

Chapter III

Guidelines on impact assessment

Key requirements

- IAs must set out the logical reasoning that links the problem (including subsidiarity issues), its underlying causes, 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.
- IAs must compare the policy options on the basis of their economic, social and environmental impacts (quantified costs and benefits whenever 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 following the "SME test" in the Toolbox; (iv) impacts on competitiveness; and (v) a detailed description of the consultation strategy and the results obtained from it.
- Initiatives supported by an impact assessment (IA) must have a validated entry in Decide, an inception impact assessment published for stakeholder feedback. An interservice group (ISG) must also be established to steer the preparation of the IA. This ISG may be chaired by the lead DG or by the Secretariat-General for politically important files. 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.
- The draft IA report must be presented to the Regulatory Scrutiny Board for its scrutiny.
- A positive opinion of the Board is necessary before a formal interservice consultation can be launched. The RSB will generally only issue two opinions.
- 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 preparing 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 Toolbox. 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 linked to the preparation of an impact assessment.

What is an impact assessment and when is it required?

The impact assessment process is about gathering and analysing evidence to support policymaking. 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.

Impact assessment 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, impact assessment is only an aid to policy-making/decision-making and not a substitute for it.**

All new financial interventions which entail significant expenditure (in excess of €5 million) should be accompanied by an ex-ante evaluation as required by the Financial Regulation. The major programmes of the multi-annual financial framework will generally be accompanied by impact assessments which fulfil the requirement for an ex-ante evaluation but which also entail consultation of stakeholders and scrutiny by the Regulatory Scrutiny Board.

An impact assessment 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 initiative²¹.

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 and seek confirmation through the political validation process.** Following validation, an **inception IA should be prepared by the lead DG and agreed by the Secretariat-General. It is then published as early as possible by the Secretariat-General on the Commission's web site²² with a view to inform stakeholders and seek their feedback.**

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.

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

²¹ See Tool #9 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.).

²² <http://ec.europa.eu/info/law/better-regulation/initiatives>

programme (or other important/sensitive initiatives), the ISG will be established and chaired by the Secretariat-General. It is recommended that a member of the lead DG's impact assessment support service participate in the ISG;

- (2) Following publication of the inception IA on the Commission's website, stakeholders will be able to provide feedback and evidence in relation to the problem, possible policy options and their likely impacts and subsidiarity considerations. This feedback needs to be considered and integrated into the work of the ISG as appropriate;
- (3) The preparation of a consultation strategy by the ISG including a mandatory 12-week internet-based public consultation²³. 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 (RSB) 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 interservice 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 that supports a new initiative. The timing and organisation of the two processes may need to be carefully planned therefore.

An IA report presents the final results of the impact assessment process and accompanies the draft initiative through the Commission decision-making process. The Commission's **Regulatory Scrutiny Board** scrutinises the quality of all draft IAs and issues one or more opinions on the draft IA report which are also available during the decision-making process. A positive opinion of the RSB is required before an initiative can proceed.

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

2. THE KEY QUESTIONS AND PRINCIPLES OF IMPACT ASSESSMENT

Impact assessment 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.

²³ Where the evaluation and IA are prepared in parallel ("back to back") it is possible to conduct only one public consultation as long as relevant stakeholders are consulted on all the main elements of the 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 be of a high quality²⁴.

The questions an impact assessment should answer	
1.	<i>What is the problem and why is it a problem?</i>
2.	<i>Why should the EU act?</i>
3.	<i>What should be achieved?</i>
4.	<i>What are the various options to achieve the objectives?</i>
5.	<i>What are their economic, social and environmental impacts and who will be affected?</i>
6.	<i>How do the different options compare (effectiveness, efficiency and coherence)?</i>
7.	<i>How will monitoring and subsequent retrospective evaluation be organised?</i>

The process of finding answers to these questions is necessarily iterative. The 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 subsidiarity 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-related issues. The conclusions of the IA report should be supported

²⁴ See details in Tool #1 on *Principles, procedures and exceptions*.

by the analysis of stakeholder views and justification given where there are any significant differences. The synopsis report summarising the results of stakeholder consultations 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 policymakers 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 definition of the problem and its underlying causes (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 size and 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. These evaluations will also describe issues related to the application of Union law such as infringements and other problems related to the existing intervention.

A problem can be caused by several factors, such as the existence of market failures, behavioural biases, regulatory inefficiencies or a failure to respect fundamental rights. A problem may already have negative consequences or simply present a risk of such consequences. 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 size and 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 policymakers 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 that 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 subsidiarity²⁵, i.e. Union action should be necessary and deliver added value compared to the actions of the Member States at central, regional or local levels.

In areas outside its exclusive competence, the IA should verify whether EU action 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 principle²⁶.

The following key questions should be reviewed when assessing whether or not the subsidiarity principle is respected: 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 to action taken solely at the level of the Member States due to its scale or effectiveness.

This assessment is likely to be an iterative process. Preliminary analyses in the inception impact assessment 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.

²⁵ See Article 5 of the Treaty on European Union.

²⁶ http://ec.europa.eu/dgs/secretariat_general/relations/relations_other/npo/

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, what the initiative aims to achieve 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 (such as simplification and improved efficiency of existing interventions);
- 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.²⁷ 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

²⁷ Specific, Measurable, Achievable, Relevant and Time-bound.

most appreciated by external stakeholders. When done badly, 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, policymakers, 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 as well promoting the principles of eGovernment²⁸;
- The option of improving implementation and enforcement of existing legislation; or simplifying existing legislation, or improving the efficiency of existing interventions by reducing unnecessary regulatory costs (including administrative costs);
- Options that take account of new technological developments and ICTs to lower the costs of implementation whilst ensuring timely data availability. All new initiatives should be "digital and internet ready" and operate effectively both in the digital and the physical worlds²⁹;

²⁸ For example, the eGovernment Action plan 2016-2020 COM(2016) 179 and the principles of "digital by default", "once-only" and "cross-border by default".

²⁹ Adaptive Governance and Internet inclusive Legislation

- Alternative policy approaches: e.g. different policy content or approaches to reach the objective;
- Alternative policy instruments: e.g. non-regulatory alternatives; self- or co-regulation³⁰; market-based solutions, regulatory alternatives; international standards³¹, or a mix;
- Alternative scope: for instance, is the "think small first" principle taken into account; are micro-enterprises excluded from the scope of any proposed legislation³².

Consider options which have been proposed by stakeholders³³ and/or are likely to be proposed during the legislative process but do not discard *a priori* options with little support or facing strong opposition³⁴.

- (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 go beyond 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 can 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

³⁰ See the principles for better self- and co-regulation in the Toolbox and at <https://ec.europa.eu/digital-agenda/en/news/principles-better-self-and-co-regulation-and-establishment-community-practice>; and the community of practice: <https://ec.europa.eu/digital-single-market/en/community-practice-better-self-and-co-regulation>

³¹ The IA report will need to recall the reasons for any divergence from international standards – where they exists – as well as from regulation with similar ambition in major jurisdictions whenever regulatory divergence may have a significant negative impact on trade and investment flows. Possible inconsistencies with obligations undertaken at the WTO or in international agreements should also be explained.

³² Where micro-enterprises must be covered by legislative proposals for public policy reasons recourse to adapted solutions and lighter regimes will be sought concerning all forms of regulatory burden including, in particular regarding administrative requirements – see COM(2011) 803 final *Adapting EU regulation to the needs of micro-enterprises*.

³³ For example, from stakeholders, experts, Member States, other EU institutions and third country partners.

³⁴ If such options are exceptionally excluded early on, this should be clearly spelled out alongside a solid justification.

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 improve them further. 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 and innovation, 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, policymakers 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 finalising.

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 actions realistically be taken in practice (for example, risks of non-compliance may high if compliance costs for business are substantial but this risk may be reduced if public authorities are obliged to promote 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. Failure to identify a significant impact may affect the overall comparison of options or weaken the case for the Commission's proposal later on.

Where relevant, the impact assessments should examine the impact of the different options on fundamental rights and the potential exposure to fraud in the context of spending programmes. In the Interinstitutional Agreement on Better Law-Making,⁴ the Commission has also committed to identify the costs and/or missed benefits of not acting at Union level (the "cost of non-Europe"³⁵). This will complement the assessment of EU added value undertaken in the context of any preceding evaluation or fitness check.

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 reusing

³⁵ Where no Union legislation exists, the "cost-of non-Europe" are the potential benefits which are forgone by deciding not to introduce new Union legislation. In other cases, where Union legislation already exists, the cost of non-Europe would be the benefits forgone if that legislation is repealed.

what exists already should not be overlooked. A "digital screening" and possible further ICT impact analysis may be needed.³⁶

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 subcomponents (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.

³⁶ See Tool #27 on *The digital economy and society & ICT systems*

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 qualitatively and quantitatively whenever possible³⁷. Quantification of impacts will not be possible in all cases but it is expected that efforts are systematically made for REFIT initiatives.³⁸ This allows a more transparent presentation of the benefits arising from simplification and measures to reduce unnecessary burdens that do not undermine policy objectives. Similarly, impacts should be monetised 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 results³⁹.

There are several methods to quantify impacts, both in terms of overall methodological approach⁴⁰ 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 ideal 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 monetise, or quantify, some impacts does not mean they should not be taken into 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 and the reasons for not having undertaken quantification explained in the IA report. 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 evidence⁴¹, including on illustrative examples, while

³⁷ I.e. if they are susceptible of being quantitatively estimated through a sound methodology and if the required data exists and can be collected at a proportionate cost.

³⁸ See Tool #2 on *The Regulatory Fitness programme and the REFIT Platform*.

³⁹ Ranges of outcomes or confidence interval should then be provided rather than precise results.

⁴⁰ For instance, general vs. partial equilibrium approaches, bottom up vs. top down methods.

⁴¹ For instance regarding a subset of the targeted sector/Member States for which data and reliable analyses are available.

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, 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 ongoing 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 monetised 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, on SMEs⁴², 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 summarise and present the results of the impact analysis in way which is accessible to the non-specialist. 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

⁴² See Tool #22 on *The SME test* (impacts on SMEs).

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 policymakers 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 multicriteria 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 monetised (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);⁴³
- 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?;

⁴³ Alternatively, the extent to which objectives can be achieved for a given cost (cost effectiveness).

- 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.
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At the end of this process, policymakers should know how the policy will be monitored and evaluated, allowing for future policy-adjustments whenever needed.
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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 cost 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. The Interinstitutional Agreement on Better Law-Making⁴ envisages a more systematic use of monitoring and evaluation provisions in basic acts to measure the performance of Union legislation and to improve the quality of subsequent evaluations and impact assessments.

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.

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. The IA report should be transparent, objective and balanced as it helps inform the Commission's decision-making and presents the evidence base underpinning the Commission's decision. Annexes should be used for the more detailed and technical parts of the analysis. The report should be presented as a Staff Working Document. A template for the format of the impact assessment report can be found on the relevant pages of GoPro.

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 should be sufficient accompanied by annexes as appropriate.

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.

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

It is useful to check the consistency of the legal proposal or initiative with the conclusions of the impact assessment. 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 certain 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? Has the recast technique been considered for proposed amendments to existing legislation (see Chapter IV)? Do the draft provisions 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?;
- Have potential impacts on innovation been considered?
- Has the need to include monitoring and evaluation provisions been considered (see Chapter V)?;
- Do the draft legal provisions take into account the challenges and opportunities offered by developments in ICTs (e.g. simplified monitoring and information reporting, reduced administrative burdens, etc.)?;
- 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, developing countries, 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 have committed themselves in the Interinstitutional Agreement on Better Law-Making to discuss its content and quality as well as to provide additional analyses to support any substantive amendments they propose and to take full account of any additional materials the Commission may make available.