

European Commission



**PART III: ANNEXES TO
IMPACT ASSESSMENT GUIDELINES***

15 January 2009

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

Title of the initiative:
Lead DG/contact person:
Expected date of adoption of the initiative (month/year):
Date of modification:
Version No:

PART I – Initial IA screening & planning of further work

NB. This part will be made public with the CLWP and on the Europa-site

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

What are the main problems identified?

Is EU action justified on grounds of subsidiarity?

B. Objectives of EU initiative

What are the main policy objectives?

Does the objective imply developing EU policy in new areas or in areas of strategic importance?

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Explain how the options respect the proportionality principle

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Who is affected?

E. 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 have been/will be consulted, how and at what stage?

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

NB. For internal use only

F. Time line

When will the impact assessment work start?

When will the inter-service steering group be set up? What DGs will be invited? How often will it meet?

In case 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 submission of the draft IA report to the Impact assessment board (no later than 1 month prior to launch of the inter-service consultation) and the inter-service consultation (draft proposal and IA report)?

G. Resources

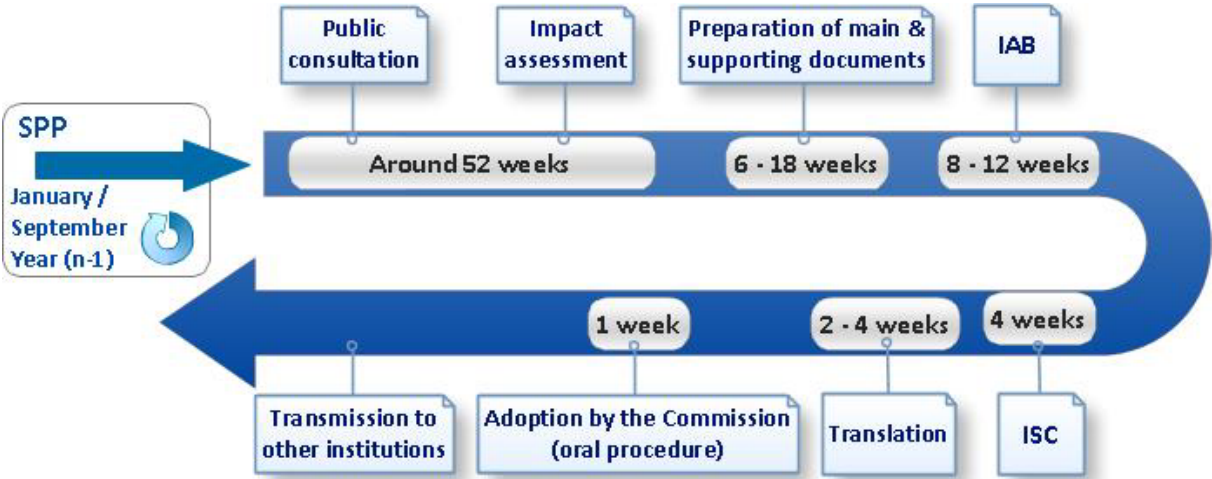
What human and/or financial resources have been put aside for the IA and finalising the draft legislation/policy document?

H. Communication

Is any particular communication or information activity foreseen? If so, what, and by when?

2. Timing of the Impact Assessment

Typical countdown for preparing a CLWP initiative for adoption by the Commission (in oral procedure)



STEP-BY-STEP PLANNING AND USEFUL LINKS

The following steps form part of the preparation of a CLWP item for adoption by the Commission. The main actions for each step are explained, and an indication is given of the minimum time you should allow for each step. While progress on some steps can certainly be made in parallel, do not count excessively on this possibility. For example, while to some extent you may work in parallel when preparing the impact assessment and the main documents, a certain sequencing is necessary to properly respect the results of public consultation and impact assessment in the actual proposal. Under most of the steps, you will find web links that provide more information about the principles and procedure to follow in each case.

Substantial preparations should already have been made, e.g. in terms of public consultation and impact assessment work, when an item is included in the Commission’s Legislative and Work Programme (CLWP).

Strategic Planning and Programming (SPP)

January/September (year n-1)

To allow the Commission to plan, prepare and present its policy initiatives efficiently and coherently you should announce your initiative early on. If your initiative contributes to the main priorities of the Commission, it should be included in the Annual Policy Strategy (APS) which is adopted by the College in February (year n-1). If your initiative is included in the Commission’s Legislative and Work Programme (CLWP) you will need to prepare a Roadmap in September (year n-1). At this point in time, you should normally have made progress on the external consultation and the impact assessment.

Regardless of whether or not your initiative is listed in the CLWP, it should be introduced into the Commission’s Agenda Planning in July (year n-1).

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

Step 1 – Public consultation

Minimum 14 weeks

For most proposals you will need to consult stakeholders and the general public. According to the rules, you should allow at least 8 weeks for a written public consultation. You will also need to allocate time for planning the consultation and preparing the background document(s) on which to consult. You will know best how long this will take but count 6 weeks as a minimum.

In case you plan to organise a meeting, this should be announced at least 4 weeks in advance. You will also need to analyse the contributions (although this could possibly be done parallel to or as part of the impact assessment) and publish contributions to open consultations. The Commission is also committed to provide feedback on the outcome of the consultation.

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

Please also take into account that for some types of proposals there may be an obligation to consult specific fora (e.g. comitology committees or expert groups).

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_grpexp&lang=en&menu=on

Step 2 – Impact assessment

around 52 weeks

The time needed for preparing an impact assessment will depend on the complexity and sensitivity of the proposal but it will also depend on how you go about it. For example, you may need to call on external expertise through a call for tender, which clearly takes time. As a general rule, you will also need to set up an inter-service steering group for the impact assessment to involve other services with an interest in the proposal early on. To this you should add time for public consultation (see above). A recent external evaluation of the Commission's impact assessment system estimated the average time for carrying out an IA to be around 1 year.

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_aimpact&lang=en&menu=on

http://www.cc.cec/home/dgserv/sg/i/impact/index_en.htm

Step 3 – Preparation of documents

6 to 18 weeks

This stage of the preparation is not regulated by the Commission's internal rules. As with the impact assessment, the time needed for drafting an initiative will obviously vary significantly from perhaps 6 weeks for a straightforward and uncontroversial Communication to 3-4 months (or more) for a complex and important legislative proposal. Only you will know how much time you should allocate to this but it should include regular coordination with other concerned DGs and the internal approval of your Director-General and your Commissioner's Cabinet to, eventually, launch the formal ISC. It is essential that you show how the proposal relates to the preceding impact assessment and consultation work.

Step 4 – Opinion of the Impact Assessment Board

8 to 12 weeks

You should submit the impact assessment to the Impact Assessment Board (IAB) at least four weeks before you plan to launch the ISC. Before doing so, you will need to have the draft documents approved by your Director-General. Once you have received the opinion of the IAB you may need to work further on the impact assessment and/or resubmit the revised impact assessment to the IAB. In this case you may have to add another 2 to 8 weeks.

http://www.cc.cec/iab/i/index_en.cfm

Step 5 – Inter-Service Consultation

Minimum 4 weeks

For documents longer than 20 pages (including the impact assessment and other supporting documents) services should be given 15 working days (3 weeks) to reply. For shorter documents you should allow 10 working days (2 weeks). To this period, you should add the time needed after the ISC to modify the text (including by taking into account editing proposals made by DGT-Edit), negotiate with other services and get the finalised text agreed by your Director-General and by your Commissioner's Cabinet. The time needed for this will depend on, among other things, to what extent the initiative is complex, politically sensitive or controversial. Coordinating as early as possible with the other services should become standard practice as it helps avoid late problems when the ISC is launched.

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_consultinterserv&lang=en&menu=on

<http://www.cc.cec/home/dgserv/sg/cis/index.cfm?page=intro&lang=en>

Step 6 – Translation

Minimum 2 weeks

Translation is also an important part that the services must include in the countdown. Being the last step before adoption, delays in the other steps can not result in a compression of the time needed (and foreseen) for translation. You should take into account the following elements:

- DGT does not begin until the ISC is finalized and the text stabilized, otherwise there is an important loss of resources that has been criticized by different audits;
- Translation has to be programmed; the translation correspondent should send beforehand their previsions (approximate number of pages and dates, based on the information appearing in Agenda Planning). This makes it possible for DGT to plan the allocation of resources and respect the deadlines, provided of course that you send the text on the foreseen date;
- With the simplification measure “Action 2”,¹ the translations will be sent back by DGT directly to SG. DGs will no longer be responsible for the quality of translations;
- For any other details, contact the demand management unit (planning) in DGT (<http://www.cc.cec/DGT/planning/index.htm>), and in particular the persons in this unit dealing with your DG;
- The number of days needed for translation is dependent on the number of pages; as a rule of thumb, for a priority (CLWP) and programmed document of less than 15 pages you can count 2 weeks. Within the framework of “Action 2” (see above), DGT is committed to respect the dates that will be agreed with the requesting DG;
- When sending the document for translation, send also any reference document that could contribute to a better understanding of the proposal and, thus, to obtain a better quality;

For the languages needed at the different moments of the procedure, see:

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_regling&lang=en&menu=on

Step 7 – Adoption by the Commission (oral procedure)

Minimum 6-9 days

The adoption of a document by the Commission is normally prepared in a special meeting of the Heads of Cabinet (“RSCC”) and subsequently in the weekly meeting of the Heads of Cabinet (“Hebdo”).

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_reunhebdo&lang=en&menu=on

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_reunspec&lang=en&menu=on

¹ See joint letter SG-DGT ref. SG D(2007)3874)

The current rules are that documents shorter than 15 pages should be submitted to the Greffe at the very latest 6 working days before the meeting of the College, i.e. the Tuesday of the week before the College meeting (Monday, in case the College meeting takes place in Strasbourg).

Longer document should be submitted at the very latest 8 working days before the adoption date (Friday two weeks before the meeting).

http://www.cc.cec/home/dgserv/sg/manupro/index.cfm?doctm=otc_decispo&lang=en&menu=on

(see also “next pages” on this site)

During the period before the adoption, you may also have to prepare a press release, briefings and speaking points for your Commissioner for the press conference or an interview.

Step 8 – Transmission to the other institutions by SG

The three procedural languages are, in principle, sent to the Council within two days after adoption. All linguistic versions must be available as soon as possible for the formal transmission to Council and the European Parliament (and to national Parliaments). Please remember that the Council considers the file to be officially submitted only when all the linguistic versions have been delivered.

NB: Revision by the legal revisers (not to be confused with the SJ opinion in CIS-net)

Please note that when revision of all the linguistic versions of a document by the legal revisers group (see <http://www.cc.cec/sj/jurrev/index.html>) is deemed necessary this additional step must take place after the translation but before the decision is taken by the Commission (i.e. between steps 6 and 7 in this countdown) if the decision is taken by written procedure. In the case of an oral procedure revision can exceptionally take place after the act is approved by the College. In such cases provisional versions are sent to the Council and Parliament.

3. Format of the IA report

To ensure consistency across the Commission, the following format should be used for the 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.). Whenever possible, direct internet links should be provided.

The report should be written in non-technical language and **should not exceed 30 pages**. Exceptions need to be agreed with the impact assessment unit of the SG.

- Standard front page and disclaimer (e.g. "This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission").
- Table of content

Section 1: Procedural issues and consultation of interested parties

- Identification: Lead DG; Agenda planning/WP reference:
- Organisation and timing: Provide the general chronology of the IA and specify which DGs participated in the Impact Assessment Steering Group (IASG).
- Consultation and expertise:
 - Indicate if external expertise was used, and, if so, how.
 - Indicate which groups of stakeholders have been consulted, at what stage in the IA process and how (public or targeted consultations, and if targeted, why?).
 - Indicate the main results, the different positions expressed and how this input has been taken into account or why it has not been taken into account.
 - Indicate if the Commission's minimum standards have all been met, and, if not, why not.

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 and is EU added-value evident – 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 or an obligation for legal action exists.
- 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.
- Include assessment of administrative burden.
- Specify uncertainties and how impact may be affected by changes in parameters.
- 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/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?

Annexes

- Present technical background material.
- Present key public consultation documents and summaries of replies (unless available via public internet link).
- Provide key studies/work carried out by external consultants (unless available via public internet link).

4. Format of the IA Executive Summary

The executive summary should be a **separate staff working document and should have no more than 10 pages**. It should a) present a summary of the problem description and the objectives; b) present the analysis of subsidiarity; c) list the range of options identified and the options assessed in detail; d) present the main economic, social and environmental impacts of each option and, where relevant, e) the result of the comparison of the options, indicating the criteria for comparison. For points d) and e) the executive summary should contain a clear presentation of any quantified benefits and costs of the various options. This should cover administrative costs for businesses and citizens, other compliance costs, and costs for administrations.

The executive summary should use the following format:

1. Problem definition: What is precisely the problem, who is most affected and why is public intervention necessary?

2. Analysis of subsidiarity: Is EU action justified on grounds of subsidiarity (Necessity and EU value added)?

3. Objectives of EU initiative: What are the main policy objectives?

4. Policy options: Which options have been considered and which have been assessed in detail?

5. Assessment of impacts: What are the main economic, environmental and social impacts of each option particularly in terms of (quantified/monetised) benefits and costs (including estimates on administrative burden), other compliance costs and implementation costs for public administrations)?

6. Comparison of options: What is the preferred option on the basis of which criteria/justification?

7. Monitoring and evaluation: What are the arrangements to establish the actual costs and benefits and the achievement of the desired effects?

5. Consultation of interested parties during the IA

“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.”²

Stakeholder consultation in the impact assessment process must be carried out according to the Commission’s general principles and minimum standards for consultation.³ Supplementing the information presented in the main text, the following chapters provide detailed guidance for application of the minimum standards.

5.1. Application of the minimum consultation standards

Minimum Standard A	Provide consultation documents that are clear, concise and include all necessary information
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In order to be successful, you have to identify clearly the objective of the consultation. You should give respondents information about what kind of input is expected from them. It would be useful e.g. to make a distinction between questions where options are open and questions where the room for deliberation is more limited. Questions should be specific and address concrete issues. Suggestive or leading formulations must be avoided. Stakeholders should be encouraged to give background information to their contributions so that the service can better assess the reasons behind the opinions expressed.

Minimum Standard B	Consult all relevant target groups
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You should define clearly the target groups before launching a consultation, because engaging the relevant stakeholders is key to a successful consultation process. 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). You should also involve bodies that have stated objectives which give them an interest in the policy.

Beware of including only the "usual suspects" into your consultation process. Consider also the less obvious stakeholders affected by the proposal as a whole and the need for a proper balance in categories selected for consultation. Note that there are differences between different types of stakeholders regarding access and availability of resources and that you may need to reach out to some new categories of stakeholders to help them take part in the consultation process.

You should seek out proactively relevant stakeholders for your consultation. Previous consultations on related topics as well as discussions within the IASG are often a good source for this. Contacting European stakeholder federations and networks as well as EC representa-

² COM(2002) 713, p.7.
³ COM(2002) 704. See http://europa.eu.int/eurex/lex/LexUriServ/site/en/com/2002/com2002_0704en01.pdf.

tions might be useful. European consultations could also sometimes profit from consultations launched at the national level and vice versa.

Minimum Standard C	Ensure sufficient publicity and choose tools adapted to the target group(s)
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You should seek the whole spectrum of views of the stakeholders and be transparent in order to avoid capture by specific constituents. For this, proactive publicity is often needed. Open public consultations must at least be publicised on the Commission’s single access point for consultation, ‘Your Voice in Europe’.⁴ Contributions to these consultations should be published on the internet. Also, the outcome of other consultations (for example, minutes of the meetings) should, as far as possible, be published.

The choice of consultation tools will largely depend on who needs to be consulted and 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. In many cases more than one tool is needed to reach all relevant stakeholders.

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 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 5.4 on ‘Using questionnaires’.

Minimum Standard D	Leave sufficient time for participation
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Consultation should start as early as possible to maximise its impact on policy development and it should take as long as is needed for it to serve the purposes for which it has been undertaken. The main rule is to give those participating in consultations sufficient time for participation. The minimum consultation period is **at least eight weeks** for open public consultations. However, a longer consultation period might be necessary under certain circumstances⁵. A notice of 20 days should be provided for meetings.

Minimum Standard E	Provide — collective or individual — acknowledgement of responses and feedback
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The receipt of contributions should be acknowledged. Publishing the contributions on the Internet within 15 working days is considered as acknowledgement.

You should report back to the stakeholders and the public how the input in your consultation was asked for and used. The consultation process, its main results (main clusters of comments) and how the opinions expressed have been taken into account (or why they have been disregarded) should be reported (in summary form) in the IA report and in the explana-

⁴ See http://europa.eu.int/yourvoice/consultations/index_en.htm.
 Minimum Standards for Consultation: "On the other hand, a consultation period longer than eight weeks might be required in order to take account of: the need for European or national organisations to consult their members in order to produce a consolidated viewpoint; certain existing binding instruments (this applies, in particular, to notification requirements under the WTO agreement); the specificity of a given proposal (e.g. because of the diversity of the interested parties or the complexity of the issue at stake); main holiday periods."

tory memorandum accompanying the Commission proposal.

Ideally, feedback should be given in various phases of the consultation process. It is good practice to publish a consultation report when an open public consultation is over. The report should include feedback on the main results of the consultation and give information about the next steps to be taken. If a consultation report is published, it should be annexed to the IA report. If not, it is recommended /best practice to annex to the report a summary note of the main outcomes of the consultation.

Internet is not the only way to give feedback. For example, it is possible to organise a public meeting for all stakeholders after a consultation deemed politically important.

5.2. Standards for consulting social partners

Specific provisions exist for consulting social partners. A distinction should be made between initiatives in the field of social policy and initiatives with social implications for a specific sector:

Social policy measures

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.

Initiatives with social implications for a specific sector

Commission Decision 98/500/EC stipulates that each sectoral social dialogue committee, for the sector of activity for which it is established, "shall be consulted on developments at Community level having social implications". You should therefore verify whether your initiatives will create social implications for a sector for which a sectoral social dialogue committee exists⁶. If this is the case a consultation of the committee has to be organised with the assistance of the Unit "Social Dialogue and Industrial Relations" in DG EMPL.

5.3. Specific guidance for consulting consumers/consumer organizations/patient groups

For proposals with an impact on consumers, a **Consumer consultation toolbox** can be used.⁷ The Consumer consultation toolbox includes:

- Consultation of the European Consumer Consultative Group (ECCG)⁸ which is composed of European and national consumer organisations
- Direct consultation of consumers through other tools such as Eurobarometers,⁹ Focus groups¹⁰, Citizens juries¹¹, public hearings, town meetings¹².

⁶ The list of committees can be found at:

http://ec.europa.eu/employment_social/social_dialogue/sectoral_en.htm#table

⁷ <http://www.cccec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=tools>

⁸ The European Consumer Consultative Group is a consultative group of the Commission, established by Commission Decision 2003/709/EC of 9 October 2003.

⁹ Standard and Special Eurobarometer: (example: EB on Consumer protection in the Internal Market). It is used by DG COMM for its general set of questions on EU-related issues. This instrument is well suited for in-depth cross analysis and for relatively long questionnaires. It uses face-to-face interviewing techniques, interviewing a sample of around 1000 respondents per Member State (depending of the population of the country). Flash Eurobarometer: (example - Businesses attitudes on Cross-border sales and consumer protection). It is well adapted to

Whenever health impacts are identified, it is advised to consult the Health Policy Forum to get input from public health actors including patients groups.¹³

5.4. Effective use of questionnaires

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.

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.

short and simple questionnaires, for which results are needed relatively rapidly. Flash surveys allow the targeting of specific groups (SME managers, farmers, teachers, etc.).

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

¹¹ Small panel of non-specialists. Similar to a criminal jury, carefully examine an issue of public significance and deliver a verdict. Good for developing creative and innovative solutions to difficult problems.

¹² The aim of these meetings is to directly involve "citizens" in the decision-making process. In these meetings a representative group of citizens is invited to comment and suggest policy options for a specific legislative initiative or a project. This tool is notably used in the US. Since 1997, America Speaks has organized Town Meetings in 31 US States. Meetings have addressed local, state and national decisions on a broad range of issues.

¹³ See at: http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm

- 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.

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.

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.

6. Problem definition

6.1. 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.

Examples: CO2 emissions and ETS/Sustainable Industrial Policy (SIP)

Burning fossil fuels leads to the release of CO₂ into the atmosphere. Although there is a cost in terms of climate change and its impacts, these costs are not reflected in market prices as they do not accrue directly to the producer but to society as a whole (private costs < social costs). Because market prices do not fully reflect costs, too much of the good is consumed. Public intervention should be aimed at ensuring that the costs of the externality are included in their market prices. In the case of CO₂ emissions, the ETS means that producers have to pay for allowances in order to emit CO₂. The cost of the externality becomes a cost directly borne by producers which will be passed on to the market and thus reduce consumption to a more optimal level. An alternative to market based internalisation mechanisms such as ETS are taxes that reflect the cost of the externality (often referred to as Pigouvian taxes).

The demand for electricity and heating is of course dependent on electrical appliances and the insulation of homes. Although the internalisation via the ETS should take care of the externality, people may decide which electrical appliance to buy based on the purchasing price in the shop and thus may not take into account the electricity costs of the appliance during its use phase. There are different reasons as to why that may be so. If the market failure is due to a lack of information, i.e. missing information about a device's electricity consumption, a possible intervention may be to provide it via a (voluntary or regulatory) labelling scheme. An example of such a scheme is the Energy Efficiency Label for kitchen and bathroom devices (white goods). But even if that is done, consumers may not make rational use of it and act in a short-sighted (myopic) manner by continuing to buy the cheaper product with higher electricity consumption needs (and thus ultimately the more expensive one). This type of market failure may require a more interventionist approach and it is why part of the SIP foresees the setting of product standards under the Eco-design Directive to ensure that products meet certain minimum standards in terms of their energy consumption.

Principal agent problems are defined by a misalignment of incentives between two parties and can be found in the rental market. Landlords are generally driven by the incentive to keep costs down and may not invest in more costly insulation materials such as better heat retention windows, while tenants, who have to pay the heating bill, do not normally have the incentive to make these investments either. A possible response as envisaged by the SIP would again involve setting product standards.

The above examples show that problems are often not because of a single failure but can also be due to a combination of failures which then necessitate different types of public intervention. In the absence of dealing with all the market failures, society's consumption decisions may lead to an overproduction and overconsumption of the goods that gives rise to the externality. Regarding the problem definition, it is important to clearly identify the failure(s) that may require public intervention.

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.

Lack of 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 actual or potential 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 may not be enough to allow you to conclude that weak competition is the cause of the problem – you may need further evidence, such as unusually high profits, or high price-cost margins, i.e. prices which are much higher than marginal cost, or signs of collusion between or abuses by firms.

Be aware that some markets may not be large 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 – may exhibit some features of natural monopolies (cf. the costs of power lines or the last mile of telephone cables), even if technological change, for example in mobile telecommunications, may help to maintain some competition. In these sectors regulation is mainly aimed at preventing abuses of significant market power by price regulation, ensuring third party 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.

Missing 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.

"Split" incentives

Another type of market failure is the "Principle-Agent" problem that occurs when two parties engaged in a contract have different goals and different levels of information (also known as split incentive problem). A common example is the landlord-tenant problem. This problem occurs when the landlord provides energy-using appliances (such as a refrigerator or lighting systems), but the tenant pays the electricity bill. In this situation, there is little incentive for the landlord to choose the most energy-efficient appliance.

Imperfect information

Reliable information is essential to the smooth working of markets as well as for the proper design of regulations and interventions by public authorities. Many decisions are however affected by imperfect information about key decision parameters such as quality, price, demand, costs or future developments. Asymmetric access to information or excessive costs of accessing information may give rise to a market failure (unless the information issue is caused by a regulatory failure). The use of instruments like the 'open method of co-ordination' or benchmarking/exchange of best practices represent possible options to approach issues of imperfect information (see section 7.2. and 7.3).

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.

6.2. 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 inter alia 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 such as barriers to entry and expansion

Public authorities may not be able to anticipate all the effects of their actions. Regulation may for example protect incumbent firms against competitive entry by firms offering products and services which are more innovative, cheaper and/or of better quality.¹⁴

Examples 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.

Examples: Past 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 favored refiners over non-refiners and

¹⁴ For further details see the additional guidance prepared by DG COMP and available on the Europa website at <http://ec.europa.eu/comm/competition/publications/advocacy>

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.

6.3. Discrepancy between the fundamental goals of the EU and the existing situation

Below is a non-exhaustive list of Treaty objectives which may help you to describe a problem and identify objectives and options to address.

- 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).
- Ensuring the protection of fundamental rights within the framework of EU policies (TEU, Article 6).
- 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).
- 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.
- 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.

7. Identifying Options – 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.

7.1. 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. It can also suggest, by a recommendation¹⁵ 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 Lawmaking¹⁶ 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 consumers.¹⁷

¹⁵ 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.

¹⁶ 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.

¹⁷ 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.

Example: The Self-Regulatory Charter of the European Advertising Standards Alliance (EASA). In June 2004, EASA publicly agreed the *EASA Advertising Self-Regulatory Charter* laying down the industry's commitment to putting in place ten key principles of effective self-regulation for advertising across the EU-25. The Charter Principles were further discussed during the EU Advertising Roundtable discussions organised by DG Health and Consumers and chaired by Robert Madelin during 2005-2006¹⁸. Key conditions for effective and accepted self-regulation were identified during the round-table, amongst them consumer awareness, consultation with stakeholders, transparency and a response to the new media challenge. Following this, EASA has now put into place a monitoring system that reports back on the state of play in the different EU Member States of national self-regulatory mechanisms against a number of best practice criteria.

7.2. 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, the area of Social Protection and Social inclusion and through Best procedure projects, notably on entrepreneurship.

7.3. 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).

7.4. Market-based instruments

Market-based instruments influence the behaviour of market players by providing (negative/positive) monetary incentives or by guaranteeing some basic rules of the game. Possible alternative types are:

- **Marketable offsets**

They allow producers to negotiate with each other and agents to ensure overall compliance, without this being necessarily enforced on all producers at the same level.

- **Marketable permits**

¹⁸ See the Commission's report of the EU Advertising Self-Regulation Round-table at: http://ec.europa.eu/dgs/health_consumer/self_regulation/index_en.htm

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 trading.¹⁹

- **Taxes or charges**

Taxes, charges and fees are potentially useful policy instrument to influence private behavior towards public objectives. As other market-based instruments, they provide flexibility and cost-effectiveness and can be used to ensure that users pay the social price of their consumption. At the EU level the ability to co-ordinate taxes is limited due to the need for a unanimous decision by the Council. When tax instruments are used to attain specific policy objectives, it must be ensured that they are in compliance with EC rules on state aid.

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

- **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.)**

7.5. Direct public sector financial interventions

Public sector financial interventions should be used when the use of other instruments is less effective in achieving policy objectives. 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 programmers. In general these payments are targeted on the provision of public goods and outcomes that would not normally be delivered by the market, or on transitional compensation for the negative effects of policy change. Such interventions can have re-distributive effects. The application of such instruments need to comply with EC rules in the State aid area.

Example: EU Structural Funds

7.6. Co-regulation and standards

Co-regulation is a mechanism in which a Community legislative act entrust the attainment of the objectives defined by the legislator to parties which are recognized in the field (such as economic operators, the social partners, non-governmental organizations, or associations – Inter Institutional Agreement on Better Lawmaking, art. 18). This approach implies setting a regulatory framework in which the deadlines and mechanisms for implementation, the methods of monitoring the application of the legislation and any sanctions are set out. The legislative authority 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 law and must be in the interests of the public.

¹⁹ COM(2001)581 of 23 October 2001.

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.

Another approach that can serve as an alternative to legislation, or can partially replace detailed regulation, is the use of European Standards. This requires the involvement of the European Standards Organisations²⁰. These organisations should also be consulted if a proposed policy option refers to European Standards, and might require changes in any of them.

Examples: (1) 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; (2) Agreements between the social partners as an alternative method of regulation in fields concerned with working conditions and access to work.

7.7. Framework directives

In its Action plan '**Simplifying and improving the regulatory environment**', 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 Lawmaking²¹ 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 Directive²² sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.

²⁰ These organisations are listed in DIRECTIVE 98/34/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations. Further information can be supplied by ENTR I/3. Standardisation.

²¹ 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.

²² 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.

7.8. 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:

1. 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 Directive²³.

2. Performance-oriented standards.

Performance-orientated standards specify the required performance of the target population. They do not detail the exact mechanisms 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)²⁴.

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.

²³ 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>.

²⁴ Directives 1998/609/EEC and 2001/80/EC (OJ L 309/1 of 27 November 2001).

8. Assessing specific aspects of economic, social and environmental impacts

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, consumers, households and public authorities.

To help in the identification of the economic impacts and the understanding of their characteristics, this annex **non-exhaustively** provides additional guidance that can be helpful when identifying potential impacts of an initiative in the fields indicated in the impact tables in chapter 8.2. of the main Guidelines.

When identifying economic impacts, particular attention should be paid to factors that are widely considered as being important to productivity²⁵, and hence to the competitiveness of the EU. 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.²⁶

8.1. Impacts on fundamental rights

This Annex contains an overview on the rights, freedoms and principles contained in the Charter of Fundamental Rights of the European Union:

Chapter I - Dignity

- Human dignity
- Right to life
- Right to the integrity of the person
- Prohibition of torture and inhuman or degrading treatment or punishment
- Prohibition of slavery and forced labour

Chapter II - Freedoms

- Right to liberty and security
- Respect for private and family life
- Protection of personal data
- Right to marry and right to found a family
- Freedom of thought, conscience and religion
- Freedom of expression and information
- Freedom of assembly and of association
- Freedom of the arts and sciences
- Right to education
- Freedom to choose an occupation and right to engage in work
- Freedom to conduct a business
- Right to property
- Right to asylum
- Protection in the event of removal, expulsion or extradition

Chapter III - Equality

- Equality before the law
- Non-discrimination
- Cultural, religious and linguistic diversity
- Equality between men and women

²⁵ I.e. investment, innovation, entrepreneurship, human capital and the competitive environment.

²⁶ See the Commission's Communication on pro-active competition policy of 20 April 2004, Section 2.1.

- The rights of the child
- The rights of the elderly
- Integration of persons with disabilities

Chapter IV - Solidarity

- Workers' right to information and consultation within the undertaking
- Right of collective bargaining and action
- Right of access to placement services
- Protection in the event of unjustified dismissal
- Fair and just working conditions
- Prohibition of child labour and protection of young people at work
- Family and professional life
- Social security and social assistance
- Health care
- Access to services of general economic interest
- Environmental protection
- Consumer Protection

Chapter V - Citizen's Rights

- Right to vote and to stand as a candidate at elections to the European Parliament
- Right to vote and to stand as a candidate at municipal elections
- Right to good administration
- Right of access to documents
- European Ombudsman
- Right to petition
- Freedom of movement and of residence
- Diplomatic and consular protection

Chapter VI - Justice

- Right to an effective remedy and to a fair trial
- Presumption of innocence and right of defence
- Principles of legality and proportionality of criminal offences and penalties
- Right not to be tried or punished twice in criminal proceedings for the same criminal offence

Chapter VII - General Provisions concerning the interpretation and application of the Charter

- Field of application
- Scope and interpretation of rights and principles
- Level of protection
- Prohibition of abuse of rights

The entire texts of the Charter as well as some explanations which intend to clarify its provisions are published in OJ C 303, 14.12.2007 and are accessible via <http://eur-lex.europa.eu/JOIndex.do?year=2007&serie=C&textfield2=303&Submit=Search&ihmlang=en>

8.2. Impacts on the number and the quality of jobs

When analysing the **impact on the number of jobs**, it is important to estimate the direct and indirect 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 indicators.²⁷

- 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;
- social dialogue and worker involvement;
- diversity and non-discrimination (on the grounds of gender, age, disability, religion and belief, race and ethnic origin, sexual orientation);
- 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 and by other groups' characteristics if available, such as disabled persons, or racial and ethnic groups,
- 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.

8.3. Impacts on consumers

In many cases proposals affecting the working of markets and the activities of firms give rise to indirect impacts on end-consumers and households. In others, consumers may be directly affected by proposals. In this context, consideration should be given to the question of whether the proposal is likely to affect:²⁸

- the prices for products and services consumers have to pay? If so, which ones are concerned and by how much will prices rise or fall?
- information about consumer products and services?
- the range/quality/safety of consumer products and services?

²⁷ 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.

²⁸In cases where a proposal is anticipated to have a significant impact on consumer welfare, or when the justification for policy intervention is based on harm suffered by consumers the following handbook can be consulted: http://ec.europa.eu/consumers/strategy/facts_studies_en.htm?update16jan

- the way in which consumer products or services can be accessed?
- data protection?
- (disposable) household income and wages?
- the level of consumer protection?
- pensions or asset holdings?
- possibilities for households to borrow/save money, for example through access to financial services?
- access to redress for consumers for recovery of loss caused by breach of the law?

8.4. Impacts on SME's (the “SME-test”)

You should take SME's into consideration in each of the analytical steps when carrying out an impact assessment. For particularly relevant steps more specific guidance is provided below:

(1) Consultation with SMEs representatives

The following suggestions on how to consult SME representatives complement the general guidelines on the consultation of interested parties.

The 2005 Report on the consultation of stakeholders in the shaping of small business policy at national/regional level provides examples of good practices:²⁹

- round table discussions with stakeholders,
- test Panels of entrepreneurs to check new initiatives in flexible and quick manner,
- specific committees,
- use of IT tools (on-line consultations, forum),

Other specific suggestions for consulting SME stakeholders with the support of DG ENTR:

- if stakeholders hearings are organised, ensure that SMEs representatives are invited (DG ENTR SME services could help in this sense),
- the regular meetings between the SME Envoy team in DG ENTR and SME organisations can be a useful and relatively quick way of getting feedback from this sector,
- the Enterprise Europe Network can be used to obtain direct feedback from SMEs from across the EU (DG ENTR unit E2 can be contacted for more information). The Network offers support and advice to businesses, especially SMEs, across Europe. It is made up of close to 500 partner organisations in more than 40 countries.
- the European Business Test Panel (EBTP), although not explicitly focused on SMEs is also an alternative to consider (managed by DG MARKT).³⁰

(2) Preliminary assessment of businesses likely to be affected

During this stage, you should establish whether SMEs are among the affected population. You should identify the characteristics of the businesses / sector(s) likely to be affected. Relevant sources of information should be explored including SME representatives. A non-exhaustive list of elements to consider includes, when applicable

- number of businesses and their size (micro, small, medium or large enterprises)
- proportion of the employment concerned in the different categories of enterprises affected

²⁹ http://ec.europa.eu/enterprise/entrepreneurship/support_measures/stakehold/index.htm

³⁰ http://ec.europa.eu/yourvoice/ebtp/faqs/index_en.htm

- weight of the different kind of SMEs in the sector(s) (micro, small and medium ones)
- links with other sectors and possible effect on subcontracting

If the preliminary assessment leads to the conclusion that SMEs are amongst the affected parties, further analysis should be carried out and – where appropriate – taken into account when defining the objectives and developing the policy options in the impact assessment.

(3) Measurement of the impact on SMEs

The distribution of the potential costs and of the benefits of the proposals with respect to the business size, differentiating between micro, small, medium and large enterprises should be analysed qualitatively and, if possible and proportionate, quantitatively.

It is important to establish to which extent the proposal affects SME's competitiveness or the business environment in which it will affect their operations.

It is likely that an EU measure would have direct and indirect beneficial effects on SMEs. The direct benefits such as improved working conditions, increased competition etc. should (at some stage) be reflected in reduced costs to SMEs. Yet, these benefits may be offset by various costs, some of which may be disproportionately felt by SMEs, notably:

- Financial costs – created by the obligation to pay fees or duties
- Substantive costs – created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards (e.g. the purchase of new equipment, training of staff, additional investments to be made)
- Administrative costs – created by the obligation to provide information on the activities or products of the company including one-off and recurring administrative costs (e.g. resources to acquire or provide information)

Cost and impacts identified for SMEs should be compared with those of large enterprises. For this purpose, one can for instance compare the overall costs identified to the number of persons employ to obtain the average cost per employee³¹. One could also compare the costs identified to the total overhead or turnover of the company³².

In addition, it would be useful to consider the following additional elements:

- possible loss of competitiveness due to external factors such as the availability of finance, tax regimes, access to resources or skills, etc.
- possible changes in the behaviour of competitors, suppliers or customers
- possible impacts on barriers to entry, competition in the market and market structure, for example in terms of possibilities for SMEs to enter markets.
- possible impact on innovation, understood as both technological and non-technological innovation (process, marketing, etc.)
- benefits, if applicable, coming from the proposal (burden reduction, improved productivity and competitiveness, greater investments or innovation etc.)

(4) Assess alternative options and mitigating measures

If the abovementioned cost/benefit analysis shows that SMEs are facing a relatively higher burden, one might consider the use of SME specific measures in order to ensure a level playing field and the respect of the proportionality principle. When the analysis made under the previous section shows that SMEs are disproportionately affected or disadvantaged compared to large companies, one should consider using possible mitigating measures.

³¹ One could use for instance the thresholds of the SME definition: 10, 50 and 250 employees.

³² Representative samples containing both SMEs and large companies can also be used.

The choice of specific measures to use will be made on a case by case basis. A non-exhaustive list of measures to be considered includes:

- **complete or partial size-related exemptions for SMEs or micro-businesses** (Example: businesses below certain thresholds do not have to comply with certain specific obligations when this does not invalidate the original purpose of the legislation)
- **temporary reduction or exemptions** (Example: transition periods during which SMEs are exempted or longer intervals for certain obligations)
- **tax reductions or direct financial aid** to compensate costs incurred provided this is compatible with existing legislation (on competition or international trade).
- **reduced fees** (Example: when these fees are particularly high and/or represent a fixed cost that would will be felt disproportionately by SMEs)
- **simplified reporting obligations for SMEs** (Example: in the area of statistics, explore possible synergies with already existing reporting obligations)
- **specific information campaigns or user guides, training and dedicated help-desks/offices** (Example: specific SME help-desks providing tailored information for small businesses)
- **systematically consider general simplification initiatives which can particularly benefit SMEs** (Example: possibility to use on-line facilities, simplified inspections)

When assessing possible mitigating measures for SMEs, it is important that the costs this could produce are also fully considered and included in the final assessment.

8.5. Impacts on technological development and innovation

Proposals may directly or indirectly lead to impacts on the technological development and innovative activities of firms as well as on the ways in which firms and institutions are organised.

A **two-step approach** is proposed to help identifying these effects:

1. Recognising innovation
2. Assessment of impacts

1. Recognising innovation

The first step in the assessment of innovation impacts is to ascertain whether and to which extent one of the possible forms of innovation is likely to take place as a direct or indirect consequence of the proposal. Conceptually, innovation can be incremental or radical: the first is a step forward along a technology trajectory with generally minor improvements made either on processes or on products; the latter involves launching an entirely novel product or service rather than providing improved products and services along the same lines as currently.

Innovations can take many forms. Innovation is not only technological, as it might relate to business areas such as organisation, finance, marketing etc. Also, innovation may involve tangibles (e.g. products) but also intangibles (e.g. services).³³ The following box provides an indicative list and practical definitions of the of the main categories of innovation:

³³ For a formal definition of innovation and for the measurement of scientific and technological activities, see the Oslo Manual (OECD/European Commission) at: <http://www.oecd.org/dataoecd/35/61/2367580.pdf>.

- ✓ **Business model innovation:** involves changing the way business is done in terms of capturing value.
- ✓ **Eco-innovation:** term used to describe products and processes that contribute to sustainable development. Eco-innovation is the commercial application of knowledge to elicit direct or indirect ecological improvements.
- ✓ **Marketing innovation:** is the development of new marketing methods with improvement in product design or packaging, product promotion or pricing.
- ✓ **Organizational innovation:** involves the creation or alteration of business structures, practices, and models, and may therefore include process, marketing and business model innovation.
- ✓ **Process innovation:** involves the implementation of a new or significantly improved production or delivery method.
- ✓ **Product innovation:** involves the introduction of a new good or service that is new or substantially improved. This might include improvements in functional characteristics, technical abilities, ease of use, or any other dimension.
- ✓ **Service innovation:** refers to service product innovation which might be, compared to goods product innovation or process innovation, relatively less involving technological advance but more interactive and information-intensive.
- ✓ **Supply chain innovation:** where innovations occur in the sourcing of input products from suppliers and the delivery of output products to customers

2. Assessment of impacts

All organisations can innovate, including for example hospitals, universities, and local governments. Impacts can materialise in the creation, diffusion and use/exploitation of knowledge and can be rated from [-] to [+++] if the expected impacts are respectively negative/none/low /medium/high. The checklist below provides a framework to scrutinise the direct impacts (differentiating short term - up to 3 years or medium/long term from other systemic impacts):

Innovation Check-list	Expected Impacts		
	Short term	Medium Long term	Indirect/Systemic
I. Creation of knowledge			
Increase in public R&D expenditures			
Share of enterprises receiving public funding for innovation			
Tackling existing blocks to research and development activities			
Provision of direct support to R&D activities (increase the level of business R&D)			
Upgrading of skills of staff or the recruitment of new staff with innovation capacities			
Provision of indirect support (organisational, information-related etc.) to R&D			
Easier links between universities and industry (including creation of spin-offs)			
Easier or cheaper access to financial resources (public funding, support private risk capital schemes etc.)			
Establishment of coordinated knowledge sharing and research networks			
II. Diffusion of Knowledge			
Exports of high technology products as a share of total exports			
Off-setting initial lack of competitiveness compared with existing products or processes (e.g. by facilitating or hampering the reorganization of production and other processes in firms)			
Increased belief in innovations (e.g. through demonstration projects)			
Contribution to the introduction/spread of new standards			
Support to Technology transfer schemes			
Avoiding "lock-in" effects of certain technologies by setting performance-based standards, and progressively treating new technologies like existing ones?			
Support to the creation of new companies (e.g. by removing any barriers to entry and expansion) and of start ups			
Contribution to the creation of innovation culture (e.g. through awareness raising events, information diffusion etc.)			
III. Use/exploitation of knowledge			
Diffusion and take up of new technologies by users			
Introduction/dissemination of:			
- new production methods			
- new technologies			
- new products/services			
Contribution to the introduction of eco-innovation (e.g. new ways of working and more efficient use of natural resources; lower clean-up costs which lower costs for companies)			
Contribution to the emergence of demand for innovation (e.g. introduction in the market of innovative goods and services or on consumer confidence in them)			
Employment in high tech services and manufacturing (% of total workforce)			
Support to creation of technological infrastructure and distribution channels			
Contribution to removing barriers to innovation (e.g. complex regulatory require-			

ments)			
Support to funding system for companies (e.g. VC, other financing facilities etc.)			
Support to development of niche/lead markets			
Effects on Intellectual Property rights:			
- patents			
- trademarks			
- copyright, other know-how rights			

Innovation indicators at EU level

The European Innovation scoreboard (EIS) has been published since 2000 on an annual basis. It is the instrument developed by the European Commission, under the Lisbon Strategy, to evaluate and compare the innovation performance of the Member States and selected third countries³⁴. The EIS 2007 was based on the 25 indicators³⁵ included in the table below.

INPUT – Innovation drivers		
1.1	S&E graduates per 1000 population aged 20-29	Eurostat
1.2	Population with tertiary education per 100 population aged 25-64	Eurostat, OECD
1.3 new	Broadband penetration rate (number of broadband lines per 100 population)	Eurostat, OECD
1.4	Participation in life-long learning per 100 population aged 25-64	Eurostat
1.5 new	Youth education attainment level (% of population aged 20-24 having completed at least upper secondary education)	Eurostat
INPUT – Knowledge creation		
2.1	Public R&D expenditures (% of GDP)	Eurostat, OECD
2.2	Business R&D expenditures (% of GDP)	Eurostat, OECD
2.3 new	Share of medium-high-tech and high-tech R&D (% of manufacturing R&D expenditures)	Eurostat, OECD
2.4 new	Share of enterprises receiving public funding for innovation	Eurostat (CIS4)
INPUT - Innovation & entrepreneurship		
3.1	SMEs innovating in-house (% of SMEs)	Eurostat(CIS4)
3.2	Innovative SMEs co-operating with others (% of SMEs)	Eurostat (CIS4)
3.3	Innovation expenditures (% of turnover)	Eurostat(CIS4)
3.4	Early-stage venture capital (% of GDP)	Eurostat
3.5	ICT expenditures (% of GDP)	Eurostat, World Bank
3.6	SMEs using organisational innovation(% of SMEs)	Eurostat(CIS4)
OUTPUT – Application		
4.1	Employment in high-tech services (% of total workforce)	Eurostat
4.2 new	Exports of high technology products as a share of total exports	Eurostat
4.3	Sales of new-to-market products (% of turnover)	Eurostat (CIS4)
4.4	Sales of new-to-firm products (% of turnover)	Eurostat (CIS4)
4.5	Employment in medium-high and high-tech manufacturing (% of total workforce)	Eurostat OECD
OUTPUT - Intellectual property		
5.1	EPO patents per million population	Eurostat OECD
5.2	USPTO patents per million population	Eurostat OECD
5.3 new	Triadic patent families per million population	Eurostat, OECD
5.4 new	New community trademarks per million population	Eurostat OECD
5.5 new	New community designs per million population	Eurostat, OECD

Other indicators on innovation activities of firms are provided by the Community Innovation Survey (CIS), covering EU Member States, EU Candidate Countries, Iceland and Norway. The data is collected on a four-yearly basis. The CIS is designed to obtain information on innovation activities within enterprises, as well as various aspects of the process such as the effects of innovation, sources of information used, costs etc. The Eurostat Statistical books 2008 edition “Science technology and innovation in Europe” puts special emphasis on the

³⁴ The EIS 2007 include innovation indicators and trend analyses for all 25 EU Member States, as well as for Bulgaria, Romania, Turkey, Iceland, Norway, Switzerland, the US Japan, Australia, Canada and Israel

³⁵ These indicators are combined into a composite indicator, the *Summary Innovation Index* (SII), which provides an overview of the relative national innovation performances www.eis.eu

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

Proposals may intentionally or unintentionally have impacts on the production and business 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 cost 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?
- 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?

8.7. 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?
- What will be the impact on WTO obligations of the Community?
- 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?

8.8. Impacts on developing countries

EU policies can affect developing countries in a number of areas. From the economic point of view, impacts on different sectors (agriculture, extractive industries, manufacturing, and services) should be distinguished where relevant. Relevant economic variables include: GDP growth, GDP per capita, current account balances, business climate, macroeconomic stability, terms of trade, export revenue, tax revenue, and inflation rates. In the social and environmental areas, the MDG indicators (health, education, food security, environment...) should be used.³⁶

EU policies can also have unintended economic, social and environmental impacts. Often, the fact that an EU policy is changed may present a challenge for a developing country when it needs to align its policy to comply with new standards. Many developing countries have weak administrations and find it difficult to adapt to changing regulations.

8.9. 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.

8.10. 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, and particularly as employers, some of the questions raised in sections 7.1 to 7.7 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.

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

9. Assessing non-market impacts in particular on environment and health

The overall list of impacts produced in Step 1 (as explained in section 8.3 of the Guidelines) may include certain non-market impacts, such as health or environmental impacts. It will then often be possible to proceed with quantification and monetisation of the impacts. As placing (quantitative and monetary) figures on these types of impacts can be difficult, it is important to use sound analysis and to set out clearly the process and methodologies that are employed.

It may be the case that it is not feasible to measure all the costs and benefits in monetary terms while it is still possible to quantify the impacts of different options. In those cases non-monetary approaches can be used to allow policy makers to make an informed choice among different alternatives.

9.1. Monetisation of non-market impacts

Monetisation of non-market impacts is easiest when the values can be linked to market prices.³⁷ For example, air pollution damage to crops might reduce crop yields, thus allowing for relatively straight forward monetisation. However, where values of impacts are not directly revealed in market prices other techniques may have to be used.

There are ways of calculating monetary costs and benefits of goods that do not have a direct market price. They either reflect the 'willingness to pay' for or the 'willingness to accept' a particular outcome and consist of **stated preference** (contingent valuation, conjoint analysis, choice experiments) and **revealed preferences** methods (travel cost method, hedonic pricing).

Revealed preference methods are based on evidence from real market transactions such as correlations between noise disturbance and house prices. As such, they are based on real actions by people that are incurring real actual costs.

Stated preference methods, on the other hand, involve the construction of hypothetical markets and asking people via questionnaires and interviews how they value a given outcome. These techniques have been used in a wide range of circumstances, and well-designed surveys are shown to provide robust estimates that are broadly similar to those from revealed preference methods. Notable uses include finding estimates for reductions in risk of premature deaths or non-fatal injuries, or to determine values for environmental outcomes, the use of public parks or historic buildings.

9.2. Quantitative analysis of health impacts

Legislation can have an impact on health, either directly if changing health outcomes is a stated objective or indirectly as a result of tackling another, related issue. Health impacts are most commonly encountered in environmental protection, health care, product safety, safety at work, consumer protection etc. While there is no uniform methodology for their analysis, it is important to ensure that Commission IAs are backed by sound analysis and that they are consistent. This does not mean reliance on a single methodology but rather that similar cases are handled in a consistent manner. Bearing in mind proportionate analysis, it is desirable to use quantitative approaches where possible to allow for a more transparent comparison of costs and benefits. Risks can often not be entirely eliminated without incurring prohibitive costs. In those instances cost benefit analysis can assist in deciding whether it is, for ex-

³⁷ "EXIOPOL, FP6 Integrated Project, provides information on a new environmental accounting framework using externality data and input/output tools for policy analysis"; <http://www.feem-project.net/exiopoli/index.php>.

ample, more efficient to spend money on reducing air pollution in order to improve health than on improvements in health care.

Several methods exist for quantitatively evaluating proposals with potential health impacts. A distinction can be made between monetary and non-monetary methods. Non-monetary approaches are potentially less controversial and may be more suitable in a cost effectiveness analysis, whereas monetary approaches are needed if the aim is to present a comprehensive cost benefit analysis. Non-monetary approaches can sometimes be monetised by placing monetary values on their results. The following paragraphs outline the most common non-monetary approaches first, which is then followed by a brief introduction into the most standard monetary approaches.

Non-monetary approaches

(1) Quality Adjusted Life Years (QALY)

The QALY method uses available information on objective improvements in health / life quality and combines it with the duration of that improvement. A year of life in perfect health is counted as 1.0 whereas years spent in less than perfect health are given values of less than 1.0. Values are generally derived from surveys of patients and doctors (stated preferences) and represent an average among different social groups. QALYs allow aggregation over the number of individuals affected. One can use equal weights for each individual or adjust weights to reflect preferences for particular target groups. Future life years may be discounted using a common discount factor.

(2) Disability Adjusted Life Years (DALY)

A DALY is very similar to a QALY, effectively being its negative value. It measures the number of quality adjusted years lost in comparison to the benchmark scenario. In all other respects it is not conceptually different from QALY and should lead to the same assessment.

(3) Healthy Life Years (HLY)

The HLY approach measures the number of quality adjusted remaining life years per person. It is similar to QALY and also here life years in the future should be discounted and weights can be used when aggregating across individuals. HLY is technically a sum of QALYs, using the remaining life expectancy as the upper bound for summation. It is included in the set of indicators used in the Lisbon strategy. However, when done correctly, QALY and HLY should lead to the same conclusions.

Previous studies in the health sector have used values of 50.000 – 80.000 Euros for a QALY. This range can be used as an indication for the purpose of an impact assessment but should be adjusted for a concrete policy proposal to reflect the specific context.

Monetary approaches

Many decisions lead to a reduction in risk but not to its complete elimination. The aim of monetising health impacts is not to place a monetary figure on someone's life, but to compare the benefits of a reduction in risk against the costs. Any decision in this context means placing an implicit monetary value on health benefits. Decision-making will be easier and may be more consistent and transparent if we have a monetary estimate of the value of health benefits.

The following monetary approaches are standard methods for this purpose:

(1) "Accounting style" approaches

(1.1) Cost of Illness (COI)

The Cost of Illness method is a rather simple measure comprising only the medical expenses related to the incidence of an illness. If an option lowers the rate of occurrence of an illness the saved medical expenses can be estimated and constitute a benefit. Conversely, if an option leads to an aggravation of a health situation, one can state the associated direct costs. However, the usefulness of this method is limited as it does not include other indirect costs to society such as loss of hours worked, or how people value their own health. Also, in some situations it leads to perverse results: for example, an action that kills somebody who otherwise would have spent time in hospital would be seen as a benefit using the COI approach.

(1.2) Human Capital

The human capital method tries to measure the loss of future earnings in case of disability or premature death. It can also be interpreted as a measure of the loss to social welfare caused by death / disability / lower productivity. Potential criticism can be that this method leads to different values of lives depending on the projected future earnings, which could be seen as immoral, and places no value on people who are outside the workforce (such as the elderly). Average values could be used to lessen these concerns or if the individuals affected by an option cannot be identified precisely enough.

(2) Preference Based approaches

Another method to evaluate health impacts is to analyse individuals' stated or revealed preferences (see above) with respect to being exposed to a particular situation that involves a health risk. This can be measured by using the concepts of Willingness To Pay (WTP) for an improvement or Willingness To Accept (WTA) compensation for a worsening. Two concepts that make use of these methodologies are the Value of a Statistical Life (VOSL) and the Value of a Statistical Life Year (VOLY).

(2.1) Value of Statistical Life (VOSL)

The VOSL is derived by investigating individuals' WTP for a lower risk of mortality, divided by that risk reduction. As such, the VOSL method does not measure the value of a life per se, instead it puts a monetary value on the willingness to accept slightly higher or lower levels of risk. Of course, if taken to the extreme, everyone's life is priceless and cannot be monetised.

(2.2) Value of Statistical Life Year (VOLY)

The VOLY measures more generally the WTP for an increase of one additional year of life expectancy. It should be noted that neither VOSL nor VOLY provides a measure of the quality of life. To do that one would have to combine them with the measures outlined above.

The use of the above mentioned valuation concepts can lead to moral criticism. The idea of 'putting a value on someone's life' is seen as unethical. Indeed, 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.

Examples: Suppose that a particular safety feature of a car (such as an airbag) reduces the risk of fatal injury in case of an otherwise fatal accident by 50% and that the likelihood of having such an accident is 0.1 % for the average driver (meaning that statistically one out of 1,000 drivers will have such an accident). If the price for an airbag is 500 Euros and 70% of the cars are equipped *voluntarily* with an airbag, this means that 70% of the drivers are willing to pay 500 Euros for a 0.05% reduction of the likelihood of having a fatal accident. This in turn means that the value the drivers of these cars attach to a life is at

least $2,000 * 500 = 1$ million Euros on average.³⁸ This illustrative example also shows that the valuation of risk differs between individuals. While 30% of the drivers (those not fitting the car with an airbag) implicitly attach a lower value (given their budget constraint), some of the drivers buying the additional safety feature may attach a substantially higher value to their life but still only have to pay 500 Euros for the airbag.

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.

Commission Use

Choosing the right methodology for assessing health impacts depends on individual circumstances such as the case itself or the level of analysis that is required (see proportionate analysis criterion). The Commission has used different methodological approaches in the past and it is important to check one's choice of methodology against how similar problems have already been dealt with. DG ENV, TREN, SANCO, ENTR and EMPL have made use of some of the methodologies introduced in this section, as have many member states and our international partners.

A practical example – Improvements in Air Quality

In the context of the Air Thematic Strategy, research was undertaken to evaluate the health impacts of improvements in air quality. These were the values in the Table below (based on surveys in France, UK and Italy undertaken as part of the New Ext project (2004). Reflecting the uncertainty in the methodologies and analysis, sensitivities were captured by using both median and mean figures and by using VOSL and VOLY figures.

Table: Values of statistical life and life years (median and mean) (Source, New Ext, 2004)

	Value of statistical life (VSL) (€)	Value of life years (VOLY) (€)
Median	980,000	52,000
Mean	2,000,000	120,000

The use of ranges shows transparently the uncertainty involved in terms of placing a value on changes in health status of the population. The adopted approach also shows the general level of impacts without spurious accuracy unjustified by the methodologies. The health benefit of different options was estimated in both quantified and monetary form.

Within the Air Thematic Strategy, morbidity was also valued. Three components were assessed for different health end-points and according to three different elements:

- (1) Resource costs i.e. medical costs paid by the health service in a given country or covered by insurance, and any other personal out-of-pocket expenses made by the individual (or family).
- (2) Opportunity costs i.e. the cost in terms of lost productivity (work time loss (or performing at less than full capacity)) and the opportunity cost of leisure (leisure time loss) including

³⁸ Since $1/2000 = 0.05\%$.

non-paid work.

- (3) Dis-utility i.e. other social and economic costs including any restrictions on or reduced enjoyment of desired leisure activities, discomfort or inconvenience (pain or suffering), anxiety about the future, and concern and inconvenience to family members and others. Note that due to lack of data, this element was rarely included.

Suggested ranges of values

Where policy specific estimates of the health impacts can be obtained, such as through external studies, they should be used in the Impact Assessment. However, where no such research has been undertaken, prior estimates from other policy areas should be used as approximations. Research undertaken in the past has resulted in values of 1 – 2 million Euros for VOSL and 50.000 – 100.000 Euros for VOLY in Europe. These ranges should be used for the purpose of an Impact Assessment if no more context specific estimates are available.

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

Databases of valuation studies have been developed to make the technique of benefits transfer easier. You can find an evaluation of the possibility of adapting one such database for use in the EU on the Europa website.³⁹ 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. It is suggested that you consult your impact assessment support unit for further guidance.

In all monetary approaches, both the quantitative and monetary estimates should be mentioned. For example the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

The cost of carbon emissions

As set out in the Guidelines, it is important to identify environmental impacts where relevant, and then to place a monetary value on them. An example of an area where this can be done is for the release of a unit of carbon dioxide (or other greenhouse gases).

- Step 1 – quantifying emissions: The first step is always to estimate whether the measure will lead to additional emissions of carbon dioxide or other greenhouse gases.
- Step 2 – equivalent emissions: Some greenhouse gases are much more damaging than others in terms of the damage for a specific quantity. When comparing options, or adding together different greenhouse gases, then it is helpful to express them in a single unit such by adjusting them according to their global warming potential so as to ensure comparability and/or equivalence.
- Step 3 – valuing emissions: Ideally greenhouse gas emissions should be valued using the social cost of carbon (SCC). This is the global cost today of an incremental unit of carbon dioxide emitted now, summing the full global cost of the damage it imposes over all of its time in the atmosphere. It represents what society should, in theory, be willing to pay now to avoid the future damage caused by additional carbon emissions.

³⁹ <http://ec.europa.eu/environment/enveco/others/index.htm#valuation> under "Assessment of Environmental Valuation Reference Inventory (EVRI) and the Expansion of Its Coverage to the EU"

The effect of putting a cost of greenhouse gases is to increase the value of options with low carbon impacts relative to those with larger carbon impacts.

The question of what value to use for valuing emissions should be discussed with experts in your Impact Assessment Unit. Given uncertainty over the issue, it is likely that a range of values might be best used.

9.3. Life cycle assessment approach

One of the tools commonly used in assessing environmental impacts is **Life-cycle Assessment (LCA)**.⁴⁰ 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 another.⁴¹

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.

⁴⁰ 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.

⁴¹ See EEA website for further details http://glossary.eea.eu.int/EEAGlossary/L/life_cycle_assessment.

10. Assessing administrative costs imposed by EU legislation

Whenever a measure is likely to impose **significant administrative costs** on business, the voluntary sector or public authorities, the **EU Standard Cost Model** presented below must be applied.⁴² The main aim of the model is to assess the **net cost of information obligations** imposed by EU legislation (net costs = costs introduced by a proposal if adopted, minus the costs it would eliminate at EU and/or national level). Services are also invited to apply the model on a tentative basis for assessing costs imposed on citizens. The possibility and need for monetisation in this case is left to their discretion.

In principle it is sufficient to measure the administrative burden only for the preferred option. However, if information obligations are at the core of the proposal (e.g. changing labeling or reporting requirements) then the administrative burden should be assessed for all policy options considered.

Implementation will of course be subject to the principle of proportionate analysis (see Scope of application of the model and expected level of accuracy). The degree of detail in the assessment will depend on the expected order of magnitude of the costs, their impact, and the availability of reliable and representative data (see Step 7 - Choice of data sources and, where necessary, development of data capture tools).

10.1. Outline of the model

Definition of administrative costs and administrative burden

Administrative costs are defined as the **costs incurred** by enterprises, the voluntary sector, public authorities and citizens **in meeting legal obligations to provide information** on their action or production, either to public authorities or to private parties. **Information is to be construed in a broad sense**, i.e. including labeling, reporting, registration, monitoring and assessment needed to provide the information (see Box 1: Types of information obligation). In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supply on request.

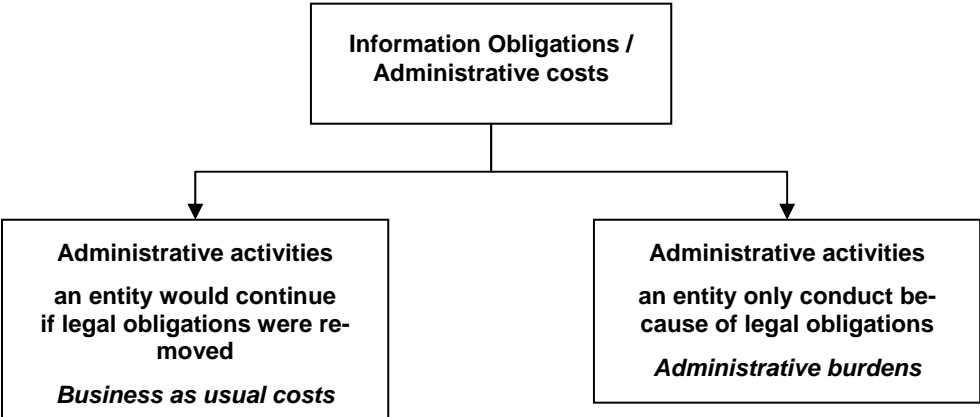
Example: A regulation on air quality sets an obligation to keep a register of pollutant emissions and an obligation to meet an air pollution threshold. Keeping a register of pollutant emissions is an administrative cost, while action taken to meet an air pollution threshold is not. That type of compliance cost is sometime referred to as 'substantive cost' because the obligation affects the essence of the (industry) activity. Keeping a register does not entail in itself any obligation to change the production process, the nature of the end-products or the treatment of emissions. Meeting the pollution threshold will require a substantive change at these levels (for instance the installation of new filters).

Recurring administrative costs and, where significant, **one-off administrative costs** have to be taken into account.

The administrative costs consist of two different cost components: the **business-as-usual costs** and **administrative burdens**. While the business-as-usual costs correspond to the costs resulting from collecting and processing information which would be done by an entity even in the absence of the legislation, **the administrative burdens stem from the part of**

⁴² see COM(2005)518 and the annexed Commission Staff Working Document SEC(2005)1329. For information about the application of the SCM by the Member States, see SCM network (<http://www.administrative-burdens.com/>).

the process which is done solely because of a legal obligation.⁴³



This distinction is particularly important for policy-making. New legal obligations codifying (business) good practices are by definition less burdensome for targeted entities than those requiring tasks never performed before. Conversely, the suppression of a ‘pure’ obligation will provide greater cost relief than the suppression of an obligation that is to a large extent part of business as usual activities.

Although determining what an entity would ‘normally’ do may be open to different interpretation reduction efforts focus on the way to minimize or reduce “real” administrative burdens.

Core equation of the cost model

Administrative costs should be assessed on the basis of the **average cost of the required administrative activity** (Price) multiplied by the **total number of activities performed per year** (Quantity). The average cost per action will be generally estimated by multiplying a tariff (based on average labour cost per hour including prorated overheads) and the time required per action. Where appropriate, other types of costs such as outsourcing, equipment or supplies’ costs will be taken into account.⁴⁴ The quantity will be calculated as the frequency of required actions multiplied by the number of entities concerned. In case of multiple relevant administrative activities per information obligation these need to be summed up to calculate the administrative cost per information obligation. The core equation of the SCM is as follows:

$$\Sigma P \times Q$$

where **P** (for Price) = Tariff x Time and

Q (for Quantity) = Number of businesses x Frequency)

Scope of application of the model and expected level of accuracy

The effort of assessment should remain proportionate to the scale of the administrative costs imposed by the legislation and must be determined according to the principle of proportionate analysis (see chapter 3 of the main text). There is therefore no need to cost obligations requiring for instance **little equipment, if the amount of time per action is small and the frequency low as these are bound to be insignificant**. Such decisions (i.e. no costing) will be taken on a case-by-case basis and should be documented. In order to keep

⁴³ Most businesses would for instance have an accounting system, even in the absence of legal bookkeeping, but would not necessarily provide caloric value information for all their products

⁴⁴ Many small businesses for instance use external accountants to fulfil certain information obligations set by Company Law. Chambers of commerce and sectoral professional associations also provide form filling services.

assessment of costs at a reasonable level and ensure compatibility with national methodologies, **estimates will be based on working assumptions** simplifying the complex reality of the Union. These assumptions are presented together with **step specific guidelines below**.

10.2. Step by step guide

The assessment of positive or negative effects on administrative burden on businesses, citizens or public administrations resulting from EU legislation should begin with a **full mapping of the introduction of new or suppression of existing information obligations** for each of the options under review. This mapping should show clearly how policy options differ in terms of information obligations. In a tabular form, such comparative mapping will usually indicate the type of information obligation, the data requirements, the target group and the obligation's frequency.

That table should also indicate which obligations are likely to impose **significant administrative burdens**. The significance (high – medium – low) is usually determined by a qualitative assessment of the likely number of entities concerned as well as the frequency and complexity of the required data.

Significant burdens will then be roughly quantified (monetary estimates) on the basis of the EU 'Standard Cost Model' (see core equation above). This will often be done with the help of the '**Administrative Burdens Calculator**' and the '**EU database on Administrative Burdens**'⁴⁵.

A greater level of detail is expected for the monetary assessment of administrative burdens stemming from the preferred option. This detailed application can be divided in a number of steps. The entire workflow is summarized in Table 1 below, followed by a description of each step.⁴⁶ Following these steps will also allow you also to fill in the Standard Reporting Sheet (see step 11).

Table 1: Step by step application of the model

Phase I: Preparatory analysis	
Step 1:	Identification and classification of information obligations (e.g. certification of products) & data requirements (e.g. the certificate must provide the date of production and composition of the product)
Step 2:	Identification of required actions (e.g. training members and employees about the information obligations, filling forms)
Step 3:	Classification by regulatory origin (e.g. EU rule on certification is the transposition of an agreement of the World Trade Organisation)
Step 4	Identification of target group(s), also called segmentation (e.g. large enterprises that have to fulfil obligation 'A' and small enterprises that have to fulfil obligation 'B', the size of the enterprise being defined by its turnover)
Step 5	Identification of the frequency of required actions (e.g. small enterprises have to fill a form once a year)

⁴⁵ See http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm

⁴⁶ Assessment is an iterative process, where earlier steps may need to be revisited in the light of work undertaken later in the process. This is of course also true here.

Step 6	Identification of relevant cost parameters (e.g. particular relevance of external costs – using accounting firms - and equipment) Qualitative assessment of significant burdens (i.e. applying de minimis threshold test to determine which information obligations need to be quantified)
Step 7	Choice of data sources and, if necessary, development of data capture tool(s) (e.g. deciding that the number of entities concerned will be extrapolated on the basis of data available on Eurostat, but that the number of hours each need to perform required actions will be based on the results of interviews of enterprises; for the later task, preparation of an interview guide and selection of a representative sample of entities)
Phase II: Data capture and standardisation	
Step 8	Assessment of the number of entities concerned (e.g. 100.000 SMEs)
Step 9	Assessment of the performance of a “normally efficient entity” in each target group, taking into account cost parameters identified in step 6 (e.g. enterprises have once a year to spend, on average, 25 hours of work by an engineer to gather information and 5 hours of work by a clerk to fill the annual form)
Phase III: Calculation and reporting	
Step 10	Extrapolation of validated data to EU level
Step 11	Final reporting and transfer to the database

Step 1	Identification and classification of information obligations
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In order to facilitate the assessment of administrative costs by analogy and to improve data analysis (identification and comparison of the most burdensome types of obligation across various sectors, ...), , services are asked to use the following typology on the nature of the administrative information obligation (box 1) when inserting relevant information obligations in the Standard Excel Report Sheet (an example is provided at the end of step 11).

Box 1: Types of obligation

- 1. Notification of (specific) activities or events** (e.g. for transportation of dangerous cargoes; when an accident affects the environment)
- 2. Submission of (recurring) reports** (e.g. annual accounts)
- 3. Information labeling for third parties** (e.g. energy labeling of domestic appliances; price labelling))
- 4. Non labeling information for third parties** (e.g. financial prospectus; disclosure obligation of employers towards employees)
- 5. Application for individual authorization or exemption** i.e. obligation to fulfill each time a particular task has to be carried out; (e.g. building permits; road transporters applying to be exempted from Sunday driving ban))
- 6. Application for general authorization or exemption** (e.g. license granting permission to engage in an activity such as banking or liquor selling)
- 7. Registration** (e.g. entry in a business register or a professional list)
- 8. Certification of products or processes, i.e.** obligation to deliver a certificate (e.g. treatment facilities having to issue a certificate of destruction of a vehicle) or to get a certificate (e.g. aeronautical products and organisations involved in their design, pro-

duction and maintenance must get the certification of the European Aviation Safety Agency - EASA)

9. **Inspection on behalf of public authorities** (e.g. businesses having to monitor conditions for employees)
10. **Cooperation with audits & inspection by public authorities** or those appointed by them (e.g. obligation for business to cooperate with working conditions inspection), **including maintenance of appropriate records** (e.g. obligation for treatment facilities to keep records of the particulars of waste electronic equipment entering and leaving the treatment facility; obligation for hotels to keep a visitor register book; these records must be presented during the inspection).
11. **Application for subsidy or grant** (e.g. to structural or cohesion funds).
12. **Other**

Distinguishing an obligation to provide information from other regulatory obligations is normally straight forward. There could however be a number of **borderline cases** where it is difficult to decide whether a rule falls within the scope of the model or not. It is important to ensure that such borderline cases are discussed and evaluated in the light of decisions taken in other similar areas so as to ensure consistency.

Box 2: Examples of borderline information obligations

Costs induced by exercising a right to complain. These costs are not considered as an administrative cost by Member States quantifying administrative costs using the Standard Cost Model because there is no 'obligation' to complain.

Costs induced by inspection. The usual purpose of an inspection is to collect the information needed to verify compliance with legal obligations (review of corporate books, etc.). Ensuing costs are clearly administrative costs. However inspections are sometimes used to collect information unrelated to legal obligations (level of satisfaction of businesses, etc.). Submitting to such inspection is by definition voluntary and ensuing costs therefore fall outside the definition of administrative costs imposed by legislation.

Costs induced by policy assessment. Some EU programmes require Member States to draw up national reform programmes. Designing a reform programme is of course quite different from an obligation to provide information. However designing monitoring schemes, collecting data on the implementation of the policy, filling tables and submitting them to the Commission are clearly linked to information obligations. So policy design should not be considered as administrative cost, with the sole exception of policy assessment design.

Costs induced by the obligation of drawing safety plans. Some EU acts require businesses to design staged evacuation strategies, conduct exercises to verify that everyone knows what to do and when, etc (cf. plans for so-called Seveso establishments, airports,...). This is of course quite different from an obligation to provide information; resulting costs should therefore not be considered as administrative burden. The only eligible costs here basically are those linked to the obligation to collect information about impending risks (safety plans must often be based on a risk assessment) and the obligation to file and/or send the safety plan.

Testing costs. When business have to submit their products & processes to the test in order to get an authorisation or a certificate, these testing costs are not considered as administrative costs.

Some EU legislative acts and proposals also mention the *possibility* for Member States to ask for additional information (i.e. "...Member States may ... require the inclusion of other statements in the annual accounts in addition to the documents referred to in the first subparagraph ..."). Such possibilities are not to be understood as EU IOs, insofar as Member

States are not obliged to ask that information. Nevertheless such possibilities will be documented as they often pave the way for Member States additions (goldplating).

Step 2	Identification of required action
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The services are asked to use the following typology on the type of required action (inserted in the excel report sheet).

Box 3: Types of required action

- | |
|---|
| <ol style="list-style-type: none"> 1. Familiarising with the information obligation 2. Training members and employees about the information obligations 3. Retrieving relevant information from existing data 4. Adjusting existing data 5. Producing new data 6. Designing information material (e.g. leaflet conception) 7. Filling forms and tables (including recordkeeping) 8. Holding meetings (internal/external with an auditor, lawyer and the like) 9. Inspecting and checking (including assistance to inspection by public authorities) 10. Copying (reproducing reports, producing labels or leaflets) 11. Submitting the information to the relevant authority (e.g. sending it to the relevant authority) 12. Filing the information 13. Buying (IT) equipment & supplies (e.g. labelling machines) to specifically used to fulfil information obligations 14. Other |
|---|

Step 3	Classification by regulatory origin
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In order to enhance transparency on who is responsible for what, the **regulatory origin of information obligations** needs to be identified. Three simple rules should be used for that:

1. if the obligation arises entirely from an authority that specifically states the way in which the obligation must be met, *attribute 100% of costs induced by the obligation to that authority.*
2. if the obligation set by an authority requires transposition by another authority and if the transposing authority limits itself to what is needed to meet the obligation, *attribute 100% of the costs to the authority which set the obligation.*
3. if the obligation set by an authority requires transposition by another authority and if the transposing authority goes beyond what is needed to meet the obligation, *attribute the %*

resulting from 'gold plating' to the transposing authority.

Gold plating in the case of administrative obligations refers, among other things, to increasing the reporting frequency, to add "data requirements" or to widen the target groups.

In the context of the Impact Assessment, services are only requested to determine costs originating from the international and EU levels, not those that may originate at national or lower levels. The reporting sheet (see step 11 - Report) has been conceived to be used by EU institutions and Member State authorities, for (ex ante) assessment of proposed measures and (ex post) evaluation of existing legislation. If a national government decides to evaluate the administrative costs put on a sector in its country, it needs to account for purely national and regional obligations in addition to obligations of international and EU origins. By contrast, when the Commission assesses a possible measure, there is no point guessing what level of gold plating transposing authorities in each Member State might introduce. The Commission only has to account for proposals transposing international obligations in the EU and those resulting from its own initiative. There is by definition no obligation of national or regional origin applying to the entire Union.

Example: The World Health Organisation has adopted a framework convention on tobacco control. The Community and the Member States, as signatories to the Convention, are bound by these international rules. Article 11 provides that information on emissions of tobacco products must appear on each package of tobacco products. It also provides that labels may include warnings in the form of pictures. Supposing that the Commission envisages a measure obliging manufacturers to provide information on tobacco emissions as well as to print cancer pictures on each package, 100% of the costs induced by the first obligation will be attributed to the 'international' level, while 100% of the costs induced by the second obligation will be attributed to the 'EU' level. By imposing the inclusion of pictures, the EU would indeed go beyond what is needed to meet WHO obligations.

Attention should be paid to the **references of the act at the origin of the obligation**. In order to ensure optimal addition and comparison of data, all parties using the EU common methodology (Commission, European Parliament, Council) or contributing data (Member States at different levels of authority) have been asked to use the EU-Lex format for existing EU legislation. The enumeration order varies with the type of act⁴⁷ and it is therefore easier to make a 'cut and paste' of the reference given by the search engine (http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en) than list referencing rules.

- For **Commission proposals**, EU-Lex will normally use the following format: "Proposal for a Directive of the European Parliament and of the Council on the exercise of voting rights by shareholders of companies having their registered office in a Member State and whose shares are admitted to trading on a regulated market and amending Directive 2004/109/EC, COM/2005/0685 final."
- For an **EU act transposing an international act**, services will also provide the name and reference of that international act, as well as information on the transposition. They will fill the simple concordance table included in the report sheet. The table is made of two columns: the first column gives the reference of the article detailing the obligation assessed; the second column gives the reference of the 'original' obligation, i.e. the article of the act laying down the obligation transposed by the act being assessed.

⁴⁷ "Regulation (EC) No 2560/2001 of the European Parliament and of the Council of 19 December 2001 on cross-border payments in euro, Official Journal L 344 , 28/12/2001 P. 0013 – 0016"; but "Council Regulation (EC) No 2580/2001 of 27 December 2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, Official Journal L 344 , 28/12/2001 P. 0070 – 0075".

Step 4	Identification of target groups
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As for the target groups, it may be useful to distinguish between groups on the basis of their size, type or location. Size may be particularly pertinent for enterprises. It is indeed often the case that an obligation is more burdensome for small enterprises than for large ones benefiting from economies of scale. Regulation often adjusts the type of information obligations according to a number of objective criteria (number of employees, turnover level, financial capacity of the citizens, etc.).

Step 5	Identification of the frequency of required actions
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The frequency indicates how many times per year an action is required.⁴⁸ If, for instance, an information has to be submitted once a year, the frequency = 1; if it is every 6 months, the frequency = 2; if it is every three years, the frequency = 0,33; etc.

In some cases, the frequency may vary in time. For instance, in a number of statistics regulations such as Intrastat, enterprises have to report if their dispatches are above a set threshold. Their level of intra-EU sales will therefore determine if they have to report or not. Here again, the advice is to keep things simple. If such fluctuations concern a limited number of enterprises, they should not be taken into account.

Step 6	Identification of relevant cost parameters
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The relevant cost parameters are of course deduced from the core equation (see core equation of the cost model). It is assumed that the main costs induced by information obligations are **labour costs**. Where appropriate, **equipments or supplies' costs** or costs per action should be taken into account or used as the basis for analysis (rather than taking time as the basis unit).

- The cost parameters for the *price per action* (administrative action carried by the targeted entity itself) are the (i) **number of minutes spent on a specific action**, (ii) the **hourly pay** of those performing the action.⁴⁹ This hourly pay should correspond to the gross salary plus overheads costs (25% by default). In order to ensure overall consistency, services are asked to use the overall tariff (all Member States & 9 qualification segments) used for the EU baseline measurement.
- The cost parameters for *equipment & supplies* (i.e. acquired by the targeted entity to comply with the information obligation and solely used for that purpose) are the **acquisition price** and the **depreciation period** (service life of 'x' years).⁵⁰
- The cost parameters for the *outsourcing costs* (administrative action contracted out) is what the service provider charges on average per information obligation, per entity and per year .

⁴⁸ By definition that notion does not apply to one-off costs such as 'familiarising with the information obligation'. These costs will therefore not be included in the standard report sheet allowing to monitor the level of recurring costs.

⁴⁹ http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm

⁵⁰ For instance, barcode printer and scanner.

Step 7	Choice of data sources and, if necessary, development of data capture tool(s)
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Data collection methods to be chosen according to the individual case include: focus groups, consultation of stakeholders, field trials, consultancy studies, and expert assessment. Irrespective of the source and mode of collection, services need to verify and interpret collected data (see Annex 11.1 approximating numbers).

In standard cases, it will be sufficient to produce overall estimates based on

(i) the ‘EU database on Administrative Burdens’ and the ‘EU Administrative Burdens Calculator’ as well as available EU statistics (provided, among others, by Eurostat <http://epp.eurostat.ec.eu.int/> and the Small and Medium-Sized Enterprises Observatory); and the overall hourly tariff (all Member States & 9 qualification segments) used for the EU baseline measurement (see step 6)⁵¹;

(ii) standard ratios (for example assessing overheads on the basis of a mark-up percentage on labour costs;

(iii) the opinion of experts and

(iv) Member State studies.

In exceptional cases, field work limited to a sample of Member States and/or questionnaires sent to a standard sample of the business community and simulation may have to be used. Key templates are provided in the ‘Starter kit for measuring and reducing administrative burdens’⁵². Even if data are not collected by these means, it is always useful to talk to the future addressees, insofar as they are well placed to identify hidden costs.

Member States have agreed to assist the Commission to collect data where standard sources do not suffice.⁵³

Box 4: Administrative Burden Reduction Programme: In 2007 Commission launched a programme to reduce administrative burden by 2012 by 25%. It is limited to 13 priority areas and includes a baseline measurement of existing costs in these areas. Even though the programme is limited to specific legal acts and to assessment of costs to business, the results are helpful in understanding the mechanisms by which the administrative costs accrue. Several Member States have performed their own national baseline measurements (the results have been taken into account in the Commission exercise). For more information: http://ec.europa.eu/enterprise/admin-burdens-reduction/action_program_en.htm

⁵¹ Specific links to data on the number of businesses, labour costs and other sectoral parameters are provided on http://www.europa.eu.int/comm/secretariat_general/impact/docs_en.htm.

⁵² http://ec.europa.eu/enterprise/admin-burdens-reduction/home_en.htm

⁵³ “The Council ... reiterates its October 2004 commitment to assist the Commission in implementing the methodology. In this context Ministers agree: to provide, on request and in a proportionate manner, the information needed to carry out assessments of EU administrative burdens and; that the methodology proposed by the Commission provides a common basis for the collection and exchange of data” (The Council of the European Union (ECOFIN) 2688th meeting, 8 November 2005). “The European Council recognises the importance for Member States to provide, on request and in a proportionate manner, the information needed to assess administrative costs imposed by EU legislation” (Presidency Conclusions of the Brussels European Council, 15/16 December 2005).

Step 8	Assessment of the number of entities concerned
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In order to ensure comparability of estimates made by different DGs and ensure compatibility with estimates conducted by a large number of Member States, services will base their assessment of administrative costs on the basis of an **assumption of full compliance by all entities concerned**. All the assumptions concerning population size (e.g. SME's), in particular for proposals with long time horizon, should be clearly explained.

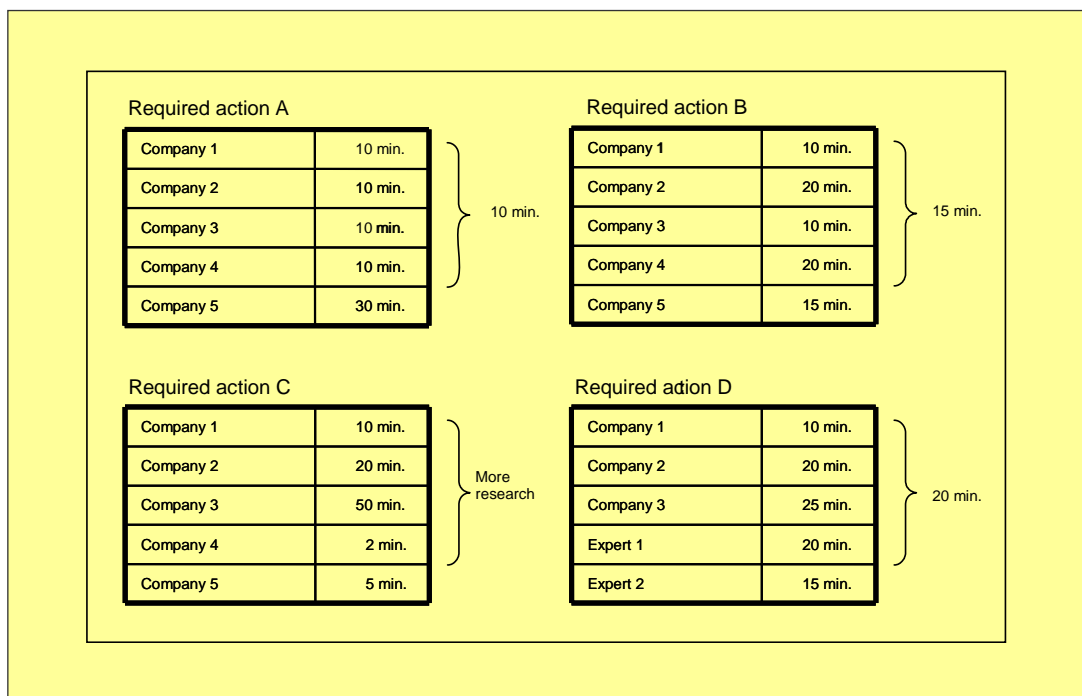
Step 9	Assessment of the performance of a “normally efficient entity”
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In order to keep assessment of costs at a reasonable level and ensure compatibility with national methodologies, the **assessment will be based on ideal types** (typical firms, typical public service, etc.). National databases don't work with ranges of estimates, but with discrete figures corresponding to standardised costs.

To start with, services will make a critical review of available data, identify and remove obvious outliers (entities whose performance is clearly eccentric, i.e. greatly below or above the other performances). In many cases, calculating the median or the average of remaining data might be sufficient. The standard deviation and variance (measuring how spread validated data are) will help deciding on the most appropriate method for identifying the performance of the “normally efficient entity”.

The following example borrowed from the 'International SCM Manual' shows how to proceed with simple cases.

Box 4: Identifying typical business



Explanation: As far as action A is concerned, Company 5 is clearly different from the others and should therefore not be taken into account to determine the performance of a typical (or normally efficient) business. The convergence of the other data is sufficient to choose 10 minutes as a basis for the calculation of the cost imposed on a “normally efficient entity”. In the case of action B, there are no obvious outliers. The standard performance could be as-

essed on the basis of the average (13 min.) or the median value (15 min.). The difference being negligible (2 min.) any method would do. No estimate can be made on the basis of data concerning action C because the latter vary too much. More research needs to be done. Consideration should first be given to whether companies selected are not representative or whether specific circumstances can explain this wide variation of performance. The segmentation (see Step 4 - Identification of target group(s)) should be reconsidered and, if necessary, more interviews done. In the case of action D, only three companies answered the questionnaire. An expert assessment was seen as necessary. The combination of the two data sets leads to opt for 20 minutes.

In addition to the **number of minutes**, services will have to determine ‘normal’ level of qualification required by the main actions linked to information obligations and the **‘normal’ labour cost per hour** including prorated overheads (expenses for premises, telephone, heating, electricity, IT equipment, etc.).

Step 10	Extrapolation of validated data to EU level
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There is **no need to provide specific estimates for each Member State** or administrative body concerned, unless to do so would be proportionate. In most cases, services will estimate EU costs by extrapolating available data at national or EU level.

When data are available for only a very limited number of Member States, extrapolation could be done on the basis of the country distribution of administrative costs in a similar sector or for a similar event. The ‘EU database on administrative burdens’ provides approx. 340 of these (see step 6). Benchmarking projects as well as national baseline measurements⁵⁴ conducted by several Member States and the most advanced Commission Impact Assessments are a prime source of information on country distributions.

Step 11	Report
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Estimates need to be reported in a standardized manner to allow for their comparison and addition. The report sheet downloadable on the SG IA website should therefore be used http://ec.europa.eu/governance/impact/docs/eu_cost_model_report_sheet_v2.xls Calculation is automatically done by the Excel report sheet.

For strategic proposals, **the common report sheet will often act as a summary of more detailed analyses**. It does not prevent services from presenting more detailed data (such as ranges of costs or key uncertainties) in separate tables and texts.

Encoding instructions: Put the equipment yearly cost based on the depreciation period in the corresponding column. When a measure amends existing provisions and if it removes administrative obligations, the sheet will include negative figures corresponding to the burden reduction. Detailed instructions are included in the standard spread sheet (see link above and example below).

Methodological caveats: When reporting on their assessment, particular care must be taken to indicate, succinctly but clearly, the working assumptions and methodological limitations. This will include assumptions concerning compliance rate and a warning about the nature of the data presented (estimates and not exact measures).

Please note that it is sufficient to present the results of the EU SCM calculations in the main text. The reporting sheet, major assumptions, costs parameters, etc. should be placed in an annex.

⁵⁴ For details see SCM network website <http://www.administrative-burdens.com/>

10.3. A capture tool

This section provides an example of a questionnaire designed to capture data needed to apply the model on administrative costs. The questionnaire is targeting a representative sample of the business community.

Some questions are meant to collect quantitative data needed to assess the monetary cost of the regulation (number of hours ...). Others are meant to collect qualitative information useful for caveats (e.g. putting into perspective the very notion of 'burden' by indicating that some obligations will correspond to business' good practices) or useful for policy design. For instance, knowing which types of obligations are a major irritant is an important element for setting simplification priorities, improving perception of the regulatory environment and improving compliance.

Table 1: Questionnaire for collecting data on a statistical regulation

European survey on the administrative costs of producing statistics on intra-EU trade in goods (European Business Test Panel)⁵⁵	
<p>In recent years the issue of better regulation and in particular, the issue of administrative costs on enterprises has gained increasing attention internationally, at EU level and in the Member States.</p> <p>The European Commission and its statistical office, Eurostat, are therefore increasing their efforts to measure and better manage the administrative costs caused by European legislation. The system known as Intrastat was devised to collect statistics on intra-Community trade. Developed by Eurostat and operational since 1 January 1993, Intrastat involves collecting information directly from businesses on a monthly basis. Companies exceeding a certain amount of trade in goods within the European Union are liable for Intrastat declarations.</p> <p>To improve our knowledge on administrative costs caused by this specific legislation, we invite you to fill in and submit this short questionnaire.</p>	
1	Does your company have to provide Intrastat declarations to your competent national administration (CNA)? (usually the national statistical office or the national bank). - YES / - NO (if NO, please go to question 9).
2	Does this information concern: - Dispatches & shipments only / - Arrivals & receipts only / - Both arrivals & receipts and dispatches & shipments
3	How much hours are spent each month, on average, for collecting the information required for the Intrastat declaration? What is the average labour cost per hour (including prorated overheads)? (please do not use currency symbols, spaces or dots between thousands)
4	How much hours are spent each month, on average, for drawing up the Intrastat declaration? What is the average labour cost per hour (including prorated overheads)? (please do not use currency symbols, spaces or dots between thousands)
5	How does your company transmit the data to the CNA? – Electronically / - On paper
6	Do you think that the preparation/transmission of your Intrastat declaration today takes less time than when it was initially introduced some 10 years ago? - YES / - NO / - DON'T KNOW. If YES, could you express the change in %:
7	Do you expect the time required by Intrastat to evolve in the future, for instance because of organisational or technological adaptations? - YES / - NO / - DON'T KNOW. If yes, will it - DECLINE / - INCREASE - Could you express the change in %:
8	Do you consider Intrastat reporting to be (on a scale of 1 to 5) not at all burdensome (1) to very burdensome (5)?
9	Does your company make use of the statistics on Intra-EU trade in goods as they are published at national level and/or by Eurostat? - YES, please specify the use: / - NO

⁵⁵ The European Business Test Panel is a representative group of around 3600 European companies that can be directly consulted on the development of important initiatives. The actual survey took place in August and September 2005.

Comments on the adaptation of the data capture tool to the regulation assessed

There was no need to ask questions on external costs, because very few enterprises out-source the management of their shipments and arrivals.

In the present case (sending a table of figures), expert judgment was sufficient to assess transmission costs. The cost of electronic transmission is negligible because it requires very little time and no specific equipment (enterprises use IT equipment and connection they need for their professional work). The time and level of qualification needed for paper transmission is fairly standard and the cost of national mail is easy to determine. It was therefore enough to assess the proportion of enterprises using paper transmission. This contributed to keep the questionnaire as short as possible and ensure higher response rate.

On the contrary, because of the specific reporting frequency and overall costs of the regulation, it was important to collect information on the enterprises' learning curve 'see questions 6 & 7) and to have a rather precise idea of routine costs to avoid overestimation. That information also helps assessing indirectly one off costs.

10.4. Example of Report Sheet filled out

Note that information obligations and figures presented in the report sheet below are **purely illustrative**. They are not based on actual estimates.

Actions 1, 2 and 10 should not have been fully assessed and reported. With a very low frequency, very limited time required and no specific acquisition required, their total cost was bound to be insignificantly low. The analysis should have been stopped after the assessment of the required number of hours. There was no need to assess other parameters such as hourly pay or overhead, and produce a monetised estimate of these information obligations (see 10.1 Scope of application of the model and expected level of accuracy).

Regulation (EC) No 2560/2001 of the European Parliament and of the Council of 19 December 2001 on cross-border payments in euro, Official Journal L 344 , 28/12/2001 P. 0013 - 0016						Tariff (€ per hour)	Time (minutes)	Price (per action)	Freq (per year)	Nbr of entities	Total number of actions	Equipment costs (per entity & per year)	Outsourcing costs (per entity & per year)	Total Administrative Costs	Business As Usual Costs (% of AC)	Total Administrative Burdens (AC - BAU)	
No.	Art.	Orig. Art.	Type of obligation	Description of required action(s)	Target group												
1	4§1		Non labelling information for third parties	Familiarising with the information obligation	Banking sector	30	60,00	30	1	500	500			15,000	0%	15,000	
2	4§1		Non labelling information for third parties	Retrieving relevant information from existing data	Banking sector	25	30,00	13	1	500	500			6,250	20%	5,000	
3	4§1		Non labelling information for third parties	Designing information material (leaflet conception...)	Banking sector			0	1	500	500		400	200,000	0%	200,000	
4	4§1		Non labelling information for third parties	Copying (reproducing reports, producing labels or leaflets)	Banking sector			0	1	500	500	3,000		1,500,000	50%	750,000	
5	4§1		Non labelling information for third parties	Submitting the information (sending it to the designated recipient)	Banking sector			0	300	500	150,000	500		75,000,000	0%	75,000,000	
6	5§1		Non labelling information for third parties	Retrieving relevant information from existing data	Banking sector	25	6,00	3	3	500	1,500			3,750	0%	3,750	
7	5§1		Non labelling information for third parties	Submitting the information (sending it to the designated recipient)	Banking sector			0	3	500	1,500	1		1,500	0%	1,500	
8	6§1		Submission of (recurring) reports	Retrieving relevant information from existing data	Banking sector	25	-10,00	-4	1	-500	-500	50	300	-172,917	0%	-172,917	
9	6§1		Submission of (recurring) reports	Filing forms and tables	Banking sector	50	-5,00	-4	1	500	500			-2,083	30%	-1,458	
10	6§1		Submission of (recurring) reports	Submitting the information (sending it to the designated recipient)	Banking sector			0	1	500	500	-80		-40,000	0%	-40,000	
No. = gives a number for each action.																	
Art. = article and § detailing the obligation assessed on that line.																	
Orig. Art. = if the act assessed is the transposition of an act adopted at another level, insert here the article and § of the 'original' act corresponding to the obligation assessed on that line																	
(for ex., article of the EC directive at the origin of one specific obligation imposed by national law)												Total administrative costs (I)	76,511,500				
Price per action (P) = Tariff * Time. Total Nbr of actions (Q) = Frequency * Number of entities. Total cost per action = P*Q + Equipment + Outsourcing.												<i>Total administrative burden (I)</i>	75,760,875				
For equipment, yearly cost is calculated on the basis of the depreciation period.												<i>Administrative costs by origin (I)</i>					
When the act amends existing provisions and reduce the value of a parameter (lower frequency, lower number of entities concerned, etc), negative figures corresponding to that reduction should be typed in																	
Regulatory act refers to legislative and statutory acts																	
For the reference of the proposal / act, use EU-Lex format ('cut and paste' of the reference given by http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en).																	
No. = gives a number for each action.																	
Art. = article and § detailing the obligation assessed on that line.																	
Orig. Art. = if the act assessed is the transposition of an act adopted at another level, insert here the article and § of the 'original' act corresponding to the obligation assessed on that line																	
(for ex., article of the EC directive at the origin of one specific obligation imposed by national law)																	
Price per action (P) = Tariff * Time. Total Nbr of actions (Q) = Frequency * Number of entities. Total cost per action = P*Q + Equipment + Outsourcing.																	
For equipment, yearly cost is calculated on the basis of the depreciation period.																	
When the act amends existing provisions and reduce the value of a parameter (lower frequency, lower number of entities concerned, etc), negative figures corresponding to that reduction should be typed in the relevant columns																	

11. Approaches and tools for impact analysis

11.1. Approximating numbers

Patton and Sawicki (1993) offer the following guidance for determining unknown figures. Most of this guidance is valid for qualitative analysis.⁵⁶

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).

11.2. Problem trees/causal models

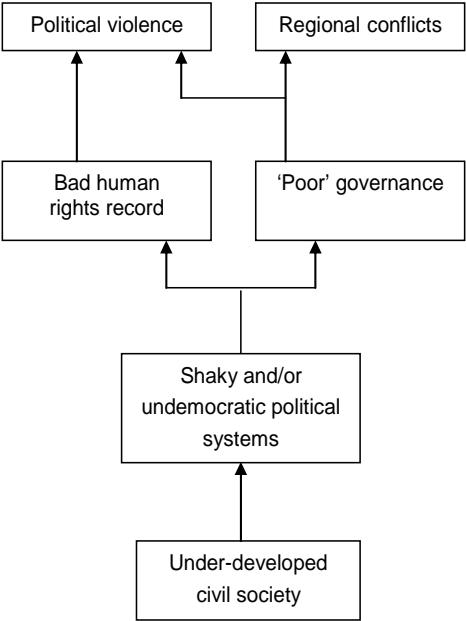
The problem tree approach consists of three steps:

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 ini-

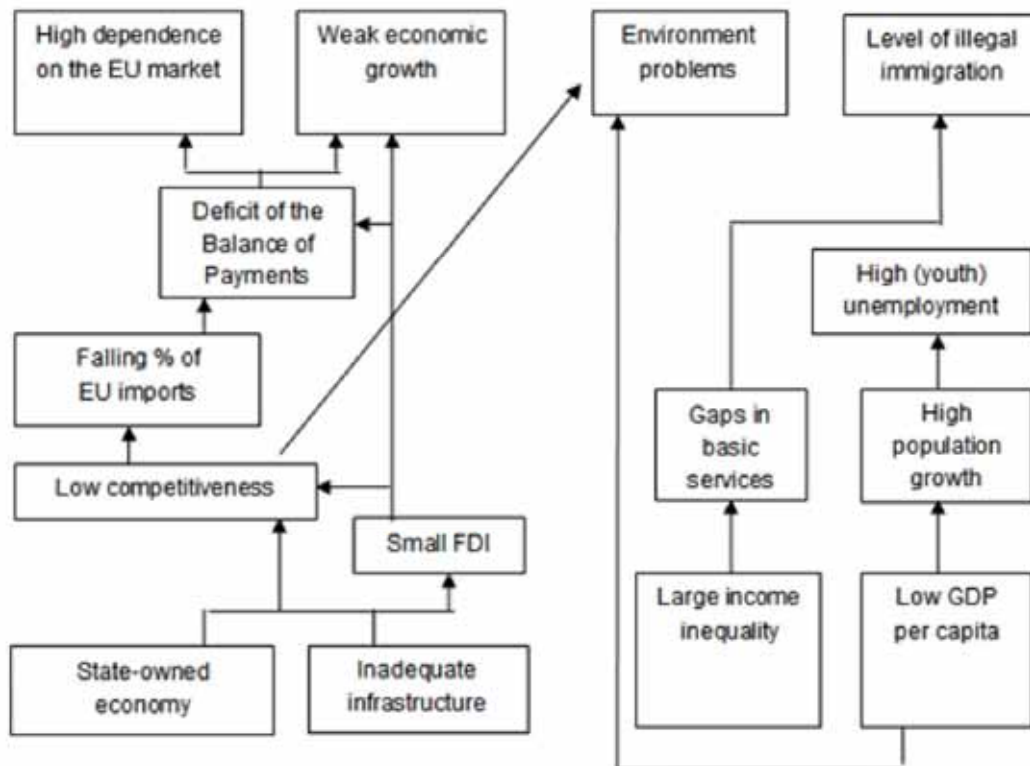
⁵⁶ In social science, qualitative analysis usually refers to research approaches concerned with investigating the phenomenon in situ – cf. studying the actual behaviour of the targeted population through face-to-face interviews. Here the term is simply used to designate non-quantitative approaches.

tial 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:



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 problems⁵⁷ and socio-economic problems⁵⁸, the tree could look like this:



⁵⁷ 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

⁵⁸ 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).

11.3. 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.

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.⁵⁹

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 cost of producing 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: (i) a road safety awareness campaign; (ii) building bridges to separate pedestrian and vehicle traffic; (iii) 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 difficult to make well-founded estimates of cost-effectiveness, the process of identifying impacts should help you to understand and explain the consequences of the proposal in terms of different types of costs. In some respects, this is just as important as carrying out exact measurements and calculations. As a minimum, an Impact Assessment should

- present a broad estimate of the cost of the proposed intervention;
- show that the objectives justify the cost – bearing in mind that ultimately this is a political judgment;

⁵⁹ For further guidance see <http://www.cc.cec/budg/preparation/en/preparation/fiche-fin/summary.htm>.

- investigate 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;
- present the most cost-effective options.

In some cases these questions may lead to a re-assessment of the objectives, and of the proposed intervention itself. It will require serious consideration of alternative options and delivery mechanisms, or combinations of these.

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.

Type of cost	Body or bodies involved in the implementation of the measure	Addressees
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. ⁶⁰ Opportunity costs. ⁶¹
Adjustment cost	See above (transaction costs)	The costs of reallocating resources because of policy-induced changes in behaviour (concerning production or consumption).

⁶⁰ Unlike 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’.

⁶¹ 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.

11.4. The 'IA TOOLS' website

Objectives

[IA TOOLS](#) is an online platform that aims to provide Commission policy actors and impact assessment practitioners throughout Europe with a repository of guidance, information and best practices for the impact assessment of new policies and legislative measures.⁶² IA TOOLS provides experts and non-experts with guidance on the main steps to be followed to perform an impact assessment. It contains an inventory of social, economic and environmental impact indicators. It also offers an overview of the qualitative and quantitative tools available for the analysis of policies impact as well as access to up-to-date databases.

The four main different IA TOOLS modules

- The [Impact Inventory](#) should help standardise the "Impact Identification, Analysis and Estimation step" of the Impact Assessment process and increase its comprehensiveness in respect to the consideration of, for example, indirect policy impacts. The links to potential data sources should also facilitate, in some cases, quantification. The Impact Inventory is structured along the impact areas breakdown (economic, environmental and social) adopted by the Commission Impact Assessment Guidelines. The Guidelines require in fact thinking over a number of key questions on the possible impacts of the different policy options. In IA TOOLS, each of those questions is complemented by a brief description, links to background information on the Commission web pages, and data sources (quantitative indicators related to each impact area) from Eurostat, from other European agencies (e.g. EEA), and from international organisations (e.g. OECD). Furthermore, it provides direct links into relevant data resources for the individual impact areas.
- This [Model Inventory](#) should make it easier for desk officers to determine, in the "Impact Identification, Analysis and Estimation step", whether the impacts of a certain policy proposal can be assessed and quantified using existing models. The provision of a central list of models, easily accessible, standardised and synthetic, is meant to guide and facilitate the adoption, when feasible and useful, of more sophisticated tools for Impact Assessment. Economic or technical modelling is not necessarily relevant or feasible for all aspects of impact assessment. IA TOOLS guides the user to those models that could be useful for the planned IA and provides background information out of a comprehensive model inventory. The Model Inventory contains a list of models that are in principle able to quantify impacts, either in physical or in monetary terms. Models are described in a non technical way and contacts and references are provided.
- The [Good Practice Inventory](#) should provide desk officers with a guide to sound procedures and tools for the identification and quantification of policy impacts, comparison of policy options, design of stakeholder consultation processes and setting up of procedures for policy monitoring and evaluation. The Good Practices Inventory includes examples of impact assessments for different years (starting in 2003) and for all stages of impact assessment (from description of the problem to stakeholder consultation) in the European Union. The Good Practices Inventory is kept up to date and in line with the Impact Assessment guidelines of the Commission. However, as updates are carried out over 1-2 year cycles, minor discrepancies may occur temporarily.

⁶² IA TOOLS has been developed along the lines of the European Commission's Impact Assessment Guidelines. It was initially developed by a consortium of European research institutes in the frame of the 6th Community Research Framework Programme. Today IA TOOLS is hosted and maintained by the JRC Institute for Prospective Technological Studies IPTS.

ily between the outline of good practices in IA TOOLS and on the Impact Assessment information pages of the Secretariat General.

- The [IA TOOLS handbook](#) provides a resource centre with information and data bases which are useful for each stage of IA. The handbook describes, categorises and provides access to information related to IA and stemming from different sources (Commission documents, EU research projects, publications by Member States and international organisations). It is a resource that can be used to answer questions that arise when a specific IA is carried out.

For further information and feedback, please visit: <http://iatools.jrc.ec.europa.eu>

11.5. Quantitative Models

The development, adaptation and use of quantitative models can be time-consuming and resource-intensive. Some quantitative models have been developed for special policy-related purposes (often with financial support of the Commission). You should therefore in particular cases start by examining if one of these models corresponds with the analytical needs of your 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.

The choice of model or instruments should be proportionate to the effects you are appraising. Economy-wide, macroeconomic results must not be based on partial-equilibrium or sectoral modelling but on macroeconomic modelling (unless spill-over effects from the affected sector to the rest of the economy are insignificant). In case only parts of these models were used or “fixes” were introduced: this must be made explicit as should the way that these changes affect the outcome. No important “open loops” should exist. This concerns for example the financing of policies, where the impact of the chosen means of funding must be taken into account. The same is valid for policies triggering expenditure in the private sector.

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.

This section provides examples of this kind of models. Some of them are available at the Commission and are owned by the Commission, but most of them have been developed by research centers under the Research Framework Programmes and are owned by these centers.

The models cover different impacts, policy areas and instruments. A software program to help you in selecting relevant models is being developed as part of the IA TOOLS project described in these guidelines (see above). 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			
potentially low	X		X		
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

Models that can be used as **quantitative tools** for impact assessment purposes fall under the following headings:

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

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, TRANSTOOLS, *Agriculture:* CAPRI. *Emissions Trading:* SIMAC

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.⁶³

Examples of EU funded macro-econometric models: E3ME; NEMESIS; QUEST II; WARM

⁶³ Models must be carefully checked if not developed in-house.

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

Micro-simulation 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

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

11.6. 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 be 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%.⁶⁴ 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**.

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).

Formula for net present value

The net present value of a project is calculated as (discounted value of benefits) minus (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

⁶⁴ This rate broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s. For impacts occurring more than 30 years in the future, the use of a declining discount rate could be used for sensitivity analysis, if this can be justified in the particular context.

as a decimal), then the net present value of the project is:

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

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:

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

For the second project

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

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 measures' European Environment Agency, Technical Report no. 27, 1999.

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%.

Discount rate in percent/ year

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
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

12. Risk analysis

Risk analysis is called for when potentially significant negative impacts can be expected to arise in the baseline scenario (or alternatively as a result of proposed policies), for which the likelihood that they may occur cannot be predicted on the basis of historical data. Such risks can be reduced by either limiting the extent of negative consequences in case of an occurrence or by reducing the probability of such an event occurring, for example by limiting risky activities, or by a combination of both. The options section should point out different alternatives to tackle the risk whose impacts then need to be analysed.

Where the origin of a risk is outside human control (*force majeure*) and its likelihood of occurring cannot be influenced it is only possible to take preventive measures to reduce its negative effects. In order to find efficient levels of precaution, the marginal costs of reducing the expected harm should equal the marginal reduction of the harm. Where marginal values are unknown or too difficult to assess total costs and total harm reduction for each option can still be used to determine whether a measure is socially desirable. If alternative means exist that lead to similar levels of risk reduction, you can also use cost effectiveness analysis to determine the one with the lowest cost.

If only the likelihood of a negative consequence but not its effects can be controlled, an analogous approach can be used by comparing the costs of reducing the probability of harm with the expected harm that is prevented. However, if you intend to limit risky activities it needs to be considered that these activities can also have positive impacts that would be foregone, for example where a pharmaceutical product has serious side effects but is the only way to cure a disease. In that case the foregone positive impacts need to be considered as part of the costs of reducing the expected harm.

Before regulating an activity it should be considered whether less restrictive measures are feasible, such as a clear assignment of liability that may lead to an internalisation of the harm and thus an efficient outcome. It should also be analysed whether private insurance is feasible. If insurance coverage is offered to potential victims at competitive rates there is no *a priori* need for government intervention. Private insurance is generally deemed to be an efficient private response to risk. Regulatory intervention may only be needed in situations where private insurance is not available or where regulatory intervention is cheaper. This may for instance be the case where the risks are extremely large and difficult to pool.

A more complex situation is one where both the probability and the scope of harm can be influenced. In that case, various levels of harm reduction can be achieved by different combinations, possibly at differing levels of costs. In order to find the most socially desirable combination, the net benefits⁶⁵ of all possible combinations should be compared and the measure should be chosen for which the expected net benefits are highest.

The mere fact that some parameters in an analysis are not known precisely or that future developments are uncertain does not mean necessarily that a risk analysis has to be carried out. **Sensitivity analysis** can be used to test whether changes in the estimated parameters lead to significant changes in the outcomes. (see section 5.4 of the main text). It thus helps to determine whether the assumptions underlying a prediction are robust or whether further information needs to be gathered. Risk analysis instead is a tool to determine the best policy to deal with uncertain but potentially harmful consequences. However, where risks are not known precisely a sensitivity analysis on the results should be carried out in addition.

Precautionary principle and irreversibility

In exceptional cases it may not be possible to collect the relevant information or estimate the parameters while there is an urgent need to make a policy decision. Only if consequences are likely to be substantial and irreversible and the likelihood of the occurrence

⁶⁵ Net benefit = reduction in expected harm - cost of harm reduction measures.

of a negative consequence cannot be assessed, the **precautionary principle** can be invoked.

The idea behind the precautionary principle⁶⁶ 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.

⁶⁶ See Communication on the precautionary principle, COM(2000) 1.

13. Indicators, Monitoring and Evaluation

13.1. 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, organizational 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: <ul style="list-style-type: none"> • the direct addressees or recipients of the programme; • people or organisations not directly addressed by the programme, as well as • c) unintended impacts. 	<ul style="list-style-type: none"> • The placement rate of trainees after twelve months; survival rate of businesses created with programme support • Impact on suppliers or subcontractors 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.

13.2. 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.

It is essential that you specify in your impact assessment which pieces of information should be collected, when they should become available, and by whom they should be provided. The design of monitoring arrangements should also take into account whether the proposed set-up would lead to unnecessary administrative burdens, by imposing disproportionate information obligations on businesses, citizens, or public authorities.

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);
- enforcement costs for public authorities;
- compliance costs;
- attainment of target levels or outcomes specified in the objectives;
- context variables.

13.3. Evaluation

According to the Commission's rules on evaluation⁶⁷, all programmes and (ABB) activities have to be evaluated on a regular basis.⁶⁸

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/dgserv/sg/i/spp/index.cfm?lang=en&page=obj_ind
- **evaluation**, consult the guide 'Evaluating EU Activities' on http://ec.europa.eu/budget/documents/evaluation_en.htm?go=t8#table-8

⁶⁷ See Communication "Responding to Strategic Needs: Reinforcing the use of evaluation" SEC(2007)213, http://ec.europa.eu/budget/library/documents/evaluation/communication/eval_comm_sec_2007_213_en.pdf, as well as Article 27(4) of the Financial Regulation and Article 21 of its Implementing Rules.

⁶⁸ 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.

14. Best practice library - Practical examples from previous Commission IA reports - Key analytical steps

This best practice library will be regularly up-dated and extended. The most recent version is available under http://ec.europa.eu/governance/impact/best_pract_lib_en.htm.

	Key analytical steps - Practical examples of previous IA reports
<i>Analytical step/issue</i>	<i>Name of Commission Impact Assessment Report and Internet short-cut</i>
Problem definition	
Nature and extent of the problem	EU Mortgage Credit White Paper http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf Communication on urban transport security http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1324_fr.pdf proposal cancelled Vapour recovery during refuelling of cars http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2937_en.pdf
Establish drivers and underlying causes	White Paper on damages actions for breach of the EC antitrust rules http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0406_en.pdf Capital Requirements Directive http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2532_en.pdf Community strategy against Illegal, Unreported and Unregulated (IUU) fishing http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1336_en.pdf EU Strategy for ship dismantling http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2846_en.pdf
Subsidiarity analysis	European Research Infrastructures http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2278_en.pdf
Baseline scenario	Regulation setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO2 emissions from light-duty vehicles http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1723_en.pdf
Risk assessment	
Sensitivity analysis	Communication on rail noise abatement measures addressing the existing fleet http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2203_en.pdf
Different situation by Member States	Amending Council Directive 92/85/EEC on Maternity Leave http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2593_en.pdf Recommendation on the Reform of the Auditors' Liability http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_1975_en.pdf
Policy context / Overview of existing measures	Communication on 'A Common Immigration Policy for Europe: Principles, actions and tools' http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2026_2_en.pdf Communication on an integrated maritime policy http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1279_en.pdf
Policy objectives	
Objectives that correspond to the problem/root causes.	EU Mortgage Credit WP http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf Capital Requirements Directive http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2532_en.pdf Cross-border payments in euro http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2598_en.pdf Communication on asylum: an integrated approach to protection across the EU http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2029_2_en.pdf
Objectives established at a number of levels	Amendment of the Eurodac Regulation http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2981_en.pdf Communication on enhancing the security of explosives http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1421_en.pdf
Overall coherent objectives	White Paper on damages actions for breach of the EC antitrust rules http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0406_en.pdf Cross-border payments in euro http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2598_en.pdf
Policy options	
Identification of options	Vapour recovery during refuelling of cars http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2937_en.pdf Minimum sanctions to employers of illegally resident third-country nationals http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0603_en.pdf

Screening of option	<p>Communication on rail noise abatement measures addressing the existing fleet http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2203_en.pdf</p> <p>Communication preparing the next steps in border management in the EU http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0153_en.pdf</p>
Options for delivery mechanisms	<p>Critical Infrastructure Warning Information Network (CIWIN) http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2701_en.pdf</p> <p>Proposal for a Directive on implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2180_en.pdf</p>
Proportionality	<p>White Paper on damages actions for breach of the EC antitrust rules http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0406_en.pdf</p> <p>Communication on public-private dialogue in security research http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1138_en.pdf</p>
Impact analysis	
Distributional impacts	<p>Decision on effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020 (Climate Change and Energy package) http://ec.europa.eu/environment/climat/pdf/climate_package_ia_draft_annex.pdf</p>
Qualitative assessment	<p>Amendment of the Eurodac Regulation http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2981_en.pdf</p> <p>Proposal for a Regulation on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2121_en.pdf</p> <p>Revision of Council Framework decision of 13 June 2002 on combating terrorism http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1424_en.pdf</p>
Quantitative assessment/ monetization	<p>Communication on rail noise abatement measures addressing the existing fleet http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2203_en.pdf</p> <p>Creation of a European Rail Freight Oriented Network http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1324_fr.pdf</p> <p>Directive on the protection of animals used for scientific purposes http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2410_en.pdf</p> <p>Communication on rail noise abatement measures addressing the existing fleet http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2203_en.pdf</p> <p>Regulation on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (EURO VI) and on access to vehicle repair and maintenance information http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1718_en.pdf</p> <p>Common organisation of the market in wine http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0893_en.pdf</p> <p>Review of the support scheme in the cotton sector http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1481_en.pdf</p> <p>Regulation on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (EURO VI) and on access to vehicle repair and maintenance information http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1718_en.pdf</p> <p>Communication on the results of the review of the Community Strategy to reduce CO2 emissions from passenger cars and light-commercial vehicles http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0060_en.pdf</p>
Administrative burden	<p>Common organisation of the market in wine http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0893_en.pdf</p> <p>Revision of the regulatory framework for electronic communications and services (European Electronic Communications Market Authority) http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1472_en.pdf</p>
Obstacles to compliance	<p>Directive on a single permit for third country workers in Member States http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1408_en.pdf</p>
Sensitivity analysis	<p>Communication on a strategy for the internalisation of external costs http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2208_en.pdf</p>
Risks/uncertainties in policy choices	<p>Communication on water scarcity and drought http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0993_en.pdf</p> <p>EU Strategy for ship dismantling http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2846_en.pdf</p> <p>Joint Technology Initiative in the area of nanoelectronics "ENIAC" http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0851_en.pdf</p> <p>Joint Technology Initiative in the area of aeronautics and air transport 'Clean Sky' http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0773_en.pdf</p>
Compare the options	

Weighing-up of positive/negative impacts	
Cost-Benefit Analysis	Communication on rail noise abatement measures addressing the existing fleet http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2203_en.pdf
Cost-Effectiveness-Analysis	
Multi-criteria analysis	Communication on a strategy for the internalisation of external costs http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2208_en.pdf
Effectiveness of preferred option in achieving objectives	EU Mortgage Credit WP http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf
Comparison presentation	White Paper on damages actions for breach of the EC antitrust rules http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0406_en.pdf Visa Information System (VIS) http://ec.europa.eu/governance/impact/docs/ia_2004/sec_2004_1628_en.pdf
Ranking/identification of preferred option.	Proposal for a Directive on the application of patient's rights in cross-border healthcare http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2163_en.pdf Directive on amending Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf
Policy monitoring and evaluation	
Progress indicators for the key objectives	Action plan on freight transport logistics http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1321_en.pdf
Evaluation arrangements.	Communication 'Preparing the next steps in border management in the EU' http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0153_en.pdf Community strategy against Illegal, Unreported and Unregulated (IUU) fishing http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1336_en.pdf
Proportionate level of analysis	
	Unit of measurements http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf From Cairo to Lisbon - The EU-Africa Strategic Partnership http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0855_en.pdf
Public Consultation	
Minimum standards	Cosmetics Directive: http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0117_en.pdf Review of the support scheme in the cotton sector http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1481_en.pdf Joint Programming in Research http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_2281_en.pdf
Presentation	
Executive summary	Towards Common principles of Flexicurity: More and better jobs through flexibility and security http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0861_en.pdf
Overall length	Directive on the use of Passenger Name Record(PNR) for law enforcement purposes http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1453_en.pdf