

TOOL #9. WHEN IS AN IMPACT ASSESSMENT NECESSARY?

An impact assessment (IA) is required when the **expected economic, environmental or social impacts of EU action are likely to be significant**.

The benchmark criterion of "significant impacts" applies both to the macro- and the micro-level. This implies that IA is not only required for proposals expected to have far-reaching impacts on the economy or society as a whole, but also for initiatives likely to have a significant impact on a particular economic sector, type of economic actor (e.g. SMEs), societal group or geographical area or environmental compartment. Clearly, the appreciation of what is considered "significant" will depend on expert judgment and should take into account the results of associated evaluations. The roadmap or inception impact assessment should already set an initial appreciation of the expected significant impacts on which stakeholders can provide feedback.

However, an IA should be carried out only when it is useful. An assessment of whether an IA is needed should therefore be done on a case-by-case basis and reported on in the roadmap when an IA is deemed not to be necessary.

In principle, such an **assessment is likely to conclude that no IA is needed when:**

- There is **little or no choice available for the Commission**. For instance when the Commission is implementing previous policy decisions already subject to an IA, or when it is specifying technical details with limited discretion available, or transposing an international agreement with no significant margin for variations, or where a previous evaluation has identified very specific problems (or means to simply or remove unnecessary regulatory costs) and an IA would not provide any further useful information in relation to the preparation of a legislative proposal that is narrowly focused on remedying the identified problems etc.; **or**
- **Impacts cannot be clearly identified** ex ante (for instance, in the case of broad policy communications); **or**
- Impacts are **small** (for instance, the repeal of a redundant act)⁷⁵.

Where no materially different policy choices are available but directly identifiable impacts are expected to be significant, these should preferably be assessed and transparently presented through an appropriate tool (explanatory memorandum, ad hoc staff working paper, etc.).

Further guidance to help judge whether an IA is necessary is provided below.

⁷⁵ Please note that it is the ultimate impact that counts. Thus, a small direct negative impact could still be large for certain stakeholders (SMEs etc.) or have a significant effect because it cumulates with other pre-existing negative factors or generates important indirect/secondary effects.

A. Initiatives for which the need for an IA should be assessed⁷⁶
New legal acts
Revision of existing legal acts
Recasts of existing legal acts
Non-technical repeal of existing legal acts ⁷⁷
Delegated acts (Art. 290 TFEU)
Implementation measures (Art. 291 TFEU)
Transposition of international agreement into EU law ⁷⁸
White papers
Policy communications
Action Plans
Recommendations
Recommendations for the negotiation of international agreements.
Social partner agreements pursuant to Articles 154-155 TFEU ⁷⁹ .
Financial programmes (i.e. all basic acts for spending programmes and financial instruments) ⁸⁰

In the specific case of white papers, action plans and policy communications, the requirement to carry out an IA (and its depth of analysis) will primarily depend on the level of ambition and the degree of commitment planned and the degree to which it binds the Commission. Communications announcing, for instance, ambitious commitments (say a ten-year strategy to achieve certain environmental targets) will most likely require an impact assessment because the impacts of such a commitment are likely to be significant and broadly identifiable already at such a general stage of policymaking.

In the case of Recommendations, an IA is generally not necessary but will depend on the level of detail (i.e. the degree of specificity/flexibility) set out in the provisions and the significance of the likely impacts that would stem from their implementation by Member States. A staff working document (i.e. not subject to the procedural requirements of an

⁷⁶ This list is given for illustrative purposes only. It is neither exhaustive nor based on a formally agreed classification of possible Commission initiatives.

⁷⁷ Repeals to remove legislation which has been superseded by new legislative provisions are neither subject to an IA nor require a roadmap. Repeals announced in the Commission Work Programme equally do not require a roadmap or an IA as the Commission has already taken a decision informed by the available evidence (for instance the results of an evaluation).

⁷⁸ A key determining factor will be whether the Commission has any policy discretion over the content of its transposing measures.

⁷⁹ See Tool #11 on *Social partner initiatives*.

⁸⁰ See Tool #10 on *Financial programmes and instruments*.

impact assessment) presenting potential impacts and policy approach is likely to be more proportionate in most cases.

Other initiatives may not require an IA at all (e.g. Communications clarifying the Commission's approach to policy decisions already taken, or announcing more in-house type of work, such as the setting-up of expert groups, etc.). In such cases, any relevant supporting analytical material could rather be presented in a technical staff working document accompanying the initiative.

Whenever it is concluded that no IA is needed, this must be flagged and explained to the public through the roadmap. When pertinent, the roadmap, and any other relevant public document, should clearly signal that an IA would accompany any follow-up initiative with directly identifiable significant impacts.

Each year the Commission adopts **hundreds of delegated acts and implementing acts**. For each delegated act or implementing act, an assessment should be made as to whether an impact assessment is necessary. This is so even in cases where the Commission is taking decisions based, for example, on scientific advice from a scientific body or agency. An impact assessment will be necessary where there are likely to be significant impacts and where the Commission has discretion about the measures which could be taken (including whether to act at all). For example, a scientific body may recommend a safe exposure level to a particular chemical but the Commission has the choice of how best to manage the risks of exposure to that chemical.

In addition, where the Commission is likely to deviate from the recommendations of an Agency then an IA is also likely to be necessary. Where an impact assessment makes no sense because the Commission has no discretion, there may still be significant impacts about which it is useful to present information to the College. In such cases, a SWD can be prepared or information presented in the explanatory memorandum in the case of delegated acts.

There are initiatives for which no impact assessment is required a priori:

Type ⁸¹	Reason
Administrative decisions	Lack of significant impact (or relevance for policymaking)
Enforcement of EU law (competition law enforcement cases, infringement decisions, etc.)	Lack of policy alternative as decision parameters are set by existing EU (case) law.
Trade defence cases and enforcement action under international trade rules	Lack of policy alternatives
Budgetary procedures and measures, Financing Decisions and programme management decisions	Lack of policy alternatives/ex-ante evaluation not required

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Commission reports /scoreboards	No policy decision, lack of impacts
Communications to the Commission	No policy decision, lack of significant impacts
Economic governance: recommendations, opinions, adjustment programmes	Specific processes supported by country specific analyses
Green papers	No policy decision, lack of significant impacts
Legal alignments	Lack of policy alternatives / no significant direct impacts
Legal codifications	Lack of policy alternatives / no significant impacts
Staff working documents	No Commission decision, lack of significant impacts
Conclusion, signature and provisional application of Bi/multi-lateral agreements with Third Countries: conclusions signature, provisional application and/or prolongation of existing protocol.	Lack of policy alternatives given finalisation of negotiations

<i>EU agencies and IAs</i>
<ul style="list-style-type: none"> • Whenever specific legislative procedures mandate an EU agency to carry out the main policy-design work and prepare an IA-like document, no Commission IA is necessary a priori. • The Commission's internal rules on better regulation and impact assessment do not apply to EU agencies⁸². However, the lead DG should ensure that the agency's analysis broadly meets the Commission's consultation and IA standards and takes responsibility/ownership for the quality of the assessment. • The lead DG should (in consultation with the Secretariat-General) consider whether the Commission's initiative would benefit from further analysis and a complementary IA due to its complexity, or the significance of the expected impacts or where the Commission is likely to deviate from the advice of the relevant agency or indeed where the Agency's work does not meet the Commission's usual standards. • During policy preparations, the lead DG may decide itself or be asked by the SG or other Commission services to supplement the agency analysis if duly justified and/or – in consultation with the SG – to undergo scrutiny by the Regulatory Scrutiny Board. In the latter case, the lead DG is responsible for submitting a draft IA report to the RSB in accordance with the better regulation Guidelines and this Toolbox.

⁸² Many agencies have established their own arrangements on better regulation as part of the agency's mandate (particularly in areas such as stakeholder consultation).