



IMPACT ASSESSMENT GUIDELINES^{*}

15 June 2005

“We should make policy choices that ensure that our various objectives are mutually reinforcing. Actions that promote competitiveness, growth and jobs, as well as economic and social cohesion and a healthy environment reinforce each other. These are all essential components of the overarching objective of sustainable development, on which we must deliver.” The Commission’s Strategic Objectives 2005-2009, COM(2005) 12.

“Proposals must be prepared on the basis of an effective analysis of whether it is appropriate to intervene at EU level and whether regulatory intervention is needed. If so, the analysis must also assess the potential economic, social and environmental impact.” White Paper on European Governance, 2001, COM(2001) 428.

^{*} The present guidelines replace the 2002 ‘Impact Assessment in the Commission – Guidelines’ and ‘A Handbook for Impact Assessment in the Commission – How to do an Impact Assessment’. They set procedural rules for IA in the Commission and explain how to practically conduct the required analysis. The Commission took note of the Guidelines, instructed the Commission services to apply them, decided to make them public and instructed the Secretariat General to regularly update them, in consultation with Commission services and in light of Commission experience and needs, see SEC(2005) 790.

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I. INTRODUCTION

The decision to develop a policy can be driven by many reasons. Ideally however, such a decision should be based in every case on sound analysis fed by the best data available. Impact assessment (IA) is a key tool in this respect.

These Guidelines and Annexes are written for Commission staff in charge of preparing policy proposals. They define a series of steps to follow when performing an impact assessment (IA). Procedural rules are presented in Part II (planning, coordination, consultation, reporting and dissemination rules regarding the IA findings). Analytical steps are developed in Part III.

1. WHAT IS IMPACT ASSESSMENT?

Impact assessment is a set of logical steps which structure the preparation of policy proposals. It involves building on and developing the practices that already accompany the process of policy development by deepening the analysis and formalising the results in an autonomous report. Responsibility for developing the impact assessment lies with the service in charge of developing the proposal.

Doing an IA involves answering a number of basic analytical questions: *What is the nature, magnitude and evolution of the problem? What should be the objectives pursued by the Union? What are the main policy options for reaching these objectives? What are the likely economic, social and environmental impacts of those options? What are the advantages and disadvantages of the main options? And, last but not least: How could future monitoring and evaluation be organised?* An IA need not involve a long and detailed study in every case (see II.5 on the ‘principle of proportionate analysis’), but it should allow for an informed debate in all cases.



Key analytical steps in impact assessment

1. Identify the problem.
2. Define the objectives.
3. Develop main policy options.
4. Analyse their impacts.
5. Compare the options.
6. Outline policy monitoring and evaluation.

Stakeholder consultation & collection of expertise can run throughout the process.

Remember:

Impact assessment is an aid to political decision-making, not a substitute for it.

The IA should not be confused with the policy proposal or with the explanatory memorandum which precedes the proposal. It gathers and presents evidence that helps in determining possible policy options and their comparative (dis)advantages. The IA work should run in parallel with and feed into the development of the Commission’s proposal. The College of Commissioners will take the IA findings into consideration in its deliberations. The IA will not, however, dictate the contents of its final decision. The adoption of a policy proposal is a political decision that belongs solely to the College, not to officials or technical experts.

2. WHY IS IMPACT ASSESSMENT IMPORTANT?

Following these steps has a multi-pronged aim. It ensures early coordination within the Commission. It demonstrates the Commission's openness to input from a wide range of external stakeholders, and shows its commitment to transparency. Further, by providing a careful and comprehensive analysis of likely social, economic and environmental impacts, both direct and indirect, it also contributes to meeting the specific commitments of the Lisbon and Sustainable Development Strategies. Also, it improves the quality of policy proposals, by keeping EU intervention as simple as possible. Finally, it will help explain why an action is necessary and that the proposed response is an appropriate choice or, conversely, demonstrate why no action at EU level should be taken.

3. ANSWERING QUESTIONS ON IMPACT ASSESSMENT

The Guidelines and their Annexes provide answers to most questions. Additional information, in particular on links to DG sites providing sectoral guidance, is available on the Secretariat General's IA IntraComm site¹.

Ad hoc help and guidance should be first sought from the IA support unit/function in your DG².

The next step is to get in touch with the policy desk officer who has responsibility for your DG in the Secretariat General's Strategic Planning and Programming Unit (SG.C.1)³. They can provide further guidance on IA work done for a specific item of the Commission's Legislative and Work Programme.

On stakeholder consultation questions, contact the Openness and Civil Society Unit of the Secretariat General, which is responsible for the Commission's minimum standards for consultation of external parties (SG.B.2).

On methodological issues, you may find it helpful to contact your colleagues in the evaluation unit/function of your DG. The evaluation unit of DG Budget (BUDG.B5) is also able to help if you have questions concerning the link between impact assessment and ex-ante evaluation required under the Financial Regulation (see II.4).

For horizontal matters and questions that cannot be answered by the above, contact the central IA team, which is part of the Secretariat General's Institutional Matters and Better Regulation Unit (SG.H.2).

¹ See <http://intracomm.sg.cec.eu.int/i/impact/>.

² See list of key IA contacts in the DGs on <http://intracomm.sg.cec.eu.int/i/impact/index.php?lang=en&page=contacts>.

³ A contact list can be found on the IA IntraComm site:
<http://intracomm.sg.cec.eu.int/i/impact/index.php?lang=en&page=officers>.

II. PROCEDURAL RULES

The following section summarises which proposals require an impact assessment. It covers (i) what needs to be done before launching/in order to launch the IA; (ii) what happens in the course of the IA (mainly how to consult and collect expertise); (iii) how to present the findings (reporting format etc.) and (iv) what happens after the adoption of the proposal.

Each DG is free to choose how to organise its IA work and support internally – there is no one model applicable to all services.

1. PROPOSALS REQUIRING AN IMPACT ASSESSMENT

Assessing, in a systematic manner, potential impacts of policy options is always desirable when preparing a proposal. However, it is not possible or necessary to write a formal IA report in all cases.

A formal IA is required for items on the Commission's Work Programme (WP)⁴. All regulatory proposals, White Papers, expenditure programmes and negotiating guidelines for international agreements (with an economic, social or environmental impact) put on the WP are concerned⁵. In addition, the Commission may, on a case-by-case basis, decide to carry out an impact assessment of a proposal which does not appear on the WP.

Green Papers⁶ and proposals for consultation with Social Partners are exempted. In such cases there is no point conducting an impact assessment since the Commission invites, in the first case, stakeholders to comment on various options or, in the second case, Social Partners to come up with their preferred option. The following are also normally exempted: periodic Commission decisions and reports, proposals following international obligations and Commission measures deriving from its powers of controlling the correct implementation of EC law and executive decisions⁷.

2. TRAINING FOR THE IMPACT ASSESSMENT

It is recommended that you participate in the general training sessions organised by DG Admin and the Secretariat General. Some DGs also offer specialized training. Given the methodological overlap between IA and ex-ante evaluation (see II.4), signing up for some of the evaluation training modules could be useful. For information and registration see Syslog⁸.

3. PLANNING THE IMPACT ASSESSMENT: THE ROADMAP & THE SPP CYCLE

As major impact assessments require early planning of time and resources, they are integrated into the Commission's annual Strategic Planning and Programming (SPP)

⁴ COM(2005)97.

⁵ See Communication of 5 June 2002 on Impact Assessment, COM(2002) 276. This Communication also states that "it should be noted that in unforeseen circumstances, or situations of *force majeure*, the Commission will apply the requirements of this Communication with the necessary flexibility. In this respect due account will be taken of the obligations which may result from emergency situations, international obligations, human rights, security and safety issues."

⁶ For Green Papers, however, it is recommended to provide, where possible, an indication of the possible pros and cons of the different options presented for consultation.

⁷ The latter category includes implementing decisions, statutory decisions, technical updates, including adaptations to technical progress, competition decisions or acts which scope is limited to the internal sphere of the Commission. COM(2002)276.

⁸ See http://www.cc.cec/di/syslog_formation/home/formation.cfm?langue=EN.

cycle⁹. To help plan the impact assessment work, services are requested to establish 'Roadmaps'¹⁰ for the initiatives they have put forward for inclusion in the Annual Policy Strategy (APS) and the Work Programme (see Impact Assessment Guidelines: Annexes - Annex 1). For WP items which follow from an APS initiative, it will be necessary to update and resubmit the Roadmap prepared at the time of the APS.

Since most Commission initiatives are embedded in policy processes and legal obligations, they are often announced or anticipated some time in advance of presentation in the APS or the WP. For that reason, many key elements for a formal impact assessment are generally already available at pre-APS / WP stage. The first step in the preparation of the Roadmap will therefore be to determine what data are available, what complementary data are needed, and how they will be produced.

Among other things, the Roadmap must provide an estimate of the time required for completing the IA as well as a brief statement on the likely impacts of each policy option and on who is likely to be affected. It also indicates which impacts warrant further analysis (cf. lists of impacts set out in III.4.2) and outlines the consultation plan (see II.7.2. below). The Roadmap must also indicate whether an Inter-Service Steering Group will be established. If your DG does not plan to do so, valid reasons must be provided.

Roadmaps, even in a preliminary form, should ideally be circulated to other Directorates-General (DGs) sufficiently early before the adoption of the APS and the WP, so as to allow the latter to verify the contents of the Roadmaps, plan their contribution to the forthcoming impact assessment and integrate the work done in other areas in their policy objectives.

The Roadmaps (Part I) are published in parallel with the WP, so external stakeholders can anticipate the timing of the policy preparatory work and be ready to provide input.¹¹

In some cases (for instance when a quantitative model must be developed), it may be necessary to launch an ad hoc study in advance of the adoption of the APS or the WP. The options to be considered when launching such a study are: an open or restricted call for tender, or the use of an existing Framework Contract. It is good practice to invite other interested services to be involved already at this stage.

4. LINK BETWEEN IA AND EX-ANTE EVALUATION

The Financial Regulation and its Implementing Rules require the Commission to carry out an 'ex-ante evaluation' for all programmes and activities entailing significant spending.

As long as your impact assessment for a proposal having budgetary implications properly addresses all items listed in Article 21(1) of the Implementing Rules¹², it will be accepted as an ex-ante evaluation. Since these items are similar to the IA requirements in many ways, no 'extra' work is likely to be necessary. Particular attention will need to be paid to the cost-effectiveness of the various options reviewed (see III.5.1 and Annex 8 on 'How to assess cost-effectiveness').

⁹ See <http://www.cc.cec/home/dgserv/sg/i/spp/index.cfm?lang=en>.

¹⁰ The 'Roadmap' replaces the 'Preliminary Impact Assessment' introduced in 2002 (COM(2002)276).

¹¹ See http://europa.eu.int/comm/secretariat_general/impact/practice.htm.

¹² "All proposals for programmes or activities occasioning expenditure or a reduction in revenue for the budget shall be the subject of an ex ante evaluation, which shall identify: (a) the need to be met in the short or long term; (b) the objectives to be achieved; (c) the results expected and the indicators needed to measure them; (d) the added value of Community involvement; (e) the risks, including fraud, linked with the proposals and the alternative options available; (f) the lessons learned from similar experiences in the past; (g) the volume of appropriations, human resources and other administrative expenditure to be allocated with due regard for the cost-effectiveness principle; (h) the monitoring system to be set up." Commission Regulation No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities. OJ L 357/1 of 31 December 2002.

For any further information or guidance, consult DG Budget's IntraComm site¹³ or speak to your DG's evaluation unit.

5. PROPORTIONATE ANALYSIS

The impact assessment's depth and scope will be determined by the likely impacts of the proposed action (principle of 'proportionate analysis'). The more significant an action is likely to be, the greater the effort of quantification and monetisation that will generally be expected. Besides, depending on the political and legal nature of the proposal under preparation, its sectoral particularities and the point in the policy-making process at which the IA is undertaken, some aspects of the analysis will often have to be developed more than others:

'New' regulatory proposals – When the action under consideration concerns an area that was previously left to Member States or an entirely new area, the IA will usually have to be particularly developed. Special care will be needed to determine whether EU intervention is justified (principle of subsidiarity) and that the policy options do not go beyond what is necessary to achieve the objectives (Treaty-based principle of proportionality – not to be mistaken for the methodological principle of proportionate analysis).

Revisions of existing legislation – By definition, in these cases, the problem at issue and the objectives pursued by the Union have been already defined. Therefore, work at those levels could often be limited to considering whether the problem has changed since the original legislation or whether the original objectives are still valid. Available evaluations of the existing legislation may already provide enough data for a proportionate analysis.

If change in the overall objective is envisaged, it will be necessary to verify whether the existing instrument(s) can deal with changed (technological) conditions and objectives. If this is not the case, alternative options will be assessed – among other things – on the basis of their capacity to meet the new objective(s), but also in terms of their versatility (i.e. their capacity to adapt to future changes). Frequent change of policy instruments may indeed be quite costly.

Broad policy-defining documents – For White Papers, Action Plans, other Communications setting out strategic orientations, or proposed framework directives (meant to be followed by daughter directives), the analysis will generally be rather broad in its problem description and objectives. The different types of action envisaged to reach these objectives should however be sufficiently detailed for stakeholders to prepare for subsequent consultation on specific actions. Assessment of impacts will necessarily be preliminary and will not provide detailed quantitative data.

Expenditure programmes - As a general rule the IA will be combined with the 'ex-ante evaluation', required under the Financial Regulation for the preparation of proposals with budgetary and resources implications (see II.4). Where the renewal or extension of an existing programme is proposed, the combined IA/ex-ante evaluation will use information from available evaluations of the expiring programme. In order to assess the added value of a programme under new circumstances, the option of discontinuing the current activities will be taken into consideration, where feasible. For new programmes, relevant findings from evaluations of similar or comparable programmes should be used. Information about the impact of past activities will often be more convincing in this context than speculation about expected impacts.

¹³ See <http://www.cc.cec/budg/networks/evaluation/en/newsite/guidance/index.htm>.

6. INTER-SERVICE STEERING GROUPS

An Inter-Service Steering Group is compulsory for all items of a cross-cutting nature. The Roadmap asks DGs to provide valid justification in those instances when no Inter-Service Steering Group is envisaged.

These groups are there to provide specialised inputs and to bring a wider perspective to the process. Involving other DGs from the early stages will also make it easier to reach agreement during the Inter-Service Consultation (see below).

The Strategic Planning and Programming Unit of the Secretariat General (SG.C.1) should always be invited to participate in the steering group. If no steering group is set up, SG.C.1 should be kept informed of the state of play on a bilateral basis.

7. CONSULTATION OF INTERESTED PARTIES DURING THE IMPACT ASSESSMENT



- Establish a Consultation Plan to ensure input from interested parties and experts.
- Identify:
 - the objective of the consultation(s)
 - the elements of the IA for which consultation is necessary
 - the target groups
 - the appropriate consultation tool(s)
 - the appropriate time for consultation(s)
- Respect the Minimum standards for consultation in the IA process and reporting – COM(2002) 704.

7.1. Why consult?

“I not only use all the brains that I have, but all that I can borrow” - Woodrow Wilson, US President, 1913-1921.

Gathering opinions and information from interested parties is an essential part of the policy-development process, enhancing its transparency and ensuring that proposed policy is practically workable and legitimate from the point of view of stakeholders¹⁴. Furthermore, the Commission is required by the EC Treaty to carry out wide consultations before proposing legislation (see Protocol on the application of the principles of subsidiarity and proportionality).

7.2. Consultation planning

The key element for a successful consultation is early planning. Your consultation plan should ideally cover the whole policy-making process and determine the objective of the consultation(s), relevant target groups, appropriate consultation tool(s), consultation time(s) and consultation document(s). However, a balance has to be struck between the

¹⁴ 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).

scope and length of the consultation and the obligation for the Commission to work in an efficient manner. Consultation must remain proportionate to the likely impact of the proposal.

Objective of the consultation

In order to be successful, you have to clearly identify the objective of your consultation (what you want to get out of it): finding new ideas (brainstorming); collecting factual data; validating a hypothesis; etc¹⁵. Another important objective may be to clarify the possible impacts of a measure on public opinion. This will help you decide whom you need to consult, when and how (see below).

Consult on 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). It may also concern the whole draft proposal.

Whom to consult

Consultation may be open to the general public, restricted to a specific category of stakeholders (any member in the selected category can participate) or limited to a set of designated individuals / organisations (only those listed by their name can participate)). You should always include all target groups and sectors which will be significantly affected by or involved in policy implementation, including those outside the EU (this mapping is part of problem identification – see III.1.2). Input from the Inter-Service Steering Group or, failing that, contacts with colleagues in other DGs will guide you on who to consult.

How to consult

The choice of consultation tools will largely depend on who needs to be consulted, on what and on the available time and resources. These tools include consultative committees, expert groups, open hearings, *ad hoc* meetings, consultation via Internet, questionnaires, focus groups, seminars/workshops, etc.

It goes without saying that a structured and focused consultation (e.g. a questionnaire with closed questions on specific issues) will produce information that is much easier to process than an unstructured and general consultation (e.g. asking stakeholders to comment on a White Paper). A growing number of services are finding it helpful to use the Interactive Policy Making (IPM) tool developed by DG MARKT to run their structured questionnaires. On 'do's' and 'don'ts' in questionnaire design, see Annex 6 on 'How to design a questionnaire'.

For further information on consultation tools and link to IPM, see the section on 'Tools' on the 'Stakeholder consultation' IntraComm site¹⁶.

When to consult

Appropriate timing must be fixed on a case-by-case basis, but consultation should start as early as possible in order to maximise its impact on policy development. Also, consultation should be seen as a recurring need in the policy development process rather than a 'one-off' event. Depending on the issue at stake and the consultation objectives, you may therefore find it useful to arrange for a series of consultations as the proposal develops. For example, an initial consultation might be held to ascertain stakeholder perceptions about the nature of the problem; a subsequent consultation

¹⁵ It is essential to differentiate between ad hoc consultation of experts to gather information and recourse to external expertise in more formal settings, typically when a panel of experts is established to analyse data, e.g. to elaborate scenarios, estimate impacts, etc.

¹⁶ See <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=tools>.

might ask stakeholders for their views about the possible range of options, while a third round of consultation might aim to sound out stakeholders on the likely acceptability of any preferred option. For efficiency reasons and in order to avoid ‘consultation fatigue’, repeated consultations should nevertheless be kept to a minimum.

For further information, see the Stakeholder consultation IntraComm site¹⁷.

7.3. Minimum standards for consultation

“The Commission’s minimum standards on public consultation (...) apply in consultations of the public at large, and also when the Commission seeks the views of civil society groups and other interested parties because of the constituencies they represent, rather than because of the expertise they possess.”¹⁸

Stakeholder consultation in the impact assessment process must be carried out according to the Commission’s general principles and minimum standards for consultation¹⁹. Paying particular attention to transparency, the key messages are:

- Provide consultation documents that are clear, concise and include all necessary information.
- Consult all relevant target group(s).
- Ensure sufficient publicity and choose tools adapted to the target group(s) - open public consultations must at least be publicised on the Commission’s single access point for consultation, ‘Your Voice in Europe’²⁰.
- Leave sufficient time for participation (minimum eight weeks for written public consultations; 20 working days notice for meeting).
- Publish the results of 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 the opinions expressed have been taken into account in the impact assessment report (see II.9) and in the explanatory memorandum accompanying the Commission proposal.²¹

For short practical guidance on how to apply minimum standards, see the IntraComm site²².

¹⁷ See <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en>.

¹⁸ COM(2002) 713, p.7.

¹⁹ COM(2002) 704. See http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2002/com2002_0704en01.pdf.

²⁰ See http://europa.eu.int/yourvoice/consultations/index_en.htm.

²¹ See http://www.cc.cec/home/dgserv/sg/em/index_en.htm.

²² See <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=guidance>.

Box 1: Consultation with social partners

Please note that there are specific provisions for consulting social partners (management and labour), regarding initiatives in the field of social policy e.g. health and safety in the workplace, working conditions, social security and social protection of workers, and information and consultation (see Treaty Articles 137-139 on social dialogue, and particularly Article 137 on the policy fields concerned). There are **two stages** to this consultation process: first, social partners are consulted on the general direction of an initiative; then, in a second stage, on its actual content. Therefore, minimum standards for consultation *do not apply* to social dialogue, but they do apply to other types of stakeholder consultations in the employment and social affairs field.

7.4. Pitfalls

When carrying out a consultation, and especially when analysing replies in public consultations, it is important to keep in mind that not all interest groups are equally able to take part or express their views forcefully. For this reason, an open consultation is unlikely to provide a representative picture of opinions. So when making use of the results of the consultation, you should be careful not to be unduly influenced by the views of one particular group, no matter how professionally these have been presented. Watch also for biases that may arise from any external groups in the context of on-line, closed-end questionnaires allowing for anonymous responses (cf. risk of a single person filling in the questionnaire many times). Consultation can never be a substitute for analysis of an issue.

Beware of 'consultation fatigue' on the part of stakeholders. Consulting stakeholders too often will always be detrimental to the number of responses and their quality. Don't repeat consultation unless you are seeking additional opinions/information, or unless there is new information to present to them. For example, it is not a good idea to consult stakeholders on the results of a previous consultation!

8. COLLECTION AND USE OF EXPERTISE

The analytical quality of an IA is contingent, among other things, on the validity of the data used. Collecting reliable data is therefore crucial to ensuring that policy choices are made on sound analysis and valid conclusions. Expertise, and more specifically scientific expertise, is increasingly becoming an element of critical importance in the design, implementation and assessment of public policies. Commission guidelines for collecting and using expertise have therefore been defined.²³

Expert groups and, in particular, scientific committees set up by the Commission and EU Agencies are a prime source of sound scientific advice. In addition, since 2005, a web application called the SINAPSE e-Network²⁴ (Scientific INformAtion for Policy Support in Europe) offers Commission services the following communication and information tools for ad hoc collection of expertise:

- A *library of scientific advice* and opinions;
- A *consultation* module which allows services to conduct informal scientific consultations, complementing formal advisory processes;

²³ COM(2002)713. See http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0713en01.pdf.

²⁴ SINAPSE is accessible at <http://europa.eu.int/sinapse> (Contact: Sinapse@cec.eu.int).

- An *early warning system* that the scientific community and other stakeholders can use as a channel for raising awareness on scientific issues which require or could benefit from the attention of public authorities;
- A ‘*Yellow Pages*’ section to quickly identify and contact scientist or scientific organisations with a specific expertise.

If important parts of the impact assessment are contracted out, the terms of reference should make clear that contractors will have to follow the analytical steps set in Part III.

9. PRESENTING THE FINDINGS: THE IMPACT ASSESSMENT REPORT



- Summarise the work undertaken for the IA into a short report.
- State any assumptions or uncertainties.
- Use simple and non-technical language.
- Use the format presented in Annex 16, which approximately follows the steps of the IA approach .
- Put technical detail or supporting documents in an annex.

9.1. Prepare a summary report

It is important to distinguish between the work undertaken for the impact assessment – the ‘process’ – and the final ‘report’ summarising that ‘process’. Various documents will often be produced in the course of the impact assessment – some written by you, others submitted by stakeholders or other DGs, or perhaps commissioned from an external consultant. It is on the basis of this information and evidence that the problem will be assessed, (some of) the objectives set, the options identified, and their impacts analysed. At the end of the process, you will need to summarise all these findings into a single document: the impact assessment report.

Box 2: IA study leads to abandoning the draft proposal? Report still required!

The IA report needs to be completed even when the preparation of a draft proposal is abandoned as a result of the IA process. These IA reports will tell why careful consideration of potential impacts led to the decision that no action should be taken. Since ‘no draft proposal’ means no formal inter-service consultation, you should arrange for the completed IA report to be sent to the responsible IA unit within your DG and to the Secretariat-General Strategic Planning and Programming Unit (SG.C.1).



Remember to flag-up uncertainties or assumptions in the final IA report. You also need to specify which analytical method was used to assess and compare the impacts, e.g. cost-benefit analysis, multi-criteria analysis, etc.

The IA support unit in your DG will perform an initial check of the report, to ensure that it meets a suitably high standard.

9.2. Keep it simple

Ideally any non-specialist should be able to follow the argumentation and understand the positive and negative impacts of each of the options considered in the IA. To enhance the clarity and readability of the IA report, use tables and diagrams to summarise some key points. Examples of such tables are given throughout Part III (in particular in III.5).

9.3. Reporting format

The IA report should contain a clear '**waiver**' on its cover and an introduction indicating that the report commits only the Commission's services involved in its preparation and that the text is prepared as a basis for comment and does not prejudice the final form of any decision to be taken by the Commission.

The report should normally be no more than 30 pages (excluding annexes) and must use the following **format**:

- Executive summary
- Section 1: Procedural issues and consultation of interested parties
- Section 2: Problem definition
- Section 3: Objectives
- Section 4: Policy options
- Section 5: Analysis of impacts
- Section 6: Comparing the options
- Section 7: Monitoring and evaluation

A checklist on what needs to be included in the various sections of the IA report is given in Annex 16.

Any supporting documents, such as expert reports or summaries of stakeholder views, should be annexed to the IA report, either physically or by html link. Where the limit on the number of pages for the IA report precludes going into detail on an important point set out in an accompanying document, you should insert a cross-reference to that document. There is, of course, no limit to the size of the annexes.

9.4. Translation

The report can be drafted in English, French or German. As a Commission Staff Working Document (see below), the IA report will normally not be translated.

10. INTER-SERVICE CONSULTATION & PRESENTATION TO THE COLLEGE

If action is deemed necessary, a proposal will be drafted and entered into formal Inter-Service Consultation (ISC), together with the IA report and its annexes. In addition, the Explanatory Memorandum accompanying the draft proposal²⁵ will briefly set out the options considered, their potential economic, social and environmental impacts, as well as the website address where the final IA report will be accessible.

Since the Secretariat General will consider the quality of the IA report as part of the formal Inter-Service Consultation procedure, it is important that it is kept up to date with progress on the IA throughout the process, either as part of the Inter-Service Steering

²⁵ See explanatory memorandum IntraComm page http://www.cc.cec/home/dgserv/sg/em/index_en.htm.

Group or on an ad hoc basis. If the IA report subjected to ISC does not reach a satisfactory level of quality, a suspended or unfavourable opinion may be issued.

Once over the hurdle of Inter-Service Consultation, the IA report accompanies the draft proposal submitted to the College of Commissioners. It is also possible that one or more of the Groups of Commissioners will examine the draft proposal and the impact assessment prior to the College's deliberation.²⁶

11. USING THE FINDINGS: THE IA REPORT IN THE LEGISLATIVE PROCESS

The proposal and the final IA report, which has the status of a Commission Staff Working Document, are transmitted to the other Institutions. The other Institutions are invited to use the final IA report in their discussions on the proposal itself. However, it is important to stress that the other Institutions should consider the report alongside the proposal and not separately.

Commission services should use the IA in the legislative process. Evidence presented in the IA report will help them to argue the merits of the Commission's proposal in the Council and/or European Parliament.

Services should also ensure that the impact assessment is mentioned in any press release or media statement made about the proposal, in order to underline that the Commission's major policy proposals are based on careful consideration of their potential impacts.

Each Institution is responsible for carrying out impact assessments in their respective areas of responsibility – the Commission carries them out for its proposals, and the Council/EP assess the impact of their substantive amendments.

In the light of new or previously unavailable information, the Commission may decide to update the original impact assessment. However, the decision on whether to do so is for the Commission alone to make. In all such cases, it is important to consult the Secretariat General as early as possible (SG.H.2).

12. PUBLICATION OF THE FINAL REPORT

The completed IA report is published on the Europa impact assessment website along with the (legislative) proposal²⁷. This will be done by the Secretariat General.²⁸

In very rare circumstances, such as when international negotiations are involved, a decision to restrict or delay the publication may be considered. Please consult the Secretariat General (SG.H.2) for further information and guidance.

²⁶ See SEC(2004)1617/4, p. 14 provides that the mandate of the Competitiveness Group of Commissioners includes to, "at the request of the President, consider the impact of significant draft Commission proposals outside the Competitiveness Council's remit, and in particular, to ensure that the impact assessments accompanying such proposals adequately take account of competitiveness".

²⁷ Completed IAs are annexed to the proposal sent to the European Parliament and/or the Council, and published on the Europa website. Contrary to the view once expressed by Otto von Bismarck that: *'Laws are like sausages, it is better not to see them being made'*, the Commission believes that transparency is indispensable in a democratic system.

²⁸ http://europa.eu.int/comm/secretariat_general/impact/practice.htm.

III. KEY ANALYTICAL STEPS IN IMPACT ASSESSMENT

Impact assessment follows six key steps in a logical order. However, it is important to understand that it is very much an iterative process, where it is likely that your earlier steps will need to be revisited in the light of work undertaken later in the process. This 'back and forth' process is relevant for all of the major impact assessment steps, but may be of particular importance for setting objectives (see III.2.2).

1. WHAT IS THE PROBLEM?



- Delineate the extent of the problem.
- Identify the key players/affected populations.
- Establish the causes.
- Is the problem in the Union's remit to act?

1.1. Why assess the problem?

When problems are stated in very general terms or when their description relies on vague concepts, it is quite difficult to set appropriate objectives and determine the best policy instrument. It is therefore crucial to provide policy-makers with a clear idea of the issue being addressed.

Box 3: Poor problem analysis = poor policy choice

Some years ago, statistics of country X revealed that a large number of children had died because of accidental poisoning in their homes caused by overdoses of medicines. Analysts quickly concluded that medicine bottles were too easy for children to open. Childproof bottles (with 'push down and turn' opening device requiring some physical strength) were then made compulsory. The trade-off was an increased difficulty for older persons to open their medicine bottles. As a result, these bottles were often left open, leading to more child poisonings.

Subsequent analysis showed that the main problem lay elsewhere: when packaging like sweets, medicines were very attractive for children; moreover, adults too often were leaving medicines easily accessible to children. Policy-makers eventually managed to tackle child poisoning through less colourful packaging integrating child warnings and an information campaign on the need to store medicines out of children's reach. Bottle caps were also redesigned so that people who can read can open them easily.

1.2. How to assess the problem

You should start by identifying and describing as concretely as possible the issue at stake²⁹. Most often, political statements at the origin of a policy initiative do not provide a detailed description of the problem. It is therefore necessary to verify and refine the preliminary definition of the problem, i.e. identifying key components, reducing conceptual ambiguity and making rough estimates of the size of the problem (are a thousand or a million people affected, and to what extent are they affected?). You should in particular identify the extent to which an issue manifests itself in the form of economic, environmental and/or social problems. The assessment of the problem should not be solely based on a general feeling.

As well as saying what the problem is, you should also explain why it is a problem, that is, why the existing or evolving situation is not ideal. A useful tip is to think the problem over from the point of view of the different stakeholder groups affected. Few things, if any, are intrinsically problematic. What is good or bad, acceptable or unacceptable for a group depends on the norms and values prevailing in that group. Stating explicitly that a situation is problematic for group 'x' because it is contrary to value 'y' (i.e. normative statements) will facilitate the analysis. You need to establish the 'drivers' – or causes – behind the problem (how particular factors lead to the problem) and the ways in which these different drivers influence one another directly or indirectly. Doing so helps you to tackle root causes rather than symptoms. For example:

<u>PROBLEMS</u>	<u>DRIVERS</u>
Rapid spread of HIV/AIDS in country X	Stigma surrounding disease leads people to stop talking about it (culture of secrecy) and undermines preventive action
Air pollution	Firms do not have to pay to emit pollution (a market failure).
Firms unwilling to trade with countries X, Y, Z.	Protection of legal rights not adequately defined (a regulatory failure).

Problems should not be defined as a 'lack of something'. This could bias the definition of objectives and ultimately the choice of policy instruments. For instance, stating that the problem of poverty and social exclusion among single parent households is due to a lack of affordable childcare, which prevents single parents from working, will logically focus attention on provision of affordable childcare as a solution. By contrast, starting out by stating that the professional qualification of single parents is often low and that childcare is unaffordable on the salaries paid for low skilled jobs, opens up additional policy options (e.g. providing special training and educational opportunities for single parents, raising single parent salary through fiscal measures, etc.).

Box 4: Problem tree

A simple, but structured, approach to analysing problems and their root causes is to draw up a **problem tree** which maps out major problems and how they relate to each other. The output is a graphical arrangement of problems differentiated according to 'causes' and 'effects,' joined by a core, or focal, problem (see Annex 3).

²⁹ Annex 2 sets out some major reasons why intervention might be necessary.

1.3. Does the Union have the right to act?

Having identified the problem and its underlying causes, you still need to verify if the EU has the right to act on it and whether it is better placed than the Member States to tackle the problem. A problem is in the Union's remit if the following conditions are met:

- First, it must be possible to link the problem and at least one article of the Treaties. Indeed, the Union can only act within the limits of the powers given to it by the Treaties and the objectives assigned to it (principle of conferral).
- Secondly, if the problem falls under a competence shared by the Union and the Member States, the Commission needs to demonstrate that the problem cannot be sufficiently solved by the Member States (this is the first condition set by the subsidiarity principle, also called the 'necessity' test).
- Thirdly, it must be kept in mind from the outset that fundamental rights, as defined in the EU Charter of Fundamental Rights, may pose legal limits to the Union's right to take action on the problem.³⁰ Impact assessment can be a useful tool in identifying possible impacts on fundamental rights and assessing whether those are proportionate.

Box 5: Conditions set by the subsidiarity principle - the necessity test

The protocol on the application of subsidiarity and proportionality offers a (non-exhaustive) set of guidelines for applying the necessity test. According to them, the above-mentioned condition is met if:

- **Transnational aspects** exist that cannot be satisfactorily regulated by Member States (e.g. acid rain transported in the atmosphere). *Note that the Treaty does not refer to 'Community-wide' but to 'transnational' problems. In other words, the Union may decide to address a problem that concerns only a limited number of Member States.*
- Action by Member States alone would conflict with the **requirements of the Treaty** (e.g. discriminatory treatment of a stakeholder group).
- Action by Member States or lack of Community action would **significantly damage Member States' interests** (e.g. action restricting the free circulation of goods).

The other conditions set by the principle of subsidiarity (the added-value test and the boundary test³¹) will be examined on the basis of the comparison of the policy options – see III.5.2.

1.4. How would the problem evolve if the current EU approach were to continue?

You should take the quantitative and qualitative 'picture' of the problem and project it into the future as a 'no policy change' scenario³². In doing so you are asking whether the problem will get better or worse if no new policy is introduced. This is the scenario against which the impacts of policy options will be compared and assessed. This

³⁰ For more detailed information see the Commission Communication on Compliance with the Charter of Fundamental Rights in Commission legislative proposals (COM(2005) 172).

³¹ Subsidiarity also provides indeed that the EU shall take action only if the objectives can be better achieved by the Union (added-value test). Finally it states that the scope of EU action shall be limited to what Member States cannot achieve satisfactorily and to what the Union can do better (boundary test).

³² 'No policy change' can mean that existing EU action is continued. It can also mean that the EU took no action so far and will not introduce any in the future (the 'wait and see' approach is a policy).

comparison is obviously easier the more specific you are in defining the baseline scenario.

Developing the 'no policy change' scenario requires considering a wide range of factors that could change the shape and/or extent of the problem, such as:

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

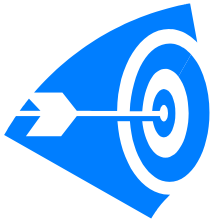
Where there is uncertainty about the underlying factors, then it is good practice to construct alternative baseline scenarios against which you can assess policy options.

1.5. Data sources, collection and analysis

In many cases, defining the problem, analysing its extent and its causes will draw on in-house knowledge along with existing studies, which means that the exercise does not necessarily require long and costly external studies. Such readily available material may include statistical data from Eurostat and others, Green Papers, monitoring or evaluation reports from previous or similar programmes, studies by EU agencies, information gathered from stakeholders (hearings, conferences), etc. Practical tips for information compilation and approximation of numbers are listed in Annex 3.

Analysing how the baseline situation is likely to evolve in the future is altogether a more delicate matter, since it involves taking the data that describe the current situation, and then making hypotheses about future conditions and establishing one or more pictures of how the future is likely to look as a result. Where projections based on quantitative data are possible and appropriate, the models described in III.4.2 may provide a suitable solution. You can also develop projections using a qualitative approach (based on best professional judgement rather than actual figures).

2. WHAT ARE THE OBJECTIVES?



- Set objectives that correspond to the problem and its root causes.
- Establish objectives at a number of levels so as to set out the 'intervention logic'.
- Ensure that the objectives are consistent with EU policies and strategies, such as the Lisbon and Sustainable Development Strategies.

2.1. Why set objectives?

Without a clear understanding of what a future policy is supposed to achieve, it is difficult to identify possible courses of action. It is even more difficult to determine the most suitable policy option. Put differently, unless you know where you are going, you are unlikely to get there.

Being explicit about pursued objectives also allows policy-makers to verify that the proposed logic of intervention is reasonably strong. Lastly, it is a way to promote a common understanding of the aims of the policy, which can help later on with implementation, monitoring progress through specified indicators, and evaluation of the success or otherwise of the intervention.

2.2. How to set objectives

The objectives should be directly related to the problem and its root causes, as identified in the previous section. They should also be set in hierarchical order and become increasingly detailed (or 'SMART' – see below) as the IA process is implemented.

Box 6: Setting SMART objectives

Objectives should be:

Specific: Objectives should be precise and concrete enough not to be open to varying interpretations.

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 (see III.6). Such objectives are either quantified or based on a combination of description and scoring scales.

Accepted: If objectives and target levels are to influence behaviour, they must be accepted, understood and interpreted similarly by all of those who are expected to take responsibility for achieving 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.

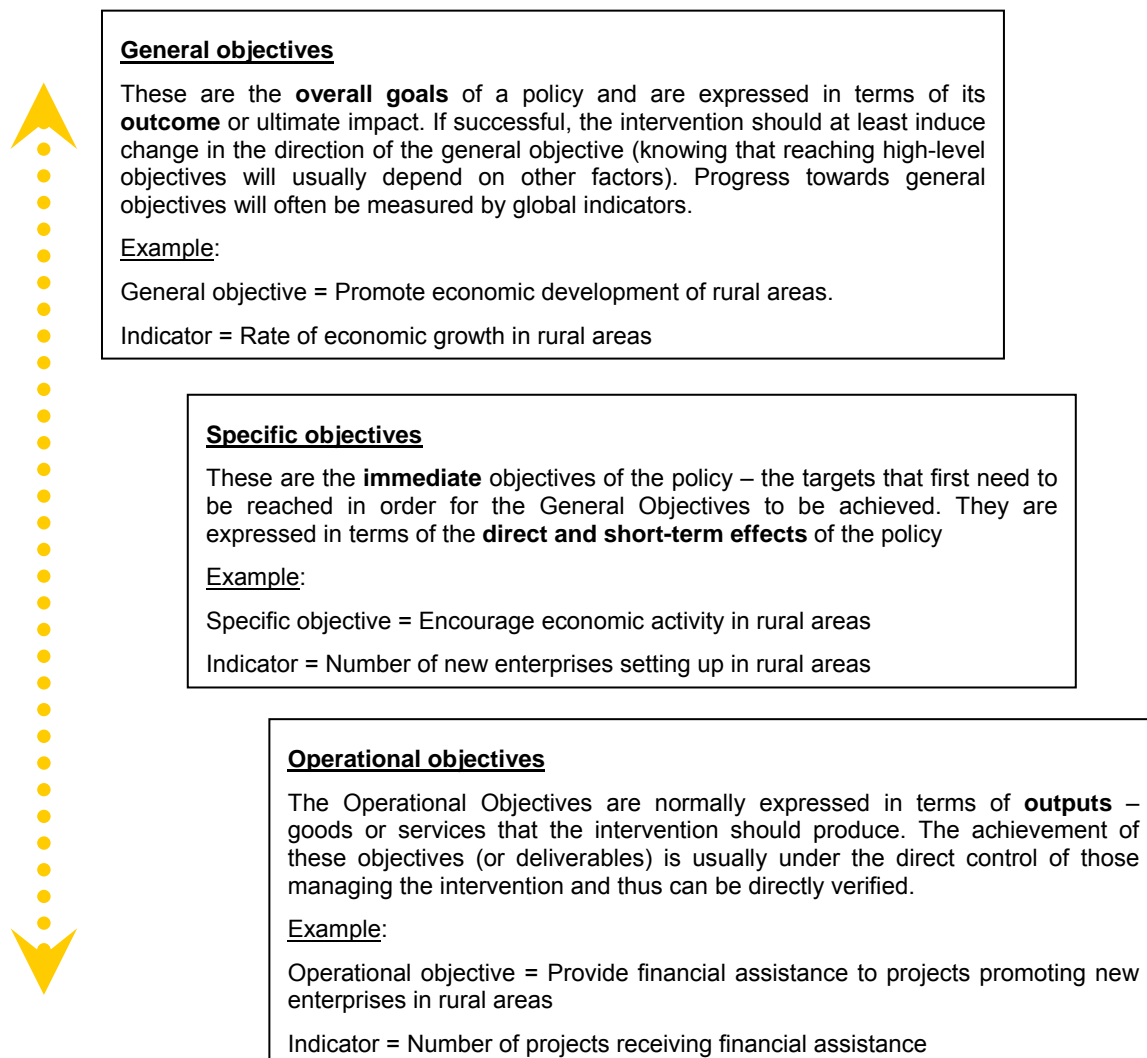
Time-dependent: Objectives and target levels remain vague if they are not related to a fixed date or time period.

In most cases, objectives apply at different levels and you should think of them as a hierarchy. It is also important to clarify the links between the objectives: indicate what

sectoral objective could be reached if some good 'x' was produced, and what general goal could be achieved as a result of that sectoral change. This kind of domino effect is usually called the 'intervention logic'.

One useful way of developing a coherent set of hierarchical objectives could be to distinguish between general objectives, specific objectives and operational objectives.

Graph 1: Three levels of objectives



As the above arrow indicates, defining the objectives can be approached by starting from either the more general or the operational. In practice, the iterative nature of objective-setting means that, regardless of where you start, you will go up and down from level to level until you are happy that the objectives are consistent with each other and with the problem to be solved.

It will not be necessary in every case to consider objectives at all three levels, since in reality the relevant number of levels will differ according to the characteristics of the policy.³³ The above example is intended as an example.

Ideally, by the end of the IA process, through progressive refinement and adjustment, objectives should also be SMART, that is, Specific, Measurable, Accepted, Realistic and Time-dependent (see Box 6 above). This is particularly necessary for developing objectives at the 'operational' level.

³³ This may be particularly the case in relation to operational objectives, which may only be finalised after the EU initiative has been agreed.

Finally, objectives should be few in number and address key elements. Setting too many objectives suggests that the objectives of the proposal have not been clarified sufficiently. Defining the problem and objectives for an Action Plan would usually take a broader approach. In this case, it would be even more important to establish clear links between problems, objectives and proposed subsequent actions.

2.3. Ensuring consistency with other EU policies and strategies

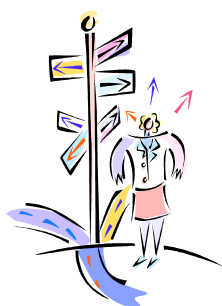
No policy action by the Commission should be taken in isolation. It is necessary to check whether the objectives envisaged are consistent with the other EU policies. In practical terms, this means that you should look at any impacts the proposal may have on other policy areas and, if necessary, adjust the proposal to ensure that it does not undermine their objectives.

3. WHAT ARE THE POLICY OPTIONS?

Once the set of objectives has been properly defined, the next phase of the IA exercise is to establish which policy options and delivery mechanisms are most likely to achieve those objectives.

The term 'policy option' is perhaps more complicated than it first appears! There may be several ways, i.e. '**basic approaches**', to achieve objectives and these need to be considered when identifying the various options. Examples of basic approaches are Community legal acts, legal acts of Member States, self-regulation and economic incentives. Remember that different choices can be combined in a package, and/or co-ordinated with Member State action.³⁴

Various alternatives exist regarding the **individual elements/design parameters** of a policy, including more or less ambitious versions to improve the '**fine tuning**' of the options, which would include the scope of legislation, implementation requirements and methods, etc.³⁵



- Identify policy options to meet the objectives.
- Consider the most appropriate delivery mechanisms (regulatory / non-regulatory approaches).
- Begin to narrow the range by means of screening for technical and other constraints, and by measuring against criteria of effectiveness, efficiency and consistency.
- Draw up a shortlist of potentially valid options for further analysis.

3.1. Why consider alternative policy options?

Considering alternative policy options will force you to think 'out of the box'. Identifying and screening a wide palette of options also offers greater transparency. It is a way to inform policy-makers and stakeholders why some options have been discarded at an early stage. It becomes easier to justify the proposed choices and to pre-empt digression on hopeless options.

3.2. How to identify policy options

The first step is to think large and to draw up an initial, extensive list of alternative possible options that are likely to be capable of achieving the proposed objectives.

Remember that you need to keep an open mind. Even if it seems that a particular option is a clear front-runner, other promising options should not be excluded outright.

³⁴ This section should be read in conjunction with Annex 4.

³⁵ In the case of expenditure programmes, for example, a key design issue is the choice of the 'method of implementation': Will the programme be managed directly by the Commission, or indirectly through an Agency? Will management be shared with Member States or international institutions? (For more on the available options, see Article 53 of the Financial Regulation). In deciding on the specific arrangements you would examine the relationship between the policy area, the geographical focus, the characteristics of beneficiaries, the scale of the projects being supported and the size of the programme.

The option of ‘**no EU action**’³⁶ should always be considered, except in cases where there is an obligation to act laid down by the Treaties. It is also advisable to consider, where relevant, including an **alternative approach to ‘classical’ forms of regulation**, unless a decision by the Commission has already ruled this out. Consideration should also be given to options leading to **streamlining or simplification** of existing regulation.³⁷

Box 7: ‘To regulate’ or ‘not to regulate’? That is the question ...

Tackling the identified problem doesn’t mean that you need automatically choose a regulatory option such as a directive or a regulation. Consider the full range of alternative actions available to the Commission. Is self-regulation a feasible option? Could the same objectives be met by securing a voluntary agreement? Is an information and education campaign sufficient?

It is important to examine closely options that can count on considerable support. The other Institutions are responsible for carrying out impact assessments on amendments to Commission proposals. Nevertheless, it is very useful in terms of facilitating the legislative process if the Commission’s impact assessment has already sought to anticipate the likely shape of the amendments from Council and Parliament.

When identifying the options you also need to take account of existing EU policies, including those awaiting transposition by Member States, and if relevant and possible, proposals currently under discussion in the European Parliament and Council. You should also take account of existing or planned Member State policies or international agreements that might affect the impact of an option.

Box 8: ‘Less can be more’

Given the amount of existing legislation, a ‘doing less’ option could also be considered. If, for example, existing measures in a certain area do not produce the expected effects, creating a new instrument is not necessarily the best remedy. Streamlining, simplifying and ‘pruning’ the existing legislation might produce better results!

In some cases, a particular option may emerge as a ‘front runner’ at a relatively early stage. Although you should not immediately exclude other options which may have the potential to meet the proposed objectives, you should consider how the impacts of the ‘front runner’ will vary if one or more key parameters change (‘fine-tuning’), for example allowing more time for objectives to be met or aiming for more or less ambitious objectives (this method is called ‘sensitivity analysis’).

3.3. How to screen policy options

The aim of the screening process is to arrive at a shortlist of the most promising options (usually three or four, excluding the ‘no EU action’ option) that will be subjected to a more in-depth analysis of impacts (See III.4).³⁸ These should be realistic. You should certainly avoid the trap of considering only the three following options: the ‘Do Nothing’ Option, the Preferred Option, and the Ridiculous Option that nobody wants! Such an

³⁶ i.e. no new EU intervention, but also the possible abandoning or downgrading of existing EU policies.

³⁷ Harmonising existing national legislation could also be beneficial in this respect as it could replace 25 laws by one and therefore make cross border activities easier for business as well as consumers.

³⁸ The reason why some policy options have been discarded at an early stage (i.e. prior to or as a result of the screening process) should be documented and subsequently presented in the IA report.

approach will run into serious trouble when others put forward realistic options that have not been analysed.

The screening process is likely to be rather informal and iterative. An important aspect of the screening process is to develop a description of the attributes of each option so that it is possible to start to differentiate between them in terms of how well they are likely to perform against the three criteria presented below. You should have sufficient information to be able to show why certain options have been adopted after screening and others eliminated before going on to a more in-depth analysis of impact. The criteria by which policy options are screened are:

- **Effectiveness.** The extent to which options can be expected to achieve the objectives of the proposal.³⁹
- **Efficiency:** The extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness).⁴⁰
- **Consistency.** The extent to which options are likely to limit trade-offs across the economic, social, and environmental domain.⁴¹

3.4. Data sources, collection and analysis

You should draw on readily available data using, by and large, the sources listed under 1.5. If the issue has been under discussion for some time, it is very likely that some policy options will have already been considered in a Green Paper. You should also look for examples of good practice and international experience (in Member States, third countries or international organisations).

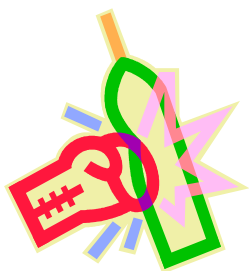
Alternatively, you could undertake the analysis in a more structured and formal way, elaborating a causal model of impacts and using that to make a qualitative assessment of the performance of the various options under review (see III.5.1).

³⁹ In the case of regulatory instruments, an issue that underlies this particular criterion is the extent to which addressees are likely to accept/comply with regulatory requirements. More detailed guidance on assessing compliance can be found in Box 9, in Section III.4.2, step 2.

⁴⁰ The criterion of efficiency is particularly relevant when the impact assessment concerns an expenditure programme (and its assessment is indeed mandatory for this type of intervention under the provisions of the Financial Regulation and its Implementing Rules). For more information, see Annex 8 on 'How to assess cost-effectiveness'.

⁴¹ i.e. between different social and economic groups, regions, etc.

4. 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 (including those outside the EU) and in what way.
- Assess the impacts in qualitative, quantitative and monetary terms where possible and appropriate.
- Consider the risks and uncertainties in the policy choices, including obstacles to compliance.

4.1. Why analyse impacts?

The analysis of the impacts of each of the options is a crucial element of the impact assessment process and should be conducted for the most relevant policy options, including the no-policy change option. This exercise will help you supply information about likely impacts across the three main policy dimensions (economic, environmental, and social), as well as potential trade-offs and synergies. It will also help identify enhancing measures (i.e. ways in which a certain policy option could be ‘fine-tuned’ to make it more effective and efficient) and/or mitigating measures (such as longer transition periods, exemptions for certain groups or redistributive measures). It will thereby provide you and, subsequently, policy-makers with sound information on the basis of which the relevant options can be compared and ranked (see III.5).

4.2. How to analyse impacts

The analysis of impacts involves trying to predict, across a range of different policy areas, the likely consequences - both intended and unintended - of each option. 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.

The ultimate aim of the impact analysis is to provide sufficient and clear information on the **impacts of the various policy options** that can then be used as a basis for comparison of those options (See III.5) against each other and against the ‘no policy change’ option or ‘baseline scenario’ elaborated as part of the problem analysis (See III.1.2).

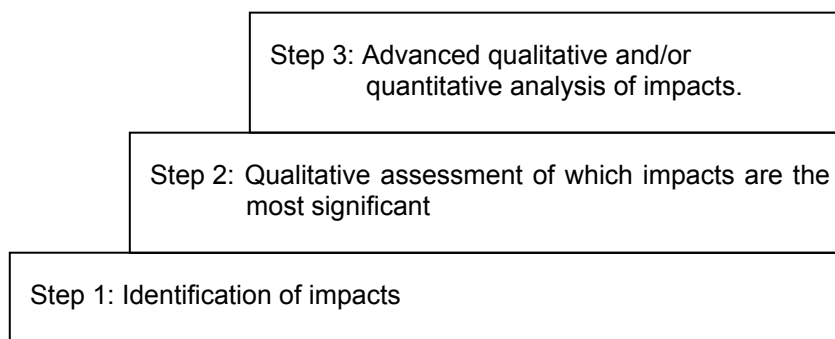
The Commission is developing an internet-based tool (IQ TOOLS – see Annex 5) to support the impact assessment process by strengthening its qualitative and quantitative tools and methods. This will help you to access information on good practice, on models and tools for quantitative analysis, and provide guidance for identifying the potential effects of policy actions on the economic, social and environmental dimensions. Please contact your IA support unit/function for further information.

The Commission has also developed a set of indicators to monitor the implementation of the EU sustainable development strategy⁴². In assessing impacts it is highly recommended to make use of these indicators to the extent they are relevant for the proposal. This will ensure comparability of the impacts of different proposals and will promote consistency of individual proposals with the EU sustainable development strategy.

⁴² SEC(2005) 161 final.

The approach proposed below consists of three steps. The first two constitute an exercise in screening policy options for their likely impacts prior to a possible in-depth or more extensive analysis as appropriate. Each step will provide you with stand-alone results, constituting the basis for the subsequent steps. The aim of such an approach is to facilitate the implementation of a **proportionate analysis**.

Graph 2: Analysis of impacts in three steps



Step 1: Identify environmental, economic and social impacts of a policy, why they occur and who is affected

The first step is to identify those impacts that are likely to occur as a consequence of implementing the policy. Some impacts of the policy will be intentional and will therefore have already been identified in the form of objectives (See III.2). However, it is also necessary to try to identify possible unintended impacts. The screening of the lists of possible impacts (see tables below), in addition to consultation with other DGs and/or external stakeholders and experts, should help you do this.

When identifying impacts you should state clearly the links between cause (the action, instrument, etc) and effects (the impacts). It should also be made clear to what extent the proposed action(s) will contribute to reaching the (operational) objective(s). You should also systematically identify who is affected by the identified impacts and over what timescale the impacts will occur.

Identifying the impacts on different groups in society is a crucial part of IA. Options that would be beneficial for society as a whole may fail to be implemented if too little account is taken of how the positive and negative impacts are spread across society. You should consider two distinct types of distributional impacts:

- Impacts on different social and economic groups. Carefully identifying ‘winners’ and ‘losers’ can help you foresee obstacles to the proposed action and may point to the need to change its design, or to introduce accompanying measures to mitigate the negative impacts.
- Impacts on existing inequalities. You should for instance compare regional, gender and ethnic impacts of the proposed action to see if the latter 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 is apparently neutral as regards gender equality will in practice have different impacts on men and women.

A useful approach to identifying impacts is to build a **causal model**. This ‘bottom-up’ exercise starts by identifying the impacts that would arise as a result of the policy attaining its set objectives. These initially identified impacts can then form the basis for identifying further rounds of impacts, and so on. A flowchart or map of impacts can then be built that sketches out cause-and-effect linkages between each of the policy options/instruments and their impacts.

How far you develop your causal model (i.e. in terms of the range of impacts addressed) and what level of detail you develop, for example including possible feedback loops, is a

Table 1: Economic impacts

Impacts on:	Key questions
Competitiveness, trade and investment flows	<p>Does the option have an impact on the competitive position of EU firms in comparison with their non-EU rivals?</p> <p>Does it provoke cross-border investment flows (including relocation of economic activity)?</p> <p>Are the proposed actions necessary to correct undesirable outcomes of market processes in European markets?</p>
Competition in the internal market	<p>Does the option affect EU competition policy and the functioning of the internal market? For example, 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?</p>
Operating costs and conduct of business	<p>Will it impose additional adjustment, compliance or transaction costs on businesses?</p> <p>Does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)?</p> <p>Does it affect access to finance?</p> <p>Does it impact on the investment cycle?</p> <p>Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited?</p> <p>Will it entail stricter regulation of the conduct of a particular business? Will it directly lead to the closing down of businesses?</p> <p>Are some products or businesses treated differently from others in a comparable situation?</p>
Administrative costs on businesses	<p>Does the option impose additional administrative requirements on businesses or increase administrative complexity?</p> <p>Do these costs weigh in relative terms heavily on SMEs (Small and Medium Enterprises)?</p>
Property rights	<p>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?</p>
Innovation and research	<p>Does the option stimulate or hinder research and development?</p> <p>Does it facilitate the introduction and dissemination of new production methods, technologies and products?</p> <p>Does it affect intellectual property rights (patents, trademarks, copyright, other know-how rights)?</p> <p>Does it promote or limit academic or industrial research?</p> <p>Does it promote greater resource efficiency?</p>
Consumers and households	<p>Does the option affect the prices consumers pay?</p> <p>Does it impact on consumers' ability to benefit from the internal market?</p> <p>Does it have an impact on the quality and availability of the goods/services they buy, and on consumer choice? (cf. in particular non-existing and incomplete markets – see Annex 2)</p> <p>Does it affect consumer information and protection?</p> <p>Does it have significant consequences for the financial situation of individuals / households, both immediately and in the long run?</p> <p>Does it affect the economic protection of the family and of children?</p>
Specific regions or sectors	<p>Does the option have significant effects on certain sectors?</p> <p>Will it have a specific impact on certain regions, for instance in terms of jobs created or lost?</p> <p>Does it have specific consequences for SMEs?</p>
Third countries and international relations	<p>Does the option affect EU trade policy and its international obligations, including in the WTO?</p> <p>Does it affect EU foreign policy and EU/EC development policy?</p> <p>Does the option affect third countries with which the EU has preferential trade arrangements?</p> <p>Does the option affect developing, least developed and middle income countries?</p>

Public authorities	Does the option have budgetary consequences for public authorities at different levels of government, both immediately and in the long run? Does the option require significant establishing new or restructuring existing public authorities?
The macroeconomic environment	What are the overall consequences of the option for economic growth and employment? Does it contribute to improving the conditions for investment and for the proper functioning of markets? Does the option have direct or indirect inflationary consequences?

Table 2: Environmental impacts

Impacts on:	Key questions
Air quality	Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (polluted soil or rivers etc)?
Water quality and resources	Does the option decrease or increase the quality or quantity of freshwater and groundwater? Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? Does it affect drinking water resources?
Soil quality or resources	Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?
The climate	Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs, etc.) and greenhouse gases (e.g. carbon dioxide, methane etc) into the atmosphere?
Renewable or non-renewable resources	Does the option affect the use of renewable resources (freshwater, fish) more quickly than they can regenerate? Does it reduce or increase use of non-renewable resources (groundwater, minerals etc)?
Biodiversity, flora, fauna and landscapes	Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? Does it affect protected or endangered species or their habitats or ecologically sensitive areas? Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones? Does the option affect the scenic value of protected landscape?
Land use	Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?
Waste production / generation / recycling	Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?
The likelihood or scale of environmental risks	Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions? Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms? Does it increase or decrease the likelihood of natural disasters?
Mobility (transport modes) and the use of energy	Does the option increase or decrease consumption of energy and production of heat? Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? Does it increase or decrease vehicle emissions?
The environmental consequences of firms' activities	Does the option lead to changes in natural resource inputs required per output? Will it lead to production becoming more or less energy intensive?

	<p>Does the option make environmentally un/friendly goods and services cheaper or more expensive through changes in taxation, certification, product, design rules, procurement rules etc.?</p> <p>Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc?</p> <p>Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?</p>
Animal and plant health, food and feed safety	<p>Does the option have an impact on health of animals and plants?</p> <p>Does the option affect animal welfare (i.e. humane treatment of animals)?</p> <p>Does the option affect the safety of food and feed?</p>

Table 3: Social impacts

Impacts on:	Key questions
Employment and labour markets	<p>Does the option facilitate new job creation?</p> <p>Does it lead directly to a loss of jobs?</p> <p>Does it have specific negative consequences for particular professions, groups of workers, or self-employed persons?</p> <p>Does it affect the demand for labour?</p> <p>Does it have an impact on the functioning of the labour market?</p>
Standards and rights related to job quality	<p>Does the option impact on job quality?</p> <p>Does the option affect the access of workers or job-seekers to vocational or continuous training?</p> <p>Will it affect workers' health, safety and dignity?</p> <p>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?</p> <p>Does it affect the protection of young people at work?</p> <p>Does it directly or indirectly affect employers' existing rights and obligations?</p> <p>Does it bring about minimum employment standards across the EU?</p> <p>Does the option facilitate or restrict restructuring, adaptation to change and the use of technological innovations in the workplace?</p>
Social inclusion and protection of particular groups	<p>Does the option affect access to the labour market or transitions into/out of the labour market?</p> <p>Does it lead directly or indirectly to greater in/equality?</p> <p>Does it affect equal access to services and goods?</p> <p>Does it affect access to placement services or to services of general economic interest?</p> <p>Does the option make the public better informed about a particular issue?</p> <p>Does the option affect specific groups of individuals, firms, localities, the most vulnerable, the most at risk of poverty, more than others?</p> <p>Does the option significantly affect third country nationals, children, women, disabled people, the unemployed, the elderly, political parties or civic organisations, churches, religious and non-confessional organisations, or ethnic, linguistic and religious minorities, asylum seekers?</p>
Equality of treatment and opportunities, non-discrimination	<p>Does the option affect equal treatment and equal opportunities for all?</p> <p>Does the option affect gender equality?</p> <p>Does the option entail any different treatment of groups or individuals directly on grounds of e.g. gender, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation? Or could it lead to indirect discrimination?</p>

Private and family life, personal data	<p>Does the option affect the privacy of individuals (including their home and communications) or their right to move freely within the EU?</p> <p>Does it affect family life or the legal, economic or social protection of the family?</p> <p>Does the option involve the processing of personal data or the concerned individual's right of access to personal data?</p>
Governance, participation, good administration, access to justice, media and ethics	<p>Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach?</p> <p>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?</p> <p>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?</p> <p>Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities?</p> <p>Will the option affect the individual's rights and relations with the public administration?</p> <p>Does it affect the individual's access to justice?</p> <p>Does the option make the public better informed about a particular issue? Does it affect the public's access to information?</p> <p>Does the option affect the media, media pluralism and freedom of expression?</p> <p>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)?</p>
Public health and safety	<p>Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (e.g. working environment, income, education, occupation, nutrition)?</p> <p>Does the option increase or decrease the likelihood of bioterrorism?</p> <p>Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment?</p> <p>Does it affect health due to changes in the amount of noise or air, water or soil quality in populated areas?</p> <p>Will it affect health due to changes energy use and/or waste disposal?</p> <p>Does the option affect lifestyle-related determinants of health such as use of tobacco, alcohol, or physical activity?</p> <p>Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?</p>
Crime, Terrorism and Security	<p>Does the option improve or hinder security, crime or terrorism?</p> <p>Does the option affect the criminal's chances of detection or his/her potential gain from the crime?</p> <p>Is the option likely to increase the number of criminal acts?</p> <p>Does it affect law enforcement capacity?</p> <p>Will it have an impact on the balance between security interests and the rights of suspects?</p> <p>Does it affect the rights of victims of crime and witnesses?</p>
Access to and effects on social protection, health and educational systems	<p>Does the option have an impact on services in terms of their quality and access to them?</p> <p>Does it have an effect on the education and mobility of workers (health, education, etc.)?</p> <p>Does the option affect the access of individuals to public/private education or vocational and continuing training?</p> <p>Does it affect the cross-border provision of services, referrals across borders and co-operation in border regions?</p> <p>Does the option affect the financing / organisation / access to social, health and education systems (including vocational training)?</p> <p>Does it affect universities and academic freedom / self-governance?</p>

The approach described above will help you to consider a wide range of possible impacts so that the analysis does not just concentrate on a few core impacts. Thus, this exercise should result in a **comprehensive picture** of the potential effects of the policy option.

In the case of the reform of a Common Market Organisation for sugar, the unintended impacts are identified as:

- reduced demand for alternative products leading to job losses in the sectors/regions concerned;
- less diversified sources of supply leading to price volatility;
- more efficient transportation.

Reduced production and job losses in the regions concerned to be balanced by the maintenance of jobs (the latter resulting from achieving the objective of switching production to alternative crops).

Remember to think about who will be affected by the policy options and over what timescale, and check this against the list of impacts you have identified. This will provide you with a basis for studying the distributional impacts as identifying ‘winners’ and ‘losers’ can help you to foresee obstacles to the proposal and may point to the need to change its design, or to introduce accompanying measures to mitigate negative impacts. For example, a proposal may lead to all or most of the benefits going to consumers, while the costs fall mainly on enterprises. There may also be important distributional effects even within a given group (e.g. between small and large companies, between market entrants and incumbents, between low-income and higher-income households, etc). Also, it can be important to take due account of the potential impacts on public opinion.

Finally, the impacts may differ significantly between Member States or regions, suggesting a need to implement the proposal flexibly.

In the example given above, there are potential redistributive effects between:

- consumers who benefit from reduced prices and producers who experience reduced profitability and the producer regions which may lose jobs as a result;
- smaller, less competitive producers who will be more vulnerable during the restructuring of the sector than larger, more efficient ones;
- jobs lost as a consequence of restructuring the sector may bear particularly heavily on women employed in product transformation activities.

Step 2: Identifying the most important impacts

Identifying the most important impacts can be done quickly and cheaply by using simple tools, such as the ones described below. Significant effort should then be spent in the analysis of these impacts.

The causal model described above is a particularly useful tool for such identification since it provides a foundation upon which more sophisticated analyses can be built, taking into account the significance and nature of each proposal (cf. the principle of proportionate analysis).

You may also proceed through qualitative assessment. In this approach, you will have to:

- Assign likelihoods (e.g. low, medium or high probability) that the identified 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 are outside the control of those managing the intervention and which may influence the probability that impacts will occur.
- Assess the magnitude of each impact (e.g. low, medium or high). 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 15 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 impacts of regulatory instruments and spending programmes will depend in part on whether they are actually implemented and not just how they are implemented. The extent to which compliance is likely to take place should be considered as a likelihood/risk of an impact occurring (See Box below).

Box 9: Identifying potential obstacles and incentives to compliance

Potential obstacles to compliance by the group whose behaviour is meant to change, and any incentives likely to increase its compliance, by considering the following questions:

Would the requirements of the options be simple and easy to understand? Inaccessible and incomprehensible rules will reduce compliance, particularly for small businesses, which often lack time and resources to read and understand large volumes of complex rules.

Would the target group be willing to comply? Their willingness may depend on:

Compliance costs, including administrative burdens, may affect overall compliance rates, in particular those of disproportionately affected groups such as small businesses.

Overly legalistic and technical regulation may appear not to relate to any substantive purpose, leading to a loss of confidence in the regulators and an 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.

Rigorous monitoring arrangements and sanctions for non-compliance can be expected to increase compliance rates.

Would the target group be able to comply? Implementation policies, including providing information and other support measures, can affect the ability of the target group to comply with the rule.

When you consider compliance issues, you need to always remember that EU rules are in general implemented by Member State authorities. Therefore, your compliance analysis needs to take account of any possible variation in how Member States implement the rule. For example, framework directives may leave lots of room for flexible implementation at Member State level. This could have a knock-on effect on compliance by the target groups in different countries. In the case of Directives, it is important to be aware of national difficulties in implementing certain requirements, in order to take them into account when setting implementation periods. Thus, to help you in your compliance analysis, it would be useful to consult with the target population and the Member States.

Apart from outlining the advantages and disadvantages of the policy options from the point of view of compliance, the analysis should also provide information about how best to design the option.

For example:

- What time scale should be set for implementation?
- What type of sanction is most appropriate - administrative, civil or criminal law?

Drawing once again on the sugar example set out above:

A key objective of the reform is to reduce the price of the product. The following assessment could be made:

Link N°	Cause	Effect	Likelihood	Intensity
1	Ending of production quotas	Reduced prices	High	High
2	Abolition of domestic price support	Reduced prices	High	High
3	Increased overseas competition	Reduced prices	High	Low

Economic theory would support the assumption that there is a direct and unambiguous link between prices and the ending of production quotas, abolition of price support and increased overseas competition. So, in this case, the impact on prices is assessed consistently as high. Furthermore, the magnitude of the impact, in terms of falling prices, will also be high, although the contribution of overseas competition to this impact might be judged as limited, due to traditional producers' output being substituted by the output from new, more efficient producer countries. This effect might also be limited as demand for imports may possibly be affected by the problem of the product deteriorating whilst in transit.

Link N°	Cause	Effect	Likelihood	Intensity
6	Reduced prices	Reduced demand for non-sugar sweeteners	High	High

The likelihood that reducing sugar prices will lead to reduced demand for non-sugar sweeteners has been assessed as high on the assumptions that sugar and non-sugar sweeteners are directly competing products, and that producers of non-sugar sweeteners are unable to lower their prices. If either of these assumptions is incorrect - for example, if consumers prefer non-sugar sweeteners because they believe they are healthier - then the effect of the sugar reform on sales of non-sugar sweeteners will be less significant. In such cases, you should try to collect evidence to test the validity of the assumptions. If this is not possible or would involve a disproportionate effort, you should indicate the possible uncertainty about the scale of the impact in the impact assessment report.

Building an **'impact matrix'** is a third way to structure the task of identifying the more important impacts of policies composed of multiple instruments. It involves the following five tasks:

1. Break the policy options down into their main actions (the rows of the matrix).
2. Identify the main types or categories of impacts (the columns of the matrix), organised according to a time horizon where possible.
3. Indicate in each cell the likelihood of an impact (certain, probable, unlikely).
4. 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.
5. Indicate in each cell the addressees (or affected populations), the timescale over which the impacts are expected to occur.

Once this basic information has been entered into the relevant cells, additional information can also be added as necessary, such as the extent to which impacts are irreversible, the causal paths by which they occur, etc.

The impact matrix and the qualitative assessment can in fact be considered as complementary tools, for example by using the matrix as a means of synthesising and presenting key results arising from the qualitative assessment exercise.

Example of an impact matrix

		Short term Impacts		Long-term Impacts	
		Prices	Environment	Employment	Restructuring
Actions	End production Quotas	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees
	Abolish domestic price support	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees
	End quantitative and tariff restrictions on trade	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees	likelihood and timescale Addressees

Whichever approach is used, you should keep the following points in mind when identifying and describing impacts:

1. Given the potential complexity of such an analysis, it is important that it is done in a structured and explicit way, both for communicating results and to provide a basis for further, in-depth analysis.
2. 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.
3. Do not overlook impacts that cannot readily be expressed in quantitative or monetary terms.
4. Remember that different factors influencing impacts interact with one another.
5. 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'.
6. Impacts should be considered in the context of promoting sustainable development, achieving the goals of the Lisbon Strategy, and respect for Fundamental Rights.

STEP 3: Advanced analysis of impacts

The above approach allows you to make a structured, qualitative analysis of a proposal's impacts. When it is considered proportionate, further in-depth analyses should be made. These can take a number of forms, building on the analysis and results of Step 2:

- In-depth qualitative analysis of selected impacts which focuses on selected impacts or chains of impacts about which both qualitative and quantitative data are collected and analysed qualitatively, typically using 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 analysis of impacts. This type of examination of impacts focuses on either a limited selection or a broad range of chains of impacts, which are subject to a quantitative analysis. The selected 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 to proper 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 5, 7, 8 and 11 provide further guidance in how to undertake a quantitative analysis and set out some important rules for economic analysis.⁴³

Box 10: Combining quantitative and qualitative methodologies is good practice

The Impact Assessment on the reform of the Common Market for Sugar demonstrates that it is possible to fruitfully combine quantitative and qualitative approaches to ensure that adequate consideration is given to a broader range of direct and indirect, social, environmental and economic impacts. This IA used in-depth modelling analysis to determine the macro-economic effects of different policy reform scenarios, as well as qualitative multi-criteria evaluation of broader impacts and diverging stakeholder views.

4.3. Data sources, collection and analysis

Data for developing a causal model (Step 1) and the qualitative assessment (Step 2) can be obtained firstly by drawing on the knowledge and expertise of your Commission colleagues. These exercises can be enriched by involving outside experts, by conducting desk reviews of existing research, studies and evaluations, and by utilising the results of consultations with stakeholders. For instance, organisations such as the European Economic and Social Committee, the Committee of the Regions and the 'Ongoing and systematic policy dialogue with local-government associations' will often be able to provide useful information on impacts. Furthermore, information on public opinion is available from Eurobarometer surveys. In order to implement an advanced analysis of impacts (Step 3), you will most probably need to draw on additional sources of qualitative and quantitative data from various stakeholders (addressees, civil society, national governments, etc.) using a variety of techniques such as interviews, focus groups, questionnaires, etc.

In both cases it is important to verify that data are readily available from statistical agencies and databases, or can be easily collected on an ad hoc basis. Quantitative models however are time-consuming and resource-intensive to develop. Some quantitative models have been developed with the financial support of the Commission. You should therefore start by examining if one of these models corresponds with the analytical needs of IA. If adaptation of an existing model is required, the use of in-house resources (such as the Joint Research Centre (JRC)) should be envisaged first (on modelling see Annex 7). If the development or adaptation of a quantitative model must be contracted out, the call for tender should ideally ensure that code environment is indicated, that the source code is supplied and becomes Commission property and that adequate training material for Commission staff is foreseen.

When undertaking quantitative analyses, it is important to remember that in some cases, the level of uncertainty may be too high to make precise quantified estimates. In these cases, ranges of plausible values or different scenarios should be given, thereby avoiding the

⁴³ For reasons of comparability it is recommended to apply the standard discount rate of 4% (see Annex 12 on discounting).

illusion of precision that results from quantitative analyses – **avoid what has been termed ‘spurious accuracy’!** Techniques such as quantitative sensitivity analysis can help in showing how changes in particular parameters, scenarios or assumptions affect the outcomes of the various options being considered.

A further development of quantitative analysis is to estimate the monetary value of both negative (costs) and positive (benefits) impacts, which has the advantage of facilitating the comparison of policy options (see III.5).

However, it is important to understand that not all impacts can be quantified; nor can they all be reliably expressed in money terms. In cases where assessing the millions of euros gained or lost as a result of the measure proves to be too difficult or uncertain, the main effort should go into describing and, where possible, quantifying impacts accurately in their own terms (e.g. calculating waste reduction in percentage terms or the increase in traffic congestion in terms of the number of hours lost).

Regardless of the analytical approach adopted, you must aim for results that are:

- **Transparent:** it must be clear to others how you arrived at your estimation of impacts.
- **Reproducible:** others must be able to arrive at the same results, using the same data and approach.
- **Robust:** if using different methods or assumptions to estimate the impacts gives very different results, this may call into question the reliability of your analysis.
- If results depend on the choice of a specific analytical method, or if the data used are not fully reliable, it is essential to set this out.

Links to additional sources of information and guidance by Commission services can be found on the IA IntraComm and Europa websites.⁴⁴

⁴⁴See <http://intracomm.sg.cec.eu.int/i/impact/> and http://www.europa.eu.int/comm/secretariat_general/impact/index_en.htm.

5. HOW DO THE OPTIONS COMPARE?

Once you have analysed the relevant impacts, the next step is to compare them so as to allow consideration of the strengths and weaknesses of each of the policy options. This may then allow the conclusion to be drawn that one option stands out above the others. However, it is important to reiterate that the final decision on whether, and how, to proceed is a political one.



- Weigh-up the positive and negative impacts for each option.
- Where feasible, display aggregated and disaggregated results.
- Present comparisons between options by area.
- Identify, where possible and appropriate, a preferred option.

5.1. How to compare the impacts of different options

For all of the options considered (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.⁴⁵

As a first step, the impacts of each option should be summarised by area of impact (economic, environmental, social) and even by sub-impacts (for example, as listed in Tables 1 to 3 in the previous section). 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 potentially to provide an assessment of the overall net impact⁴⁶ of each option. However, when this type of cumulative presentation of impacts is made, care should be taken to avoid 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.

Summary Table 1 – Policy option A

	Qualitative Description	Quantitative Description	Monetised Value
Economic Impacts			
Costs to Enterprises sub-impacts	Obligation to install new air pollution equipment	Approx. 400 firms affected	€ 400 million
Social Impacts			
Communities sub-impacts	Better quality of life in communities	Around 100 benefiting (near to firms)	Not monetised
Environmental Impacts			
Air pollution sub-impacts	Reduced mortality rates	'X' premature deaths avoided each year	€ Y billion (value of 1 life multiplied by 'X')

⁴⁵ The approach presented here is a simple multi-criteria analysis, which compares positive and negative impacts expressed in a mixture of qualitative, quantitative and monetary terms. Alternative approaches are cost-benefit analysis, which compares positive and negative impacts expressed in the same units, normally in monetary terms, and cost-effectiveness analysis, which compares the costs of achieving a given objective. Other methods exist and can be used when appropriate. Annexes 12 and 13 provide additional information on pros and cons of the different methods and the use of real prices and discount rate.

⁴⁶ The definition of net impact here is positive impact minus negative impact.

An example of good practice in presenting results for each option simply can be seen in the summary table below, which breaks down the economic, social and environmental impacts into individual impacts, described in qualitative, quantitative and monetary terms as appropriate. This makes clear what is and is not included in the aggregated data, thereby avoiding the ‘black-box’ approach of providing only a single overall monetised value.

A further example of good practice is to summarise the impacts of all policy options side by side. In the example below, taken from the Impact Assessment on the Visa Information System (VIS)⁴⁷, the costs and benefits of each of the options have been set out in an easily understandable way.

Costs	Financial costs	Opportunity costs for visa applicants	Retaliation costs for EU travellers	Reductions in business travel and tourism	Impact on fundamental rights, in particular the protection of personal data and privacy
No VIS	-	-	-	-	-
Entry-exit system	√√√√	√√	√	√	√√√√
VIS without biometrics	√	-	-	-	√√
VIS with biometrics	√√	√√	√	√	√√√

Benefits	Efficiencies in implementation of Common Visa Policy	Reductions in fraud and visa shopping	Increased efficiency of border checks	Reductions in illegal migration / facilitation of the Dublin Regulation	Contribution towards internal security	Increased efficiencies for bona fide travellers	Other spin offs
No VIS	-	√*	√*	√*	√*	-	-
Entry-exit system	√√√	√√√	√√√	√√√	√√	√√√	√√√
VIS without biometrics	√√	√√	√√	√	√	√√	√
VIS with biometrics	√√√	√√√	√√√	√√	√√	√√√	√√√

⁴⁷ SEC(2004) 1628.

This other example on sugar market reform summarises the advantages and drawbacks of each of the options.

	Advantages	Drawbacks
Status quo	<ul style="list-style-type: none"> • Maintains production and income in the majority of regions, although the level of both gradually decreases. • Progressively decreases the budget cost of the regime. • Maintains current benefits to ACP/EBA countries. 	<ul style="list-style-type: none"> • Delays restructuring and improved competitiveness of the sector. • Attracts non-restricted quantities of imports, under preferential agreements, at non-competitive prices, to the EU market, which threaten continued EU production in the long run. • Maintains distortions in competition. • Maintains inequalities among farmers. • Trade balance is very sensitive to the removal of the safeguard clause and the abolition of C sugar. • Complicates the EU's WTO negotiating position. • The common market organisation for sugar remains complex and non-transparent.
Price fall	<ul style="list-style-type: none"> • Facilitates restructuring and improved competitiveness of the sector. • Reduces production surpluses and world market distortion. • Reduces distortions in competition. • Reduces inequalities among producers. • Reduces cost to consumers and users. • Promotes diversification in the market for sweeteners. • Facilitates WTO negotiations. • Promotes application of cross-compliance. • Reduces budget cost of the regime slightly. 	<ul style="list-style-type: none"> • Producer incomes fall. • Revenue of ACP countries falls. • Cost of possible accompanying measures for restructuring.
Fixed quotas	<ul style="list-style-type: none"> • Ensures stable supply and protects from fluctuations in world market prices. • Raises the sector's visibility, allowing it to resume investing. • Maintains production in more of EU with beneficial effects on rural communities, unless quotas are transferred. • Reduces budget cost of sugar regime. 	<ul style="list-style-type: none"> • Backtracking on EBA would affect credibility of EU. • Delays restructuring and improved competitiveness of the sector, unless quotas are transferred. • Maintains distortions in competition. • Maintains inequalities among farmers. • Complicates the EU's WTO negotiating position. • The common market organisation for sugar remains complex and non-transparent.

Liberalisation	<ul style="list-style-type: none"> • Competitiveness of the sector is improved in the long term. • World market distortions are reduced. • Facilitates WTO negotiations. • Eliminates the budget cost of the regime, unless compensation is granted. • Eliminates distortions in competition. • Greatly simplifies the common market organisation for sugar. 	<ul style="list-style-type: none"> • Regularity of supply and price stability are no longer assured to the same degree. • A large part of the EU sugar industry disappears. • Agricultural incomes fall, with a significant impact on some rural communities. • Revenue falls for non-competitive traditional partners (ACP). • Production of alternative sweeteners is no longer competitive and disappears. • Profitability of sugar refineries is threatened. • Cost of possible accompanying measures for restructuring. • Budget cost if compensation is granted to farmers.
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You may also add a table comparing impacts on certain groups. In the impact assessment carried out on the Reform of the European Union's Sugar Policy, a table was used which set out who would gain an advantage, who would remain the same, and who would be put at a disadvantage by each of the options. Inserting a table like this into your final impact assessment report (see II.9) should help the political decision-makers to see which groups are likely to be affected by their decision on how or whether to proceed.

	Advantaged	Disadvantaged
Status quo	EBA, Balkans, Refineries, Importers, Brazil, Budget	Farmers, Sugar mills, Environment
	AFI, ACP, Consumers, Sweeteners, Agricultural inputs, Rural areas	
Price fall	AFI, Consumers, Environment, Budget	EBA, Balkans, ACP, Farmers, Sugar mills, Refineries, Importers, Agricultural inputs, Rural areas
	Sweeteners, Brazil	
Fixed quotas	Refineries, Importers, Sweeteners, Budget	EBA, Balkans, Farmers, Sugar mills, Environment
	AFI, ACP, Consumers, Agricultural inputs, Rural areas, Brazil	
Liberalisation	AFI, Importers, Consumers, Brazil, Environment	EBA, Balkans, ACP, Farmers, Sugar mills, Refineries, Agricultural inputs, Rural areas, Sweeteners, Budget
* The impact on stakeholders is evaluated in relation to the current situation.		

5.2. The set of evaluation criteria

The set of evaluation criteria will vary with the policy area(s) concerned and the nature of the proposed objectives. There are, however, some generic evaluation criteria that apply to all proposals of the Commission, namely: effectiveness, efficiency and consistency.

Other criteria are set by the Treaties. The principles of subsidiarity and proportionality are probably the most important of these.

In order to comply with the principle of subsidiarity, the comparison of policy options should 1) confirm that the proposed objective could not be sufficiently achieved by the Member States (the necessity test)⁴⁸ and 2) indicate that the proposed objective could be better achieved by the Union (the added-value test)⁴⁹.

Comparative effectiveness is not the only evaluation criterion set by the Protocol on the application of the principles of subsidiarity and proportionality. The Treaty also requires that the proposed form of action should be as simple as possible and that proposed measures leave as much scope for national decision as possible (for instance, directives being preferred to regulations, and framework directives preferred to detailed measures). Policy options should also be ranked according to the financial and administrative burden falling upon the Community, national governments, regional and local authorities, economic operators and citizens. That burden has to be as low as possible and proportionate to the proposed objective(s).

The table below is one way to present a summary comparison of the policy options in terms of their effectiveness, efficiency, consistency, and other criteria where appropriate. The good practices presented at the end of III.4.3 also apply here.

	Effectiveness	Efficiency	Consistency
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

Indeed, on the basis of these tables, it should be clear whether one option stands out as the preferable option or if some options are close together.

5.3. Ranking the options

The impact assessment process will not necessarily generate clear-cut conclusions or recommendations regarding the final policy choice. Moreover, that final choice is always left to the College of Commissioners. For that reason it will not always be possible for the IA

⁴⁸ PM. This point has to be examined first when assessing the nature of the problem and its likely evolution (see III.1).

⁴⁹ In other words, there should be no (proposal for) EU action if it is not clear that one policy option at least is likely to deliver better results than what Member States alone could do. PM. If a problem falls under the exclusive competence of the Community, the subsidiarity principle does not apply.

report to conclude that one option is better than any of the others. In these cases it will be possible and desirable to rank the options according to various criteria, and to different rankings based on the various selection criterions.

However, as an important aid to decision-making, the results and the alternative options considered – in all cases – need to be presented in a transparent and understandable way to provide the basis for a political discussion on the relative advantages and disadvantages of the relevant options. This allows political 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 so as to help minimise trade-offs, to identify accompanying measures aimed at mitigating any negative effects, and to maximise the opportunities for a ‘win-win’ outcome. Once the political decision has been made, its justification should be given in the Explanatory Memorandum. In addition, where possible, the final choice should also be set out in the IA report, as long as this does not amount to suppressing the presentation of alternative options and their rankings.

6. HOW COULD FUTURE MONITORING AND EVALUATION BE ORGANISED?



- Identify core progress indicators for the key objectives of the possible intervention.
- Provide a broad outline of possible monitoring arrangements.
- Provide a broad outline of possible evaluation arrangements.

6.1. Why examine monitoring and evaluation arrangements at the IA stage?

Policymakers need systems in order to verify whether implementation is ‘on track’, and to what extent the policy is achieving its set objectives. When a policy is not achieving its objectives, they also need to know whether this is due to flawed policy design or 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 to the letter? Is inadequate implementation due to weak administrative capacity?).

Monitoring and evaluation arrangements – including generating data on the basis of carefully designed indicators – provide valuable information in this regard and help in defining how to optimise the intervention.

6.2. What needs to be done at the IA stage?

Within the framework of the impact assessment analysis, an attempt should be made to define some core indicators for the main policy objectives and to outline the monitoring and evaluation arrangements envisaged. There is, however, no point in laying down detailed indicators, monitoring and evaluation arrangements for all the options identified as part of the impact assessment. This will be done after the political choice of the most appropriate policy option has been made, as this is the last step in the policy design process.

That being said, it makes sense to define some core indicators for the key policy objectives (i.e. for the so-called ‘general objectives’). It is fair to assume that these general objectives are reasonably stable across the various alternative policy options envisaged in the impact assessment.

Indicators must be checked against the purpose they are supposed to serve, i.e. measuring to what extent a policy has been properly implemented and its objectives achieved. Consequently, their credibility and clarity are very important. Another important factor in the choice of indicators is the ease with which relevant data can be collected; collecting data on an indicator should not be more costly than the value of the information they provide.

Where a preferred option has been identified, you should:

- (1) describe briefly how the data needed for the monitoring of the intervention’s implementation and effects are to be collected and
- (2) outline the nature, frequency and purpose of subsequent evaluation exercises⁵⁰.

⁵⁰ See also Article 21(2) of the Implementing Rules to the Financial Regulation.

Questions to be addressed should include:

- What will the monitoring data and evaluation findings be needed/used for?
- Who are the key actors in providing and using such information? (e.g. the Commission, Member States, intermediaries such as Agencies, operators/beneficiaries, etc)?
- What will be, in general terms, the roles and responsibilities of these actors? How will information be shared and eventually aggregated?
- 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?

For more detailed guidance (including examples) on indicators, monitoring and evaluation, see Annex 14.

6.3. What needs to be done after the IA stage?

The proposal adopted by the Commission will normally include indicators corresponding to operational and specific objectives, in particular as far as spending proposals are concerned.⁵¹ With regard to monitoring and evaluation, the proposal will provide, where appropriate, for a specific Article laying down the main foundations of the arrangements envisaged. This is particularly important when data from the Member States or intermediary organisations are needed for monitoring and reporting.

The final set of indicators will usually be defined at a later stage, when the amendments of the Council and/or Parliament are known⁵².

⁵¹ For spending proposals, the Financial Regulation requires that information on indicators, monitoring and evaluation has to be entered into the legislative financial statements accompanying the proposal.

⁵² In the case of shared management, monitoring arrangements (including indicators) are usually finalised in the framework of committees involving Member States representatives.

Graph 4: Summary of the key procedural and analytical steps in impact assessment

A. Key procedural steps

First phase

- Planning of the impact assessment/integration in the SPP cycle:
 - Draft and circulate the Roadmap in the run up to the Annual Policy Strategy (APS).
 - Fix the initiative's Roadmap in view of its inclusion in the (APS).
 - Update the Roadmap to be included in the Work programme (WP).
- Set up an Inter-Service Steering Group (ISG):
 - Compulsory for all items of a cross-cutting nature;
 - Include SG.C.1;
 - Need to justify in the Roadmap in case an ISG is not set up.
- Consult interested parties and collect expertise (see box A1 below).
- Carry out the IA analysis.

Second phase

- Present the findings in the impact assessment report even if the initiative is withdrawn (see also box A2 below).
- IA goes into Inter-Service Consultation alongside proposal.
 - Some of the key elements are repeated in the Explanatory Memorandum.
- Examination by a Group of Commissioners in some cases.
- Submission to the College of Commissioners.

Third phase

- Transmission of the IA report alongside the proposal to the other Institutions.
 - Press release should mention the IA.
 - In the case of new information the Commission may decide to update the IA report > contact SG.H.2.
- Final report normally published on Europa website by SG.

A1. Running throughout the process: stakeholder consultation & collection of expertise

- Establish a Consultation Plan to ensure input from interested parties and experts.
- Identify:
 - the objective of the consultation(s)
 - the elements of the IA for which consultation is necessary
 - the target groups
 - the appropriate consultation tool(s)
 - the appropriate time for consultation(s)
- Respect the Minimum standards for consultation in the IA process and reporting – see COM(2002)704.

A2. Presenting the findings: the IA report

- Summarise the work undertaken for the IA into a short report.
- State any assumptions or uncertainties.
- Use simple and non-technical language.
- Use the format presented in Annex 16.
- Put technical detail or supporting documents in an annex.

B. Key analytical steps

1. Identify the problem

- Delineate the extent of the problem.
- Identify the key players/affected populations.
- Establish the causes.
- Is the problem in the Union's remit to act?

2. Define the objectives

- Set objectives that correspond with the problem and its root causes.
- Establish objectives at a number of levels so as to set out the 'intervention logic'.
- Ensure that the objectives are consistent with EU policies and strategies, such as the Lisbon and Sustainable Development Strategies.

3. Develop main policy options

- Identify policy options to meet the objectives.
- Consider the most appropriate delivery mechanisms (regulatory/non-regulatory approaches).
- Begin to narrow the range through screening for technical and other constraints, and measuring against criteria of effectiveness, efficiency and consistency.
- Draw-up a shortlist of potentially valid options for further analysis.

4. Analyse their impacts

- Identify (direct and indirect) environmental, economic and social impacts and how they occur.
- Identify who is affected (including those outside the EU) and in what way.
- Assess the impacts in qualitative, quantitative and monetary terms where possible and appropriate.
- Consider the risks and uncertainties in the policy choices, including obstacles to compliance.

5. Compare the options

- Weigh-up the positive and negative impacts for each option.
- Where feasible, display aggregated and disaggregated results.
- Present comparisons between options by area.
- Identify, where possible and appropriate, a preferred option.

6. Outline policy monitoring and evaluation

- Identify core progress indicators for the key objectives of the possible intervention.
- Provide a broad outline of possible monitoring arrangements.
- Provide a broad outline of possible evaluation arrangements.