

2014 REVISION OF THE EUROPEAN COMMISSION

IMPACT ASSESSMENT GUIDELINES

PUBLIC CONSULTATION DOCUMENT

BACKGROUND

The European Commission is determined to meet policy goals at minimum cost, ensuring maximum benefits to citizens, businesses and workers while avoiding all unnecessary regulatory burden. This is key to support growth and job creation – allowing the EU to ensure its competitiveness in the global economy while maintaining social and environmental sustainability.

EU legislation must be smart in achieving its objectives: demonstrating clear added value, delivering full benefits at minimum cost and respecting the principles of subsidiarity and proportionality. The final result must be a simple, clear, stable and predictable regulatory framework for businesses, workers and citizens. EU legislation must be fit for purpose and remain so as problems evolve, new solutions emerge and political priorities change.

To achieve this, the European Commission ("the Commission") employs a wide set of smart regulation tools covering the full policy-cycle, from when a policy is designed to when it is implemented, evaluated and revised.¹ Impact assessment (IA) is one such tool, operating at the early stage of the policy cycle, when proposals are being developed. It contributes to the quality of policy-making by ensuring that Commission initiatives and proposals for EU legislation are prepared on the basis of transparent, comprehensive and balanced evidence on the nature of the problem to be addressed, the added value of EU action and the economic, social and environmental costs and benefits of alternative courses of action for all stakeholders. While the adoption of a policy proposal remains a political decision by the Commission, better informed policy-making contributes to better policies.

The European Commission's impact assessment system was first established in 2002 and covers all proposals likely to have significant impacts. It has undergone continuous strengthening over the years with the establishment of the Impact Assessment Board (IAB) in 2006 as an independent quality checker, the publication of revised guidelines in 2009 and complementary guidance in various areas (competitiveness and micro-enterprises, fundamental rights, social and territorial impacts) since then. The system has been assessed by numerous independent bodies to be on par with international standards, transparently assessing legislative and non-legislative options by comparing both potential benefits and costs in economic, social and environmental terms and by subjecting the assessments to rigorous scrutiny².

¹ http://ec.europa.eu/smart-regulation/index_en.htm

² OECD 2011 'Sustainability in Impact Assessments — A review of Impact Assessment Systems in selected OECD Countries and the European Commission'; European Parliament 2011, 'Comparative study on the purpose, scope and procedures of impact assessments carried out in the Member States of the EU'; CEPS/University of Exeter 2012, 'Regulatory Quality in the European Commission and the UK: Old questions and new findings'.

As announced in 2012, the Commission committed itself to review its impact assessment guidelines in 2014.³ While the Commission considers the 2009 Guidelines⁴ to remain largely relevant, there is always scope for improvement, including by updating and streamlining some sectoral guidance that was developed after 2009⁵. In its preliminary revision of the guidelines, the Commission has drawn upon an analysis of the experience so far, a European Court of Auditors' evaluation⁶, annual IAB Reports⁷, an ad-hoc preparatory study by leading experts in the field⁸ and relevant OECD documentation.⁹

The new guidelines (see draft attached in annex I) set out the parameters of the Commission's impact assessment system, outline the questions that must be asked during an impact assessment process, and explain the fundamental principles that should be respected when answering them.

³ COM(2012) 746 'EU Regulatory Fitness'.

⁴ http://ec.europa.eu/smart-regulation/impact/commission_guidelines/commission_guidelines_en.htm

⁵ http://ec.europa.eu/smart-regulation/impact/key_docs/key_docs_en.htm

⁶ http://ec.europa.eu/smart-regulation/impact/docs/coa_report_3_2010_en.pdf

⁷ http://ec.europa.eu/smart-regulation/impact/key_docs/key_docs_en.htm

⁸ http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

⁹ 2012 OECD 'Recommendation on Regulatory Policy and Governance' and 2014 OECD 'Regulatory Compliance Cost Assessment Guidance'.

PUBLIC CONSULTATION QUESTIONS

Stakeholders are invited to answer the following questions and/or provide any other comments they may have on the basis of the attached material.

General questions on the draft Impact Assessment Guidelines (annex I)

1. In line with international best practice, the Commission's Impact Assessment system is an integrated one, covering costs and benefits; using qualitative and quantitative analysis; and examining impacts across the economic, environmental and social areas. Do you agree that this is the right approach?
2. Do you agree with the scope of coverage of proposals requiring an impact assessment? If not, why not?
3. Are the appropriate questions being asked in the Impact Assessment guidelines? Are there other issues that the impact assessment should examine? How would this help to improve the quality of Commission policy proposals?
4. Do you have any other suggestion on how to improve the guidance provided to Commission services carrying out an impact assessment and drafting an impact assessment report?

Specific questions (annex II)

5. Problem analysis: do you think the draft text in annex II.B provides a clear description of the issues to be taken into account when analysing a problem? If not, how should it be improved?
6. Subsidiarity: do you think the draft text in annex II.C provides a clear description of the issues to be taken into account when verifying compliance with the subsidiarity principle? If not, how should it be improved?
7. Objectives: do you think the draft text in annex II.D provides a clear description of the issues to be taken into account when setting out objectives? If not, how should it be improved?
8. Option identification: do you think the draft text in annex II.E provides a clear description of the steps to be followed when identifying alternative policy options? If not, how should it be improved?
9. Identification of impacts: Is the list of questions included in the 2009 guidelines (see annex II.F) considered complete and up-to-date? Are there any impacts that should be added or taken out?

ANNEX I

DRAFT REVISED IMPACT ASSESSMENT GUIDELINES

I. INTRODUCTION

WHO SHOULD READ THESE GUIDELINES?

All Commission officials and Cabinet members at all hierarchical levels involved in the development of a Commission proposal, in particular when this needs to be accompanied by an impact assessment (IA).

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.

By allowing informed decisions, IA contributes to smart regulation, i.e. regulation which meets its objectives at minimum cost and respects the principles of subsidiarity and proportionality.

An IA is required when the Commission has to decide whether EU action is needed and there are both:

- (1) Choices among noticeably different policy alternatives;
- (2) Significant direct economic, environmental or social impacts expected.

Provided that the above conditions are fulfilled, impact assessments need to 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.

The IA work is **led by the service(s) responsible for the relevant policy initiative**. They **should establish as early as possible in the policy planning process whether an IA is required or not**, in line with Commission procedures. This decision should be made public in a **Roadmap**¹⁰, providing 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 IA should begin as early as possible during the process of policy-development. IA is an aid to policy-making and not a substitute for it.

¹⁰ See http://ec.europa.eu/smart-regulation/impact/planned_ia/planned_ia_en.htm

An Impact Assessment Report presents the final results of the IA process and accompanies the draft proposal through the Commission decision-making process. Following adoption, the final IA Report is published and transmitted to the co-legislators together with the adopted proposal.

II. THE FUNDAMENTAL PRINCIPLES OF IMPACT ASSESSMENT

IA is a tool to help structure reflection and conduct analyses supporting policy design. It is not a list of tasks to tick off. IA is not a science and 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, there are a number of principles that always apply.

Impact Assessment Analysis Should Be	
<i>Comprehensive</i>	IA analysis should be comprehensive, considering relevant economic, social, and environmental impacts of alternative policy solutions.
<i>Proportionate</i>	The scope and depth of the IA should be proportionate to the type of initiative, the importance of the problem, and the magnitude of the expected impacts.
<i>Evidence-based</i>	All Commission proposals should be based on the best available evidence and scientific advice, or a transparent explanation of why some evidence is not available and why it is still considered appropriate to act.
<i>Open to stakeholders' views</i>	Stakeholders' views must be collected on all key issues and reported on in the IA Report. Every effort should be made to ensure that the Commission has sought and considered a wide and balanced range of views. The reasons for disagreeing with dissenting views must be explained.
<i>Unbiased</i>	IA analysis must be objective and balanced. An IA should inform political choices with evidence - not the other way around.
<i>Conducted in cooperation with other services</i>	An IA is carried out by the lead DG, with the support of other relevant DGs through an Impact Assessment Steering Group.
<i>Embedded in the policy cycle</i>	Lessons from implementation and retrospective evaluations must be taken into account. Future monitoring needs and implementation challenges should be considered.
<i>Transparent</i>	The credibility of IA hinges on the transparency with which results are presented, estimations explained, choices justified and limits acknowledged.

III. THE KEY QUESTIONS OF IMPACT ASSESSMENT

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 and not Member States alone?</i>
3.	<i>What should be achieved?</i>
4.	<i>What are the various ways 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 in terms of their benefits and costs?</i>
7.	<i>How will monitoring and retrospective evaluation be organised?</i>

While the IA Report should present the answers to these questions in a sequential manner, **the process of finding these answers is necessarily iterative**. You 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 can only be fully verified once objectives are set and the impacts of alternative options assessed.

When answering, you should apply the principles identified in the previous section:

1. When making choices about the focus and depth of the analysis, always ask yourself what is relevant to inform decision-making and what is not. Focus on the former.
2. Use¹¹ the results of retrospective evaluations of the existing policy framework as the starting point for the IA. Tap the expertise of other services in the Commission so as to consider and properly assess all relevant issues.
3. Select the most appropriate method to collect data and analyse impacts. Decide on the possible need for external studies.
4. Design a consultation strategy allowing you to consult on all key IA issues and compare your conclusions with stakeholder views. Justify any significant difference.
5. Throughout the IA Report, back your statements with evidence (e.g. data, estimations, scientific findings) whenever you can and, if not, explain why. Also refer to stakeholder views.

¹¹ And thus plan in advance.

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.

Smart regulation is about regulating only when necessary and proportionate. In this vein, high quality policy proposals crucially depend on getting it right from the start, building on a clear problem definition and understanding of the underlying factors and behaviours (so-called “problem drivers”). Therefore, the first step of an IA is to verify the existence of a problem and identify who is affected, estimating the problem's scale, analysing its causes and consequences, identifying its EU-dimension, and assessing the likelihood that it will persist. Key input to this assessment will be any retrospective evaluations or fitness checks of relevant policy frameworks already in place.

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

Developing a clear understanding of these underlying factors is important. It is equally important to make clear in your analysis how individuals and enterprises 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?

Asking yourself this sort of questions will keep the analysis 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.

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

QUESTION 2

WHY SHOULD THE EU ACT AND NOT MEMBER STATES ALONE?

Having established the existence of a problem, the IA analysis should verify whether Member States alone could resolve it sufficiently and whether the EU has the competencies, and would be better 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.

Having identified a problem does not automatically mean the EU is best placed to solve it. According to the principle of subsidiarity¹², the Union should not take action (except in the areas that fall within its exclusive competence), unless it would be more effective than action taken at national, regional or local level.

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, under the Treaty of Lisbon, the respect of the principle of subsidiarity is closely scrutinised by the other EU institutions and by national Parliaments.¹³

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 clear 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 roadmap and early in the IA process should clarify the legal basis and indicate whether advancing further at EU level would make sense. A full verification will only be possible once all relevant information is collected and the analysis of impacts is completed.

Assessing subsidiarity necessarily involves elements of judgement, particularly when evidence is inconclusive and/or stakeholder views diverge. All elements should, therefore, be presented objectively **in your IA Report** avoiding general statements and circular reasoning in favour of concrete arguments, specific to the issues being analysed and substantiated with qualitative, and where possible, quantitative evidence.

¹² See Article 5 of the Treaty on European Union.

¹³ http://ec.europa.eu/dgs/secretariat_general/relations/relations_other/npa/

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, clarifying 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:

- Establishing the logical chain between the identified problems and the solutions considered.
- Clarifying the relation between an initiative's specific goals and any horizontal EU objectives.
- Highlighting any trade-off between policy goals.
- Setting out the criteria for comparing the different policy options.
- Establishing the monitoring and evaluation framework for any policy eventually implemented.

Objectives should be as S.M.A.R.T.¹⁴ as possible. While providing general objectives is important to put the proposed initiative into the overall context of Commission policy, **the IA Report** should focus on the presentation of the more specific and operational objectives the proposed initiative aims to achieve.

¹⁴ Specific, Measurable, Achievable, Relevant and Time-bound.

QUESTION 4 *WHAT ARE THE VARIOUS WAYS 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, you must first identify and screen the available options with a view to selecting the most relevant ones for further analysis and comparison.

At the end of this process, you should have isolated those alternative policy options that are truly relevant for political decision-making.

In many cases, the IA analysis may start from an idea, stakeholder or political input, about what the policy proposal may look like. Often there is already an existing policy framework in place in the area under analysis.

However, such 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). It is therefore important to consult widely about alternatives, think outside the box and give due consideration to all different options. A justification should be given for any relevant option discarded early on.

It is best to do this 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, always ask yourself how a certain measure could influence the drivers of the problem and change the relevant behaviours in a manner that leads towards the desired objectives. Your 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").
 - Alternative policy approaches: e.g. different policy content / approaches to reach the objective; improving implementation and enforcement of existing legislation; doing less / simplifying existing legislation.
 - Alternative policy instruments: e.g. non-regulatory alternatives; self- or co-regulation¹⁵; market-based solutions, regulatory alternatives; international standards¹⁶.

¹⁵ See the principles for better self- and co-regulation at <http://ec.europa.eu/digital-agenda/en/principles-better-self-and-co-regulation-1>

- Alternative scope: for instance, micro-enterprises should a priori be excluded from the scope of any proposed legislation unless the necessity and proportionality of their being covered can be demonstrated¹⁷.
- You should consider those options which have strong outside support¹⁸ and (to the extent possible) those likely to be proposed during the legislative process. However, you should not exclude a priori options with little support or facing strong opposition.¹⁹
2. **Having identified a broad range of policy alternatives, you should screen them.** In many cases, little analysis will be needed to justify discarding some alternatives (e.g. those not technically feasible, not legally viable, 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 your options, you should retain the baseline and those alternatives that should be further examined in a deeper assessment.**
- "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 you have difficulty identifying at least two credible alternatives on top of the baseline, think carefully whether you may not have implicitly made some choices which in reality are still open (for instance, by defining objectives too narrowly). If this is not the case, the focus of your subsequent analysis should be on determining the detailed design of such an option, for example, by considering alternative "sub-options" for some of the individual elements of the proposal.

¹⁶ Your 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 flows. Possible inconsistencies with obligations undertaken at the WTO or in international agreements should also be explained.

¹⁷ 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'.

¹⁸ That is to say from stakeholders, experts, Member States, other EU institutions and third country partners.

¹⁹ If such options are exceptionally excluded early on, this should be clearly spelled out alongside a solid justification.

- After a first assessment of impacts, you should be ready 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, regions, trade partners, etc.). Do not consider an option inferior before having experimented with it and considered possible mitigating measures for 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.

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 regulatory 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 IA Steering Group work should be organised in a manner which allows collecting views and testing results with regard to all the following phases of the impact analysis.

1. **Identify all potential impacts of the options.**

For all 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 to first 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 they need to take?
- Would these realistically be taken?
- Would this allow the objectives to be reached?

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

It will also highlight how different options can trigger different changes and thus have different types of impacts. Cast the net wide by reviewing a wide range of possible impacts across the economic, social and environmental policy areas. Identify all

potential impacts regardless of whether or not it will be possible to assess them precisely and do not immediately focus on the most obvious consequences of the proposed policy. Avoid "missing" a relevant impact as this may affect the overall comparison of options or weaken the case for the Commission's proposal later on.

Also consider whether there would be indirect impacts, 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 cumulative costs borne by a party or positive spill-overs from one affected sector to another).

Impacts can be positive (also known as benefits) or negative (also known as costs). 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.

At the end of this analysis, you should have mapped out all potential impacts – positive or negative - 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.
- Relation with the underlying initiative: direct impacts are those directly generated by a policy measure. Indirect (or second-round) impacts are incidental to the main purpose of the initiative, arise as a result of the behavioural changes prompted by the direct impacts and often affect third parties.
- 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 etc.
- Affected party: businesses of different sizes (SMEs or not), citizens, workers, consumers, public administrations, third country actors etc.
- Frequency and certainty: one-off, recurrent; certain or likely (risks).

While all of the above classifications are useful in principle, you should make sure your analysis uses the categories that are most appropriate for the initiative at hand. Importantly, you should always be transparent about the methodological choices made, the underlying reasons and the exact definitions used (and any divergence from international practices).

2. **Select the significant impacts.** To do so, look in particular at:

- Expected overall magnitude.
- Relevance for specific stakeholders (enterprises and in particular SMEs, trading partners, economic sectors, consumers, workers, public administrations, regions, 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 your selection, remember the principle of proportionate analysis but do not leave out anything that is of relevance for political decision-making. Take account of stakeholders' views and relevant expertise, including within the IA Steering Group, and have a sound justification for your choices.

3. **Assess the most significant impacts.**

Broadly speaking, impacts need to be assessed in quantitative or qualitative terms.

To do this, 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, do not let methodological complexity obfuscate the practical implications of different options for affected parties.

In addition, 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 stage²⁰. It is therefore often difficult to provide accurate estimates, at the Commission proposal stage, even of such key impacts as compliance or implementation costs. Nevertheless, "known unknowns" should not be cast aside in the analysis. On the contrary, you should readily acknowledge them, strengthen the qualitative assessment and discuss the impact that such uncertainties may have on the comparison of options.

Keeping the above in mind, all relevant impacts should be assessed quantitatively, if possible²¹, as well as qualitatively. Similarly, impacts should be monetized whenever possible.

There are several methods to quantify impacts, both in terms of overall methodological approach²² and specific techniques for individual types of impacts. For each case, the

²⁰ Or on future delegated and implementing acts.

²¹ 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.

²² For instance, general vs. partial equilibrium approaches, bottom up vs. top down methods.

most appropriate method should be used and you must be ready to provide a valid justification for your choice.

When quantifying, you should avoid spurious precision and consider providing range values, 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 debatable, you should use sensitivity analysis to check whether changing it would lead to significantly different results.²³

When quantitative analysis is not possible or proportionate, you should assess impacts qualitatively. You should be rigorous and thorough in your qualitative analysis, focussing on the practical implications for affected parties. Rely on all available evidence²⁴ and on illustrative examples to support your conclusions, also referring to stakeholder views. Acknowledge limits and clearly distinguish between facts and expert opinions. If a broad order of magnitudes cannot be given, at least try to identify the reasons why one option is likely to have larger (or smaller) impacts than under another.

In the case of both quantitative and qualitative analysis, 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, you should not simply determine changes relative to the current situation.
- 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 your assessment, discounting monetized estimates as appropriate when these are available.
- Impacts should be assessed from the point of view of the whole society 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).

At the end of this analysis, you should have 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, etc.) should have been identified along with any significant risk of unintended consequences. This will help you compare options in

²³ Ranges of outcomes or confidence interval should then be provided rather than precise results.

²⁴ For instance regarding a subset of the targeted sector / Member States for which data and reliable analyses are available.

terms of their coherence with horizontal EU objectives as well as identify mitigating measures for any preferred option.

Your IA Report should summarize the results of the impact analysis in an accessible manner. Be frank about any limitations (e.g. data, methodological) and risks of unintended consequences. While the more technical aspects of the assessment are important, you should keep the final concrete impacts for individuals and enterprises at the forefront of your analysis and IA Report. Distinguish clearly between (aggregated) costs and benefits and distributional impacts and transfers. Avoid double-counting of the same impact. Use annexes to justify your choices in the selection of relevant impacts and in the methods for their assessment. Give data sources and illustrate the methodologies and underlying assumptions of any quantification.

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.

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 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.

You do not need to identify a preferred option in the IA but you should try your best to objectively compare the options against common criteria, in particular:

- The extent to which different options would achieve the objectives (effectiveness),
- The ratio between benefits and costs (efficiency),²⁵
- The coherence of each option with the overarching objectives of EU policies.

Remember that your results are only as good as the underlying analysis and hypotheses. Make sure to always verify the robustness of your comparison, flag trade-offs between objectives and clarify whether “known unknowns” could significantly affect the result of the comparison.

The IA Report should present the results of this comparison in an accessible manner clearly flowing from the previous analysis. When no preferred option is indicated, this should be clearly stated.

²⁵ Alternatively you can compare the extent to which objectives can be achieved for a given cost, a.k.a. cost effectiveness.

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 allow tracking whether the final policy choice is delivering as foreseen or whether adjustments would be warranted.

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 and at what costs. 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, one needs 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, together with indicators, provide valuable information in this regard. The IA should therefore outline what these arrangements will be.

You should define core indicators for the main policy objectives in relation to the preferred option. It is not necessary to do this in detail for all the options examined in the IA.

Indicators must allow measuring to what extent the objectives of the policy have been achieved. 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, you should sketch out how you plan to solve this issue 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, and many other policy initiatives also contain a review clause. 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 the operational objectives and the main monitoring and evaluation provisions of the preferred option (including any relevant data collection aspects). A more detailed analysis can be added in a dedicated annex.

IV. SUMMING IT ALL UP: THE IMPACT ASSESSMENT REPORT

The Impact Assessment Report summarises and presents the final results of your IA analysis. 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 accompany the IA Report²⁶. Annexes should be used for the more detailed / technical parts of the analysis.

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 (reports, scientific findings etc.) should also be systematically referenced.

²⁶ This would substitute the current ten page summary. It would be structured along the line of the current two-page executive summary sheet but made available in all EU languages.

V. 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 smart 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 double-checking questions which should have already been answered 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?
- Are microenterprises exempted from the scope of the initiative, and if not, why?
- Do the draft legal provisions take into account the challenges and opportunities implied by on-going technological developments such as the growth of the internet 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;
 - Any other disproportionate impact (on specific parties, 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?

ANNEX II

A. PRINCIPLES OF IMPACT ASSESSMENT ANALYSIS

WHEN CARRYING OUT AN IA, YOUR ANALYSIS SHOULD BE:

I. Comprehensive

The analysis should be comprehensive, considering the relevant economic, social and environmental impacts of alternative policy solutions in an integrated manner.

2. Proportionate

The scope and depth of your analysis should be commensurate to the importance of the problem being addressed, the magnitude of the expected impacts and the type of initiative.

Proportionality refers to the resources invested in:

- Carrying out the **overall IA** process (including data collection and public consultation);
- Answering the key **IA questions** (i.e. should the focus be on verifying the existence of a problem or on analysing alternative policy options?);
- Tackling different **issues under each question** (i.e. should the comparison of policy choices focus on broad options or on alternative measures within a given policy approach? Which impacts should the assessment focus on? Can and should impacts be quantified or can a qualitative assessment suffice?)

The importance of the problem addressed depends upon various factors including its magnitude, the risks it poses, its political importance and whether or not the related initiative would break new ground or not.

The magnitude of expected impacts does not only refer to their absolute size but also to their relevance for specific stakeholders (SMEs, individual industries, social groups, EU regions, third countries etc.).

For example: the IA analysis for a legislative proposal affecting millions in an area never before covered by EU legislation should differ from that required for an implementing measure with significant impacts on a narrow set of stakeholders. While in both cases, an impact assessment should inform political decision-making, the depth and focus of the analysis as well as the scope of the related public consultation should differ.

Deciding the most appropriate and feasible level of analysis is likely to be an iterative process. It should be done as **early in the planning process as possible and discussed**

within the IASG. Proportionality might have to be adjusted in a flexible manner as the analysis and public consultation evolve.

For transparency and accountability, the key choices with regard to the level of analysis and their justification should be presented in the IAR.

3. Based on Evidence

All Commission proposals should be based on the best available evidence. Throughout the IA you should collect this evidence and analyse it objectively. **The IAR should present this evidence in a transparent and balanced manner,** allowing informed policy-making and granting access to the evidence upon which decisions affecting stakeholders were taken.

You should always indicate when the evidence is limited or non-conclusive while showing that all commensurate ways to procure and analyse the required information have been exhausted.

It is important to plan ahead how to collect evidence since this is a costly and time-consuming activity. Great care should be taken to maximize the use of available official statistics minimize the risk of new information needs emerging late into the process.

4. Open to Stakeholders Views

No one knows more about a problem and about possible solutions than those concerned. **Consulting those who will be affected by a new policy or initiative is a Treaty obligation and a mandatory component of all IAs.**

In the IA process, stakeholders must be consulted according to the Commission's minimum standards on all key IA questions, including the existence of a problem, the alternatives polices to address it and their impact and compliance with subsidiarity. The manner and timing of consultation should maximize the usefulness of stakeholders' contribution to the IA process and policy-making.

Experience shows that **the quality of the public consultation process is very important for the value of an IA and its credibility vis-à-vis the external stakeholders.** A poor public consultation process inevitably weakens the Commission's case. Stakeholder consultations should be used to gather relevant information and test initial views and estimates. It should not be approached as formal requirement or seen as a tool to gather support for preconceived views.

For these reasons, **all IARs must** refer to stakeholder main views on all the key IA questions, showing how they have been taken into account or why they have been discarded. All IARs should include an annex summarizing consultation processes and their results.

5. Unbiased

Information and stakeholder views should be analysed in an objective manner and the IAR should present them in a transparent and balanced way. Opinions should not be passed off as facts and the IAR is not the place to present political arguments²⁷. A partial presentation of the facts weakens, rather than strengthens, the argument for a policy initiative in the face of a high level of internal and external scrutiny.

An IA should inform policy preferences with evidence - not the other way around. Naturally, IA analysis hardly ever starts from zero. There is frequently an idea, and often political guidance, about which issues to address and how. However, there should be no bias in favour of one specific outcome, including EU legislative action. The IA allows testing pre-existing views on the need and modality of EU action against evidence. When preliminary views are confirmed, the IA builds upon them. When they are not, the IA process highlights the lack of supporting evidence and shows how they could be modified or even discarded. When there is no strong supporting evidence for any particular view, the IAR should clearly states so.

6. Conducted in cooperation with Other Services

An IA is carried out by the lead DG with the support of the other relevant DGs organised in an Impact Assessment Steering Group (IASG). The IASG should be set up at the beginning of work and be involved in all phases, including preparatory studies, consultation strategies and documents, and IAR drafts.

The purpose of the IASG is to ensure early coordination within the Commission and mobilize relevant expertise outside of the lead service. In doing so, the IASG allows the IA process to take a broader view of the issues at hand, alternative solutions and likely impacts on relevant horizontal EU objectives and principles (e.g. respect of fundamental rights, smart, sustainable and inclusive growth, "Think small first principle", policy coherence for development, competitiveness, etc.).

7. Embedded in the Policy Cycle

To better support policy design, IAs should both look back and forward.

First, the large majority of Commission initiatives either review existing legislation and actions or is linked to it. In all these cases, the IA should take the relevant experience into account when analysing the problem and assessing policy options. Otherwise, it will fail to fully inform policy-makers and lack credibility vis-à-vis the external world.

²⁷ There are other ad hoc communication tools for this.

The IAR should present, and **feed into the analysis, the lessons drawn from any relevant retrospective evaluations, fitness checks, implementation experience and infringement activity**. When no retrospective evaluations have been carried out, the IAR should clarify why it is still considered opportune to go ahead with a policy initiative²⁸.

Secondly, the **IA analysis should take into account future policy stages**. In particular:

- When identifying **policy options**, try, if possible, to anticipate the major variants which are **likely to come up during the legislative process and assess them**.²⁹
- When assessing costs and benefits, remember that these will vary depending upon the way in which options are implemented and enforced. The choice of preferred option may well change once **Member States' implementation and enforcement costs** are added to the picture.
- Make sure a proper **monitoring and evaluation framework** is set up.

8. Transparent

Ultimately, the usefulness of an IA rests upon its **credibility** and this **hinges on the transparency with which results are presented, estimations explained, choices³⁰ justified and, above all, limits acknowledged**. A transparent process and a candid IAR strengthen rather than weaken the case for a policy proposal and are likely to lead to smarter policy.

²⁸ This is important given that the Commission is committed in principle to an "evaluate first" policy.

²⁹ IARs are increasingly used as a basis for discussions with co-legislators and IA work will help the Commission pre-empt or answer the questions posed after adoption

³⁰ In terms of proportionality and focus of the analysis, targets and tools for public consultation, methods used to estimate impacts etc.

B. PROBLEM ANALYSIS

The first step of an IA is to verify the existence of a problem and identify who is affected, estimating the problem's scale, analysing its causes and assessing the likelihood that it will persist in the absence of EU policy intervention. Key input to this assessment will be any retrospective evaluations, fitness checks, implementation report and infringements of relevant policy frameworks already in place.

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

A problem can refer either to:

- A situation that is unwelcome or harmful from the point of view of the objectives of the EU Treaties³¹ and the Commission's political priorities, or
- Excessive risk of all types of negative occurrences.

While inefficient regulations, obstacles to the single market, market failures etc. can all be targeted by policy initiatives, it is important to keep at the forefront of problem analysis what the drawbacks are for citizens and enterprises and what will have to be changed in the way actors (i.e. enterprises, consumers, workers, citizens, public authorities, etc.) behave to solve the problem.

When analysing a problem, the following five issues should be covered.

THE FIVE COMPONENTS OF PROBLEM ANALYSIS	
A. Establish what the problem is and why it is a problem.	
Why?	To identify the issues that might have to be addressed.
How?	Clearly but succinctly describe the current situation (the "status quo").
	Show what, and whose behaviour, would need to change and why.
	Briefly recalling any relevant political objectives as expressed in, for instance, Commission Communications, Council Conclusions and European Parliament Resolutions.

³¹ As per Art.5 of the Treaty of the European Union: "Under the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States."

	Consider whether there may be additional (or related) problems linked to the pursuit of general objectives and principles (for instance, international competitiveness disadvantages, lack of coherence with EU development objectives etc.)
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B. Assess the magnitude and EU dimension of the problem	
Why?	To show whether a problem is relevant or not.
How?	The extent to which a problem can be "quantified" or even "monetized" varies from case to case. You should, however, make (and show) the effort to collect and use all the evidence that can help giving an idea of the importance of the problem.
	Explore the relevance of possible cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital.

C. Establish the causes ("drivers") and assess their relative importance.	
Why?	To help identifying how to address the problem.
How?	Map the main causes and their underlying factors While an exhaustive list of all possible causes and sub-causes is not needed, you should approach this part of the analysis with an inquisitive mind.
	Distinguish between different types of causes. These typically fall into of the following families: <i>Market failures</i> : refer to a situation where the market system alone cannot provide the desired outcome (for instance, because there is no market supporting the outcome in question, or a party to a market exchange enjoys a dominant position or when transactions take place on the basis of imperfect information and/or prices that do not reflect the real costs and benefits to society). <i>Regulatory failures</i> : refer to a situation where existing regulation has failed to achieve objectives which remain valid, has proven needlessly costly and/or has become out of date. <i>Behavioural biases</i> : refer to the way individuals may make choices in a manner that does not lead to the most rational / desired outcome, as evidenced by the accumulating literature of behavioural economics.
	Identify what drives the behaviour that would have to change to address the problem.
	Isolate those drivers that play a major role in determining a problem and differentiating those that could be targeted by the initiative from those falling

	outside of the scope (because they are targeted by other initiatives or are outside the remit of EU public policy). Relevant interactions among drivers should also be identified.
	Consider using a "problem tree" to graphically depict the relations among drivers and problems.

D. Identify who the relevant stakeholders are	
Why?	To help target your consultations and prepare the analysis of problem drivers and impacts distribution.
How?	Identify those (EU and non-EU) stakeholders who are affected by the problem and those whose behaviour causes it.
	Relevant groups will depend on the nature of the problem. You should, however, think beyond the narrow boundaries of the specific policy sector. Whenever relevant, you should distinguish within categories (i.e. micro, SMEs and large enterprises), look at non-EU actors (i.e. developing countries, non-EU producers etc.) and differentiate across Member States and EU regions.

E. Describe how the problem is likely to evolve with no EU intervention.	
Why?	To verify if the need for a possible policy initiative is going to persist.
	To set a no-policy change , or baseline, scenario against which the impacts of policy options will be measured and compared.
How?	The nature of the baseline scenario will depend on the methodological choices made in the IA and will range from an evidence-based qualitative assessment to a fully-fledged modelling scenario.
	The baseline scenario is different from the status quo because your analysis should look at the likely evolution of the identified problem drivers and show how this will affect the existence and magnitude of the problem.
	To do this you should consider recent trends and implementation of existing policy at whatever level may be relevant (national, EU, international).
	Policy changes that have already been adopted (but not yet implemented) should be taken into account. The same applies to EU proposals put forward by the Commission but not yet approved by the co-legislators.
	The hypotheses underlying the analysis must be explicit and well justified.
	Whenever future trends in some underlying drivers are particularly uncertain and/or highly significant for the expected development of the problem, this should be highlighted and some form of sensitivity analysis considered.

C. SUBSIDIARITY ANALYSIS

Subsidiarity is an overarching principle of Union action enshrined in art. 5 of the Treaty of the EU. **In areas which do not fall within its exclusive competence, the Union can only act if the principle of subsidiarity is complied with**, i.e. if the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, and can be better achieved at Union level.

Subsidiarity needs to be verified for both legislative and non-legislative initiatives according to the following steps.

SUBSIDIARITY COMPLIANCE

I. Verify compliance with the principle of conferral.	
Question	Is the problem you aim to address linked to at least one article of the Treaties and the objectives contained therein?
Answer	Identify the relevant Treaty article – the so-called legal basis - and state it explicitly in the IAR.

II. Verify whether the Union has exclusive competences or not	
Question	Does the legal basis (action under consideration) fall within one of the areas where the Treaty gives the Union exclusive competence (as defined by Art.3 of the Treaty on the Functioning of the European Union)?
If yes	State it in the IAR (for examples: "Trade policy and the negotiation of international trade agreements are areas of exclusive EU competence pursuant to Article 207 of the Treaty and therefore the subsidiarity principle does not apply"). No need for further analysis.
If no	Move to next steps.

III. Perform the necessity test	
Question	Can the objectives of the proposed action be achieved sufficiently by Member States acting alone?
If yes	Union action in the area would not be justified. The initiative under consideration should be abandoned or refocused as needed.
If no	Explain the case at hand clarifying the specific limits of Member States' action, their underlying drivers, and why they would not

	be "sufficient". Move to next step.
Examples	Relevant situations could involve cross-border effects (e.g. pollution) or obstacles to the free movement of persons, goods, services and capital.

IV. Perform the EU added value test	
Question	Can the objectives of the proposed action be better achieved at Union level?
If yes	Explain why for the case at hand, explicitly considering both the advantages and the disadvantages that Union action may have relative to Member States action. The principle of subsidiarity is complied with.
If no	Union action in the area would not be justified on the basis of subsidiarity. The initiative under consideration should be abandoned or refocused as needed.
Examples	Situations where EU action produces clear benefits compared to action at Member State level by reason of its scale or its effectiveness or efficiency.

Verifying subsidiarity is an iterative process. Early in the IA process, you should complete step I and II and carry out a cursory analysis of step III and IV to make sure advancing the analysis further makes sense. The necessity test and the value added tests can only be carried out in full once the analysis of impacts is completed.

The analysis of subsidiarity should be proportionate:

When	Then
There has been limited Community action before (or none at all)	Provide an extensive assessment and justification
Revising existing legislation	Rely on past subsidiarity analysis but check that EU action would remain in conformity with the subsidiarity principle.
Preparing delegated acts / implementing measures	Refer to the relevant legislative act.

Assessing subsidiarity is not always a black and white case as evidence may not univocally point in one direction. It is therefore important to **gather stakeholders' views** and refer to them in the IAR. When presenting your assessment in the IAR, you should **avoid general statements and circular reasoning** in favour of concrete arguments specific to the issues being analysed. Substantiate your points with qualitative, and where possible, quantitative evidence.³²

Don't just say:	Do explain that:
The subsidiarity principle is respected because the initiative's objectives cannot be achieved sufficiently by Member States.	Action by Member States could not solve the problem for the following reasons... (e.g. spill-over effects, insufficient scale of the project...)
EU action is necessary to level the playing field	Only EU action could eliminate the costs (of up to €X on average) that EU enterprises incur to apply for additional authorisations in every EU host countries they wish to operate in.
EU action will ensure an equivalent level of consumer protection across the Union	Without EU action consumers affected by... would continue to find no remedy in X Member States as shown by the statistics presented in the problem section.
EU action is needed to avoid the fragmentation of the internal market	EU action is needed to eliminate the following obstacles faced by producers to enter into other national markets:... As shown in the problem section, this is estimated to...

³² To be referred to rather than repeated if already presented in the problem analysis.

D. OBJECTIVES SETTING

Objectives link the analysis of the problem to the policy response. They set the level of policy ambition, fix the yardsticks for comparing policy options and determine the criteria for monitoring and evaluating the achievements of implemented policy. **Objectives can be set at different levels and at different times.**

Objectives setting	
<i>After the analysis of the problem</i>	
General	These are the Treaty-based goals which the policy aims to contribute to.
Specific	These set out concretely what the policy intervention is meant to achieve. They should be broad enough to allow consideration of all relevant policy alternatives without prejudging a particular solution.
<i>After identifying the preferred option (if there is one)</i>	
Operational	These are defined in terms of the deliverables or outputs of policy actions. As such, they are typically option-specific.

Objectives should be as 'S.M.A.R.T' as possible (and the "SMART-er" the more exact the objectives).

What are S.M.A.R.T. objectives?	
Specific	Objectives should be precise and concrete enough not to be open to varying interpretations by different people.
Measurable	Objectives should define a desired future state in measurable terms, to allow verifying its achievement or not. Such objectives are either quantified or based on a combination of description and scoring scales.
Achievable	Policy aims must be set at a level which is ambitious but at the same time realistically achievable.
Relevant	The objectives should be directly linked to the problem and its root causes.
Time-Bound	Objectives should be related to a fixed date or precise time period to allow an evaluation of their achievement.

When objectives are multiple and inter-related, it is important to highlight the links between them, particularly any possible trade-off. When problems are complex and have many underlying drivers, numerous objectives are often identified, be they general, specific or operational. In these cases, an "objectives tree" can be used to graphically depict the relations among different goals.

E. OPTIONS IDENTIFICATION

Identifying alternative policy options is, in most cases, an iterative process. The aim is to consider as many realistic alternatives as possible and then narrow them down to the most relevant ones for further analysis.

To reach this objective, the following steps are suggested.

I. Consider a wide variety of policy options (content and tools).	
Why?	To think outside the box and avoid regulatory bias.
	To show other parties that their preferred policy option has been considered (and explain why it might not be pursued).
How?	<p>Ask yourself: what could affect the drivers of a problem? What could influence behaviours in a manner that would address the problem / help achieving the policy objectives?</p> <p>Answer with an open mind, trying to identify as many policy responses as possible. Then identify which policy instruments could be used to deliver these measures. Consider the widest range of instruments, from the less intrusive to the more interventionist and from the more "classical" tools to those suggested by the more recent developments in relevant academic fields, like behavioural economics.</p>
	Policy options must be closely linked to the drivers of the problems and the identified objectives: a clear logic should underpin the intervention under consideration.
	Do not forget to ask for stakeholders' proposals and opinions.
	Make sure to consider those options that can count on considerable support among stakeholders, experts, policy-makers, Member States and other EU institutions.
	However, do not exclude a priori options with little support or facing strong opposition by some groups.
What?	You should make sure that you always consider at least the following:
	The "No policy change" baseline scenario
	<p>A good baseline scenario should have a strong factual basis and, as far as possible, be expressed in quantitative terms.</p> <p>It should also be set for an appropriate time horizon. The length of the latter depends on the likely life-time of any individual option and on the need to allow for impacts to be realised.</p>

	Alternative policy responses
	<p>Consider alternative types of policy responses to reach the objective as regards the content/design of the measure. For instance:</p> <ul style="list-style-type: none"> - Could the objectives be reached through alternative basic policy approaches? If there are clear arguments in favour of a particular general policy approach, are there different options for the more detailed parameters of the initiative? - When EU policy already exists in an area and it is not producing the desired effects, consider the option of "doing less" – i.e. can it be streamlined, simplified or even repealed (where the Treaties do not lay down a specific obligation to act)? - Whenever EU policy already exists, could the objective be reached by improving implementation and/or enforcement of existing legislation? Ways to facilitate better policy-making by Member States could also be considered. - Where they exist, international standards (or regulatory solutions of similar ambition implemented by third countries) should be considered with a view to avoid unnecessary regulatory differences.
	Alternative policy instruments (regulation, self/co-regulation, etc.)
	Consider non-regulatory alternatives (such as self- or co-regulation ³³), market-based solutions, regulatory alternatives as well as international standards ³⁴

II. Screen your options	
Why?	To focus the analysis on the viable options.
How?	Excluding options at this stage should be easy to justify. Reasons should be as clear, self-evident and incontrovertible as possible.
	The key criteria for screening the viability of your options are:
	Legal feasibility
	Options must respect the principle of conferral. They should also respect any obligation arising from the EU Treaties (and relevant international agreements) and ensure respect of fundamental rights. Legal obligations incorporated in existing primary or secondary EU legislation may also rule out

³³ See the principles for better self- and co-regulation at <http://ec.europa.eu/digital-agenda/en/principles-better-self-and-co-regulation-1>

³⁴ Your 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 flows. Possible inconsistencies with obligations undertaken at the WTO or in international agreements should also be explained.

	certain options.
	Technical feasibility
	Technological constraints may not allow for the implementation of theoretical options.
	Previous policy choices
	Certain options may be ruled out by previous Commission policy choices or mandates by EU institutions.
	Coherence with other EU policy objectives
	Certain options may be ruled out early due to poor coherence with other general EU policy objectives.
	Effectiveness and efficiency
	It may already be possible to show that some options would uncontrovertibly achieve a worse cost-benefit balance than some alternatives.
	Proportionality
	Some options may clearly restrict the scope for national decision making over and above what is needed to achieve the objectives satisfactorily.
	Political feasibility
	Options that would clearly fail to garner the necessary political support for legislative adoption and/or implementation could also be discarded.
	Relevance
	When it can be shown that two options are not likely to differ materially in terms of their significant impacts or their distribution, only one should be retained.

III. Check the suitability of the set of retained options	
Why?	To make sure the impact analysis will properly inform political decisions.
How?	The baseline scenario can never be discarded as it provides the basis for determining the impacts of the other options.
	All options should be realistic. Do not artificially select the baseline, a "pre-selected preferred" option and a "straw-man" option.
	If you are having difficulty identifying even two credible alternatives to the baseline, think harder or consider a different level of option aggregation (sub-options, alternative detailed parameters, implementation modes, etc. - see below). Alternatively, provide a strong justification for the fact that only

	the baseline and an alternative option are retained for in-depth analysis.
What?	You will often have two sets of options, one for the content of the policy and one for the delivery instruments (regulation, directive etc.).
	<p>You will also have to choose the level of aggregation of your policy options: broad alternative options, alternative packages of measures, individual sets of measures targeting specific issues to be bundled together at the end of the analysis or a mix of high-level options and sub-options.</p> <p>Different methodological choices are possible, each with its pros and cons. The best choice depends upon the specificities of the case at hand, notably the number of problems to address, the extent of spill overs from one measure to another, the nature of the problem, the logic of the intervention etc.</p> <p>In choosing the options, it is important to focus in on those elements being most critical for the Commission to decide on (i.e. those with significant impacts). More detailed analysis of choices at a micro level is useful during the technical preparations of a proposal and should be included in the IAR when significant impacts depend upon it. Otherwise, considering a different level of aggregation may be more appropriate for the main text of the IAR.</p>

IV. Outline the retained options in greater depth	
Why?	To allow the identification of the impacts of alternative options.
	For transparency.
How?	<p>Options should be sufficiently well developed to allow you to differentiate them on the basis of their performance in achieving the identified objectives.</p> <p>The retained options should thus not be described too vaguely. Enough detail on their actual content should be provided for the analysis of impacts to provide insights on the key elements for political choice (e.g. level of benefits and costs, distributional impacts, impact on SMEs, citizens, EU competitiveness, sustainability, etc.).</p> <p>Similarly, remember that you will have to finalize the analysis of compliance with the subsidiarity principle as well as show the proportionality of any preferred option.</p>

F. KEY IMPACT IDENTIFICATION QUESTIONS

The following replicates the list of key questions to screen options against possible economic, social and environmental impacts in the current guidelines (See http://ec.europa.eu/smart-regulation/impact/commission_guidelines/commission_guidelines_en.htm, p.32 to 37).

ECONOMIC IMPACTS	KEY QUESTIONS
Functioning of the internal market and competition	<ul style="list-style-type: none"> • What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc?
Competitiveness, trade and investment flows	<ul style="list-style-type: none"> • What impact does the option have on the global competitive position of EU firms? Does it impact productivity • What impact does the option have on trade barriers? • Does it provoke cross-border investment flows (including relocation of economic activity)?
Operating costs and conduct of business/Small and Medium Enterprises	<ul style="list-style-type: none"> • Will it impose additional adjustment, compliance or transaction costs on businesses? • How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? • Will it lead to new or the closing down of businesses? • Are some products or businesses treated differently from others in a comparable situation?
Administrative burdens on businesses	<ul style="list-style-type: none"> • Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)? • What is the impact of these burdens on SMEs in particular?
Public authorities	<ul style="list-style-type: none"> • Does the option have budgetary consequences for public authorities at different levels of government (national, regional, local), both immediately and in the long run? • Does it bring additional governmental administrative burden? • Does the option require the creation of new or restructuring of existing public authorities?
Property rights	<ul style="list-style-type: none"> • Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? • Or will there be a complete loss of property?
Innovation and research	<ul style="list-style-type: none"> • Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production methods, technologies and products? • Does it affect intellectual property rights (patents, trademarks, copyright, other know-how rights)?

ECONOMIC IMPACTS	KEY QUESTIONS
	<ul style="list-style-type: none"> • Does it promote or limit academic or industrial research? • Does it promote greater productivity/resource efficiency?
Consumers and households	<ul style="list-style-type: none"> • Does the option affect the prices consumers pay? • Does it impact on consumers' ability to benefit from the internal market? • Does it have an impact on the quality and availability of the goods/services they buy, on consumer choice and confidence? (cf. in particular non-existing and incomplete markets – see Annex 8) • Does it affect consumer information and protection? • Does it have significant consequences for the financial situation of individuals / households, both immediately and in the long run? • Does it affect the economic protection of the family and of children?
Specific regions or sectors	<ul style="list-style-type: none"> • Does the option have significant effects on certain sectors? • Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? • Is there a single Member State, region or sector which is disproportionately affected (so-called “outlier” impact)?
Third countries and international relations	<ul style="list-style-type: none"> • How does the option affect trade or investment flows between the EU and third countries? How does it affect EU trade policy and its international obligations, including in the WTO? • Does the option affect specific groups (foreign and domestic businesses and consumers) and if so in what way? • Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist? • Does it affect EU foreign policy and EU/EC development policy? • What are the impacts on third countries with which the EU has preferential trade arrangements? • Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries?
Macroeconomic environment	<ul style="list-style-type: none"> • Does it have overall consequences of the option for economic growth and employment? • How does the option contribute to improving the conditions for investment and the proper functioning of markets? • Does the option have direct impacts on macro-economic stabilisation?

SOCIAL IMPACTS	KEY QUESTIONS
Employment and labour markets	<ul style="list-style-type: none"> • Does the option facilitate new job creation? • Does it lead directly or indirectly to a loss of jobs? • Does it have specific negative consequences for particular professions, groups of workers, or self-employed persons? • Does it affect particular age groups? • Does it affect the demand for labour? • Does it have an impact on the functioning of the labour market? • Does it have an impact on the reconciliation between private, family and professional life?
Standards and rights related to job quality	<ul style="list-style-type: none"> • Does the option impact on job quality? • Does the option affect the access of workers or job-seekers to vocational or continuous training? • Will it affect workers' health, safety and dignity? • Does the option directly or indirectly affect workers' existing rights and obligations, in particular as regards information and consultation within their undertaking and protection against dismissal? • Does it affect the protection of young people at work? • Does it directly or indirectly affect employers' existing rights and obligations? • Does it bring about minimum employment standards across the EU? • Does the option facilitate or restrict restructuring, adaptation to change and the use of technological innovations in the workplace?
Social inclusion and protection of particular groups	<ul style="list-style-type: none"> • Does the option affect access to the labour market or transitions into/out of the labour market? • Does it lead directly or indirectly to greater equality or inequality? • Does it affect equal access to services and goods? • Does it affect access to placement services or to services of general economic interest? • Does the option make the public better informed about a particular issue? • Does the option affect specific groups of individuals (for example the most vulnerable or the most at risk of poverty, children, women, elderly, the disabled, unemployed or ethnic, linguistic and religious minorities, asylum seekers), firms or other organisations (for example churches) or localities more than others? , firms, localities more than others? • Does the option significantly affect third country nationals?
Gender equality, equality treatment and opportunities, non - discrimination	<ul style="list-style-type: none"> • Does the option affect the principle of non-discrimination, equal treatment and equal opportunities for all? • Does the option have a different impact on women and men? • Does the option promote equality between women and men? • Does the option entail any different treatment of groups or individuals directly on grounds of sex, racial or ethnic origin, religion or belief, disability, age, and sexual orientation? Or could it lead to indirect discrimination?
Individuals, private and family life, personal data	<ul style="list-style-type: none"> • Does the option impose additional administrative requirements on individuals or increase administrative complexity? • Does the option affect the privacy, of individuals (including their home and communications)? • Does it affect the right to liberty of individuals? • Does it affect their right to move freely within the EU?

SOCIAL IMPACTS	KEY QUESTIONS
	<ul style="list-style-type: none"> • Does it affect family life or the legal, economic or social protection of the family? • Does it affect the rights of the child? • Does the option involve the processing of personal data or the concerned individual's right of access to personal data ?
Governance, participation, good administration, access to justice, media and ethics	<ul style="list-style-type: none"> • Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? • Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? • Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? • Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? • Will the option affect the individual's rights and relations with the public administration? • Does it affect the individual's access to justice? • Does it foresee the right to an effective remedy before a tribunal? • Does the option make the public better informed about a particular issue? Does it affect the public's access to information? • Does the option affect political parties or civic organisations? • Does the option affect the media, media pluralism and freedom of expression? • Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)?
Public health and safety	<ul style="list-style-type: none"> • Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)? • Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise, air, water or soil quality? • Will it affect health due to changes energy use and/or waste disposal? • Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? • Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?
Crime, Terrorism and Security	<ul style="list-style-type: none"> • Does the option improve or hinder security, crime or terrorism? • Does the option affect the criminal's chances of detection or his/her potential gain from the crime? • Is the option likely to increase the number of criminal acts? • Does it affect law enforcement capacity? • Will it have an impact on security interests? • Will it have an impact on the right to liberty and security, right to fair trial and the right of defence (?) • Does it affect the rights of victims of crime and witnesses?
Access to and effects on social protection, health and educational systems	<ul style="list-style-type: none"> • Does the option have an impact on services in terms of quality/access for all? • Does it have an effect on the education and mobility of workers (health, education, etc.)? • Does the option affect the access of individuals to public/private education or vocational and continuing training? • Does it affect the cross-border provision of services, referrals across borders and co-

SOCIAL IMPACTS	KEY QUESTIONS
	<p>operation in border regions?</p> <ul style="list-style-type: none"> • Does the option affect the financing / organisation / access to social, health and care services? • Does it affect universities and academic freedom / self-governance?
Culture	<ul style="list-style-type: none"> • Does the proposal have an impact on the preservation of cultural heritage? • Does the proposal have an impact on cultural diversity? • Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?
Social impacts in third countries	<ul style="list-style-type: none"> • Does the option have a social impact on third countries that would be relevant for overarching EU policies, such as development policy? • Does it affect international obligations and commitments of the EU arising from e.g. the ACP-EC Partnership Agreement or the Millennium Development Goals? • Does it increase poverty in developing countries or have an impact on income of the poorest populations?

ENVIRONMENTAL IMPACTS	KEY QUESTIONS
The climate	<ul style="list-style-type: none"> • Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane etc) into the atmosphere? • Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs etc)? • Does the option affect our ability to adapt to climate change?
Transport and the use of energy	<ul style="list-style-type: none"> • Does the option affect the energy intensity of the economy? • Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc) used in energy production? • Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? • Does it increase or decrease vehicle emissions? • Will the option increase/decrease energy and fuel needs/consumption?
Air quality	<ul style="list-style-type: none"> • Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc)?
Biodiversity, flora, fauna and landscapes	<ul style="list-style-type: none"> • Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? • Does it affect protected or endangered species or their habitats or ecologically sensitive areas? • Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones? • Does the option affect the scenic value of protected landscape?
Water quality and resources	<ul style="list-style-type: none"> • Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources?
Soil quality or resources	<ul style="list-style-type: none"> • Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or

ENVIRONMENTAL IMPACTS	KEY QUESTIONS
	increase the amount of usable soil (e.g. through land decontamination)?
Land use	<ul style="list-style-type: none"> • Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? • Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?
Renewable or non-renewable resources	<ul style="list-style-type: none"> • Does the option affect the use of renewable resources (fish etc) and lead to their use being faster than they can regenerate? • Does it reduce or increase use of non-renewable resources (groundwater, minerals etc)?
The environmental consequences of firms and consumers	<ul style="list-style-type: none"> • Does the option lead to more sustainable production and consumption? • Does the option change the relative prices of environmental friendly and unfriendly products? • Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc? • Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?
Waste production / generation / recycling	<ul style="list-style-type: none"> • Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?
The likelihood or scale of environmental risks	<ul style="list-style-type: none"> • Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms?
Animal welfare	<ul style="list-style-type: none"> • Does the option have an impact on health of animals? • Does the option affect animal welfare (i.e. humane treatment of animals)? • Does the option affect the safety of food and feed?
International environmental impacts	<ul style="list-style-type: none"> • Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?