



Guidelines on Impact Assessment

Key requirements

- IAs must set out the logical reasoning that links the problem (including subsidiarity issues), its underlying drivers, the objectives and a range of policy options to tackle the problem. They must present the likely impacts of the options, who will be affected by them and how.
- Stakeholders must be able to provide feedback on the basis of an Inception Impact Assessment which describes the problem, subsidiarity related issues, objectives, policy options and an initial consideration of relevant impacts of these policy options.
- A 12-week internet-based public consultation covering all of the main elements of the IA as part of a broader consultation strategy to target relevant stakeholders and evidence.
- IAs must compare the policy options on the basis of their economic, social and environmental impacts (quantified as far as possible) and present these in the IA Report.
- Certain elements must be included in the final IA Report. These include: (i) a description of the environmental, social and economic impacts and an explicit statement if any of these are not considered significant; (ii) a clear description of who will be affected by the initiative and how; (iii) impacts on SMEs; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.
- The draft IA Report must be presented to the Regulatory Scrutiny Board for its scrutiny. A positive opinion of the Board is necessary before an interservice consultation can proceed.
- The IA report must be complemented by a 2-page executive summary sheet available in all languages.

1. INTRODUCTION

Who Should Read These Guidelines?

All officials involved in the preparation of an impact assessment (IA) should read these guidelines including officials and managers who are responsible for ensuring the quality of impact assessments in the lead DG.

More detailed guidance is also available in a separate "tool box" which accompanies this guide. This is aimed at those directly involved in preparing the various elements of an IA. These "tools" contain important guidance on specific issues such as when an IA is necessary, on the identification of the various social, environmental and economic impacts, including on SMEs and competitiveness, and many other aspects regarding methodological or other aspects in the preparation of an impact assessment.


What is Impact Assessment and when is it required?

Impact assessment is about gathering and analysing evidence to support policy making. In this process, it verifies the existence of a problem, identifies its underlying

causes, assesses whether EU action is needed, and analyses the advantages and disadvantages of available solutions.

IA promotes more informed decision-making and contributes to Better Regulation which delivers the full benefits of policies at minimum cost while respecting the principles of subsidiarity and proportionality. However, IA is only an aid to policy-making/decision-making and not a substitute for it.

An IA is required for Commission initiatives that are likely to have significant economic, environmental or social impacts.

Provided that the above conditions are fulfilled, impact assessments should be carried out for both legislative and non-legislative initiatives as well as delegated acts and implementing measures, taking into account the principle of proportionate analysis. When the above conditions are not met, no impact assessment is needed regardless of the nature of the initiative  18.

18 See tool on when an impact assessment is necessary for more detail and cases when no IA is necessary such as when the Commission has no discretion over the policy content etc.

What are the procedural steps?

The IA work is led by the Directorate-General(s) responsible for the relevant policy initiative. DGs should establish as early as possible in the policy planning/political validation process whether an IA is required on the basis of the associated Roadmap. If it is established that an IA will be carried out, the Roadmap should be developed and presented as an Inception IA.

The Inception IA provides a first description of the problem and possible policy options along with an overview of the different planned stages in the development of the initiative, including foreseen impact assessment work and consultation of stakeholders. If an impact assessment will not be carried out, this should equally be explained in the regular Roadmap.

The subsequent preparation of an IA involves the following main steps:

- (1) The creation of an interservice group (ISG) which will steer the IA process and collectively prepare the IA report. For those initiatives in the Commission's work programme (or other important/sensitive initiatives), the ISG will be established and chaired by the Secretariat-General;
- (2) Finalisation of the Inception IA by the ISG and publication on the Commission's website, allowing stakeholders to be informed and to provide feedback and evidence in relation to the problem, possible policy options and their likely impacts and subsidiarity considerations.
- (3) The preparation of a consultation strategy by the ISG including a mandatory 12-week internet-based open public consultation  19. The consultation strategy should ensure that stakeholders' views are sought on all key impact assessment questions;
- (4) The collection and analysis of all relevant evidence, including data, scientific advice, other expert views, stakeholder input, etc;
- (5) Drafting of the IA Report;
- (6) Submission of the draft IA report to the Regulatory Scrutiny Board for quality review, followed by revision to take account of its recommendations for improvement;
- (7) Subject to a positive opinion by the Board, submission of the IA report to inter-service consultation together with the accompanying policy initiative.


The IA should begin as early as possible during the process of policy-development subject to the political validation requirements. The time needed to prepare an IA will vary from case to case. It should also be remembered that there is close link with ex-post evaluations or Fitness Checks of existing policy frameworks and programmes, whose results should be ready in time to feed meaningfully into the IA of a new proposal. The timing of the two processes may need to be carefully planned therefore.

An Impact Assessment Report presents the final results of the IA process and accompanies the draft proposal through the Commission decision-making process. The Commission's Regulatory Scrutiny Board (RSB) scrutinises the quality of all draft IAs and issues an opinion on the draft IA Report. A positive opinion by the RSB is required before an initiative can proceed.

Following adoption, the final IA Report is published and transmitted to the co-legislators together with a 2-page executive summary sheet and the adopted initiative.

2. THE KEY QUESTIONS AND PRINCIPLES OF IMPACT ASSESSMENT

IA is a tool to help structure reflection and conduct analyses informing policy design. It is not a list of tasks to tick off. There is no recipe for the perfect IA. Given the widely differing nature of Commission initiatives, the best way to carry out an IA and present its results will vary from case to case.

However, all impact assessments must answer a set of key questions and respect a number of principles. An impact assessment should be comprehensive, proportionate, evidence-based, open to stakeholders' views, unbiased, prepared collectively with relevant Commission services, embedded in the policy cycle, transparent and of a high quality.  20

The Questions An Impact Assessment Should Answer

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| 1. | What is the problem and why is it a problem? |
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| 2. | Why should the EU act? |
| 3. | What should be achieved? |
| The Questions An Impact Assessment Should Answer | |
| 4. | What are the various options to achieve the objectives? |
| 5. | What are their economic, social and environmental impacts and who will be affected? |
| 6. | How do the different options compare in terms of their effectiveness and efficiency (benefits and costs)? |
| 7. | How will monitoring and subsequent retrospective evaluation be organised? |

The process of finding answers to these questions is necessarily iterative. The IA process should start from broad definitions of the problem, the objectives and the possible solutions and then narrow them down to what is most relevant. The questions are also interrelated. Compliance with subsidiary and proportionality, for example, can only be fully verified once objectives are set and the impacts of alternative options assessed. The following should guide the IA process:

- (1) When making choices about the focus and depth of the analysis, the IA should concentrate on what is relevant to inform decision-making, leaving out what is not.
- (2) The results of any relevant evaluations of the existing policy framework should be used as the starting point for the IA. The expertise of other services in the Commission should also feed into the IA in order to consider and properly assess all relevant issues.
- (3) The most appropriate methods should be identified to collect data and analyse impacts. Where necessary, external studies may be contracted out to provide input on specific elements.
- (4) A consultation strategy should be designed, keeping in mind the need to consult on all key IA issues. The IA Report should corroborate the conclusions of the analysis with stakeholder views and justify any significant differences. The synopsis report summarising the results of stakeholder consultation should be integrated into the IA Report as a mandatory annex.
- (5) Throughout the IA Report, conclusions should be substantiated with evidence (e.g. data, estimations, scientific findings) together with appropriate citations and, if this is not possible, it should be explained why. Stakeholder views should also be referred to.

2.1. Question 1: What is the problem and why is it a problem?

An IA starts by verifying the existence of a problem, identifying who is affected, estimating the problem's scale, analysing its causes and consequences, and assessing its likelihood to persist in the absence of (further) EU policy intervention.

The answer to this question should give policy-makers the information needed to decide whether there is a problem for which a policy response may be warranted.

Better regulation is about regulating only when necessary and in a proportionate manner. High quality policy proposals are built on a clear problem definition and understanding of the underlying factors and behaviours (so-called "problem drivers"). The first step of an IA, therefore, is to (i) verify the existence of a problem and identify who is affected; (ii) estimate the problem's scale and analyse its underlying causes and consequences; and (iii) identify the EU-dimension and assess the likelihood that the problem will persist. A key input to this assessment should be relevant evaluations or Fitness Checks of existing policy frameworks as well as stakeholder feed-back.

A problem can be caused by several factors, such as the existence of market failures, behavioural biases, regulatory inefficiencies or the need to ensure respect of fundamental rights. It may already have negative consequences or simply present a risk of

negative occurrences. Developing a clear understanding of these underlying factors is important, using relevant internal and external expertise including scientific advice.

It is equally important to make clear in the analysis how individuals, enterprises or other actors are affected by the problem:

- How much does the "problem" affect their daily life?
- Whose behaviour would have to change for the situation to improve?


Addressing these questions will ensure that the analysis stays concrete, focused, close to stakeholders' concerns and mindful of the practical implications of any initiative. This will facilitate the subsequent identification of proportionate policy alternatives and analysis of impacts.


The problem description in the IA Report should be clear and specific. It should focus on the issues to be addressed by the initiative under consideration, avoiding lengthy presentations of general issues and/or Commission objectives in the relevant policy area.

2.2. Question 2: Why should the EU act?

Having established the existence of a problem, its scale and the causes, the IA analysis should verify whether Member States alone could resolve it sufficiently and whether the EU has the competence to act (i.e. a legal basis), and would be best placed to do so.

The answer to this question should give policy-makers the information needed to decide whether a policy response at the EU level is needed.

The fact that the Union has the competence to address a problem (i.e. that there is a legal basis for it) does not automatically mean the EU is best placed to solve it. In areas that fall outside its exclusive competence, the Union must act in accordance with the principle of subsidiarity  21, i.e. act only where Union action would be more effective than action taken by the Member States at central, regional or local level.

The IA should verify whether EU action in areas outside its exclusive competence is compatible with the principle of subsidiarity. This is not to be taken for granted and it is important to remember that, pursuant to the Treaty of Lisbon, the respect of the principle of subsidiarity is closely scrutinised by the other EU institutions and by national Parliaments and that Union acts can be annulled by the Court for non-respect of the principle.  22

When assessing whether or not the subsidiarity principle is respected the following key questions should be reviewed: whether the problem addressed has transnational aspects which cannot be adequately addressed by action by Member States and whether action at EU level would produce greater benefits compared with action at the level of Member States due to its scale or effectiveness.

This assessment is likely to be an iterative process. Preliminary analyses in the Inception IA and early in the IA process should clarify the legal basis and indicate whether advancing further at EU level would make sense. A final verification of compliance with the subsidiarity principle will only be possible once all relevant information is collected and the analysis of impacts is completed. In addition, the assessment of whether an initiative is proportionate is clearly linked to the assessment of subsidiarity and the need to match the nature and intensity of a given measure to the identified problem.

Assessing subsidiarity necessarily involves elements of political judgement, particularly when evidence is inconclusive and/or stakeholder views diverge. All elements should, therefore, be presented objectively in the IA Report, providing the basis for a political appreciation by the College. General statements and circular reasoning should be avoided in favour of concrete arguments, specific to the issues being analysed and substantiated with qualitative, and where possible, quantitative evidence.


2.3. Question 3: What should be achieved?

The IA should set out what EU policy should achieve.

The objectives of policy action should be clearly identified, including the level of policy ambition and the criteria against which alternative policy options would be compared and the success of any initiative assessed.

For reasons of transparency and accountability, any EU policy intervention should have clear objectives. These should help in:

- Establishing the logical chain between the identified problems and the solutions considered;
- Clarifying the relationship between an initiative's specific goals and any horizontal EU objectives and any other agreed political goals in the area;
- Highlighting any trade-off between policy goals;
- Setting out the criteria for comparing the different policy options;
- Defining indicators to measure performance and progress towards the declared objectives;
- Establishing the operational monitoring and evaluation framework for the implemented policy measure.

Objectives should be as S.M.A.R.T.  23 as possible. Providing general objectives is important to put the proposed initiative into the overall context of the Union's policies and to assess later if and how the initiative has contributed. However, the IA Report should focus on the presentation of the more specific and operational objectives (for the preferred option) the proposed initiative aims to achieve. For non-legislative policy initiatives, it may be sufficient to set out the general and specific objectives, leaving the definition of more detailed operational objectives to the relevant follow-up initiatives.

2.4. Question 4: What are the various options to achieve the objectives?

There are different ways to achieve policy objectives. The IA should allow for an informed decision about which one to pursue. To do so, available options should be identified and screened with a view to selecting the most relevant ones for further analysis and comparison.

At the end of this process, the most relevant alternative policy options should have been identified for further examination in the impact analysis stage.

It is important to consult widely about alternatives, think outside the box and give due consideration to all different options. This is one of the key functions of an impact assessment process. When well done, this is perhaps the impact assessment component most appreciated by external stakeholders. When badly done, it tends to be the most criticised and significantly undermines the credibility of the whole exercise and its usefulness for political decision making. Keeping an open mind is important even if, in many cases, the IA analysis may start from an idea, stakeholder view or political statement, about what a policy proposal may look like. Often there is already an existing policy framework in place in the area under analysis and this affects the breadth of choices realistically available but initial ideas should be comprehensively tested in the IA process.

However, existing policies may have fallen short of their objectives, proved too costly or no longer be fit for purpose. Also, views on the best policy typically differ (among stakeholders, Member States, policy-makers, Commission services and experts). In addition, a solid justification should be given for any relevant option that is discarded early on.

This should be done through an iterative process:

- (1) Start by considering the widest range of policy alternatives both in terms of content and instruments. Consider regulatory and non-regulatory means, less or more prescriptive measures, actions at national, EU and international level.

When identifying options, the guiding principle should be whether and how a certain measure could influence the drivers of the problem and change the relevant behaviours in a way that would lead towards the desired objectives. The IA Report will need to show

that there is a clear logic between the problems, objectives and policy interventions under consideration.

When designing the policy options, always consider:

- The option of changing nothing (also known as the "baseline"): The "baseline scenario" should always be developed and used as the benchmark against which the alternative options should be compared. As such, it should take account of both national and EU policies in place and reflect possible developments of these in the absence of new EU-level action. It should also try to anticipate important technological or societal developments such as the pervasive role of the internet and other ICTs;
- The option of improving implementation and enforcement of existing legislation; or doing less / simplifying existing legislation;

- Options that take account of new technological developments. All new initiatives should be "digital and internet ready" and operate effectively both in the digital and the physical worlds. ↩ 24 ;
- Alternative policy approaches: e.g. different policy content / approaches to reach the objective;
- Alternative policy instruments: e.g. non-regulatory alternatives; self- or co-regulation ↩ 25; market-based solutions, regulatory alternatives; international standards ↩ 26, and their mix;
- Alternative scope: for instance, is the "think small first" principle taken into account; are micro-enterprises excluded from the scope of any proposed legislation ↩ 27.

Consider options which have been proposed by stakeholders ↩ 28 and/or are likely to be proposed during the legislative process but do not discard a priori options with little support or facing strong opposition. ↩ 29

(2) Screen the previously identified policy alternatives. In many cases, little analysis will be needed to justify discarding some alternatives (e.g. those not technically feasible, not legally viable, difficult to implement, disrespecting fundamental rights or with other unacceptable or disproportionate impacts). Options that clearly restrict the scope for national decision making over what is needed to achieve the objectives satisfactorily should also be abandoned early on (as they would fail to respect the principle of proportionality).

(3) Having screened the options, the most relevant ones should be retained, together with the baseline, for further detailed examination.

- "Straw man" options (i.e. clearly more costly or less effective alternatives retained only to highlight the benefits of the preferred option) should be avoided. They do not strengthen the argument for any preferred option but rather undermine the credibility of the IA;
- If it is difficult to identify at least two credible alternatives on top of the baseline, make an extra effort to think 'outside of the box' (e.g. have all choices been considered?). If there are no other alternatives, the focus of the subsequent analysis should be on determining the detailed design of the retained option, for example, by considering alternative "sub-options" for some of the individual elements of the proposal or different implementation modes;
- After a first assessment of impacts, it may be necessary to go back to the drawing board and experiment with modifications to the original alternatives to further improve them. This will typically be the case when options fail to meet the objectives in a satisfactory way or when they are likely to lead to disproportionate negative effects (of any type, for instance, on fundamental rights, SMEs, competitiveness, trade partners, regions, developing countries, etc.). An option should not be judged inferior before having reviewed possible improvements and/or mitigating measures to reduce its negative impacts.

The IA Report does not need to describe this process in detail. It should, however, demonstrate that all relevant options have been considered, taking into account stakeholders' views and justifying why some options were discarded without a full assessment of their impacts. A sufficiently detailed description of the alternatives retained should be provided.

A particularly strong justification should be provided when, exceptionally, only one option is retained for full assessment against the baseline.

2.5. Question 5: What are the impacts of the different policy options and who will be affected?

Once a set of policy options is selected, a robust assessment should be carried out of their economic, social and environmental impacts and of who will be affected.

At the end of this process, policy-makers should know to what extent different policy

options would meet their objectives, with what benefits, at what cost, with what implications for different stakeholders, and at what risk of unintended consequences.

To support policy decisions that deliver the best balance between benefits and costs, the IA analysis must assess all the relevant advantages and disadvantages of the retained policy alternatives ("the options") against the reference of the baseline. Once again, it is best to do this through an iterative process that starts with a wide reach and then focusses, and deepens, the analysis on the most relevant impacts, being ready to go back and improve the retained options before finalizing.

Using internal and external expertise along with stakeholders' knowledge is particularly helpful when analysing impacts. The consultation strategy, any external studies and the ISG work should be organised in a manner which allows views to be collected and results tested with regard to all elements of the impact analysis.

2.5.1. Identify all potential impacts of the options.

For all retained options, the impact assessment should specify how they would tackle the identified problems and meet the policy objectives.

To do this, there is a need first to identify the changes that a proposal would imply for those affected, notably those who would have to comply with any new legislative requirement, those who would have to implement and enforce it and those who are expected to be the final beneficiaries:

- What actions and measures would affected parties need to take (to comply or to enforce compliance)?;
- Would these realistically be taken (balance between compliance costs and costs for public authorities involved in ensuring compliance)?;
- Would this allow the objectives to be reached?

Answering these questions at the very beginning of the analysis is important to ensure that the technical assessment of the impacts remains concrete and closely related to the practical implications of the various policy options.

Answering such questions will also highlight how different options can trigger different changes and thus have different types of impacts. A wide range of possible impacts should be reviewed across the economic, social and environmental policy areas, going beyond the most obvious consequences of the proposed policy. All potentially important impacts should be identified regardless of whether or not it will be possible to assess them precisely. It is important not to "miss" a significant impact as this may affect the overall comparison of options or weaken the case for the Commission's proposal later on. The impact assessments should, in particular, examine the impact of the different options on fundamental rights, when such an assessment is relevant and address the potential exposure to fraud in the context of spending programmes.

Potentially important indirect impacts should also be considered, i.e. positive or negative consequences that are incidental to the main purpose of the initiative (such as those stemming from an increase in the accumulated costs borne by a party, evasive behaviour by those who need to comply, or positive spill-overs from one affected sector to another).

Both positive impacts (i.e. the benefits) as well as negative impacts (i.e. the costs or adverse environmental and social impacts) should be identified. A positive impact for one party can be negative for another. It is therefore important to identify who would be specifically affected by each impact.

It is also likely that a policy option will require some sort of IT system or network to automate business processes, publish/exchange information, deliver online services via web-based Portals, etc. It means that the impact related to the implementation of new or the adaptation of existing ICT solutions should be assessed. The possibility of re-using what exists already and not "reinvent the wheel" should not be overlooked. A "digital screening" and possible further ICT impact analysis may be needed (see the tool on ICT impacts in the BR toolbox). "

At the end of this analysis, all potential impacts— positive or negative - should be mapped out according to their expected magnitude and likelihood and to the specific parties that would be affected. The following classifications can be used when describing identified impacts:

- Broad nature: economic, social and environmental.
- Specific nature, for instance: increases (or decreases) in compliance costs, i.e. those costs incurred by the relevant parties (businesses, citizens etc.) to comply with any new legislative requirement, their sub-components (administrative burdens, labour costs; equipment costs etc.) and the administration and enforcement costs incurred by the responsible authorities; gains (or falls) in market efficiency, competitiveness, innovation; impacts on health, quality of the environment, combating climate change, levels of education and training, fundamental rights, employment and skills, social inclusion, poverty etc.;
- Relation with the underlying initiative: direct impacts are those directly generated by a policy measure. Indirect (or second-round) impacts arise as a result of the behavioural changes prompted by the direct impacts and often affect third parties and can be just as significant as direct impacts.
- Affected parties, groups or regions: businesses of different sizes (SMEs or not), citizens, workers, learners, consumers, public administrations, third country actors, developing countries, different territories and regions (less developed or prosperous regions, cities, rural areas, border regions, overseas territories etc.);
- Frequency and certainty: long/short term, one-off, recurrent; certain or likely (risks).

While all of the above classifications are useful in principle, each analysis should use the categories that are most appropriate for the initiative at hand. Importantly, the IA Report should always be transparent about the methodological choices made to assess impacts, the underlying reasons particularly where non-standard approaches are deployed).


2.5.2. Select the significant impacts.


The choice of impacts to be retained for deeper assessment should be clearly justified, taking account of their:


- Expected overall magnitude;
- Relevance for specific stakeholders (enterprises and in particular SMEs, trading partners, economic sectors, consumers, learners, workers, public administrations, regions, developing countries etc.);
- Importance for Commission horizontal objectives and policies.

The expected significance of impacts should be assessed in terms of changes relative to the baseline. In making the selection, the principle of proportionate analysis should be applied. However, it is important not to leave out anything that is of relevance for political decision-making. The choice should take account of stakeholders' views and relevant expertise, including within the Interservice Group.


2.5.3. Assess the most significant impacts.

All relevant impacts should be assessed quantitatively, if possible  30, as well as qualitatively. Similarly, impacts should be monetized whenever possible.

When quantifying, spurious precision should be avoided and ranges provided, complemented by qualitative comments. In many cases, quantification will rely on a given set of assumptions. These should be clearly presented. Whenever an assumption is particularly important or uncertain, sensitivity analysis should be used to check whether changing it would lead to significantly different results.  31

There are several methods to quantify impacts, both in terms of overall methodological approach  32 and specific techniques for individual types of impacts. For each case, the most appropriate method should be used. The choice of method should be clearly justified and explained in the IA Report.

There is no best method which would apply to all possible Commission initiatives. There is, however, an obligation to make the most sensible methodological choice given the specificities of the case at hand, the availability of data and the requirement to carry out a proportionate analysis. In all cases, methodological complexity is not an excuse for not presenting the practical implications of different options for affected parties. Similarly, the fact that it may not be possible to monetize, or quantify, some impacts does not mean they should not be taken into due account. All significant impacts should be analysed regardless of the nature of the available methodology to do so.

When quantitative analysis is not possible or proportionate, impacts should be assessed qualitatively. Also the qualitative analysis should be rigorous and thorough, focussing on the practical implications for affected parties. As for quantitative assessments, important underlying assumptions will have to be stated. The conclusions should rely on available theory and evidence  33, including on illustrative examples, while also referring to

stakeholder views. They should acknowledge limits and clearly distinguish between facts, expert opinions and stakeholder views. If a broad order of magnitudes cannot be given, a qualitative reasoning should be provided of why one option is considered likely to have larger (or smaller) impacts than another.

In the case of both quantitative and qualitative analysis, it is important to remember that:

- Changes should be assessed relative to the baseline scenario. Normally, this will evolve overtime (for instance as a result of on-going policies). Therefore, changes should not simply be determined relative to the current situation but to how the latter would evolve in the absence of a new planned initiative;
- Different impacts are likely to occur at different times (with costs often being incurred early on and benefits emerging only later). This should be reflected in the assessment, discounting monetized estimates as appropriate when these are available;
- Impacts should be assessed from the point of view of society as a whole although distributional effects and cumulative burdens on individual parties should also be proportionately assessed and considered. Whenever impacts are aggregated, you should make sure you avoid any double-counting (for instance, businesses transferring increased compliance costs on consumer prices, public authorities imposing fees to cover for the costs of enforcing a regulation).

Assessing impacts can be particularly challenging at the EU level. First, data across the EU may not be available or comparable. Secondly, final impacts will often depend on Member States' choices at the implementation stage (or on future delegated and implementing acts). It is often difficult, therefore, to provide accurate estimates, at the Commission proposal stage, even of direct impacts such as compliance or implementation costs. Nevertheless, "known unknowns" should not be cast aside in the analysis. On the contrary, they should be readily acknowledged. In case of lack of data or uncertainties, the qualitative assessment needs to

be strengthened (e.g. based on theoretical approaches), while being transparent about the impact that such uncertainties may have on the comparison of options.

At the end of this analysis, there should be a solid understanding of the extent to which each option achieves the objectives, with what benefits and at what costs at the aggregate level and for affected parties. Potentially disproportionate impacts (e.g. on fundamental rights, SMEs, competitiveness, specific communities, workers' health and safety, employment, poverty, regions or Member States, developing countries etc.) should have been identified along with any significant risk of unintended consequences. This will help compare the options in terms of their coherence with horizontal EU objectives as well as to identify potential mitigating measures for any preferred option.

The IA Report should summarize the results of the impact analysis in an accessible manner. It should be clear and transparent about any limitations (e.g. data, methodological) and risks of unintended consequences. While the more technical aspects of the assessment are important, the final concrete impacts for individuals, enterprises or public administrations, and where possible the societal or geographical distribution of such impacts, should be kept at the forefront of the analysis and the IA Report. Aggregated costs and benefits should be clearly distinguished from distributional impacts and transfers. The choices made in the selection of relevant impacts and in the analytical

methods should be clearly justified in the annexes. Data sources should be provided and underlying assumptions illustrated in relation to any quantification.

2.6. Question 6: How do the options compare?


Based on the assessment of the various impacts and their distribution across affected stakeholders, the IA should compare the different options with regard to their effectiveness, efficiency and coherence, as well as their compliance with the proportionality principle.

At the end of this process, the IA should present the relevant information for policy-makers to make a choice and, where appropriate, suggest a preferred option.

Having assessed the likely economic, social and environmental impacts, as well as their distribution across stakeholders, the IA analysis should bring together the results in a clear comparison of the options. This should facilitate the identification of the preferred option.

Cost-benefit analysis, cost-effectiveness analysis, compliance cost analysis and multi-criteria analysis are the most commonly used methods to do this. Choosing one (or a mix of them) depends on several factors including the number and nature of impacts and objectives, the extent to which benefits and costs can be monetized (or quantified) and the relevance of distributional concerns.

The IA does not need to identify a preferred option, but it should attempt objectively to compare the options against common criteria, in particular:

- The extent to which different options would achieve the objectives (effectiveness);
- The benefits versus the costs (efficiency);  34
- The coherence of each option with the overarching objectives of EU policies (coherence).

The compliance of the options with the proportionality principle, and in particular of any preferred option, should also be considered by answering additional questions such as:

- Whether the option goes beyond what is necessary to achieve the objectives satisfactorily?;
- Whether the scope of the option is limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?;
- Whether costs for the Union, national governments, regional or local authorities, economic operators or citizens, are minimised in relation to the objective to be achieved?;
- Whether the form of action (choice of instrument) is as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?

When comparing the options, the underlying analysis and hypotheses should be kept in mind: the robustness of the comparison should be verified, sensitivities and limitations of the analysis highlighted, trade-offs between objectives flagged and uncertainties

that could significantly affect the result of the comparison referred to.

The IA Report should present the results of this comparison in an accessible manner, for example in a summary table, clearly flowing from the previous analysis. When no preferred option is indicated, this should be clearly stated. In case the IA leads to the conclusion that no proposal is warranted, this should be communicated in the IA Report that should still be published.

2.7. Question 7: How would actual impacts be monitored and evaluated?

Having the entire policy cycle in mind, the IA should identify monitoring and ex-post evaluation arrangements to track whether the policy measure actually delivers the intended results and to inform any future revisions of the policy.

At the end of this process, policy-makers should know how the policy will be monitored and evaluated, allowing for future policy-adjustments whenever needed.

Policy makers and stakeholders need to be able to check if policy implementation is 'on track', and the extent to which it is achieving its objectives, at what costs and with what benefits. To do so, one should start from a clear idea of how the situation should look like in the future if the initiative is successful. What will be different and for whom after a few years of implementation? How can this be verified?

Actual results are likely to differ from those estimated or desired, regardless of the quality of the IA and the proposed initiative. However, when a policy is not achieving its objectives, or the costs and negative impacts are more significant than expected, it is important to know if this is the result of unexpected exogenous factors, problems with the design of the policy, amendments introduced during the legislative process (if relevant) or poor implementation.

Monitoring and evaluation arrangements (including the definition of a set of indicators), provide valuable information in this regard. The IA should outline, therefore, what these arrangements will be. Core indicators should be defined for the main policy objectives in relation to the preferred option where one is stated. Where no preferred option is presented in the IA Report, monitoring and indicators should refer to the specific objectives of the initiative.

Indicators must allow measuring to what extent the objectives of the policy have been achieved (and on potential negative impacts). Indicators on transposition, implementation and enforcement in Member States might also be useful.

Underlying data should be easily available and the cost of data collection, proportionate. If lack of data was a significant concern for the IA, the IA Report should sketch out how this issue will be addressed for the future policy evaluation.

According to the Commission's evaluation rules, all its activities have to be evaluated on a regular basis. For spending programmes evaluation is compulsory (including anti-fraud measures) and many other policy instruments also contain a review clause. Where, such a review is requested it should be based on an evaluation of the existing policy framework. 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.

The IA Report should sketch out core indicators relating to the operational objectives and the main monitoring and evaluation provisions of the preferred option (including any relevant data collection aspects).

3. SUMMING IT ALL UP: THE IMPACT ASSESSMENT REPORT

The Impact Assessment Report should summarise and present the final results of the IA analysis. Annexes should be used for the more detailed / technical parts of the analysis. The Report should be presented as a Staff Working Document.

As the previous pages have made clear, the IA Report is not the IA. The IA is an iterative process supporting the design of a policy proposal. The IA Report is a document through which you communicate the results of this process to policy makers to inform their decision and to stakeholders, to show the evidence basis on which a Commission has taken a decision.

The IA Report should be transparent, objective and balanced.

While IA analysis can be complex, the IA Report should be written with non-expert readers in mind. In most cases, a main report of some 30-40 pages of text, accompanied by annexes for the more detailed technical parts of the analysis, should be sufficient.

A reader should easily be able to understand what the problem being addressed is, why EU level action is appropriate, what the pros and cons of different courses of action are and who would be affected. Stakeholder views and how these have been

considered should be transparently referred to throughout the IA Report. All external material used (studies, reports, scientific findings etc.) should also be systematically referenced.

Certain elements must be included in the final IA Report. These include (i) a description of the environmental, social and economic impacts and an explicit statement if any of these are not considered significant; (ii) a clear description of who will be affected by the initiative and how; (iii) impacts on SMEs; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.

To allow for an easily accessible overview of the main findings of the IA, an executive summary sheet of a maximum of 2 pages should also be prepared. It should be presented as a separate Staff Working Document and be translated into all EU languages.

4. FROM IMPACT ASSESSMENT TO POLICY-MAKING

The IA process should have allowed for the identification of one (or more) preferred options. When developing the proposal, it is useful to double-check a number of key questions to ensure that the final proposal linked to the IA is fit for purpose and in line with better regulation principles.

Policy-makers should cross-check that the final proposal would contribute positively to regulatory fitness in the EU.

It is useful to test the preferred option for its regulatory fitness at the end of the process. This is not necessary when the impact assessment indicates no (further) EU policy response is needed. However, it should always be done when a legislative option has been chosen.

Verifying regulatory fitness for a proposal requires checking issues some of which will have already been touched upon during the impact assessment process:

- Does the draft (legal) text fully comply with subsidiarity?;
- Is the proposal proportionate?;
- Is it in line with the Charter of Fundamental Rights?;
- Are the draft legal provisions as simple and clear as possible? Do they avoid unnecessary deviations from international standards? Can they be made easier to implement?;
- Has the "Think Small First" principle been applied? Could microenterprises be exempted from the scope of the initiative, and if not, why?;
- Do the draft legal provisions take into account the challenges and opportunities offered by developments in ICTs (e.g. simplified monitoring and information reporting)?;
- Without affecting the overall achievement of the objectives, is there scope to modify some of the legal provisions so as to reduce:
 - Expected compliance costs for SMEs and any other relevant stakeholder;
 - Any negative impact on sectoral EU competitiveness;
 - Any potential negative impacts on international trade, developing countries etc.;
 - Impact on human rights in the partner country in relation to its obligations arising from international treaties (for proposals with an external dimension);
 - Any other impact (including social, environment, or those on specific groups, territorial areas, Member States, innovation, etc.).
- Without affecting the overall cost of the proposal, are there still ways to modify some of the proposed legal provision so as to increase the effectiveness and coherence of the proposed text?

For legislative initiatives, the Commission's political appreciation of its final proposal is set out in the Explanatory Memorandum, which describes how the proposal conforms to the subsidiarity, proportionality and better regulation principles. After Commission

adoption of the concerned policy initiative, the IA is transmitted to the European Parliament and to the Council who are likely to discuss its content and quality. The European Parliament and the Council have made commitments to provide additional analyses to support any substantive amendments they propose.