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PART 2/3

COMMISSION STAFF WORKING DOCUMENT

Vademecum on European standardisation in support of Union legislation and policies

PART II

**Preparation and adoption of the Commission's standardisation requests to the
European standardisation organisations**

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0. INTRODUCTION

This *Vademecum on European standardisation* consists of the following parts relating to standardisation requests:

Part I on the **role** of the Commission's standardisation requests to the European standardisation organisations (ESOs); this part is addressed to Commission officials and all actors in the European standardisation system;

Part II on the **preparation and adoption** of the Commission's standardisation requests; this part is addressed to Commission officials; and

Part III on **guidelines** for the ESOs' **execution** of standardisation requests; this part is addressed to the ESOs and their technical bodies.

The *Vademecum* was originally published in 2003 and revised for the first time in 2009. This second revision reflects the actions identified in the Commission's June 2011 Communication on *A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020*¹ and the requirements of Regulation (EU) No 1025/2012² on European standardisation (hereinafter 'the Regulation').

Parts I to III do not deal with formal objections against harmonised standards or publication of references of harmonised standards in the *Official Journal of the European Union*.³

This part of the *Vademecum* (Part II) sets out guidance for Commission officials on drafting and adopting standardisation requests. The general role and status of requests and general conditions for issuing them are set out in Part I, which officials should consult in parallel with this document before starting any drafting work.

¹ COM(2011) 311 final, 1.6.2011; see Annex II.

² Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012); see Annex II.

³ These will be covered in other documents.

1. OBJECTIVES

This document clarifies the principles to be followed in the drafting and adoption of Commission **standardisation requests** ('mandates')⁴ to European standardisation organisations (ESOs). It is addressed to Commission officials and is structured as follows:

- Section 2 gives guidance on **preparation and adoption procedures**;
- Section 3 gives **generic drafting guidance**;
- Section 4 sets out **the model structure for a request**; and
- Section 5 gives some **basic information on the execution phase**.

This document gives **guidance on the preparation and adoption of standardisation requests** in order to comply with Articles 8, 10(2) and 12 of the Regulation (EU) No 1025/2012 and **ensure proper and wide consultation** of the ESOs, the Annex III organisations,⁵ all other relevant stakeholders and the Member States before the Commission adopts the requests.

In addition, **the model structure will help officials to draw up requests** in line with Article 10(1) with **greater accuracy and efficiency**.

Pursuant to Article 10(2), requests are adopted as implementing acts. The formalities that need to be observed during the process are described generally in this document. Other internal Commission guidance contains more detailed instructions on drafting principles, file preparation and the application of Regulation (EU) No 182/2011⁶ (Comitology Regulation); this should be consulted in parallel.

Our ultimate goal is to ensure that all requests sent for consultation and prepared on the basis of this document:

- contain **realistic deadlines** for execution;
- are **acceptable** to the ESOs;
- enjoy broad acceptance, including from Member States and other stakeholders; and
- enable **efficient and transparent follow-up** during execution.

Specific attention is paid to ensuring the **transparency and efficiency of requested-work programmes**⁷, **harmonised standards** and **any other European standards supporting the application of Union legislation**. This is also in order to

⁴ Article 10(1) to (5) of Regulation (EU) No 1025/2012

⁵ Organisations representing environmental, consumers', workers' and SMEs' interests in European standardisation and funded by the Union on the basis of the Regulation; see: http://ec.europa.eu/growth/single-market/european-standards/key-players/index_en.htm

⁶ OJ L 55, 28.2.2011

⁷ The requested-work programme is an extract from the reference information stored in the 'work programme of a standardisation body (ESO)' (see Article 3(1) and (2) of the Regulation), which is limited to information on the execution of a request and indicates the deliverables actually covered by it at a given moment. The requested-work programme in the context of this document contains no project planning or reporting elements.

promote the involvement of societal stakeholders and to achieve SME-friendly standardisation and SME-friendly harmonised standards.

The conditions for issuing a standardisation request are described in section 5 of Part I and should be consulted before starting any drafting work.

2. PROCEDURE FOR THE PREPARATION AND ADOPTION OF A STANDARDISATION REQUEST

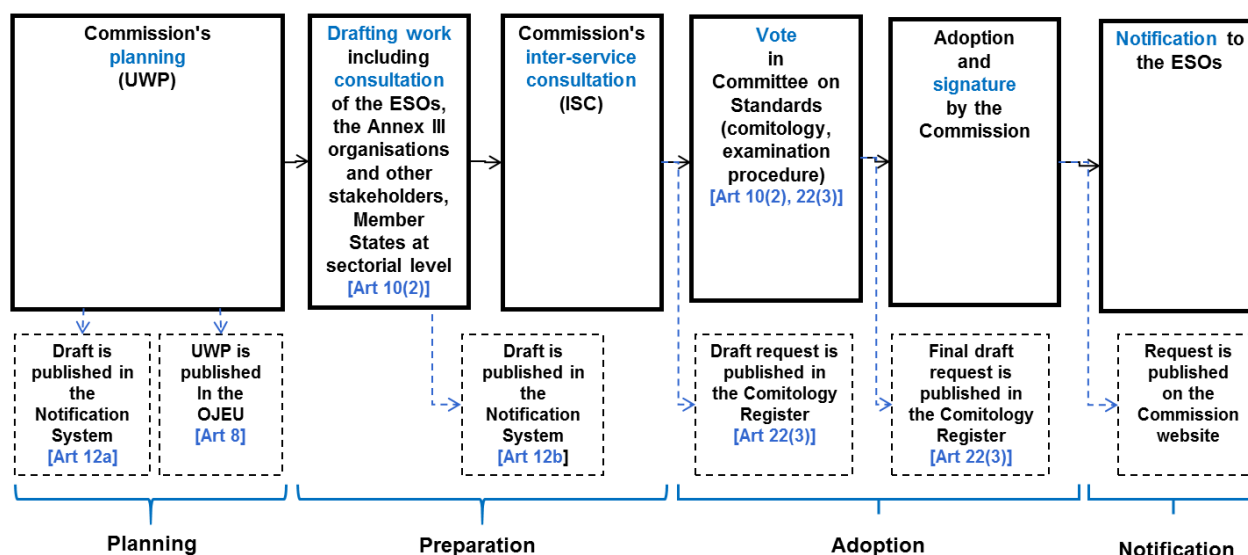
2.1. Responsibilities of Commission departments

Standardisation requests are drawn up on the initiative of a Commission department responsible for an area of Union legislation and policy. The legal basis for a request comes from the relevant sectoral legislation or policy, in line with Article 10(1) of the Regulation. The relevant department is ultimately responsible for the content of the request and monitoring its execution.

That department also manages the Commission's internal processes (except comitology in the Committee on Standards) and internal tools and practises for planning, drafting and adopting legislative proposals.

The 'standardisation unit' in the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) coordinates the **planning**, **preparation** and **adoption** of standardisation requests (see Table 1 and Figure 1), aiming to ensure the **uniform application of the Regulation** and **chairing the Committee on Standards** (which is a comitology committee). This Committee establishes the opinion of

Figure 1: Issuing standardisation requests – overall workflow⁸



⁸ Public websites or web services mentioned in the flowchart:
 Notification system: http://ec.europa.eu/growth/single-market/european-standards/notification-system/index_en.htm
 Comitology Register: <http://ec.europa.eu/transparency/regcomitology/index.cfm>
 Database on Commission's standardisation requests: http://ec.europa.eu/growth/single-market/european-standards/requests/index_en.htm.

Table 1: Commission departments' responsibilities and task allocation

Tasks	Sectoral department	DG GROW	Vademecum section
Planning phase (Articles 8 and 12a)			5 (Part I); 2
Ideas and proposals for possible new standardisation request	x	[frequent surveys]	5.1-5.2 (Part I) 2.2.1
Annual Union work programme for European standardisation (UWP)	[consulted]	x	2.2.1
Possible preliminary work is launched (outside requests)	x	[guidance is given]	5.3 (Part I)
Preparation phase (Articles 10(1) and (2) and 12b)			6 (Part I); 2-4
Setting target dates for preparation and adoption [in SIGNIFERI]	x	-	2.3-2.4; Annex I
Drafting work using available templates [in SIGNIFERI]	x	[gives drafting support before consultations start]	3 (Part I); 6 (Part I), ; 3-4; Part III
Consultation of Commission's research facilities when relevant. This includes in particular the Joint Research Centre (JRC).	x	-	3.10
Discussions with the ESOs and simultaneous consultation of the ESOs, Annex III organisations, other relevant stakeholders and Member States' sectoral experts [main facts are recorded in SIGNIFERI]	x	[gives contact points, participates in meetings if appropriate]	2.5-2.6
Background note (summary) on the consultation of Member States' sectoral experts is drafted (to be available before the examination procedure is initiated during the adoption phase)	x	[distributes to the Committee on Standards]	2.2.2; 2.5.3
Draft standardisation request is uploaded to the notification system. This is done before an ISC is initiated.	[provides the draft in SIGNIFERI]	x	Figure 1; Table 3
Initiation of ISC after uploading of required information in SIGNIFERI and receiving authorisation from SIGNIFERI (Commission internal process)	x	[preferably co-responsible; gives drafting support before launching ISC]	Figure 1
Adoption phase (Article 10(2) and (3))			2
Initiation of the adoption file	x	[co-responsible]	
Translations (EN/FR/DE) (through the adoption file)	x	-	
Obtaining the opinion of the Committee on Standards under the examination procedure (vote in a meeting or by written procedure)	[provides the draft request in EN/FR/DE and the background note]	x	2.5.4
Uploading the draft Implementing Act and other required documents to the Comitology Register (public and internal) before and after the vote and making the opinion of the Committee available to the sectoral department	-	x	
Actions needed for final adoption (signature)	x	-	
Notification phase			2.2.3; 5
Secretary-General notifies the ESOs of the request	-	-	
Action to record ESO acceptance (or rejection) and all deadlines in a request to allow follow-up of execution [recorded in SIGNIFERI]	-	x	5.4-5.6

the Member States under the examination procedure, in accordance with Article 10(2) of the Regulation. It has to accept a request (by qualified majority vote) before the Commission can adopt its implementing decision on the request.

DG GROW also provides tools⁹ for planning and preparing requests and monitoring their execution.

2.2. Overall workflow during preparation and adoption

2.2.1. Planning phase (Articles 8, 10(1) and 12(a))

Article 8 of the Regulation requires the Commission to adopt an annual Union work programme for European standardisation (UWP). This gives the ESOs an indication of possible future standardisation requests (see section 5.1 in Part I).

DG GROW collects information on items for possible future requests (including preliminary and ancillary action; see section 5.3 in Part I) from all the Commission departments via a survey launched in the first quarter of every year. However, departments should inform DG GROW as soon as possible of their intentions as regards future requests or other action, without necessarily waiting for the survey.

After the survey, DG GROW prepares a draft UWP, on which it then consults the ESOs, the Annex III organisations, other relevant stakeholders and the Member States through the Committee on Standards, in accordance with Article 8(4) of the Regulation.

The draft UWP then undergoes Commission inter-service consultation (ISC) and is entered in the notification system in accordance with Article 12(a).

Once adopted, the UWP is published in the *Official Journal*, usually by the end of the second quarter.

2.2.2. Preparation phase (Articles 10(1) and (2) and 12(b))

In the preparation phase, the standardisation request is drafted and consultations and discussions on it are held in parallel with the ESOs, the Annex III organisations, any other relevant stakeholders¹⁰ and Member States' sectoral experts, typically in committees set up under the corresponding Union legislation. This is the most important phase of the drafting process in that it ensures that requests are acceptable for the ESOs and that execution deadlines are realistic.

Sectoral departments must record the required evidence on consultations held in the preparation phase (see section 2.5) and produce a background note to report on consultations with the Member States' sectoral experts. This note is used by the chair of the Committee on Standards to inform the Committee of the opinions of the sectoral committees before the examination procedure.

⁹ SIGNIFERI is an IT tool to plan and manage the overall process, provide access to templates, contact details, annual reports, etc. which also provides internal links to Commission guidance documents and applications concerning file preparation and comitology.

¹⁰ It is under the responsibility of sectoral departments to identify and select "relevant stakeholders" consulted and whether this should also include non-European or national stakeholders

The number of consultations during the preparation phase and the time taken should be proportionate in the light of the subject matter and the issues concerned. To avoid unexpected delays, it is strongly recommended that all interested parties be consulted in parallel on the basis of the same draft text. The ESOs and the Annex III organisations have a specific status (see section 4 in Part I) under the Regulation and the time needed to consult them should be agreed with them. It is never possible to proceed without their contributions.

At the end of the preparation phase, DG GROW uploads the draft standardisation request to the notification system. Considering that this notification may be a source of further remarks from stakeholders the sectoral department should wait for a sufficient and reasonable period of time before launching an ISC.¹¹ Before doing so, the department needs to record the required consultation information and upload the draft request in SIGNIFERI to allow DG GROW to check the text.

2.2.3. Adoption and notification phases (Articles 10(2) and (3), 22(3) and (4))

After completion of the ISC, the sectoral department launches the adoption phase.

First, it sends a request to DG Translation for translation of the standardisation request into English, French and German. Where the implementing act (the request) is addressed to the ESOs only, it is not published in the *Official Journal*. In specific cases where a request establishes requirements which have additional legal effect, e.g. they set a generally applicable benchmark for safety assessment of a product or a service, translations into all official languages and publication in the *Official Journal* may be needed.

Once the translations are available, the department submits the draft implementing act to DG GROW, which launches the comitology (examination) procedure. The Committee on Standards delivers its opinion in a meeting (attended by the sectoral department) or through written procedure. Where written procedure is applied the draft request needs to be presented by the sectoral department in a meeting of the Committee before initiating the procedure.

Where the Committee is delivering its opinion in a meeting, the chair can table an amended version, on the basis of members' proposals, before the Committee gives its opinion. In the case of a written procedure, the Committee members are simply asked to give their opinion on the draft implementing act submitted for a vote. If the written procedure is terminated without result then the Committee's opinion is delivered in a meeting.

Where the Committee delivers a positive opinion, the Commission shall adopt¹² the draft implementing act and cannot change the text on which the Committee gave a positive opinion.

Where the text, as amended on the basis of Committee members' proposals, differs too radically from the initial draft that underwent ISC, another ISC is required, with a shorter deadline if necessary.

¹¹ Preferably with DG GROW (as *co-responsible*).

¹² However, in very exceptional circumstances, the Commission may take into account new circumstances that have arisen since the vote and decide not to adopt a draft implementing act.

Shortly after the Commission has adopted the implementing act, the relevant ESO(s) are notified automatically¹³ and the Act is made available on the DG GROW website.

2.3. Timing during preparation

In some cases, a standardisation request is intended to support the application of Union legislation or policy that is still under consideration in the Council and in the European Parliament on the basis of a Commission proposal. The preparation work should start while these discussions are ongoing, or even before, and the Commission should signal in the UWP its intention to issue a request as soon as this becomes evident.

Thus, in the case of new legislation to be supported by European standards or European standardisation deliverables, it is not always necessary to wait for final adoption before initiating the examination procedure in the Committee on Standards. However, a stable legislative text¹⁴ must be available before closure of the consultations referred to in Article 10(2) in the preparation phase and before launching the ISC.

If there is any doubt as to whether the legislator would accept the use of European standardisation to support the legislation or as to the nature of the legal requirements to be supported, the preparation phase must not be closed.

By submitting a standardisation request to examination procedure in the Committee on Standards or adopting it before the new legislation is formally approved by the legislator or published in the *Official Journal*, the Commission can save time in carrying out the standardisation work and implementing the legislation. However, it should evaluate carefully case by case whether this is possible or advisable.

2.4. Deadline planning

Before starting the drafting work, officials should set and record an estimated adoption date and other important target dates (see Annex I). This helps in giving an idea of the time needed for drafting and consultations and also helps the ESOs to start their resource planning at an early stage. It is recommended that deadline planning be based on a target date for launching the ISC, as the subsequent workflow is quite predictable. Also, it is then possible to estimate the final notification date.

In practice, given the time needed for the normal ISC procedures¹⁵ (four to six weeks), translation (three to four weeks), the comitology procedure (five to six weeks) and the adoption of an implementing act (three to six weeks), an optimistic minimum lead time from ISC launch until final notification of the ESO(s) is at least four months.

2.5. Regulated consultations

2.5.1. Consultation and provision of information

In the planning and preparation phases, it is essential to consult appropriately and widely with all relevant interested parties in order to ensure that the standardisation request

¹³ Normally in 48 hours.

¹⁴ i.e. there is already agreement between the Council and the Parliament on the provisions of the future legislation and its final content is known, but time is still needed to formalise this agreement.

¹⁵ Counting the time needed for the procedure itself and action to open and close the procedure.

enjoys wide technical and political acceptance and that its execution is based on realistic deadlines.

Articles 8, 10(2) and 12 of the Regulation provide for two types of consultation (see Table 3). All consultations and information provision under headings I and II in Table 3 are mandatory under the Regulation or the Comitology Regulation.

DG GROW is fully responsible for managing and coordinating the provision of public information (heading I). It ensures access to information for all interested parties and for stakeholders or organisations that have no direct relations with the Member States' representatives or with the European-level organisations that must be consulted on the basis of Article 10(2). These parties can therefore feed in their input where appropriate.

The sectoral department is responsible for the consultations referred to in Article 10(2) (i.e. item 6 under heading II). During these consultations (see sections 2.5.2 to 2.5.4), the department can decide on the forms of consultation (correspondence, emails, bilateral or other meetings, online tools etc.) and how many times the issue is discussed with each interested party. However, consultees should have at least one opportunity to submit written contributions. The department must record in SIGNIFERI the dates or deadlines and principal outcome of the consultations.

It should be borne in mind that draft requests submitted for consultation by sectoral departments under Article 10(2) should not have confidentiality classification and the recipients may usually pass them on to third parties. This same applies to draft requests made available in the Notification System and through the Comitology Register.

Table 3: Regulated consultations and information provision

I. Public information provision	
Planning and preparation	1. The draft UWP is made publicly available in the Notification System (Article 12(a));
	2. The UWP is published as a Commission Communication in the <i>Official Journal</i> in all official EU languages (Article 8);
	3. Draft standardisation requests are made publicly available in the Notification System (Article 12(b));
	4. Draft implementing acts submitted to comitology are made publicly available in the Comitology Register ¹⁶ (Article 10(1) of the Comitology Regulation);
	5. Final draft implementing acts (following delivery of the opinion of the Committee on Standards) are made publicly available in the Comitology Register (Article 10(1) of the Comitology Regulation);
II. Consultations with limited target audience and comitology	
Preparation and adoption	6. Consultations of the ESOs, Annex III organisations and Member States' sectoral experts; these are to be transparent and include all industrial or other stakeholders who are observers or members of sectoral committees or expert groups ¹⁷ (Article 10(2));
	7. Obtaining the opinion of the Committee on Standards under the examination procedure (vote by qualified majority (Articles 10(2) and 22(3))).

¹⁶ <http://ec.europa.eu/transparency/regcomitology/index.cfm>.

¹⁷ <http://ec.europa.eu/transparency/regexpert/>.

2.5.2. Consulting the ESOs

It should be feasible¹⁸ for the ESOs to fulfil a standardisation request within the deadlines given in it.

Bilateral discussions and negotiations with the ESOs on the Commission's intentions should therefore start at an early stage and at the latest after a possible new request is referred to in the UWP. Suitable preparatory or ancillary work may be needed in cooperation with the ESOs during the planning phase (see section 5 in Part I).

Sectoral departments should contact the ESOs' central secretariats directly and not any individual technical bodies (committees, working groups or other equivalent drafting entities), NSBs or other ESO members, as these are not in a position to discuss either the content of a possible request or the deadlines in it.

The ESOs are solely responsible for identifying and communicating any relevant technical bodies, NSBs or other members or partners that should be involved in any discussions. They are the only contact points representing all members, at national (NSB) or other levels, and should actively inform and consult their members and other stakeholders as appropriate during discussions with the Commission.

Sectoral departments should endeavour to prepare requests that the ESOs will find acceptable. The technical content of drafts submitted for ISC and the deadlines in them should therefore have already been agreed with the ESOs.

During the preparation phase, the sectoral department should systematically inform the ESOs of changes in a draft request.

The reasons for proper consultation of the ESOs are twofold:

- to maximise the likelihood that they can accept all requests of which they are finally notified and that all deadlines are in line with their capabilities and resources to execute the work within agreed deadlines; and
- to ensure that they can start planning their (human, technical, financial) resources and call for the involvement of interested volunteer experts at an early stage.

It may become clear through consultations in the planning and preparation phases that, on the basis of their priorities, the ESOs are not in a position to execute a possible request. In this event, preparation must stop and the department in question should consider, on the basis of its sectoral legislation or policy, other means of supporting the achievement of the policy objectives.

2.5.3. Consulting the Annex III organisations

In order to increase their involvement in and 'ownership' of the whole standardisation process, the Regulation makes special provision for involving certain stakeholders, represented by the Annex III organisations, in the adoption of requests (see also section 4.6 in Part I).

¹⁸ Under Article 10(1) of the Regulation, the requested 'European standards and European standardisation deliverables shall be market driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus'.

Experience has shown that these stakeholders provide valuable input but do not have the means to participate effectively at all levels of standardisation. The ESOs' obligation to encourage and facilitate the representation and effective participation of all relevant stakeholders does not entail giving them voting rights, unless they have such rights under the ESOs' internal rules of procedure. Consequently, the Regulation requires the Commission to listen to these 'weaker stakeholders' when it plans and prepares its standardisation requests. By doing so, the Commission can guarantee that its UWP and requests are drafted in a balanced way.

Other stakeholders' organisations not explicitly recognised in Annex III but claiming to represent the same stakeholder groups should be encouraged to cooperate with the Annex III organisations to agree on a consolidated position.

2.5.4. Consulting Member States' sectoral experts

The Regulation applies to all sectors and the Committee on Standards is consulted at the end of the process for its opinion on all standardisation requests. The Member States thus have a crucial role in accepting any Commission proposal for a request.

It is therefore important, and a legal obligation under Article 10(2) of the Regulation, that sectoral departments duly inform the Member States at sectoral level when planning possible requests and in particular during the preparation phase.

The department responsible for a request should consult its usual Member State contacts, e.g. through sectoral committees or expert groups,¹⁹ including administrative cooperation groups.²⁰ This is even more important where a request supports the Union's policy in areas where it does not have exclusive competence.

The Member States' sectoral experts are expected further consulting their national stakeholders and public administrations.

Under the rules and procedures of the Committee on Standards, the chair (the Commission) must inform it of the opinions of the Member States' sectoral experts during the consultation phase. For this purpose, the sectoral department in question must draft a note covering the basic facts of the consultations.

2.6. Other consultations

Other relevant European-level stakeholder organisations (such as industry organisations) representing the typical users of any requested deliverable should also be consulted. When accepting meetings or dialogue with organisations other than those referred to in Article 10(2) of the Regulation, such organisations must be found in the Transparency Register.²¹

Sectoral departments should not consult or accept dialogue with individual members of the organisations referred to in Article 10(2), but should ask national authorities and

¹⁹ Member States not represented in an expert group should be consulted directly (e.g. via their permanent representations).

²⁰ Administrative cooperation groups (ADCOs) enable cooperation between market surveillance authorities in the field of product legislation.

²¹ <http://ec.europa.eu/transparencyregister/info/homePage.do?locale=en>.

institutions, etc. to submit any comments or opinions through their representatives on the relevant sectoral committees or to the ESOs through their relevant membership.

2.7. Union financing of European standardisation activities

The ESOs are private organisations that, together with their members, must find for themselves the (human, technical, financial) resources they need to carry out any European standardisation work.

Under Articles 15 and 17 of the Regulation, Union financing may be granted to enable the ESOs and NSBs to develop or revise European standards and standardisation deliverables (among other activities mentioned in the Regulation) as necessary or appropriate to support Union legislation or policies. Such financing is available within the limits of the Commission's annual budget and on the basis of proposals from the ESOs, which must satisfy established quality criteria for the awarding of such funding.

However, the Commission can never link a standardisation request to a guarantee for public funding for specific activities and requests must make no direct commitment or reference to funding. The ESOs can apply for Union funding on formally accepting a request and the Commission must then inform them about the award of a grant within two months (see Article 10(4)).

When consulting the ESOs, it is important to make sure that the deadlines agreed in a draft request include any time needed for them to plan resources and apply for funding. Under Article 17(4) of the Regulation, grants for the development and revision of European standards and European standardisation deliverables should take the form of lump sums²².

3. GENERAL GUIDANCE FOR DRAFTING A STANDARDISATION REQUEST

3.1. Introduction

Before starting the drafting work, it is useful to consult the following articles of the Regulation to understand which aspects of the planning, preparation and execution of standardisation requests are directly regulated:

- Article 1: Subject matter;
- Article 2: Definitions;
- Article 3(6): 'Standstill' for harmonised standards;
- Articles 5 to 7: Stakeholder participation at European and national levels;
- Article 8: Annual Union work programme;
- Article 9: Scientific input from Commission research facilities;
- Article 10: Standardisation requests to the ESOs, including the requirements to assess the compliance of requested documents;
- Article 12: Notification system; and
- Article 15: Standardisation activities which may be financed by the Union.

²² See C(2015)3697 final

3.2. Addressees

All ESOs should be contacted in the preparation phase in order to clarify which would be competent, and/or willing to execute it. In general, all ESOs should be notified of the final request, but in some clear-cut cases it can be addressed to particular ESOs.

Where joint action by two or all three ESOs is expected or requested, this should be specifically indicated in the request, e.g. by asking for a joint work programme and joint reporting.

3.3. Clarity in indicating the legal framework and justifying a request

A standardisation request conveys the public authorities' expectations to the ESOs. It is therefore important to pay close attention to clarity. The quality of a request has a significant bearing on the standardisation activities and therefore also on the quality of the resultant deliverables and any other action.

A request should clearly answer the following questions:

- **why?** – the reasons for a request, i.e. the Union legislation or policy it is intended to support;
- **what?** – a description of the deliverables requested or expected; and
- **when?** – the deadlines for delivery.

Article 10(1) and (2) establishes the legal framework for issuing requests to the ESOs in terms of generic requirements as to content, and consultation and adoption procedures.

However, the Regulation alone should not be used to justify requests – there must always be a well-defined sectoral reason too, based on:

- **Union legislation**, e.g. where Union harmonisation legislation foresees a need for harmonised standards with a specific legal effect; or
- established **Union policy**, e.g. where non-legislative documents state that European standardisation could promote defined policy objectives (in such cases, the ESO deliverables cannot have a specific legal effect on the basis of the standardisation request).

A request can also be based on a combination of these two elements that will justify the request, on the one hand, and provide the framework within which the ESOs are asked to work, on the other.

3.4. Scope of requirements in a standardisation request

When drafting the requirements of a request, it is important to understand the public-private partnership between the Union and the ESOs. The cooperation agreement between the ESOs and the Commission and EFTA sets out the principles for this partnership and the common policy objectives.

The Regulation establishes legally binding requirements as regards transparency and stakeholder participation in European standardisation (Chapter II, Articles 3 to 6) and annual reporting to the Commission (Article 24).

Standardisation requests must not duplicate the requirements in the Regulation, in particular those in its Chapter II. They may, however, require special reporting on how the latter are met in practice during execution of the request and what specific action has been taken to ensure compliance.

The requirements in a request should cover:

- the subjects to be covered by the deliverables requested;
- reporting to the Commission; and
- the deadlines for execution; but
- not any matters already covered by the ESOs' internal rules.

The purpose of a standardisation request is to initiate European standardisation activities while accepting the ESOs' established framework for producing, revising, and adopting their deliverables and making them available.²³ Thus, all requests must respect the ESOs' internal rules on:

- consensus-building in their technical work;
- procedures for adopting their deliverables; and
- the structure and drafting of their deliverables.

Similarly, the Commission expects the ESOs to respect the requirements applying to them under the Regulation and to apply their own internal rules for drafting standards correctly and consistently.

A request may also set requirements for specific testing and related validation (see section 3.8) during the standardisation work outside the usual consensus-building process.

3.5. Reference to legal requirements in a standardisation request

Where European standards are needed to support application of Union legislation, the standardisation request must, at least, clearly indicate any legal restrictions and requirements to be observed during the standardisation work. Where these are very general, it is useful to clarify and explain them.²⁴ The more precise a request, the easier it is subsequently to verify whether a deliverable complies with it.

Also, the more precise the request, the less likely it is to be interpreted differently, possibly leading to a deliverable that does not entirely satisfy the legal requirements which it aims to cover and that needs to be amended in accordance with Article 11 of the Regulation. The level of precision should be discussed with the ESOs when they are consulted on a draft request.

²³ CEN and CENELEC make their European standards available in three languages (DE, EN, and FR) for their national members (NSBs), who then make them available as identical national standards. ETSI makes its European standards publicly available on its website, in English only.

²⁴ Because requests are implementing acts, care should be taken not to decide on legal interpretations that could subsequently be used in other context.

3.6. Indicating legal requirements aimed to be covered by European standards – general principles

In the case of harmonised standards and other European standards supporting Union legislation, the relevant request must clearly refer to the legal requirements to be supported. Also, when the ESOs deliver standards at the end of the process, it should always be clear:

- which standards are linked to which requests;
- to what extent they cover the legal requirements; and
- whether they contain specifications that are not, and cannot, be linked to any of them.

The ESOs are free to choose the content of their own standards, how and to what extent they cover legal requirements and whether requested standards also cover subject matter not supporting the application of Union legislation. They may also decide to offer European standards not originally developed in response to Commission standardisation requests. This includes standards originally developed by other bodies which are afterwards transposed by the ESOs as European standards. In such cases, the relevant ESO is responsible for verifying the extent to which such standards can be submitted to the Commission in response to a request.

Requests should always ask for a clear and precise²⁵ indication of the relationship between the normative clauses²⁶ of a requested European standard and the legal requirements aimed to be covered together with a reference to the relevant Commission Implementing Decision (request). This will improve transparency and avert subsequent problems of legal uncertainty.

The above applies, in particular, in the case of standards that will have a legal effect²⁷ once their references are published in the *Official Journal*.²⁸ In practice, the information is usually given in an annex to the requested standard. Until the references of the standard are published in the *Official Journal*, the annex has no legal status, but is only indicative of intention. However, as from publication in the *Official Journal*, it shows how the legal requirements in the request and the corresponding Union legislation can be satisfied.

3.6.1. Rationale for indicating legal requirements covered

Indicating the above relationship (between the clauses of a standard and the legal requirements it is intended to address) during the preparation phase allows all parties to

²⁵ The level of required precision would depend on the nature of the legal requirements being supported and the subject matter dealt with by a standard.

²⁶ Under the ESOs' internal rules, only a **normative element** (of a standard) sets out provisions. Consequently, provisions supporting the application of Union legislation can be given only in the normative clauses of a standard.

²⁷ However, this legal effect can be challenged under Article 11 of the Regulation or on the basis of sectoral legislation.

²⁸ In the case of direct referencing, this information is unnecessary (and may even be inappropriate), as the legislator selects the clauses referred to in the relevant legislation.

assess the work in progress and the extent to which it satisfies the legislation and the request.

In particular, this information allows the users of a standard to establish the extent to which it provides (or would provide) presumption of conformity with the legally binding requirements that it aims to cover.

Other reasons why it is important to indicate clearly the legal requirements covered by a particular standard are that:

- it enables the technical bodies of the ESOs to take a systematic approach during the drafting work by continuously assessing it for compliance with the request;
- it helps the Commission departments, the Member States and the European Parliament to assess whether a European standard actually covers the legal requirements appropriately and the extent to which it may (also) contain elements that cover matters outside Union legislation and thus cannot be claimed to support it;
- it enables market surveillance authorities to identify the extent to which they should accept *a priori* presumption of conformity when compliance with a harmonised standard, or clauses thereof, is declared;
- it helps notified bodies to perform their functions, including identifying how compliance with a harmonised standard should be reflected in conformity assessment procedures under the relevant Union legislation;
- it provides manufacturers, especially SMEs using the standard, with a working tool enabling them to benefit from the legal effect (typically ‘presumption of conformity’)²⁹ when declaring compliance with the applicable legal requirements; and
- it enables the ESOs to provide the Commission with European standards originally developed by other bodies that could be used to provide presumption of conformity with Union harmonisation legislation to the extent indicated in the informative annex (to be drafted by the relevant ESO(s)).

3.7. Requirements for indicating significant changes in European standards supporting the application of Union legislation

Requested European standards supporting the application of Union legislation are subject to periodic review and revision, like any other European standards. The ESOs initiate review or revision according to their internal rules; however, in some cases it can also be initiated by standardisation requests adopted by the Commission.

When they revise such standards (typically harmonised standards), the ESOs amend, add or remove specifications or revise the scope. The references of the revised standards should be published again in the *Official Journal* (see Article 10(6) of the Regulation). This leads to the references to previous editions being removed from the *Official Journal*

²⁹ The manufacturer retains full responsibility for assessing all the risks of the product in order to determine which essential (or other) requirements apply. However, ‘benefiting from presumption of conformity’ means that a product’s technical documentation can usually simply refer to harmonised standards (or clauses thereof) applied and no other rationale on implemented specifications is needed.

and losing legal effect which comes from the application of the older editions withdrawn.³⁰

When revising a standard, the ESOs can amend the specifications that enable the legal effect under Union legislation.³¹ If standard users want to continue to benefit from the presumption of conformity, they must adapt their products and services and related technical documentation to the revised standard referred to in the *Official Journal*. In some cases, the revision of a standard can also have consequences for conformity assessment procedures to be followed under the relevant Union legislation.

Requests should ask the ESOs to provide information on any change arising from subsequent revision or amendment; this is to:

- avoid legal uncertainty in cases where voluntary standards are applied;
- enable easier application of conformity assessment against revised standards;
- ensure full transparency of the legislative technique based on indirect referencing to European standards; and
- minimise the financial burden on manufacturers and service providers, especially SMEs.

3.8. Requirements for validation of provisions in a standard

Where provisions in the requested ESO deliverables should be validated during the standardisation work (e.g. repeatability and reproducibility testing for a measurement method), the request should specify the testing requirements (inter-laboratory tests, etc.).

3.9. Possible requirements for cooperation with other bodies

Where the requested ESO deliverables could be based on standards or technical specifications originally developed and published by other bodies,³² a request may refer to these and to the need for cooperation with the other bodies only if the relevant ESO has already established relations with them.

3.10. Cooperation with Commission's research facilities

Where the Commission's research facilities³³ are to provide the ESOs with scientific input in their areas of expertise during execution, the request shall set out their exact role, their responsibilities and applicable deadlines.

³⁰ The last date for the legal effect of a withdrawn standard is established by the Commission in the *Official Journal* (to be covered by other documents).

³¹ Revision of a voluntary harmonised standard can, to some extent, have an effect equivalent to that of a legislative amendment, as it may lead to the redesign and/or modification of technical design documentation if a manufacturer or service provider wants to continue to benefit from the presumption of conformity.

³² In this context, 'other bodies' refers to standardisation organisations (including fora/consortia, etc.) outside the European standardisation system, other than ISO, IEC or ITU.

³³ This includes in particular the Joint Research Centre (JRC).

3.11. Deadlines for execution of a standardisation request

Deadlines in the final request should be precise dates. However, during the preparation phase, dates counted from the notification date³⁴ to the ESOs should be used. Where the Commission and the ESOs set and/or agree on deadlines after the request is issued, the work programmes must also use precise dates.

4. MODEL STRUCTURE FOR A STANDARDISATION REQUEST

4.1. Standardisation requests as implementing acts

The legal form of a standardisation request is an implementing act (Commission implementing decision) drafted in line with Commission drafting rules.³⁵

Annex II to this document establishes the main elements (articles and annexes) that should be found in each request. The required content of recitals, articles and annexes is described generally in this section.

The model structure also establishes common practice for reporting and the availability of work programmes in order to establish an agreed level of compliance with Articles 3(1)-(4) and 10(5) of the Regulation during requested standardisation work and to enable transparent follow-up during execution.

In specific cases, such as when amending requests adopted on the basis of Article 10(2), it may be necessary to apply these main elements only partly or to include other specific elements.

4.2. Recitals of a Commission implementing decision

The recitals of a request should contain at least the following:

- information on **the sectoral legal basis**, the **public interests** at stake and the **policy objectives** that justify the request. These recitals should be drafted clearly, so that even someone unfamiliar with the subject matter can easily understand:
 - what is requested;
 - why the request is being issued (including its market-relevance);
 - what is the public interest in having these deliverables; and
 - what are the policy objectives to respond to the requirements in Article 10(1) and any relevant sectoral provisions;
- where applicable, **a reference to the mention of the request in the UWP**;
- **a reference to the practical guidelines in this Vademecum**;
- where applicable, **a reference to a consolidation of previous requests** or to an amendment to or repeal of a previous request;
- where applicable, a reference to the fact that **a request is addressed to one or two ESOs only**;
- a reference to **consultations** on the basis of Article 10(2); and

³⁴ 'Notification date' should be considered as the 'date of receipt' within the meaning of Article 10(3).

³⁵ <http://www.cc.cec/wikis/display/dap/Home>.

- a reference to **the opinion of the Committee** established by Article 22 having been sought.

4.3. Articles of a Commission implementing decision

A request should contain at least the following articles (in order):

Article 1: Requested standardisation activities

This article makes clear reference to:

- the requested standardisation activities (legal reference and subject matter covered);
- the requested deliverables or subject matter;
- the content of the deliverables (usually described in an annex); and
- the deadlines for adoption of the requested deliverables by the ESO(s) (usually given in a separate annex).

Article 2: Establishment of the work programme

This article asks the ESO(s) to establish and provide a work programme by a certain deadline. A request should not specify any internal action to be taken by the ESOs in determining and setting up a work programme or give any deadlines for the start of their work. However, it may set more than one deadline for the establishment and provision of a work programme, e.g. to allow more time for work on certain parts of the programme or to allow the ESOs to provide and set up certain part(s) of a work programme after clearly defined milestones.

Article 3: Agreement on the work programme

This article refers to any priorities set by the Commission as regards execution of the work programme and asks the ESOs to inform it of any amendments. In the case of harmonised standards, it is strongly recommended that this article contain a procedure for expanding a work programme during its execution (see section 6.2 in Part I).

Article 4: Reporting

This article establishes an annual reporting requirement and sets a deadline for the first report. In the case of requests of limited duration, a deadline should also be given for the final report.

Article 5: Harmonised standards³⁶

This article is for harmonised standards and other standards that can give presumption of conformity with a particular piece of legislation. It asks the ESOs to:

³⁶ The title of this article could be adapted to take into account the specificities of relevant Union legislation in the case of other European standards the references of which are to be published in the *Official Journal* in order to establish the legal effect specified by the relevant Union legislation.

- indicate the relationship between the content of a (harmonised) standard and the corresponding legal requirements (referred to in Article 1 of the request) aimed to be covered by it;
- refer to the relevant Commission implementing decision (request) in all (harmonised) standards covered by the request;
- indicate significant changes introduced by a revised or amended (harmonised) standard; and
- provide the Commission with the titles of (harmonised) standards.

Article 6: Validity and repeal

This article sets validity conditions in the event of no ESO accepting the request. It can also be used to set other conditions for validity or repeal, where the request repeals previous requests.

Article 7: Addressees

This article identifies the addressees (the ESO(s)) of a standardisation request.

4.4. Annexes to a Commission implementing decision

Each request should have at least two separate annexes (see below), which must be referred to in its articles. However, in specific cases where there are only limited requirements and few requested deliverables, the information can be included directly in the articles themselves.

4.4.1. Annex I: Requirements for the [European]/[harmonised] standards [and European standardisation deliverables]

The purpose of this annex is to establish the requirements to be met by the content of the requested European standards and/or European standardisation deliverables.

This technical annex is the most important part of a request, as it specifies all requirements for the requested deliverables and possibly for other specific action during the standardisation work. Where appropriate, these requirements are used afterwards to evaluate whether the objectives of a request have been fulfilled.

The annex contains a general explanation of the standards or other deliverables requested or subject matter to be standardised. This includes a general description of the expected deliverables and requirements as to scope and content. In the case of harmonised standards or other European standards which should provide a legal effect with legally binding requirements given in the Union legislation, there must be a clear reference to the essential or other legal requirements that are the starting point for the requested deliverables.

This annex may specify coordination or follow-up action (e.g. task forces or steering committees) beyond the usual annual reporting as appropriate. It is also possible to include request-specific content for the work programme and for reporting.

The annex should also always have a section establishing requirements for the standards or other deliverables. Other request-specific sections may be needed:

- to set out requirements for specific action during the standardisation work;
- where Commission research facilities will need to contribute to the work (see section 3.10); or
- to set out specific requirements for the validation of technical specifications (see section 3.8).

4.4.2. *Annex II: [European]/[harmonised] standards [and European standardisation deliverables] and deadlines for adoption*

The purpose of this annex is to identify clearly the requested deliverables and the deadlines for their adoption by the ESOs.

The annex establishes a clear list of all requested deliverables or subject matter in tabular format on the basis of the requirements (usually) given in Annex I, together with the respective deadlines on the basis of policy needs and as agreed with the ESOs.

4.5. Guidelines for the execution of standardisation requests

The ESOs should adhere consistently to a number of commonly agreed principles and practices in the execution of all standardisation requests. These should be stable and it is not appropriate to include detailed requirements in the articles or annexes of each individual request. This is why the recitals of each request refer to the guidelines in this *Vademecum*. To avoid conflict with the general principles, officials should consult Parts I and III of this document when drafting requests.

4.6. Internal reference number and access to the texts of standardisation requests

For internal purposes, DG GROW assigns an informal reference number (M/xxx) to each request once the ESOs have been notified of it. This facilitates informal reference to a request and continuity with the previous numbering system under Directive 98/34/EC.

Soon after notification, requests are made publicly available on the Commission's website in the 'mandates database'.³⁷ The reference number is displayed on the top right-hand corner of all requests in the database.

5. ACCEPTANCE AND EXECUTION OF A STANDARDISATION REQUEST

5.1. ESOs' acceptance of a standardisation request

According to Article 10(3) of the Regulation the ESOs shall indicate within one month, after the receipt, whether they accept a standardisation request addressed to them.

In order to limit cases of requests being rejected by the Member States in the Committee on Standards (before they have been adopted) or by the ESOs (after they have been adopted), it is crucial that all consultations are carried out during the planning and preparation phases and enable all interested parties to express their views clearly (see section 2.5).

³⁷ http://ec.europa.eu/growth/single-market/european-standards/requests/index_en.htm.

The Commission should submit a request to draft European standards and European standardisation deliverables for formal adoption only when it is confident that it will be acceptable to the ESOs. Whether the ESOs are finally in a position to execute the Commission request to draft European standards and European standardisation deliverables in support of Union legislation and policies shall be always formally verified according to Article 10(3).

When a request is rejected by all ESOs to which it was addressed, it no longer constitutes a basis for the drafting of requested deliverables. There are no further possibilities to negotiate amendments with the ESOs without re-initiating Article 10(2) procedures. The relevant Commission departments should then consider:

- restarting preparation and consultations under Article 10(2), but with shorter deadlines for both; or
- establishing the requisite technical specifications by other means provided for in the relevant sectoral legislation.

5.2. Starting the work and agreement on the requested-work programme

Standardisation is a voluntary and independent activity and the ESOs are free to decide when to start their preparatory or drafting work.

For the Commission, however, it is desirable that the ESOs' members decide early on whether to accept a request and what resources are available, so that the standardisation work can get under way as soon as possible.

Requests must not contain dates for 'starting execution' or any preconditions dependent on further Commission action or decisions. However, after receiving the initial requested-work programme from the ESO(s), the Commission department should be proactive and respond promptly, acknowledging receipt and making any remarks needed to ensure correct execution of the request.

5.3. Updates to the requested-work programme

Where the requested-work programme is updated on the basis of a proposal from the ESO and according to the procedure in the relevant request, the Commission department must examine the proposal without delay and respond to the ESO after informing the Committee on Standards.

5.4. Commission follow-up during the execution phase

Once the ESOs have been notified of a standardisation request, DG GROW immediately records the specific deadlines in it to enable follow-up of reporting and execution. DG GROW records and monitors all such deadlines and related deliverables centrally (via SIGNIFERI). However, it remains the sole responsibility of the sectoral department in charge of a request to:

- monitor execution through annual reporting and other appropriate forms of cooperation with the ESOs (possibly as specified in a request) including possible participation in the ESO work; give appropriate guidance to the ESOs; and
- ensure that appropriate assessment measures are implemented, as required by Article 10(5) of the Regulation (see section 7 in Part I).

5.5. Informing the Committee on Standards during the execution phase

DG GROW keeps the Committee on Standards informed of progress on all requests during the execution phase. To enable it to do so, sectoral departments should always ensure that DG GROW itself is fully informed of all major events (e.g. reports or other documents specified in requests, changes in the requested-work programmes of which the Committee should be informed, etc.).

5.6. Common principles for deadlines and events during the execution phase

The main elements of a request (see section 4 and Annex II) establish a model for setting deadlines and events during the execution phase. This uniform approach enables consistent monitoring of the execution of all requests.

Figure 2 shows the main steps in the process of drafting a standardisation request and the immediate execution of a request. It identifies some dates on the basis of which it is possible to track progress in the production of new requested deliverables. The relevant events and deadlines are further explained in Table 3.

Figure 2: Harmonised standards – overall workflow for issuing and executing a standardisation request

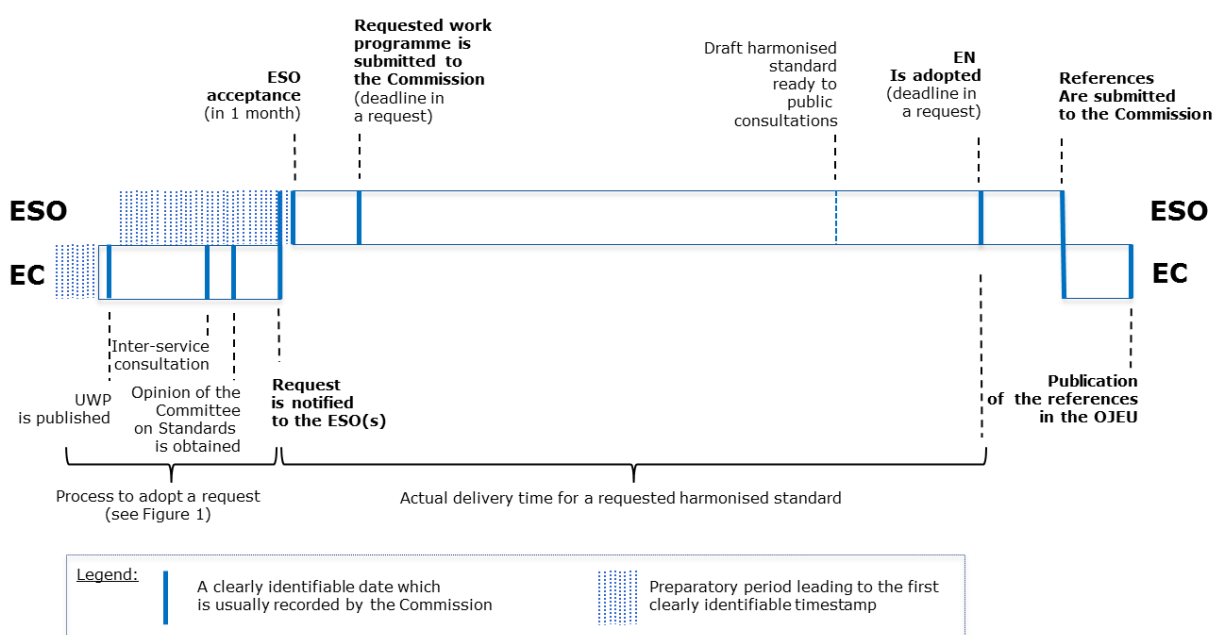


Table 3: Most common deadlines and events during the execution phase

Action/event	Deadline/date
ESOs are notified of a standardisation request	The date on which to base other deadlines in a request (if relative dates are used)
ESO acceptance (or rejection)	One month after notification under Article 10(3)
Possible ESO funding request (the need for funding is established by the ESO)	Submission date decided by the relevant ESO (Commission responds within two months); can be the same as ESO acceptance date.
Provision of a requested-work programme	Date set case by case in each request (there could be more than one deadline if the work programme needs to be established in several phases)
First annual report	Date set case by case in each request
Final report (possible for requests supporting Union policies)	After completion of request or a set date given in request (for requests on harmonised standards, annual reporting needs to continue even after completion)
Requested document adopted by ESOs	Deadline set in each request ; actual planned deadline confirmed in requested-work programme

ANNEX I: Checklist for planning the overall process

Tasks	Remarks	Target	Done
Planning phase			
Information on a possible request is sent to DG GROW			
Draft request is published in the UWP			
Possible preliminary work is launched			
Preparation phase			
Start drafting work in cooperation with DG GROW (standardisation unit)			
Inform and consult Joint Research Centre when relevant			
Consultation of the ESOs (Article 10(2)) [include several contacts as appropriate]			
CEN			
CENELEC			
ETSI			
Consultation of Member State sectoral experts, including observers or other members of committees or expert groups			
Consultation of the Annex III organisations [include several contacts as appropriate]			
SME stakeholders			
Consumer stakeholders			
Environmental stakeholders			
Social stakeholders (trade unions)			
Consultation of other stakeholders or interested parties at European level			
Finalise preparation phase			
Prepare background note summarising opinions of Member State experts during consultation (required by Committee on Standards rules and procedures)			
Finalise draft request			
Send draft request to DG GROW (standardisation unit) for review and notification in the Notification System			
Presentation of draft to the Committee on Standards			
Start ISC (after checking that the notification was done)			
Close ISC			
Adoption and notification phases			
Initiate adoption file			
Ask for translations			
Submit all three language versions (DE/EN/FR) to DG GROW (standardisation unit) to start comitology (examination) procedure			
Examination procedure in the Committee on Standards			
Ask for translations if text is amended			
Provide voting results, final texts and other required information to enable adoption and notification to the ESOs			

ANNEX II: Main elements of a standardisation request

1. Recitals [see section 4.2]

2. Articles [see section 4.3]

Article 1: Requested standardisation activities

Article 2: Establishment of the work programme

Article 3: Agreement of the work programme

Article 4: Reporting

[Article 5: Harmonised standards]

Article 6: Validity [and repeal]

Article 7: Addressees

3. Annexes [see section 4.4]

Annex I: Requirements for the [European]/[harmonised] standards [and European standardisation deliverables]

Annex II: [European]/[harmonised] standards [and European standardisation deliverables] and deadlines for adoption

Table [1] — Requested [new] [harmonised]/[European] standards [and European standardisation deliverables] for

Reference information	Deadline for adoption³⁸
1.	<i>[MM/YYYY]/[XX months after notification of Decision to the ESOs]</i>
2.	<i>[MM/YYYY]/[XX months after notification of Decision to the ESOs]</i>

Table [2] — Existing harmonised standards and draft harmonised standards covered by this request³⁹

Reference information	Deadline for adoption
<i>Harmonised standards in the latest list of references of the harmonised standards under published in the Official Journal (OJ C xxx, xx.xx.20xx), including those still under development on the basis of .</i>	<i>Adoption according to internal planning of [CEN]/[Cenelec]/[ETSI]</i>

³⁸ ‘Adoption’ refers to the relevant ESO making a standard available to its members or the public.

³⁹ This is used when a request consolidates an old request.