

IMPACT ASSESSMENT IN THE COMMISSION

INTERNAL GUIDELINES ON THE NEW IMPACT ASSESSMENT PROCEDURE DEVELOPED FOR THE COMMISSION SERVICES

THIS DOCUMENT MUST BE REGARDED AS WORK IN PROGRESS. IT WILL BE AMENDED IN VIEW OF THE IMPACT ASSESSMENT PROCEDURE IMPLEMENTATION. IF YOU HAVE SUGGESTIONS TO IMPROVE THE GUIDELINES, PLEASE CONTACT THE STRATEGIC PLANNING AND PROGRAMMING UNIT IN THE SECRETARIAT-GENERAL.

"Proposals must be prepared on the basis of an effective analysis of whether it is appropriate to intervene at EU level and whether regulatory intervention is needed? If so, the analysis must also assess the potential economic, social and environmental impact, as well as the costs and benefits of that particular approach. A key element in such as assessment is ensuring that the objectives of any proposal are clearly defined." – European Governance, a White Paper

"Sustainable development should become the central objective of all sectors and policies. This means that policy-makers must identify likely spillovers – good and bad – onto other policy areas and take them into account. Careful assessment of the full effects of a policy proposal must include estimates of its economic, environmental and social impacts inside and outside the EU." – A sustainable Europe for a better world, A European Union Strategy for Sustainable Development

"Impact assessment is intended to integrate, reinforce, streamline and replace all the existing separate impact assessment mechanisms for Commission proposals."
– Communication on Impact Assessment, 5 June 2002

SUMMARY

These guidelines are intended to help Commission staff to organise, design, carry out and/or review an Impact Assessment.

Context

Within the framework of the better regulation package, the Commission is proposing several concrete actions to improve the way it designs policy. One of these is the introduction of a new integrated impact assessment method.

The Göteborg and the Laeken Councils introduced two important political considerations:

- First, to consider the effects of policy proposals in their economic, social and environmental dimensions.
- Second, to simplify and improve the regulatory environment.

The new process is set out in the Commission's **Communication COM 2002/276 on Impact Assessment**.

What is impact assessment?

Impact assessment helps structure the process of policy making. It identifies and assesses the problem at stake and the objectives pursued. It identifies the main options for achieving the objective and analyses their likely impacts. It outlines the advantages and disadvantages of each option as well as synergies and trade-offs.

Impact Assessment is an **aid** to political decision, not a substitute for it.

Added value of the method

The Commission has in the past used a wide range of tools to assess its proposals: environmental assessments, SME *fiches*, regulatory analyses, economic studies, *ad hoc* consultations, business assessments, gender mainstreaming, green books and dialogues with lobbies.

The existing tools, however, tend to concentrate on a single sector and are therefore too narrowly focused to grasp the complexity and cross-cutting nature of the impacts of present day policy proposals. Traditional approaches make it difficult for policy-makers to assess trade-offs and compare different scenarios when deciding on a specific course of action, in particular for initiatives with a trans-sectoral dimension.

The Commission has therefore decided to introduce a new Impact Assessment tool that integrates, reinforces, streamlines and replaces all existing separate practices, hence helping decision makers to make better informed decisions. **Proportionate analysis** will drive the process: the detail and extent of the impact assessment to be carried out will vary the likely impacts of a proposal.

Using Impact Assessment in the Commission will thus improve **the quality and coherence** of policy design.

Reporting

The Commission will make public the results of its impact assessment when it adopts its proposals, so **increasing transparency, communication and information**. This should make it easier for the services to justify the policy option chosen to Council and Parliament.

Coverage

Impact assessment will be applied to major proposals adopted by the Commission, i.e. those listed in its Annual Policy Strategy or its Work Programme, be they either **regulatory** proposals or other proposals having an **economic, social and environmental** impact.

Calendar

The impact assessment process has two stages:

- firstly a filtering exercise based on a **short preliminary assessment** of all proposals presented in the context of the Annual Policy Strategy or the Work Programme of the Commission; and
- secondly an **extended assessment** of selected proposals.

The impact assessment procedure is integrated into the Commission's Strategic Programming and Planning cycle.

The new method will be introduced gradually over a period of two years, and applied with flexibility given the different nature of the proposals covered.

As a pilot, the Commission will, starting with the adoption of its Work Programme for 2003, identify certain proposals where an extended impact assessment should be carried out.

Preliminary impact assessments will be required for all proposals submitted in the context of the Annual Policy Strategy for 2004, which the Commission will adopt in **February 2003**. On the basis of the preliminary assessments, the Commission will in this Decision select the proposals needing extended impact assessments.

The system will be fully operational in 2004/2005.

PURPOSE OF THE GUIDELINES

These guidelines aim to put impact assessment into action. They are written for Commission staff and experts in charge of designing policy proposals and thus also for those who will carry out the impact assessments.

Every policy is different, so each impact assessment should reflect this. These guidelines are intended to help staff work through the impacts of their proposals and to put these into a comprehensive and consistent framework.

The guidelines define a series of principles to follow when performing an impact assessment. Some of these are prescriptive, in particular as far as transparency, internal coordination, consultation and reporting are concerned. Others are just common- sense suggestions on how best to proceed.

The guidelines will be refined in the light of your experience, so your feedback is most welcome.

PLAN

The Guidelines consist of three parts:

An **operational guide**, to clarify the role and identify the deliverables expected from the policy units concerned and to define the procedures and timetables. This contains the basic elements for policy units on how to prepare and conduct an impact assessment.

A **reference manual** with technical instruments and methods available for impact assessment.

A set of specific **technical annexes** which are addressed to specialists.

PART I: OPERATIONAL GUIDE

Content:

1. Definition and aim of the instrument
2. Coverage
 - Proposals to be assessed
 - Force majeure
 - Impact assessment and *ex-ante* evaluation
3. Former assessment obligations
 - Guiding principles
 - Impact assessment in the Commission planning cycle
 - First step
 - Preliminary Assessment
 - Integration with the Strategic Planning and Programming cycle
 - Second step:
 - Extended impact assessment
 - Role of the lead DG
 - Coordination with other DGs
 - Results and reporting
 - Quality control
 - Timetable
4. Preliminary Impact Assessment
 - Reporting format
 - Instructions
 - Examples
5. Extended Impact Assessment
 - Reporting format
 - Instructions
 - Reporting on results

1. Definition and aim of the instrument

Impact assessment aims to structure the process of policy making. The Impact Assessment is adapted to the subject of the proposal and is applied in a flexible manner.

Impact Assessment is the systematic analysis of:

- the **problem** addressed by the proposal concerned,
- the **objective** it pursues,
- the **alternative options** available to reach the objective;
- their **likely impacts**; and
- respective **advantages and disadvantages**, including synergies and trade-offs.

The analysis works on a step by step basis to provide **a structured way to raise and then deal with questions and issues** through the development of a proposal.

Impact assessment is an aid, not a substitute , for political decision.
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The objectives of the new impact assessment process are to **improve the quality of Commission proposals, to ensure an analysis of the economic, environmental and social impacts of a proposal** and to **improve and simplify the regulatory environment**.

Systematic assessment of impacts should help ensure **consistency** between Community policies and deliver sustainable development. It should lead to proposals that not only tackle the problem they aim to solve but also take into account side effects on other policy areas.

Impact assessment is not a “fiche” to be filled in just before the Commission adopts a proposal. It requires you to think through the proposal’s possible impacts from the beginning of the process and, in addition, to continue to review them until the final drafting of the proposal.

Impact assessment will support better policymaking but will not be a substitute for political decision. Providing better information to Commissioners will enable them to choose between different policy options based on a full understanding of their positive and negative impacts and the synergies and trade-offs between competing objectives. This should result in Commission proposals based on a clear analysis of the impacts of the most significant possible alternatives. The Commission will use the impact assessments to present the rationale for its proposals to Parliament, Council and the public.

2. Coverage

Proposals to be assessed

The impact assessment procedure covers both:

- regulatory proposals such as Decisions, Directives and Regulations, and
- non-regulatory proposals that have an economic, social or environmental impact. These include proposals such as white papers, expenditure programmes, communications on policy orientations and negotiating guidelines for international agreements.

Certain types of proposal will normally be exempt from the impact assessment procedure. These would include proposals like Green Papers where the policy formulation is still in process, periodic Commission decisions and reports, proposals relating to international obligations and executive decisions for example, implementing decisions, statutory decisions and technical updates, including adaptations to technical progress.

To decide whether a proposal should undergo an impact assessment, the policy unit should check that both the criteria below apply:

- the proposal is either :
 - a legislative proposal OR
 - a non-legislative proposalwith social, environmental or economic impacts

AND

- the proposal forms part of the list of key initiatives and/or specific concrete proposals presented as a “priority” in the context of the planning process of the Commission (i.e. included in the Annual Policy Strategy AND/OR in the “priority list” (List 1) of the Commission Work Programme.)

Force majeure

Particularly urgent proposals, in response to cases of emergency or force majeure, may be exempted from the normal impact assessment procedures. Exemption will be the exception to the rule and will be assessed on a case by case basis between the lead DG, the other services concerned and the SG, and, if necessary, between the relevant cabinets.

Impact assessment and ex-ante evaluation

These are two separate exercises: *ex-ante* evaluation focuses on the value for money of financial programmes, i.e. the cost-effectiveness of EU budgetary expenditure, while impact assessment looks at the impact on society at large, i.e. examining the impact of major proposals in terms of sustainability and better regulation.

The Commission's decision to introduce impact assessment does not replace the obligation to carry out *ex-ante* evaluation of programmes and actions resulting in expenditure from the general budget of the European Communities. Likewise, the traditional 'financial fiche' must still be completed in accordance with the Financial Regulations (See also the [Practical Guide on ex ante evaluation](#)¹).

In contrast, it should be noted that *ex-ante* evaluation applies to expenditure programmes but not to pure policy proposals, which can only be subject to impact assessment when the criteria of the present guidelines are met.

However, an expenditure programme may be one of the major proposals selected for impact assessment. In order to avoid unnecessary duplication, where a proposal has been selected for an extended impact assessment but will also incur budgetary expenditure, the *ex-ante* evaluation requirements of the Financial Regulation will be integrated into the Impact Assessment. In this way the requirements of the Financial Regulation will be met.

See also the [Practical Guide on ex ante evaluation](#)².

Former assessment obligations

Following the adoption of the Communication on Impact Assessment in June 2002, all former assessment obligations are replaced by impact assessment from the Commission Work Programme 2003 onwards. These include SME fiches, environmental assessment, gender assessment, business assessments, and regulatory assessment etc.

¹ http://europa.eu.int/comm/budget/evaluation/pdf/ex_ante_guide_en.pdf

² http://europa.eu.int/comm/budget/evaluation/pdf/ex_ante_guide_en.pdf

Guiding principles

When undertaking or reviewing an impact assessment, you should bear in mind the following principles:

Get things in proportion. Adapt the level of analysis to the likely impact of the initiative being examined (principle of proportionate analysis). In other words, the amount of work and the depth of the analysis for the impact assessment should be balanced against the significance of the proposal concerned.

There is no point in spending more on an impact assessment than the actual policy would cost society in terms of its likely impacts. On the other hand, for projects with significant potential impacts, detailed assessment is needed. For such policies, minor refinements in decisions could lead to much better outcomes.

It will, of course, take time to understand the expected impacts fully. Therefore, the analysis can be an iterative process, based on common sense and dialogue: the findings at one stage may identify the need for wider analysis, or, on the other hand, may prove that the case is sufficiently well-documented and that no further examination is needed.

Impact Assessments will, therefore, vary from simple qualitative assessments to more complex quantitative analyses. This will depend on the subject at issue, which will determine the level of detail and accuracy required from the Impact Assessment and with it the choice of analytical techniques.

Think “outside the box”. For example, do not limit your assessment to your own policy area or areas with which you are familiar. Take into account both short and long term considerations. Be open-minded about alternative policy options. Consider the impacts of individual elements of the policy proposal and the effects of more or less ambitious versions of the policy. Use the assessment process to increase dialogue with other services and ensure policy coordination from the onset.

Consult interested parties and relevant experts. In order to be credible, impact assessment cannot be carried out behind "closed doors". Where appropriate, consult with interested parties and relevant experts. Benefit from their knowledge, for example to *gather* new information, *verify* existing data or analyses, and consider *the provisions needed for* compliance and implementation.

Be transparent. Decision-makers and external stakeholders do not want to base their decisions on “black box” analysis: they want to understand the chain of logic in the policy process. Therefore write the impact assessment report in a clear and concise manner, explaining the analysis performed and its findings in such a way that a non-expert can understand it. This should include an explanation of the underlying assumptions and the basis on which they were reached.

Use existing knowledge and experience. Previous evaluations are an essential starting point for an impact assessment. In some cases, enough information may be available from existing sources, such as evaluation reports, statistics and research studies to support an impact assessment. Equally, monitoring and evaluation of the proposed intervention will strengthen future impact assessments and improve the quality of Commission proposals.

Compare negative and positive impacts: Decision-makers want policies where the overall positive impacts are greater than the negative impacts – where the ‘gain’ exceeds the ‘pain’, whether now or later. The Impact Assessment must clearly and systematically present all the positive and negative impacts.

Use your judgement. Every policy is different, so each impact assessment should reflect this. These guidelines provide general rules but use your common sense and judgement when applying them.

3. Impact assessment in the Commission planning cycle

The impact assessment procedure is fully integrated into the Commission's Strategic Planning and Programming cycle.

All initiatives and proposals that Directorate-Generals wish to include in the Annual Policy Strategy (APS) in February and/or later in the Commission's Legislative and Work Programme (WP) in November are in principle subject to impact assessment.

So let's take such a given proposal and see how the corresponding impact assessment is to be organised.

First step

The lead DG defines how the principle of **proportionate analysis** applies to the initiative concerned. This means that the policy unit in charge of the proposal will assess whether an impact assessment is needed and how broad and deep this analysis should be. These considerations will form the:

Preliminary Assessment

This is a first short statement (one or two pages) of the key problems to be addressed by the proposal, its objectives, the regulatory and non-regulatory options and their possible social, environmental and economic impacts. The need for action at EU level should also be justified, according to the principles of subsidiarity and proportionality. See the standard form and instructions given in section 5.

The policy unit responsible for the proposal is normally also responsible for the preparation of the preliminary assessment.

Detailed analysis is not required at this stage: it is a first basic assessment of the proposal to identify the knowledge gaps that need to be filled and to help decide whether an extended assessment is required.

The conclusion of the preliminary impact assessment should clearly indicate whether the lead Directorate-General in charge recommends a more extensive assessment.

Integration with the Strategic Planning and Programming cycle

The preliminary assessment statements must normally be submitted with the Directorate-General's reply to the APS circular each January (or exceptionally submitted at the latest with the response to the Work Programme circular in September where a particular proposal cannot be identified with a sufficient degree of detail at the time of the Annual Policy Strategy).

The Secretariat-General will review the preliminary assessments together with the review of the DGs' replies to the APS circular.

All preliminary assessments will be made available to other DGs for comments in the context of the preparation of the Annual Policy Strategy in February.

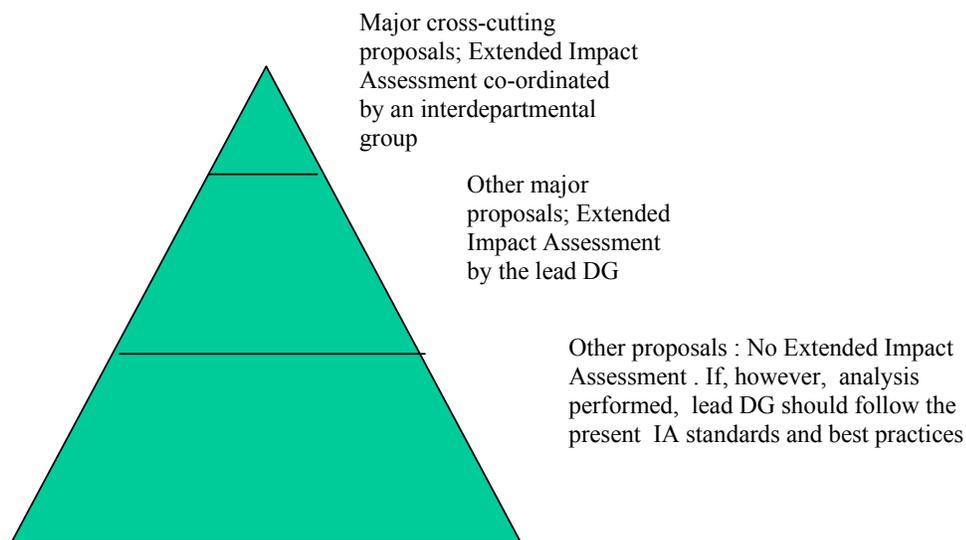
Where new, additional proposals, or more details, are identified for the Commission's Work Programme, the preliminary assessment statements must be completed as early as possible and sent to the Secretariat-General to ensure that additional proposals requiring an extended assessment can be identified as early as possible.

Deciding whether an extended impact assessment is necessary

On the basis of the preliminary assessment statements, the Commission will decide in its Annual Policy Strategy decision and/or Work Programme which proposals will require an extended impact assessment. The Commission will *inter alia* take the following criteria into account:

- Whether the proposal will result in substantial economic, environmental and/ or social impacts on a specific sector or sectors, and whether the proposal will have a significant impact on major interested parties, and/or
- Whether the proposal represents a major policy reform in one or more sectors.

There may be cases where the preliminary assessment will conclude that no further work is necessary. When the lead DGs consider it useful to undertake further analysis they will be encouraged to follow the practices and reporting format set out in the extended impact assessment.



Second step:

Extended impact assessment

This further examination of the impacts of a proposal will take the form of an ‘extended impact assessment’. The guiding principles and the reporting format will generally remain the same for all extended impact assessments (cf. the expert guide for further details on the recommended methods and standards). However, their form, content, volume and degree of detail will vary widely according to the nature of the proposal and its expected significance (principle of proportionate analysis).

Role of the lead DG

The lead DG is responsible for the extended impact assessment and leads the policy design process. The lead DG is free to organise the assessment exercise but will be accountable for:

- the relevance and quality of the analyses,
- proper coordination with other interested DGs and the SG,
- appropriate consultation of interested parties.

The lead DG is free to carry out the assessment internally (likely case for the least complex proposals) or to call on external expertise (analyses may be contracted outside in part or in full).

The lead DG is free to organise itself, as it wants. However, it is expected that in most cases, the unit(s) in charge of the policy should carry out the impact assessment (as impact assessment is to be viewed as the motive force of the policy design process).

Coordination with other DGs

For all extended impact assessments, the lead DG is responsible for informing, consulting and co-ordinating with other interested DGs at a very early stage. Indeed, early coordination between services is essential in order to avoid the single-sector “chimney” approach and to anticipate and resolve potential issues as early as possible in the process. It also allows for an optimal use of all relevant in-house knowledge and expertise.

All services will be informed of the initiatives proposed by other DGs through the preliminary assessment forms at the time of the adoption of the Annual Policy Strategy and the Work Programme. They are free to express their interest in being involved in the corresponding impact assessment by writing to the lead DG and copying this request to the SG. Such involvement may take a number of forms; however, at the very least all DGs should be informed and consulted at the main stages in the drafting of the impact assessment.

When adopting the Annual Policy Strategy or the Commission Work Programme, the Commission will identify proposals where an interdepartmental group will coordinate the extended impact assessment. This will apply for initiatives that have a high cross-cutting dimension and/or that are deemed of major importance by the Commission.

The lead DG will set up and chair the interdepartmental group, which will also contain representatives of the SG and other DGs who wish to participate.

The SG will co-ordinate the basic support structure for the new impact assessment procedures through the SPP/ABM cycle and its network, in particular regarding the selection and monitoring of the proposals subject to impact assessment. In this work it will draw heavily on DGs' experience and knowledge.

Results and reporting

An example of a reporting format is given in Section 6. It may be adjusted to fit each case. It is not a checklist with boxes to tick. It lists a typical set of questions that should be answered during the impact assessment process, based on the evidence made available. The principle of proportionate analysis should always be borne in mind.

The report must be attached to the text of the proposal when it is sent to the interservice consultation (ISC). Note that the content of the final report is the responsibility of the lead DG. Although it is preferable that the Impact Assessment reflect a consensus of the DGs concerned, this is not a must. However, it is mandatory to ensure that all relevant information is made available to all services in the Inter Service Consultation.

No proposal can be submitted for adoption to the Commission if all the completed impact assessment reports are not attached, be this the preliminary assessment alone, or, for proposals selected for extended impact assessment, the extended assessment report as well.

For proposals for which no formal extended assessment has been required, but where analysis has been carried out beyond the preliminary assessment, this should also be reported as appropriate.

In addition, a summary and/or the results of the impact assessment (preliminary or extended) must appear in the explanatory memorandum.

Publication:

The extended impact assessment report will be attached *to the proposal in question* when it is submitted to the Commission for final adoption and adopted as a working document of the services. After adoption by the Commission, the extended impact assessments will be sent to the other institutions along with the proposals and made available on the web.

Quality control

The lead DG will perform the first internal quality checks. It is recommended that the assessment function be involved in that process to ensure that relevant standards are respected.

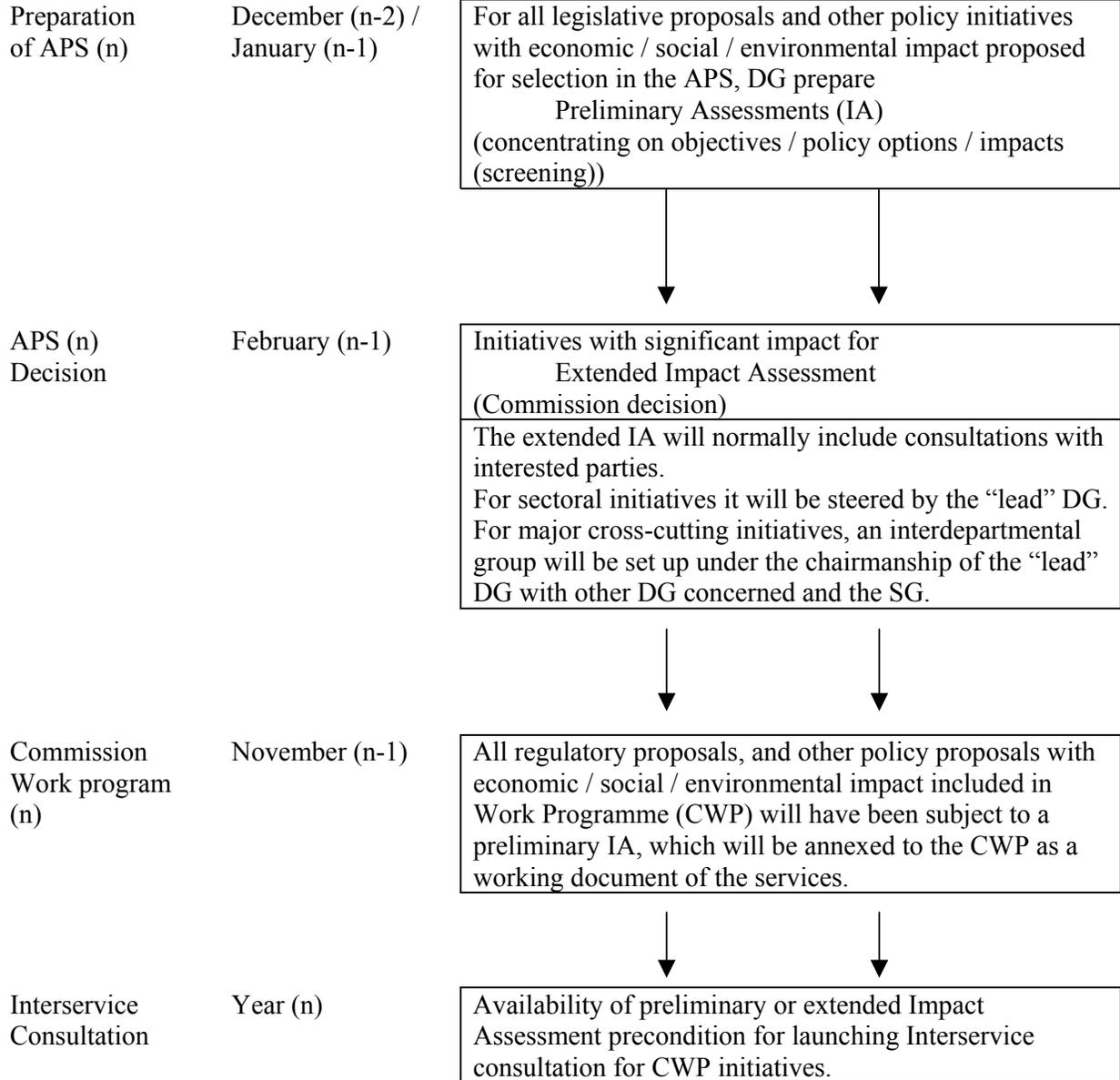
A second check will be done by the DGs participating in the assessment or by other DGs during the interservice consultation.

The SG will be responsible for both overall quality control throughout the process and final quality control, in particular during the interservice consultation. An impact assessment will be submitted together with a proposal for the agenda of the Commission.

Many stakeholders, including but not exclusively Council and Parliament, are watching the Commission's application of the new impact assessment procedure closely. They will take the opportunity to comment on the quality of an impact assessment when the results are released

to the public, i.e. once the Commission makes its proposal. This provides a further informal check which should also be a strong incentive for the lead DGs to improve the quality of their assessments still further.

Timetable



4. Preliminary Impact Assessment

Reporting format (mandatory)

(NOT TO EXCEED TWO PAGES)

Name of the proposal – lead DG – associated DGs

1. PROBLEM IDENTIFICATION

Describe the problem that the policy/proposal is expected to tackle:

2. OBJECTIVE OF THE PROPOSAL

What is the overall policy objective in terms of expected impacts?

3. POLICY OPTIONS

What policy options are available to reach the objective? What range of alternatives will be considered?

How have the principles of subsidiarity and proportionality been taken into account?

4. IMPACTS – POSITIVE AND NEGATIVE

On a preliminary basis, what are the likely positive and negative impacts of the selected options, particularly in terms of economic, social and environmental consequences? Who would be affected?

5. FURTHER ANALYSIS

What further analysis is proposed?

Is a consultation planned? On what basis?

6. FOLLOW-UP

Is a formal extended assessment recommended? Justification if not?

Instructions:

Because this is a *preliminary* assessment, you should keep it short. **You should complete the assessment using existing information and knowledge.** It is better to give a range of possible impacts, or a qualitative assessment of the likely direction and size of change, than to give exact figures when the underlying information does not really support them.

Guidance on how to answer the questions in each of its sections follows:

Section 1: Problem Identification

You should briefly describe the problem in terms of its economic, environmental and/or social impacts, both within and outside the EU, including developing countries. You should show why it is a problem, and state who or what is affected by it. Part 2 of the guide gives more guidance on these issues.

Section 2: Objective of the proposal

Unless you have enough information to support a detailed, quantitative objective, you should limit yourself to quite general statements about tackling the problem. For example, the objective at this stage might be “reduce over-fishing” or “restore fish stocks to sustainable levels”. For more on setting objectives, see Part 2.

Section 3: Policy options

Sometimes, even at this early stage, the nature of the problem and its causes may point strongly to a particular type of policy response. In other cases, your choice may be less clear-cut. The important thing is to keep an open mind, and not to eliminate potentially effective ways to tackle the problem just because you are unfamiliar with them or because they may appear to be more difficult to put in place.

See Part 2 and Annex 3 for more guidance on policy instruments.

Throughout this process, you must always keep in mind that the Commission has an obligation to respect the principles of subsidiarity and proportionality. That means you should check if a Community initiative/action is needed in this area to compensate for lack of results at national level. You should also assess the non-regulatory and legislative options in order to choose a proportionate response. The subsidiarity analysis is specifically required for the proposals made in areas of joint competencies, while the proportionality assessment applies to both exclusive and joint competencies.

Section 4: Impacts – positive and negative

You should **consider a wide range of possible economic, environmental and social impacts**, keeping in mind that interventions can have unintended impacts. Taking this broad view can help to identify possible spillovers and may point to the need to adjust the proposal or to propose mitigating measures. It reduces the risk of unnecessary delays to the proposal later on because some important issue has been overlooked.

You should also try to identify **who** is affected, and **when** the different impacts will occur. For details see Part 2 and the list in Annex 5.

Section 5: Further analysis

Depending on the proposal, you may consider it necessary to:

- deepen your analysis of the cause(s) of the problem;
- refine the objectives;
- further analyse alternative policy options;
- make more detailed and quantified estimates of their impacts;
- define indicators and arrangements to monitor and evaluate the impacts of the proposal once it has been implemented.

You should state whether any further consultation is planned. As far as possible, you should include information on the target groups that are going to be consulted, the purpose and the mode of consultation, and the work involved.

Section 6: Follow-up

You should state whether the proposal needs an ‘extended impact assessment and explain why.

Examples of Preliminary Assessment

NATIONAL EMISSION CEILING DIRECTIVE

DG ENVIRONMENT

1. Problem identification

Acidifying pollutants cause damage to the environment (acid rain), as well as to human health. Sulphur dioxide and nitrogen oxides have direct impacts on human health, and indirect impacts through the formation of aerosols (nitrates and sulphates) that can travel long distances. Ozone affects human health, buildings and vegetation. Ground level ozone and acidification are best tackled together, as many of the same pollutants are responsible for both problems.

2. Objective of the proposal

The Acidification Strategy³ of 1997 set out an approach for tackling the problems caused by these pollutants. The Commission is committed to coming forward with an Air Quality Daughter Directive setting target values for ozone in ambient air, as a follow up to the Air Quality Framework Directive⁴.

The objective of the National Emissions Ceilings Directive is therefore to set national ceilings in kilotons for four pollutants, to be complied with by 2010. The pollutants concerned are sulphur dioxide (SO₂), nitrogen oxides (NO_x), volatile organic compounds (VOC) and ammonia (NH₃). These pollutants contribute to problems of acidification, ground level ozone and eutrophication.

3. Policy options

The Directive will set binding ceilings for emissions of the key pollutants contributing to these problems. At this stage we would like to leave it open to Member States to choose the means by which they comply with the ceilings. The proposed approach therefore allows member states maximum flexibility in implementation. Alternative approaches could have been to develop specific legislation sector by sector, but would be less flexible and likely to be less cost effective.

4. Impacts - positive and negative

An extensive cost benefit analysis of different possible scenarios and targets will be performed. The environmental benefits appear to be significant at this stage, though need to be defined. The economic costs also appear to require investigation.

- ◆ The economic costs of different options will be assessed by identifying technical abatement options for each pollutant. Given the targets and options available, we will use the RAINS model to choose a set of emission ceilings that will

³ Commission Communication on a Community strategy to combat acidification (COM(97)88 final and COM(97)88 final/2 (addendum).

⁴ Council Directive 96/62/EC on ambient air quality assessment and management

meet environmental targets at the lowest costs for Europe as a whole, by putting most weight on reducing emissions where the costs are relatively low (per unit effect). In other words, analysis will identify how the emission reductions needed to meet different environmental targets for ozone and acidification could be apportioned among Member States in a cost-effective manner.

- ◆ For the social aspect, the principal issue is the distribution of costs between sectors. Given that most of the costs arise in power generation and similar upstream industry and would therefore get passed on into a wide range of products, the impacts on end users (consumers) would be widely dispersed and no individual group will be particularly harshly affected. We have no reason to believe that there would be an aggregate employment loss associated with the Directive.

- ◆ To assess risks to human health we will use risk factors to model the likely health effects at different ambient pollution concentrations, and how changes in concentrations of the different pollutants would increase chronic and acute effects. This will allow us to quantify the physical impacts (premature deaths, morbidity effects). These impacts will then be valued using a value of statistical life approach.

- ◆ Environmental damage. For ozone there is some information on estimating, for example, changes in crop yields. However, for acidification we will have to use a "critical load" and "gap closure". Given the state of knowledge in the area, this work will represent a good attempt to tackle the issue in a systematic way.

5. Further analysis

Discussion of air quality issues takes place regularly in the Air Quality Steering Group - an expert group to which member states, NGOs (both business and environmental) and some outside experts are invited. All the main technical aspects of both the studies will be extensively discussed in the group. All reports will be widely distributed for comments throughout the process.

A number of reports on both the costs *and* benefits of different acidification and ozone reduction scenarios will be generated. These reports will provide an extensive description of the modelling approach and the methodological assumptions employed (rather complex in the case of transboundary air pollution). This work is under way and the most recent reports are available on the DG ENV website.

6. Follow-up

An extended impact assessment will be necessary. Modelling of the economic, social and environmental impacts has begun, and the methodology is established, but the analysis needs to be extended over the coming year to produce a proportionate analysis of the proposal.

REVISION OF LEGISLATION ON PRE-PACKAGING – RANGES

DG ENTREPRISE

1. Problem identification

In 2000, the need for simplification and improvement of existing legislation on sizes of pre-packed consumer goods was identified in a Simpler Legislation for the Internal Market (SLIM) exercise. The SLIM team recommended a Community-wide coherent and updated harmonised regulatory system.

In the follow-up, the Commission services are now examining the justifications for Community legislation.

Due to market and regulatory developments, the original justifications for existing Directives 75/106 and 80/232, fixing mandatory ranges of sizes for certain products, can be put into question:

- Barriers to trade: It is questionable whether differences in national legislation can be considered as "justified" trade barriers which need harmonisation, taking into account the mutual recognition principle and related case-law.
- Consumer deception: Unit price labelling requirements today allow consumers to compare the price of different sizes and cast doubt on the need for fixed mandatory ranges of sizes to protect consumers from being misled.

2. Objective of the proposal

The overall policy objective is a properly-functioning internal market, based on competition, innovation and consumer choice. The proposed revision represents a major policy review in this area.

3. Policy options

The basic approaches available to reach the objective is to correct regulatory and market failures either by freeing or mandating ranges.

The policy instruments under consideration include 1) deregulation, both by the EU and by Member States, 2) regulation of sectors where justified, at EU level only (as advised by SLIM), and 3) voluntary standardisation. None of these options are excluded at this stage.

4. Impacts - positive and negative

No policy change: The likely impacts of a continuation of the existing situation can be found in the alternative options described below, as it consists of a mixture of national legislation, EU harmonisation and voluntary standardisation, depending on the sector. In more general terms, negative impacts of the "no policy change" option are a complex and unclear regulatory framework, leading to possible barriers to trade.

The likely positive and negative impacts of the alternative policy options are as follows:

Deregulation at EU and national level: Likely positive impacts include enhanced innovation, competition and consumer choice. On the other hand, this option could have the negative impact of increasing retailer buying power, negative scale effects and inefficient transport.

Regulation of sectors where justified, at EU level only: Likely positive impacts include reduced buying power of large retailers, increased economies of scale and efficient transport leading to environmental benefits. On the other hand it might affect innovation, consumer choice and competition negatively.

Voluntary standardisation: The flexibility of this option could allow for rapid adaptation to innovation. Other likely positive impacts include reduced retailer buying power and increased consumer choice. However, it could potentially have a negative impact on competition.

A very wide range of groups is affected by each of these options: all producers, retailers and consumers of pre-packed goods. Most producers and retailers are small and medium-sized companies (SMEs).

5. Further analysis

So far, information and data has been gathered through: existing sources (e.g. statistics, reports, case law, etc.), specific studies carried out, for example, on the relationship between pre-packaging regulation and innovation, and on consumers' views on pack sizes, informal interservice consultations with interested DGs, consultations with stakeholders and national experts through workshops, bilateral contacts and requests for written comments.

The information collected so far has been analysed in a recent Working Paper, setting out the policy issues. An Interactive Policy Making (IPM) survey and an on-line interactive discussion forum are just about to be launched to test the ideas set out in the Working Paper. These consultations will be announced in so-called "soft media" to better attract citizens' participation. Making use of the Commission's business test panel is being considered. Based on the results of the consultations, the advantages and disadvantages of each policy option will be analysed. For the moment, this analysis is planned to be carried out internally. More information can be found at: <http://europa.eu.int/comm/enterprise/prepack/index.htm>

6. Follow-up

The issue of sizes of pre-packed consumption goods covers a very wide-ranging area, which concerns the protection of economic interests of consumers and many businesses. For this reason and due to the knowledge gaps identified above, an extended assessment is recommended.

5. Extended impact assessment

Reporting format (illustrative)

Name of the proposal – lead DG – associated DGs

1. WHAT ISSUE/PROBLEM IS THE POLICY/PROPOSAL EXPECTED TO TACKLE?

- What is the issue/problem in a given policy area expressed in economic, social and environmental terms including unsustainable trends?
- What are the risks inherent in the initial situation?
- What is (are) the underlying motive force(s)?
- What would happen under a “no policy change” scenario?
- Who is affected?

2. WHAT MAIN OBJECTIVE IS THE POLICY/PROPOSAL EXPECTED TO REACH?

- What is the overall policy objective in terms of expected impacts?
- Has account been taken of any previously established objectives?

3. WHAT ARE THE MAIN POLICY OPTIONS AVAILABLE TO REACH THE OBJECTIVE?

- What is the basic approach to reach the objective?
- Which policy instruments have been considered?
- What are the trade-offs associated with the proposed option?
- What “designs” and “stringency levels” have been considered?
- Which options have been discarded at an early stage?
- How are subsidiarity and proportionality taken into account?

4. WHAT ARE THE IMPACTS – POSITIVE AND NEGATIVE – EXPECTED FROM THE DIFFERENT OPTIONS IDENTIFIED?

- What are the expected positive and negative impacts of the options selected, particularly in terms of economic, social and environmental consequences, including impacts on management of risks? Are there potential conflicts and inconsistencies between economic, social and environmental impacts that may lead to trade-offs and related policy decisions?
- How large are the additional (“marginal”) effects that can be attributed to the policy proposal, i.e. those effects over and above the “no policy change” scenario? Description in qualitative terms and quantified as far as possible. Monetisation may be used where appropriate.
- Are there especially severe impacts on a particular social group, economic sector (including size-class of enterprises) or region?
- Are there impacts outside the Union on the Candidate Countries and/or other countries (“external impacts”)?
- What are the impacts over time?
- What are the results of any scenario, risk or sensitivity analysis undertaken?

5. **HOW TO MONITOR AND EVALUATE THE RESULTS AND IMPACTS OF THE PROPOSAL AFTER IMPLEMENTATION?**

- How will the policy be implemented?
- How will the policy be monitored?
- What are the arrangements for any *ex-post* evaluation of the policy?

6. **STAKEHOLDER CONSULTATION**

- Which interested parties were consulted, when in the process, and for what purpose?
- What were the results of the consultation?

7. **COMMISSION DRAFT PROPOSAL AND JUSTIFICATION**

- What is the final policy choice and why?
- Why was a more/less ambitious option not chosen?
- Which are the trade-offs associated to the chosen option?
- If current data or knowledge are of poor quality, why should a decision be taken now rather than be put off until better information is available?
- Have any accompanying measures to maximise positive impacts and minimise negative impacts been taken?

Instructions

The “Extended Impact Assessment Report” will be part of the interservice consultation on the proposal and will be made public when the Commission adopts the proposal. The report should describe the results of the impact assessment and **justify the choice made in the Commission’s proposal**.

The report should follow the format given in these guidelines, answering the questions so that a reader can follow the logic of the proposal’s development and understand why a given option was chosen. Pages 26 and 28 of Part 2 - Reference Manual - give further guidance on how to complete the sections.

It is possible to use the structure of the Extended Impact Assessment Report as a **basis for reporting analysis internally** throughout the impact assessment process. It is not, of course, possible to write Section 7 on the “Commission Proposal and Justification” until after the Commissioner has made a choice.

What issue/problem is the policy/proposal expected to tackle?

You should analyse the problem and its underlying causes in detail, and in particular, identify the different groups affected (see the section 1 of the reference Manual). You should identify any potentially unsustainable trends and, in particular, potential inconsistencies between the economic, environmental and social dimensions of the problem. The baseline scenario should aim to quantify how the situation will develop if no action is taken.

What main objective is the policy/proposal expected to reach?

The general objectives you identified in the preliminary assessment should be expressed more precisely (see Part 2 - section 2). If relevant, you should show how these objectives relate to any previously established objectives in the same policy area or in other areas, including the policy objectives set out in the [Commission's proposal for an EU sustainable development strategy](#).

What are the main policy options available to reach the objective?

You should show how the options you have selected are better than those you have rejected. This should make it clear how the options proposed will achieve the objectives of the proposal while satisfying the requirements of subsidiarity and proportionality, keeping in mind what kind of competencies you are dealing with (exclusive or joint). For example, the proposal should rule out any provisions that go beyond the Community competencies, or any illogical, superfluous or excessive constraints on the national, regional or local authorities. You should also explain how the options perform in an efficient, effective and consistent manner (see Part 2 - section 3).

What are the impacts – positive and negative – expected from the different options identified?

You need to show in detail the economic, environmental and social impacts of your proposal. You should aim to quantify the impacts wherever possible. Uncertainties about the scale of impacts, including the sensitivity of the results to changes in important variables, should also be reported. You should clearly describe any potential conflicts or trade-offs between different policy areas, and highlight any particular adverse impacts on specific social groups, sectors or regions, including impacts outside the EU, such as in developing countries. You should also look at factors that could impact on compliance with the proposal. More detail on these issues is in Part 2 - section 5.

How to monitor and evaluate the results and impacts of the proposal after implementation?

You should describe the arrangements for monitoring the implementation of the proposal and its impacts. You should define the indicators that will be used, and how the information needed will be collected. You should specify the procedures for evaluating the proposal, including the timing of the evaluations, their focus, and responsibility for their organisation. Finally, you should explain how the outcome of monitoring and evaluation would feed back into policy. See Part 2 section 8 for further material on monitoring and evaluation.

Stakeholder consultation

This section should summarise any consultations held – how they were organised, who was invited to take part and what views were expressed. You should indicate how the consultation influenced the development of the proposal, and any remaining critical or dissenting opinions.

Commission draft proposal and justification

This section cannot be completed until the Commissioner(s) decide the form the proposal should take, and it cannot be fully finalised until the full Commission has adopted the proposal. See Part 2 section 6 for details.

If the options assessed involved trade-offs between economic, environmental and social impacts, you should set out the reasons for choosing one option over the others.

Presenting the Results to the College

Impact assessment does not necessarily generate clear-cut conclusions or recommendations regarding the final policy choice. However, as an important aid to decision-making, **the results need to be presented in a transparent and comprehensible way** to provide the basis for a political discussion on the relative advantages and disadvantages of the relevant options.

Responsibility for the final policy choice always lies with the Commissioners.

In presenting the analysis, it is good practice for you to:

- present all options, rather than a single “take it or leave it” choice. Highlight the differences in impacts between each option, and between more or less ambitious variants of the same option;
- give a clear and transparent summary of the positive and negative impacts of each option, that is, the benefits and costs to society. Impacts should be given in qualitative, quantitative and monetary forms where possible and be proportionate;
- display aggregated and disaggregated results. For example, the results of a cost-benefit analysis should never be shown solely as the net difference between costs and benefits, but should always show the individual impacts which make up the net outcome;
- state clearly any critical assumptions and uncertainties;
- show clearly any distributional effects;
- show how each option compares against the criteria of efficiency, effectiveness and consistency;
- summarise the other policy issues (stakeholder consultation, problem identification, etc);
- describe the data used, explaining why one set of data was preferred over another, whether the information has been validated, and what are its strengths and shortcomings;
- indicate the analytical methods used.

The advantages of this process to the decision-maker are that it:

- **highlights trade-offs** between affected groups and/or between the economic, environmental or social impacts, as well as any win-win situations associated with the options;

- helps to **improve the design** of options in order to minimise trade-offs and maximise win-win situations;
- **identifies accompanying measures** needed to mitigate disproportionate negative distributive effects.