

Euro-Med Workshop on Better Regulation

Regulatory Impact Assessment: Its Role in the Development of Policies – A European Union Perspective

Background Paper

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1. Impact Assessment – why?

Impact assessment is designed to help in structuring and developing policies. It identifies and assesses the problem at stake and the objectives pursued. It helps to identify the main options for achieving the objectives and analyses their likely impacts in the economic, environmental and social fields. It outlines advantages and disadvantages of each option and examines possible synergies and trade-offs.

It consists of a set of logical steps to help structure the preparation of Commission proposals. By testing the need for intervention at the EU level and by examining the potential impacts of a range of policy options, it should lead to improvements and simplification of the regulatory environment.

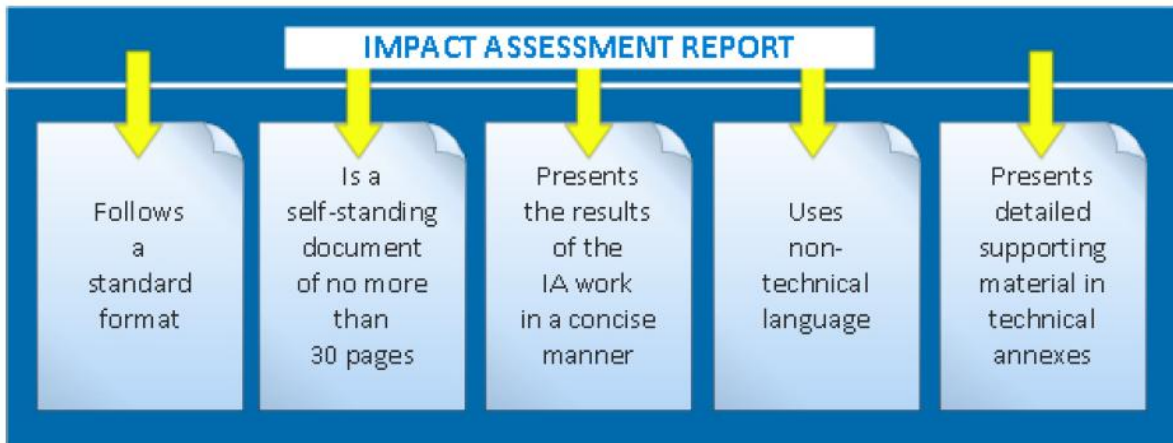
Impact assessment is an aid to political decision-making, not a substitute for it. The impact assessment informs the political decision-makers of the likely impacts of proposed measures to tackle an identified problem, but leaves it to them to decide if and how to proceed.

To summarise, the Commission's impact assessment system:

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

2. What is an IA?

An "Impact Assessment" (IA) is a **process that prepares evidence** for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impacts. The results of this process are summarized and presented in an "**IA Report**".



It needs to answer a number of standardised key questions:

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

The report should be no longer than 30 pages. Supporting documents, such as results of studies, expert reports or summaries of stakeholder views, should be presented in annexes. The report must nevertheless be a self-standing document which presents the analysis and all relevant results of the IA work, including summaries of information that are presented in annexes.

The report should be written in clear and simple language. A non-specialist reader should be able to follow the reasoning and understand the impacts of each of the options. To enhance the clarity and readability of the report, tables and diagrams should be used to summarise key points. The report can be drafted in English, French or German, and is generally not translated. The executive summary must, however, be translated into all official languages of the EU. The IA report commits only the Commission services involved in preparing it and does not prejudice the final decision to be taken by the Commission.

3. How long does it take?

Typical countdown for preparing an impact assessment:



4. Data gathering

Good quality data – facts as well as figures – are an essential part of any IA. Particular attention needs to be paid to quality and credibility of data.

This information may include monitoring or evaluation reports from previous or similar programmes, earlier IAs, studies carried out by or for the Commission, statistical data from Eurostat and others, studies and research by EU agencies, information gathered from stakeholders (hearings, conferences), results of consultation documents such as Green Papers or data available at national or regional level in the Member States and from third countries or international organisations (e.g. World Bank, OECD). It may also be necessary to use external experts to gather data and undertake some of the analysis.

5. Using external expertise

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

Scientific and technical expertise is important for developing public policies. The Commission has produced guidelines for collecting and using such expertise. Expert groups and, in particular, scientific committees set up by the Commission and EU Agencies are a prime source of scientific advice. External contractors should follow the key analytical steps set out in the IA Guidelines. If external experts are used to carry out public consultations, they need to adhere to the Commission's minimum standards on consultation.

6. Consulting interested parties

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

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

Why consult?

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

When and what?

Depending on the objective pursued and the issue at stake, consultation can be carried out on different elements of the impact assessment (nature of the problem, objectives and policy options, impacts, comparison of policy options, assessment of costs and benefits).

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

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

Minimum consultation standards

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

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

Reporting on the consultation in the IA

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

7. Key analytical steps of an IA:

What is the problem?

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

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

The baseline scenario

The problem definition must include a clear baseline scenario as the basis for comparing policy options. The aim of the baseline scenario is to explain how the current situation would evolve without additional public intervention – it is the ‘no policy change’ scenario. A clear baseline scenario also provides the basis for comparing policy options. The baseline scenario depends on whether there are already national and EU policies in place:

- if there is no EU policy, the baseline means the continuation of ‘no EU policy’. The ‘no EU policy’ includes the expected effects of legislation which has been adopted but not yet implemented
- where there is already an EU policy, the baseline is the continuation of the current policy without any change, i.e. without any new or additional EU intervention

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

To develop the ‘no policy change’ scenario, the IA needs to consider a wide range of factors other than EU intervention. These include:

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

A good baseline should have a strong factual basis and, as far as possible, be expressed in quantitative terms. The baseline projection has to provide a clear indication of how serious the problem is, or to what extent it would become more serious without immediate intervention, and whether there are irreversible consequences.

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

What are the policy objectives?

All Commission IAs must have clear objectives which are directly related to solving the problems which have been identified. Only clearly defined objectives will make the level of ambition visible, show that the proposal respects the principles of subsidiarity and proportionality, help ensure coherence of Commission policies, and allow for identification and comparison of options for action and their likely impacts. Without clear objectives, it is impossible to evaluate the extent to which the action has generated its intended effects.

The IA should:

- set out objectives that are clearly linked to the problem and its root causes, respect the subsidiarity and proportionality principles, and correspond to Treaty objectives and

Commission priorities and strategies (such as the Lisbon and Sustainable Development Strategies or the EU Chart of Fundamental Rights);

- set out general objectives and translate them into specific and, where appropriate, operational objectives, thus setting a hierarchy of objectives.
- express the objectives in SMART terms (Specific, Measurable, Achievable, Realistic, Time-dependent)

What can be done? – Policy options

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

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

How to identify and screen policy options

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

- all of the options should be realistic
- Even if a particular option seems to be a clear front-runner, other promising options should not be excluded outright.
- the option of ‘no EU action’ must always be considered as a viable option, except in cases where the Treaties lay down a specific obligation to act
- where legislation is already in place, better enforcement and implementation should always be considered, perhaps with improved guidance
- less can be more: again where legislation is already in place, a ‘doing less’ option could be considered. If existing measures do not produce the desired effects, creating a new instrument may not be the best remedy. Streamlining, simplifying or even repealing the existing legislation might produce better results
- always consider alternative approaches to ‘classical’ forms of regulation. Consider the full range of alternative actions available to the Commission. Is self-regulation a feasible option? Could the objectives be met through a voluntary agreement? Is an information and education campaign sufficient? Could the objectives be met by introducing a new or amending an existing European Standard?
- take account of existing EU policies, including those which Member States are still transposing and, if possible, relevant proposals which are still being discussed in the European Parliament and Council if you have not included them in the baseline. You

should also take account of existing or planned Member State policies or international agreements that might affect the impact of an option

- do not just look at the different legal (implementation) options, but also at the content. The choice between Directives, Regulations, Recommendations etc. should be clearly driven by what needs to be done to achieve the objectives
- examine closely options that can count on considerable support, but be aware that public and/or political support alone cannot be the sole determining factor in defining and analysing alternative options. You should be careful about discarding too quickly options which do not have considerable support from a certain sector
- options should be 'complete' and sufficiently well developed to allow you to differentiate them on the basis of their performance against the criteria of effectiveness, efficiency and coherence with overarching EU objectives (see Chapter 9). You should also avoid 'bundling' individual elements/sub-options of different options into a 'preferred' option after the analysis, as this makes it difficult to assess the impact of the preferred option as a whole against the baseline. Where you do adopt this approach, you should carry out an analysis of this preferred option.

What are the likely economic, social and environmental impacts?

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

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

In presenting the impacts of different policy options the IA should assess the impacts of policy options as net changes compared to the 'no policy change'/baseline. The credibility of an IA depends to a large extent on providing results that are based on reliable data and robust analysis, and which are transparent and understandable to non-specialists. This exercise will usually require an inference from the collected data, either formally through statistical analysis or model runs, or more informally by drawing on an appropriate analogy with measured impact or activities. This assessment should go beyond the immediate and desired aspects (the direct effects) and take account of indirect effects such as side-effects, knock-on effects in other segments of the economy and crowding out or other offsetting effects in the relevant sector(s).

Examples of possible economic, social and environmental impacts can be found in the IA guidelines (pp. 33-38), available under link on the last page of this paper.

Special attention needs to be given to impacts on small and medium-sized businesses (SMEs) as these usually find it more burdensome to comply with legislation:

The "SME test"

Due to their size and scarce resources, SMEs can be affected by the costs of regulations more than their bigger competitors. At the same time, the benefits of regulations tend to be more evenly distributed over companies of different sizes. SMEs may have limited scope for benefiting from economies of scale. SMEs in general find it more difficult to access capital and as a result the cost of capital for them is often higher than for larger businesses.

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

The IA should analyse whether SMEs are disproportionately affected or disadvantaged compared to large companies and if so, options should cover alternative mechanisms and flexibilities in approach that might help SMEs to comply.

Comparing the options

The following criteria should be used for the comparison of options:

- effectiveness of the option in relation to the objectives,
- efficiency of the option in achieving the objectives,
- coherence of the option with overarching EU objectives, strategies and priorities.

The options should be compared against the baseline scenario.

It must be clear that all these assessments are based on evidence, including quantitative data. The reasoning that leads from the evidence to the assessments has to be fully transparent.

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

Monitoring and evaluation arrangements

Policy makers need to be able to check if implementation is 'on track' and the extent to which the policy is achieving its objectives. When a policy is not achieving its objectives, they also need to know if this is the result of problems with the design of the policy, or of poor implementation e.g. was the problem analysis accurate? Were the objectives relevant and

attainable? Was implementation entrusted to parties capable of understanding the policy and willing to apply it? Is poor implementation the result of weak administrative capacity?

Monitoring and evaluation arrangements, together with indicators, provide valuable information in this regard. The IA should therefore outline what these arrangements will be and define core indicators for the main policy objectives.

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

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

8. Where to find more information:

- European Commission Better Regulation website
http://ec.europa.eu/governance/better_regulation/index_en.htm
- Impact Assessment guidelines
http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm
- Commission work programme http://ec.europa.eu/atwork/programmes/index_en.htm
- Detailed information about forthcoming initiatives – roadmaps
http://ec.europa.eu/governance/impact/planned_ia/planned_ia_en.htm
- Past IA reports and IAB opinions
http://ec.europa.eu/governance/impact/ia_carried_out/ia_carried_out_en.htm