

European Commission



IMPACT ASSESSMENT GUIDELINES

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INTRODUCTION

These guidelines replace the Commission guidelines adopted in June 2005 and updated in March 2006.¹ A public consultation on the Guidelines was carried out in June and July 2008. Contributions from stakeholders and the consolidated response prepared by the Commission services are available on the Commission's Public Consultation website.²

How to use these Guidelines?

These Guidelines are for Commission staff preparing impact assessments. They consist of a core text (this document) and annexes.³ The **core text** explains what IA is, presents the key actors, sets out the procedural rules for preparing, carrying out and presenting an IA, and gives guidance on the analytical steps to follow in the IA work. The **annexes** contain more detailed guidance that may also be of help. **Additional guidance** material to help with analysing specific impacts has been prepared by various Directorates General, and is available on their internal websites.

Where to find more advice and support?

These Guidelines should provide answers to many of your questions. The **IA support unit/function in your DG** will also be a key source of help and should be your **central contact point for all IA related questions**. For general questions on IA, you should contact the Secretariat General's Impact Assessment Unit (SG.C.2). The Impact Assessment Board (IAB) can also be consulted on methodological issues.

The desk officer who follows the work of your DG in the Secretariat General's Policy co-ordination units (SG directorate D) can also provide advice.

The evaluation unit of the Secretariat General will help if you have questions on the link between IA and ex-ante evaluation required under the Financial Regulation (see section 1.4).

In DG Enterprise and Industry, Unit B.5 can provide advice on administrative burdens and on the European Standard Cost Model. Unit E4 in DG Enterprise will help you on questions related to SME impacts.

Units D.1 and D.5 in DG Justice, Freedom and Security can provide assistance as regards possible impacts on fundamental rights, including data protection.

For questions related to stakeholder consultations, contact the "Transparency, Relations with Stakeholders and External Organisations" unit of the Secretariat General (SG.E.3).

¹ The Commission decision of June 2005 (SEC(2005)790) instructs the Secretariat-General to regularly up-date the Impact Assessment Guidelines, in consultation with Commission services and in the light of Commission experience and needs.

² http://ec.europa.eu/governance/impact/consultation/ia_consultation_en.htm

³ Also available under http://ec.europa.eu/governance/impact/docs_en.htm

PART I: IMPACT ASSESSMENT BASICS AND PROCEDURES

1. UNDERSTANDING IMPACT ASSESSMENT

- **Impact assessment is a key tool to ensure that Commission initiatives and EU legislation are prepared on the basis of transparent, comprehensive and balanced evidence.**
- **Impact assessment is an *aid to political decision-making*, not a substitute for it.**
- **While many actors may be involved in an impact assessment, *the lead service* remains fully responsible for its quality. The Impact Assessment Board provides support and advice, and scrutinizes the quality of all impact assessments.**

1.1 What is impact assessment?

Impact assessment is a set of logical steps to be followed when you prepare policy proposals. It is a process that prepares evidence for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impacts. The results of this process are summarized and presented in the IA report.

In doing an IA, you will have to answer a number of questions:

- What is the nature and scale of the problem, how is it evolving, and who is most affected by it?
- What are the views of the stakeholders concerned?
- Should the Union be involved?
- If so, what objectives should it set to address the problem?
- What are the main policy options for reaching these objectives?
- What are the likely economic, social and environmental impacts of those options?
- How do the main options compare in terms of effectiveness, efficiency and coherence in solving the problems?
- How could future monitoring and evaluation be organised?

The IA work is a key element in the development of Commission proposals, and the College of Commissioners will take the IA report into account when taking its decisions. The IA supports and does not replace decision-making - the adoption of a policy proposal is always a political decision that is made only by the College.

The key analytical steps which you have to follow when carrying out an IA are summarized in the table below. A detailed description of these steps is provided in Part II of the guidelines. Annex 14 provides practical examples of how these steps have been carried out in previous Commission IAs.

Summary of key analytical steps	
1	Identifying the problem
	<ul style="list-style-type: none"> Describe the nature and extent of the problem.
	<ul style="list-style-type: none"> Identify the key players/affected populations.
	<ul style="list-style-type: none"> Establish the drivers and underlying causes.
	<ul style="list-style-type: none"> Is the problem in the Union's remit to act? Does it pass the necessity and value added test?
2	Define the objectives
	<ul style="list-style-type: none"> Set objectives that correspond to the problem and its root causes.
	<ul style="list-style-type: none"> Establish objectives at a number of levels, going from general to specific/operational
	<ul style="list-style-type: none"> Ensure that the objectives are coherent with existing EU policies and strategies, such as the Lisbon and Sustainable Development Strategies, respect for Fundamental Rights as well as the Commission's main priorities and proposals.
3	Develop main policy options
	<ul style="list-style-type: none"> Identify policy options, where appropriate distinguishing between options for content and options for delivery mechanisms (regulatory/non-regulatory approaches)
	<ul style="list-style-type: none"> Check the proportionality principle.
	<ul style="list-style-type: none"> Begin to narrow the range through screening for technical and other constraints, and measuring against criteria of effectiveness, efficiency and coherence.
4	Analyse the impacts of the options
	<ul style="list-style-type: none"> Identify (direct and indirect) economic, social and environmental impacts and how they occur (causality).
	<ul style="list-style-type: none"> Identify who is affected (including those outside the EU) and in what way.
	<ul style="list-style-type: none"> Assess the impacts against the baseline in qualitative, quantitative and monetary terms. If quantification is not possible explain why.
	<ul style="list-style-type: none"> Identify and assess administrative burden/simplification benefits (or provide a justification if this is not done)
5	Compare the options
	<ul style="list-style-type: none"> Weigh-up the positive <u>and</u> negative impacts for <u>each</u> option on the basis of criteria clearly linked to the objectives
	<ul style="list-style-type: none"> Where feasible, display aggregated and disaggregated results.
	<ul style="list-style-type: none"> Present comparisons between options by categories of impacts or affected stakeholder
6	Outline policy monitoring and evaluation
	<ul style="list-style-type: none"> Identify core progress indicators for the key objectives of the possible intervention.
	<ul style="list-style-type: none"> Provide a broad outline of possible monitoring and evaluation arrangements.

1.2 Why is impact assessment important and what are the objectives?

All policy-decisions should be based on sound analysis supported by the best data available. The Commission's impact assessment system:

- helps the EU institutions to design better policies and laws;
- facilitates better-informed decision making throughout the legislative process;
- ensures early coordination within the Commission;
- takes into account input from a wide range of external stakeholders, in line with the Commission's policy of transparency and openness towards other institutions and the civil society;
- helps to ensure coherence of Commission policies and consistency with Treaty objectives such as the respect for Fundamental Rights and high level objectives such as the Lisbon or Sustainable Development strategies;
- improves the quality of policy proposals by providing transparency on the benefits and costs of different policy alternatives and helping to keep EU intervention as simple and effective as possible;
- helps to ensure that the principles of subsidiarity and proportionality are respected, and to explain why the action being proposed is necessary and appropriate.

1.3 Who are the actors?

The lead service for the proposal is responsible for preparing the IA. It will need the input of stakeholders and in many cases to involve internal and external expertise. Other Commission services, including the Secretariat-General, provide support through the impact assessment steering groups and the inter-service consultation. The Impact Assessment Board (IAB), which will control the quality of your IA, can also provide support and advice on your report before it is finalized.

1.4 When is an impact assessment necessary?

These guidelines do not define which Commission initiatives need to be accompanied by an IA. This is decided each year by the Secretariat General/Impact Assessment Board and the departments concerned. In general, IAs are necessary for the most important Commission initiatives and those which will have the most far-reaching impacts. This will be the case for all legislative proposals of the Commission's Legislative and Work Programme (CLWP) and for all non-CLWP legislative proposals which have clearly identifiable economic, social and environmental impacts (with the exception of routine implementing legislation) and for non-legislative initiatives (such as white papers, action plans, expenditure programmes, negotiating guidelines for international agreements) which define future policies. It will also be the case for certain implementing measures (so called 'comitology' items) which are likely to have significant impacts. You should establish at an early stage of the planning process, in consultation with your IA support unit and the Secretariat General, whether your initiative is likely to need an IA. You should also establish at an early stage what scope and level of analysis would be proportionate (see chapter 3 below).

Link between IA and ex-ante evaluation

Some initiatives will be financed from the Community budget, and will need an ex ante evaluation in line with Article 21(1) of the implementing rules of the Financial Regulation. If an IA is also considered to be necessary for such an initiative, it is important to avoid duplication of efforts. As long as the IA addresses the points listed in Article 21(1), a separate ex ante evaluation is not required. You will need to pay particular attention in the IA, however, to the cost-effectiveness of the various options reviewed (see section 9.1.). If your proposal does not need an IA, but does have budgetary implications, then you will of course need to do an

ex ante evaluation. If you are not sure whether an IA or an ex-ante evaluation is more appropriate, you should contact the evaluation unit or the IA unit in the Secretariat General.

2. WHAT ARE THE PROCEDURES?

	Summary of key procedural steps
1	Planning of impact assessment: Roadmap, integration in the SPP cycle and timetable
2	Work closely with your IA support unit throughout all steps of the IA process
3	Set up an Impact Assessment Steering Group and involve it in all IA work phases
4	Consult interested parties, collect expertise and analyse the results
5	Carry out the IA analysis
6	Present the findings in the IA report
7	Present the draft IA report together with the executive summary to the Impact Assessment Board (IAB) and take into account the possible time needed to resubmit a revised version
8	Finalise the IA report in the light of the IAB's recommendations.
9	IA report and IAB opinion(s) go into Inter-Service Consultation alongside the proposal
10	Submission of IA report, executive summary, IAB opinion(s) and proposal to the College of Commissioners
11	Transmission of the IA report and the executive summary with the proposal to the other Institutions
12	Final IA report and IAB opinion(s) published on Europa website by SG
13	In the light of new information or on request from the Council or the EP, the Commission may decide to update the IA report

2.1 Planning the IA: The Roadmap and the SPP cycle

IA should be carried out before the development of the legislative or policy proposal reaches an advanced stage. Thereafter they can be fine-tuned in line with development of the initiative.

Roadmaps are essential tools for internal and external transparency of policy preparation and allow all actors involved in IA work to prepare their contributions in a timely manner.

As IAs require time and resources, planning for them must be integrated into the Commission's annual Strategic Planning and Programming cycle (SPP).⁴ All initiatives which are included in the Commission Legislative and Work Programme (CLWP) and all non-CLWP legislative proposals which have significant impacts (with the exception of routine

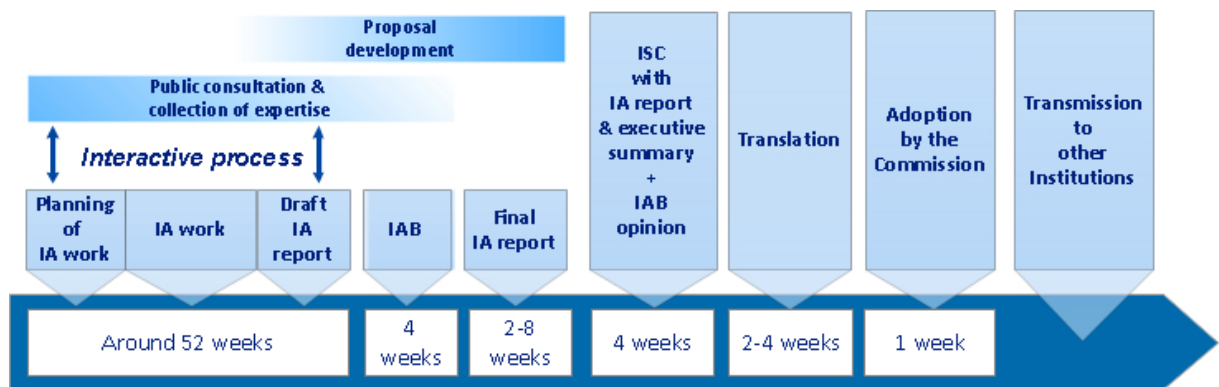
⁴ Cf. http://ec.europa.eu/atwork/index_en.htm

implementing legislation) must be accompanied by a Roadmap⁵ which should include information on each of the analytical steps and the timing of the IA, or explain why an IA is not necessary. In any case it must identify clearly the problems to be addressed by the initiative and a proper justification of EU action on grounds of subsidiarity. It should indicate which DGs will be invited to the impact assessment steering group (IASG). It should also outline the consultation plan (see also section 4.3).

You should circulate your Roadmaps, even in an early form, to other DGs for information/comments well before the adoption of the CLWP. This will allow them to plan how to contribute to the IA and to ensure coherence with their own policy objectives. The Secretariat-General and the IAB also screen the Roadmaps to identify those initiatives that would benefit from up-stream quality support.

Given that it normally takes more than 12 months to produce an IA, including the periods needed for public consultation, planning will in most cases have to start well before the CLWP/ Roadmap exercise. The following chart gives you an overview and indicative timing of the steps between planning an IA and adoption of the related proposal. Annex 2 provides further guidance on this.

Typical countdown for preparing an impact assessment



2.2 Impact Assessment Steering Groups

An Impact Assessment Steering Group should be set up for each IA and should be fully involved in all phases of the IA work. The group should review the final draft of the IA report before it is submitted to the IAB.

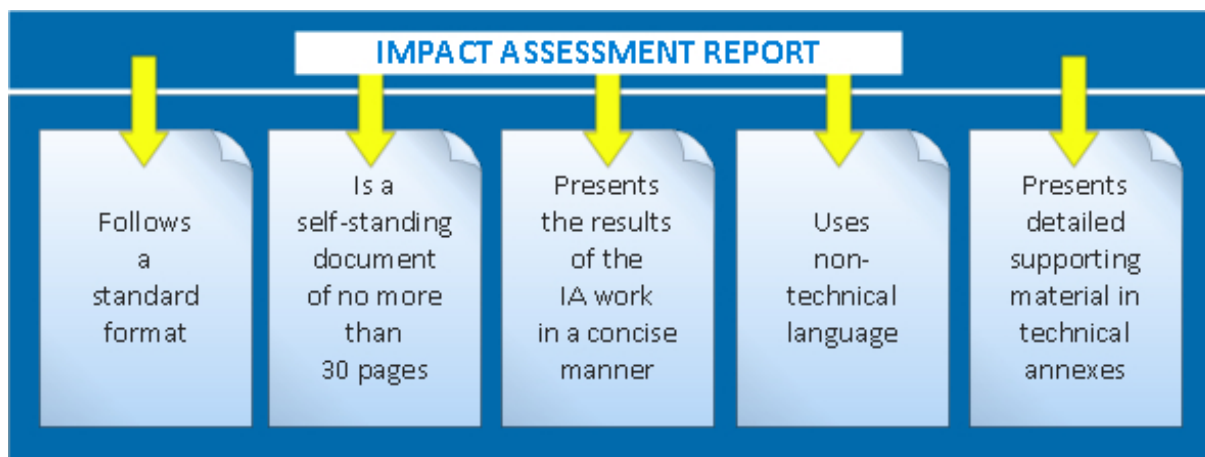
Set up: You must set up an Impact Assessment Steering Group (IASG) for every IA. Existing inter-service groups – for example to accompany a study that feeds into the IA work or for the development of the proposal - can be used to steer the IA work.

Composition: A member of your IA support unit should always participate in the IASG. You should include in the IASG the DGs whose policies are likely to be affected by or contribute to the objectives of your initiative, and the relevant policy coordination unit of the SG (Directorate D). . You should use fully the expertise available in other DGs to ensure that all relevant impacts of your policy options are assessed, for example on fundamental rights, social issues, on SMEs, or on consumers. The IASG is also the best way for other services to ensure that their views are taken into account. It is therefore important that other services participate actively in the steering groups and plan participation well in advance. This process should also make it easier to reach agreement during the Inter-Service Consultation.

⁵ The current Roadmap template is presented in annex 1.

Timing: You should set up the IASG at the beginning of the work, and involve it in all phases, including preparatory studies, consultation, and drafting. The IASG should review the final draft of the report before it is submitted to the IAB. The minutes of the last IASG meeting, where the final draft IA report was discussed should be attached to the IA report submitted to the IAB.

2.3 Presenting the findings: The IA report



- The report should always present the results of the IA process in the following **format** (more guidance is available in Annex 3):
 - Section 1: Procedural issues and results from consultation of interested parties
 - Section 2: Policy context, problem definition, and subsidiarity
 - Section 3: Objectives
 - Section 4: Policy options
 - Section 5: Analysis of impacts
 - Section 6: Comparing the options
 - Section 7: Monitoring and evaluation
- The report should be no longer than 30 pages (excluding the executive summary, tables, diagrams and annexes). If the report covers several initiatives, you may need to go beyond 30 pages. You should discuss this at an early stage with the Secretariat General's IA unit (SG.C.2). Supporting documents, such as results of studies, expert reports or summaries of stakeholder views, should be presented in annexes.
- The report must nevertheless be a **self-standing document** which presents the analysis and all relevant results of the IA work, including summaries of information that are presented in annexes.
- The report should be **written in clear and simple language**. A non-specialist reader should be able to follow the reasoning and understand the impacts of each of the options. To enhance the clarity and readability of the report, tables and diagrams should be used to summarize key points.
- You should provide an **executive summary** of not longer than 10 pages. This should be a **separate document**. It should a) present a summary of the problem description and the objectives; b) present the analysis of subsidiarity; c) list the range of options identified and the options assessed in detail; d) present the main economic, social and environmental impacts of each option and, where relevant, e) the result of the comparison of the options, indicating the criteria for comparison. For points d) and e) the executive summary should contain a clear presentation of any quantified benefits and costs of the various options. This should cover administrative costs for businesses and

citizens, other compliance costs, and costs for administrations. The executive summary should be submitted to the IAB together with the main IA report.

- The report can be drafted in English, French or German, and is generally not translated. The **executive summary** must, however, be **translated** into all official languages.
- The IA report should have a **disclaimer** on the cover page, and should also indicate in the introduction that the report commits only the Commission services involved in preparing it, and that the text is a basis for discussion and does not prejudice the final decision to be taken by the Commission.⁶
- The IA report should be accompanied a by transmission letter signed by your Director-General assuming responsibility for the content of the submitted IA documents.

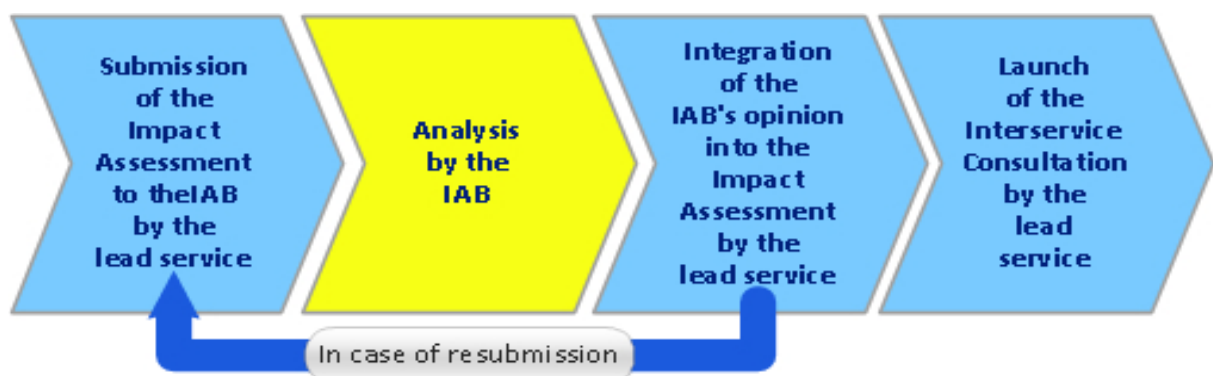
2.4 The Impact Assessment Board

You should aim to discuss the draft IA report with the IAB at least 4 weeks before the launch of inter-service consultation to ensure that you have sufficient time to take account of the IAB's opinion.

The IAB should receive your IA at least 4 weeks before the meeting where it will be discussed, i.e. at least 8 weeks before the launch of the inter service consultation.

Upstream advice: While the IA unit in your DG should be your primary source of advice, you can seek advice from the IAB for example on methodology or on the depth of analysis that is likely to be proportionate for your initiative.⁷

Quality control: The IA unit in your DG and the IASG play a key role in ensuring the quality of your IA report before it is submitted to the IAB. You should submit the IA report and the executive summary to the IAB **4 weeks before the meeting** in which you plan to discuss it.⁸ The IAB **must** give an opinion on your IA report before you put it into inter-service consultation (ISC), and given that it may ask to see a revised version of your initial report, you should plan the timing carefully and realistically. The IAB may also recommend **further work in the IASG** if it feels that the potential of this group has not been sufficiently exploited. You should therefore plan at least 4 weeks between the initial meeting with the IAB and the start of the ISC to leave you time to take the IAB's opinion fully into account in the revised IA. The issues which the IAB will analyse when carrying out its quality control⁹ as well as technical details on how the IAB hearings will take place are published on the IAB IntraComm site¹⁰.



⁶ A disclaimer text that can be used is provided in annex 3.

⁷ For more information on the IAB see http://ec.europa.eu/governance/impact/iab_en.htm

⁸ IA documents should always be sent to the functional IAB mailbox: IMPACT ASSESSMENT BOARD

⁹ Cf. http://www.cc.cec/iab/i/docs/key_docs/revised_iagc_final_empty_clean_sept_2007.doc (access Commission only)

¹⁰ Cf. http://www.cc.cec/iab/i/docs/key_docs/one_pager_on_iab_proceedings.doc (access Commission only)

2.5 Inter-service consultation, presentation to the College and publication

The IA report and executive summary are presented to the College and published as two separate Staff Working Documents.

If the responsible Commissioner concludes from the IA that action is necessary, a corresponding proposal will be finalised and put into ISC, together with the IA report (with annexes) and the IAB opinion(s). You may need to make final adjustments to the IA report to take on board comments made during the ISC. If there are significant changes to the objective, options, or to the conclusions, you should resubmit your report to the IAB.

In addition, the **Explanatory Memorandum** accompanying the draft proposal should set out briefly the options that have been considered, their potential economic, social and environmental impacts, the website address where the final IA report can be found and how the recommendations of the IAB have been incorporated¹¹.

After ISC, the final texts of the IA report and the executive summary should be presented to the College of Commissioners as two separate Staff Working Documents with the draft proposal and the IAB opinion(s).

The fact that an IA has been produced should 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 on the Europa IA website along with the proposal and the IAB opinion. 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.

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 IAB will examine them, and they will be published on the Europa website as Staff Working Documents.

2.6 Use of the IA report by the Council and Parliament



You should use your IA actively when presenting the merits of the proposal during the legislative process. Both Council and the European Parliament have made a commitment to assess the impact of substantial amendments they make to Commission proposals.¹² Your IA should try to anticipate issues that are likely to be raised in Council and Parliament, for example the choice of instrument for EU action or possible amendments. In the light of new information, the Commission may decide on a case by case basis to update the original IA. In all such cases, it is important to consult the IA unit of the Secretariat General (SG.C.2) as early as possible.

¹¹ See explanatory memorandum http://www.cc.cec/home/dgserv/sg/em/index_en.htm. (access Commission only)

¹² See the Inter-Institutional Common Approach for Impact Assessment, Council Doc. 14901/05 of 14.11.05 http://ec.europa.eu/governance/better_regulation/ii_coord_en.htm#_iia.

3. DEFINING THE SCOPE AND LEVEL OF ANALYSIS OF THE IA

- **Legal obligations or previous political choices relevant to the scope of the IA (in terms of objectives and options analysed) must be explained in the section on policy context.**
- **The analysis of political acceptability should however be kept separate from the analysis of substance.**
- **The level of analysis which is proportionate relates to the entire IA process, including for example data collection, provisions for stakeholder consultation and quantification of impacts.**
- **While guidance for typical cases is available, you will need to define the level of analysis for each IA. This may be an iterative process.**
- **Significance of likely impacts: The more significant and the more likely the impacts are expected to be, the deeper the analysis should be.**
- **Political importance: the IA should provide sufficient evidence to respond to concerns that are likely to arise in the decision-making process, or the public reaction after the Commission adopts the initiative.**
- **Stages of policy development: requirements for the IA will change depending on whether or not the initiative is in a policy field where EU-action already exists and whether (parts of) the initiative have been analysed in an earlier IA or will be analysed at a later stage in a follow-up IA.**

3.1 Legal obligations or political choices influencing the scope of the analysis

The IA may be influenced by legal obligations or previous political choices. Where such limitations result from the legal context i.e. limitations/obligation for EU action fixed in primary or secondary EU legislation, international law, or obligations related to fundamental rights, the IA should explain why certain policy options are necessary or not feasible. In such cases, the IA will need to place a strong emphasis on the subsidiarity/proportionality issues in the description of options.

It should be understood that certain fundamental rights are absolute and cannot be limited or subject to derogation: others can only be limited or derogated from subject to a demonstration of necessity and, thereafter, proportionality.

Council or Parliament may also have expressed a preference for a certain form of action. The Commission should nevertheless analyse all realistic options for action. On the basis of this analysis, the Commission may conclude that the action preferred by the other institutions has drawbacks that can be avoided by choosing an alternative option (including 'no new action'). In such cases you will have to provide strong evidence and analysis in the IA to explain the choice of the proposed option.

In general, political mandates, previous political choices or political expectations by EU institutions, Member States or stakeholders can be presented in an IA report as reasons to dismiss an option but the reasons for the discarding should be discussed. The origin and rationale of earlier political choices for the scope of the IA should be explained in all cases.

3.2 Criteria for defining the proportionate level of analysis for an IA

An IA should provide decision-makers in the EU institutions with solid evidence on the impacts and advantages and disadvantages of a range of policy options, but it should also avoid unnecessary effort that would not lead to further insights or alter the conclusions or their robustness. The concept of "**proportionate level of analysis**" for an IA relates to the appropriate level of detail of analysis which is necessary for the different steps of IA.¹³

¹³ It should not be confused with the "**principle of proportionality**" which is relevant when examining whether or

The "proportionate level of analysis" is not only about the depth and scope of the analysis or the drafting of the IA report. It refers to the whole IA process - data collection efforts and stakeholder consultation, the level of ambition of the objectives, options and delivery mechanisms, the type of impacts to be examined, and the arrangements for monitoring and evaluation.

It is the responsibility of the author service to determine the level of analysis. You should do this as early in the planning process as possible, taking into account that your assessment of what is proportionate may change as your analysis evolves. Even if you decide to carry out an IA which is relatively limited in terms of depth and scope, you should still produce a report which follows the structure presented in section 2.3. A proportionate IA may also need to quantify certain impacts.

The following paragraphs provide some guidance for defining the right level of analysis, and advice is also available from the IA steering group, the Secretariat-General and from the IAB.

In defining the right level of analysis for your IA, you should answer the following questions:

- How significant are the likely impacts?
- How politically important is the initiative?
- Where is the initiative situated in the policy development process?

3.2.1 Significance of impacts

An initiative may have a particularly significant impact in one or more of the fields analysed in the IA (economic, social or environmental). It may have impacts on fundamental rights, certain economic sectors, on economic actors, groups of citizens, on businesses, SMEs, or on regions, cultural goods, species or habitats. Other issues may also be relevant – the impact on a third country or the contribution to Commission programmes such as the programmes for simplification of legislation or for the reduction of administrative burdens.

The first step in deciding whether these impacts need special attention in the IA will be in the IASG on the basis for example of past experience, observation of markets, political developments, and preliminary contacts with stakeholders. This preliminary test of impacts will feed into step 1 of the impact analysis described in chapter 8.2.

3.2.2 Political importance

You can assess the political importance of a Commission initiative by answering the following questions:

- Does the initiative relate to Commission strategic or annual priorities (such as promoting growth and jobs, promoting energy efficiency)? Does it cut across several policy fields?
- Could the initiative raise concerns related to subsidiarity and proportionality?
- Is it particularly controversial? Who might contest the initiative?
- Is the initiative particularly important in the inter-institutional context or for certain Member States?

In such cases, you should present particularly solid evidence in the IA to underpin the Commission's action, and anticipate amendments or alternative solutions that may be raised in the decision-making process.

3.2.3 IA and the stages of policy development

The level of analysis which is proportionate for an IA is linked to where you are in the policy development process. This process can stretch from a Green Paper, via a White Paper, possible presentation of an Action Plan, and finally the presentation of a legislative proposal.

not the options for EU action go beyond what is needed to achieve the objectives (cf. section 7.2).

If decisions on EU-action are carried out in steps, the IA should only assess those elements which are new compared to the previous step. An IA for a specific legislative proposal, for example, should be able to draw on previous analytical work, data collection, and preliminary estimates from the IA of the strategy or action plan that it implements. If the problem description and objectives are already available, you should not repeat them but only update them if necessary. Likewise, in an IA for a comitology decision you should not repeat the analysis of the IA for the basic legislation (if it exists) but, rather, focus on the actual decision at stake. In all these cases, you need to set out clearly the link with other assessment work.

If an initiative breaks new ground, however, you will have to explain its rationale and analyse its impacts more thoroughly than would be the case for established policies or for legislation which follows up on existing legislation. In such cases, the IA report should provide a thorough description of the policy context and problems, and demonstrate clearly the necessity and added value of EU action.

Initiatives in "new" areas of existing policy fields need to analyse a credible range of options for action (a "no new action" option, non-legislative action and, where applicable, different options for legislative action).

3.3 Defining the proportionate level of analysis for different types of initiative

3.3.1 Types of initiatives

For each IA, it will of course be the content rather than any formal classification that determines the degree of analysis needed. For guidance purposes, however, you might consider six categories of initiative.

- **Non-legislative initiatives/Communications/Recommendations/White papers** which set out commitments for future legislative action, such as the Thematic Strategy on Air Pollution; Action Plan for biomass;
- **"Cross-cutting" legislative action**, such as regulations and directives that address broad issues and are likely to have significant impacts in at least two of the three pillars (economic, environmental and social) and on a wide range of stakeholders across different sectors (e.g. Regulation on motor vehicles emissions; Directive on the legal framework for payments)
- **"Narrow" legislative action** in a particular field or sector, and unlikely to have significant impacts beyond the immediate policy area (e.g. Framework Decision on procedural rights in criminal proceedings; Directive on common rules and standards for ship inspection and survey organisations)
- **Expenditure programmes**: Decisions to establish or renew spending programmes (e.g. Decision to establish the programme "Citizens for Europe" to promote active European citizenship; General Programme Solidarity and Management of Migration Flows)
- **Comitology decisions**: Different executive initiatives defined by the procedure of adoption, (e.g. Commission Regulation implementing Directive 2005/32/EC with regard to ecodesign requirements for external power supplies).

3.3.2 Guidance for different types of initiatives

The following table illustrates how impact assessments may differ for the types of initiatives presented in section 3.3.1. 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 three criteria in chapter 3.2, will help you to establish the right level of analysis for your IA.

Non-legislative initiatives/ Communications/ Recommendations/ Strategy papers, which set out commitments for future legislative action (such as White Papers and action plans)

IA SHOULD FOCUS ON:

- Relevant problems and drivers if this is an new policy field or an extension of the scope of policy intervention
- Identification of general and specific objectives.
- Subsidiarity and proportionality analysis to explain the necessity and added value of EU action.
- Identification of different options for action, including clarification of instruments to implement broad options, level of ambition, etc. Identify alternatives for the individual actions which are planned.
- A description, of the most significant potential impacts of different approaches or instruments, clearly linked to the objectives; focus on trends, causalities and mechanisms.
- Identification of need for follow-up IAs and data necessary for future actions if impacts cannot be fully assessed at this stage.
- Identification of broad monitoring and evaluation arrangements.

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 contained in the initiative.
- A disproportionate analysis of "no EU policy" and "no change" options and merely repeating the problem description.
- Excessive monitoring and evaluation approaches, but could include indicators to measure achievement of general objectives.

Cross-cutting legislative action

IA SHOULD FOCUS ON:

- Detailed description of problems/ challenges that necessitate EU legislation, and how they are likely to evolve.
- Subsidiarity and proportionality analysis to explain the necessity and added value of EU action.
- Identification of options, including self- and co-regulation.
- 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 economic, social and environmental impacts for all options unless non-consideration is justified.
- In case of a simplification initiative: clearly spell out the simplification benefits and quantify these where possible.
- Measurement of administrative burden.
- Monitoring and evaluation arrangements as well as indicators for general objectives.

IA SHOULD AVOID:

- Excessive efforts on objective setting: set clear general and specific objectives; operational objectives only where possible and pertinent.
- Repetition in detail of what will be presented in the explanatory memorandum.

"Narrow" legislative action

IA SHOULD FOCUS ON:

- Detailed description of problems/ challenges (and their likely evolution) that necessitate EU legislation.
- Subsidiarity and proportionality analysis to explain the necessity and added value of EU action.
- Short description of general objectives and detailed identification of specific and operational objectives.
- Options as in minimum standards, if feasible; if the range of options is limited by political constraints or previous policy, analyse different implementation modes or choices of instruments for preferred option.
- Thorough analysis of impacts of all options in relevant pillar(s).
- In case of a simplification initiative: clearly spell out the simplification benefits and quantify these where possible.
- Measurement of administrative burden.

- Monitoring and evaluation arrangements to include indicators for general and specific objectives.

IA SHOULD AVOID:

- Disproportionate assessment of impacts in relation to the objectives of wider EU-strategies, if the impact is clearly marginal.
- Repetition in detail of what will be presented in the explanatory memorandum.

Expenditure programmes

IA SHOULD FOCUS ON:

- Short description of change of problems/context that necessitates action and link with other EU policies or programmes.
- Subsidiarity and proportionality analysis to explain the necessity and added value of EU action.
- In case of expiry/renewal use of monitoring and evaluation results.
- Detailed identification of specific and operational objectives.
- Thorough analysis of baseline option (no EU-policy or no change); assessment of options of alternative delivery mechanisms.
- impacts on costs (quantitative) vs. benefits (quantitative or where not possible qualitative).
- Concrete monitoring and evaluation provisions, including indicators reflecting specific and operational objectives.
- If the IA is also the ex ante assessment foreseen in the Financial Regulations it should contain all necessary elements.

Comitology items

IA SHOULD FOCUS ON:

- Identification of specific and operational objectives, linked to the objectives/requirements of the basic legislation.
- Subsidiarity and proportionality analysis to explain the necessity and added value of EU action.
- Options should include non-legislative action (short analysis of feasibility) and different implementation modes and/or technical detail of envisaged Commission decision (Consideration of whether "doing less" is possible).
- Thorough assessment of impacts in relation to specific and operational objectives, taking full account of relevance of technical detail and using quantification to the extent possible.
- Monitoring and evaluation provisions should include concrete indicators reflecting specific and operational objectives.

IA SHOULD AVOID EXCESSIVE EFFORT ON

- Description of policy context/constraints and general objectives.
- Assessment of impacts in relation to general objectives of basic legislation or wider EU-policies.

4. GATHERING INFORMATION AND CONSULTING STAKEHOLDERS

4.1 Data sources, collection and analysis

Good quality data – facts as well as figures – are an essential part of any IA. You need them to define the problem and the baseline scenario, and to identify the impacts of alternative options for dealing with the problem. Particular attention needs to be paid to quality and credibility of data.

You should identify data needs at an early stage of the IA work. In some cases, certain information that you need for the IA will be available in the Commission, either in your own DG or in other services. This information may include monitoring or evaluation reports from previous or similar programmes, earlier IAs, studies carried out by or for the Commission, statistical data from Eurostat and others, studies and research by EU agencies, information gathered from stakeholders (hearings, conferences), and results of consultation documents such as Green Papers. In many cases, you will also have to rely on data available at national or regional level in the Member States. You may need the support of Member States and/or stakeholders to identify and use these data, and you should seek this support as early as possible. It may also be necessary to use external experts to gather data and undertake some of the analysis.

You should also look for examples of good practice in Member States, and at the experiences of third countries or international organisations (e.g. World Bank, OECD). When the EU is involved in an international dialogue, or if there are internationally agreed standards, you should reflect this in the report.

4.2 Using external expertise

IA can draw on work produced by consultants or external expertise, but must be drafted by the Commission services which remain fully responsible for the report.

Scientific and technical expertise is important for developing public policies. The Commission has produced guidelines for collecting and using such expertise.¹⁴ Expert groups and, in particular, scientific committees set up by the Commission and EU Agencies are a prime source of scientific advice. In addition, since 2005, a web application called the SINAPSE e-Network¹⁵ (Scientific INformAtion for Policy Support in Europe) offers Commission services the tools for the collection of expertise. SINAPSE enables in particular the creation of e-communities¹⁶ that can be used as communication platforms to facilitate the consultation and involvement of external experts in the process.

NB: The lead service always remains responsible for the content and quality of the IA report. When you use external experts for parts of the IA, the terms of reference should make clear that contractors should follow the key analytical steps set out in Part II of these guidelines. If you use external experts to carry out public consultations, you must ensure that they adhere to the Commission's minimum standards.

¹⁴ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0713:FIN:EN:PDF>

¹⁵ SINAPSE is accessible at <http://europa.eu/sinapse> (Contact: Sinapse@ec.europa.eu).

¹⁶ The e-community tools include a library of documents, a library of web links, a shared calendar and the capacity to launch discussions or surveys (based on questionnaires which are designed online).

4.3 Consulting interested parties

Consulting interested parties is an obligation for every IA and it must follow the Commission's minimum standards. You should

- plan your consultations early,
- ensure that you engage all affected stakeholders, using the most appropriate timing, format and tools to reach them,
- ensure that stakeholders can comment on a clear problem definition, subsidiarity analysis, description of the possible options and their impacts,
- maintain contact with stakeholders throughout the process and provide feedback,
- analyse stakeholders' contributions for the decision-making process and report fully in the IA report on how the input was used.

Why consult?

Consulting those who will be affected by a new policy or initiative and those who will implement it is a Treaty obligation. It is an essential tool for producing high quality and credible policy proposals. Consultation helps to ensure that policies are effective and efficient, and it increases the legitimacy of EU action from the point of view of stakeholders and citizens.

When and what?

Depending on the objective pursued and the issue at stake, consultation can be carried out on different elements of the impact assessment (nature of the problem, objectives and policy options, impacts, comparison of policy options, assessment of costs and benefits). As the Roadmaps for CLWP items are published in parallel to the CLWP, i.e. at a relatively early stage in the planning process, you should encourage stakeholders to examine these and to give early feedback on your plans for the IA.

Consultation is not a one-off event, but a dynamic process that may need several steps. Planning should cover the whole policy-making process and include information on:

- the objective of the consultation(s): finding new ideas (brainstorming); collecting factual data; validating a hypothesis; etc;
- the elements of the IA for which consultation is necessary, e.g.: nature of the problem, subsidiarity aspects, objectives and policy options, impacts, comparison of policy options;
- the target groups: general public, a specific category of stakeholders or designated individuals / organisations;
- the appropriate consultation tool(s): consultative committees, expert groups, open hearings, *ad hoc* meetings, consultation via Internet, questionnaires, focus groups, seminars/workshops, etc.;
- the appropriate time for consultation(s): it should start early but can run at intervals throughout the IA process.

The consultation plan, key consultation documents and the results achieved **should be discussed with the IASG**. There is no one-size-fits-all solution for stakeholder consultations, but there are minimum standards which must be applied.¹⁷

Minimum consultation standards

- Provide clear, concise consultation documents that include all necessary information.

¹⁷ Cf. "Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission" (COM(2002) 704 final).

- Questions and problems included in a consultation questionnaire should be unambiguous.
- Consult all relevant target groups. Ask yourself: who will be affected by the policy and who will be involved in its implementation?
- Ensure sufficient publicity and choose tools adapted to the target groups - open public consultations must at least be publicised on the Commission's single access point for consultation, 'Your Voice in Europe'¹⁸.
- Leave sufficient time for participation. While eight weeks is the minimum period recommended for written public consultations, there are circumstances where a longer period might be necessary (e.g. proposals which are particularly complex or sensitive, or if you are consulting over a holiday period). You should provide 20 working days notice for meetings.
- Publish the results of the public consultation on 'Your Voice in Europe'.
- Provide – collective or individual – acknowledgement of responses.
- Provide feedback: report on the consultation process, its main results and how you have taken the opinions expressed into account in the IA report (see below) and in the explanatory memorandum accompanying the Commission proposal.

More information on these issues is available in annex 5 and on the IntraComm site on stakeholder consultation¹⁹. You should note that there are specific provisions for consulting social partners on initiatives in the field of social policy based on articles 137-139 of the Treaty and on initiatives having a social impact for a specific sector (see also annex 5.2).

Pitfalls

When carrying out the consultation and using the information it produces, you should be aware of a number of pitfalls that may introduce a bias into the results. It is important to **distinguish evidence from opinions**. Not all interest groups are equally able to take part in consultations or express their views with the same force. For this reason, an open consultation is unlikely to provide a fully representative picture of opinions. 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. You should also be careful in drawing conclusions if there are only a small number of responses and they come from a narrow range of interests.

While you should be careful, however, not to be unduly influenced by the views of one particular group, no matter how professionally these have been presented, you should also give a response its due weight if it represents a large number of citizens or stakeholders.

When you use a consultation to gather data, you should *verify* carefully that the method you use is correct and appropriate, and try to *validate* the robustness of the results. Peer-reviewing, benchmarking with other studies and sensitivity analysis can significantly enhance the quality of data.

Reporting on the consultation in the IA

Public consultations are an essential part of your IA work. They also require significant time and effort on the part of stakeholders. It is therefore essential that you present clearly the results of the consultation in your IA. You should provide details of how, who and on what you consulted.²⁰ **You should present the different positions expressed and how you have taken them into account.** If you have used the consultation to gather factual data, **you should indicate what you requested, what you received, and how you used it.**

¹⁸ See http://ec.europa.eu/yourvoice/consultations/index_en.htm

¹⁹ See <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=guidance>.

²⁰ More guidance is provided in annexes 3 and 5.

PART II: KEY ANALYTICAL STEPS IN IMPACT ASSESSMENT

5. WHAT IS THE PROBLEM?

A good definition of the problem and a clear understanding of what causes it are preconditions for setting objectives and identifying options to address the problem. A good problem definition should

- describe the nature of problem in clear terms and support the description with clear evidence,
- set out clearly the scale of the problem,
- set out clearly who is most affected by it,
- identify clearly the drivers or underlying causes of the problem,
- describe how the problem has developed over time and how existing policies at Community or Member State level affect it,
- identify a clear baseline, i.e. describe how the problem is likely to develop in the future without new EU action,
- identify clearly assumptions made, risks and uncertainty involved,
- describe why the problem needs action at Community level on the basis of principles set in the Treaty (Conferral and Subsidiarity).

5.1 Defining the problem

The problem definition should describe and provide evidence of the nature and scale of the problem. You should identify the actors, sectors and social groups that are primarily affected by it. Where the problem is not confined to the EU, you should also identify international aspects of the problem. You should explain why it is a problem, why the existing or evolving situation is not sustainable, and why public intervention may be necessary. Public intervention is normally justified on the grounds of market/regulatory failures, or because of equity concerns or a discrepancy between the fundamental goals of the EU and the existing situation. In practice, the need for intervention often arises from a combination of these reasons. Some of the major **reasons for public intervention are presented in the box below** and more details and examples are provided in Annex 6.

Market failures

- Market prices do not reflect the real costs and benefits to society ('externalities')
- Insufficient supply of public goods
- Missing or weak competition (including abuse of market power)
- Missing or incomplete markets
- Information failures, such as imperfect information or lack of access to information for decision takers (including consumers and public authorities), unless caused by a regulatory failure

Regulatory failure

- Inadequately defined property rights/legal framework
- Poorly defined targets and objectives
- Unintended consequences by public intervention
- Regulatory capture of public authorities
- Implementation and enforcement failures

Discrepancy between the fundamental goals of the Union and the existing situation, for example protection of fundamental rights, combating discrimination, safeguarding the security of citizens, strengthening social cohesion or promoting distributional justice

You need to establish the **'drivers'** – or causes – behind the problem (how particular factors lead to the problem). This will help you to tackle causes rather than symptoms (see example below). Problems should not be defined as a 'lack of something' or as 'need for something', as this can bias the definition of objectives and the choice of policy instruments.

Illustrating the incidence of the impacts associated with the problem

Tables and maps: A useful method may be to link problems with their underlying drivers on the basis of overview tables while considering the problem from the point of view of the different stakeholder groups affected:

PROBLEMS	DRIVERS
Air pollution	Firms do not bear the cost of pollution caused by their operations (market failure).
Firms unwilling to trade with countries X, Y, Z.	Protection of legal rights in these countries not adequately defined (regulatory failure).
Regional conflicts	Underdeveloped civil society/undemocratic political systems

Concrete examples: The problem definition chapter can also benefit from a simple, small-scale example of the essential aspects of the problem, for example in the context of a small business ('think small first').

5.2 Verifying the EU's right to act, and the justification for EU action

Once you have identified the problem and its causes, you should verify if the EU has the right to take action and if it is better placed than the Member States to tackle the problem. You should keep in mind that the EU Charter of Fundamental Rights places legal limits on the Union's right to act. The Commission has therefore decided that proposals must be scrutinized for compatibility with the Charter²¹.

You should link the problem to at least one article of the Treaties and the objectives they contain, as this is the basis for Union's right to act (**principle of conferral**):

- **Is the issue you are dealing with linked to at least one article of the Treaty, and the objectives it sets out?**
- **Is it an issue on which the Community has exclusive competence? If this is the case, then subsidiarity does not apply.**

If the Community does not have exclusive competence in the area in question, the **principles of subsidiarity** and **proportionality** apply.

The **subsidiarity principle** has two aspects which must both be analysed when you are examining whether Community action, legislative or non-legislative, is justified.

1. **Why can the objectives of the proposed action not be achieved sufficiently by Member States (Necessity Test)?**
2. **As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?**

²¹ See also the Communication on Compliance with the Charter of Fundamental Rights in Commission legislative proposals (COM(2005) 172). See also section 8.3.

Respecting the subsidiarity principle

The following box contains the questions you should answer when examining whether the two aspects are met in your case. You should not answer them on a yes/no basis, but rather use them to identify the arguments relating to subsidiarity which are relevant in the context of your initiative so that you can elaborate them in your IA report. These points should be substantiated with qualitative, and where possible, quantitative indicators

1. Does the issue being addressed have transnational aspects which cannot be dealt with satisfactorily by action by Member States? (e.g. reduction of CO2 emissions in the atmosphere)
2. Would actions by Member States alone, or the lack of Community action, conflict with the requirements of the Treaty? (e.g. discriminatory treatment of a stakeholder group)
3. Would actions by Member States alone, or the lack of Community action, significantly damage the interests of Member States? (e.g. action restricting the free circulation of goods)
4. Would action at Community level produce clear benefits compared with action at the level of Member States by reason of its scale?
5. Would action at Community level produce clear benefits compared with action at the level of Member States by reason of its effectiveness?

The answers to these questions may not be the same for each policy option that you examine. You should then answer the questions under each policy option. You should also bear in mind that in some cases the appropriate level for action may be international, rather than European or national.

An additional point should be borne in mind: any assessment of subsidiarity will evolve over time. This has two implications.

- First, it means that Community action may be scaled back or discontinued if it is no longer justified because circumstances have changed. It is important to bear this in mind when reviewing existing Community activities, for example in the context of the Commission's better regulation and simplification agenda. For this type of initiative, the IA report should demonstrate that EU action is still in conformity with the subsidiarity principle; you should not rely exclusively on a subsidiarity analysis that was made in the past.
- Secondly, it means that Community action, in line with the provisions of the Treaty, may be expanded where circumstances so require. This may include areas where there has been no, or only limited, Community action before. Given the potential political sensitivity of such new activities, the clearest possible justification on the basis of the above questions is essential. Reference to similar activities already carried out at Community level may be useful.

The Treaty also requires that Community action meets the conditions set by the **principle of proportionality**. This should be examined as part of the assessment and comparison of policy options (see section 7.2.).

The **Executive Summary** of the IA should contain a section presenting clearly your reasoning on subsidiarity and proportionality.

5.3 Developing a baseline scenario

**The problem definition must include a clear baseline scenario
as the basis for comparing policy options**

The aim of the baseline scenario is to explain how the current situation would evolve without additional public intervention – it is the "no policy change" scenario. A clear baseline scenario also provides the basis for comparing policy options. (Chapter 9 deals with this).

The baseline scenario depends on whether there are already national and EU policies in place:

- If there is no EU policy, the baseline means the continuation of "no EU policy". The "no EU policy" includes the expected effects of legislation which has been adopted but not yet implemented.
- Where there is already an EU policy, the baseline is the continuation of the current policy without any change, i.e. without any new or additional EU intervention.
- If the existing EU policy foresees a change (e.g. abolition of the milk quota in 2015), or a sunset clause, then the baseline can over time lead to a "no EU policy" scenario. For practical reasons, you may use the existing policy without the 'sunset' as the baseline, provided you have an option only reflecting the introduction of the sunset clause.

For these reasons it is important that you explain clearly the policy context of the initiative in an introductory chapter of the IA report.

To develop the 'no policy change' scenario, you will also need to **consider a wide range of factors** other than EU intervention; these include:

- Member State policies/regulations already in place;
- actions already decided or proposed by third countries, industries and other parties;
- evolution of relevant markets;
- recent trends in the problem and likely changes to the causes of those trends.

A good baseline should have a strong factual basis and, as far as possible, be expressed in quantitative terms. It should also be set for an appropriate time horizon (neither too long nor too short). The baseline projection has to provide a clear indication of how serious the problem is, or to what extent it would become more serious without immediate intervention, and whether there are irreversible consequences.

The baseline scenario should take into account the expected results of relevant legislation which has been adopted but not yet fully implemented. While the baseline should not include developments that depend on political decisions that have not yet been taken, there is one important exception to this: if the initiative is linked to other policy proposals already put forward by the Commission but not yet adopted by the legislator, these proposals need be assumed to be part of the baseline.

In describing the baseline scenario – as when assessing the impacts of any policy option – you may face the challenge that the projections are uncertain or that there is a risk attached to them, i.e. that an undesired development may – or may not - happen. Sensitivity analysis and risk assessment are tools to respond to these challenges in your problem description.

5.4 Sensitivity analysis

When the assumptions underlying the baseline scenario might vary as a result of external factors, you need to do a sensitivity analysis to assess whether the impacts of the policy options differ significantly for different values of the key variables.

This analysis will have to address the impact of different assumptions on the effectiveness of policy options, and where necessary describe alternative versions of the baseline scenario.

Sensitivity analysis can be used to explore how the impacts of the options you are analysing would change in response to variations in key parameters and how they interact²². The impact of your measure may be affected, for example, by changes in the rate of economic growth (x %) or the proportion (y %) of producers who adopt a voluntary standard. While these values are rarely known for sure, there is often a range of values that is more or less likely. Sensitivity analysis can be used to establish how variations in such parameters affect the impact of your measure. A useful form of sensitivity analysis is to identify switching points. In other words, by how much does the value of an uncertain factor or a key assumption have to change in order for the preferred option to change. You should then determine how likely it is that that critical value could be reached. You should ask for help from the IA or economic analysis unit in your DG.

5.5 Risk Assessment

An IA that addresses a problem in which uncertainty about serious negative outcomes (risk) is an issue should contain a risk assessment. If these risks may involve irreversible damage or fatalities on an unforeseeable scale, a separate formal risk assessment will have to be carried out on the basis of scientific expertise.

Decision-makers are often faced with the need to reduce or eliminate the risk of adverse effects to the environment or to health. When the problem you are dealing with is affected by risk, i.e. you can attach probabilities to different possible outcomes; the IA will have to include a risk assessment as a tool to determine the best policy to deal with this.

As a working definition you can equate the value of a given risk with the magnitude of the hazard, multiplied by the probability that it will occur. When the hazard under consideration may have consequences that are not yet fully scientifically established, and that may be irreversible, a full risk assessment by a scientific committee is necessary.

In such cases, particularly when risks to the environment and human, animal and plant health are involved, the 'precautionary principle' may be applied as a first step towards the **management of risk**.²³ This means that temporary decisions may need to be taken on the basis of limited or inconclusive evidence, and that more permanent arrangements are postponed until the necessary scientific assessment is available. In the light of the risk assessment, you will have to prepare further measures to manage the risk.

When will risk assessment be required?

A risk assessment will be necessary when:

1. there is a non-zero probability that a certain adverse event or development will occur
AND

²² For more on this see the JRC: <http://sensitivity-analysis.jrc.ec.europa.eu>

²³ For more information on the precautionary principle and its use by decision-makers for the management of risk, see the "Communication from the Commission on the precautionary principle", COM (2000) 1.

2. it is not predictable who will be (worst) affected AND
3. the negative consequences for certain parties (individuals, businesses, regions, sectors) will be very serious (fatalities, invalidity) and irreversible.

How to carry out risk assessment in the IA?

Three steps are necessary for risk analysis:

1. The first step is to **identify relevant risks**. You need to provide a clear description of the origin of the risk and the nature of the consequences it might have. The problem definition should set out who or what might be negatively affected, under what circumstances, and in what way.
2. The next step is to **determine the probability** that a negative consequence can occur and the **extent of the harm** that would materialise. You should quantify these two parameters as far as possible. All available scientific evidence should be used rather than subjective estimates. The extent of the harm can be difficult to measure in monetary terms, for example where harm relates to health or environmental impacts. Nevertheless, methods exist that can be used to monetise them (see annex 9).
3. Finally, you need to **describe alternative ways to reduce the identified risks** in the options section of the IA reports. Risks can rarely be reduced to zero without incurring large costs, and indeed risk analysis does not aim to eliminate risks at any cost but is rather a method to determine which measures can be used to reduce them in an efficient way. This can be done either by reducing the probability of such an event occurring, or by limiting the extent of negative consequences if it does occur, or by a combination of both. The impacts on the risk need to be quantified so that you can compare the different costs of reducing the risk with the actual risk reduction.

The results of the risk assessment should feed directly into the definition of objectives (i.e. whether the objective will be to eliminate or diminish the risk), and into the different policy options for managing the risk (e.g. remedies like compensation). Annex 10.4 gives more technical detail on issues of risk analysis.

6. WHAT ARE THE POLICY OBJECTIVES?

All Commission IAs must have *clear objectives* which are *directly related to solving the problems* which have been identified.

Only clearly defined objectives will make the level of ambition visible, show that the proposal respects the principles of subsidiarity and proportionality, help ensure coherence of Commission policies, and allow for identification and comparison of options for action and their likely impacts.

Without clear objectives, it is impossible to evaluate the extent to which the action has generated its intended effects.

Defining objectives may be an iterative process: the objectives are refined in the course of the IA work. The definition should:

- Set out *objectives that are clearly linked to the problem and its root causes*, respect the subsidiarity and proportionality principles, and correspond to Treaty objectives and Commission priorities and strategies (such as the Lisbon and Sustainable Development Strategies or the EU Chart of Fundamental Rights);
- Set out *general objectives* and *translate them into specific* and, where appropriate, *operational objectives*, thus setting a hierarchy of objectives.
- *Express the objectives in SMART terms* (Specific, Measurable, Achievable, Realistic, Time-dependent)

6.1 The role of objectives in an Impact Assessment

Without a clear understanding of what a future policy is supposed to achieve, it is difficult to identify possible courses of action, and even more difficult to compare policy options. Objectives provide the only effective criteria for assessing the success or failure of the proposed policy options. Without clear objectives it is also impossible to monitor implementation of the policy and to evaluate whether it has produced the desired effects. Finally, setting objectives is a key step in determining the level of ambition of any policy and in linking it to existing Community policies.

You should screen all objectives in terms of subsidiarity and proportionality (see chapter 5.2.).

6.2 Setting general, specific and operational objectives

To develop a coherent set of objectives, you should distinguish three levels: general objectives, specific objectives and operational objectives. You will not always need to consider objectives on all three levels. For example, an IA accompanying a strategy or White Paper may not need to set out operational objectives. On the other hand, the IA of a comitology decision might focus on operational objectives, because general and specific objectives will already have been formulated in the IA for the legislation on which the comitology process is based.

When you define objectives at different levels, there should be clear links between them. Sometimes these relationships are not only vertical (as in a hierarchy of objectives), but also horizontal, when objectives can reinforce but also contradict one another. You should also take account of any external factors outside your policy (and control) that may have favourable or adverse effects on your objectives.

General objectives	<ul style="list-style-type: none"> • These are Treaty-based goals which the policy aims to contribute to. • They are therefore the link with the existing policy setting. • These objectives should induce policy-makers to take account of the full range of existing policies with the same or similar objectives. • They relate to impact indicators.²⁴
Specific objectives	<ul style="list-style-type: none"> • They take account of the envisaged specific domain and particular nature of the policy intervention under consideration. • The definition of these objectives is a crucial step in the appraisal as they set out what you want to achieve concretely with the policy intervention. • They correspond to result indicators.
Operational objectives	<ul style="list-style-type: none"> • These are the objectives defined in terms of the deliverables or objects of actions. • These objectives will vary considerably depending on the type of policy examined. • They need to have a close link with output indicators.

6.3 When should you set objectives?

Given that objectives are closely linked to the other stages of the IA process, you may not be able to define them in one go.

²⁴ Annex 13 provides more details.

- Once you have defined the problem, you should be able to establish **the general policy objectives** which the *intervention aims to contribute to*.
- The **specific and operational objectives** may change during the IA process as you gain more insight into the effectiveness and efficiency of various policy options. For example, as you work on a particular option you may encounter a drawback that you had not thought about before. It is then good practice to define a new (specific or operational) objective on avoiding this drawback. This ensures that the other options are also assessed on this aspect and consequently that the scoring and comparison of the options is carried out on the same set of criteria.

6.4 Making your objectives SMART

Your objectives should be directly related to the problem and its root causes. They should be 'SMART' - it may not be possible to make them all fully SMART, but you should aim to satisfy as many of the criteria as possible.

SMART-Objectives should be:

Specific: Objectives should be precise and concrete enough not to be open to varying interpretations. They must be understood similarly by all.

Measurable: Objectives should define a desired future state in measurable terms, so that it is possible to verify whether the objective has been achieved or not. Such objectives are either quantified or based on a combination of description and scoring scales.

Achievable: If objectives and target levels are to influence behavior, those who are responsible for them must be able to achieve them.

Realistic: Objectives and target levels should be ambitious - setting an objective that only reflects the current level of achievement is not useful - but they should also be realistic so that those responsible see them as meaningful.

Time-dependent: Objectives and target levels remain vague if they are not related to a fixed date or time period.

6.5 Linking objectives with other parts of the analysis

The objectives you set constitute the link between the problem description and the policy options that you will identify, assess and compare.

- **Link objectives with your problem analysis:** Be sure that your objectives are directly related and proportionate to the problem and its root causes.
- **Link objectives with the identification of policy options:** this is an iterative process in which you revise your objectives and define your policy options more clearly. You cannot identify policy options without having a clear idea of the objectives, but equally you cannot lay down detailed objectives without taking into account the specificities of various policy options.
- **Link objectives with the assessment and comparison of policy options:** The criteria that you should use when comparing the policy options are closely linked to the objectives. These criteria, "effectiveness", "efficiency" and "consistency", play a role already at the initial screening of "candidate" policy options. (For more information on the criteria see section 9.2.)
- **Link objectives with your future monitoring and evaluation activities:** Without clear objectives you cannot monitor and evaluate whether your policy is on track. SMART objectives are needed to define good indicators. This in turn will allow you to monitor progress and evaluate the extent to which you have achieved your objectives.

7. WHAT ARE THE POLICY OPTIONS?

- Options must be clearly related to the objectives and must be proportionate.
- Start by considering a wide but credible range of options
- Avoid presenting only the status quo option, the "extreme" option and the preferred option or presenting complementary actions only.
- The set of options should include:
 - the "no policy change" baseline scenario;
 - "no EU action" (e.g. discontinuing existing EU action)
 - where legislation already exists, improved implementation/ enforcement, perhaps with additional guidance;
 - self- and co-regulation.
 - international standards where these exist
- Narrow down the options by screening them for technical and other constraints, and by assessing them against criteria of effectiveness, efficiency and coherence with other overarching EU policy objectives.
- Explain clearly the reasons for excluding certain options from further analysis.
- Analyse the remaining options in depth.
- Where relevant, distinguish options at two levels:
 - Options for *the content* of the intervention.
 - Options for *the type of intervention* - Regulation, Directive, Recommendation, Communication, self-regulation, co-regulation

In an IA for a legislative proposal, try to anticipate and assess in your options major amendments that Council and the European Parliament may introduce in the policy process.

7.1 Why consider alternative policy options?

Once you have defined the objectives, the next phase of the IA exercise is to establish which options and delivery mechanisms are most likely to achieve those objectives.

Considering a wide range of policy options will force you to think 'out of the box', and also provides greater transparency. It is a way to show policy-makers and stakeholders that alternative options that they may prefer have been analysed seriously, and to explain why they were not pursued. It makes it easier to explain the logic behind the proposed choices and to avoid unnecessary discussions of options that will not help to achieve the objectives.

Policy options must be closely linked both to the causes of the problem and to the objectives. You should define the appropriate level of ambition for the options in the light of constraints such as compliance costs or **considerations of proportionality**. You also need to identify the appropriate policy instrument (legal acts, legal acts of Member States, self-regulation, co-regulation and economic incentives). These instruments can of course be combined in a package, and/or co-ordinated with Member State action. Annex 7 provides further information on identifying options.

7.2 Respecting proportionality when defining options

The principle of proportionality states that any Community action should not go beyond what is necessary to achieve satisfactorily the objectives which have been set. It is closely linked to the principle of subsidiarity discussed in section 5.2. Community action should be as simple as possible and leave as much scope for national decision as possible, and should respect well established national arrangements and legal systems. However, when defining options, you should also take aspects of transposition (such as setting appropriate

implementation periods) and potential obstacles to compliance (such as clarity of the requirements) into account (see section 8.6 for more details).

The following questions should be used to examine the proportionality of the options proposed in an IA. They are not designed to be answered on a yes/no basis but rather should be explained and supported with qualitative and quantitative evidence where possible. Examining the proportionality of a range of options will help you to establish a shortlist of feasible options to be analysed in depth.

Applying the proportionality principle

<p style="text-align: center;">Scope of instrument</p> <ol style="list-style-type: none">1. Does the option go beyond what is necessary to achieve the objective satisfactorily?2. 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)3. If the initiative creates a financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens, is this cost minimised and commensurate with the objective to be achieved?4. Will the Community action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?5. While respecting Community law, are well-established national arrangements and special circumstances applying in individual Member States respected? <p style="text-align: center;">Nature of instrument</p> <ol style="list-style-type: none">6. Is the form of Community action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?7. Is there a solid justification for the choice of instrument - regulation, (framework) directive, or alternative regulatory methods such as co-regulation or self-regulation?
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7.3 How to identify and screen policy options?

The first step is to think large and to draw up an extensive list of possible options that are likely to be able to achieve the proposed objectives. This initial list of options can then be reduced by a first screening of their likely impacts to arrive at a shorter list of options that is then analysed in depth (see also section 8.2). During this process you should bear the following points in mind:

- All of your options should be **realistic** - you should avoid the trap of considering only the “no new action option”, the “preferred option”, and an “extreme option” which is not credible.
- Remember to **keep an open mind**. Even if a particular option seems to be a clear front-runner, other promising options should not be excluded outright. You should also consider how the impacts of this ‘front runner’ will vary if key parameters change, e.g. allowing more time for objectives to be met or aiming for more or less ambitious objectives. You can use ‘sensitivity analysis’ for this (see 5.4).
- The option of ‘**no new EU action**’ must always be considered as a viable option, except in cases where the Treaties lay down a specific obligation to act.
- Where legislation is already in place, **better enforcement and implementation** should always be considered, perhaps with improved guidance.
- **Less can be more**: again where legislation is already in place, a ‘doing less’ option could be considered. If existing measures do not produce the desired effects, creating a new instrument may not be the best remedy. Streamlining, simplifying or even repealing the existing legislation might produce better results.

- Always consider **alternative approaches to ‘classical’ forms of regulation**. Consider the full range of alternative actions available to the Commission. Is self-regulation a feasible option? Could the objectives be met through a voluntary agreement? Is an information and education campaign sufficient? Could the objectives be met by introducing a new or amending an existing European Standard?
- **Take account of existing EU policies**, including those which Member States are still transposing and, if possible, relevant proposals which are still being discussed in the European Parliament and Council if you have not included them in the baseline. You should also take account of existing or planned Member State policies or international agreements that might affect the impact of an option.
- Do not just look at the different legal (implementation) options, but also at the **content**. The choice between Directives, Regulations, Recommendations etc should be clearly driven by what needs to be done to achieve the objectives.
- Examine closely options that can count on **considerable support**, but be aware that public and/or political support alone cannot be the sole determining factor in defining and analysing alternative options. You should be careful about discarding too quickly options which do not have considerable support from a certain sector.
- **Options should be ‘complete’ and sufficiently well developed** to allow you to differentiate them on the basis of their performance against the criteria of effectiveness, efficiency and coherence with overarching EU objectives. (see Chapter 9).. You should also avoid 'bundling' individual elements/sub-options of different options into a 'preferred' option after the analysis, as this makes it difficult to assess the impact of the preferred option as a whole against the baseline. Where you do adopt this approach, you should carry out an analysis of this preferred option.

The aim of all interventions is of course to provide benefits that exceed any possible negative impacts. In the terminology of cost-benefit analysis this means that you should select options that promise the greatest net benefits.

Annex 7 provides further information on identifying options.

8. WHAT ARE THE LIKELY ECONOMIC, SOCIAL AND ENVIRONMENTAL IMPACTS?

- **Identify direct and indirect environmental, economic and social impacts and how they occur.**
- **Identify who is affected by these impacts (including those outside the EU) and in what way.**
- **Identify whether there are specific impacts that should be examined (fundamental rights, SMEs, consumers, competition, international, national, regional).**
- **Assess the impacts in qualitative, quantitative and monetary terms or explain in the IA why quantification is not possible or proportionate.**
- **Consider the risks and uncertainties in the policy choices, including expected compliance patterns.**

8.1 How to approach the analysis of impacts?

In your analysis of impacts, you should address the likely economic, social and environmental impacts - both intended and unintended - for each option, as well as potential trade-offs and synergies.

The aim of this analysis is to provide clear information on the impacts of the policy options as a basis for comparing them both against one other and against the status quo, and possibly for ranking them in relation to clearly identified evaluation criteria (see chapter 9.3).

In presenting the impacts of different policy options **the IA should assess the impacts of policy options as *net changes* compared to the ‘no policy change’/baseline** (see chapter 5.3). You should show how each policy option differs from the baseline scenario, in terms of their characteristics and of the results that they would produce. **The more quantification you can provide, the more convincing the analysis will generally be.**

You should keep in mind that the credibility of an IA depends to a large extent on providing results that are based on reliable data and robust analysis, and which are transparent and understandable to non-specialists. This exercise will usually require an inference from the collected data, either formally through statistical analysis or model runs, or more informally by drawing on an appropriate analogy with measured impact or activities. This assessment should go beyond the immediate and desired aspects (the direct effects) and take account of indirect effects such as side-effects, knock-on effects in other segments of the economy and crowding out or other offsetting effects in the relevant sector(s).

A variety of tools and models is available for assessing impacts and these are presented in Annex 11. The Commission has also developed a set of indicators to monitor the implementation of the EU sustainable development strategy.²⁵ In assessing impacts it is recommended that you use these indicators if they are relevant for the proposal.

8.2 The three steps of impact analysis

The analysis of impacts consists of three major steps:

Step 1	Identification of economic, social and environmental impacts
Step 2	Qualitative assessment of the more significant impacts
Step 3	In-depth qualitative and quantitative analysis of the most significant impacts

The sources of information and data you need for the three steps will vary. You may be able to carry out steps 1 and 2 by drawing on expertise available in the Commission, desk reviews of existing research, studies and evaluations, possibly enriched by involving outside experts, and by using the results of consultations with stakeholders. For step 3, you will probably need to draw on the information sources mentioned in chapter 4.

Step 1	Identify, economic, social and environmental impacts of a policy, why they occur and who is affected
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The first step is to identify those impacts, both inside and outside the EU, that are likely to occur as a consequence of implementing the policy. Some of those will be intentional and are indeed the objectives of the policy. However, it is also necessary to try to identify possible unintended impacts and the impact of how different options might interact.

Tables 1 to 3 provide a useful basis on which to screen options against possible economic, social and environmental impacts.²⁶ **Certain questions also address issues of compatibility with the Charter of Fundamental Rights.** These questions are designed to help you to develop your analysis, and should not be answered with a simple 'yes' or 'no'.

²⁵ SEC(2005) 161 final.

²⁶ The IA TOOLS 'Impact inventory' may also be helpful for this <http://iatools.jrc.ec.europa.eu>.

You may of course need to identify additional questions which are relevant to your area. This approach should result in a **comprehensive picture** of the potential effects of the policy option.

You should always identify who is affected by the impacts and when. Options that would be beneficial for society as a whole may have positive and negative impacts that are spread unevenly across society and over time. You should consider two distinct **types of distributional impacts**:

- **Impacts on different social and economic groups:** identifying ‘winners’ and ‘losers’ can help you to anticipate obstacles to the proposed action and may point to the need to change its design, or to introduce measures to mitigate the negative impacts. For example, a proposal may be beneficial for consumers, but have costs which fall mainly on enterprises. There may be distributional effects even within a given group (e.g. between SMEs and larger companies, between market entrants and incumbents, between low-income and higher-income households, etc). Finally, the impacts may differ between Member States or regions (see section 8.3).
- **Impacts on existing inequalities.** You should for instance compare regional, gender impacts and impacts on vulnerable groups of the proposed action to see if it is likely to leave existing inequalities unchanged, aggravate them, or help to reduce them. This is not a simple matter: for example, differences between male and female lifestyles may mean that a proposal which appears to be neutral as regards gender equality will in practice have different impacts on men and women.

Table 1: Economic Impacts

ECONOMIC IMPACTS	KEY QUESTIONS
Functioning of the internal market and competition	<ul style="list-style-type: none"> • What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc?
Competitiveness, trade and investment flows	<ul style="list-style-type: none"> • What impact does the option have on the global competitive position of EU firms? Does it impact productivity • What impact does the option have on trade barriers? • Does it provoke cross-border investment flows (including relocation of economic activity)?
Operating costs and conduct of business/Small and Medium Enterprises	<ul style="list-style-type: none"> • Will it impose additional adjustment, compliance or transaction costs on businesses? • How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? • Will it lead to new or the closing down of businesses? • Are some products or businesses treated differently from others in a comparable situation?
Administrative burdens on businesses	<ul style="list-style-type: none"> • 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)? • What is the impact of these burdens on SMEs in particular?
Public authorities	<ul style="list-style-type: none"> • Does the option have budgetary consequences for public authorities at different levels of government (national, regional, local), both immediately and in the long run?

ECONOMIC IMPACTS	KEY QUESTIONS
	<ul style="list-style-type: none"> • Does it bring additional governmental administrative burden? • Does the option require the creation of new or restructuring of existing public authorities?
Property rights	<ul style="list-style-type: none"> • Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? • Or will there be a complete loss of property?
Innovation and research	<ul style="list-style-type: none"> • Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production methods, technologies and products? • Does it affect intellectual property rights (patents, trademarks, copyright, other know-how rights)? • Does it promote or limit academic or industrial research? • Does it promote greater productivity/resource efficiency?
Consumers and households	<ul style="list-style-type: none"> • Does the option affect the prices consumers pay? • Does it impact on consumers' ability to benefit from the internal market? • Does it have an impact on the quality and availability of the goods/services they buy, on consumer choice and confidence? (cf. in particular non-existing and incomplete markets – see Annex 8) • Does it affect consumer information and protection? • Does it have significant consequences for the financial situation of individuals / households, both immediately and in the long run? • Does it affect the economic protection of the family and of children?
Specific regions or sectors	<ul style="list-style-type: none"> • Does the option have significant effects on certain sectors? • Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? • Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?
Third countries and international relations	<ul style="list-style-type: none"> • How does the option affect trade or investment flows between the EU and third countries? How does it affect EU trade policy and its international obligations, including in the WTO? • Does the option affect specific groups (foreign and domestic businesses and consumers) and if so in what way? • Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist? • Does it affect EU foreign policy and EU/EC development policy? • What are the impacts on third countries with which the EU has preferential trade arrangements? • Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries?
Macroeconomic environment	<ul style="list-style-type: none"> • Does it have overall consequences of the option for economic growth and employment? • How does the option contribute to improving the conditions for investment and the proper functioning of markets? • Does the option have direct impacts on macro-economic stabilisation?

Table 2: Social Impacts

SOCIAL IMPACTS	KEY QUESTIONS
Employment and labour markets	<ul style="list-style-type: none"> • Does the option facilitate new job creation? • Does it lead directly or indirectly to a loss of jobs? • Does it have specific negative consequences for particular professions, groups of workers, or self-employed persons? • Does it affect particular age groups? • Does it affect the demand for labour? • Does it have an impact on the functioning of the labour market? • Does it have an impact on the reconciliation between private, family and professional life?
Standards and rights related to job quality	<ul style="list-style-type: none"> • Does the option impact on job quality? • Does the option affect the access of workers or job-seekers to vocational or continuous training? • Will it affect workers' health, safety and dignity? • Does the option directly or indirectly affect workers' existing rights and obligations, in particular as regards information and consultation within their undertaking and protection against dismissal? • Does it affect the protection of young people at work? • Does it directly or indirectly affect employers' existing rights and obligations? • Does it bring about minimum employment standards across the EU? • Does the option facilitate or restrict restructuring, adaptation to change and the use of technological innovations in the workplace?
Social inclusion and protection of particular groups	<ul style="list-style-type: none"> • Does the option affect access to the labour market or transitions into/out of the labour market? • Does it lead directly or indirectly to greater equality or inequality? • Does it affect equal access to services and goods? • Does it affect access to placement services or to services of general economic interest? • Does the option make the public better informed about a particular issue? • Does the option affect specific groups of individuals (for example the most vulnerable or the most at risk of poverty, children, women, elderly, the disabled, unemployed or ethnic, linguistic and religious minorities, asylum seekers), firms or other organisations (for example churches) or localities more than others? , firms, localities more than others? • Does the option significantly affect third country nationals?
Gender equality, equality treatment and opportunities, non - discrimination	<ul style="list-style-type: none"> • Does the option affect the principle of non-discrimination, equal treatment and equal opportunities for all? • Does the option have a different impact on women and men? • Does the option promote equality between women and men? • 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?
Individuals, private and family life, personal data	<ul style="list-style-type: none"> • Does the option impose additional administrative requirements on individuals or increase administrative complexity? • Does the option affect the privacy, of individuals (including their home and communications)? • Does it affect the right to liberty of individuals? • Does it affect their right to move freely within the EU? • Does it affect family life or the legal, economic or social protection of the family? • Does it affect the rights of the child? • Does the option involve the processing of personal data or the concerned individual's right of access to personal data ?
Governance, participation, good administration, access to justice, media and ethics	<ul style="list-style-type: none"> • Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? • Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? • Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action?

SOCIAL IMPACTS	KEY QUESTIONS
	<ul style="list-style-type: none"> • Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? • Will the option affect the individual's rights and relations with the public administration? • Does it affect the individual's access to justice? • Does it foresee the right to an effective remedy before a tribunal? • Does the option make the public better informed about a particular issue? Does it affect the public's access to information? • Does the option affect political parties or civic organisations? • Does the option affect the media, media pluralism and freedom of expression? • 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)?
Public health and safety	<ul style="list-style-type: none"> • Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)? • Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise, air, water or soil quality? • Will it affect health due to changes energy use and/or waste disposal? • Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? • Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?
Crime, Terrorism and Security	<ul style="list-style-type: none"> • Does the option improve or hinder security, crime or terrorism? • Does the option affect the criminal's chances of detection or his/her potential gain from the crime? • Is the option likely to increase the number of criminal acts? • Does it affect law enforcement capacity? • Will it have an impact on security interests? • Will it have an impact on the right to liberty and security, right to fair trial and the right of defence (?) • Does it affect the rights of victims of crime and witnesses?
Access to and effects on social protection, health and educational systems	<ul style="list-style-type: none"> • Does the option have an impact on services in terms of quality/access for all? • Does it have an effect on the education and mobility of workers (health, education, etc.)? • Does the option affect the access of individuals to public/private education or vocational and continuing training? • Does it affect the cross-border provision of services, referrals across borders and co-operation in border regions? • Does the option affect the financing / organisation / access to social, health and care services? • Does it affect universities and academic freedom / self-governance?
Culture	<ul style="list-style-type: none"> • Does the proposal have an impact on the preservation of cultural heritage? • Does the proposal have an impact on cultural diversity? • Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?
Social impacts in third countries	<ul style="list-style-type: none"> • Does the option have a social impact on third countries that would be relevant for overarching EU policies, such as development policy? • Does it affect international obligations and commitments of the EU arising from e.g. the ACP-EC Partnership Agreement or the Millennium Development Goals? • Does it increase poverty in developing countries or have an impact on income of the poorest populations?

Table 3: Environmental impacts

ENVIRONMENTAL IMPACTS	KEY QUESTIONS
The climate	<ul style="list-style-type: none"> • Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane etc) into the atmosphere? • Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs etc)? • Does the option affect our ability to adapt to climate change?
Transport and the use of energy	<ul style="list-style-type: none"> • Does the option affect the energy intensity of the economy? • Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc) used in energy production? • Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? • Does it increase or decrease vehicle emissions? • Will the option increase/decrease energy and fuel needs/consumption?
Air quality	<ul style="list-style-type: none"> • 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)?
Biodiversity, flora, fauna and landscapes	<ul style="list-style-type: none"> • Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? • Does it affect protected or endangered species or their habitats or ecologically sensitive areas? • Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones? • Does the option affect the scenic value of protected landscape?
Water quality and resources	<ul style="list-style-type: none"> • Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources?
Soil quality or resources	<ul style="list-style-type: none"> • Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?
Land use	<ul style="list-style-type: none"> • Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? • Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?
Renewable or non-renewable resources	<ul style="list-style-type: none"> • Does the option affect the use of renewable resources (fish etc) and lead to their use being faster than they can regenerate? • Does it reduce or increase use of non-renewable resources (groundwater, minerals etc)?
The environmental consequences of firms and consumers	<ul style="list-style-type: none"> • Does the option lead to more sustainable production and consumption? • Does the option change the relative prices of environmental friendly and unfriendly products? • Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc? • Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?
Waste production / generation / recycling	<ul style="list-style-type: none"> • Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?
The likelihood or scale of environmental risks	<ul style="list-style-type: none"> • Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms?

ENVIRONMENTAL IMPACTS	KEY QUESTIONS
Animal welfare	<ul style="list-style-type: none"> • Does the option have an impact on health of animals? • Does the option affect animal welfare (i.e. humane treatment of animals)? • Does the option affect the safety of food and feed?
International environmental impacts	<ul style="list-style-type: none"> • Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?

Step 2	Identifying the more important impacts
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The assessment of impacts in this step is generally qualitative. In this approach, you should:

- Identify the areas in which the proposed action is intended to produce benefits, as well as the areas where this may lead to direct costs or unintended negative impacts.
- Assign likelihoods (e.g. low, medium or high probability) that the impact will occur (or conversely the risk that the impact will not occur). This can be done by setting out your assumptions about factors that may influence the probability that impacts will occur, but which are outside the control of those managing the intervention.
- Assess and estimate the magnitude of each impact (providing reasonable ranges). This can be done by considering the influence of the intervention on the behaviour of addressees and vis-à-vis the socio-economic and environmental context in which the intervention takes place. Ask yourself whether some of the impacts could be irreversible (See also Annex 12 on the precautionary principle).
- Assess the importance of impacts on the basis of the two preceding elements (e.g. from low likelihood/low magnitude through to high likelihood/high impact).

The **causal model** described in Annex 11.2 provides a basis on which you can identify the main drivers and causal links underlying the impacts you have identified.

When identifying impacts, you should keep the following points in mind:

- Consider both short-term and long-term impacts - it is often easier to identify short-term effects, but this does not mean that they are more important.
- Do not overlook impacts that cannot readily be expressed in quantitative or monetary terms.
- Remember that different factors which influence impacts also interact with one another.
- Take account of how the impacts of the proposal may be affected by the implementation of other proposals, particularly if the proposal is part of a 'package' and
- Consider impacts in the context of Treaty objectives and the EU's over-arching policy goals, such as respect for Fundamental Rights, promoting sustainable development, achieving the goals of the Lisbon Strategy, and the EU energy strategy.

One way of presenting this sort of assessment of impacts is to build an impact matrix. This involves the following five tasks:

- Break the policy options down into their main actions (the rows of the matrix).
- Identify the main types or categories of impacts (the columns of the matrix), organised according to a time horizon where possible.
- Indicate in each cell the likelihood of an impact (certain, probable, unlikely).
- Indicate in each cell whether the impact is expected to be positive or negative, or uncertain. Where it is positive or negative the magnitude can also be indicated.

- Indicate in each cell the addressees (or affected populations), the timescale over which the impacts are expected to occur.

Step 3	In-depth analysis of the most significant impacts
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Building on the structured, qualitative analysis of step 2, further in-depth analyses should be undertaken to produce a quantitative/monetary estimate of expected benefits and costs. This can take a number of forms:

- In-depth analysis of expected impacts over time which typically requires a case study/scenario approach. This type of analysis can be implemented on its own, though in reality it is generally used in conjunction with a quantitative analysis of impacts.
- Quantitative estimation of impacts: the impacts are estimated using quantitative techniques, varying from simple extrapolation - based for instance on previously derived coefficients (e.g. units of CO₂ per unit of industrial activity) - through statistical inference on the basis of similar impacts and occurrences elsewhere (e.g. impact assessment work in Member States and other countries) to full-fledged quantitative modelling. Essentially, the aim is to understand the extent of the impacts of the policy options and to estimate the costs and benefits in monetary form when this is feasible. Annexes 9 and 11 provide guidance on how to undertake a quantitative analysis and set out some important rules for economic analysis.²⁷

If quantification/monetisation is not feasible, explain why.

8.3 Assessing specific aspects of economic, social and environmental impacts

This section provides summaries of further guidance that was developed for assessing specific or sectoral aspects of economic, social and environmental impacts. This information is presented more fully in annexes 8, 9 and 10

Impacts on fundamental rights: All Commission proposals have to be compatible with the EU Charter of Fundamental Rights, and the Commission has decided that impact assessments must take into account the impacts of initiatives on fundamental rights as laid out in the Charter.²⁸ These impacts should be fully identified and assessed qualitatively. The full list of fundamental rights is provided in annex 8.1 and will help you to identify where your policy options may have an impact. As fundamental rights are horizontal in nature, they may be relevant in each of the three pillars of impact assessment – economic, social and environment – as indicated in the questions in tables 1 to 3. Certain fundamental rights are absolute and cannot be limited or subject to derogation: others can only be limited or derogated from subject to a demonstration of necessity and, thereafter, proportionality. This analysis of impacts will be complemented by the legal verification of compliance with the Charter that takes place when the related proposal is being prepared.

Social impacts: A "Toolkit" is available on the website of DG EMPL²⁹ which provides guidance on potential impacts in the areas of:

- (1) Employment and labour market;
- (2) Standards and rights related to job quality;
- (3) Social inclusion and protection of particular groups;
- (4) Gender equality, equal treatment and opportunities, non –discrimination;

²⁷ For reasons of comparability it is recommended to apply the standard discount rate of 4% (see Annex 11.6)

²⁸ COM(2005)172.

²⁹ http://ec.europa.eu/employment_social/evaluation/guidance_en.html

(5) Access to and effects on social protection, health and educational systems and

(6) Public Health³⁰ and Safety

An overview of statistics and available information, both internal and external to the Commission, as well as a review of available models and the most relevant recent studies is provided. For each of the selected areas, a description of the EU policy and legal framework, and the main potential effects to be explored is also described. Annex 8.2 provides further guidance on how to assess impacts on the number and quality of jobs.

Proposed policy options can often have different impacts on specific social groups, which may affect their income or the quality of their lives. The result can be that more people will be reduced to poverty or see their chances to participate fully in society negatively affected. The questions in Table 2 (social impacts) of the previous section under "Social inclusion and protection of particular groups" may be used for a first identification of such groups. In these cases it is essential to include relevant organisations and NGOs in your consultation efforts, with a view to suggest remedies or alternative approaches. Unit 03 of DG EMPL will help you to identify the relevant contacts.

Impacts on SMEs:

Due to their size and scarce resources, SMEs can be affected by the costs of regulations 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 for benefiting from economies of scale. SMEs in general find it more difficult to access capital and as a result the cost of capital for them is often higher than for larger businesses.

The Commission in the **Small Business Act** has made a commitment to implementing the "**Think Small First**" principle in its policy-making, to assess the impact of forthcoming legislation and administrative initiatives on SMEs (the "SME-test"), and to take the results of this analysis into account when designing proposals.³¹ Your IA should reflect this in each of the analytical steps.

The IA should analyse whether SMEs are disproportionately affected or disadvantaged compared to large companies and if so, options should cover alternative mechanisms and flexibilities in approach that might help SMEs to comply. Annex 8.4 provides further guidance on assessing impacts on SMEs and on possible mitigation measures. Unit E4 of DG Enterprise and Industry will provide advice and support on all issues related to impacts on SMEs.

Impacts on competition in the internal market:³² Options may have an influence on competition, and to screen them for possible negative impacts, you should start by determining in particular if they include:

- Rules on liberalisation (of formerly monopolised network utilities such as electricity, telecoms, postal sector, public transport, etc.) and internal market measures;
- Measures raising or lowering the barriers to entry or exit, making it harder or easier for firms to enter or leave the market;
- Rules introducing special commercial rights (e.g. IPRs) or exempting certain activities from the application of the competition rules;
- Sectoral rules pursuing economic, environmental or regional policy goals;
- General rules (e.g. corporate law) governing economic activity

³⁰ To assess impacts on health/health systems the following tool available via DG SANCO website can be useful: http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf

³¹ See COM(2008)394 A Small Business Act for Europe. See also the report of the expert group "Models to reduce the disproportional regulatory burden on SMEs" (http://ec.europa.eu/enterprise/entrepreneurship/support_measures/regmod/index.htm).

³² For consideration of competition impacts you should consult the additional guidance prepared by DG COMP and available on the Europa website at <http://ec.europa.eu/comm/competition/publications/advocacy>

- If so, you should assess whether the option contains rules which:
- exempt a market/sector from competition rules, thus creating/strengthening a monopoly? (e.g. the defence sector or certain agricultural products);
- interfere with the way firms market or price their products/services, limit or reserve distribution for certain channels/ intermediaries, thus reducing consumer choice or creating barriers for newcomers (e.g. advertising or marketing restrictions, rules on prices/ quality standards);
- facilitate or induce companies to agree on prices or divide up customers/markets, thus driving up consumer prices or decreasing innovative activity? (e.g. certain market organizations for agricultural products);
- restrict access to resources (such as raw materials, land, IPRs, know-how or process technology) in concentrated markets, thus excluding or delaying market entry of alternative products/services (e.g. in new media, IT sectors or in the pharmaceutical sector);
- favour incumbents at the expense of new entrants thus mitigating the beneficial effects of liberalisation (e.g. depriving consumers of benefits such as increased choice or more competitive prices in the telecoms, energy, or transport sectors).

Consumer impacts: These impacts should be identified and possibly quantified. A handbook is available on DG SANCO website.³³ Annex 8.3 provides additional guidance on how to take account of consumer impacts.

External effects of transport: A handbook with the available estimates and methodologies to assess impacts of noise, air pollution, CO2 emissions and accidents of transport activities is available on DG TREN website.³⁴

Impacts at national and regional level: While your IA will typically examine problems that can be addressed by action at EU-level, the problem may have specific relevance for certain Member States, groups of Member States (such as new or smaller Member States, Mediterranean/Nordic MS), or regions. The options you develop to tackle the problem may also affect different parts of the EU in very different ways, and you should therefore take account of impacts in relation to Treaty objectives such as convergence. It can be helpful to present data on a range of Member States, e.g. four of five different Member States in terms of new and old, small and large and north and south.

The IA should take these disaggregated effects into account. Policy options should be assessed for the possibility that impacts, positive or negative, will be spread unevenly. When a single Member State or region is disproportionately affected (so-called “outlier” impact), this should be mentioned. Where such disparities appear to be significant, they should be analysed as they may be a reason to adapt the initiative, for instance to offer mitigating or transitional measures for the “outlier”. This may in some cases justify a further quantification and monetisation of costs and benefits for specific regions.³⁵

If you need additional information on these impacts, you should organise targeted consultations for the relevant stakeholders and affected parties in such regions. The Committee of the Regions may be able to provide assistance in these cases.

International impacts: Every IA should establish whether proposed policy options have an impact on relations with third countries. In particular they should look at:

³³In cases where a proposal is anticipated to have a significant impact on consumer welfare, or when the justification for policy intervention is based on harm suffered by consumers the following handbook can be consulted: http://ec.europa.eu/consumers/strategy/facts_studies_en.htm?update16jan

³⁴ http://ec.europa.eu/transport/costs/handbook/index_en.htm

³⁵ DG REGIO C.3 can provide access to its regional databases and the Geographic Information System (GIS) services as well as contact with the European Spatial Planning Observatory (ESPON), which has undertaken research on the territorial impact of EU policies.

- The competitiveness of European businesses: you should analyse the impacts of the policy to see how the objectives can be achieved while avoiding or minimising potential negative impacts on European competitiveness. This could include an analysis of similar regulations which already exist in the EU's main trading partners.
- Trade relations with third countries: some policies may affect trade or investment flows between the EU and third countries; the IA should analyse how different groups (foreign and domestic businesses and consumers) are affected, and help to identify options which do not create unnecessary barriers.
- Impact on WTO obligations: it should be analysed which impact each proposed policy option has on the international obligations of the EC under the WTO Agreement; the IA should examine whether the policy options concern an area in which international standards exist.
- Impacts on developing countries: initiatives that may affect developing countries should be analysed for their coherence with the objectives of the EU development policy. This includes an analysis of consequences (or spill-overs) in the longer run in areas such as economic, environmental, social or security policy.³⁶

You should already identify in the problem definition whether international aspects need to be analysed. You should refer where relevant to existing bilateral dialogues, agreements, or standards, e.g. the regular EU-US regulatory dialogue or the provisions on Policy Coherence for Development of the ACP-EC partnership agreement. The policy options and impacts sections should analyse in greater detail what the specific impacts may be, how undesired effects can be avoided or minimised, how the options compare in this respect and what trade-offs have to be addressed in the final policy choice. The IA report should reflect how and to what extent the evaluation of international impacts has been taken into account in the comparison of options.

To ensure that these aspects are dealt with appropriately in the IA, it is essential that you involve the relevant services in the IASG. Their representatives can also help to ensure that stakeholders in third countries participate in the consultation process. Existing international policy dialogues can also be used to keep third countries fully informed of forthcoming initiatives, and as a means of exchanging information, data and results of preparatory studies with partner countries and other external stakeholders.

8.4 Assessing administrative burdens

For all policy options, the IA should provide details of the information obligations for businesses, for citizens and national/regional/local administrations that are likely to be added or eliminated if the option were implemented.

In those cases in which the change in administrative burden is likely to be significant, the effects should be quantified using the EU Standard Cost Model.

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 information obligations** for each of the options. This mapping should show how policy options differ in terms of information obligations. You should then determine which are likely to impose **significant** administrative burdens (usually through a qualitative assessment of the likely number of entities concerned as well as the frequency and complexity of required actions). Significant burdens should then be roughly quantified (monetary estimates) on the basis of the EU 'Standard Cost Model'. This can be done through reasoning by analogy, with the help of the '**Administrative Burdens Calculator**'

³⁶ Further information on the assessment of impacts on developing countries can be found in annex 8.8 and in a guidance document available on DG DEV website: <http://www.cc.cec/home/dgserv/dev/newsite/index.cfm?objectid=B2B23341-9062-F9B0-3B44AB431A98B352>

and the 'EU database on Administrative Burdens'.³⁷ A greater level of detail is expected for the monetary assessment of administrative burdens stemming from the preferred option. In cases where the reduction of the administrative burden is an explicit objective, the effects should be quantified using the EU Standard Cost Model.

For policy options that entail new information obligations, you should indicate in the IA how this information contributes to the effectiveness of the option in achieving the objectives. You should always consider alternative options that do not lead to additional information obligations. It is important that the analysis of the impacts clarifies the trade-offs between information obligations and the principal objectives of the proposal.

Annex 10 provides further guidance on assessing administrative burden using the EU Standard Cost Model. Unit B5 in DG Enterprise and Industry can also provide advice on this issue.

8.5 Assessing simplification potential

All proposed policy options should be assessed for coherence with the Better Regulation objective. If simplification of existing legislation is one of the specific objectives of the proposal, the IA should provide an overview for all policy options of the potential simplification benefits for businesses, for citizens, and for national/regional/local administrations. In those cases in which simplification benefits are likely to be significant, the potential cost savings and any other significant changes that would result from implementation should be assessed quantitatively.

All policy options should be assessed for coherence with the Better Regulation objective that EU legislation should be made simpler and more transparent. For proposals which are included in the Rolling Programme for simplification, and for which an IA is carried out, the IA should provide a qualitative description and where possible a quantitative estimate of the simplification benefits for businesses, citizens and national, regional or local administrations. The IA analysis should specify the extent to which each of the policy options achieves this simplification, and the difference that this will make in practice.

When a piece of legislation is being simplified and at the same time updated with new rules, you should analyse the simplification aspects and the new elements separately, and then assess the aggregate effect.

8.6 Assessment of transposition and compliance aspects

The Treaty requires that any action should be as simple as possible and leave as much scope for national decision as possible. IAs must therefore deal with issues of implementation, management and enforcement. "Maximum effort should be made to ensure the clarity, simplicity, operability and enforceability of legislation"³⁸.

When you consider compliance issues, you need to remember that EU rules are in general implemented and enforced by Member State authorities, often at regional or local level. Your compliance analysis therefore needs to take account of possible variations in how Member States implement the rule. For example, framework directives leave considerable scope for flexible implementation at Member State level. This could have a knock-on effect on compliance by the target groups in different countries. A realistic time should be given for transposition in the light of the obligations involved. Detailed requirements, leaving little or no discretion to Member States, can often be adopted through regulations which should be used to the greatest extent possible for technical implementing measures. Consulting the target population and the Member States will help you with your compliance analysis.

³⁷ Available on DG ENTR website.

³⁸ Cf. Commission Communication "A Europe of results – applying Community law", COM (2007)502 final.

To be effective, the law may require enforcement mechanisms, such as quick and simple systems for citizens and business to appeal against administrative decisions, inspection programmes or reporting obligations.

Identifying potential obstacles and incentives to compliance

The following questions will help you to identify potential obstacles to compliance by the group whose behaviour is meant to change, and any incentives that might increase compliance:

Are the requirements of the options simple and easy to understand?

Inaccessible and incomprehensible rules will reduce compliance, particularly for SMEs, which may lack time and resources to deal with large volumes of complex rules.

Would the target group be able and willing to comply?

This may depend on the following:

- **Compliance costs**, including administrative burdens, may affect overall compliance rates, in particular for SMEs.
- **Overly complicated and technical regulation** may not be properly understood. Moreover, it may appear not to have any clear purpose, leading to a loss of confidence in the regulators and a tendency to evasive behaviour.
- **Coherence** with existing market practices or cultural norms may help raise compliance rates.
- **Prior consultation** builds in a sense of 'ownership', or at least understanding, of the rule and can ease compliance concerns.
- **Co-ordinating implementation with regulatory authorities** can improve awareness and understanding.
- **Networking and co-ordination between Member State authorities** can be required for the effective application of the law.
- **Rigorous monitoring arrangements, appeal mechanisms and sanctions for non-compliance** can be expected to increase compliance rates and be more effective than the Commission being called on to intervene.
- **Providing information and other support measures** can affect the ability of the target group to comply with the rule.

In some policy areas material has been developed by Member States, often in co-operation with the Commission services, to help you to assess compliance issues. One example is the checklist developed by IMPEL (EU Network for Implementation and Enforcement of Environmental Law)³⁹. This covers questions relating to choice of legislative instrument, practicability of compliance for the target group, and the enforceability of legislation. The Internal Market Information system (IMI) provides an example of networking to support effective application of the law.

The evaluation of implementation, management and enforcement issues in the IA should lead to appropriate provisions being included both in the legislative proposal and the 'Implementation Plan' that should accompany the proposal.

³⁹ More Information on IMPEL website at <http://europa.eu/environement/impel/>

9. HOW DO THE OPTIONS COMPARE?

1. Use the following criteria for the comparison of options, and explain how they have been applied:
 - Effectiveness of the option in relation to the objectives
 - Efficiency of the option in achieving the objectives
 - Coherence of the option with overarching EU objectives, strategies and priorities
2. Compare the options against the baseline scenario.
3. Present a summary overview of all positive and negative economic, social, and environmental impacts for the options you have analysed in detail.

9.1 How to present the comparison of the impacts of the options?

Regardless of the way you present the impacts, it must be clear that *all these assessments are based on evidence, including quantitative data*. The reasoning that leads from the evidence to the assessments has to be fully transparent.

For all of the options you analyse (including the 'no EU action' option), you need to consider all the relevant **positive** and **negative** impacts alongside each other, regardless of whether they are expressed in qualitative, quantitative or monetary terms. Thinking in terms of costs- and benefits of the various options provides a powerful framework for the analysis. The three most relevant methods for comparing options that can be used in this respect (cost-benefit analysis, cost-effectiveness analysis, and multi-criteria analysis) are presented below:

Cost-benefit analysis

Full cost-benefit analysis should be used when the most significant part of both costs and benefits can be quantified and monetized, and when there is a certain degree of choice as regards the extent to which objectives should be met (as a function of the costs associated with the proposed measures). It entails identifying and evaluating expected economic, environmental and social benefits and costs of proposed public initiatives. A measure is considered to be justified where net benefits can be expected from the intervention.

A **partial cost-benefit analysis** can be done if only a part of the costs and benefits can be quantified and monetized. The resulting net benefits should be confronted with the qualitative assessment of the other costs and benefits.

Advantages	Disadvantages
<ul style="list-style-type: none"> • accounts for all (negative and positive) effects of policy measures • allows comparison of the ordering of costs with the ordering of benefits of the proposal over time • can also be used to rank alternative (including non-regulatory) proposals in terms of their net social gains (or losses) 	<ul style="list-style-type: none"> • cannot include impacts for which there exist no quantitative or monetary data • needs to be supplemented by additional analysis to cover distributional issues

Main steps are:

- List all expected benefits and costs, and calculate (or estimate) their expected magnitude (in physical terms).
- List the expected time-path of the impacts.
- Express the value of the impacts in monetary terms, using the standard discount rate (4%) for impacts that occur in the future.
- Add up all the expected benefits and costs, and calculate the net benefits (= the value of the policy option in terms of cost-benefit analysis).
- Indicate which margins of error or uncertainty need to be taken into account.

Cost-effectiveness analysis

This method should be used when your initiative consists of a fixed objective (a certain level or target to be realised by a given date). It requires calculating the cost needed to achieve the objective, and then comparing the costs of the different options. It is an alternative to cost-benefit analysis in cases where it is difficult to value benefits in money terms. Cost-effectiveness analysis results in a ranking of regulatory options based on 'cost per unit of effectiveness' of each measure.

Advantages	Disadvantages
<ul style="list-style-type: none">• does not require exact benefit measurement or estimation• can be used to compare alternatives that are expected to have more or less the same outcome	<ul style="list-style-type: none">• does not resolve the choice of the optimal level of benefits• concentrates on a single type of benefit (the intended effect of the measure), but would lead to an incomplete result if possible side-effects would not be assessed• provides no clear result as to whether a regulatory proposal would provide net gains to society

How to assess budgetary cost-effectiveness:

Where an initiative involves expenditure, you may need to carry out a *cost-effectiveness analysis*. This analysis will relate the total expenditure to the effects it produces (for example, the budget cost per job). A measurement of this type will allow you to compare and rank different options on their budgetary cost-effectiveness. You should consider the following types of cost when assessing budgetary cost-effectiveness:

- 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.
- administrative costs for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc).

Budgetary cost-effectiveness needs to be distinguished from the criteria of effectiveness and efficiency discussed in chapter 3.3. Budgetary cost-effectiveness deals only with the expenditure element of each of your options, whereas effectiveness and efficiency criteria deal much more broadly with each option in its entirety.

More information on cost-effectiveness analysis can be found in Annex 11.3 and in a study on DG Budget's Europa website.⁴⁰

⁴⁰ http://ec.europa.eu/budget/library/documents/evaluation/studies/cea_finalreport_en.pdf

Cost benefit thinking through multi-criteria analysis

The term multi-criteria analysis covers a wide range of techniques that share the aim of combining a range of positive and negative impacts into a single framework to allow easier comparison of scenarios. Essentially, it applies cost benefit thinking to cases where there is a need to present impacts that are a mixture of qualitative, quantitative and monetary data, and where there are varying degrees of certainty.

Advantages	Disadvantages
recognises multi-dimensionality of sustainability • allows different types of data (monetary, quantitative, qualitative) to be compared and analysed in the same framework with varying degrees of certainty • provides a transparent presentation of the key issues at stake and allows trade-offs to be outlined clearly; contrary to other approaches such as cost-benefit analysis, it does not allow implicit weighing • enables distributional issues and trade-offs to be highlighted.	• includes elements of subjectivity, especially in the weighting stage where the analyst needs to assign relative importance to the criteria • because of the mix of different types of data, cannot always show whether benefits outweigh costs • time preferences may not always be reflected.

Key steps generally include

- identifying the objective;
- identifying options to achieve the objective;
- establishing criteria to be used to compare the options (these criteria must be measurable, at least in qualitative terms);
- assigning weights to each criterion to reflect its relative importance in the decision, using e.g. participatory techniques, ethical principles, technical grounds or an interactive procedure with the policy-makers;
- scoring how well each option meets the criteria; the scoring needs to be relative to the baseline scenario;
- ranking the options by combining their respective weights and scores;
- perform sensitivity analysis on the scoring so as to test the robustness of the ranking

As a first step, you should summarize the impacts of each option by area of impact (economic, social, environmental) and even by sub-impacts. In this summary, the impacts should not be aggregated; negative and positive impacts should be stated next to each other. In some cases, it may be possible to assess net impacts per area of impact and to provide an assessment of the overall net impact (positive impact minus negative impact) of each option. However, when this type of cumulative presentation of impacts is made, you should be careful not to give the impression that impacts are zero or low when, in fact, it is a case of significant positive and negative impacts of the same type having simply cancelled each other out.

9.2 The evaluation criteria

The evaluation criteria you use will depend on the policy area and the nature of the objectives. The most important criteria are those which are directly related to the objectives - in simple terms, the options should achieve the objectives, and do so with a minimum of undesirable side effects (such as compliance costs or administrative burdens).

In relation to the objectives, the most general criteria for evaluating the policy options are:

- **Effectiveness:** The extent to which options achieve the objectives of the proposal⁴¹.
- **Efficiency:** The extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)⁴².
- **Coherence:** The extent to which options are coherent with the overarching objectives of EU policy, and the extent to which they are likely to limit trade-offs across the economic, social, and environmental domain.

9.3 Ranking the options

The IA process will in some cases lead to the conclusion that one option best achieves the objectives for the initiative in terms of effectiveness, efficiency and coherence. In other cases it may not be possible or desirable to provide such clear-cut conclusions; the IA should then serve to highlight the major trade-offs and basic choices involved, and how they have been valued.

While identifying a preferred option is not a strict requirement, you should nevertheless always rank the options on the basis of the evaluation criteria which have been used. This should allow decision-makers to examine the trade-offs between affected groups and/or between the impacts on the social, economic and environmental dimensions. It also allows the design of any proposal to be improved to help minimise trade-offs, to identify accompanying measures to mitigate any negative effects, and to maximise the opportunities for a 'win-win' outcome.

To **rank the options**, you should analyse:

1. **the performance of the different policy options in achieving the defined policy objective and present the results in form of a clear comparison table.** The various steps to be carried out are mentioned in section 5.3.1. on multi-criteria analysis.
2. **the balance of positive and negative impacts associated with the preferred option and possible alternatives**

The first step will be to focus on the performance of the option, in terms of its effectiveness, efficiency and coherence with the defined policy objectives. You should start by ranking the option on the basis of the effectiveness criteria and so identify the option that scores best on effectiveness i.e. meets the defined objectives best. In the second step you should consider the efficiency of the various options, and look at the costs that are associated with implementation of the policy options. In many cases this may show trade-offs that are relevant for the political choices. For instance, you may find that the most effective option also implies higher costs or that a less effective option generates many positive side effects. How you weigh these efficiency aspects against the effectiveness aspects will determine the overall ranking of the options. To ensure full transparency of the process, you should report clearly on how the estimated impacts lead to the various scores, and also on the weights which you have used. In some cases you may consider reformulating your objectives or your options, or to develop sub-options/variants to identify the major trade-offs.

In the next step of the selection process, you should list the expected positive and negative impacts of the policy options, including unintended side-effects. This presentation should be made in quantitative terms for all variables for which this is feasible, expressed in deviations from the baseline scenario. It is often useful to illustrate this in a table or a graph. You may want to mention that there are non-quantified impacts to provide a complete picture.

⁴¹ In the case of regulatory instruments you should, for example, assess the extent to which addressees are likely to accept/comply with regulatory requirements. Section 8.6 has more detailed guidance on this.

⁴² You must assess this criterion for expenditure programmes (c.f. Financial Regulation/ Implementing Rules).

The most effective and efficient policy option will usually also produce the highest net benefits, and any option that convincingly passes this dual test will be credible. However, you may need to discuss how the non-quantified items would affect the net benefit estimate which you have produced. If the differences in net benefits are not significant, or cannot be sufficiently quantified or supported by evidence, you may need to reconsider the design of the options.

Proposed options that cannot be convincingly shown to produce net benefits should normally be discarded.

The table below is one way to present a summary comparison of the policy options in terms of their effectiveness, efficiency, and coherence.

	Effectiveness	Efficiency	Coherence
Option A	Achievement of policy objectives 'A', and 'B'	'X' resources needed to achieve level of impacts 'y'	Good balance of positive and negative (un)intended/(in)direct impacts in economic, social and environmental matters
Option B	Achievement of policy objective 'A' only	'2X' resources needed to achieve level of impacts 'y'	Positive economic impacts; negative unintended impacts on the environment, namely...
Option C

10. ARRANGEMENTS FOR FUTURE MONITORING AND EVALUATION

Identify *core progress indicators* for the key objectives of the possible intervention. Provide a broad outline of *possible monitoring and evaluation arrangements*. Ensure that evaluations are designed and timed in a way that the results can be used as input for future impact assessments.

Policy makers need to be able to check if implementation is 'on track', and the extent to which the policy is achieving its objectives. When a policy is not achieving its objectives, they also need to know if this is the result of problems with the design of the policy, or of poor implementation e.g. was the problem analysis accurate? Were the objectives relevant and attainable? Was implementation entrusted to parties capable of understanding the policy and willing to apply it? Is poor implementation the result of weak administrative capacity?

Monitoring and evaluation arrangements, together with indicators, provide valuable information in this regard. The IA should therefore outline what these arrangements will be and define core indicators for the main policy objectives. It is not necessary to do this in detail for all the options examined in the IA. This will be done after the political choice of the most appropriate policy option has been made, as it is the last step in the policy design process. It does make sense, however, to define some core indicators for the key policy objectives (i.e. for the so-called 'general objectives') as these are valid for all policy options.

Indicators must serve a clear purpose, i.e. measuring to what extent a policy has been properly implemented and its objectives achieved. Another important factor in choosing your indicators is the ease with which data can be collected; collecting data should not be more costly than the value of the information they provide.

According to the Commission's evaluation rules all its activities have to be evaluated on a regular basis. For spending proposals evaluation is compulsory, and many other policy initiatives also contain a review clause, that will require evaluation of such policies since they have been put in place. Evaluations should be announced and described in advance, with a clear indication of the timing, the main focus and purpose, who will be responsible for carrying them out, and to whom the results will be addressed.

If you are planning to do a further IA, this section is the appropriate place to identify the corresponding data needs.

Where a preferred option has been identified, you should:

1. describe briefly how the data needed for monitoring are to be collected and
2. outline the nature, frequency and purpose of subsequent evaluation exercises.

Questions to be addressed include:

- What will the monitoring data and evaluation findings be used for?
- To what extent do monitoring/evaluation structures already exist? Does new capacity need to be put in place?
- Is the baseline situation sufficiently well known or will further data collection be necessary once the proposal has been adopted?
- Who are the key actors in providing and using such information? (e.g. the Commission, Member States, intermediaries such as Agencies, operators/beneficiaries, etc)?
- In general terms, what will be the roles of these actors? How will information be shared and eventually aggregated?
- What will be the additional use for gathering this information? If they imply administrative burden which is significant, it should be measured through the Standard Cost Model as part of the IA.

Annex 13 provides more detailed guidance (including examples) on indicators, monitoring and evaluation.

PART III: ANNEXES (SEPARATE DOCUMENT)