



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/sq/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>.

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:

PROBLEMS	DRIVERS
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.

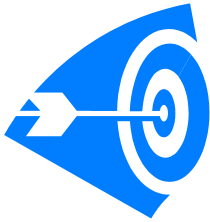
Where there is uncertainty about the underlying factors, then it is good practice to construct alternative baseline scenarios against which you can assess policy options.

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.

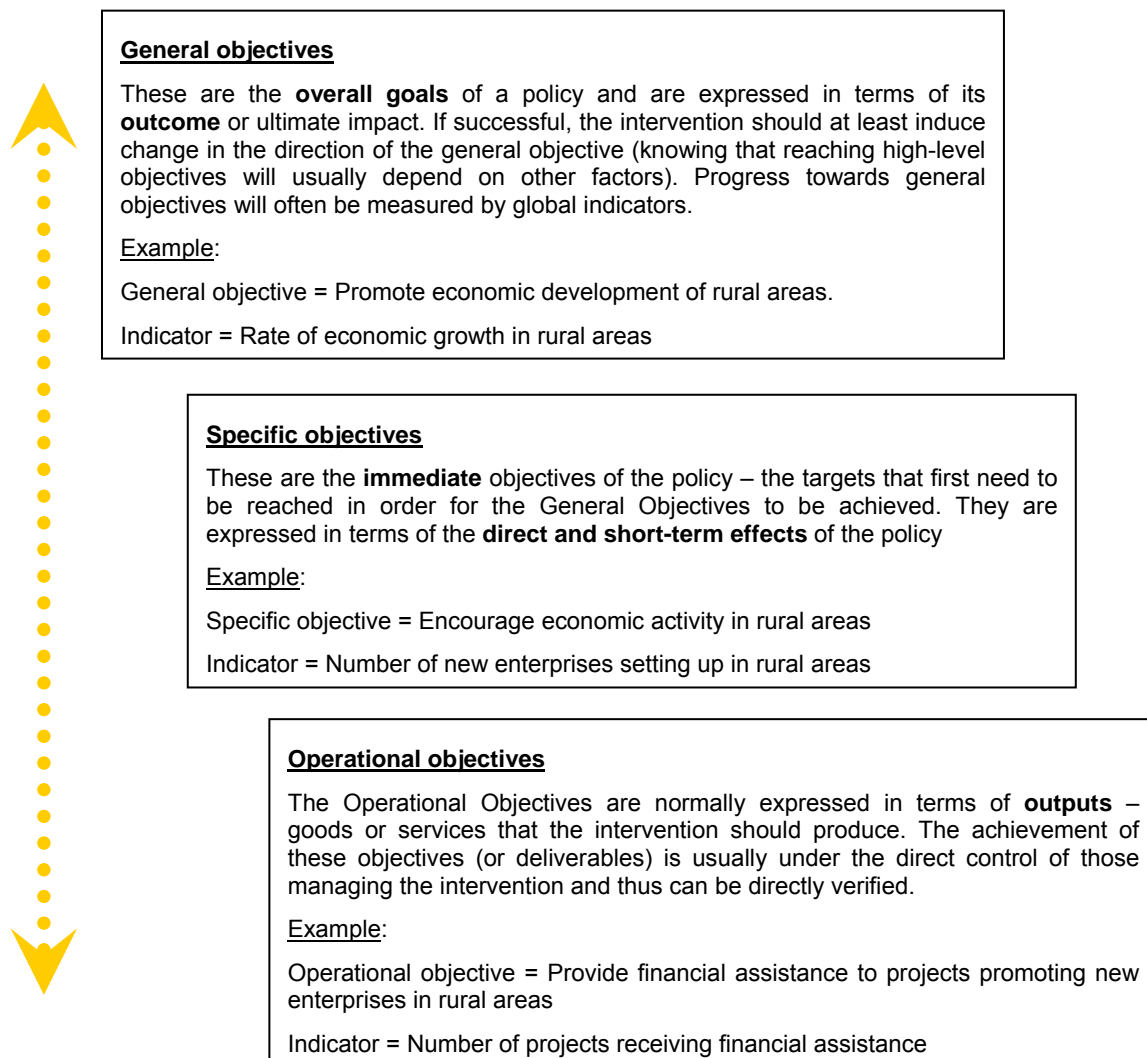
Time-dependent: Objectives and target levels remain vague if they are not related to a fixed date or time period.

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

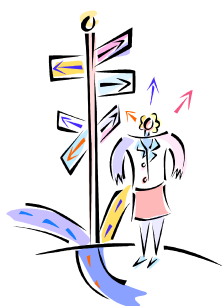
No policy action by the Commission should be taken in isolation. It is necessary to check whether the objectives envisaged are consistent with the other EU policies. In practical terms, this means that you should look at any impacts the proposal may have on other policy areas and, if necessary, adjust 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).

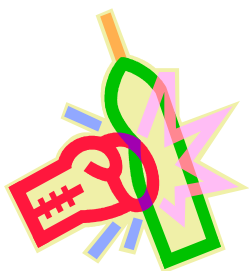
Alternatively, you could undertake the analysis in a more structured and formal way, elaborating a causal model of impacts and using that to make a qualitative assessment of the performance of the various options under review (see III.5.1).

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).

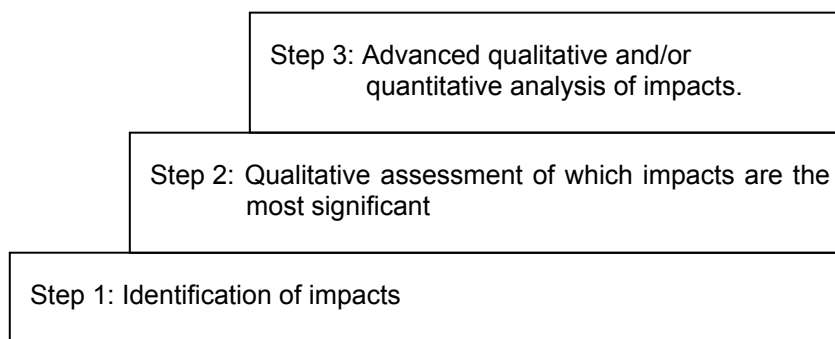
The Commission is developing an internet-based tool (IQ TOOLS – see Annex 5) to support the impact assessment process by strengthening its qualitative and quantitative tools and methods. This will help you to access information on good practice, on models and tools for quantitative analysis, and provide 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.

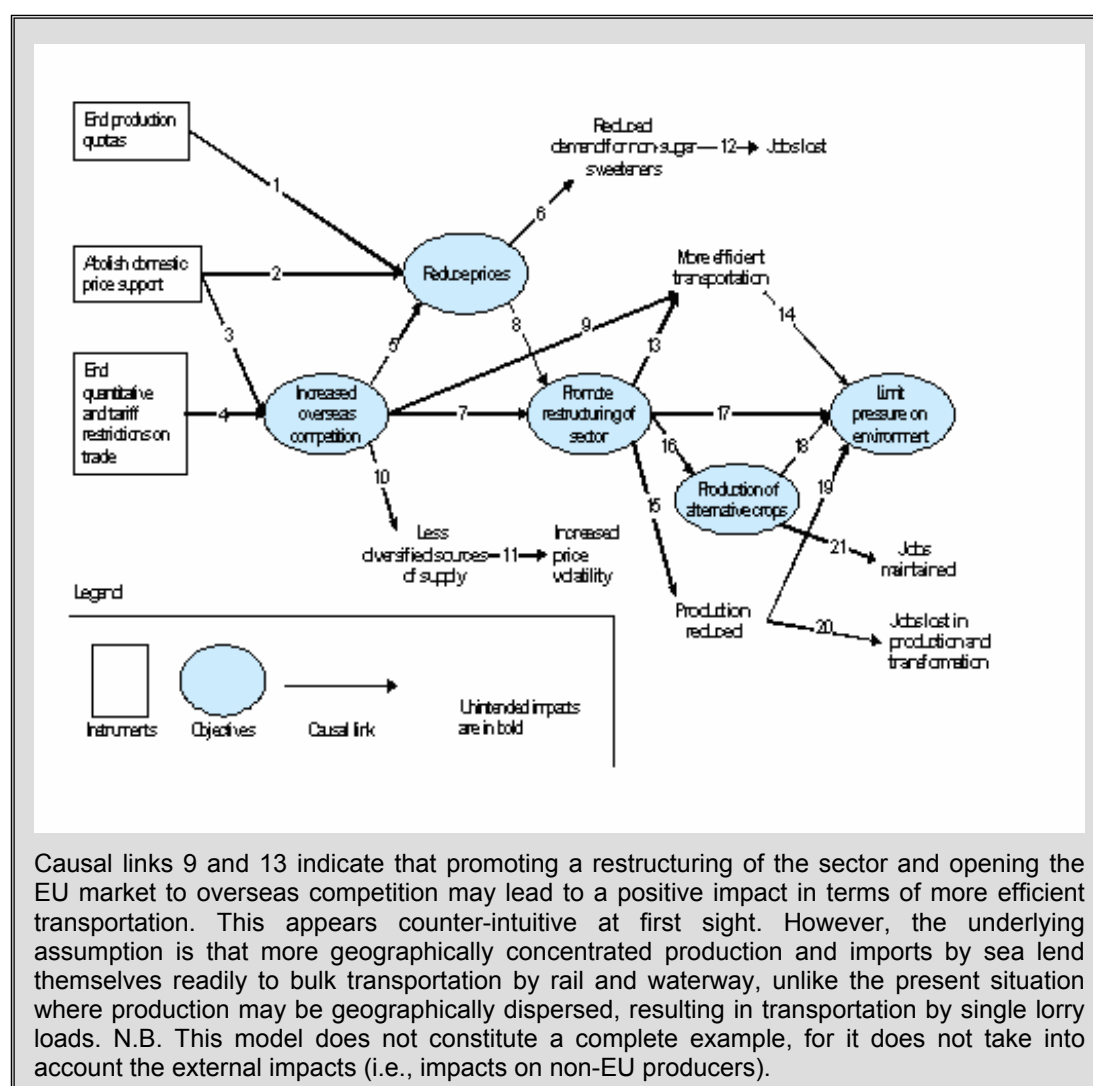
A useful approach to identifying impacts is to build a **causal model**. This ‘bottom-up’ exercise starts by identifying the impacts that would arise as a result of the policy attaining its set objectives. These initially identified impacts can then form the basis for identifying further rounds of impacts, 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

matter of judgement. A more detailed model makes for greater clarity, but obviously requires a greater investment in time and effort. What is important is that those involved in the process of drawing up the model are agreed that it represents a sufficiently accurate and explicit image of impacts and their causes, and that it can be used as a foundation on which further analyses can be built.

In some cases, the basis for establishing a causal relationship between impacts may not be self-evident from the diagram. If this is so, intermediate impacts should be added and/or the assumptions on which the link is made should be made explicit.

Graph 3: Causal model of impacts - reform of the sugar market



When identifying likely impacts inside and outside the EU, you should screen shortlisted options against the economic, environmental and social impacts presented in the following tables. Certain questions in these tables are aimed at examining the impacts on fundamental rights to ensure compatibility with the Charter of Fundamental Rights. It is important to note that the questions presented in the tables are neither exhaustive nor definitive. They are intended to guide you towards ensuring that impacts and issues that have particular policy relevance are considered during the impact analysis. Types of impacts falling outside those listed in the tables but which are relevant for a particular IA should therefore also be considered.

The tables should not be used as a 'checklist' against which you are supposed to answer with a simple 'yes' or 'no'. They are meant as an aid for you to use in developing your thinking about a wider range of potential impacts for the policy options than perhaps you thought relevant at the beginning of your IA work.

Table 1: Economic impacts

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

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	
Actions		Prices	Environment	Employment	Restructuring
	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.

<u>Costs</u>	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	√√	√√	√	√	√√√

<u>Benefits</u>	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.

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.

European Commission



ANNEXES TO IMPACT ASSESSMENT GUIDELINES*

15 June 2005

* These Annexes replace the 2002 'A Handbook for Impact Assessment in the Commission – How to do an Impact Assessment: Technical Annexes'. As indicated in the Guidelines, some of these Annexes are of a compulsory nature (format of the roadmap; discounting; format of the IA report). Other annexes provide detailed guidance on specific moments in the IA analytical process. The more technical annexes are proposed as a non-exhaustive collection of tools open to further improvement and update.

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1. FORMAT OF THE ROADMAP

ROADMAP (max. 5 pages)

Title of the proposal:

Lead DG/contact person:

Expected date of adoption of the proposal:

PART I – Initial IA screening & planning of further work

N.B. This part will be made public on the Europa website at the stage of the WP

A. Initial impact assessment screening

What are the main problems? Are they likely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

What are the main policy objectives?

What are the policy options? What regulatory or non-regulatory instruments could be considered?

What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the enclosed guide)?

B. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Which stakeholders & experts will be consulted, how and at what stage?

Will an inter-service steering group be set up for the IA?

PART II – More detailed planning, including of time & resources

N.B. For internal Commission use only

C. Time line

When will the impact assessment work start?

If there is to be an inter-service steering group*, when will it be set up? What DGs will be invited? How often will it meet? * Required for major, cross-cutting proposals and is strongly recommended for others. If no group is planned, please state the reasons why.

If you are planning any external contracts (e.g. for analytical studies, information gathering, etc.), what is the timing foreseen for the procurement process & the contract?

What is the planned timing for the Inter-service consultation (draft proposal and IA report)? Launch? End?

When will the draft proposal be submitted to DGT? N.B. The IA report is a Commission staff working paper and is normally not translated.

When will the draft proposal and the IA report be submitted to Greffe?

What is the planned date for the approval of the draft proposal? What procedure is foreseen (oral or written)?

D. Resources

What human and/or financial resources have been put aside for conducting the IA and finalising the draft legislation/policy document?

2. PROBLEMS CALLING FOR A SOLUTION

2.1. Discrepancy between the fundamental goals of the Union and the existing situation

- Promoting a harmonious and sustainable development of economic activities and non-inflationary growth (Article 2 EC Treaty)
- Promoting a high level of employment and social protection (Article 2 EC Treaty). Under the EC Treaty, social protection is taken to include the promotion of employment, improved living and working conditions, proper social protection, dialogue between management and labour, the development of human resources with a view to lasting high employment and the combating of exclusion.
- Promoting a high degree of competitiveness and convergence of economic performance (Article 2 EC Treaty).
- Preserving peace and international security and promoting international co-operation objectives of the Common Foreign and Security Policy (TEU, Article 11).
- Safeguarding the security of citizens, or citizens' rights recognised by the Treaty. This includes preventing and combating crime and terrorism (TEU, Article 29)
- Preventing and combating discrimination based on nationality, sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation (Articles 12 and 13 EC Treaty)
- Promoting public health (Article 152 EC Treaty) and a high level of consumer protection, which includes the protection of health, safety, and economic interests of consumers (Article 153 EC Treaty).
- Paying full regard to the welfare of animals in the Community's agriculture, transport, internal market and research policies (Protocol 33 on protection and welfare of animals).
- Strengthening economic and social cohesion. Under the EC Treaty (Article 158), this is to be achieved through reducing disparities between different levels of development of the various regions and the backwardness of the least favoured regions or islands, including rural areas.
- Protecting the environment. Environmental protection is a fundamental component of sustainable development.
- Ensuring the protection of fundamental rights within the framework of EU policies.

2.2. Market failures

The outcome of market forces may fall short of society's ideals for a number of reasons:

Market prices do not reflect the real costs to society

Externalities generate costs ('negative externalities') and benefits ('positive externalities') that are not reflected in market prices. When this happens, the prices of goods and services do not reflect their value to society. In the case of a negative externality, such as pollution, this means that we tend to produce and consume too much of the goods and services that give rise to the externality. The opposite is true of positive externalities.

Example: Externalities and Agriculture

Agriculture gives rise to a broad range of positive and negative externalities. Farming's contribution to the viability of rural communities is a positive externality, but using too much

pesticide or fertiliser can cause water pollution, a negative externality. Agriculture's impacts on landscape and biodiversity can give rise to either positive or negative externalities, depending on the particular circumstances.

Insufficient supply of public goods

The key characteristics of a public good are that (i) one person's consumption of a public good does not reduce the amount available for consumption by others, and (ii) once a public good is supplied, it is available to be consumed by all of society. The consequence is that it is difficult and/or undesirable from the point of view of society to charge individuals directly for consuming the good or service in question, so that unregulated markets will supply too little of the public good, if they supply it at all.

While very few goods and services can *strictly* be called 'public goods' – national defence is one example – many show some of the features of public goods.

Example: traffic congestion

Provided a road is not congested, then one extra car using the road does not affect other drivers' use of the road, and historically, except for special cases such as toll motorways, it has been impossible or prohibitively expensive to charge road users directly for the benefit they get from using the road.

There is some overlap between public goods and 'services of public interest', but the concepts are not identical. The latter term covers services such as health, or energy and water supply. While private markets may simply fail to supply public goods at all (because it is impossible to charge consumers directly), no such technical obstacle prevents private markets supplying services of public interest. However, they may supply too few of them, or do so at a price which society judges unacceptable.

Technological progress can alter the boundaries between public and private goods, or the likelihood that markets will deliver services of public interest at an acceptable price. For example, it should soon become technically possible and relatively inexpensive to charge road users directly, while developments in electricity generation may make it cheaper to deliver electricity to remote rural communities.

Missing or weak competition

Article 98 EC Treaty provides that the Member States and the Community shall act in accordance with the principle of an open market economy with free competition, favouring an efficient allocation of resources. If firms face no, or only weak competition, then the quantity and quality of goods and services they produce may fall short of the socially efficient level.

In assessing whether a market suffers from insufficient competition, you should look not only at the number of firms supplying the market from within the EU, but also at whether there is competition from firms in other countries. You should also look at whether existing firms face potential competition from new entrants.

These indicators of market structure serve as a warning that the market may not be working well, but on their own they are not enough to allow you to conclude that weak competition is the cause of the problem – you need more direct evidence, such as unusually high profits, or prices which are much higher than marginal cost, or signs of collusion between firms.

Be aware that some markets may not be big enough to support more than a small number of firms. This is the case where a firm cannot survive below a high level of production bringing large economies of scale – meaning that average production costs fall within a firm the more it produces – are indispensable. The risk is that, over time, the strongest firm might drive the remaining competitors out of the market and become a monopolist. As economies of scale

are often related to high market entry costs (for example, expensive equipment or research), a monopolist in such a market does not have to fear potential new competitors.

Economies of scale can also give rise to natural monopoly, a situation in which it is efficient for a single firm to supply the entire market. So-called 'network' industries – transport, energy, and telecommunications – have many of the features of natural monopolies (cf. the costs of power lines or telephone cables), even if technological change, such as the development of mobile telecommunications, may help to maintain some competition. In these sectors regulation is mainly aimed at replacing competition e.g. in order to control market power directly by setting prices or controlling entry or access or tendering rules to ensure competitive bidding to prevent abuse. Some of these rules may become obsolete over time due to changes in technology or change in the market structure.

Non-existing or incomplete markets

Markets cannot provide some goods and services, although society values them. An example is unemployment insurance. Other goods and services may be supplied under restrictive conditions. Small firms and the self-employed, in particular, may be unable to raise money to fund investment if banks require their loans to be backed by collateral; potential students may be unable to borrow against their expected future earnings.

Imperfect information

Reliable information is essential to the smooth working of markets. As information is in some ways a public good, unregulated markets will tend to supply too little of it.

Example: consumer choices and information

If consumers are unaware of factors such as the energy consumption of different models of household appliances, or the nutritional content of foodstuffs, they are unable to make well-informed choices in their own interest or the wider interests of society.

2.3. Regulatory failures

The actions of public authorities can also have results that are not in the best interests of society. In such cases we talk about 'regulatory failure'.

Inadequately defined property rights/legal framework

Well-functioning markets depend on the existence of well-defined and recognised property rights.

Example: inadequate property rights

You will not be willing to buy a car if the person you buy it from can take it back from you without fear of sanction. Externalities such as pollution arise due to a failure of public authorities to define property rights in the environment, thereby implicitly giving them to polluters.

Poorly defined targets and objectives

Policy makers or public authorities might use imprecisely defined notions to describe targets and objectives. This might lead to regulatory failures.

Unintended consequences

Public authorities may not be able to anticipate all the effects of their actions.

Example of unintended consequences

1. Environmental regulation which imposes tighter emission standards on new sources of pollution than on existing installations may prolong the operating life of older, dirtier plants, slow the diffusion of new technologies, raise the cost of entry to the industry and thereby reduce competition instead of leading to less pollution.
2. Regulation directly interfering with the ways companies compete is often intended to make up for market failures (e.g. information asymmetries, lack of buyer power, insufficient incentives to invest in innovation, etc). Examples include regulation on maximum prices or minimum quality standards, regulation determining the characteristics of products and services, restrictions on advertising or the provision of certain services. Regulation may also restrict access to important resources such as raw materials, land, IPRs, know-how or technology concerning production methods. These rules may have unintended side effects as they reduce the variety of innovative goods and services. They may create or increase entry barriers and suppliers of certain goods and services may be excluded from the market, thus reducing the choice for consumers. As market participants' incentives and possibilities to compete decrease, so does consumer welfare;
3. A further type of regulation which may have negative side effects is legislation which facilitates anti-competitive behaviour by market participants or strengthens its effects (e.g. regulation establishing fixed sales quota for certain products or regulation facilitating the discussion and coordination of business conditions between companies). Such regulation may, as a by-product, induce businesses to agree on prices and business conditions; this makes it more difficult for newcomers to enter the market and prices may be maintained at an artificially high level. Customers will be worse off.

'Regulatory capture'

Public authorities are unlikely to have perfect information about the effects of actions they propose to undertake. Interest groups in society may therefore volunteer information to the authorities in the hope of influencing regulation in their favour. Since some sections of society, such as small businesses, or consumers, are less able to make their views known to the authorities than others, this may lead to regulation which benefits one group at the expense of others, and is not in the best interests of society as a whole.

Implementation and enforcement failures

Policies may be implemented using complex mechanisms or structures. If responsibility for implementing them is delegated to other levels of government – as is the norm for EU policies – then we may find it difficult to ensure that the policy is adequately implemented and enforced by the national authorities who are ultimately responsible for it. In addition, implementation and enforcement might be insufficiently regulated in the policy proposal. This may lead to the introduction of distortions to competition in the internal market when EU law is transposed into national law. One practical example of the past is Directive 98/93 obliging Member States to hold crude oil reserves to supply the domestic market. The absence of clearly defined implementing principles gave rise to competition and internal market problems (e.g. national rules favoured refiners over non-refiners and obliged companies to keep security stocks in the Member State of consumption thus impeding free circulation of motor fuels).

Another interesting example is Directive 97/13 on a Common Framework for general authorisations and individual licences in the field of telecommunications services (UMTS licences). Under this Directive Member States must grant individual licences through open, non-discriminatory and transparent procedures but are free to decide to request fees for the grant of those licences. While some Member States organised tenders to benefit from the high revenues for the sale of these licences, others granted the same licences for free. This issue raised important questions regarding discrimination of certain undertakings.

3. APPROACHES TO PROBLEM DEFINITION

Describing a problem is sometimes quite difficult. Approximation approaches and problem tree, among other basic methods, may help in overcoming this difficulty.

3.1. Approximating numbers

Patton and Sawicki (1993) offer the following guidance for determining unknown figures. Most of this guidance is valid for qualitative analysis⁵³.

Using reference sources

- Check the details of how the numbers were derived. Various sources may use different operational definitions.
- Use multiple sources, but ensure that your valuations are consistent.
- Avoid, if you can, sources that don't offer operational definitions.

Using surveys

- Survey systematically interested parties.
- If there is not enough time / resources to conduct an ad hoc survey, look for national / local surveys done on a regular basis by well-known organisations (research centres, leading newspapers, ...)

Guessing

- Use rates that do not vary much from place to place to guess an absolute number (to guess the number of deaths, multiply death rates by a population – instead of compiling actual figures from population registries)
- Look if there are widely accepted rules of thumb.
- Use rates characterizing similar phenomena.
- Use a known variable to guess another when a relationship between the two is known (population growth as a function of time and previous growth rates).
- Set boundaries by reference to another variable (the maximum number of children using diapers cannot be larger than the population between the age of birth to four years).
- Employ triangulation, i.e. using several separate approaches / data sources to estimate a quantity and comparing the results.

Using experts

- Verify the credentials of the experts.
- Use methods for pooling their estimates and lowering their estimate margin of error (see Delphi method).⁵⁴

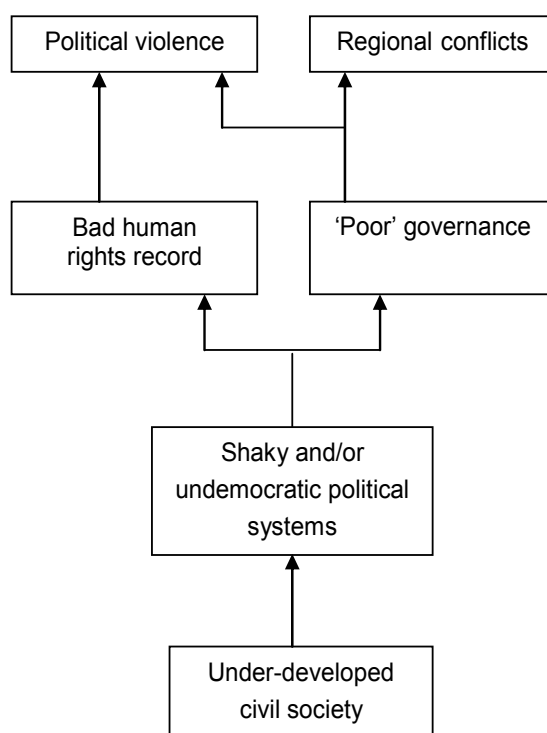
⁵³ In social science, qualitative analysis usually refers to research approaches concerned with investigating the phenomenon in situ – cf. studying the actual behaviour of the targeted population through face-to-face interviews. Here the term is simply used to designate non-quantitative approaches.

3.2. Problem tree

The problem tree approach consists of three steps:

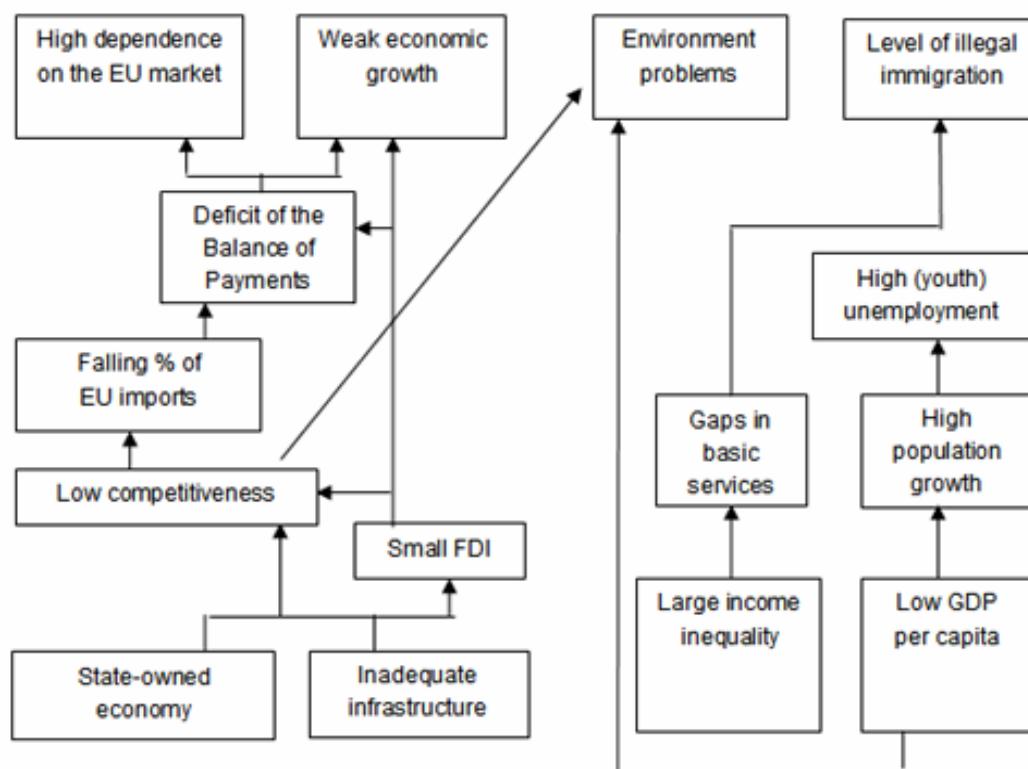
1. listing the various problems linked to the issue at stake;
2. setting out problems in a hierarchical order, i.e. identifying the relationship between problems (primary causes at the lower level; effect going above; if neither a cause nor an effect, it goes on the same level);
3. draw a tree-like structure (in complex situations, there can be several root problems or initial nodes of the tree).

Take for example a region in the world posing security and economic problems for the Union. Start by writing on separate fiches the various political and security problems in the region: regional conflicts, political violence, poor respect for human rights, shaky democratic political systems, undemocratic political systems, bad governance (accountability) and under-developed civil society. Examine the relationship between, say, bad human rights record and undemocratic political systems. Conclude that the human rights record is a consequence of the authoritarian nature of the regime. Put the authoritarian fiche below the human right record fiche. Once all likely causal relationships have been identified, draw the problem tree. For instance:



⁵⁴ Delphi method: "A technique to arrive at a group position regarding an issue under investigation, the Delphi method consists of a series of repeated interrogations, usually by means of questionnaires, of a group of individuals whose opinions or judgments are of interest. After the initial interrogation of each individual, each subsequent interrogation is accompanied by information regarding the preceding round of replies, usually presented anonymously. The individual is thus encouraged to reconsider and, if appropriate, to change his previous reply in light of the replies of other members of the group. After two or three rounds, the group position is determined by averaging." (IIASA).

The higher the number of problems a policy is supposed to address the more complex the tree. If you add to your list economic and financial problems⁵⁵ and socio-economic problems⁵⁶, the tree could look like this:



⁵⁵ For instance, falling economic growth, small volume of foreign direct investment, inadequate infrastructure, unsustainable balance of payments deficits, comparatively low competitiveness, falling share in EU imports, incompatible legislative framework with WTO rules, and high dependence on the EU market.

⁵⁶ For instance, huge and widening per capita income gap between the EU and the countries in the region, huge inequalities in income within the countries, gaps in basic services among areas and population groups (depressed rural areas, underprivileged farmers, women and the young), high population growth, high youth unemployment, severe environmental problems (coastal areas, quality of the water, desertification, urban and industrial waste).

4. POLICY INSTRUMENTS

Normally there are a number of different policy instruments available to reach (operational) objectives. It is very important that several options are considered as part of the impact assessment, and that careful consideration is given in all impact assessments to alternatives to 'traditional' forms of regulation. The instruments described below are not given in any order of preference.

4.1. Regulatory watch (monitoring self-regulation)

The Commission may consider it preferable not to make a legislative proposal where voluntary agreements already exist and are sufficient to achieve the objectives set out in the Treaty and do not create competition problems (see Chapter 9.2). It can also suggest, by a recommendation⁵⁷ for example, that this type of agreement be concluded by the parties concerned to avoid having to use legislation, without ruling out the possibility of legislating if the agreement proves insufficient or inefficient. In the Inter-Institutional Agreement on Better Lawmaking⁵⁸ the three institutions recognise the potential of self-regulation. The Commission has committed to undertake monitoring of self-regulatory agreements. It may consider proposing a legislative act if the self-regulatory practice is not considered satisfactory in terms of the representativeness of the parties concerned, sectoral and geographical cover and the added value of the commitments given.

Self-regulation covers a large number of practices, common rules, codes of conduct and voluntary agreements by which economic actors, social players, NGOs and organised groups establish themselves voluntarily to regulate and organise their activities. Self-regulation does not involve a legislative act.

The ability to use self-regulation largely depends on the existence of bodies and processes to support self-regulation, including the building up of consensus amongst market players on the contents and the monitoring of enforcement.

Self-regulation may provide greater speed, responsiveness and flexibility as it can be established and altered more quickly than legislation. It may therefore be preferable in markets that are changing rapidly.

Self-regulation needs to be an open and transparent process as it may provide an opportunity for collusive arrangements amongst rivals. In some cases however self-regulation may prepare the ground for industries to abstain from competing and to coordinate their actions to fence off competition by newcomers to the disadvantage of consumers. This could also be true for liberal professions characterised by a high level of self-regulation by professional bodies. Price fixing, recommended prices, advertising regulations, entry requirements, reserved rights and rules governing business structure and multi-disciplinary practices enacted by such bodies may indeed be restrictive and harmful for consumers⁵⁹.

Example: The Self-Regulatory Charter of the European Advertising Standards Alliance (EASA).

⁵⁷ On the basis of Article 249 EC Treaty the Commission may make recommendations. Furthermore Article 211 EC Treaty states that the Commission shall formulate recommendations or deliver opinions on matters dealt with in this Treaty, if it expressly so provides or if the Commission considers it necessary. The difference with legislative instruments is that a recommendation has no binding force and that they do not necessarily bear a direct link to existing EC regulation or Treaty provisions. Recommendations are often used to stimulate coordination of national policies. They can be used in the context of self-regulation rather than that of co-regulation, because the latter typically involves a legislative act.

⁵⁸ OJ C 321/1 of 31 December 2003. See http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_321/c_32120031231en00010005.pdf.

⁵⁹ See the Commission's report of 9 February 2004 on competition in liberal professions; http://europa.eu.int/comm/competition/liberal_professions/final_communication_en.pdf.

4.2. Open method of co-ordination

In some areas, EU measures could be complemented or reinforced by Member States' actions using the so-called 'open method of co-ordination'. This implies encouraging co-operation, the exchange of best practice and agreeing common targets and guidelines for Member States, sometimes backed up by national action plans. The method can be a way of adding value at Community level in areas where there is little scope for legislative action.

Example: The method is being successfully used in the European Employment Strategy and through Best procedure projects, notably on entrepreneurship.

4.3. Provide information and guidelines

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

The instrument has some important advantages. In many cases, it is cost-effective. Moreover, it is easily adaptable to changing situations. It is generally most useful in areas where sociological and psychological factors have a great impact on behaviours. However, in fields where economic or legal factors are predominant, the instrument has to be used with caution, as its efficiency might be limited.

Examples: impose transparency obligations on service providers (e.g. hospitals to publish statistics on success rates for certain treatments, or service providers such as lawyers providing information on their special skills).

4.4. Market-based instruments

Unlike classical 'command and control' approach (legislation prescribing one course of action - see below), market-based instruments influence the behaviour of market players through (negative/positive) incentives or by guaranteeing some basic rules of the game.

Possible alternative types are:

- Marketable offsets. Allowing producers to negotiate with each other and agents to ensure overall compliance, without this being necessarily enforced on all producers at the same level.
- Marketable permits.

The main advantage of marketable offsets and permits is their flexibility and cost-effectiveness. They allow potentially major reductions in compliance costs, since these can be redistributed to firms facing the lowest adjustment costs. Moreover, they may be easier to police since they offer incentives to firms to comply.

Their main disadvantages are their potential complexity related to issues such as the need to ensure a satisfactory initial distribution of permits. The use of market based instruments most likely involves legislation.

Example: The Commission's proposal for an EC scheme for greenhouse gas allowance trading⁶⁰. In environmental policy, taxes are often used to make polluters pay.

⁶⁰ COM(2001)581 of 23 October 2001.

- Taxes or charges

The use of taxes and/or fees is potentially useful as a policy instrument to influence private behaviour towards public objectives. Such instruments are market-based and could in principle ensure that users pay the social price of their consumption. However, the ability to co-ordinate taxes at EU level is highly limited due to the need for a unanimous decision by the Council. The applicability of such instruments depends on their compliance with EC rules on state aid

Example: In environmental policy, taxes are often used to make polluters pay.

- Under certain circumstances, enforcement of the competition rules⁶¹;
- Imposing insurance and financial assurance requirements. Besides ensuring that sufficient resources are available to remedy potential damages, such rules create incentives to minimise such damage;
- Property and liability rules
- Limits to price and/or quantity (licences, quotas, etc.)

4.5. Direct public sector financial interventions

Public sector financial interventions should be used to complement other forms of intervention or when the use of other instruments is more expensive or infeasible. They are often used in emergency cases or as transitional measures. These financial interventions usually mean public sector provision of goods and services through public expenditure programmes. Such interventions can have re-distributive effects. The application of such instruments depends on their compliance with EC rules in state aid.

Example: EU Structural Funds

4.6. Co-regulation

The co-regulation approach implies a regulatory framework in which the overall objectives, the deadlines and mechanisms for implementation, the methods of monitoring the application of the legislation and any sanctions are set out. The regulator also determines to what extent defining and implementing the measures can be left to the concerned parties. Such provisions, for example sectoral agreements, must be compatible with Community law⁶² and must be in the interests of the public.

Co-regulation must be transparent. Members of the public must have access to the act and to the implementing provisions. Sectoral agreements and means of implementation must be made public in accordance with arrangements that have yet to be defined. The parties concerned must be considered to be representative, organised and responsible by the Commission, Council and European Parliament and according to the IIA they must be 'recognised in the field' (such as economic operators, the social partners, non-governmental organisations, or associations). Co-regulation combines the advantages of the binding nature of legislation with a flexible self-regulatory approach to implementation that encourages innovation and draws on the experience of the parties concerned. A drawback is the need to set up monitoring arrangements.

⁶¹ For more information please consult DG COMP.

⁶² The Inter-Institutional Agreement on Better Lawmaking (OJ C 321/1 of 31 December 2003) specifically mentions the proportionality principle and as far as agreements between social partners are concerned the Articles 138 and 139 of the EC Treaty. See http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_321/c_32120031231en00010005.pdf.

Examples:

- The 'New Approach' to product regulation, where essential requirements are laid down in a regulatory framework, leaving business and industry to decide for themselves how to meet their obligations, including through the use of harmonised standards;
- Agreements between the social partners as an alternative method of regulation in fields concerned with working conditions and access to work.

4.7. Framework directives

In its Action plan 'Simplifying and improving the regulatory environment⁶³, the Commission committed itself to revert to the original definition of a directive as laid down in the Treaty, that is, to limit the content of a directive to the essential aspects of legislation. Hence, directives should, as far as possible, be general in nature and cover the objectives, periods of validity and essential aspects of legislation, while technicalities and details should be a matter of executive measures or be left to Member States.

Framework directives set out general principles, procedures, and requirements for legislation in different sectors. Subsequent 'daughter' directives in each sector must conform to the general requirements of the framework directive.

While framework directives offer greater flexibility to Member States, their disadvantage is that they risk resulting in a diversity of more or less incompatible measures being implemented in different Member States. However 'daughter directives' should not undo the flexibility gained by being overly prescriptive. In accordance with the Inter-Institutional Agreement on Better Lawmaking⁶⁴ a proper balance should be struck between general principles and detailed provisions, in a manner that avoids excessive use of Community implementing measures.

Example: The National Emissions Ceilings Directive⁶⁵ sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.

4.8. Prescriptive regulatory actions

Incorporating obligatory standards into legislation (regulations, directives or decisions) is a frequently used policy solution. A useful distinction can be made between:

- **Traditional 'command and control' policies.** These specify the use of certain practices, technologies, or designs. The advantage is relative ease of monitoring and enforcement. The disadvantages are that they are likely to be less cost-effective and they do not encourage technological innovation or to go beyond standards.

Examples: The most relevant examples can be found in a large number of regulations applicable to the manufacturing of automotive products or in some of the BREFs ('Best available techniques REFERENCE documents') prepared under the Integrated Pollution Prevention and Control Directive⁶⁶.

- **Performance-orientated standards.** Performance-orientated standards specify the required performance of the target population. They do not detail the exact mechanisms

⁶³ COM(2002) 278, see http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0278en01.pdf.

⁶⁴ OJ C 321/1 of 31 December 2003, see http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_321/c_32120031231en00010005.pdf.

⁶⁵ Directive 2001/81/EC, OJ L309/22 of 27 November 2001, see http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_309/l_30920011127en00220030.pdf.

⁶⁶ Directive 1996/61/EC, OJ L 257/26 of 10 October 1996, see <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0061:EN:HTML>.

by which compliance is obtained, but rather specify the criteria to be followed to achieve such compliance. They are often to be preferred to engineering or design standards, since they increase flexibility to achieve the regulatory standard. Standards should be flexible allowing aggregation or offsetting between different plants or agents, even regionally or nationally provided this does not unacceptably affect the overall outcome.

Example: The standards expected to be achieved by new plants under the Large Combustion Plants Directives (1998 and 2001)⁶⁷.

If existing legislation seems to work inefficiently, an alternative to tighter rules or regulations might be reinforcing investigation and sanctioning powers or perhaps simplification of the rules with which compliance seems to be difficult.

⁶⁷ Directives 1998/609/EEC and 2001/80/EC (OJ L 309/1 of 27 November 2001).

5. THE 'INDICATORS AND QUANTITATIVE TOOLS' SOFTWARE (IQ TOOLS)

The 'Indicators and Quantitative Tools for Improving the Impact Assessment Process for Sustainability' (IQ TOOLS) project is funded by the 'Scientific Support to Policies' initiative under the Community's Sixth Research Framework Programme. The project Steering Group includes representatives from RTD, SG, ENV, ECFIN, EMPL and ENTR.

5.1. Objectives – Computer-assisted IA

By early 2006, internet-based software will provide desk officers with information on good practice and on models and tools available for quantitative assessment. In addition, it will provide guidance on identifying the possible economic, environmental and social impacts of policy initiatives. It will also include features to assist with planning, inter-service communication and transparency.

5.2. The tools

Several interactions with the IA process are planned. The user is guided by a list of keywords (including policy areas, impacts and instruments) through a review of previous IAs, an overview of impact data and a guide to selecting models.

A **good practice inventory** will be set up on the basis of a review of IAs carried out in 2003 and 2004. The inventory will provide a brief description of these practices with references to completed IAs.

An **impact inventory** will provide information about the main impacts listed in Tables 2, 3 and 4 of the Guidelines (links to relevant information from Eurostat regarding data and methodology for each impact). The inventory should help desk-officers to identify and structure the impacts associated with a given policy proposal.

A **model inventory** will provide information on tools used at the Commission and integrating the different dimensions of sustainable development. It describes the potentials and limitations of existing models, including their interlinkages (e.g. which outputs of a model can be used as inputs in other models). This tool intends to assist desk officers when launching external quantitative studies for IAs. In addition, a **quantitative model** will be made available to analyse interlinkages and indirect effects across specific impacts and separate policy areas or sectors. A Computable General Equilibrium (CGE) model will be expanded to provide quantitative results for selected measures and basic impacts. The software will also provide simplified **on-line simulations** for specific policy issues. Extensions of the CGE model are under development to respond to additional needs e.g. in the area of carbon storage and imperfect competition. This constitutes Part Q of the IQ TOOL (Q for Quantification).

Note that these inventories should be used as an aid to the impact assessment process; the IQ TOOLS software can never be a substitute for sound analysis and judgment.

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6. HOW TO DESIGN A QUESTIONNAIRE

6.1. Structure of the questionnaire

- Include an introduction summarising the context, scope and objectives of the consultation. Explain what feedback respondents can expect, and provide information on the next stages of the process.
- Ask respondents to provide sufficient identification information (i.e. enough to assess the representativeness of responses etc.), while including an appropriate data protection clause into the questionnaire.
- Put instructions to respondents where they are directly relevant.
- If the questionnaire is not or only partially addressed to the general public, then indicate unequivocally the targeted respondent(s). If not all questions are applicable to all respondents then put 'filtering' questions first (for example, in the Commission consultation on pre-packaging respondents were asked if they were consumers, producers or retailers, and were subsequently directed to specific sets of questions).
- Proceed from general to detailed questions.
- Where appropriate, consider including standard questions or questions used in previous consultations. Such questions allow comparability across studies.
- At the end of the questionnaire, ask whether or not the Commission may contact the respondent if further details on the submitted information are required.
- At the end of the questionnaire, leave room for feedback (allow respondents to comment on the consultation – relevance of the questionnaire, etc.) and thank respondents for completing the questionnaire.

6.2. Formulation of the questions

Good practices in general

- Keep questions as short and simple as possible, especially if they are to be translated. In particular avoid double negatives. For example, don't ask: *How much would you dislike the inability to receive all relevant information from a single source? It makes for difficult reading. Say: How much would you like the possibility...?*
- If it is impossible to come up with a short and simple question, insert a 'control question'. A control question is a reformulation of the problematic question, placed in a different part of the questionnaire. If the answer to both questions is not identical, it indicates that the respondent has not fully understood the question. Both answers should therefore be discarded.
- Ask only one question at a time. The answers to double-barrelled questions might be difficult or impossible to interpret. Don't ask: *Did you try to collect information about new rules from government services, but failed to get appropriate answers? Yes / No.* If the answer is 'No', does this mean that the respondent did not try to collect information or that they failed to get appropriate answers? When the question is formulated this way, there is no way to tell.
- Include enough sufficient information to jog people's memories or to make them aware of features of a phenomenon they might otherwise overlook, but avoid questions suggesting

the 'right' answer. Do not formulate questions like in the following way: *'Wouldn't you say that.....'* or *'Don't you agree that.....'*

- Make the question specific. Don't ask: Are consultation opportunities well publicised? The word 'well' is too vague to be analytically useful. Ask instead: Are consultation opportunities publicised through (tick all relevant answers): 1) the press; 2) TV; 3) internet; ... Be particularly wary of the word 'regularly'. Replace it with a specific reference such as 'how many times over the last three months'. When asking respondents to recall past events, it is preferable to limit the time period.

Closed-ended questions

Closed-ended questions allow for rapid answers. They are easy to code and level differences between articulate and inarticulate respondents. However, because of their limited range of options, closed-ended questions can lead to misleading conclusions. Therefore when designing a closed-ended question:

- Try to avoid 'yes/no' questions which give relatively little information.
- Instead, provide several types of scaled answers. In particular make sure that the available options allow a 'neutral' or 'medium' answer. Common formats include:
Tobacco advertising should be banned from sport events: I 'agree strongly', 'agree', 'undecided', 'disagree strongly' (Likert scaling).
I would like to see tobacco advertising: 'banned completely', 'more restricted than it is now', 'continue as it is now', or 'less restricted than it is now' (Guttman scaling).
Alternatively ask where the respondent would place him- or herself on a scale from 1 to 10, where 1 means 'not at all' and 10 means 'completely.'
- Make sure that the available options include answers such as 'don't know', 'decline to state', or 'not applicable', if there is any chance that these may represent some people's answers.

Open-ended questions

Open-ended questions allow for greater freedom of expression. Respondents can qualify their answers. There is therefore no bias due to limited response's range. However, it is much more time consuming to code/interpret such replies and there is a greater risk of misinterpretation.

6.3. Presentation of the questionnaire

- Use graphics sparingly. Graphics significantly slow download times, especially for respondents connecting to the internet via modem.
- Use appropriately colours and fonts. Using bolds and italics, or changing the colours of key words, can make your questions easier to understand. On the other hand, too much diversity of design may be distracting for respondents.
- Avoid designing large pages that require respondents to scroll horizontally to view part of the questionnaire.
- Allow enough space for long replies, especially when dealing with open-ended questions.

6.4. After the questionnaire has been designed...

- If a consultation is conducted in several languages, provide sufficient time and resources for translation of the questionnaire, working instructions etc. Translation of an electronic instrument should take place only after the original version is completed and tested.
- Thoroughly test the finalised questionnaire before putting it on the website. Check the presentation of the pages and make sure that all skips, features, randomisations and other links work as you intend them to (for example check whether the respondent can only choose one option when answering multiple choice questions with mutually exclusive answers).
- When analysing responses to open ended questions, be sensitive to cultural differences. Your respondents are likely to be very multinational in their composition.

7. QUANTITATIVE MODELS

The tools illustrated here are well suited to defining impacts in a quantitative way, either in physical terms if multi-criteria analysis is applied in policy appraisal or in monetary terms if cost-effectiveness and cost-benefit analysis are used.

The models described here illustrate the kind of models that have been developed with the financial support of the Commission. Some of them are available at the Commission and are owned by the Commission, but the majority have been developed by research centres within the Research Framework Programmes and are owned by them.

The models cover different impacts, policy areas and instruments. A software program for selecting relevant models using keywords is being developed as part of the IQ TOOLS project described in these guidelines (see Annex 5). Table 1 illustrates selected criteria for choosing the appropriate model:

Table 1: Suitability of models with respect to selected criteria

	CGE models	Sectoral models	Macro-econometric models	Environmental impact assessment models	Micro-simulation models
Range of coverage of measure					
Single-market analysis without economy-wide impacts		X			
Single-market analysis with economy-wide impacts	X		X		
Multi-market analysis with effects in secondary markets	X		X		
Ecosystem				X	
Purpose of model analysis					
Simulation (long-term)	X	X		X	X
Forecasting (short-/medium term)			X		
Effects to be analysed					
Economic effects (within given model framework)	X	X	X		
Ecological effects of economic activities	X	X	X	X	
Ecological effects				X	
Distributional effects					
between countries	X	X	X	(X)	
between sectors	X		X		
between households	X		X		X
Degree of disaggregation					
Between sectors or households					
potentially high	X				X
potentially low			X		
Within a sector					
potentially high	X	X	X		
potentially low					
Effects on:					
GDP	X		X		
Ecological damages				X	
Unemployment	X		X		
Public budget	X		X		
International trade	X		X		
Emissions	X	X	X	X	
Immission/deposition				X	
Household income	X		X		X

Most of the relevant and well-developed **quantitative tools** for impact analysis purposes are models, which can be broken down into:

7.1. Computable General Equilibrium (CGE) models

CGE models calculate a vector of prices such that all the markets of the economy are in equilibrium, implying that resources are allocated efficiently. They are based on economic theory and theoretical coherence (i.e. the Walrasian representations of the economy). Therefore, parameters and coefficients are calibrated with mathematical methods and not estimated as in econometric modelling. They can be static – comparing the situation at one or more dates – or dynamic, showing developments from one period to another. CGE models require a Social Accounting Matrix that is built by combining Input-Output tables (to model interrelations between productive sectors) with national account data.

The strength of CGE models is their internal consistency; i.e. they allow for consistent comparative analysis of policy scenarios by ensuring that in all scenarios the economic system remains in general equilibrium (however, extensions to model market imperfections are possible). They integrate micro-economic mechanisms and institutional features into a consistent macro-economic framework and consider feedback mechanisms between all markets. All behavioural equations (demand and supply) are derived from microeconomic principles. Since CGE models are calibrated to a base year data set, data requirements are limited even if the degree of disaggregation is high. This allows for the evaluation of distributional effects, across countries, economic sectors and agents. CGE models are advantageous in analysing general economic policies like public finance, taxation and social policy, and their impact on longer-term structural change.

The weakness of CGE models is their somewhat tautological construction (all results are implicitly linked to the assumptions and calibration made). In contrast to macro-econometric models CGE models can be used only for simulation purposes, not for forecasts. Another disadvantage compared to sectoral models is that, in following the top-down approach, CGE models typically lack a detailed bottom-up representation of the production and supply side. Since top-down models rely on the assumption that all ‘best available technologies’ have already been installed, the calculated cost of a specific emission reduction measure is typically higher than in bottom-up studies.

Examples of EU-funded CGE models:

EDGE
GEM-CCGT
GEM-E3
OECDTAX
PACE
WORLDSCAN

7.2. Sectoral models

These models are constructed on the equilibrium of one specific sector of the economy.

The strength of sectoral models is that they focus only on one economic sector and thus enable a relatively high degree of disaggregation and a detailed representation of the specific economic and institutional factors. Partial models are an appropriate tool if the focus of policy analysis is on a specific sector (e.g. transport) and if feedback between the rest of the economy (e.g. via substitution and demand effects) can be ignored to a large extent. Note that the importance of these indirect feedback effects increases with the degree of regulatory intensity. Sectoral models are often very detailed since they are sometimes complemented by more specific (e.g., engineering-economic) bottom-up models. The latter are advantageous since they, for example, are able to handle nonlinearities.

The most important drawback of sectoral models is their inability to capture the effects on other markets and the feedback into the specific market under consideration.

Examples of EU funded sectoral models:

Energy: PRIMES, POLES, SAFIRE

Transport: ASTRA, EXPEDITE, SCENES, TREMOVE
Agriculture: CAPRI
Emissions Trading: SIMAC

7.3. Macro-econometric models:

These models are empirical and are therefore developed using coherent datasets. The parameters of the equations are estimated using econometric methods. They are fundamentally designed to evaluate macro-sectoral impacts of economic policies, although they have been extended to incorporate environmental dimensions.

The strength of macro-economic models lies in the validation of the equations of the model with statistical methods and on the model's ability to provide short-medium term forecasting and to evaluate the impact of policies. These models also ensure a coherent framework for analysing inter-linkages between variables. The weakness of such models is that it is difficult to catch longer run phenomena, since the equations on which they are based are linked to a given time framework. Moreover, due to the extensive need for data the degree of sectoral disaggregation is usually smaller than in calibrated CGE models. Behavioural assumptions do not always rely on microeconomic theory.⁶⁸

Examples of EU funded macro-econometric models:

E3ME
NEMESIS
QUEST II
WARM

7.4. Environmental impact assessment models.

These models are intended to measure and evaluate the environmental impact of economic activities or policy measures. An established approach in these models is 'impact pathway analysis'. This is a bottom-up approach for estimating external costs starting from a particular process and its emissions, moving through their interactions with the environment to a physical measure of impact (the main component being health), and where possible a monetary valuation. The Dose-Response step of analysis uses data from the physical, biological sciences and epidemiology to link a particular pollutant at different levels (the dose) with different levels of physical damage to human health and ecosystems. The calculation process is highly site-sensitive, as the aggregate impact is determined by the geographical distribution of victims or receptor ecosystems.

Impact pathway analysis has allowed the Commission to review many of its decisions in the environmental sphere, in order to reach a better compromise between economic and environmental objectives. By quantifying the environmental and health damages, the methodology has often helped to produce better-informed policy decisions that are more consonant with the goals of Sustainable Development.

Examples of EU funded environmental impact assessment models:

ECOSENSE
FUND
IMAGE
RAINS
SMART

⁶⁸ Models must be carefully checked if not developed in-house.

7.5. Microsimulation models.

Based on micro-data these models compute the impacts of various policy changes on small units such as individuals, households or firms. These are characterised by individual properties (e.g. income and expenditures, age, family status, profits). By using a representative sample micro-level changes can be aggregated in order to reproduce macro-level effects. Microsimulation models are tools for policy recommendations: over the last ten years they have been widely used particularly in empirical tax policy analysis in several European and OECD countries. Typical applications of tax-benefit models are, for example, the calculation of the distributional effects of different tax-benefit policy scenarios (i.e. the calculation of the tax payable, identification of individuals who would gain or lose under a specific policy, etc.).

Examples of EU funded microsimulation models:

EspaSim
ETA
EUROMOD
TAXBEN

7.6. Projects and Programmes.

This category includes projects and programmes funded by the European Commission. Typically these projects/programmes use other models, but are well known and widely used. Due to their importance it was decided to include the following projects and programmes:

CITY DELTA

DYNAMO

EMEP

Information on single models can be found at the current website of the IQ TOOLS project:
<http://gloster.iwr.uni-heidelberg.de>

8. HOW TO ASSESS COST-EFFECTIVENESS

Public funds should be used in accordance with the principles of sound financial management, which includes aiming for the best relationship between resources employed and results achieved. A public intervention could hence be considered as 'efficient' or 'cost effective' if its set objectives are achieved at least cost, or if its desired impact is maximised at a given level of resources.

An Impact Assessment should provide a reasonable basis for making this judgement. The purpose of this part of the Impact Assessment is to analyse and compare the cost effectiveness of the various policy options.

All proposals with financial implications for the Community budget must also be accompanied by a legislative financial statement that includes a detailed calculation of the financial and human resources to be allocated to the intervention.⁶⁹

8.1. How to assess cost-effectiveness of spending measures (e.g. expenditure programmes)

A budgetary *cost-effectiveness analysis* relates the effects of an intervention to the total amount of inputs (total cost) needed to produce those effects. The criterion for judgement is usually the cost per unit of outcome achieved (for example, the cost per job created or child fed). This unit cost is then compared to other interventions or to other methods for delivering the same outcome. Whether or not a policy proposal is cost-effective depends on whether it outperforms other competing proposals in reaching given objectives for less cost.

Example

If the objective of an intervention is to reduce traffic accidents in a given area by a certain amount, an Impact Assessment of cost-effectiveness could involve comparing the costs and expected results of the following three options for action:

- a road safety awareness campaign;
- building bridges to separate pedestrian and vehicle traffic;
- introducing more traffic lights.

Types of cost that you should take into account are:

- direct financial outlays (to beneficiaries or third parties) from the EU budget and other public funds;
- administrative costs for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc);
- human resources needed to manage the intervention.

The level of cost and the expected level of results that can be achieved are obviously different in each of the three options. Their cost-effectiveness could be compared with the help of quantified estimates for the cost per number of accidents avoided in each case.

The more clearly objectives and expected results are specified, the easier it will be to assess the cost-effectiveness of the proposal. If the objectives of an initiative are multiple and not well specified in terms of expected results, it will be difficult to attribute costs to any impacts. Calculating cost-effectiveness ratios may require making a number of assumptions. These should always be clearly stated in the Impact Assessment Report.

However, even if it is not possible to make well-founded estimates of cost-effectiveness, the process of identifying impacts should help you to understand and explain the consequences

⁶⁹ For further guidance see <http://www.cc.cec/budg/preparation/en/preparation/fiche-fin/summary.htm>.

of the proposal in terms of different types of costs. In some respects, this is more important than doing exact measurements and calculations. As a minimum, an Impact Assessment should

- present a broad estimate of the cost of the proposed intervention;
- ask if the objectives justify the cost – bearing in mind that ultimately this is a political judgement;
- ask if the same results could be achieved at less cost by using a different approach or other instruments, or if more or better results could be achieved with the same cost by using a different approach or other instruments.

These questions might lead to a re-assessment either of the objectives, of the action itself, of alternative options and delivery mechanisms, or any combination of them.

This part of the analysis can be combined with the comparison of alternative delivery mechanisms. Evidence for the comparisons can be drawn, for example, from earlier evaluations of similar interventions.

8.2. How to assess the cost-effectiveness of non-expenditure measures

The types of cost identified above occur in the context of expenditure programmes (or comparable measures), which are targeted towards clearly identified addressees that are meant to *benefit* from the intervention (hence, they are usually referred to as ‘beneficiaries’).

By contrast, not all addressees of a non-spending measure (e.g. a policy, a piece of legislation) will necessarily ‘benefit’ from it. Such measures tend to aim at more global (or high-level) objectives than a spending programme, and may create both advantages and disadvantages for various addressees. Such disadvantages may very well constitute additional ‘costs’ to some addressees.

These additional costs represent a potentially major category of negative impact of a policy instrument, and should therefore be included in the analysis of its cost effectiveness. The below table presents the most typical types of cost that may result from policies containing spending as well as non-spending elements, both at the level of the body or bodies implementing the measure and its addressees.

<i>Type of cost</i>	<i>Body or bodies involved in the implementation of the measure</i>	<i>Addressees</i>
Budgetary cost	Direct financial outlays from the EU budget and other public funds. Administrative costs (e.g. studies) for the Commission and public authorities (e.g. Member States). Human resources needed to implement the intervention.	Not applicable
Transaction cost	Costs associated with implementing, monitoring and enforcing the policy.	Costs incurred in identifying and selecting the most appropriate compliance route.
Compliance cost	Not applicable	Direct costs incurred by addressees in order to comply

		with the policy measure, including administrative cost ⁷⁰ . Opportunity costs ⁷¹ .
Adjustment cost	Not applicable	The costs or reallocating resources because of policy-induced changes in behaviour (concerning production or consumption).

⁷⁰Unlike the administrative costs incurred by the Commission and other public authorities when implementing the measure in question, the administrative costs incurred by addressees stem from their 'legal obligations to provide information on their action or production, either to public authorities or to private parties'.

⁷¹ Opportunity costs refer to the most valuable alternative forgone to comply with the policy requirements. Resources needed to make a policy possible cannot be allocated for other uses. In order to assess the true costs of a policy, it is therefore necessary to take into account what these resources could have earned if allocated to the best, safe investment alternative. The reference is often the interest rate paid by saving banks on deposited funds or prevailing wage rates.

9. ASSESSING IMPACT ON GROWTH, COMPETITIVENESS AND JOBS

As a rule, the economic impacts of a policy, whether it is aimed at achieving economic, social or environmental objectives, are transmitted to the economy through changes in prices and costs. These changes affect the behaviour of (some) economic actors, which in turn affect firms, households and public authorities.

To help in the identification of the economic impacts and the understanding of their characteristics, this annex provides a **non-exhaustive** list of questions that can be used as a **first step** in the undertaking of an impact analysis.

When identifying impacts, particular attention should be paid to factors that are widely considered as being important to productivity⁷², and hence to the competitiveness of the EU, which are embedded in 9.1 to 9.5. Competitiveness is a measure of an economy's ability to provide its population with high and rising standards of living and high rates of employment on a sustainable basis. Vigorous competition in a supportive business environment is a key driver of productivity growth and competitiveness.⁷³

9.1. Impacts on international trade and cross-border investments

Proposals may have consequences for the conditions under which European enterprises operate in comparison with their main competitors in non-EU countries. These consequences may differ between the short and the long term. Awareness of the main characteristics of the regime that these foreign competitors face is an essential element for the scrutiny of economic impacts.

In the context of likely impacts on trade and cross-border investments, will the proposal:

- Increase or reduce differences between the regulatory regime faced by EU companies and competitors in non-EU countries?
- Place EU firms at an advantage or disadvantage compared to their international competitors?
- Will cleaner companies and sectors be boosted either directly or indirectly through shift of demand away from polluting companies and sectors?
- Help or hinder trade and cross-border investment into the EU or from the EU to third countries?
- Contribute to the relocation of economic activity to or from non-EU countries?
- Will a 'first-mover' advantage be generated with other countries likely to follow

9.2. Impacts on competition in the internal market⁷⁴

Competition helps companies to grow by outperforming one another and by improving their offer to consumers. Competition at the same time helps them to remain competitive on a European and global scale. Proposals may have an influence on the way companies compete against each other.

⁷² I.e. investment, innovation, entrepreneurship, human capital and the competitive environment.

⁷³ See the Commission's Communication on pro-active competition policy of 20 April 2004, Section 2.1.

⁷⁴ For consideration of competition impacts you should consult the additional guidance prepared by DG COMP and available via the IA website at <http://intracomm.sg.cec.eu.int/ia/impact/>.

To screen the proposal for **possible negative impacts on competition**, you should start by determining in particular if the proposal includes:

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

If so, you should ask yourself the following questions (*non-exhaustive list*):

- Does the proposal contain rules which (partially) exempt a market/sector from the application of the competition rules⁷⁵, thus possibly creating/strengthening a monopoly?
- Does the proposal contain rules which directly interfere with the way firms market or price their products/services⁷⁶; does it limit or reserve distribution for certain channels/intermediaries, thus reducing consumer choice or creating barriers for newcomers?
- Does the proposal contain rules which facilitate or induce companies to agree on prices or divide up customers/markets⁷⁷, thus driving up end consumer prices or decreasing innovative activity?
- Does the proposal contain rules which restrict access to important resources (such as raw materials, land, IPRs, know-how or process technology) in concentrated markets, thus excluding or delaying market entry of alternative products/services⁷⁸?
- Does the proposal contain rules which (de facto) favour incumbent providers at the expense of new entrants thus mitigating the beneficial effects of liberalisation⁷⁹?

9.3. Impacts on firms in terms of investment, operating costs, products and services

Proposals may intentionally or unintentionally have impacts on the production decisions of firms. In the context of likely impacts on firms in terms of investment, operating costs, products and services, will the proposal:

- Directly or indirectly affect the availability or cost⁸⁰ of inputs, for example:
 - raw materials, semi-finished products, components, etc.?
 - machinery and equipment?
 - labour?
 - licence fees, inspection costs, etc.
- Have an effect on the cost and/or availability of firm financing?

⁷⁵ E.g. certain products used in the defence industry or certain agricultural products.

⁷⁶ E.g. advertising restrictions, or marketing restrictions, rules determining maximum prices/minimum quality standards.

⁷⁷ E.g. certain market organisations for agricultural products such as tobacco.

⁷⁸ E.g. in the new media or IT sectors, or in the pharmaceutical sector.

⁷⁹ E.g. depriving consumer of these benefits, such as more choice and more competitive prices in the telecoms, energy, public transport sectors.

⁸⁰ Costs can also be broken down into fixed or variable costs.

- Affect the level and/or timing of investment by firms?

As a consequence of investment decisions and changes to the availability and/or cost of inputs will the proposal affect:

- how firms produce products and services?
 - the range of goods and services firms produce (new products or substitutes)?
 - the quantity of goods and services firms produce?
 - the financial viability of firms currently operating in the relevant market?
- Will companies benefit from improved brand and corporate image or through the benefits of adopting Corporate Social Responsibility practices?

Finally, if firms face increased costs as a result of the proposal, is the structure of the market such that they are able to pass on some or all of these costs downstream to their customers, or upstream to their suppliers?

9.4. Impacts on technological development and innovation

Proposals may directly or indirectly lead to impacts on the technological development and innovative activities of firms and the ways in which firms and institutions are organised. When impacts on technological development and innovation⁸¹ are likely, will the proposal:

- Affect the level and/or timing of research and development activities, for example by making it easier or harder for firms to finance these activities?
- Stand in the way of/promote:
 - firms' potential for innovation (know-how, finance)?
 - the development and implementation of new technologies?
 - the diffusion and take up by users of new technologies?
 - greater knowledge and know-how ?
 - the exploitability of inventions and innovations?
- Will the proposal lead to eco-innovation, for example, through new ways of working and more efficient use of natural resources and lower clean-up costs, which lower costs for companies?

9.5. Impacts on firms, especially SMEs, in terms of administrative burden

Proposals may result directly in an increased administrative burden on firms (e.g. through increased formalities and paperwork) or may conversely lead to reduction in administrative burden due to simplification/harmonisation⁸². Both cases will have consequences on resource needs and firm costs. When there is a likely impact on firms in terms of administrative burden, will the proposal:

- Impose or reduce the administrative burden on firms, especially newly created firms and other SMEs? In particular would it decrease/increase administrative complexity or have an impact on the clarity of legal requirements and legal certainty?

⁸¹ Innovations take many forms. An innovation may, for example, improve the way in which products are produced (process innovation). It may concern the development of a new product (either standalone or embodied in a piece of machinery, a component, etc.). Or it may involve the development and delivery of a new service. Another type of less tangible innovation is the introduction of new structures and ways of working within organisations and institutions.

⁸² Harmonisation may lead to increased costs in the short term as firms adjust to changes in legalisation, but may give rise to more medium and longer term gains from simplification, especially with respect to intra-EU cross-border activities.

- Impose significant adjustment, compliance or transaction costs⁸³ on firms?
- Include technical, legal and/or administrative requirements that require/enable/encourage firms to implement new activities and functions?

9.6. Impacts on consumers

In many cases proposals affecting the working of markets and the activities of firms give rise to indirect impacts on households. In others, households may be directly affected by proposals. In this context, consideration should be given to the question of whether the proposal is likely to:

- Affect the prices for products and services consumers have to pay? If so, which ones are concerned and by how much will prices rise?
- Affect the range/quality/safety of consumer products and services?
- Affect data protection?
- Affect (disposable) household income and wages?
- Affect the level of consumer protection?
- Affect pensions or asset holdings?
- Make it easier or harder for households to borrow or save money, for example through access to financial services?

9.7. Impacts on the number and the quality of jobs

When analysing the **impact on the number of jobs**, it is important to estimate the effects in terms of absolute variations of the number of jobs (created, destroyed or transformed), distinguishing the anticipated short-term effects from the anticipated medium-term effects. As far as possible, these estimations should also be expressed in terms of employment rates, unemployment rates and net effects. It will often be useful to establish more detailed breakdowns, by sector and type of employment (types of contract, levels, etc.). It is important to identify which population group will benefit from the creation of new jobs.

The **effects on job quality** need to be considered. Job quality depends on a number of factors. The ten main ones were outlined in a Commission Communication and in a Decision of the European Council on quality indicators⁸⁴ :

- intrinsic job quality (including level of remuneration and fairness);
- skills, life-long learning and career development ;
- gender equality;
- health and safety at work;
- balance between flexibility and security;
- inclusion and access to the labour market;
- work organisation and work-life balance;

⁸³ Adjustment costs are the one-off costs arising from the reallocation of resources as a result of policy induced changes. Compliance costs are the direct costs arising from complying with a policy measure. Transaction costs are incurred during the identification of the most appropriate compliance route.

⁸⁴ Communication from the Commission (2001), 'Employment and social policies: a framework for investing in quality', COM(2001) 313 final; European Council (2001), 'Indicators of Quality in Work'; Communication on 'Improving Quality in work', COM(2003) 728 final.

- social dialogue and worker involvement;
- diversity and non-discrimination;
- overall work performance (including productivity).

In analysing **the distribution of the impacts**, particular attention should be paid to:

- the sectoral distribution of the anticipated effects;
- the geographical distribution of the anticipated effects;
- the opportunities opened up for groups and individuals at present excluded from the labour market;
- distribution by sex and age-band;
- effects on the income and purchasing power of different groups.

Where there are likely to be major effects in terms of company restructuring in a particular sector, the analysis must not be confined to a static time horizon but should take account of **the implementation process and the process of adaptation** of the players. It should thus be possible to estimate the capacity of any workers affected to anticipate the changes and adapt to the pace of these changes, as well as the social backup resources available. Further, effects on the 'transitions' between work and initial education, training, inactivity and retirement should be considered.

9.8. Impacts on third countries and overseas relations

Certain proposals may have an impact on third countries and overseas relations in general. In this case, consideration should be given to whether the proposal will have an impact on:

- International agreements and alliances (e.g. WTO rules)?
- Enlargement and/or neighbouring countries?
- Developing countries?
- Other countries?

9.9. Impacts on public authorities

In the case of public authorities, consideration should be given to their role vis-à-vis the proposal:

- Are public authorities actually involved in its implementation?
- Are public authorities affected as its direct or indirect addressees?

In the first case, costs incurred (e.g. human and infrastructure costs, co-funding of projects, enforcement costs...) should not be assessed as economic impacts but as **implementation costs** and considered alongside the implementation costs incurred by the EU. In this context, consideration should be given to the likely implications of the proposal on the public expenditure, future budget commitments, taxation and where appropriate on the public sector budget balance and the quantity of government debt.

In the second case, when public authorities are addressees of an initiative often in the guise of economic agents, some of the questions raised in 9.1 to 9.7 may then be relevant.

Public authorities may also be concerned both as an actor in the implementation of a proposal and as its direct or indirect addressees.

9.10. Macroeconomic impacts

The previous sections address impacts that are of a microeconomic or sectoral nature. Although these impacts will have some effect on how the economy works, the effect on key macroeconomic aggregates such as economic growth, the unemployment rate and so on, will often be rather small, and need not be considered in much detail in the analysis. However, in some instances a proposal may have impacts that are discernable at the macroeconomic level or impacts at the microeconomic level might accumulate to an impact at the macroeconomic level and in these cases the following should be considered:

- Economic growth and its links with investment in human and physical capital, labour market participation, unemployment, the functioning of product and capital markets, etc.
- Price levels and stability and their links to aggregate demand and supply, production costs, etc.

10. ASSESSING ADMINISTRATIVE COSTS IMPOSED BY LEGISLATION

The Commission has developed a possible model for measuring net administrative costs in the EU⁸⁵. The Commission launched a test phase in March 2005. The results are expected by the end of 2005. The Commission will then decide whether and how to incorporate it into the Guidelines for Impact Assessment. For further information, see SG.H.2.

The main aim of the model proposed is to assess the net costs of administrative obligations imposed on enterprises, the voluntary sector, public authorities and citizens (net costs = costs introduced by legislation minus the costs suppressed by legislation at EU and/or national level). It will also allow the origin of administrative obligations to be determined, distinguishing between regional, national, EU and international obligations.

10.1. Definition of administrative costs

Administrative costs are defined as the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be taken in a broad sense, including costs of labelling, reporting, monitoring to provide the information and registration.

10.2. Core equation of the cost model

It is suggested to assess administrative costs on the basis of the average cost of an action (Price) multiplied by the total number of actions performed per year (Quantity). The average cost per action is estimated by multiplying a tariff (based on average labour cost per hour including prorated overheads) and the time required per action.

$$\Sigma P \times Q \text{ (Price = Tariff} \times \text{Time; Q: Quantity = Number of businesses} \times \text{Frequency).}$$

The model focuses on labour costs and overheads because, in most cases, these costs are the main input required to meet administrative obligations. However, other types of costs will be taken into account where appropriate. For instance, in the case of an obligation to inform all customers by mail, the time spent by staff in drafting the leaflet is generally marginal compared to the printing and mailing costs.

10.3. Some examples

Steps followed for the REACH Impact Assessment⁸⁶:

- Calculate how many man-days required at all stages – completion of forms for registration and authorisation, meetings to discuss risk measures etc.
- Estimate cost of each man-day, including overheads (which would be high in this case e.g. including chemical labs), at €1000
- Multiply number of man-days by unit cost of €1000.

For INSPIRE, €75,000 per man-year was assumed. These different costs reflect:

⁸⁵ See Staff Working Paper, *Minimising administrative costs imposed by legislation - Detailed outline of a possible EU Net Administrative Cost Model* SEC(2005) 175.

⁸⁶ SEC(2003) 1171.

- How people are used. Where consultancy input is bought in, then 'man-days' may be the appropriate unit and the going consultancy rate might be used. Where someone is employed full-time, then 'man-years' may be the more appropriate unit.
- The skills of the people involved (IT specialists, lawyers, etc tend to cost more than average).

10.4. Tips for good practice

- There is no off-the-peg estimate of costs since they differ from case to case (see above, need to make different assumptions for REACH and INSPIRE).
- Talk therefore to the addressees (businesses, public administrations, citizens, etc. They can tell you about how implementation would work, and the hidden costs for them.
- Check for double-counting. Estimates of the costs of installing a piece of machinery may already include associated administrative costs.
- Approximation of overhead costs. Typically, the wages paid to an employee represent around half of the overall costs to a firm of employing somebody (personnel costs such as hiring costs, provision of computers, buildings, travel expenses, etc).

11. ASSESSING NON-MARKET IMPACTS, IN PARTICULAR ON ENVIRONMENT AND HEALTH

A first step in identifying non-market impacts, such as environmental impacts is obviously to undergo the general scoping (Step 1 in III.4.2 of the main Guidelines). Having done this, it is important to proceed, when possible, with quantification and then monetisation of those impacts. Given the difficulty of valuing some impacts, particularly environmental ones, it is especially useful to set out the process from qualitative to quantified to monetised estimates in a transparent manner and avoid a black-box approach.

11.1. Monetisation of non-market impacts

Monetisation of non-market impacts is easiest when the values are revealed in the market. For example, air pollution damage to crops might reduce crop yields and thus be relatively easily monetised. However, where values of impacts are not directly revealed through markets then it may be necessary to use other techniques.

Techniques have been developed to estimate the costs and benefits in money terms of goods that do not have a market value, describing the ‘willingness to pay’ or the ‘willingness to accept’ a particular outcome. They include **Stated preference methods** (contingent valuation, conjoint analysis, choice experiments) and **Revealed preferences methods** (travel cost method, hedonic pricing).

Stated preference methods can be obtained by constructing hypothetical markets and asking people via questionnaires and interviews the value of a given outcome. These techniques have been used, for example, to value reduction in risks of premature deaths and non-fatal injuries, and existence value for the environment and historic buildings. Revealed preference methods are based on evidence from market transactions, for example the correlation of noise disturbance with house prices.

The technique of **benefit or cost transfer** (usually just called ‘benefits transfer’) can also be used to estimate values of impacts that do not have market prices. In this technique, values obtained in one study are transferred to a different study. For example, estimates of the costs of preventing a motorway accident in one Member State might be used to estimate the costs in other Member States. Using this technique increases the uncertainty of the estimated values, but can be helpful to give an order of magnitude of likely impacts, or if there are time and money constraints.

Databases of valuation studies have been developed to make the technique of benefits transfer easier. You can find an evaluation of the possibility of adapting one such database for use in the EU on the Europa website⁸⁷. When valuing impacts, the proportionality principle applies, as in all parts of Impact Assessment: don’t devote a lot of energy to putting a value on non-marketed impacts if they are a very small part of the overall impacts. DG RTD is also building up a database of externalities, called RED (Review of Externalities Data).

Example: valuing health impact

Health impacts are often a significant portion of the benefits of improvements in environmental quality. For instance, in air quality benefit assessments, the value of reducing the risk of fatalities can often be 80 per cent of the total benefits. We often cannot reduce risks to zero without incurring significant costs. If we did not seek a balance, then we might spend money on reducing air pollution that would save more lives if spent on health care.

Q. Why do we want a monetary value of risk?

If we seek to balance the costs of a policy against its benefits, then we must compare the benefit of reductions in risk against costs. Any decision in this context means placing an implicit monetary value on health benefits. Decision-making will be easier and become more

⁸⁷ <http://europa.eu.int/comm/environment/enveco/others/evripart1.pdf>.

consistent if we have a monetary estimate of the value of health benefits. The monetary value represents the strengths of society's preferences.

Q. Can we value risk?

We cannot – and do not seek to – place a monetary value on our own lives or on other individuals' lives. However, changes in risks are a different matter. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time. We can therefore identify the value individuals place on small changes in risk.

Q. How can we value health using small changes in risk over large populations?

Suppose that air pollution can be expected to generate a risk of premature death of 1 in 1,000. Also suppose that 1,000 people were subject to this risk and each was willing to pay an average of €1,500 to reduce this risk of premature death to zero. Then, as this risk factor applied to this group would lead us to expect one death on average (1 in 1,000 * 1,000), and aggregate willingness to pay to avoid this risk is €1,500 * 1,000, then the value of preventing that statistical fatality is €1.5 million.

Q. What value should I use?

It is recommended that you use a figure of €1.0m as a best estimate. Reflecting the difficulty in analysis, figures of €2.5m and €0.65m are recommended for the upper and lower bounds in sensitivity analysis. These estimates are used for the value of preventing a fatality in the environmental context where small reductions in risk occur over a large population. They are applicable to deaths in a largely elderly population where the reduction in life expectancy is likely to be short – maybe one year or less.

Q. How should these be presented?

In all cases, the quantitative and monetary estimates should be presented together. This means that the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

11.2. Life cycle assessment approach

One of the tools commonly used in assessing environmental impacts⁸⁸ is **Life-cycle Assessment (LCA)**. This is the process of evaluating the effects that a product has on the environment over the entire period of its life. It can be used to study the environmental impact of either a product or the function the product is designed to perform. LCA is commonly referred to as a 'cradle-to-grave' analysis and can be used to ensure that maximum resource-use efficiency has been achieved and that environmental problems are not simply being shifted from one part of its life to another⁸⁹.

The LCA approach is useful because some materials are used in many different products – aluminium, for example, is present in window frames, aeroplanes and beverage cans – and looking at the environmental impact of such a resource in only one product does not tell us much about its overall impact, and how best to tackle it. This approach can also be used for products: for example, any consumer electrical good will have had environmental impacts (such as energy use) in its production, transport to market and disposal and not just during its use. Finally, understanding how end-of-pipe technologies shift environmental impacts upstream can be another example.

Key elements of LCA are:

- Identifies and quantifies the environmental loads involved; e.g. the energy and raw materials consumed, the emissions and wastes generated;
- Evaluates the potential environmental impacts of these loads;
- Assesses the options available for reducing these environmental impacts.

⁸⁸ Another useful tool for the identification and assessment of environmental impacts is the **Driving Forces, Pressures, States, Impacts, Responses (DPSIR) framework** (see EEA website (<http://www.eea.eu.int/main.html>) 'how we reason' brochure (accessed Feb 2005)). The DPSIR framework, used extensively by the European Environment Agency is an extension of the Pressure-State-Response model developed by the OECD.

⁸⁹ See EEA website for further details http://glossary.eea.eu.int/EEAGlossary/L/life_cycle_assessment.

12. DISCOUNTING

Most policy options result in costs and benefits that arise at different times. Building a railway line has an immediate cost, but provides benefits over a long period. When beneficiaries receive a constant amount of money over a set period of time, their benefit will worth more on the first year than on the last year of the programme. Conversely, costs to be paid in the future are less onerous.

The discount rate is a correction factor reflecting these facts. All in all, discounting allows the direct comparison of costs and benefits occurring in different points in time, valuing immediate costs and benefits more highly than those that occur later. When 'discounting' is used, it should be applied both to costs and benefits.

You should use a discount rate of 4%⁹⁰. This discount rate is expressed in real terms, taking account of inflation. You should therefore apply it to costs and benefits expressed in constant prices. The total of the discounted costs and benefits of a policy option is called its **net present value**.

12.1. An example

Suppose a project incurs costs of €1,000,000 this year, and yields benefits of €200,000 each year for the following 6 years, after adjusting for inflation.

Then, using the discount rate of 4% recommended by these guidelines, the **net present value** of the project is

$$\frac{200,000}{1.04} + \frac{200,000}{1.04^2} + \frac{200,000}{1.04^3} + \frac{200,000}{1.04^4} + \frac{200,000}{1.04^5} + \frac{200,000}{1.04^6} - 1,000,000$$

This equals 1,048,427 – 1,000,000, so that the net present value of the project is

€48,427.

Thus, the project generates net benefits to society, and as long as the distribution of costs and benefits among different social groups is judged acceptable, the project should go ahead.

For some cases involving very long horizons – such as the effects of climate change – it may be appropriate to use a lower discount rate. This might be justified by the longer-term implications of sustainable development and in particular, the need to take proper account of the preferences of future generations (for more on this see 'Discounting and sustainability: Issues on the choice of discount rate for long-term environmental policy', background paper prepared for ENVECO meeting, 2-3 June 1999).

12.2. Formula for net present value

The net present value of a project is calculated as

(discounted value of benefits) – (discounted value of costs).

Algebraically, if B_i and C_i are the benefits and costs in year i of a project which has a lifetime of $n+1$ years (counting this year as year 0), and if r is the discount rate (expressed as a decimal), then the net present value of the project is

⁹⁰ This rate broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s.

$$\sum_{i=0}^{i=n} \frac{Bi}{(1+r)^i} - \sum_{i=0}^{i=n} \frac{Ci}{(1+r)^i}$$

12.3. Annualised costs and benefits

You need to be careful when comparing policies with different time horizons, because the net present value criterion is no longer valid. To make valid comparisons in such circumstances, it is often useful to calculate the *annualised value* of alternative policies. This is defined as the fixed annual stream of income that would be paid by a fixed-interest annuity with the same net present value as the policy. It is determined by the formula:

$$\text{Annualised value} = \frac{\text{present value} \times \text{discount rate}}{1 - (1 + \text{discount rate})^{-\text{time horizon}}}$$

where the time horizon is defined in years and the discount rate is divided by 100 (that is, 4% is 0.04).

So to compare a project with a present value of €1500 and a lifetime of 5 years with a project with a present value of €1750 and a lifetime of 7 years, we calculate their annualised values. For the first project:

$$\frac{1500 \times 0.04}{1 - (1 + 0.04)^{-5}}, \text{ which equals } \frac{60}{1 - 0.822}, \text{ so that its annualised value is €336.94.}$$

For the second project:

$$\frac{1750 \times 0.04}{1 - (1 + 0.04)^{-7}}, \text{ or } \frac{70}{1 - 0.76}, \text{ giving an annualised value of €291.57.}$$

Thus, although the second project yields higher net benefits, because these are spread out more thinly over time the first project in fact represents better value.

For additional material on discounting see sections 3.7 and 3.8 of DG ENV's 'Guidelines on costing environmental policies', October 1999, and 'Guidelines for defining and documenting data on costs of possible environmental protection measures⁹¹', European Environment Agency, Technical Report no. 27, 1999.

12.4. Table of discounted present values

The table shows the value of €1,000 discounted at various rates for periods from 1 to 25 years. Thus, a benefit of €1,000 (in constant prices) which occurs in the 12th year has a present value of €624.60 when discounted at 4%, or €318.63 when discounted at 10%.

year	Discount rate in percent									
	1	2	3	4	5	6	7	8	9	10
0	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000
1	990.10	980.39	970.87	961.54	952.38	943.40	934.58	925.93	917.43	909.09

⁹¹ <http://reports.eea.eu.int/TEC27/en>.

2	980.30	961.17	942.60	924.56	907.03	890.00	873.44	857.34	841.68	826.45
3	970.59	942.32	915.14	889.00	863.84	839.62	816.30	793.83	772.18	751.31
4	960.98	923.85	888.49	854.80	822.70	792.09	762.90	735.03	708.43	683.01
5	951.47	905.73	862.61	821.93	783.53	747.26	712.99	680.58	649.93	620.92
6	942.05	887.97	837.48	790.31	746.22	704.96	666.34	630.17	596.27	564.47
7	932.72	870.56	813.09	759.92	710.68	665.06	622.75	583.49	547.03	513.16
8	923.48	853.49	789.41	730.69	676.84	627.41	582.01	540.27	501.87	466.51
9	914.34	836.76	766.42	702.59	644.61	591.90	543.93	500.25	460.43	424.10
10	905.29	820.35	744.09	675.56	613.91	558.39	508.35	463.19	422.41	385.54
11	896.32	804.26	722.42	649.58	584.68	526.79	475.09	428.88	387.53	350.49
12	887.45	788.49	701.38	624.60	556.84	496.97	444.01	397.11	355.53	318.63
13	878.66	773.03	680.95	600.57	530.32	468.84	414.96	367.70	326.18	289.66
14	869.96	757.88	661.12	577.48	505.07	442.30	387.82	340.46	299.25	263.33
15	861.35	743.01	641.86	555.26	481.02	417.27	362.45	315.24	274.54	239.39
16	852.82	728.45	623.17	533.91	458.11	393.65	338.73	291.89	251.87	217.63
17	844.38	714.16	605.02	513.37	436.30	371.36	316.57	270.27	231.07	197.84
18	836.02	700.16	587.39	493.63	415.52	350.34	295.86	250.25	211.99	179.86
19	827.74	686.43	570.29	474.64	395.73	330.51	276.51	231.71	194.49	163.51
20	819.54	672.97	553.68	456.39	376.89	311.80	258.42	214.55	178.43	148.64
21	811.43	659.78	537.55	438.83	358.94	294.16	241.51	198.66	163.70	135.13
22	803.40	646.84	521.89	421.96	341.85	277.51	225.71	183.94	150.18	122.85
23	795.44	634.16	506.69	405.73	325.57	261.80	210.95	170.32	137.78	111.68
24	787.57	621.72	491.93	390.12	310.07	246.98	197.15	157.70	126.40	101.53
25	779.77	609.53	477.61	375.12	295.30	233.00	184.25	146.02	115.97	92.30

13. METHODS OF COMPARING IMPACTS

13.1. Cost-benefit analysis

This entails identifying and evaluating expected economic, environmental and social benefits and costs of proposed public initiatives. A measure is considered justified where net benefits can be expected from the intervention.

Advantages

- accounts for all (negative and positive) effects of policy measures
- allows comparison of the ordering of costs with the ordering of benefits of the proposal over time
- can also be used to rank alternative (including non-regulatory) proposals in terms of their net social gains (or losses).

Disadvantages

- cannot include impacts for which there exist no quantitative or monetary data
- difficulties in establishing the social discount rate
- usually more expensive and time consuming than other, less broad, methods
- may lead to distributional issues being overlooked.

13.2. Cost-effectiveness analysis

This requires calculating the cost needed to achieve a desired outcome, allowing the costs of different options to be compared. It is an alternative to cost-benefit analysis in cases where it is difficult to value benefits in money terms. Cost-effectiveness analysis offers a ranking of regulatory options based on 'cost per unit of effectiveness' of each measure.

Advantages

- offers a more relaxed approach towards benefit measurement than cost-benefit analysis
- useful to compare alternatives that are expected to have more or less the same outcome.

Disadvantages

- does not resolve the choice of the optimal level of benefits
- concentrates on a single type of benefit (the intended effect of the measure), excluding possible side-effects
- provides no assistance as to whether a regulatory proposal would provide net gains to society

13.3. Multi-criteria analysis

This term covers a wide range of techniques that share the aim of combining a range of positive and negative impacts in a single framework to allow easier comparison of scenarios and decision-making. The technique can be useful where there is a large amount of information on a number of different impacts, and that information is in different formats. It allows impacts to be presented that are a mixture of qualitative, quantitative and monetary and of varying degrees of certainty.

Key steps generally include

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

Advantages

- recognises multi-dimensionality of sustainability
- allows different types of data (monetary, quantitative, qualitative) to be compared and analysed in the same framework with varying degrees of certainty
- provides a transparent presentation of the key issues at stake and allows trade-offs to be outlined clearly; contrary to other approaches such as cost-benefit analysis, it does not allow implicit weighing
- enables distributional issues and trade-offs to be highlighted.

Disadvantages

- includes elements of subjectivity, especially in the weighting stage where the analyst needs to assign relative importance to the criteria
- because of the mix of different types of data, cannot always show whether benefits outweigh costs
- time preferences may not always be reflected.

13.4. Risk analysis

This assesses the risk of an undesirable event occurring, and the possible consequences to individuals and to society if it occurs. Risk appraisals can then be used to determine the options available to reduce or eliminate the risk and/or its consequences.

To carry out risk analysis, you need to:

- identify the risk
- assess how likely that risk is to happen
- assess the potential impact to the proposed programme / measure if the risk identified were to occur.

Advantages

- scientific assessments of risks make crucial contributions to regulatory decisions, especially in the areas of public health and safety, environmental protection, resource exploitation, wealth creation, innovation and national security indicating whether the policy will be effective in reducing risks in a significant manner.

Disadvantages

- risk impacts may be diverse and not commensurate (that is, brought into a common measure);
- does not normally involve an assessment of the costs likely to occur if the undesirable event does happen;
- takes no account of negative and positive impacts other than risks linked with the proposed measures to deal with the risk and/or its consequences;
- should not be used as the sole basis for deciding whether to take action or for determining the type of action to be taken.

Variants of these methods exist and can be used when appropriate. Examples are cost assessment, risk-risk assessment, etc.

We can also use techniques to value changes in risks of events occurring. This is extremely useful, indeed necessary, when looking at many environmental or health impacts. For example, many policies will try to reduce the risk of illness or death. We cannot – and do not seek to – place a monetary value on our own lives or on other individuals' lives. However, changes in risks are a different matter. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time. We can therefore identify the value individuals place on small changes in risk.

13.5. Sensitivity analysis

Sensitivity analysis explores how the outcomes or impacts of a course of action would change in response to variations in key parameters and their interactions. Useful techniques are presented in a book published by the JRC.⁹² It may be that a single factor is crucial to the decision of whether or not an option is worth implementing. In such cases a useful form of sensitivity analysis is to identify how much the value of the factor would have to fall (if it is a benefit) or rise (if it is a cost) to make it not worth undertaking the option.

To carry out sensitivity analysis, you need to:

- Focus on the most important alternatives
- Search for switching value / point

Advantages

- it is often the best way to handle the analysis of uncertainties.

⁹² <http://sensitivity-analysis.jrc.cec.eu.int/>.

14. ADDITIONAL GUIDANCE ON INDICATORS, MONITORING AND EVALUATION

14.1. Indicators

Like objectives, indicators should be defined at different levels. For expenditure programmes, these levels are as follows:

<i>Level of objective</i>	<i>Type of indicator</i>	<i>Definition</i>	<i>Examples</i>
	Resource indicators	Provide information on the financial, human, material, organisational or regulatory means needed for the implementation of the programme	Annual budget absorption; n° of people working on the implementation of the programme; etc.
Operational objective	Output indicators	Relate to the deliverables that the programme is expected to produce	Kilometres of roads built; n° of SMEs receiving advice; n° of training places offered; etc.
Specific objective	Result indicators	Represent the immediate effects of the programme on the direct addressees or recipients	Time saved by users of a road; qualifications earned by trainees; satisfaction of businesses which have received consultancy services; etc.
General objective	Impact indicators	Represent the consequences of the programme beyond its direct and immediate interaction with the addressees or recipients. These include the medium-term impacts on: a) the direct addressees or recipients of the programme; b) people or organisations not directly addressed by the programme, as well as c) unintended impacts.	a) The placement rate of trainees after twelve months; survival rate of businesses created with programme support b) Impact on suppliers or sub-contractors of the assisted firms c) Net jobs lost after the introduction of a product ban.
	Context indicators	Apply to an entire territory, population or category of population – without distinguishing between those that have been reached by the programme and those that have not.	Number of jobs in the tourist sector; Level of connection to the internet in territory X; unemployment rate in territory Y

As far as **purely regulatory proposals** (or policies) are concerned, most of the elements contained in the above table can be applied *mutatis mutandis*. The most striking difference between spending programmes and regulatory proposals concerns the concept of outputs. In a spending programme, the output is considered as that which is financed and accomplished with the money allocated to the intervention (e.g. 20 kilometres of road built). What would be the output in the case of a Directive? Neither the adoption of the Directive by Council and Parliament, nor its transposition into the national laws of Member States should be considered as outputs (although both steps are important parameters in the monitoring of the implementation of the proposal). The outputs at EU level could in such a case be based on a typology of the 'key types of measures' adopted by Member States in order to comply with the Directive.

To the extent that this is feasible (which *inter alia* depends on the nature of the proposed intervention) all indicators should be 'RACER', i.e.:

- relevant, i.e. closely linked to the objectives to be reached;
- accepted (e.g. by staff, stakeholders);
- credible for non experts, unambiguous and easy to interpret;
- easy to monitor (e.g. data collection should be possible at low cost);
- robust against manipulation.

14.2. Monitoring

By the time you present your concrete proposal, you have to give more detailed thought on the need for, and nature of, appropriate monitoring arrangements.

You should in particular:

- plan how to collect data on indicators and other factors relevant for later analysis of achievement;
- analyse the soundness and reliability of the proposed methods and instruments for collecting, storing and processing follow-up data;
- ensure that the monitoring system works from the outset and that adequate legal provisions are in place to ensure that data from Member States or from third parties will be collected reliably and smoothly. Often it is necessary to spell out monitoring requirements in the legal basis for the action.

The above is particularly true for **expenditure programmes**, where systematic monitoring provides data in particular with regard to inputs/resources consumed (e.g. rate of consumption of budget; compliance with project costs programmed); the implementation process (e.g. number of project applications approved; time taken for payments; etc.); outputs (e.g. number and average size of projects funded; number and average size of subsidies granted); results (e.g. number of trainees qualifying with the required level); and context (e.g. rate of unemployment in territory X).

In the case of purely **regulatory proposals** (or policies), monitoring systems are likely to have a different scope and purpose. They could, for instance, focus on:

- implementation at Member State level (e.g. transposition of Directives);
- compliance of addressees (e.g. enterprises producing according to certain minimum standards);

- context variables.

14.3. Evaluation

According to the Commission's rules on evaluation⁹³, all programmes and (ABB) activities have to be evaluated on a regular basis⁹⁴. With regard to proposals occasioning expenditure from the EU budget:

- multi-annual programmes 'shall be periodically evaluated in accordance with a timetable which enables the findings of that evaluation to be taken into account for any decision on the renewal, modification or suspension of the programme';
- activities financed on an annual basis have to be evaluated at least every six years.
- When planning evaluations, you should aim to set up a clear link between the evaluation, its results and decision-making. Where relevant, you should identify, at the latest at the time of making the concrete proposal for the intervention envisaged:
 - what types of evaluations are needed and when;
 - the main focus and purpose of these exercises;
 - who is responsible for carrying them out (e.g. Commission, Member States);
 - how, and to whom, the evaluation results are to be communicated (for example, by means of a Communication to European Parliament, Council of Ministers, where appropriate); as a minimum, the results should be communicated to the institution(s) that approve(s) the proposal in question.

Example:

Integrated Action Programme in the field of Life-long Learning

The Commission commits itself to proceed to the following evaluation exercises:

- A series of independent external evaluations of various aspects of the integrated programme; a work plan will be proposed for agreement to the integrated programme Committee.
- An interim evaluation report on the qualitative and quantitative implementation of the programme and on the results so far achieved by 31 March 2011.
- A communication on the continuation of the programme by 31 December 2011.
- An ex post evaluation report by 31 March 2016.
- On the accession of new Member States, a report on the financial consequences of these accessions, followed, if appropriate by financial proposals to deal with the financial consequences of these accessions.

For more information on

- **objectives and indicators**, consult the guide on the SPP website:
http://www.cc.cec/home/dqserv/sg/i/spp/index.cfm?lang=en&page=obj_ind
- **evaluation**, consult the guide 'Evaluating EU Activities' on
http://europa.eu.int/comm/budget/evaluation/Key_documents/evalguides_en.htm

⁹³ See Communication on Evaluation SEC(2000)1051, as well as Article 27(4) of the Financial Regulation and Article 21 of its Implementing Rules.

⁹⁴ However, as 'ABB activities' typically embrace a complex set of sub-activities, it will be necessary in practice to carry out evaluations at a disaggregated level (e.g. by action, theme, budget line, etc.). These individual evaluations should always include an analysis of the contribution of the sub-activity in question to the attainment of the overall policy objectives at activity level.

15. THE PRECAUTIONARY PRINCIPLE AND IRREVERSIBILITY

Put simply, the idea behind the precautionary principle⁹⁵ is that action can be taken to protect the environment and human, animal or plant health even where scientific certainty is lacking, for example initial scientific evaluation indicates reasonable grounds for concern that the potentially dangerous effects may be inconsistent with the chosen level of protection. Similarly, the precautionary principle could also lead to refraining from an action that entails the placing on the market of certain substances or the authorisation of the use of certain techniques.

The principle applies where:

1. we have identified potentially unacceptable risks, and
2. we cannot determine these risks with sufficient certainty. In these circumstances, a decision can be taken despite a lack of certainty.

The principle must therefore be viewed within the overall framework of risk analysis, with the possible extreme scenarios identified by undertaking routine sensitivity analysis.

The use of the precautionary principle is often advocated for cases with irreversible impacts. For example, once a particular species has been lost, it is lost forever. In such cases, the possibility of irreversible losses may point towards caution and the application of the precautionary principle.

Measures based on the precautionary principle should comply with the basic principles for all other legislation, such as proportionality to the chosen level of protection, non-discrimination and consistency with similar measures already taken, and should be based on an examination of the potential benefits and costs of action or inaction. They should assign responsibility for producing the scientific evidence needed for a more comprehensive risk assessment and be subject to review in the light of new scientific data.

⁹⁵ See Communication on the precautionary principle, COM(2000) 1.

16. FORMAT OF THE IA FINAL REPORT

To ensure consistency across the Commission, the following format should be used for the final IA Report. The bullet points follow the key points of the impact assessment analysis. Assumptions, possible uncertainties and lack of (reliable) data must be flagged in the sections presenting the key steps of the IA analysis. Reference should also be made in the various sections to the underlying material on which the conclusions have been drawn (e.g. external studies, reports, statistical data, expert advice, stakeholder input, etc.).

The IA support function/unit in your DG and the Secretariat General will check that all these key points have been adequately addressed.

When the impact assessment work has led to the decision not to present a draft proposal or to postpone it, this format should be followed as far as possible. This will allow readers to follow the reasoning behind the decision to amend the Commission's Work Programme. The report should be written in non-technical language and should not normally exceed 30 pages.

Lead DG:

Other involved services:

Agenda planning or WP reference:

Executive summary

No more than one page, written in non-technical language, presenting the conclusions of the comparison of short-listed options.

Section 1: Procedural issues and consultation of interested parties

- Organisation and timing
 - Clearly state the reference to the associated item in Agenda Planning or the Work Programme.
 - Provide the general chronology of the IA and specify if an inter-service steering group was established (if so, state which DGs participated).
- Consultation and expertise
 - Indicate if external expertise was used, and, if so, how
 - Indicate how and at what stage(s) stakeholders have been consulted.
 - Indicate if the Commission's minimum standards could all be met and, if not, why.
 - Indicate the main results and how this input has been taken into account⁹⁶ or why it has not been taken into account.

⁹⁶ Report on specific input in the following sections presenting the key steps of the IA analysis.

Section 2: Problem definition

- What is the issue or problem that may require action?
- What are the underlying drivers of the problem?
- Who is affected, in what ways, and to what extent?
- How would the problem evolve, all things being equal? N.B. Scenario(s) should take into account actions already taken or planned by the EU, Member States and other actors.
- Does the EU have the right to act – Treaty base, ‘necessity test’ (subsidiarity) and fundamental rights limits?

Section 3: Objectives

- What are the general policy objectives? What are the more specific/operational objectives?
- Underline the consistency of these objectives with other EU policies and, if applicable, horizontal objectives, such as the Lisbon and Sustainable Development strategies or respect for fundamental rights.

Section 4: Policy options

- What are the possible options for meeting the objectives and tackling the problem? N.B. the ‘no EU action’ option should always be considered and it is highly recommended to include a non-regulatory option, unless a decision of the College has already ruled this out.
- Which options have been discarded at an early stage and why? N.B. Refer to the pre-screening criteria (poor effectiveness, efficiency or consistency with other objectives and policies). Be particularly specific and precise for discarded options enjoying significant support among stakeholders.

Section 5: Analysis of impacts

- What are the likely economic, social and environmental impacts of each of the short-listed options?
- List positive and negative impacts, direct and indirect, including those outside the EU.
- Specify uncertainties and how impact may be affected by changes in parameters (uncertainty and sensitivity analysis).
- Include impacts in the EU and outside the EU.
- Specify which impacts are likely to change over time and how.
- As relevant, specify which social groups, economic sectors or particular regions are affected.
- What are the potential obstacles to compliance?

Section 6: Comparing the options

- Indicate how positive and negative impacts have been weighed for each short-listed option.
- Present results of the weighing.
- Present the aggregated and disaggregated results?
- Indicate if the analysis confirms whether EU action would have an added value.
- Highlight the trade-offs and synergies associated with each option.
- If possible, rank the options in terms of the various evaluation criteria?
- If possible and appropriate, set out a preferred option.

Section 7: Monitoring and evaluation

- What are the core indicators of progress towards meeting the objectives?
- What is the broad outline for possible monitoring and evaluation arrangements?