

Chapter 4 – Compliance, implementation and preparing proposals

TOOL #38.	Compliance promotion and verification tools	338
TOOL #39.	Compliance assessment: explanatory documents, transposition and conformity checks	342
TOOL #40.	Drafting the explanatory memorandum	347
TOOL #41.	Guidance documents containing legal interpretation of EU law.....	355
TOOL #42.	Delegated and implementing acts	358

TOOL #38. COMPLIANCE PROMOTION AND VERIFICATION TOOLS

1. INTRODUCTION

Compliance tools can be categorised according to several dimensions: a distinction can be made between:

- 'compliance promoting' tools, which are mainly used during the implementation period of the EU act, before expiry of the transposition deadline or date of application, and
- 'verification' tools, which help to identify and correct an instance of non-compliance. The latter are activated after the transposition deadline or the date of application of the EU act has been reached.

The following tools are included in the first category – *compliance promoting* tools:

- implementation strategies (drawn up by the Commission);
- implementation plans (drawn up by the Member States);
- networks, expert groups, committees, workshops;
- guidelines on interpreting and implementing EU law (Commission)⁵⁰³.

The following tools are included in the second category – *compliance verification* tools:

- explanatory documents (drawn up by the Member States);
- package meetings;
- compliance dialogues;
- guidelines on interpreting and implementing EU law (Commission);
- implementation reports;
- scoreboards and barometers;
- Commission controls (for instance, EU inspections, audits, financial corrections procedure);
- expert groups.

Some of the tools can be used both proactively and reactively (e.g. guidelines). In practice, both sets of tools complement each other.

For some of the tools, a definition already exists in specific EU acts (e.g. committees, expert groups).

2. COMPLIANCE TOOLS EXPLAINED

Given the use of certain tools in areas going beyond the monitoring and enforcement of EU law, the definitions below should be understood exclusively in the context of the use of such tools to help prevent and correct infringements:

- Implementation strategy drawn up by the Commission – An implementation strategy identifies the main challenges Member States will face in transposing and applying the EU legislation, as well as the tools that the Commission may use to carry out its monitoring activities, depending on the nature and content of the legal instrument. It should also list the various support actions which the Commission will provide to the Member States (i.e. the other compliance promotion tools to be used). Implementation strategies may also include Member States' implementation plans – if communicated

⁵⁰³ See Tool #41 (*Guidance documents containing legal interpretation of EU law*)

to the Commission – and monitoring arrangements to track progress and report on the transposition or implementation of EU specific legislation (e.g. calendar of compliance assessment, enforcement actions and implementation reports). Such a strategy is drafted by the responsible DG after the Commission's legislative proposal has been adopted by the co-legislators. It should include the issues of digital implementation where relevant.

- Implementation plans drawn up by the Member States – Member States may draw up their own implementation plans for a given EU legal act. These detail the implementation process at national level, identifying concrete actions to be taken by the different authorities at local, regional, or central level.
- Networks – The Commission may set up various networks composed of Member State authorities or other national bodies in charge of the implementation of specific EU law. Networks may also include stakeholder representatives.
- Expert groups – The Commission may set up expert groups to get advice on the application, implementation and transposition of EU law. Expert groups consist of stakeholder representatives, organisations or Member States' authorities. They provide specific expertise in a given policy area. Expert groups do not take binding decisions, but may formulate opinions and recommendations or submit reports.
- Committees – An EU legal act may set up a committee to assist the Commission in the implementation and application of that specific legislation. They are composed of representatives of Member States and chaired by the Commission. Some of these committees (comitology) provide formal opinions on proposals for implementing acts. In some other cases, committees play an advisory role, acting as expert groups⁵⁰⁴.
- Workshops – The Commission may organise on an ad-hoc basis workshops to facilitate and promote the implementation of EU legislation. Workshops may be organised at a technical, political or judicial level (involving a Commissioner and/or high-ranking Member State officials).
- Guidelines on interpreting and implementing EU law, including interpretative Communications – This is written guidance to Member States on how to implement and apply certain EU legal instruments. Guidelines contain interpretation of EU law, which bind the Commission. The Commission may also address written guidance to stakeholders on how to implement/apply certain EU provisions. The Commission can issue guidelines, for example on digital platforms⁵⁰⁵, including digital compliance assessment tools⁵⁰⁶, reference architectures⁵⁰⁷ and data models⁵⁰⁸. Such guidelines must in principle be adopted by the Commission⁵⁰⁹. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.
- Explanatory documents – These documents, prepared by the Member States, explain the relationship between the components of a directive and the corresponding parts of the national transposition instruments. Such documents may take the form of

⁵⁰⁴ [Register of Commission expert groups and other similar entities \(europa.eu\)](https://ec.europa.eu/euipo/interoperability-test-bed-repository/solution/interoperability-test-bed)

⁵⁰⁵ Example for Knowledge Base for the implementation of the INSPIRE directive: <https://inspire.ec.europa.eu/>

⁵⁰⁶ Example: <https://joinup.ec.europa.eu/collection/interoperability-test-bed-repository/solution/interoperability-test-bed>

⁵⁰⁷ Example: <https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/solution/eira>

⁵⁰⁸ Example: <https://joinup.ec.europa.eu/collection/eprocurement/solution/eprocurement-ontology>

⁵⁰⁹ See also Tool #41 (Guidance documents containing legal interpretation of EU law)

correlation tables spelling out the link between each provision or legal obligation set by the directive and the corresponding legal obligation transposed in the national legislation. Explanatory documents must accompany Member States' notification of their transposition measures⁵¹⁰. The Commission DGs use these documents when assessing (i) the compliance with the obligation to adopt and communicate complete transposition measures and (ii) the correctness the compliance of the national transposition measures⁵¹¹.

- Package meetings – These meetings are convened with individual Member States to discuss implementation issues and infringement cases in a given policy area. These may help to find solutions in compliance with EU law and should therefore take place regularly, whenever useful. Package meetings could be combined or organised together with other meetings with Member States (e.g. compliance dialogues)⁵¹².
- Compliance dialogues⁵¹³ – This refers to a systematic better law-making dialogue with the Member States on compliance with EU law and on broader enforcement issues and policy considerations, across the range of legislative areas. Compliance dialogues could be organised in different settings: bilateral meetings, meetings with groups of Member States with similar issues to be tackled, sectoral meetings on specific issues concerning all Member States. Compliance dialogues could also help to assess together with the Member States the effects of non-compliance on the country's economic performance in terms of growth and investments (e.g. by looking at compliance with EU law in the light of the country specific recommendations issued for the European Semester exercise). The responsible DGs should define the format of compliance dialogues and to initiate them. Carrying out such dialogues could be a resource-intensive exercise for both Commission and Member States. The criteria for establishing these dialogues and for identifying candidate Member States must be clear and transparent. Compliance dialogues do not exclude other specific dialogues with the Member States (such as package meetings or technical meetings).
- Implementation reports – An EU directive or regulation may require the Commission to prepare an implementation report focussed on the Member States' implementation measures. This describes the state of play based on available national legislation and monitoring data and provides information on progress against the legal obligations laid down in the EU legislation and for obligations of results against agreed timetables or objectives, to the extent possible and in the limits of the data available. It often has a wider scope than a purely legal compliance report, but nonetheless builds on existing conformity/compliance checking.
- Scoreboards and barometers – The Commission may publish scoreboards (or barometers) to enable the public to compare the performance of Member States in achieving specific goals, including regarding the correct and timely application and implementation of EU law in particular policy areas.
- Commission controls – In certain policy areas, where the Commission has specific investigative or controlling powers, its DGs may carry out on-the-spot checks, audits

⁵¹⁰ Judgment of the Court of Justice in *Commission/Belgium*, [C-543/17](#).

⁵¹¹ See Tool #39 (*Compliance assessment: explanatory documents, transposition and conformity checks*).

⁵¹² Action 22, [Long term action plan for better implementation and enforcement of single market rules](#), COM (2020) 94 final.

⁵¹³ These were set up by the Communication [EU law: Better results through better application](#), C (2016) 8600.

inspections or financial correction procedures⁵¹⁴. Their objective is to collect the information needed to verify compliance with EU legal obligations and verify that the EU funds are spent in line with all relevant financial rules.

3. REFERENCES

Contact point for compliance promotion tools: SG-UNITE-E-3@ec.europa.eu

⁵¹⁴ Technologies like blockchain offer the possibility for automated controls: <https://digital-strategy.ec.europa.eu/en/policies/ebsi>. On-the-spot checks can in some cases be replaced by the use of geo-spatial information. Example for such practices in agriculture: <https://ec.europa.eu/jrc/en/research-topic/agricultural-monitoring>

TOOL #39. COMPLIANCE ASSESSMENT: EXPLANATORY DOCUMENTS, TRANSPOSITION AND CONFORMITY CHECKS

1. A TWO-STAGE SYSTEMATIC APPROACH

When it comes to the compliance of national legislation with EU directives, a clear line is to be drawn between infringements for failure to notify national transposition measures and infringements for non-conformity. These two types of infringements are assessed by two distinct methods: **transposition checks** for the former and **conformity checks** for the latter. When assessing national transposition measures, **explanatory documents** allow the Commission to better understand how Member States transpose EU directives.

1.1. Explanatory documents

The explanatory documents, prepared by Member States, explain the relationship between the components of a directive and the corresponding parts of the national transposition instruments.

In its judgment of 8 July 2019 in Case C-543/17⁵¹⁵, the Court clarified the respective roles of the Member States and of the Commission in setting out the correlation between the provisions of a directive and the corresponding rules of national law. The Court held that, when notifying national transposition measures to the Commission, Member States must provide sufficiently clear and precise information and state, for each provision of the directive, the national provision(s) ensuring its transposition.

Thus, Member States must accompany their notifications of national transposition measures to the Commission by explanatory documents. It is no longer necessary to include, in the new directives, a recital recalling the requirement to provide such documents.

The explanatory documents should preferably take the form of correlation tables, but this is not an obligation. Explanatory documents do have to be sufficiently clear and precise to allow the Commission services to identify, for each provision of the directive requiring transposition, the relevant text of national transposition measure creating the corresponding legal obligation in the national legal order, whatever the form chosen by the Member State.

1.2. Transposition check

As Member States must transpose directives in a complete way, every obligation of the directive to be transposed should be covered by the check. Hence, the transposition check should ensure that the national transposition measures notified by the Member State cover each obligation contained in each article and sub-article/paragraph of the directive, including in its annexes where relevant.

In a first step, services carry out a *prima facie* check. In case of partial transposition, the services then, in a second step, clearly identify the provisions that have not been transposed or that have not been completely transposed.

⁵¹⁵ Judgment of the Court of Justice in Commission/Belgium, [C-543/17](#). Confirmed in C-550/18, Commission/Ireland, C-549/18, Commission/Romania and C-628/18, Commission/Slovenia.

Box 1. Examples of incomplete transposition

- The concept of completeness of transposition measures in terms of geographic scope is relatively straightforward⁵¹⁶. For instance, when, for federally organised Member States, certain regions have not yet transposed or are erroneously not covered by the national implementing measures, the directive is incompletely transposed in terms of geographic scope⁵¹⁷;
- The concept of completeness of transposition measures in terms of substantive scope means that every obligation of a directive should be reflected in the national transposition measures⁵¹⁸. Therefore, all obligations contained in a directive fall within the scope of the transposition check. For example, if a provision contains an obligation, and the subparagraphs contain specific non-optional derogations therefrom, both should be checked during the transposition check⁵¹⁹. Hence, if national transposition measures contain only the general obligation, but not the [non-optional] derogations, it is an evidence of incomplete (partial) transposition.
- Occasionally, Member States notify transposition measures that merely specify a framework for future implementation. For example, a Member State could notify a measure stating that: *The Minister decides on the methodology for calculating a building's energy performance through a decree*. Nothing specific has been transposed, only the national authority responsible for transposition has been identified. These so-called 'empty shell' transpositions are to be considered as a lack of transposition.

The transposition check starts upon the expiry of the transposition deadline; it may even start before (to be decided by the competent service) if national transposition measures for individual Member States have been received in advance.

If Member States fail to notify the transposition measures by the deadline, an infringement procedure will be launched as soon as possible. In its judgment of 8 July 2019 in Case C-543/17, the Court clarified that the sanction scheme of Article 260(3) TFEU may also be applied to cases of partial failure to adopt and communicate transposition measures.

To facilitate and speed up the transposition checks, DGs should prepare a table indicating which articles, sub-articles or paragraphs include self-standing obligations that require transposition by Member States. The Legal Service should be consulted if a scope of a particular obligation is not clear.

⁵¹⁶ See the guidance in Box 48, SEC(2010)922/3.

⁵¹⁷ For an example, see Case [C-428/04, Commission v. Republic of Austria \[2006\]](#) ECR I-3325.

⁵¹⁸ See the guidance in Box 48, SEC(2010)922/3.

⁵¹⁹ For an example, see Case [C-350/02, Commission v. Kingdom of the Netherlands \[2004\]](#) ECR I-6213, para. 41, where failure to notify implementing measures for a sub-article (article a of directive 97/66/EC) is qualified as incomplete transposition.

Box 2. Under what conditions can the Commission launch or pursue an infringement procedure, if explanatory documents are missing?

- Member States are in breach of their obligation to notify measures transposing a directive if they failed to indicate in a sufficiently clear and precise manner which provisions of national law transpose which provisions of the directive. Without such information, the Commission is not able to verify whether the Member State has transposed the directive effectively and completely. The Commission can launch or pursue an infringement procedure based on Article 258 and 260(3) TFEU without having to analyse the notified transposition measures.
- Member States should no longer make 'bare notifications' of national laws, i.e. notifications that are not accompanied by explanatory documents.
- Such notifications, which do not indicate clearly for each provision of a directive which national provision ensures its transposition (no explanatory documents provided), should not be accepted by the Commission services, unless they are self-explanatory (e.g. appropriate level of clarity is provided in the notification as to which national provision corresponds to which directive's provisions).
- Refusing 'bare notifications' should be done with caution, in full respect of the principle of proportionality.
- The refusal should only cover the extent that sufficiently clear and precise information is missing. If, for example, a Member State gives such information with respect to several provisions of a directive but not with respect to others, the notification should be qualified as a partial failure to communicate, but not be completely discarded.
- Where a Member State has provided sufficiently clear and precise information on the transposition, the Commission should pursue only manifest gaps under the procedure provided for by Article 260(3). This is the case when, despite indications to the contrary given by the Member State, no corresponding transposition measure exists for a self-standing obligation of a directive.
- Any objection to the clear indications given by the Member States on the matching transposition measure requires a well-substantiated explanation in the subsequent infringement step that the Commission takes (letter of formal notice, reasoned opinion, or referral to the Court), beyond the mere identification of the transposition gap. In case of doubt, the debate as to whether the national transposition measure implements the directive sufficiently should be held in the context of a 'non-conformity' case under Article 258 TFEU alone.
- The Commission can launch or pursue an infringement procedure based on Article 258 and 260(3) TFEU for notifications of national transposition measures, which do not comply with the above standards and were submitted to the Commission after the Court's judgment in case C-543/17 of 8 July 2019.

The Commission aims at completing the transposition check within six months after the transposition deadline expires. If the Commission launches an infringement procedure for failure to communicate national transposition measures, the six-month period will start when the measures are notified.

1.3. Conformity check

This check entails the assessment of the compatibility of the national implementing measures with the directive's provisions/obligations, including definitions.

Box 3. Issues related to incorrect transposition or bad application

- The implementation of parts of provisions of directives that require subsequent administrative practice or judicial interpretation to be applied in specific cases should normally be assessed within the conformity check. This holds especially true for so-called 'open norms' that grant significant discretionary power to national administrations⁵²⁰.
- Frequently, directives contain provisions that require Member States to notify specific reports / action plans / facilities. These provisions often contain separate deadlines and are different from the general obligation to notify transposition measures. Non-compliance with such provisions should be classified as bad application, as opposed to a failure to notify⁵²¹. Therefore, they are not part of the transposition check.
- For directives requiring the setting-up of national enforcement bodies, structural issues with the national regulatory body should be examined during the conformity check⁵²².
- National definitions broader than definitions included in a directive do not, as such, qualify as non-conform, unless it is demonstrated that the use of an extensive definition could be the cause of practical difficulties or confusion in application of the directive's rules⁵²³.

As a rule, the conformity check should start only once the previous phase of the transposition check, including a possible infringement procedure for failure to communicate transposition measures, has been completed. Exceptionally, a conformity check may be started in parallel to an ongoing transposition check for well-defined parts of a directive which have been identified as being completely transposed and which are clearly distinct from the provisions that require transposition measures which have not yet been notified.

Box 4. Example on running the transposition check and the conformity check in parallel

A Member State notified transposition measures for almost all provisions of a directive and only residual, non-essential parts have not been transposed. In this case, it is appropriate that the conformity check can already start for the well-defined parts of a directive, which have been identified as being completely transposed.

The Commission aims at completing the conformity check within 16 to 24 months from the date of the communication of the national transposition measures.

⁵²⁰ Open norms are those rules that depend for a large extent on judicial interpretation and that enable judges to administer justice in individual cases; examples of open norms are terms such as 'unnecessary', 'disproportionate', 'fair', 'adequate' and 'requisite legal standard'.

⁵²¹ For an example, see provision 11(1) of [Directive 2000/60/EC](#).

⁵²² For an example, see article 3 of [Directive 2002/21/EC](#).

⁵²³ See Case C-281/11, *Commission v. Poland*, EU:C:2013:855.

If during this subsequent conformity check the service finds that the Member State has not notified all the measures necessary for full transposition, the service should launch an infringement procedure for late notification in relation to the parts that are missing⁵²⁴.

Reports on conformity assessment from external contractors need to be verified by the Commission; any final decision that is taken based on such reports should be the result of an independent assessment by the Commission services.

Given that compliance studies may feed into infringement proceedings, they should not be published or disclosed before the compliance check is completed and a decision whether to pursue the matter or not is made. Requests for access to such studies will be assessed in the context of Article 4(2), third indent of Regulation No 1049/2001⁵²⁵.

Compliance assessment should finally feed into the evidence base used for effective evaluation; therefore, the conformity check should lead to a clear tangible result in the form of a written document containing the assessment results.

Several challenges in the implementation phase stem from historical reasons. Some information may be lost over time. It would be extremely useful for those who deal with compliance checks to know difficulties linked to the design of the legal instrument, foreseeable shortcomings in the concrete enforcement on a daily basis, articles that were subject to more intense debate and interpretation, as well as articles that resulted from a political compromise and that may generate interpretation difficulties. If the service / team of desk officers that ensures the conformity checks is different from the service, which has drafted and negotiated the directive or discussed with national authorities during the transposition period, DGs must put in place appropriate arrangements.

This can be achieved in different ways, depending on the organisation of each department. Useful tools are:

- hand-over notes detailing the challenges faced during the preparation and the negotiation phases;
- co-ordination mechanisms, such as task forces involving policy and enforcement units;
- integrated units covering all the activities of the policy cycle for a specific piece of legislation.

2. REFERENCES

For any queries on compliance assessment, please contact SG.E3 - SG-UNITE-E-3@ec.europa.eu

⁵²⁴ SEC(2010)923/3 Box 48

⁵²⁵ See especially Case [T-111/11, ClientEarth v. European Commission \[2013\]](#), n.y.r; Case [T-29/08, LPN v. Commission \[2011\]](#) ECR II-6021; Case [T-36/04, API v. Commission \[2007\]](#) ECR II-3201; Case [T-109/99, Petrie and Others v. Commission \[2001\]](#) ECR II-3677; Case [T-105/95, WWF v. Commission \[1997\]](#) ECR II-313.

TOOL #40. DRAFTING THE EXPLANATORY MEMORANDUM

1. WHEN IS AN EXPLANATORY MEMORANDUM NECESSARY?

All Commission proposals and delegated acts should include an explanatory memorandum.

For delegated acts, a simpler form is used covering: (i) the context of the delegated act; (ii) consultations prior to the adoption of the act; (iii) legal elements of the delegated act.

2. WHAT IS THE PURPOSE OF THE EXPLANATORY MEMORANDUM?

The purpose of the explanatory memorandum is to explain the reasons for, and the context of, the Commission's proposal drawing on the different stages of the preparatory process. It presents the results of the 'better regulation' processes and tools used to prepare the initiative, including opportunities for legislative simplification and reducing unnecessary regulatory costs. It also serves as a basis for the examination of the proposal by national Parliaments under the subsidiarity control mechanism (Protocol No. 2 to the Treaties).

The explanatory memorandum should be available in the same languages as the proposal it introduces. In principle, it should not exceed 15 pages, although in particularly complex cases a longer text may be justified. The explanatory memorandum is transmitted to the other institutions together with the accompanying act and is available to the public through [EUR-Lex](#). The explanatory memorandum is not published in the Official Journal and has no legal effect.

The explanatory memorandum should not be confused with the recitals, which are part of the act itself, which will be published in its entirety in the Official Journal.

The explanatory memorandum ensures the transparent exercise by the Commission of its right of initiative. Therefore, it should be reader-friendly, clearly worded, concise, and written with the non-specialist in mind. Commission services can seek the advice of DGT-EDIT during the interservice consultation⁵²⁶.

3. THE CONTENT OF THE EXPLANATORY MEMORANDUM⁵²⁷

The explanatory memorandum should satisfy all applicable requirements, including those following from Protocol No. 2 on the application of the principles of subsidiarity and proportionality, the Interinstitutional Agreement on Better Law-Making and the Commission's 'better regulation' agenda.

The Commission should summarise in the explanatory memorandum the following:

- the context of the proposal,
- how it complies with the principle of conferral (i.e. reasons for the choice of legal basis) and with the principles of subsidiarity and proportionality,
- explain the choice of the legal instrument.

⁵²⁶ DGT-EDIT can be included in the list of DGs consulted during the interservice consultation.

⁵²⁷ The template presented in this tool is not entirely appropriate for proposals adopted under Article 218 TFEU. Specific templates should be used which will be available on GoPro following the revision of the current Vademecum on the external action of the European Union: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/External+representation+of+the+EU>

- how it complies with the 'better regulation' principles, as well as with the fundamental rights. Generally, proposals are subject to fitness checks or evaluations of the existing policy framework, where relevant, to an impact assessment and scrutiny by the Regulatory Scrutiny Board and informed by stakeholder consultations. The results of this preparatory work should therefore be reflected in the explanatory memorandum.

(1) CONTEXT OF THE PROPOSAL

- Reasons for and objectives of the proposal:
 - Describe the reasons behind the proposal and/or the problem(s) that the proposal intends to tackle (e.g. obstacle to free movement, dangerous products, environmental pollution).
 - State if this is a REFIT initiative⁵²⁸.
 - State the relevant institutional background of the proposal (e.g. mandate from the European Council, undertaking by the Commission to revise an act, Commission work programme, reply/reaction to a legislative initiative resolution of the EP, reply/reaction to a European Citizens' Initiative).
- Consistency with existing measures in the area:
 - Mention any important Union measures and initiatives already undertaken in the relevant area (existing legislation, linked policy proposals, white papers) or comparable relevant initiatives in the Member States.
 - Provide a clear description of the similarities and differences of the proposal as compared with existing acts (e.g. different field of application, complementarity).
 - Explain the timing of the proposal (why the proposal is presented now) and the sequencing of proposals related to the same policy sector.
- Consistency with other Union policies
 - Mention links with other Union policies, in particular in cases of 'mainstreaming', where significant and relevant (economic, competition, employment, environment, equal opportunities and gender equality, external implications of the policy on third countries, etc.). Keep this part concise and avoid overlaps with the 'impact assessment' section.

(2) LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- Legal basis

In accordance with the Interinstitutional Agreement on Better Law-Making⁵²⁹, the Commission should justify the legal basis of the proposal in a clear and complete way, especially where it would seem that several options exist.

⁵²⁸ See Tool #2 (*The Regulatory fitness and performance programme (REFIT) and the Fit for Future Platform*)

⁵²⁹ Interinstitutional agreement of 13 April 2016 on Better Law-Making, [EUR-Lex - 32016Q0512\(01\) - EN - EUR-Lex \(europa.eu\)](#)

- Explain what the legal basis of the proposal is. When several feasible options seem to exist, justify the choice based on objective criteria.
- Clarify whether the concerned policy area falls under an exclusive or shared competence or under other categories of competence (support and coordination competences).

- Subsidiarity and proportionality:

Demonstrating compliance of the proposal with the principles of subsidiarity and proportionality is a fundamental part of the explanatory memorandum. Refer to the main elements of the subsidiarity [grid](#)⁵³⁰. Avoid standard, general phrases that merely state that the proposal respects these principles. Aspects to include:

- Subsidiarity (the subsidiarity principle does not apply in areas where the Union has exclusive competence)
 - Explain what the Union dimension of the problem is. While respecting Union law, are well-established national arrangements and special circumstances applying in individual Member States respected?
 - Necessity test: Why can the objectives of the proposal not be adequately achieved by Member States? Is the scope of action limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?;
 - Effectiveness test: What is the most effective solution – that achieved by Union action or that achieved by possible national means? What specific EU-added value is expected by the envisaged Union measure and what would be the cost of taking no action at all?

- Proportionality

Explain the scope of chosen policy option:

- Does the option go beyond what is necessary to achieve the objective satisfactorily?
- Will the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?

- Explain the choice of instrument:

- Has the simplest form of Union action (instrument) been chosen?; is this choice consistent with the pursued objective and effective enforcement? Where appropriate, it should also be justified why a recast is or is not proposed⁵³¹.
- Is there a solid justification for the choice of instrument – regulation, (framework) directive, or alternative regulatory methods?

⁵³⁰ See Tool#5 (*Legal basis, subsidiarity and proportionality*)

⁵³¹ <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Recasting>

(3) **RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

In support of evidence-based policymaking, the Commission should explain the preparatory analytical work undertaken, including evaluations and fitness checks of existing provisions, stakeholder consultations, the collection and use of expertise and impact assessments⁵³². Clearly describe any approved exemption from procedural requirements of the 'better regulation' and provide the justification. **If no evaluation or fitness check, consultation activity or impact assessment have been undertaken, this section should explain why.**

The section should provide a short overview of the main findings and how they have been taken account in the final proposal – for further details, references should be made to the relevant evaluation, impact assessment reports or staff working documents and to the Regulatory Scrutiny Board's opinion, where relevant.

- Evaluation/fitness check and related opinions of the Regulatory Scrutiny Board (RSB)
 - Summarise the results of any evaluations/fitness checks of existing measures related to the policy objectives, clarifying the link to the identified problems that the proposal aims to tackle. Provide relevant links to available staff working documents, studies or reports;
 - In the case that the RSB issued an opinion on the evaluation/fitness check (or made comments related to the evaluation/fitness check included in the related IA report), summarise the Board's findings and explain how they were taken into account;
- Stakeholder consultation
 - Describe the consultation(s) carried out and the tool(s) used (public consultation, consultation targeted at pre-selected organisations, hearings, etc.).
 - State briefly the main sectors and/or institutional bodies from which responses have been received, giving an objective and balanced summary of their answers. Avoid vague wording such as "the associations consulted broadly welcomed this initiative". Provide link to published consultation results/reports (e.g. on '[Have Your Say](#)' portal).
 - Summarise how the results of the consultation were considered in the proposal and, where appropriate, explain where the Commission's views diverged and why;
- Use of expertise

If the Commission has relied on expertise⁵³³, describe the methodology used, the range of expertise consulted, the advice received, how expertise was taken into account and, where appropriate, indicate how to access any publicly available information (e.g. website).

- Impact assessment and opinion of the Regulatory Scrutiny Board

⁵³² <https://ec.europa.eu/info/sites/info/files/working-methods.pdf>. The explanatory memorandum will present the better law-making dimension and how the Commission plans to address the burdens added or reduced for business and citizens.

⁵³³ See Tool #4 (*Evidence-informed policymaking*)

A summary presentation of the main elements of the impact assessment (IA) process serves to strengthen the motivation underlying the proposed policy choice, and to show that the careful assessment of the policy options and significant impacts have been fully considered by the Commission. Given that some elements of the impact assessment process are reported on under other sections in the explanatory memorandum, this section should focus on the assessment of policy options and their significant impacts, as set out below.

- Where relevant, explain why the proposal is not supported by an impact assessment⁵³⁴. If the College has chosen not to undertake an impact assessment, the reasons therefore should be explained.
- Reference should be made to the initial political validation, the 'call for evidence' in which the need for an impact assessment has been addressed and also to the 'better regulation' guidelines;
- Provide the links to the IA summary and the final opinion of the Regulatory Scrutiny Board. Where no positive opinion was issued, a clear justification should be given for proceeding with the initiative;
- Summarise the main content of the Regulatory Scrutiny Board's opinion and explain clearly how the opinion was taken into account.
- Explain which policy options were examined, how they compare and why the final proposal was the preferred policy choice.
- Describe the main economic, social, and environmental impacts of the preferred option, who would be affected and how.
- Summarise the key findings of the impact assessment (or ex-ante evaluation) relevant to the sustainable development goals (SDGs)⁵³⁵, based on the analysis presented in Annex 3 of the impact assessment (or the relevant analysis in ex-ante evaluation).
- Explain how the proposal upholds the 'do no significant harm'⁵³⁶ and 'digital by default'⁵³⁷ principles and contributes to achieving the European way for a digital society and economy.
- Explain the consistency of the draft measure or legislative proposal, including budgetary proposals, with the climate-neutrality objective set out in European Climate Law⁵³⁸, Article 2(1) and the Union 2030 and 2040 targets before adoption, as included in the impact assessment accompanying these measures or proposals. Also include the assessment whether these draft measures or legislative proposals, including budgetary proposals are consistent with ensuring progress on adaptation as referred to in Article 5. In any case of non-alignment, the Commission shall provide the reasons.
- Explain, where relevant, how the Commission screened and assessed territorial impacts in its proposals and accompanying explanatory memoranda⁵³⁹.

⁵³⁴ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁵³⁵ See Tool #19 (*Sustainable development goals*)

⁵³⁶ See Tool #36 (*Environmental impacts*)

⁵³⁷ See Tool #28 (*Digital-ready policymaking*)

⁵³⁸ Regulation(EU) 2021/1119 of 30 June 2021 establishing the framework for achieving climate neutrality (European Climate Law)

⁵³⁹ See Tool #34 (*Territorial impacts*)

- Quantified estimates of the impacts should be provided wherever possible, and reasons given where this is not possible;
 - If the final policy proposal deviates from the options assessed in the impact assessment, clarify in which way it deviates from these options and the likely impacts of this change. If there are additional costs created by the measure that have not been considered in the IA (particularly on SMEs), they should also be analysed and reported. Indicate if the final choice will reduce burden as compared to the preferred option of the IA.
- Regulatory fitness and simplification (REFIT)

This section aims at providing specific and clear information on the regulatory fitness of the final proposal and the extent to which regulatory burdens are minimized and proportionate to the objective to be achieved. **All revisions of existing legislation should assess the potential to simplify the legislation and to identify the potential to reduce any unnecessary regulatory costs. Quantification should be presented wherever possible. This REFIT-related work should be based on impact assessments and/or evaluations and fitness checks that support the initiative.**

The European Parliament and the Council are encouraged to take account of the burden reduction objective in their legislative work and the Member States in respect of their transposition and implementation of the legislation at national level.

This section of the explanatory memorandum should outline, in particular:

- If the proposal includes a revision of existing legislation and if the possibility to simplify the legislation and/or reduce unnecessary costs has been identified, then the explanatory memorandum should explain how these possibilities will be exploited by the proposal without undermining the achievement of the objectives of the legislation.
- Wherever pertinent, a **burden reduction objective**⁵⁴⁰ included for tackling unnecessary regulatory costs should be presented for the specific legislation. This should be based on the REFIT-related findings of the impact assessment and any earlier evaluation or fitness check.
- Quantified information should be presented, whenever possible.
- The Fit for Future Platform's opinion and how it was used in the impact assessment, evaluation or fitness check should be highlighted, where relevant.
- Who will be affected and how? What will the affected parties have to do to comply and what will public authorities have to do to ensure compliance?
- Why microenterprises are not exempted from the scope of the initiative, and whether there is a lighter regulatory regime for SMEs generally⁵⁴¹;
- How the expected compliance costs for SMEs and any other relevant stakeholders have been minimised, providing quantitative estimates, to the extent possible;
- How any negative effects on sectoral EU competitiveness or on international trade have been minimised;

⁵⁴⁰ See COM (2017) 651

⁵⁴¹ See Tool #23 (*The 'SME test'*) for examples of mitigating measures for SMEs.

- How the proposal is digital-ready and consistent with the operation of the internet, social media, and other digital developments. Will the proposal operate effectively in both the digital and physical worlds?⁵⁴²;
- **If there is no scope to simplify or reduce regulatory costs a short justification should be provided.**
- Fundamental rights

Where the proposal has significant consequences for fundamental rights, explain how the fundamental rights obligations have been met⁵⁴³. Where relevant, specify significant gender equality impacts and data protection aspects⁵⁴⁴.

(4) BUDGETARY IMPLICATIONS

Briefly outline the budgetary implications of the initiative (if any) and, where appropriate, refer to the 'financial statement' showing the budgetary implications and the human and administrative resources required.

(5) OTHER ELEMENTS

- *Monitoring, evaluation, and reporting arrangements:* Reference should be made to the compliance tools associated with the measure and a concise description should be given of the monitoring, evaluation and reporting framework proposed to assist the Commission with the implementation and application of the proposed act and with the reporting on its performance.
- *Variable geometry:* In case of proposals under Title V of Part Three of the TFEU (justice and home affairs), particular arrangements apply to the Ireland (protocol 21), Denmark (Protocol 22) and to different EU Member States and associated countries depending on their participation in Schengen (protocol 19). The implications of the proposal on these countries should be explained where relevant.

(6) DETAILED EXPLANATION OF THE SPECIFIC PROVISIONS OF THE PROPOSAL

In addition to the general explanation of the reasons for the Commission proposal, more information should be provided on the various provisions, with a commentary on each chapter or article. Such a commentary may focus on selected key articles including those provisions intended to simplify the legislation or tackle unnecessary regulatory costs. This text should have added value for the future interpretation of the proposed act. A more detailed commentary may be useful for explaining any new ideas in the proposal (in particular if such an explanation goes beyond the general framework of the explanatory memorandum). An article-by-article commentary may be very useful in case of doubts on the interpretation of a particular provision. Where the proposal codifies or replaces an existing text, the detailed

⁵⁴² See Tool #28 (*Digital-ready policymaking*)

⁵⁴³ See Tool #29 (*Fundamental rights, including the promotion of equality*)

⁵⁴⁴ Including if the European Data Protection Supervisor and European Data Protection Board have been or will be consulted. See Article 42, Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

commentary may indicate those provisions from the existing text that are taken over (or codified) in the proposal.

TOOL #41. GUIDANCE DOCUMENTS CONTAINING LEGAL INTERPRETATION OF EU LAW

1. INTRODUCTION

Commission documents frequently provide guidance to Member States and/or stakeholders in applying and implementing EU law. Such guidance may contain interpretation of EU law⁵⁴⁵. In such cases, according to the case law⁵⁴⁶ of the Court of Justice of the European Union, Commission guidance documents may produce legal effects, i.e. they may legally bind the Commission⁵⁴⁷.

Guidance documents are any texts with guidance on how Member States and/or stakeholders are to apply EU legal instruments. Guidance on the interpretation of EU legal instruments may bind the Commission and must in principle be adopted by the College of Commissioners.

2. GUIDANCE DOCUMENTS CONCERNED

College endorsement is required for guidance documents that contain interpretation of EU law, including interpretation provided in the framework of compliance promotion tools⁵⁴⁸, unless such documents are part of the Commission's normal administrative operations.

Box 1. Interpretation of EU law

Interpretation of EU law means that the document sets out a position on how one or more EU law provisions should be interpreted and/or applied. This is typically the case when, for example:

- an EU law provision can be understood in various ways and the guidance document sets out the Commission's understanding (or defines the Commission's interpretation);
- the guidance document clarifies whether a certain activity falls under the scope of a given EU legal instrument;
- the Commission adjusts its earlier position after a Court judgment⁵⁴⁹.

⁵⁴⁵ The Commission has an autonomous power to issue guidance documents (Article 292 TFEU referring to the Commission's power to issue recommendations) so the legislator may not impose obligation to issue guidance. Frequently, however, legislative measures contain such obligations. See, for example, Annex I, points (a) and (b), to Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions.

⁵⁴⁶ See, for example, Case T-472/12 *Novartis v Commission*, point 67; Case T-376/12, *Greece v. Commission*, point 108; Joined Cases T-61/00 and T-62/00, *APOL*, point 72. See also the Opinion of AG Mazak in case C-527/07, point 37.

⁵⁴⁷ Therefore, staff working documents should, as a rule, not include such guidance. See the joint note from the Legal Service and the Secretariat-General in relation to the use of staff working documents (SEC(2013)663, Ares(2014)642944).

⁵⁴⁸ See Tool #38 (*Compliance promotion and verification tools*).

⁵⁴⁹ Examples: [The Practical Guide on Posting of Workers](#); [Guidance on the interpretation and application of Council Directive 93/13/EEC on unfair terms in consumer contracts](#); Guidance on the application of exemptions under the Environmental Impact Assessment Directive ([C/2019/8014](#)). Examples of guidance documents can be found in the Commission's annual reports on monitoring the application of EU law.

Services should assess on a case-by-case basis and based on the content of the document whether it contains interpretation of EU law and whether interpretation goes beyond the Commission's normal administrative operations. The services' contact points in the Legal Service and or the Secretariat-General (SG Infractions) may assist in identifying whether this is the case.

The following documents are not considered guidance documents containing legal interpretation going beyond the Commission's normal administrative operations:

- guidelines used only internally;
- documents of a factual nature illustrating best practices;
- documents that contain only information on the existence of EU law provisions or merely paraphrase their contents (such as basic explanation given in a simplified, citizen-friendly way) or on their application (such as defined in the compliance tools⁵⁵⁰).

As part of their normal administrative operations, the Commission services have regular contacts with Member States' administrations and other stakeholders. In this context, the Commission services are frequently requested to provide *ad hoc* interpretation of legal provisions or technical advice on the practical application of those provisions.

In so far as the interaction with the Member States does not take the form of general guidance on the legal provisions or remains at a very technical level, or when the interpretation presented merely confirms a Commission position already approved by the College, the requirement to seek College endorsement does not apply.

For example, this may be the case where services are requested to clarify the interpretation of certain legal provisions during expert group meetings, committees⁵⁵¹ or in bilateral contacts with a Member State's administration or any other meetings with one or more Member States or stakeholders⁵⁵².

Whenever a formal written reply is provided (for example, in the summary minutes of an expert group meeting, in letters or in e-mails with more than ephemeral significance, or Q&As published on sites accessible to relevant Member State authorities⁵⁵³), the service should mention that the reply reflects the position of the Commission services and does not commit the Commission. In those cases, the following disclaimer should be added:

"This [...] was prepared by/ expresses the view of the [Commission services/ DG ...] and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law."

The Legal Service must be consulted on the envisaged interpretation of EU law and will help, if needed, to determine whether the envisaged action is covered by this note. The Legal Service may also assist in specific cases where submitting general guidance documents to College endorsement raises particular problems.

⁵⁵⁰ A collection of statistical and factual information on, for example, how a certain directive has been implemented so far across the Member States.

⁵⁵¹ This includes meetings of comitology committees or non-comitology committees (e.g. the European Social Fund Committee).

⁵⁵² This is the case, for instance, for monitoring committee meetings of European Structural and Investment Funds, where the Commission participates in an advisory capacity.

⁵⁵³ Example: Coronavirus Response Investment Initiative Platform

3. PREPARATION AND FORMAT

In preparing guidance documents, services should check if any of the **'better regulation' requirements** are to be applied⁵⁵⁴. Guidance documents falling under the scope of Decide should have the appropriate planning entry and political validation before preparatory work begins⁵⁵⁵. Guidance documents are normally subject to an **interservice consultation**⁵⁵⁶.

A guidance document containing an interpretation of EU law to be used by Member States, stakeholders and the general public is to be adopted by the Commission in the form of a Commission interpretative Communication or Notice (with a 'C' serial number). It should be adopted in all official EU languages and published in the C series of the Official Journal.

In those cases where the guidance document exclusively concerns interinstitutional relations⁵⁵⁷, it should be adopted by the Commission as a Commission 'Communication' (with a COM serial number) addressed to the other institutions and published on EUR-Lex⁵⁵⁸. Such Communication may be adopted in the three working languages, but its publication requires translation into all official EU languages.

In choosing the format for the guidance document, it is recommended that services consider that Commission communications (contrary to Commission notices) may not extend to more than 15 pages (unless agreed with the DGT). Detailed information on the procedures necessary to issue these documents is provided on GoPro⁵⁵⁹.

Where documents contain both factual information and interpretation of legislative provisions and the scope and length of the document so justifies, the factual information may be set out in a staff working document accompanying the Commission communication or Commission notice.

Such Commission guidance documents containing interpretation of EU law should have a disclaimer to clarify that it is ultimately for the Court of Justice to ensure the uniform interpretation of EU law. The following sentence should be added in the document:

"This [...] is intended to assist [citizens and businesses/ national authorities] in the application of this [EU legislation]. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law."

Regarding guidance documents which have already been made public (or released to third parties), services are requested to follow these guidelines once they decide to revise/update the interpretation of EU law in these documents.

⁵⁵⁴ For example, an impact assessment may be needed.

⁵⁵⁵ See Tool #6 (*Planning and political validation of initiatives*)

⁵⁵⁶ To note that documents that are not adopted by the College (staff working documents) should also be submitted to an interservice consultation, see LS/SG note mentioned above.

⁵⁵⁷ For example, Commission Communication of 9 December 2009 - Implementation of Article 290 of the Treaty on the Functioning of the European Union (COM(2009)673 final).

⁵⁵⁸ It is to be noted that in certain languages, no distinction is made between a Commission interpretative notice and a Commission interpretative communication (for example, in French, both documents will be entitled 'communication').

⁵⁵⁹ [https://eceuopa.eu.sharepoint.com/:u:/r/sites/gopro/SitePages/Autonomous-acts\(1\).aspx?csf=1&web=1&e=ZLOnEu](https://eceuopa.eu.sharepoint.com/:u:/r/sites/gopro/SitePages/Autonomous-acts(1).aspx?csf=1&web=1&e=ZLOnEu)

TOOL #42. DELEGATED AND IMPLEMENTING ACTS

1. INTRODUCTION

The vast majority of EU legal acts are adopted by the Commission in accordance with powers conferred on it by the legislator in basic legislation, either in accordance with Article 290 (delegated acts) or Article 291 (implementing acts) of the Treaty on the Functioning of the European Union⁵⁶⁰. The institutions agreed non-binding delineation criteria in 2019⁵⁶¹ to guide the choice between the two instruments.

A legislative act may grant the Commission powers ('empowerments') to adopt delegated acts: legal acts of general application to supplement or amend certain non-essential elements of a legislative act. The Interinstitutional Agreement on Better Law-Making⁵⁶² between the European Parliament, the Council and the Commission and the **Common Understanding on Delegated Acts**, as annexed to it, set out the practical arrangements and commitments of the institutions on the exercise of these powers.

Empowerments for implementing acts are used where uniform conditions for implementing legally binding Union acts are needed. The rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers have been laid down in the Comitology Regulation⁵⁶³. Implementing powers shall be conferred on the Commission in the legally binding acts concerned.

Guidelines for the Commission services are in place providing detailed explanations on how empowerments for delegated and implementing acts should be included in basic acts, how the empowerments should be used, how delegated and implementing acts should be prepared and how the respective control mechanisms work⁵⁶⁴.

'Better regulation' principles apply to the preparation of delegated and implementing acts as specified in this tool. The key principles are explained below.

2. REQUIREMENTS THAT APPLY TO DELEGATED AND IMPLEMENTING ACTS

Standard clauses must be used when including empowerments for delegated and implementing acts in basic acts. For delegated acts these standard clauses have been agreed between the institutions in the appendix to the Common Understanding on Delegated Acts. For implementing acts, templates for the empowerments are set out in the Drafters' Assistance Package (DAP)⁵⁶⁵.

⁵⁶⁰ An important number of acts are also still adopted under the regulatory procedure with scrutiny (RPS), set out in Article 5a of Council Decision 1999/468/EC. 'Better regulation' principles apply to these measures as well.

⁵⁶¹ The delineation criteria were negotiated and agreed between the Parliament, Council and Commission pursuant to a commitment to that end in point 26 of the Interinstitutional Agreement on Better Law-Making. The criteria are published in OJ 2019/C 223/01.

⁵⁶² [Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making](#) of 13 April 2016 (OJ L 123, 12.5.2016, p. 1)

⁵⁶³ Regulation (EU) 182/2011, OJ L 55, 28.2.2011, page 13.

⁵⁶⁴ Guidelines on Delegated and Implementing Acts, [SEC\(2020\)361](#).

⁵⁶⁵ <https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=dap&title=Home>

The **use of empowerments must be properly planned**. Basic acts often contain several empowerments, sometimes with an obligation for the Commission to act by a specific time and may contain reporting obligations relating to delegated acts.

Delegated and implementing acts should be entered in **Decide planning**, either as 'politically sensitive and/or important' (PSI) initiatives (at the latest 12 months before planned adoption date) or as non-politically sensitive and/or important, as for any other initiative⁵⁶⁶.

A **'call for evidence'**⁵⁶⁷ should be prepared for all delegated and implementing acts identified as PSI initiatives.

Impact assessments should be prepared for delegated and implementing acts when the expected economic, environmental, or social impacts of EU action are likely to be significant and the Commission has a margin of discretion regarding the content of the act⁵⁶⁸. The principle of proportionate analysis applies and the appropriate level and focus of the impact assessment is linked to the type of policy initiative. The impact assessment should be sent to the Regulatory Scrutiny Board for its scrutiny in the usual way⁵⁶⁹. Once the impact assessment report has received a positive opinion from the RSB, it should accompany the implementing act or delegated act as part of the interservice consultation.

Whenever **broader expertise** is needed in the early preparation of delegated and implementing acts the Commission will make use of expert groups, consult targeted stakeholders and carry out public consultation, as appropriate⁵⁷⁰.

Whenever Commission services share early drafts of acts or measures or other preparatory documents with Member State representatives in the relevant committee or expert groups, it must be absolutely clear that these documents are in no way endorsed or adopted by the College⁵⁷¹.

An **interservice consultation** must be carried out, followed by publication for a **4-week public feedback** with certain exceptions⁵⁷².

Where applicable **notifications** of drafts under the Agreement on Technical Barriers to Trade (TBT) or the Agreement on the application of Sanitary and Phytosanitary measures (SPS) in the WTO framework need to take place.

Subsequently, delegated acts are adopted by the Commission and implementing acts are submitted to the committee for an opinion and then adopted by the Commission (if the committee opinion allows).

When the basic acts provides for such a possibility, in the relevant (and duly justified) cases an urgency procedure can be applied for both delegated and implementing acts, allowing them to be adopted and enter into force immediately. However, the control mechanisms (see below) remain applicable post-adoption.

⁵⁶⁶ See Tool #6 (*Planning and validation of initiatives*)

⁵⁶⁷ See Tool #6 (*Planning and validation of initiatives*) and Tool #7 (*What is an impact assessment and when it is necessary*)

⁵⁶⁸ See Tool #7 (*What is an impact assessment and when it is necessary*)

⁵⁶⁹ See Tool #3 (*Role of the Regulatory Scrutiny Board*)

⁵⁷⁰ See Chapter VII on stakeholder consultations

⁵⁷¹ For practical guidance please see <https://webgate.ec.europa.eu/fpfis/wikis/x/fwIUCQ>

⁵⁷² See Chapter VII on stakeholder consultations

2.1. Delegated Acts

Delegated acts need to be prepared in line with the commitments in the Interinstitutional Agreement on Better Law-Making and in the **Common Understanding**, in particular **Member State experts must always be consulted on draft delegated acts** and the **European Parliament and the Council must receive all documents sent to Member State experts** and can send experts to **participate in expert groups** or ad hoc meetings preparing the delegated acts.

Expert groups assisting in the preparation of delegated acts are subject to the rules applicable to expert groups⁵⁷³.

Delegated acts must include an explanatory memorandum⁵⁷⁴.

A basic act may contain several empowerments for delegated acts. On the condition that the Commission provides objective justifications based on the substantive link between two or more empowerments contained in a single legislative act, and unless the legislative act provides otherwise, empowerments may be **bundled**. Consultations in the preparation of delegated acts also serve to indicate which empowerments are considered to be substantively linked (see Interinstitutional Agreement on Better Law-Making, point 31 and Guidelines on Delegated and Implementing Acts, points 130-133). A single delegated act may not be based on empowerments from different basic acts.

After adoption of the delegated act by the Commission, the European Parliament and the Council have the right to object (*two months, generally*). If they do not or if they inform the Commission before the objection period expires that they are not going to object, the delegated act can be published and enters into force.

In case of objection, the Commission must decide on the next steps to take.

The [Register of delegated and implementing acts](#) provides an overview of all the steps in the lifecycle of delegated and implementing acts, from planning to publication in the Official Journal. Draft and final delegated acts and draft and final implementing acts and their progress in the internal decision-making process can be found in the related bibliographic page for the relevant legal acts, under the 'Internal Procedure' tab⁵⁷⁵, in EUR-Lex⁵⁷⁶.

2.2. Implementing Acts

Implementing acts need to be prepared and, where provided for by the basic legal act, submitted to Member State control in the respective committee in accordance with the Regulation laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers – the Comitology Regulation⁵⁷⁷.

⁵⁷³ See rules on expert groups: <https://webgate.ec.europa.eu/fpfis/wikis/display/REGISTRY/Expert%20groups>

⁵⁷⁴ See Tool #40 (*Drafting the explanatory memorandum*)

⁵⁷⁵ For further details, see the Frequently asked questions in EUR-Lex: <https://eur-lex.europa.eu/content/help/faq/intro.html>

⁵⁷⁶ <https://eur-lex.europa.eu/homepage.html>

⁵⁷⁷ Regulation (EU) 182/2011, OJ L 55, 28.2.2011, p.13.

The European Parliament and the Council are informed through the [Comitology Register](#). The European Parliament and the Council have a scrutiny right until adoption which is limited to the exceedance of the implementing powers provided for in the basic act (Art. 11 of the 'Comitology' Regulation). The exercise of this right does not prevent the Commission from adopting the draft implementing act, however in case the European Parliament or the Council indicate that in its view the draft act exceeds the implementing powers, the Commission shall review the draft implementing act (taking into account the position expressed) and inform whether the draft act is maintained, amended or withdrawn.

3. FURTHER READING AND REFERENCES

- [OJ L 55, 28.2.2011](#), page 13
- [GoPro pages](#)
- Guidelines on Delegated and Implementing Acts, [SEC\(2020\)361](#)
- [Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016](#) (OJ L 123, 12.5.2016, p. 1)
- [Non-Binding Criteria for the application of Articles 290 and 291 of the Treaty on the Functioning of the European Union](#) — 18 June 2019, OJ 2019/C 223, page 1.
- [Register of delegated and implementing acts](#)
- [Comitology Register](#)