for an SME panel consultation: the questionnaire should be short (max 15 questions) and should be written in a clear plain language (to make it easy to translate for the national partners)<sup>438</sup>.

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<sup>434</sup> Small panel of non-specialists. Similar to a criminal jury, carefully examine an issue of public significance and deliver a verdict. Good for developing creative and innovative solutions to difficult problems.

<sup>435</sup> The aim of these meetings is to directly involve "citizens" in the decision-making process. In these meetings a representative group of citizens is invited to comment and suggest policy options for a specific legislative initiative or a project. This tool is notably used in the US. Since 1997, America Speaks has organized Town Meetings in 31 US States. Meetings have addressed local, state and national decisions on a broad range of issues.

<sup>436</sup> See at: [http://ec.europa.eu/health/ph\\_overview/health\\_forum/policy\\_forum\\_en.htm](http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm)

<sup>437</sup> Managed by DG GROW

<sup>438</sup> See tool on the SME test

## **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 multicriteria analysis (MCA) and life cycle Analysis (LCA) techniques;
- Tips on how to present information visually in evaluation and impact assessment reports.

## TOOL #51: 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 policy making.

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 below<sup>439</sup>.

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:

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<sup>439</sup> [Assessing the Costs and Benefits of Regulation; CEPS \(2013\)](#) a study prepared for the European Commission; Chapter 1.

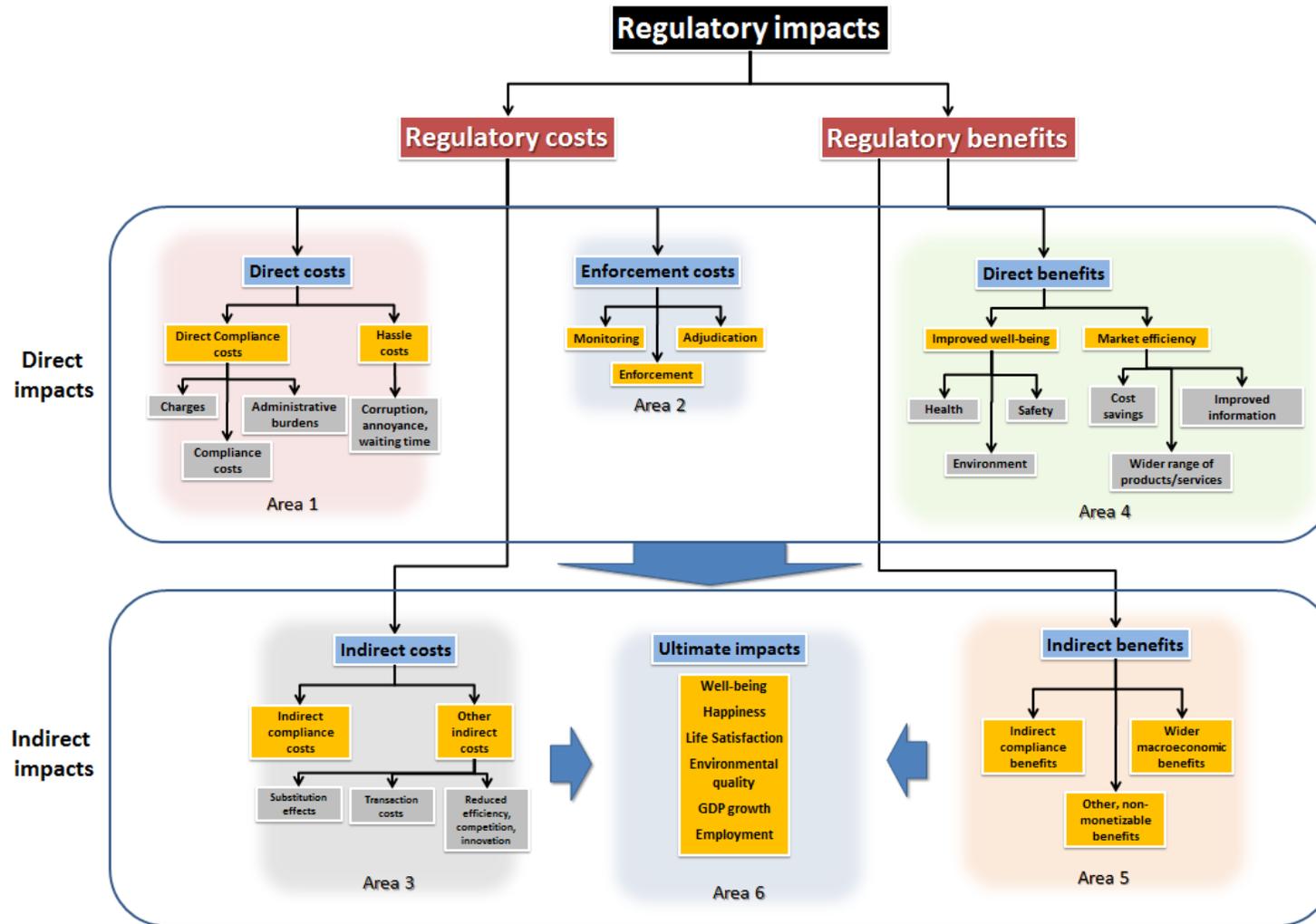
*Direct costs from regulation* include direct compliance costs and hassle/irritation burdens:

- 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	<ul style="list-style-type: none"> <li>• Monitoring costs</li> <li>• Transaction costs</li> <li>• Direct compliance cost</li> </ul>
Co-regulation	<ul style="list-style-type: none"> <li>• Monitoring costs</li> <li>• Enforcement costs</li> <li>• Transaction costs</li> <li>• Direct compliance cost</li> </ul>
Market-based instruments	<ul style="list-style-type: none"> <li>• Transaction costs</li> <li>• Charges</li> <li>• Direct compliance costs</li> <li>• Indirect compliance costs</li> </ul>
Performance-based standards	<ul style="list-style-type: none"> <li>• Monitoring costs</li> <li>• Direct compliance costs</li> <li>• Indirect compliance costs</li> </ul>
Command and control	<ul style="list-style-type: none"> <li>• Charges</li> <li>• Administrative burdens</li> <li>• Direct compliance costs</li> <li>• Indirect compliance costs</li> <li>• Monitoring costs</li> <li>• Enforcement costs</li> <li>• Adjudication</li> </ul>

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. 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-monetizable 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 coin<sup>440</sup>.

<sup>440</sup> 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,

- 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.

(3) *The “ultimate impacts” of regulation (Area 6 of the figure in Box 2),*

which overlap with the ultimate goals of an intervention. Even if some regulations directly aim at achieving these benefits (in which case, we would include them in Area 4), all regulations usually aim, as an ultimate impact, at achieving 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.

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as a result of the price increase, will decide not to buy a car should be counted separately, as a net loss for society.

## TOOL #52: 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.

### 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 option<sup>441</sup>. **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.<sup>442</sup>

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	
<i>Charges</i>	
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.	
<i>Administrative costs</i>	
That is the costs of complying with information obligations stemming from policy option under consideration.	
<i>Substantive compliance costs</i>	
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.	
They can be one-off or recurrent and <i>can be broken down in further sub-categories</i> <sup>443</sup> :	
<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

<sup>441</sup> [Assessing the Costs and Benefits of Regulation: CEPS \(2013\)](#) a study prepared for the European Commission.

<sup>442</sup> [OECD \(2014\), OECD Regulatory Compliance Cost Assessment Guidance](#). See page 62 for a list of regulatory compliance activities

<sup>443</sup> The categorization proposed in the OECD Regulatory Compliance Cost Assessment Guidance is presented below

	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 <sup>444</sup> .	

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:**

- 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

<sup>444</sup> CEPS (2013), p.25-26.

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 analysis<sup>445</sup>.

<b>Methods to estimate compliance cost components</b>
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.
<b><i>Charges</i></b>
(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) Estimate the unit cost (cost of the fee, license, and permit).
(5) 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 $(2,500 \times 500 \times 2) = \text{€}2.5$ million.
<b><i>Administrative costs</i></b>
See later section on the Standard Cost Model
<b><i>Substantive compliance costs</i></b>
(1) <i>Identify substantive duties (SDs)</i> These are all the activities necessary to comply but for those linked to the provision of 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

<sup>445</sup> See tool on useful analytical methods to compare options or assess performance

inefficiency of some of the targeted companies: in order to assess *ex ante* 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) *Estimate the “BAU” factor for each SD and each of the alternatives, based on direct assessment or empirical data.*

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) *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.).*

If different case groups can be established, you might consider adopting different notions of “normal efficiency” and BAU for each of the groups.

(2) *Estimate the compliance cost associated with each SD for each segment and each alternative.*

Useful guidance on this can be found in chapter 3 of the OECD (2013)

(3) *Assess whether compliance costs are likely to change over the life of the proposed legislation.*

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 must 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**

considered broadly indicative.<sup>446</sup> 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 must 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.

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-compliance<sup>447</sup>.

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

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<sup>446</sup> 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.

<sup>447</sup> For a list of possible implementation and enforcement activities, see p. 63 in OECD (2013).

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 costs<sup>448</sup>. 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.

#### 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, 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.

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 stemming from different regulations. 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.

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<sup>448</sup> 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.

**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.  Similarly, the impact of a marginal increase in compliance costs for citizens (or micro and small enterprises) differs depending on total regulatory costs across all policy areas, particularly if citizens (or micro and small enterprises) are income constrained (i.e. have a limited capacity to borrow because of credit rationing).
	<p><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.</p> <p><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 (and notably fitness checks and REFIT evaluations) should provide a useful source of information.</p> <p><u>When assessing impacts and, notably indirect impacts and impacts on micro and small enterprises</u><sup>449</sup>. No generally recognised standard methodology exists for the consideration of cumulative impacts. However, a growing number of studies are generating data by sector and type of enterprise. The results of these studies may prove particularly relevant for certain initiatives. The methodologies used can also provide useful models for new specific estimations.</p>
How and when?	

A prominent tool for making CCAs is the Dutch Compliance Cost Assessment tool ("CAR model") which was conceived essentially for retrospective analyses of existing legislation<sup>450</sup>.

<sup>449</sup> See Tool on the SME test

<sup>450</sup> 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.

## **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 do<sup>451</sup>;

Indirect benefits include:

**(3) *Spill over effects related to third party compliance with new legal rules ("indirect compliance benefits").***

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-monetizable 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.

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<sup>451</sup> See tools on the health impacts, consumer impacts, resource efficiency, employment, education/youth/culture etc. which cover a wide range of social and environmental benefits (impacts).

**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
<b>Whenever a policy option leads to a reduction in regulatory charges</b> , you could follow the same approach as suggested in chapter 4 of this Tool to estimate the value of the reduction.
<b>Whenever a policy option leads to a reduction in compliance costs</b> (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.
<b>Whenever a policy option leads to a reduction in implementation and enforcement costs</b> 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.</i> Administrative burdens (Abs) constitute only a subset of costs imposed on businesses by legislative 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.
<i>A reduction proposal may reduce administrative burdens, but at the same time increase administrative burdens of a different origin.</i> 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 harmonize 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 TFEU<sup>452</sup>, 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 monetized 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.

<sup>452</sup> [http://ec.europa.eu/internal\\_market/retail/docs/140711-study-utp-legal-framework\\_en.pdf](http://ec.europa.eu/internal_market/retail/docs/140711-study-utp-legal-framework_en.pdf)

A number of *caveats* must 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 must 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 elasticity<sup>453</sup>. It is suggested to seek expert guidance for this type of estimation<sup>454</sup>. 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 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 policy making. 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 described in Appendix 3 and the relevant IA tool on comparing policy options<sup>455</sup>).

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

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<sup>453</sup> 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](http://www.iata.org/whatwedo/Documents/economics/Intervistas_Elasticity_Study_2007.pdf)

<sup>454</sup> For a general presentation see CEPS (2013), p. 178-182.

<sup>455</sup> See tool on comparison of policy options

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" methods<sup>456</sup>.

***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.

The approaches described above can be used to estimate the value of improved health outcomes<sup>457</sup> (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 must 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

<sup>456</sup> See overview in Table 29 of the CEPS 2013 study on Assessing the Costs and Benefits of Regulation, pp. 185. [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

<sup>457</sup> See tool on health impacts

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 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 an area used for recreation<sup>458</sup>.

#### ***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

<sup>458</sup> "[The Green Book – Appraisal and Evaluation in Central Government](#)", HM Treasury, pp.67

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 as well as estimated benefits associated with reduced incidences of acute and chronic mortality due to exposure to air pollution (fine particles)<sup>459</sup>.

**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

<sup>459</sup> [SWD\(2013\) 531](#):

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

### 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.

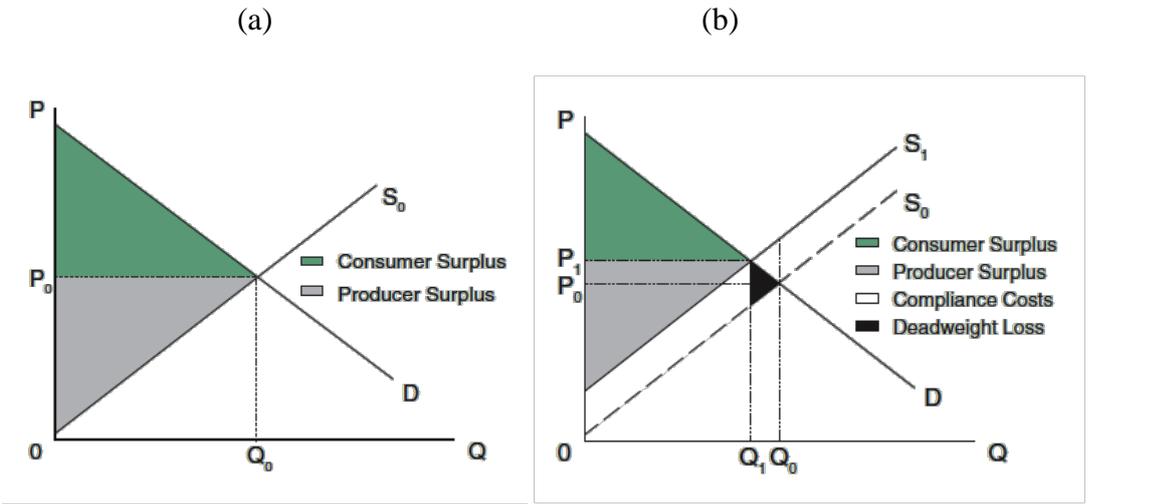
The use of partial equilibrium analysis assumes that the effects of the regulation on all other markets will be minimal and can either be ignored or estimated without employing a model of the entire economy. This means, in most cases, that indirect impacts will be less significant than direct impacts, 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](mailto:SG-C-2@ec.europa.eu).

## TOOL #53: THE STANDARD COST MODEL FOR ESTIMATING ADMINISTRATIVE COSTS

### 1. THE "STANDARD COST MODEL" (ASSESSING ADMINISTRATIVE COSTS IMPOSED BY EU LEGISLATION)

Whenever a measure is likely to impose **significant administrative costs** on business, the voluntary sector or public authorities, the **EU Standard Cost Model** presented below must be applied<sup>460</sup>. 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). 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.

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.

Implementation will of course be subject to the principle of proportionate analysis. The degree of detail in the assessment will depend on the expected order of magnitude of the costs, their impact, and the availability of reliable and representative data.

### 2. OUTLINE OF THE MODEL

#### 2.1. Definition of administrative costs and administrative burden

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.

**Example:** A regulation on air quality sets an obligation to keep a register of pollutant emissions and an obligation to meet an air pollution threshold. Keeping a register of pollutant emissions is an administrative cost, while action taken to meet an air pollution threshold is not. That type of compliance cost is sometimes referred to as 'substantive cost' because the obligation affects the essence of the (industry) 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 at these levels (for instance the installation of new filters).

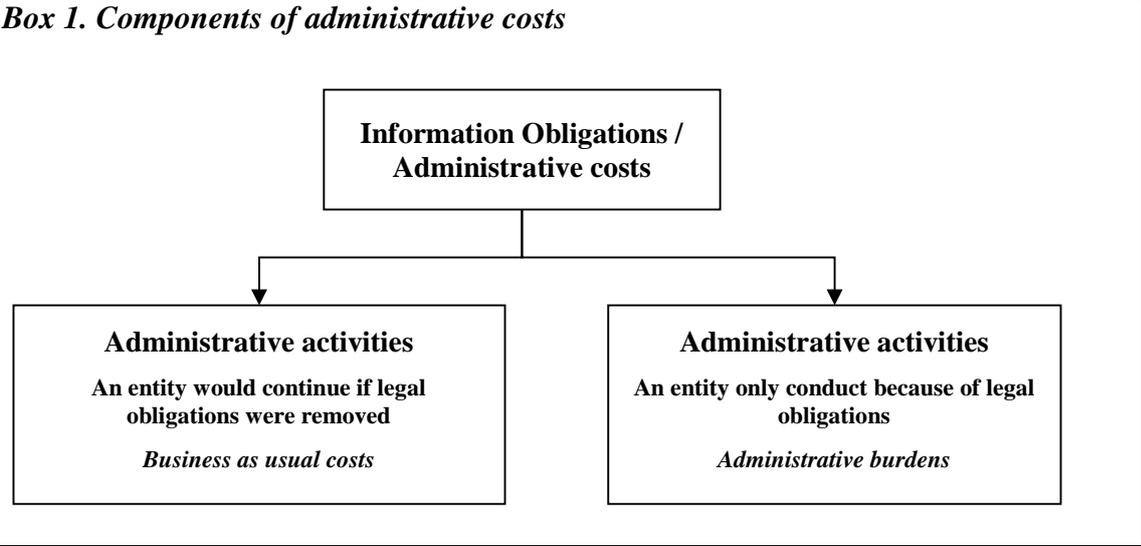
**Recurring** administrative costs and, where significant, **one-off administrative costs** have to be taken into account.

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

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<sup>460</sup> [http://ec.europa.eu/smart-regulation/refit/admin\\_burden/scm\\_en.htm](http://ec.europa.eu/smart-regulation/refit/admin_burden/scm_en.htm) .

resulting from collecting and processing information which would be done by an entity even 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**<sup>461</sup>.



This distinction is particularly important for policy-making. 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 different 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 action will be generally estimated by multiplying a tariff (based on average labour cost per hour including prorated overheads) and the time required per action. Where appropriate, other types of costs such as outsourcing, equipment or supplies’ costs should be taken into account<sup>462</sup>. 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:

**Box 2: Core equation of the Standard Cost Model**

<sup>461</sup> 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

<sup>462</sup> 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.

$\Sigma P \times Q$

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 must 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). This will often be done with the help of the '**Administrative Burdens Calculator**' and the '**EU database on Administrative Burdens**',<sup>463</sup>.

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 step<sup>464</sup>. Following these steps will also allow you to fill in the Standard Reporting Sheet (see step 11).

*Table 1: Step by step application of the model*

<sup>463</sup> See [http://ec.europa.eu/enterprise/admin-burdens-reduction/home\\_en.htm](http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm)

<sup>464</sup> 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.

<b>Phase I: Preparatory analysis</b>	
<b>Step 1:</b>	<b>Identification and classification of information obligations</b> (e.g. certification of products) & data requirements (e.g. the certificate must provide the date of production and composition of the product)
<b>Step 2:</b>	<b>Identification of required actions</b> (e.g. training members and employees about the information obligations, filling forms)
<b>Step 3:</b>	<b>Classification by regulatory origin</b> (e.g. EU rule on certification is the transposition of an agreement of the World Trade Organisation)
<b>Step 4</b>	<b>Identification of target group(s), also called segmentation</b> (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)
<b>Step 5</b>	<b>Identification of the frequency of required actions</b> (e.g. small enterprises have to fill a form once a year)
<b>Step 6</b>	<b>Identification of relevant cost parameters</b> (e.g. particular relevance of external costs – using accounting firms – and equipment)  <b>Qualitative assessment of significant burdens</b> (i.e. applying de minimis threshold test to determine which information obligations need to be quantified)
<b>Step 7</b>	<b>Choice of data sources</b> 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)
<b>Phase II: Data capture and standardisation</b>	
<b>Step 8</b>	<b>Assessment of the number of entities concerned</b> (e.g. 100.000 SMEs)
<b>Step 9</b>	<b>Assessment of the performance of a ‘normally efficient entity’ in each target group, taking into account cost parameters identified in step 6</b> (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)
<b>Phase III: Calculation and reporting</b>	
<b>Step 10</b>	<b>Extrapolation of validated data to EU level</b>
<b>Step 11</b>	<b>Final reporting and transfer to the database</b>

### 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 obligation (box 1) when inserting relevant information obligations in the Standard Excel Report Sheet (an example is provided at the end of step 11).

#### ***Box 3: 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 those appointed by them (e.g. obligation for business to cooperate with working conditions inspection), including maintenance of appropriate records (e.g. obligation for treatment facilities to keep records of the particulars of waste electronic equipment entering and leaving the treatment facility; obligation for hotels to keep a visitor register book; 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 4: 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 5: 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 act<sup>465</sup> and it is therefore easier to make a ‘cut and paste’ of the reference given by the search engine ([http://europa.eu.int/eur-lex/lex/RECH\\_menu.do?ihmlang=en](http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en)) 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 required**<sup>466</sup>. 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 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.

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<sup>465</sup> 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.

<sup>466</sup> 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.

### 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.<sup>467</sup> 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).<sup>468</sup>

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**

the 'EU database on Administrative Burdens' and the 'EU Administrative Burdens Calculator' as well as available EU statistics (provided, among others, by [Eurostat](#) and the Small and Medium-Sized Enterprises Observatory); and the overall hourly tariff (all Member States & 9 qualification segments) used for the EU baseline measurement (see step 6)<sup>469</sup>;

- standard ratios (for example assessing overheads on the basis of a mark-up percentage on labour costs;
- the opinion of experts;
- Member State studies.

**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

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<sup>467</sup> [http://ec.europa.eu/enterprise/admin-burdens-reduction/home\\_en.htm](http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm)

<sup>468</sup> For instance, barcode printer and scanner.

<sup>469</sup> Specific links to data on the number of businesses, labour costs and other sectoral parameters are provided on [http://www.europa.eu.int/comm/secretariat\\_general/impact/docs\\_en.htm](http://www.europa.eu.int/comm/secretariat_general/impact/docs_en.htm).

the ‘Starter kit for measuring and reducing administrative burdens’<sup>470</sup>. 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.

**Member States have agreed to assist the Commission to collect data where standard sources do not suffice**<sup>471</sup>.

***Box 6: Administrative Burden Reduction Programme:***

In 2007 Commission launched a programme to reduce administrative burden by 2012 by 25%. It is limited to 13 priority areas and includes a baseline measurement of existing costs in these areas. Even though the programme is limited to specific legal acts and to assessment of costs to business, the results are helpful in understanding the mechanisms by which the administrative costs accrue. Several Member States have performed their own national baseline measurements (the results have been taken into account in the Commission exercise). For more information: [http://ec.europa.eu/enterprise/admin-burdens-reduction/action\\_program\\_en.htm](http://ec.europa.eu/enterprise/admin-burdens-reduction/action_program_en.htm).

### **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.

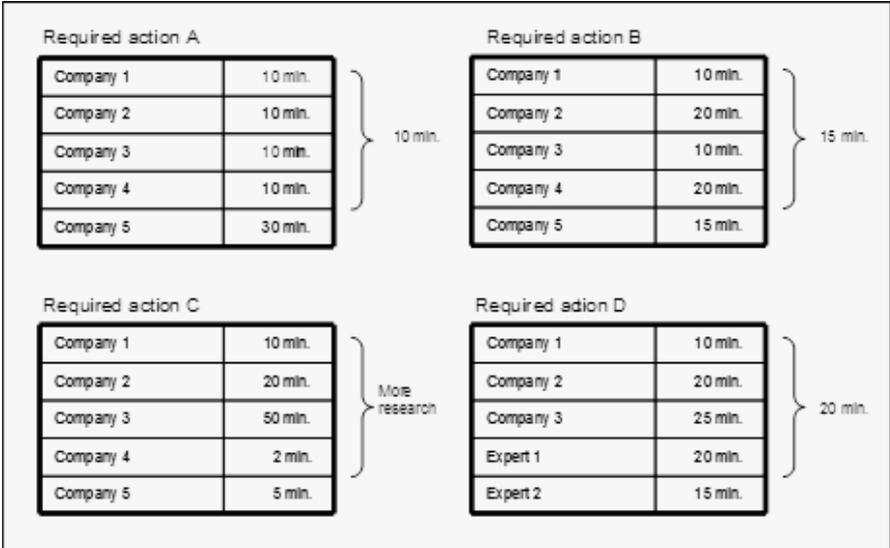
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<sup>470</sup> [http://ec.europa.eu/enterprise/admin-burdens-reduction/home\\_en.htm](http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm)

<sup>471</sup> 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).

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.).

**Box 7: Identifying typical business**



**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 measurements<sup>472</sup> conducted by several Member States and the most advanced Commission Impact Assessments are a prime source of information on country distributions.

<sup>472</sup> 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 used [http://ec.europa.eu/governance/impact/docs/eu\\_cost\\_model\\_report\\_sheet\\_v2.xls](http://ec.europa.eu/governance/impact/docs/eu_cost_model_report_sheet_v2.xls). 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 must 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.

### *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)<sup>473</sup>**

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.

<sup>473</sup> 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.

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

### ***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 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						Tariff (€ per hour)	Time (minutes)	Price (per action)	Freq (per year)	Nbr of entities	Total number of actions	Equipment costs (per entity & per year)	Outsourcing costs (per entity & per year)	Total Administrative Costs	Business As Usual Costs (% of AC)	Total Administrative Burden (AC - BA)	
No.	Art.	Orig. Art.	Type of obligation	Description of required action(s)	Target group												
1	4§1		Non labelling information for third parties	Familiarizing with the information obligation	Banking sector	30	60.00	30	1	500	500			15,000	0%	15,000	
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	Filing forms and tables	Banking sector	50	-5.00	-4	1	500	500			-2,083	30%	-1,250	
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.																	
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																	
<b>(for ex., article of the EC directive at the origin of one specific obligation imposed by national law)</b>														<b>Total administrative costs (I)</b>	<b>76,511,500</b>		
Price per action (P) = Tariff * Time. Total Nbr of actions (Q) = Frequency * Number of entities. Total cost per action = P*Q + Equipment + Outsourcing.																	<i>Total administrative burden (I)</i>
For equipment, yearly cost is calculated on the basis of the depreciation period.																	<i>Administrative costs by origin (I)</i>
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 <a href="http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en">http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en</a> ).																	
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 #54: 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	€62	€25	€89	€55	€22

- 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	
<b>Option A</b>						
<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	<b>-0.93</b>
<b>Option B</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	<b>0.44</b>

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 generations<sup>474</sup>.

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

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<sup>474</sup> 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 used<sup>475</sup>. 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.<sup>476</sup> 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 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

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<sup>475</sup> 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.

<sup>476</sup> 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.

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 #55: USEFUL 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 regulation<sup>477</sup>.

### 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 (monetized 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.

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

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<sup>477</sup> [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/131210\\_cba\\_study\\_sg\\_final.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf)

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**

*Multi-criteria analysis* is a technique to reach a judgement based on an explicit set of objectives and associated criteria. 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 to capture and evidence 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 prime advantage of MCA over BCA is indeed that it does not hide distributional impacts and trade-offs into one overall score, but on the contrary enables to judge the pros and cons of various policy options based on their profile along the main comparison criteria (usually multiple, since not just efficiency but effectiveness and coherence are prime considerations to be included when ranking options). Unlike CBA, which can illustrate the overall additional welfare generated by an intervention but without any consideration whatever of how costs and benefits are distributed among stakeholders, in space or in time.

In the evaluation context, MCA is typically used at the end of the evaluation process with the aim to produce the final conclusion. 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).

## **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 monetized or even quantified but their relative magnitude across options must be determined.

## **2.4. Cost-effectiveness Analysis**

*Cost-effectiveness analysis* (CEA) entails that you quantify (not monetize) the benefits that would be generated by one Euro of costs imposed on society. While CEA is closely 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?”<sup>478</sup>

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 methods 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: Difference in Difference; Propensity Score matching; Discontinuity design and Instrumental Variables.

Counterfactual can be used when one wants to know whether an observed change can be attributed to a given policy/intervention or whether it have occurred anyway.

**Strengths:** The observed differences (over time, across individuals) display facts in an objective and quantified way.

**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

## 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.

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<sup>478</sup> See tool on the IA requirements for spending programmes

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 monetized, covering where possible the economic, social and environmental impacts of the proposal at hand (if benefits can be quantified, but not monetized, 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 models<sup>479</sup>.

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.

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<sup>479</sup> See tool on the use of analytical models

## 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](mailto:SG-C-2@ec.europa.eu)

## 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 study<sup>480</sup> and the IA tool on describing methods to estimate impacts<sup>481</sup>.

Step	Description
1	<b><i>Decide whether CBA is the most appropriate approach</i></b> to formulate a judgment. The advantages and disadvantages described in the main body of this tool should guide this decision.
2	<b><i>Identify the full range of Costs and Benefits</i></b> to be measured. Failure to identify significant impacts may skew the final judgment.
3	<p><b><i>Partial or general equilibrium analysis.</i></b> 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.</p> <p>In this respect, you have to answer the following questions.</p> <ul style="list-style-type: none"> <li>– Does the problem at hand affect several markets and present significant cascading and cumulative effects?</li> <li>– Are there very significant impacts on the economy?</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>– Affects a limited number of markets/economic sectors, and/or</li> <li>– Produces mostly direct effects on stakeholders, and/or</li> <li>– Generates limited indirect, macroeconomic effects,</li> </ul> <p>Then you can address the problem and the related assessment of impacts through a partial equilibrium analysis.</p>
4	<p><b><i>Monetize direct costs for the public intervention in question or for all policy alternatives and calculate total direct costs.</i></b></p> <ul style="list-style-type: none"> <li>• Are direct charges imposed on particular stakeholders/societal group?</li> <li>• Are compliance costs increased including administrative burdens?</li> <li>• What are the enforcement costs?</li> </ul>

<sup>480</sup> See Chapter 3 pp156 of the 2013 CEPS Study on [Assessing the Costs and benefits of Regulation](#).

<sup>481</sup> See common on tool on methods to estimate impacts (costs and benefit)

5	<p><b><i>Monetize direct benefits.</i></b> The following issues are relevant:</p> <ul style="list-style-type: none"> <li>• Are there cost reductions in regulatory charges, compliance costs and enforcement costs?</li> <li>• Improvements in market efficiency should be monetized as far as possible (consumer surplus, producer surplus, and deadweight loss).</li> <li>• Monetization of non-market benefits (health, safety, environment etc.)</li> </ul>
6	<p><b><i>Assess indirect impacts.</i></b></p> <ul style="list-style-type: none"> <li>• Are there significant indirect costs?</li> <li>• Are there significant indirect benefits?</li> <li>• Are there other non-monetizable benefits (protection of fundamental rights, legal certainty, reduced infringement of legal rules etc.)</li> </ul>
7	<p><b><i>Determine when costs and benefits occur in the life of the initiative and apply social discounting to determine net present values<sup>482</sup>.</i></b></p>
8	<p><b><i>Present impacts and formulate the judgement on the performance of existing public intervention or the comparison of the policy options.</i></b></p> <ul style="list-style-type: none"> <li>• Present the different types of costs and benefits which have been monetized</li> <li>• Present qualitative information on non-monetized costs and benefits</li> <li>• Comparison should be performed in terms of the various cost/benefit categories, net benefits and net present value, distributional impacts on stakeholders.</li> </ul>
9	<p><b><i>Check the robustness of the results</i></b></p> <ul style="list-style-type: none"> <li>• Sensitivity cases to assess influence of key variable/assumptions on uncertainty and on conclusions</li> <li>• Check methods (no double counting, baseline versus policy option, consistent base currency used, spurious accuracy in results)</li> <li>• Recognise any behavioural biases</li> <li>• Assess interaction/interdependency between the categories of costs and benefits (e.g. enforcement costs rising as compliance costs decline)</li> </ul>
10	<p><b><i>Consider distributional and cumulative impacts</i></b></p> <ul style="list-style-type: none"> <li>• On Member States if proportionate</li> <li>• On future generations</li> <li>• Richer and poorer sections of society</li> <li>• SMEs</li> </ul>

<sup>482</sup> See tool on the typology of costs and benefits

## TOOL #56: THE USE OF ANALYTICAL MODELS IN IA OR EVALUATION

### 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 model types typically used in IA and evaluation studies (N.B. models often span the arbitrary boundaries presented below)**

**CGE 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. CGE models suffer from a lack of historical validation and rely heavily on economic assumptions. 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) and are inflexible such that changes to models often require significant resources. 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.

**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. They are flexible, transparent and can be applied to any sector that is defined in the IO table. 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 models** 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 JRC<sup>483</sup> can provide advice and support related to IA modelling activities including uncertainty analysis

<sup>483</sup> Unit JRC-DDG.01; [JRC-DDG-01-SEC@ec.europa.eu](mailto:JRC-DDG-01-SEC@ec.europa.eu)

(see below). The JRC has established an on-line inventory<sup>484</sup> of all the models that are currently in use in JRC with the intention that this will be expanded to cover all models used by the Commissions Services at a later date.

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 must 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.

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 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.

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<sup>484</sup> MIDAS or Model Inventory and Access Services. This provides access to a comprehensive description of the models themselves, and of the support that each model gives to policy and ex-ante impact assessments in particular as well as contact points. <http://midas.jrc.it>

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 scrutinise the quality of the evidence provided in terms of whether the external studies have been subjected to same degree of quality assurance and uncertainty analysis as this tool advises for modelling work undertaken within the Commission services.

#### **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 cases 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.

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. 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.

##### ***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.

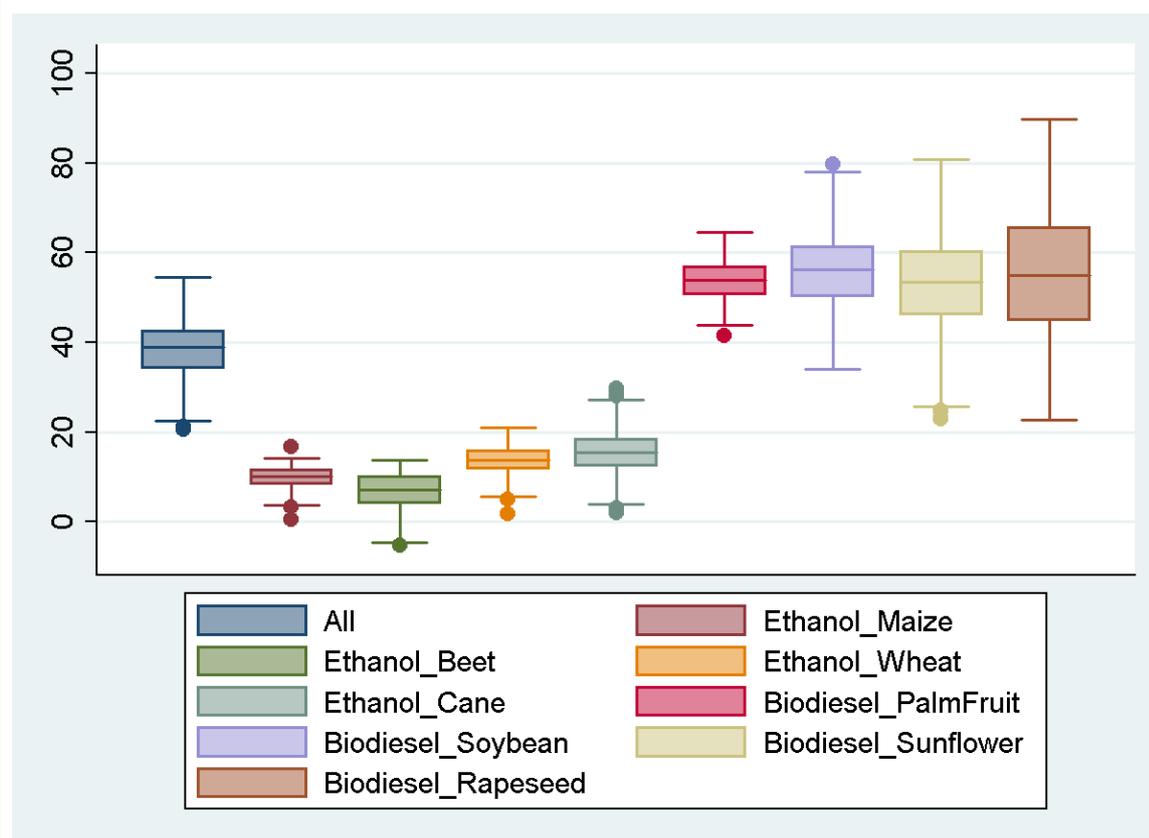
A “global” approach for quantifying uncertainty allows for the simultaneous exploration of all sources of known uncertainty and which can capture nonlinearities and interactions between model inputs. In global uncertainty and sensitivity analysis (GSA), probability distributions are assigned to uncertain 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 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  $gCO_2/MJ$  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 ( $gCO_2/MJ$ )-under scenario of current trade policy. The bars indicate 1st and 99th percentile, while the boxes are 25<sup>th</sup> 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, it is good practice to add to the IA report a dedicated annex presenting the following information:

- A brief description of the main model 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 must 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)<sup>485</sup> and GDP projections<sup>486</sup> are regularly produced by ESTAT and DG ECFIN. Projections on energy, transport and GHG emissions are regularly prepared by DGs ENER, CLIMA and MOVE.

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<sup>485</sup> [http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search\\_database](http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database)

<sup>486</sup> [http://ec.europa.eu/economy\\_finance/publications/european\\_economy/2012/2012-ageing-report\\_en.htm](http://ec.europa.eu/economy_finance/publications/european_economy/2012/2012-ageing-report_en.htm)

## TOOL #57: MULTI-CRITERIA ANALYSIS

Multi-criteria analysis (MCA) can be a useful complement or alternative to cost benefit analysis, when the information necessary for a CBA are not available, are controversial or volatile, for example, when robust methods to monetize different impacts are not available.

### 1. THE STEPWISE PROCEDURE

The standard procedure for performing a MCA consists of 3 steps. Same approach can be followed in the evaluation context by replacing different policy options with different categories of impacts:

**(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 summarizes 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 must 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 ( $0.1+0.30+0.30=0.7$ ). 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**).

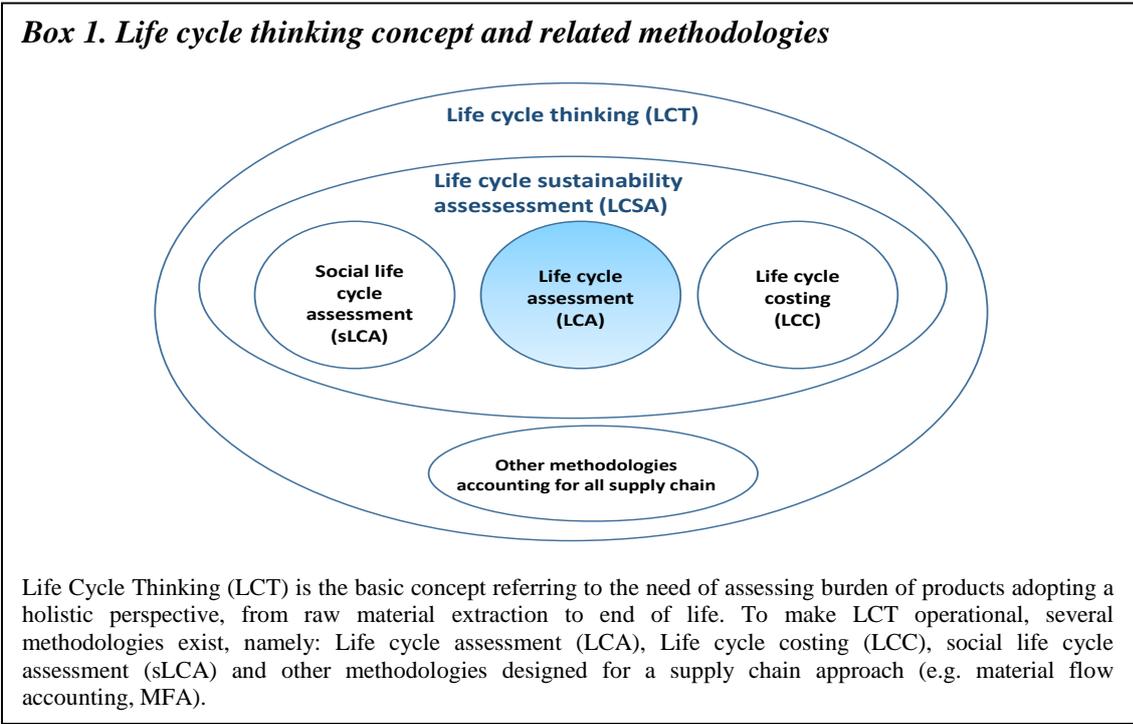
Policy ranking permutation	Policy pairings	Coefficients of policy pairings	Final score
ABC	AB + AC + BC	$0.3 + 0.9 + 0.7$	1.9
ACB	AC + CB + AB	$0.9 + 0.3 + 0.3$	1.5
BAC	BA + AC + BC	$0.7 + 0.9 + 0.7$	2.3
BCA	BC + CA + CB	$0.7 + 0.7 + 0.1$	1.5
CAB	CA + AB + CB	$0.1 + 0.3 + 0.3$	0.7
CBA	CB + CA + BA	$0.3 + 0.1 + 0.7$	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.



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).

## TOOL #58: 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 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<sup>487,488,489,490</sup> and internationally<sup>491,492</sup>. Life Cycle Assessment (LCA) 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

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<sup>487</sup> Stimulating technologies for sustainable development: an environmental technologies action plan for the European Union. Communication from the Commission; COM (2004) 38 final

<sup>488</sup> Stimulating technologies for sustainable development: an environmental technologies action plan for the European Union. Communication from the Commission; COM (2004) 38.

<sup>489</sup> Stimulating technologies for sustainable development: an environmental technologies action plan for the European Union. Communication from the Commission; COM (2004) 38.

<sup>490</sup> Stimulating technologies for sustainable development: an environmental technologies action plan for the European Union. Communication from the Commission; COM (2004) 38.

<sup>491</sup> Why take a life cycle approach? UNEP, Paris, p 28

<sup>492</sup> 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.

### **3. RESOURCES INSIDE OF THE COMMISSION TO HELP WITH LCA**

The Commission has established the European Platform on Life Cycle Assessment (EPLCA)<sup>493</sup>. 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 **Resources inside of the Commission** le Data System (ILCD) Handbook was launched. The Handbook provides a series of guidance documents for different types of LCA applications<sup>494</sup>. More recently, this has been complemented for example by the launch of the Life Cycle Data Network, which aims to provide an international basis for inter-operable, quality assured 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 organisations<sup>495</sup>. 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 (PEF) 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 ;

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<sup>493</sup> <http://eplca.jrc.ec.europa.eu/>

<sup>494</sup> 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:

<sup>495</sup> Recommendation 2013/179/EU.

- 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 recommendations<sup>496</sup> 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).

#### 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;
- 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 is interpreted in accordance with the aim defined in the goal and scope of the study.

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). 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. 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 step 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.

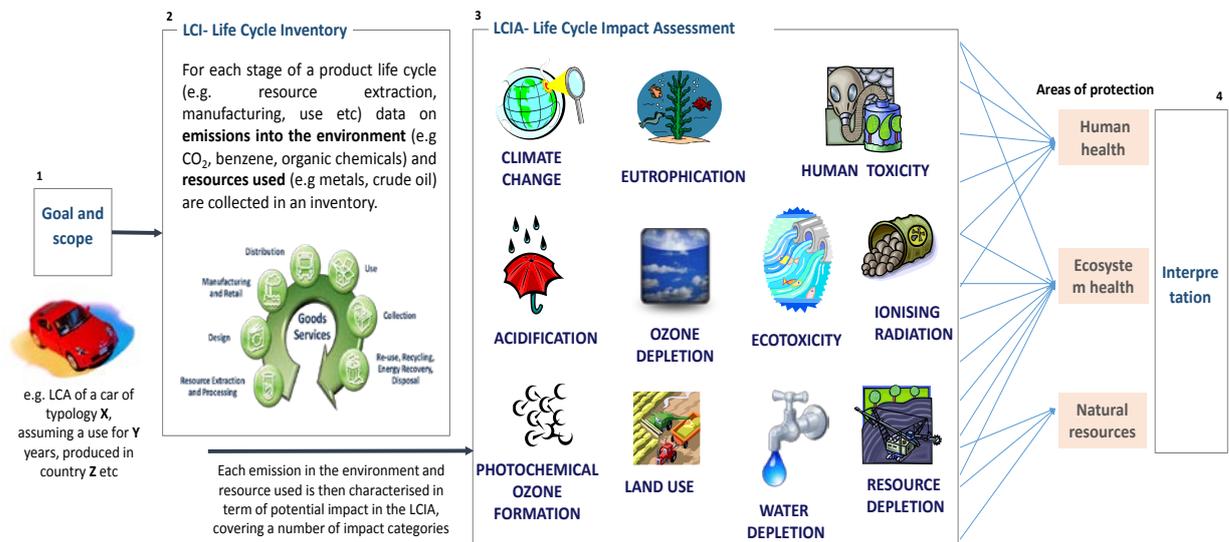
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<sup>496</sup> JRC (2011) Recommendations based on existing environmental impact assessment models and factors for life cycle assessment in European context. First edition EUR24571EN. ISBN 978-92-79- 17451-3. Available at <http://eplca.jrc.ec.europa.eu/>

**Box 1 Examples of use of LCA in EU policies and impact assessment**

- 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 policy making. Additionally, some examples of use of LCA in EU policies development and in impact assessment are reported below:
- 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

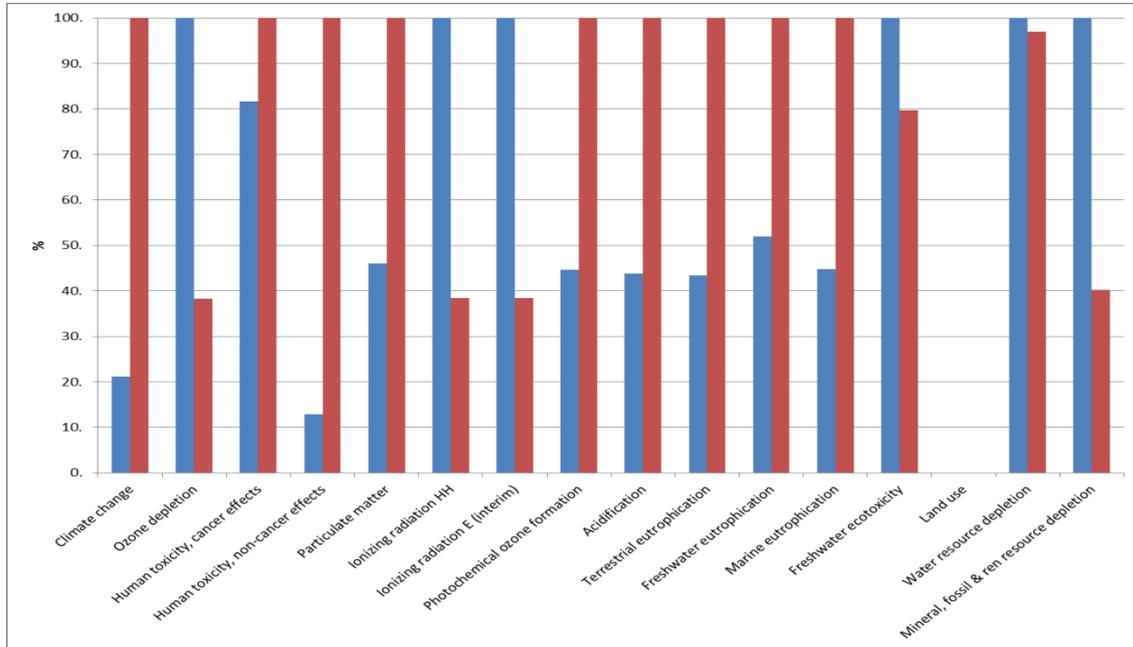
**Box 2. Procedural steps of LCA**



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.). The impact on different impact categories may then, be associated with three Area of Protections (AoP): human health, ecosystem health, natural resources.

**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) we obtain the figure below.



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	
I M P A C T C A T E G O R I E S	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

In the European Platform on Life Cycle Assessment<sup>498</sup>, inventory data, existing studies, sectorial and general guidance on how to conduct an LCA are available as well as guidance documents on how to integrate LCA in policy development and evaluation. Furthermore, the JRC may provide training on LCA for DGs and may support DGs in conducting specific LCA studies at micro (product) and meso/macro scale as well as helping reviewing existing studies developed by third parties.

<sup>498</sup> <http://eplca.jrc.ec.europa.eu/>

## Annex 1: LCIA impact categories and recommended models and indicators

The International Reference Life Cycle Data System (ILCD)<sup>499</sup> 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
<b>Climate change</b>	Baseline model of 100 years of the IPCC	Radiative forcing as Global Warming Potential (GWP100)
<b>Ozone depletion</b>	Steady-state ODPs 1999 as in WMO assessment	Ozone Depletion Potential (ODP)
<b>Human toxicity, cancer effects</b>	USEtox model (Rosenbaum et al, 2008)	Comparative Toxic Unit for humans (CTU <sub>h</sub> )
<b>Human toxicity, non- cancer effects</b>	USEtox model (Rosenbaum et al, 2008)	Comparative Toxic Unit for humans (CTU <sub>h</sub> )
<b>Particulate matter/Respiratory inorganics</b>	RiskPoll model (Rabl and Spadaro, 2004) and Greco et al 2007	Intake fraction for fine particles (kg PM2.5-eq/kg)
<b>Ionising radiation, human health</b>	Human health effect model as developed by Dreicer et al. 1995 (Frischknecht et al, 2000)	Human exposure efficiency relative to U <sup>235</sup>
<b>Ionising radiation, ecosystems</b>	No methods recommended	
<b>Photochemical ozone formation</b>	LOTOS-EUROS (Van Zelm et al, 2008) as applied in ReCiPe	Tropospheric ozone concentration increase
<b>Acidification</b>	Accumulated Exceedance (Seppälä et al. 2006, Posch et al, 2008)	Accumulated Exceedance (AE)
<b>Eutrophication, terrestrial</b>	Accumulated Exceedance (Seppälä et al. 2006, Posch et al, 2008)	Accumulated Exceedance (AE)
<b>Eutrophication, aquatic</b>	EUTREND model (Struijs et al, 2009b) as implemented in ReCiPe	Fraction of nutrients reaching freshwater end compartment (P) or marine end compartment (N)
<b>Ecotoxicity (freshwater)</b>	USEtox model, (Rosenbaum et al, 2008)	Comparative Toxic Unit for ecosystems (CTU <sub>e</sub> )

<sup>499</sup> [http://eplca.jrc.ec.europa.eu/?page\\_id=86](http://eplca.jrc.ec.europa.eu/?page_id=86)

<b>Impact category</b>	<b>Recommended default LCIA method</b>	<b>Indicator</b>
<b>Ecotoxicity (terrestrial and marine)</b>	No methods recommended	
<b>Land use</b>	Model based on Soil Organic Matter (SOM) (Milà i Canals et al, 2007b)	Soil Organic Matter
<b>Resource depletion, water</b>	Model for water consumption as in Swiss Ecoscarcity (Frischknecht et al, 2008)	Water use related to local scarcity of water
<b>Resource depletion, mineral, fossil and renewable</b>	CML 2002 (Guinée et al., 2002)	Scarcity

## TOOL #59: 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 or Excel 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)<sup>500</sup>. 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.

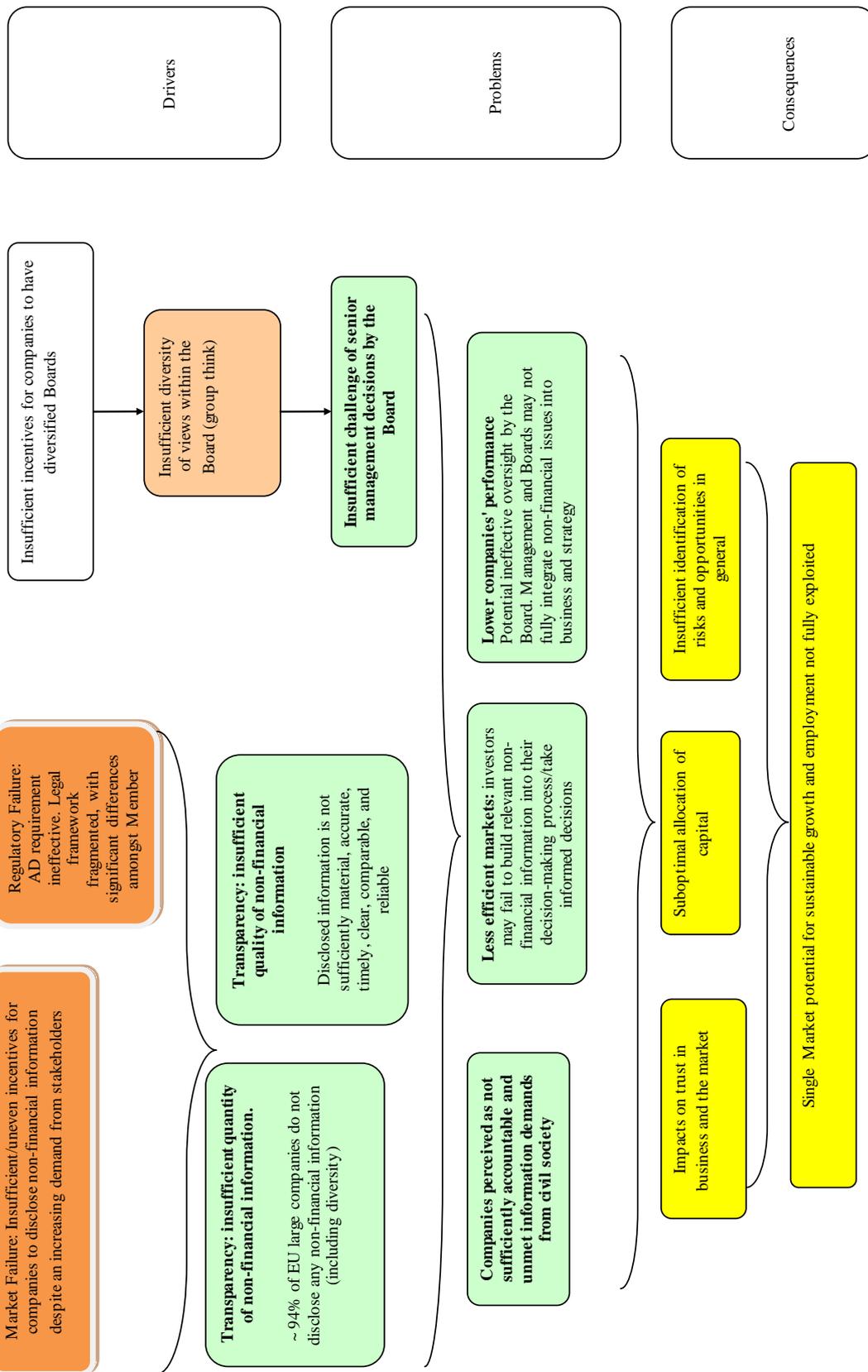
Problem trees can also usefully illustrate what is outside the scope of the EU intervention; for instance because not all of the problem(s) can or should be addressed by EU level action. The example in Box 2 on the initiative on e-invoicing in public procurement<sup>501</sup> illustrates this:

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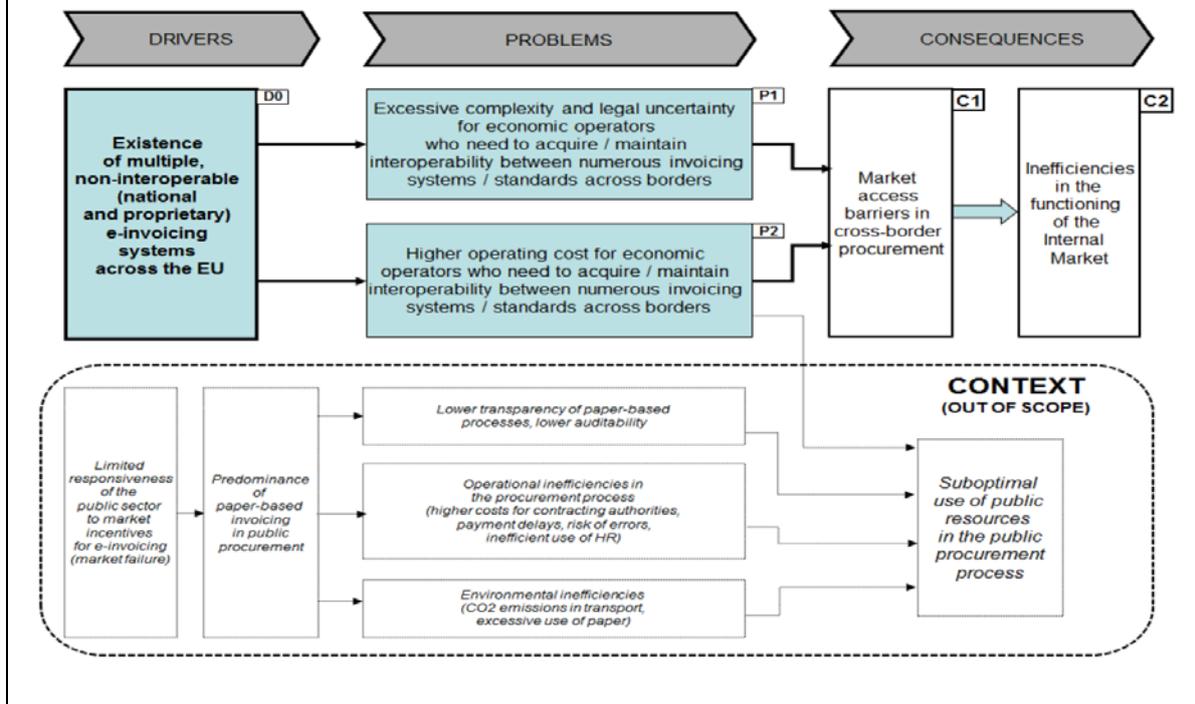
<sup>500</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0127&from=EN>

<sup>501</sup> <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)<sup>502</sup>.

**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

<sup>502</sup> <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 Community<sup>503</sup>.

**Box 4. Intervention logic diagram: authorized weights of road vehicles**

<b>Problem/Driver</b>	<b>Objective</b>
<p><u>Problem (Part 1)</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</p>	<p><u>General objective (Part 1)</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.</p>
<p><u>Root cause 1</u> Certain maximum weights and dimensions prevent the market uptake of more aerodynamic electric hybrid trucks and reduce the attractiveness of certain coach services.</p>	<p><u>Specific objective 1</u> To enable the market uptake of more aerodynamic electric hybrid trucks and to increase the attractiveness of certain coach services.</p>
<p><u>Root cause 2</u> Certain maximum weights and dimensions have not kept pace with the technical development of intermodal transport and containerisation.</p>	<p><u>Specific objective 2</u> To enhance the development of intermodal/combined transport</p>
<p><u>Problem (Part 2)</u> The Directive is not applied in an effective manner.</p>	<p><u>General objective (Part 2)</u> To improve the internal market for road transport by providing a fairer playing field for hauliers.</p>
<p><u>Root cause 3</u> Lack of common and dissuasive enforcement methods.</p>	<p><u>Specific objective 3</u> To ensure better enforcement of the maximum weights and dimensions across the EU.</p>

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

<sup>503</sup> <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.

## 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**:

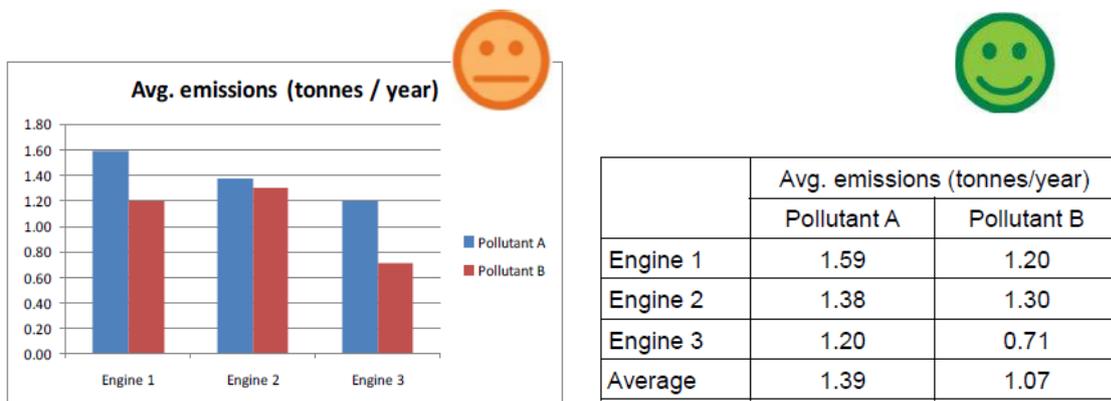
- **Line graphs** can show more detail than bar charts. They should be used when the horizontal axis represents a continuous quantity (such as time).
- When the horizontal axis is a qualitative factor - such as countries, products, etc. - **bar charts** are natural.

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 6. Tables versus graphs**

In general, tables are better than graphs for giving structured numeric information. For instance:



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 7. Clear tables

A first version sent to the IAB:

**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 **must clearly outline the advantages and disadvantages of each option**. Visual aids can be helpful in this regard.

### Radar charts

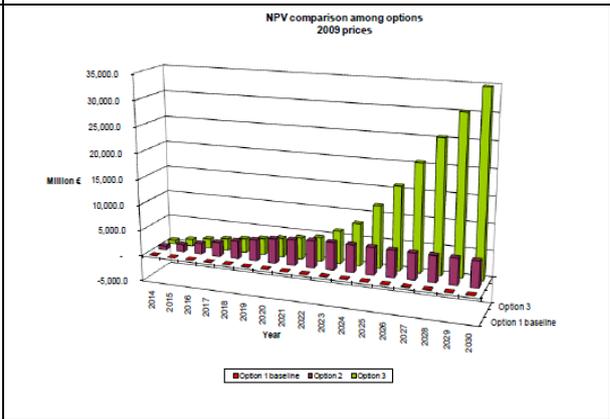
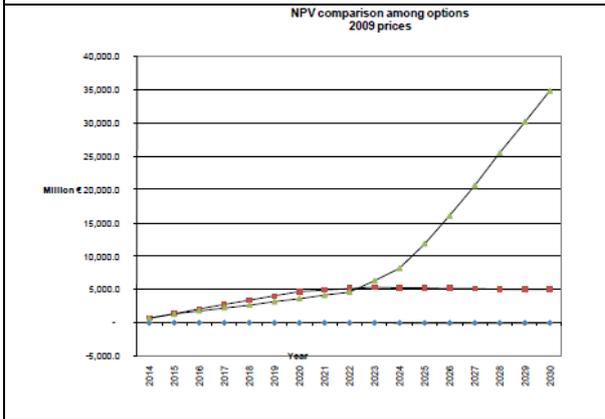
Radar charts can be used to compare options. To make any sense, you need at least 5 quantifiable criteria. The order of criteria is important to convey meaning. Radar charts are primarily suited for strikingly showing outliers and commonality, or when one chart is greater in every variable than another. They are less well suited for making trade-off decisions – when one chart is greater than another on some variables, but less on others.

**Box 8. Example of visual aids used to compare options**

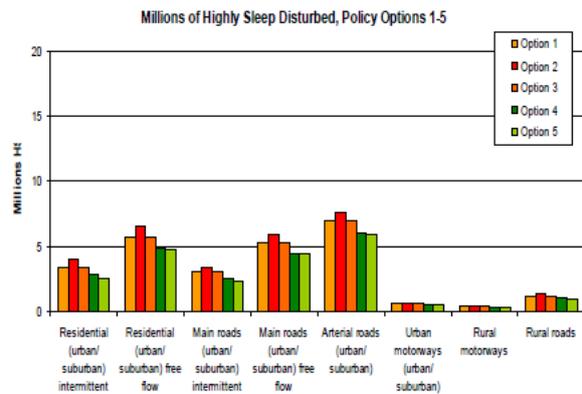
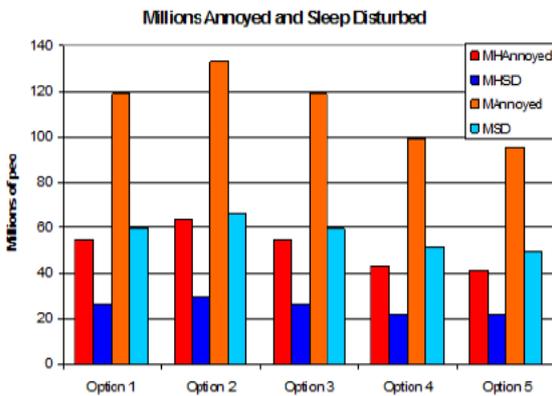
*Example 1:* IA on communication analysing the specific challenges for the space components of GMES (Global monitoring for environment and security). “In quantitative terms, the options can be compared most easily on the basis of their generated NPV in the period under consideration.”

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 9. Example of radar charts**

