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Vademecum on European Standardisation in support of Union Legislation and policies

PART I

Role 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'). The original version came in response to a request from the Council in a resolution in 1999:³

'The Council calls upon the Commission

- to ensure that standardisation mandates under the new approach are prepared accurately and efficiently, affording Member States and the European standards bodies sufficient opportunity to contribute;
- to ensure that standardisation activities covered by mandates are subject to thorough monitoring and that appropriate measures are examined with the European standards bodies in order to ensure proper progress.'

The revised *Vademecum* (like the Regulation) also responds to the European Parliament's Resolution of 21 October 2010 on the future of European standardisation:⁴

'The European Parliament, [...]

15. [...] stresses that the European legislator must be highly vigilant and precise when defining the essential requirements in regulation, while the Commission must clearly and accurately define the objectives of the standardisation work in the mandates; stresses that the role of standardisers should be limited to defining the technical means of reaching

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 OJ C 141, 19.5.2000

⁴ 2010/2051(INI);
[http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2010/2051\(INI\)](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2010/2051(INI)).

the goals set by the legislator as well as ensuring a high level of protection; [...]

22. Calls on the Commission to revise and rationalise the process to deliver standardisation mandates to ESOs, so as to include a consultation phase with relevant stakeholders and a thorough analysis that justifies the need for new standard-setting activity, in order to ensure the relevance of standard-setting and avoid duplication and the proliferation of divergent standards and specifications; [...]

While the original *Vademecum* mainly concerned standardisation requests issued under Union harmonisation legislation for products only (i.e. ‘new approach’ legislation), this revised version is much wider in scope and reflects the Union’s revised standardisation policy as set out in 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*.⁵

In preparing the revised *Vademecum* (which it has submitted to the Committee on Standards), the Commission has sought to bring it up to date and reflect changes introduced by the Regulation as regards the rules on the establishment of European standards and European standardisation deliverables for products and services in support of Union legislation and policies.

1. OBJECTIVES

The objective of this document is to ensure a common understanding of the role of Commission’s standardisation requests (‘mandates’) to the European standardisations organisation (ESOs)⁶ and the role and responsibilities of the various actors in planning, preparing and executing these requests. It is addressed to all actors of the European standardisation system (ESS) and in particular to Commission officials, public authorities in the Member States and EFTA countries, the ESOs, the organisations identified in Annex III⁷ to the Regulation, the national standardisation bodies (NSBs) and all stakeholders in European standardisation.

In line with Articles 1 and 10(1) of the Regulation, **the Union may use European standardisation as a policy tool to support the application of Union legislation and policies for products and for services**. The Commission may ask the ESOs, through a standardisation request, to develop ‘**European standards**’ or ‘**European standardisation deliverables**’ which:

- take into account the public interest and policy objectives clearly stated in the request;
- are market-driven; and

⁵ These will be covered in other documents.

⁶ See Annex I to the Regulation: the ESOs are the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).

⁷ http://ec.europa.eu/growth/single-market/european-standards/key-players/index_en.htm.

- are based on consensus.

The request also **sets out “requirements as to the content to be met by the requested document and a deadline for its adoption”**.

The Regulation makes major changes to the processes of **planning, preparing, adopting, accepting and executing** standardisation requests, in terms of inclusiveness, transparency and compliance with the requirements given in a request. It also provides a firm legal basis for issuing requests in domains beyond Union harmonisation legislation on products (i.e. also on services) and allows the Commission to issue requests in support of Union policies where there is no Union legislation and to ask the ESOs to develop European standardisation deliverables⁸ rather than European standards.

This *Vademecum* is a guidance document concerning all standardisation requests to the ESOs adopted by the Commission on the basis of Article 10(1) and (2) of the Regulation. It also explains the impact of the Regulation on the execution of requests issued before it became applicable.

Certain sectoral Union legislation⁹ may contain specific provisions on the scope, content and adoption of standardisation requests that are not specifically addressed in this document.

This document pays particular attention to requests for European standards that support the application of Union legislation to ensure coherent application of ‘indirect referencing’¹⁰ to harmonised or other European standards and related processes.

Annexes provide background information concerning role of standardisation in public policies and links to key reference documents.

2. ROLE OF EUROPEAN STANDARDISATION IN THE EUROPEAN UNION

2.1. Reference documents setting and implementing the Union’s standardisation policy

The basic principles of the Union’s standardisation policy are set out in the following:

(a) Regulation (EU) No 1025/2012 on European standardisation

⁸ The term ‘European standardisation deliverable’ is defined in Article 2(2) of the Regulation as ‘any other technical specification than a European standard, adopted by a European standardisation organisation for repeated or continuous application and with which compliance is not compulsory’.

⁹ e.g. Regulation (EU) No 305/2011 on construction products

¹⁰ In the context of this document:

- ‘indirect referencing’ (to standards in Union legislation) is a technique whereby Union legislation makes a collective reference to unspecified harmonised or other European standards adopted on the basis of a Commission request and where the Commission subsequently publishes the exact references of such standards in the *Official Journal* in line with Article 10(6) of the Regulation and/or sectoral legislation;
- ‘direct referencing’ (to standards in Union legislation) is where the relevant Union legislation itself contains an exact reference to a standard or parts thereof as set by the legislator.

The Regulation is the legal basis for the Commission's requests to the ESOs to draw up European standards or European standardisation deliverables in support of Union legislation and policies.

It gives a strong preference to the use of these 'ESO deliverables' in support of Union legislation and policies. It also lays down the procedures to be applied when harmonised standards are used to provide a presumption of conformity with legal requirements:

- setting requirements on the quality of harmonised standards;
- conditions for the publication of references of a harmonised standard in the *Official Journal*; and
- a procedure concerning formal objections against harmonised standards in order to prevent, remove, restrict or confirm the presumption of conformity.

The Regulation imposes requirements on the ESOs and NSBs with respect to transparency and inclusiveness, in order to avoid possible negative effects caused by insufficient direct participation by or representation of stakeholders (e.g. SMEs or consumers) in the standard-setting process or by a lack of information on the standardisation bodies' work programmes. It also establishes the legal basis for the financing of European standardisation activities.

(b) Sectoral legislation

Some Union sectoral legislation may refer to European standards as a voluntary means of ensuring compliance with legal requirements, or in some cases as a compulsory means¹¹ (e.g. in order to classify regulated subjects). Such legislation sets a baseline for technical specifications to be detailed further in European standards requested by the Commission. It may also impose further requirements or conditions for the processes set out in the Regulation, such as for the adoption of standardisation requests, publishing a reference of standard in the *Official Journal* and objecting to standards. These specificities are not detailed in this document.

(c) Annual Union work programme for European standardisation (UWP)

Pursuant to Article 8 of the Regulation, the Commission adopts an annual Communication identifying strategic priorities for European standardisation, taking into account the Union's long-term strategies for growth and other Union policies. The UWP also indicates what European standards and European standardisation deliverables the Commission intends to request from the ESOs.

(d) General guidelines for cooperation with the ESOs

The general guidelines¹² for cooperation between CEN, Cenelec and ETSI, the European Commission and the European Free Trade Association (EFTA) are set out in a political document and based on an understanding first established in 1984 and reviewed in 2003.

¹¹ Commission policy is to promote the voluntary use of standards and to avoid compulsory referencing to standards in Union legislation.

¹² OJ C 91, 16.4.2003

In the document, the partners confirm their common understanding of the role of European standardisation and its principles (e.g. openness, transparency and impartiality), and their willingness to cooperate, on the basis of the principles, in support of European policies. Some of the principles were later expressed as legal requirements in the Regulation.

(e) Framework partnership agreements (FPAs)

Regularly reviewed framework partnership agreements¹³ between the Commission and the ESOs set out the common cooperation objectives and the administrative and financial conditions applying to grants awarded to the ESOs on the basis of Articles 15 and 17 of the Regulation.

2.2. Recognised ESOs

In the European Union, successful implementation of the single market requires not only sufficient harmonisation of legal requirements, but also other measures, including application of the principle of mutual recognition and rules for European and national standardisation work. European standardisation creates common standards which are widely used and recognised throughout the Union, and ensures that national standardisation does not create unnecessary obstacles to trade that would be against the fundamental rules of the single market.

The Regulation specifically recognises the ESOs and European standards as important means of implementing the objectives of the Union's standardisation policy. The ESOs are selected on the basis not only of historical factors but also the fact that they work according to recognised procedures aiming to promote the harmonisation of voluntary national standards.

Since the entry into force of Directive 83/189/EEC,¹⁴ European and national standardisation bodies have been regulated in the Union through information exchange provisions in order to prevent barriers to trade arising. Through their partnership with ESOs, the NSBs have a common voluntary commitment to harmonising voluntary national standards, which in turn contributes significantly to the functioning of the single market.

The ESOs are appropriate strategic partners for the Union for a number of reasons:

- within ESO work at European level, the NSBs cooperate to produce common European standards; this prevents national standards from being developed, which, even when not referred to in national legislation, could create technical barriers to trade;
- internal ESO rules require the NSBs to transpose all European standards as national standards and to withdraw any conflicting national standards;

¹³ Article 17(5) of the Regulation

¹⁴ Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations. Directive 98/34/EC (OJ L 204, 21.7.98) is a codification of Directive 83/189/EEC and its amendments.

- the ESOs have cooperation agreements with international standardisation organisations (e.g. the Vienna Agreement between CEN and ISO¹⁵, the Dresden Agreement between Cenelec and IEC¹⁶, ETSI’s Memorandum of Understanding with ITU¹⁷), which ensure that European, and thus also national, standard-setting is aligned as much as possible with international standardisation. Such agreements enable EU/EEA countries to be the biggest user of equivalent international ISO/IEC standards; and
- as members or partners of CEN and Cenelec, the NSBs have an interest in promoting European standardisation at national level, including through the distribution of European standards in national languages¹⁸ and the provision of services for all stakeholders using the national language at local level.

These reasons show why the Union’s standardisation policy, as reflected in the Regulation, gives a strong preference to European standards as the predominant technical specifications to be referred to in Union legislation when such specifications are needed.

For the same reasons, references to other standards or technical specifications in Union legislation should be done only after careful considerations, because:

- it is sometimes not possible to determine whether such standards or technical specifications were developed in line with the ‘founding principles’¹⁹ of standardisation;
- access to them (like national points of sale and distribution) may be limited;
- their availability in national languages could be hampered by copyrights and/or exploitation rights; and
- they may not comply with the principles applied in the EU.

European standards also have a specific role under the Union’s public procurement legislation,²⁰ which specifies that technical specifications in public procurement should be formulated, primarily, with reference to national standards transposing European standards.

Articles 13 and 14 of the Regulation lay down specific rules for identifying, for public procurement purposes, ICT technical specifications which are not European standards or European standardisation deliverables.

¹⁵ the International Organization for Standardization

¹⁶ the International Electrotechnical Commission

¹⁷ the International Telecommunication Union

¹⁸ The language of European or national standards is not regulated by the Union.

¹⁹ The principles recognised by the World Trade Organisation (WTO) in the field of standardisation, i.e. coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency.

²⁰ Directives 2014/24/EU and 2014/25/EU

3. ROLE OF COMMISSION'S STANDARDISATION REQUESTS

3.1. Concept of a standardisation request

Standardisation is a process based, in principle, on the needs of the market. Public authorities are among the actors on this market and they may consider that technical specifications are needed in order to support the implementation of public policies.

In the EU, such public needs are addressed in a standardisation request ('mandate') which aims to safeguard public interests, for example:

- to establish an agreed way of meeting legal requirements on health, safety, environmental protection, civil security and interoperability;
- to promote technical development, the harmonisation of national standards; or
- to create better framework conditions for the competitiveness of European industry.

The practice of asking ESOs to draw up technical specifications required by the public authorities was established by Directive 83/189/EEC. Through a standardisation request, the public authorities (in practice, the Commission after consulting the Member States) ask the ESOs to draw up technical specifications meeting 'their' requirements in order to support the implementation of Union legislation or general public policies. In the case of harmonised standards, the original purpose of a request is to ensure the quality of harmonised standards developed by the ESOs (see the Council Resolution of 7 May 1985 on *A new approach to technical harmonization and standards*).²¹

A standardisation request may ask that deliverables (such as harmonised standards) be based on legally binding requirements in Union legislation. In this case, by accepting a request, the ESOs undertake to establish technical specifications that should match with the legal requirements (such as essential requirements) and should reflect a high level of health and safety or other precondition dictated by the relevant legislation.

A standardisation request may also ask for deliverables not linked to specific pre-set legal conditions, such as deliverables promoting general harmonisation or technological progress. In such cases, the ESOs do not have to observe any specific preconditions on the basis of Union legislation in their standardisation work.

In the case of European standards aiming to provide a specific legal effect,²² the legislator needs to lay down strict requirements through legislation in order to safeguard the public interest and it is the responsibility of those preparing the standards to draw up technical specifications meeting such requirements, as referred to in a standardisation request, and to take due account of the generally acknowledged 'state of the art'.

²¹ 'In order that this system may operate it is necessary: — on the one hand that the standards offer a guarantee of quality with regard to the 'essential requirements' established by the Directives ... The quality of harmonized standards must be ensured by standardization mandates, conferred by the Commission ... ', OJ C 136 of 4.8.1985

²² In the case of harmonised standards, this effect is defined in the sectoral legislation and is usually a 'presumption of conformity'. The term is used in this document to cover all possible effects.

Therefore, in issuing a standardisation request, the Commission does not delegate political powers to the ESOs and their members, but recognises their specific technical roles in the process. It is the request — together with the Regulation and the relevant sectoral legislation — that describes and justifies the tasks that the public authorities assign to the ESOs. This assignment is purely technical and addressed to private organisations. Consequently, specifications delivered by the ESOs in support of Union legislation can never be automatically regarded as complying with the initial request,²³ as this is a political responsibility. As the requesting authority, the Commission will always have to assess compliance²⁴ with its initial request, in cooperation with the ESOs (see also section 7), before deciding to publish the references of a delivered standard in the *Official Journal* or referring to it ‘by other means in accordance with the conditions laid down in the corresponding Union harmonisation legislation’ (Article 10(6) of the Regulation).

The legal requirements, e.g. essential requirements laid down in legislation and requirements in a standardisation request, should be defined precisely in order to avoid misinterpretation on the part of the ESOs or leaving them to make political choices. This is fundamental to allow those preparing standards in support of Union legislation to provide high-quality specifications, as all political choices are to be made by the legislator. Such choices may include setting certain limits on a person’s exposure to a hazard²⁵ or (with harmonised standards) setting dates when the presumption of conformity should start or end. Thus, close attention must be paid to establishing detailed and precise legal requirements to be supported by technical specifications, taking due account of existing opinions issued by the Commission or its scientific committees.

A standardisation request accepted by an ESO should be regarded as a reference framework for European standardisation in support of the Union’s policy objectives. The requests should be regarded as reference documents for the standardisation activities, together with the Regulation and the ESOs’ internal rules meaning that they give requirements or guidance for standardisation work.

3.2. A standardisation request as an implementing act

Under the Regulation, standardisation requests are adopted using the procedure set out in Regulation (EU) No 182/2011²⁶ (Comitology Regulation) and issued by means of a Commission implementing decision. The Committee set up on the basis of Article 22(1) of the Regulation (‘Committee on Standards’) produces opinions on draft implementing acts and these are obtained using the examination procedure. Where the Committee on Standards gives a positive opinion on a draft implementing act by qualified majority, the Commission shall adopt the decision and notifies it to the ESOs.

The procedure ensures that a standardisation request to the ESOs reflects wide acceptance among public authorities and the will of the Member States.

²³ The same principle applies when Commission agencies develop technical specifications that are used in Union legislation or endorsed by the Commission as legally binding.

²⁴ In this context, the Commission and the ESOs may consult anybody they wish for their assessment.

²⁵ e.g. Directive 2006/42/EC on machinery gives no limit values for noise emissions as a condition for placing machinery on the market and provides that such values cannot be given in voluntary harmonised standards either.

²⁶ OJ L 55, 28.2.2011.

A standardisation request should not be regarded merely as an indicative invitation to start voluntary standardisation activities; by accepting it, the ESOs commit themselves to publishing clearly identified deliverables meeting the requirements in the request in line with the agreed deadlines.

Also, if the ESOs want to ask for Union financing, they should respect in their funding request the deadlines of the standardisation request.

The ESOs may reject a standardisation request, but they cannot reject or veto the legal framework for the products or services that it establishes or refers to. If a request to develop European standards or European standardisation deliverables is rejected by all the ESOs to which it was addressed, it may not constitute a basis for drafting such European standards or European standardisation deliverables.

Standardisation requests issued before the Regulation was applicable remain valid reference points for standardisation work provided they are not in conflict with the Regulation (see also section 6.5). However, since these old requests were not issued as implementing acts, they cannot be amended by implementing acts adopted under the Article 10(2) of the Regulation.

3.3. Implications of non-compliance with a standardisation request

Cases where the ESOs are unable to respect the provisions in a standardisation request can be classified into two categories on the basis of Article 10(1) of the Regulation:

- i. 'the requirements as to the content to be met by the requested document' are not (entirely) fulfilled; and/or
- ii. 'a deadline for its adoption' (of the requested deliverable) is not met (late or no adoption).

In addition, there may be cases where the standardisation process itself does not comply with the requirements in the Regulation (transparency, inclusiveness and reporting requirements).

In none of these cases does the Regulation provide for specific sanctions, but non-respect of the requirements in a standardisation request can have implications (see Articles 10(6), 11(1) and 17(4)). These relate to the **recognition of deliverables** produced by the ESOs and **Union funding** for the ESOs; for example:

- if a harmonised standard does not comply with a relevant request, it is not referenced (in the *Official Journal* or by other means) at all according to the relevant Union legislation or the reference is removed or restricted;
- if a harmonised standard is not available by the agreed deadline, other means or technical specifications may continue to provide or be used to provide a presumption of conformity in line with the provisions of the relevant sectoral legislation;
- the annual or action-based Union funding provided to the ESOs may be affected; and
- there may be a need to amend the request to agree on new deadlines for the adoption of the requested deliverables.

4. ACTORS IN COMMISSION-REQUESTED EUROPEAN STANDARDISATION

4.1. Main actors as recognised by the Regulation

The concept of a standardisation request is based on the principles of partnership and cooperation, and on the clear division of tasks and roles between the main actors, as recognised by the Regulation.

Table 1: Tasks and roles of the main actors in setting and executing Union’s standardisation policy (Commission-requested standardisation)

| Main actors | Tasks and/or roles |
|---|--|
| The legislator (the Council, including Member States, and the European Parliament) | Legislative and political actor <ul style="list-style-type: none"> – sets the legal framework and boundaries for standardisation policy; – decides how to use standards or other technical specifications in Union legislation; – may challenge harmonised standards providing, or intended to provide, a legal effect (formal objection); – in some cases, a Member State may regulate how standards requested by the Commission can be used to comply with national conditions. |
| Commission | Policy setter and executor <ul style="list-style-type: none"> – implements Union standardisation policy and sets priorities; – proposes new legislation where application is supported by standards; – manages other specific standardisation-related tasks assigned to it in Union legislation (e.g. adoption of standardisation requests, assessment of compliance of documents drafted by ESOs with its initial requests, publication of the references of harmonised standards in the <i>Official Journal</i>, adoption of decisions to remove publication of the references of harmonised standards from the <i>Official Journal</i>, management of Union financing on European standardisation); – manages relations between the Union and the ESOs. |
| ESOs (together with their members and stakeholders) | Technical actor <ul style="list-style-type: none"> – execute the technical work requested in standardisation requests; – coordinate the technical work to develop and adopt state-of-the-art technical specifications in cooperation with their members on the basis of consensus between those participating in the standardisation work; – ensure that the transparency and inclusiveness requirements in the Regulation are respected and appropriately reported; – offer the references of the requested technical specifications to the Commission, which then assesses compliance of technical specifications with the requirements of the relevant Union legislation. |
| European stakeholder organisations meeting the criteria in Annex III and financed by the Union (Annex III organisations) | Industrial and societal stakeholders <ul style="list-style-type: none"> – have a specific status under the Regulation to make the Commission-requested standardisation process more inclusive; – ensure that SMEs’, consumers’, workers’ and environmental interests are made known to the Commission before the UWP or new standardisation requests are adopted; – have direct access to policy development and technical work within the ESOs on the basis of the Regulation. |

4.2. Role of the Commission

4.2.1 Drawing up standardisation requests

The Commission establishes the Union's policy and priorities for the European standardisation used to support Union legislation and policies (see section 5) and coordinates the overall process of drawing up standardisation requests, from planning to notification to the ESOs. It is responsible for the final content of a request, which it drafts after consulting the ESOs, the Annex III organisations, the Member States and other relevant stakeholders (see section 2 of Part II).

4.2.2 During the standardisation work

Under the ESOs' internal rules, the Commission can nominate representatives to participate **as observers or counsellors** in the standardisation work. This enables the Commission to explain and clarify the requirements in a standardisation request and related Union legislation, for example, but it cannot unduly influence the ESOs in their selection of certain specifications or veto decisions they take in accordance with their internal rules.²⁷ The Commission should, however, give its opinion on standardisation priorities on the basis of work programmes established by the ESOs. It can also express its opinion on priorities when financing standardisation activities.

The Commission should guide the ESOs in the standardisation work on the basis of the requirements in a request and as established by the Regulation and sectoral legislation. At least, the Commission department responsible for a request should establish permanent liaison with the contact point(s) provided by the relevant ESO(s).

During the standardisation work and after the ESOs have adopted the deliverables, the Commission must respect, in its guidance and assessment, the requirements of relevant sectoral legislation or policy and as given in its request. Should the relevant Union legislation or policy evolve during execution of a request having effect to standardisation needs, the Commission should amend the request in line with Article 10(1) and (2) of the Regulation.

4.2.3 During the compliance assessment (Article 10(5))

The Commission must take appropriate measures in cooperation with the ESOs to assess the compliance of the requested deliverables with its initial standardisation requests (see section 7).

4.2.4 When publishing references of European standards in the Official Journal (Article 10(6))

Where a standardisation request in support of Union legislation and application of a standard it has requested should have a particular legal effect, the Commission needs to

²⁷ However, on the basis of Article 4 of the Regulation, the Commission can act and submit comments on any draft technical specification whether mandated or not, in particular where there are doubts as to possible negative impacts on the single market.

verify²⁸ in due time²⁹ whether the final deliverable satisfies the requirements aimed to be covered and as expressed in the request and the relevant Union legislation.

The Commission should do this on the basis of the compliance assessment (see section 7). If the conditions of Article 10(6) are met, the Commission must publish the references in the *Official Journal* without delay. Where, on the basis of all information available, delivered European standards fail to fulfil the initial request and the regulatory needs, the Commission should, on the basis of the relevant request, refuse referencing (publishing the references in the *Official Journal* or by other means in accordance with Article 10(6) of the Regulation) to such a European standard or may decide to refer to it in a limited way.

In the case of harmonised standards supporting Union harmonisation legislation, the Commission can refuse to publish the references in the *Official Journal* on the basis of Article 10(5) and (6) of the Regulation.

4.3. Role of the Member States during the standardisation work

National public authorities have a formal right to participate in the European standardisation process **by nominating experts directly or as members of a national delegation**. Article 7 of the Regulation requires the Member States to encourage national public authorities, including market surveillance authorities, to participate in the development or revision of Commission-requested standards through their NSBs.

The active participation of national public authorities at all stages of the development and revision of standards is one of the most effective means of promoting the quality of the standards and minimising subsequent formal objections.

4.4. Role of the ESOs

Standardisation requests specify the public authorities' expectations as regards the provision of requested European standards and European standardisation deliverables, and indicate the legal framework or policy context and the policy objectives for voluntary standardisation work. Although they are unilateral acts, they are prepared after close dialogue with the ESOs and invite them to draw up deliverables responding to certain conditions (e.g. risks or other aspects) and involving certain tasks to be completed within a given deadline.

Where a standardisation request asks the ESOs to develop European standards supporting Union legislation, such as harmonised standards, the ESOs should pay particular attention to compliance with the initial request and any specificities it refers to and laid down in sectoral legislation as regards the standards' content, conditions for revision and availability.

The ESOs are responsible for accepting standardisation requests. Acceptance of a request for harmonised standards restricts their ability to launch new conflicting standardisation initiatives.

²⁸ The extent of these verifications should be considered case by case on the basis of sectoral legislation, the role of such standards and the information available.

²⁹ *Code of Administrative Conduct*; http://ec.europa.eu/transparency/code/index_en.htm.

Articles 3 to 5 of the Regulation lay down legally binding requirements as regards the transparency of work programmes, on transparency of draft standards and other standardisation deliverables, and the inclusiveness of standardisation processes (not restricted to standardisation requested by the Commission). Although the ESOs are private organisations, in Commission-requested standardisation work they execute tasks of high public interest on the basis of requests from public authorities and sometimes with public financing. They should therefore adhere to Articles 3 to 5 in the course of such requested work.

Where cooperating in standard development with other bodies (e.g. the ISO, the IEC or European sectoral standardisation bodies), the ESO that accepted the request remains fully responsible and accountable, in the course of elaborating or revising a standard, for its compliance with the initial request.

4.5. Role of ESO members, including NSBs

The ESO members decide whether a standardisation request is accepted or not by the relevant ESO. Once a request has been accepted, it is up to the members to decide whether delegates or experts should participate in the standardisation work in line with the ESOs' internal rules.

ESO acceptance of a request for a harmonised standard limits the NSBs' ability to develop or publish national standards that are not fully in line with an existing harmonised standard (see Article 3(6) of the Regulation). In addition, all national standards which conflict with a harmonised standard must be withdrawn within a reasonable time.

An ESO's acceptance of a request also means that its members accept the request as a binding reference document for the European standardisation in question. Successful execution of a request requires the ESO members to communicate its terms of reference to their national or other delegations and to all nominated experts participating in the Commission-requested standardisation work.

In line with their internal rules, the NSBs are expected to consult their national stakeholders on all issues where a decision needs to be made at ESO level. The same applies in the case of European standardisation requested by the Commission. Article 6 of the Regulation, which is not restricted to standardisation requested by the Commission, requires the NSBs to encourage and facilitate SME access to standards and standard development processes. In addition, Article 24(1) requires them to report annually on how SMEs, consumer organisations and environmental and social stakeholders are represented in their work.

4.6. Role of European stakeholder organisations financed by the Union

Experience has shown (and this was confirmed by the impact assessment³⁰ linked to the Commission proposal for the Regulation and by public consultation on the matter) that certain stakeholders are underrepresented in standardisation activities that concern them and their representation, participation and contribution should therefore be improved. The Union's standardisation policy identifies such weaker stakeholders as SMEs, consumers, workers and organisations representing environmental interests: 'Significant

³⁰ SEC(2011) 671 final, 1.6.2011; SEC(2011) 672 final, 1.6.2011

scope also exists to increase SMEs' and societal stakeholders' participation in European standardisation committees, although issues related to time and cost form significant barriers to access'.³¹ These stakeholders do not always have sufficient resources to take part in the standard-setting process and consequently sometimes lack the means to put forward their position during the consensus-building process or in final voting.

In order to improve the inclusiveness of the European standardisation process, including but not only in the case of Commission-requested standardisation, the Regulation establishes a legal basis for the Union financing of European-level stakeholder organisations representing SME, consumer, workers' and environmental interests in European standardisation. Annex III to the Regulation sets out eligibility criteria for selecting and financing one organisation in each of the four categories.

The Regulation specifically recognises these 'Annex III organisations' and asks the Commission to consult them directly when it is planning and preparing standardisation requests. This privileged position compensates for the fact that enterprises and stakeholders represented by these organisations usually have no or insufficient resources to participate in the standardisation work through normal channels (i.e. through a national delegation or participating directly at national or European levels) when such requests are executed.

Under Article 5(1) of the Regulation, the Annex III organisations shall also have access to specific stages in the development of European standards and European standardisation deliverables, including access at policy development level within the ESOs' standardisation activities (including but not only as regards Commission-requested standardisation).

Also, Article 23 gives the Annex III organisations (and the ESOs) a specific role as regards cooperation with the Committee on Standards, and consequently they are invited to participate as permanent observers of this committee.

4.7. Role of industry

Industry³² (i.e. enterprises in general) is the key stakeholder in standardisation, the 'engine' of all standardisation and the main influencer of European standardisation, the main purpose of which is to provide standards for the market. It is also the primary direct and indirect financial contributor to European and national standardisation by providing experts to take part in standard development at national, European and international levels and by buying standards. In ETSI, enterprises or representative industrial organisations can have direct ESO membership allowing them to participate directly in standards development while in CEN and Cenelec, where the national delegation principle applies, industry experts are mainly nominated by NSBs.

When the Commission consults the ESOs, it should be able to assume that the positions of all stakeholders, including industry, have been taken into account.

The Commission also consults industry (i.e. the relevant sectoral organisations representing enterprises) directly through its sectoral committees or expert groups (see

³¹ COM(2011) 311 final, 1.6.2011

³² In Europe, 99.8% of enterprises are SMEs.

Article 10(2) of the Regulation), as relevant industrial stakeholders are usually members or observers in such committees or groups (see also sections 2.5 and 2.6 in Part II).

5. CONDITIONS FOR ISSUING A STANDARDISATION REQUEST

5.1. Annual planning of standardisation requests

Pursuant to Article 8 of the Regulation, the Commission undertakes forward planning of possible future standardisation requests to the ESOs. This is set out in the annual Union work programme (UWP) for European standardisation, which is published as a Communication to the European Parliament and to the Council after broad consultation under Article 8(4).

The UWP is a planning and communication tool which allows the ESOs to start planning their resources and to initiate discussions with the relevant Commission departments on the feasibility and content of possible future standardisation requests.

For each possible future request, the UWP clearly defines the objectives and the legal or other policy framework. It should always be clear whether a request supports Union legislation or a policy.

In urgent cases, the Commission may issue a standardisation request also without prior indication in the UWP.

The UWP does not only identify possible future requests, so that the ESOs can be prepared to respond, but also other standardisation priorities where European standardisation is generally welcome, but where the Commission is planning to take action other than issuing a standardisation request. The UWP indicates the policy and regulatory initiatives for which support from European standardisation is needed³³ and provides indicative timing for such action. Consideration should always be given to whether preliminary or ancillary action (see section 5.3) should be initiated during this annual planning phase.

5.1.1 Market relevance of the proposed subject matter

Under Article 10(1) of the Regulation, 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 request.

In order for its requests to produce successful standards, it is important that the Commission analyses the market-relevance of the proposed subject matter from the outset, particularly on the basis of information it receives from the ESOs and Annex III organisations. The ESO(s) and Annex III organisations are thus responsible for consolidating the opinions of their respective constituencies as regards the

³³ In addition to the UWP the Commission may also outline standardisation needs or priorities in detail by means of sector specific actions (like for information and communications technologies). For ICT standardisation, the standardisation needs in support of Union policies by the ESOs but also by other global standards development organisations are outlined in the Rolling Plan for ICT standardisation, see <https://ec.europa.eu/digital-agenda/en/news/rolling-plan-ict-standardisation-0>, and the priorities in the Priority ICT Standards Plan, an action included in the initiative "A Connected Digital Single Market" COM(2014) 910 final.

market-relevance of a possible request and related deliverables as defined by stakeholders on the basis of their own objectives and priorities.

The Regulation requires the Commission then to duly consider those opinions in order to establish if there is sufficient support to start the work.

In the case of policy-related standardisation requests, where standards do not support Union legislation, the Commission should analyse the market-relevance of the subject matter carefully when drafting the UWP.

In the case of harmonised standards, the public-policy relevance is provided by the legislator in the relevant sectoral legislation.

5.2. Basic conditions for issuing a standardisation request

Standardisation requests should only be based on Union legislation or policies.

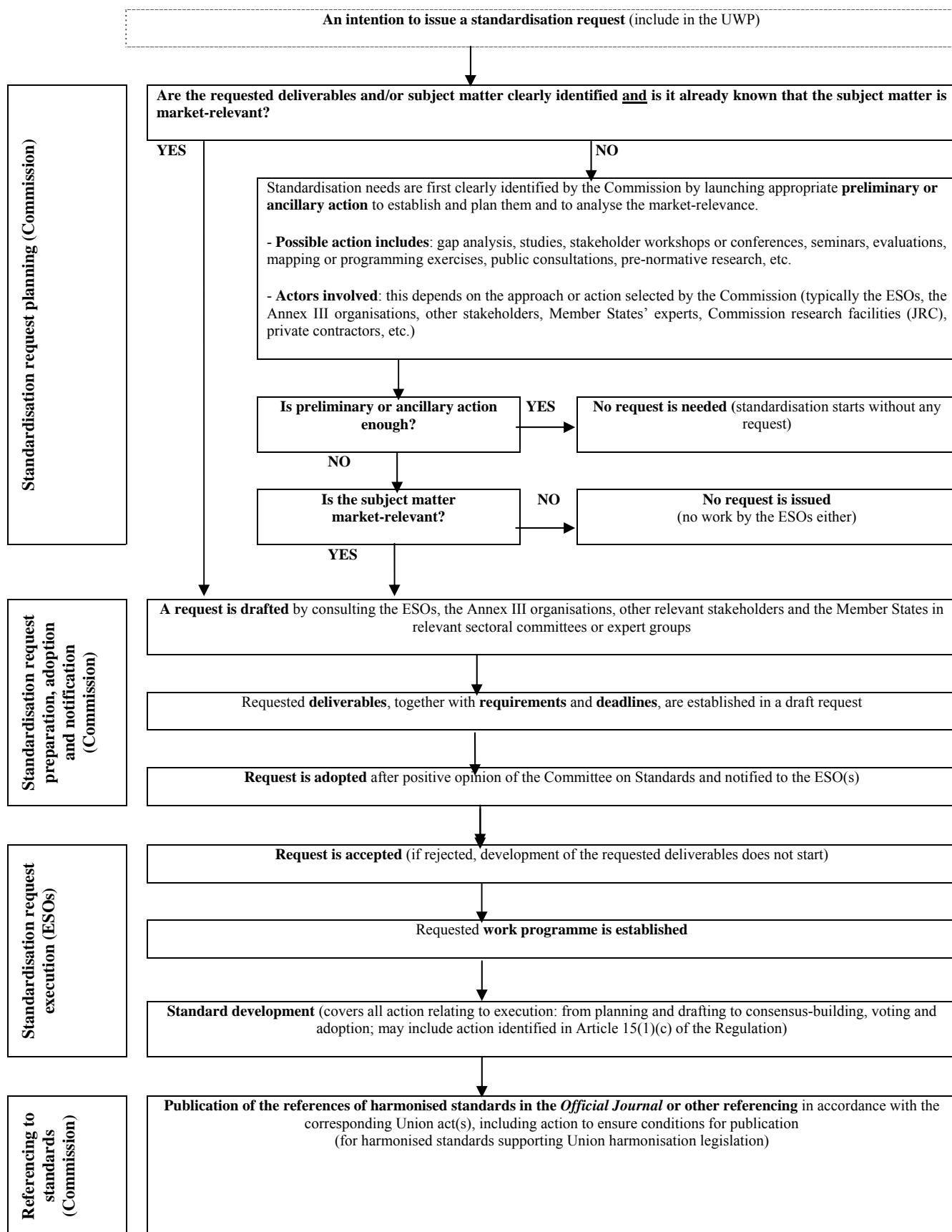
Where it is unable to clearly identify the requisite deliverables or subject matter, or the market-relevance of the subject matter has yet to be properly analysed, the Commission should not start preparing a standardisation request but first take other action (see section 5.3) in close cooperation with the ESOs. The overall process is outlined in Figure 1.

Under Article 10(1) of the Regulation, all standardisation requests must identify the requested deliverables, and thus also the subject matter, together with the deadlines for publication. The Commission should ascertain the standardisation needs after consulting the ESOs, the Annex III organisations, the Member States and other relevant stakeholders, and analysing the market-relevance of the subject matter on the basis of available information. Consequently, **standardisation requests within the meaning of Article 10(1) cannot be used to launch studies or equivalent action** which do not involve a request to draft European standards or European standardisation deliverables.

It should be noted that the ESOs are free to plan any standardisation needs or standardisation activities without a standardisation request. The purpose of a request is to identify what ESO deliverables are needed to support Union legislation and policies from the point of view of the public interest.

A clear distinction must be made between ‘planning or establishing standardisation needs for public-policy purposes’ and ‘planning the execution of requested standardisation’. In the context of a standardisation request, the former is the responsibility of the Commission and needs to be done before a request is adopted, while the latter is the responsibility of the ESOs on the basis of the requirements in a request.

Figure 1: Identifying standardisation needs and the overall process from planning requests to publication of the references of harmonised standards



5.3. Preliminary and ancillary actions in connection with European standardisation

Where conditions for issuing a request are not yet fulfilled, the Commission should launch appropriate **preliminary or ancillary action** in connection with European standardisation to identify the standardisation needs and to be able to analyse whether the subject matter is market-relevant. Preliminary action could be useful, for example, where new legislation referring to harmonised standards is under discussion, in order to produce information required for issuing a standardisation request at a later stage.

Where the Commission needs to launch preliminary or ancillary action only, Article 10(1) and (2) of the Regulation are not applicable and no standardisation request can be issued.

This allows for flexibility during the planning phase, as no implementing act is needed and the Commission may select the most appropriate means and actors with whom to cooperate. The Commission can initiate preliminary and ancillary action:

- (i) internally, in cooperation with its own research facilities;
- (ii) together with the ESOs³⁴ (where the relevant ESO may launch an open call); or
- (iii) by launching an open call (also open to the ESOs and the NSBs).

All such action should be identified in the UWP and the normal Commission practices for informing the Member States and relevant stakeholders at sectoral level should be followed beforehand. In case (ii), a suitable written assignment needs to be produced to allow the ESO to apply for Union funding where appropriate.

A standardisation request for the development of European standards or European standardisation deliverables may, under conditions acceptable to the ESOs, include similar preliminary and ancillary action as part of its execution. However, this is not recommended, as a long programming or equivalent phase may lead to a situation where it is impossible to agree on the requested deliverables and related deadlines in a request before completion of this programming phase.

In the event of cooperation with the ESOs (or the NSBs or other bodies within the meaning of Article 15(2) of the Regulation), Article 15(1)(c) allows for Union financing³⁵ for such preliminary and ancillary work. This does not apply where the Commission elects to cooperate with other private contractors.

³⁴ In this case, the Union financing may be granted in line with Article 15(1)(c) of the Regulation.

³⁵ Financing depends on the availability of the Commission's budget for European standardisation activities and on the Union's priorities as set out in the UWP.

5.4. Areas in which standardisation requests may be used

The Regulation establishes the legal basis for establishing European standards and European standardisation deliverables³⁶ **for products and for services in support of Union legislation and policies.**

However, Article 10(1) stresses that the Commission may issue a standardisation request ‘within the limitations of the competencies laid down in the Treaties’. In the case of standardisation supporting Union legislation, those (exclusive, shared or supporting) competencies derive from Union legislation identifying European standards or European standardisation deliverables as one means of supporting the application of relevant Union legislation or supporting Union policies.

Given the voluntary nature of European standards and European standardisation deliverables, the Commission’s scope for issuing standardisation requests to the ESOs is rather broad, even where there is no sectoral (secondary) legislation. In such cases, however, the Commission cannot ask for harmonised standards or standards having a specific legal effect, but may simply ask the ESOs to develop European standards or European standardisation deliverables; the former could remove conflicting national standards and thus contribute to the Union’s policies and objectives.

In certain cases, the Union legislation itself may limit the subject matter that can be covered by European standards. In particular, standardisation requests cannot be issued in relation to technical rules or technical standards for which the Union legislation provides that they are adopted by a Commission delegated or implementing act. For example, in Articles 15(11), 16(2) and 20(13), the Tobacco Products Directive 2014/40/EU³⁷ provides a specific empowerment to the Commission to determine the technical standards relevant for its implementation. Moreover, in this particular example, as a matter of international law, here Article 5(3) of the WHO Framework Convention on Tobacco Control (FCTC) to which the European Union is a party, the process of defining the relevant technical standards cannot be delegated to the standardisation organisations or to any other entity in which the tobacco industry may be represented.

For example, where Union legislation (e.g. on occupational health and safety) provides only minimal protection, standardisation requests can address certain issues to a limited extent only, as requested European standards should not overlap with or contradict the minimum legal requirements or national measures implementing them.³⁸ European standards always lead to the harmonisation of national standards, which (even when voluntary) should not contradict existing national legislation.

The formal adoption process under Articles 10(2) and 22(3) of the Regulation (examination procedure) ensures that a request, once adopted, has broad political acceptance from the Member States.

³⁶ However, normally only European standards can be used to provide legal effect with legal requirements.

³⁷ OJ L 127, 29.4.2014

³⁸ This does not necessarily mean that the Commission cannot give standardisation requests. For example, European standards could contain harmonised measurement methods to determine exposure levels even where the regulated national exposure levels are different.

Where a request is based on a Union policy, rather than on Union legislation, it is essential to consult the Member States properly before starting the preparation. The UWP is an important means of anticipating the discussion, as it allows the Member States and all relevant stakeholders to contribute.

European standardisation and standardisation requests are a policy tool that the Union can use within a specific technical sector, provided there is political acceptance from the legislator. Sectoral legislation may set specific conditions or requirements for its use.

The Regulation invites and promotes wider use of European standardisation, and thus also Commission requests, within new policy domains. Decisions to adopt a policy-related standardisation request (not in support of Union legislation) should be taken case by case in the light of the sectoral specificities and the ESOs' willingness and ability to produce the requested European standards or European standardisation deliverables.

5.5. Areas in which standardisation requests must be used

In the case of harmonised standards on the basis of Article 2(1)(c) of the Regulation, a standardisation request must be issued where the relevant legislation provides for the publication of references in the *Official Journal*. Failure to issue a request prevents citation in the *Official Journal*, because by definition such a standard cannot be regarded as harmonised standard. Similarly, a standard not covered by a request cannot be cited in the *Official Journal* as a harmonised standard providing the intended legal effect. This principle emphasises the role of standardisation requests and the responsibilities of the ESOs: to ensure open and transparent standard-setting, all interested parties must know from the outset which ESO work is covered by a Commission request.

Standardisation requests are also compulsory in the case of European standards (other than harmonised standards) which, under the relevant sectoral legislation, are to provide a presumption of conformity or other legal effect (e.g. European standards supporting application of General Product Safety Directive 2001/95/EC) following publication of the references in the *Official Journal*.

Both cases referred to above relate to the application of 'indirect referencing' (see footnote 10 in section 1) to harmonised or other European standards, where the Commission subsequently publishes references in the *Official Journal*. In such cases, a standardisation request must be addressed to the ESOs to indicate clearly the public needs and legal framework, requirements and conditions, as decision-making on such matters can never be delegated to private actors.

The legislator sometimes applies 'direct referencing'³⁹ (see footnote 10 in section 1) to existing European standards or parts thereof, or to European standards to be developed and published in the future. Where existing standards are referred to, the legislator may select the standards, or parts thereof, without the need for a standardisation request. However, sometimes the relevant basic act requires that such references be amended or updated subsequently, e.g. through Commission delegated acts. Normally in such a case,

³⁹ The referencing technique used in the legislation does not as such determine whether standards are voluntary. In the context of the Regulation, standards, as published by standardisation organisations, are voluntary technical specifications. This also gives a strong signal to the legislator to keep standards as voluntary means to support the application of Union legislation.

the basic act makes a reference to a standardisation request within the meaning of the Regulation and only references to European standards covered by that request can subsequently be incorporated through delegated acts.

As a general rule, where sectoral legislation makes a non-specific reference to future European standards yet to be adopted, there is a need to:

- issue a standardisation request (Article 10(1) and (2) of the Regulation);
- assess whether the delivered standards fulfil the request (Article 10(5));
- where appropriate, publish the references of harmonised standards in the *Official Journal* (Article 10(6)); and
- provide for the possibility of objecting to the standards (Article 11 or provisions in sectoral legislation).

Other cases where a standardisation request or an amendment to an existing request are necessary include:

- where sectoral legislation refers to a request as a precondition for the Commission to request the drafting or revision of specific European standards it refers to;
- when appropriate, after a Commission implementing decision on a formal objection to a harmonised standard (Article 11 or provisions in sectoral legislation);
- after the requirements or scope of legislation already supported by standards are modified and relevant European standards need to reflect these changes; and
- where the requested work programme under an adopted standardisation request has to be extended to cover new standards not covered in the initial request and the initial request contains no procedure for extending the programme.

6. SCOPE, REQUESTED WORK PROGRAMME AND VALIDITY OF A STANDARDISATION REQUEST

6.1. Scope of a standardisation request

The scope of a standardisation request is determined by the products, services and related subjects or processes (e.g. regulated risks, interoperability, accessibility, etc.) that it covers. The scope must always be well-defined and reflected in the ESO's requested work programme⁴⁰.

However, any standard produced in response to a request may also deal with other issues not covered by the request. Therefore, especially with standards supporting Union legislation, a distinction must be drawn, as far as possible, between specifications aimed at supporting Union legislation and other specifications.

⁴⁰ 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.

Where standardisation needs evolve beyond its initial scope (i.e. to take in new products, services or subjects) the request must be amended on the basis of Article 10(1) and (2) of the Regulation. This is particularly important where the legal requirements supported by European standards have been amended. An amendment to an existing request or a new self-standing request are the only ways of amending the scope of a request and ensuring that the Commission and the ESOs have a common understanding of what new or revised standards are expected and the deadlines for their availability.

In some cases, a new standardisation request under new, more detailed Union harmonisation legislation (*lex specialis*) may need to amend or directly restrict the scope of a previous request.

6.2. Requested work programmes and amendments to work programmes

All standardisation requests adopted on the basis of Article 10(1) and (2) of the Regulation must be ‘definite’, i.e. clearly identify itself all the requested deliverables or subject matter, or give other clear criteria and instructions on the basis of which the ESOs are to establish the requested work programme.

In this context, ‘definite’ also means that the Commission and the relevant ESO(s) have agreed and/or noted the work programme, which can be extended by the issuing of a new standardisation request. However, a request may give deadlines or a procedure for updating the work programme at a later stage, e.g. after certain requested standards have been published, or set only general boundaries for the requested specifications, leaving the ESOs to propose how many deliverables are needed to execute the request.

With standardisation requests for harmonised standards, it is important that all updates to the requested work programme can be seen to derive directly from the initial request, i.e. from its initial scope and requirements, to allow publication of the references in the *Official Journal*. Where this is the case, a request may establish a procedure⁴¹ whereby the relevant ESO can add a new subject for a harmonised standard to the requested work programme after consulting the Commission and the Commission agrees after informing the Committee on Standards.

6.3. Validity of a standardisation request

Once the initial requested work programme is executed and all deliverables are published, a standardisation request is considered to have been **completed**. Subsequently, new subjects for standardisation (not revisions of existing deliverables) can be added by:

- issuing a new request;
- issuing an amendment to the original request; or
- following a procedure established in the original request.

A completed request still serves as terms of reference for the revision of Commission-requested deliverables. However, as a general rule, completed requests do not automatically **expire**; this is particularly important in the case of requests for

⁴¹ In the case of policy-related standardisation requests, no procedure is needed or even appropriate because there are no subsequent regulated procedures (such as publication in the *Official Journal*) that require requested-work programmes to be updated and because such requests do not limit the ESOs’ ability to start other standardisation activities outside requested-work programmes.

European standards in support of Union legislation, which must be revised, in line with technical progress, under the terms of reference of the original request (including any amendments).

After adopting an implementing decision on a formal objection to a harmonised standard, the Commission may issue a supplementary standardisation request according to the procedures in Article 10(1) and (2). This is not because the original request would not be sufficient and valid, but to address shortcomings clearly and set deadlines for revising or amending the standard.

There are cases where a request is considered to have expired or been repealed; these include:

- where a new request or amendment replaces it; in some such cases, the previous request may become narrower in scope and can be considered as partly expired;
- where a request contains a specific clause identifying conditions for its expiry, e.g. a request may expire when the requested work programme is fully executed (i.e. the request is completed) or if no ESO accepts it; and
- where the Commission considers that a request has become obsolete,⁴² e.g. where the supported legislation is repealed or, in the case of old requests, the ESO(s) never drew up a requested-work programme.

Once a request has expired or been repealed, revisions to deliverables developed under it no longer fall under its terms of reference.

6.4. Revisions to European standards supporting Union legislation

All Commission-requested European standards supporting Union legislation are developed under the same ESO rules and principles as any other European standards. The only difference is that, during preparation of such standards, the requirements in the request, on the basis of specific Union legislation, must be followed and respected in order to establish European standards fulfilling the public interest and legal needs.

The same rules and principles apply when such standards are revised. In particular, for the revision of a harmonised standard supporting Union harmonisation legislation, the same standardisation principles must continue to apply in order for its reference to be published in the *Official Journal*.

When revising European standards supporting Union legislation (as when preparing new requested standards), the relevant ESO should also consider any possible restrictions or specific conditions for such standards under sectoral legislation, e.g. whether it is possible to introduce new subjects for standardisation in a revised harmonised standard without a revised standardisation request or other Commission action.

6.5. Implications for standardisation requests issued under Directive 98/34/EC

In view of Article 1 of the Regulation and the fact that Article 10(1) and (2) are the only directly applicable criteria and process for establishing new European standards and

⁴² Usually, the Committee on Standards should be consulted before a request is considered to have expired; in some cases, the same procedure should be used as that used for adoption.

standardisation deliverables for products and services in support of Union legislation and policies, there are limits on the use of requests issued under Directive 98/34/EC procedures ('old mandates') to initiate totally new subjects for standardisation and include them in the requested work programmes under those old requests.

However, old requests continue to be valid in particular where:

- all revisions of deliverables already covered by a requested-work programme are covered by the initial, old standardisation request;
- previously requested work is still under consideration according to requirements and deadlines in the old request; and
- a requested-work programme is updated according to procedures, criteria and deadlines clearly identified in the initial request and the expected deliverables are relevant to support Union legislation or policy in question.

Where an old request contains no clear procedure or does not authorise the ESOs to initiate new subjects for standardisation, any new public standardisation needs should be addressed in a new request issued on the basis of Article 10(1) and (2). This is particularly important with old standardisation requests for harmonised standards.

In duly justified cases, a work programme for an old request for harmonised standards could be extended by issuing an amendment, which is not an implementing act, after consulting the Committee on Standards. However, in such cases it is recommended that only a single subject for standardisation, rather than a new set of subjects, is added to the requested-work programme. Where a new set of harmonised standards is needed or Union harmonisation legislation has been revised, when relevant, a consolidated request repealing the old request should be issued in order to establish coherent and legally correct terms of reference⁴³ for all standardisation work and a single request under which the requested-work programme is executed.

7. ASSESSMENT OF COMPLIANCE OF DOCUMENTS DRAFTED BY THE ESOs

7.1. Reasons for and coverage of compliance assessment

Under Article 10(5) of the Regulation, 'the Commission together with the European standardisation organisation shall assess the compliance of the documents drafted by the European standardisation organisation with its initial request'. This compliance assessment should preferably be carried out before a deliverable is formally adopted by an ESO as a European standard or a European standardisation deliverable. It should produce feedback on the standardisation process (including technical bodies and/or technical boards as relevant) to fulfil a standardisation request, but not detail how the ESOs should select specifications in the requested deliverables, as this is fully their responsibility.

The compliance assessment is particularly important with requests for harmonised standards, to ensure that they satisfy the requirements in the request and enable the Commission to publish the references in the *Official Journal* without delay. Its purpose is

⁴³ For the sake of transparency and legal certainty standardisation requests asking harmonised standards should be easily accessible for all stakeholders and should be based on Union legislation in force.

also to ensure the ESOs' access to additional guidance on the requirements under the relevant Union legislation.

In principle, the assessment of a document's compliance with a request and any related legal requirements should focus on two principal issues:⁴⁴

- identifying and assessing **the extent to which the document covers and deals with the requirements in the request**, i.e. in the case of a draft harmonised standard, the extent to which applicable legal (and essential) requirements are actually covered and dealt with; and
- assessing whether **the document sufficiently addresses the covered requirements of a request**, i.e. in the case of a draft harmonised standard, is each covered legal (and essential) requirement addressed sufficiently in terms of relevant legal requirements (e.g. health, safety, security, environmental protection, accessibility and interoperability) and the generally acknowledged 'state of the art'?

Additionally, in the case of a draft harmonised standard, the existence and general content of the information indicating the legal requirements aimed to be covered by the draft harmonised standard (see section 2.8.4 of Part III) must be checked and assessed during the compliance assessment.

Assessment of 'compliance with a standardisation request' should also involve overall verification that the recognised drafting principles, including possible sectoral drafting rules, established by the ESOs themselves have been sufficiently respected. The ESOs are generally expected to apply their own drafting rules consistently, in particular the rules which are equivalent for drafting and the presentation of international standards, to ensure that their standards are of an appropriate quality and international relevance.

7.2. Method of compliance assessment

For each standardisation request, the issuing Commission department must agree with the ESO(s) on the practical execution of compliance assessment. On the basis of Article 10(5) of the Regulation, the ESOs must give persons responsible for the assessment work unrestricted access to all requisite documents, including normative references, and to the relevant meetings of technical bodies or equivalent drafting entities.

This can be done in three ways:

- i. The ESOs themselves provide the Commission with the required assessment information and conclusions on the basis of self-assessment and the assessment results are supported by appropriately documented evidence describing the means and tools used to ensure fulfilment of a standardisation request, like dedicated checklists, reports, etc. recorded and produced during the drafting work and assessment; or
- ii. The ESOs contract experts who are independent from the standardisation process of the ESOs to perform clearly defined tasks at various stages of drafting and to report the assessment results to them and to the Commission; or

⁴⁴ For deliverables supporting Union policies, no assessment against legal requirements is usually needed.

- iii. The responsible Commission department takes an active role during the standardisation process, assesses the results at various drafting stages and initiates dialogue on the assessment results with the relevant ESO.

In the case of policy-related standardisation requests, information produced by the ESOs themselves should always be enough for the Commission department to conclude that the outcome complies with the initial request.

More detailed information on the means for monitoring execution of standardisation requests, from both the Commission's and the ESOs' point of view, is given in a separate *Follow-up of mandates* document.⁴⁵

7.3. Use of the results of a compliance assessment

Technical specifications are included in a requested document on the basis of consensus and adopted according to the ESOs' internal rules. The compliance assessment according to Article 10(5) is not part of this consensus-building process, but an additional action required by the Regulation to ensure the quality of European standards and European standardisation deliverables requested by the Commission.

The extent to which the results of the assessment are followed should always be left to the ESOs' discretion. After adoption of a harmonised standard, the relevant ESO should decide on the basis of its own principles and rules whether the terms of the initial request were fully or partially fulfilled and whether the reference information can be submitted to the Commission for publication of the references in the *Official Journal*.

Before it can decide whether to publish the references of a harmonised standard in the *Official Journal* according to under Article 10(6), the Commission must have access to the results of a compliance assessment and information indicating how these results were possibly implemented in practice by the ESO in question. This information should help the Commission to decide, without delay, whether publication of the references in the *Official Journal* can be done. It is the Commission's prerogative to evaluate whether or not to accept the assessment results when it applies Article 10(6).⁴⁶ Regardless of its evaluation, the Commission will make the relevant documents available, for the sake of transparency and in line with the principles of good administrative conduct.

⁴⁵ http://ec.europa.eu/growth/single-market/european-standards/vademecum/index_en.htm

⁴⁶ In practice, a decision (not) to publish the references in the *Official Journal* could be subject to an inter-service consultation, in which case a Commission department cannot decide unilaterally.

ANNEX I — BACKGROUND

1. Importance of voluntary standardisation for society

Standardisation is the process of setting the voluntary technical specifications needed by the market. It is a tool used by all stakeholders (market players, civil society, public authorities, industry) to establish technical or quality specifications to ensure performance, safety, interoperability or other required conditions to rationalise, save costs, facilitate trade, etc. The standardisation process involves interested parties agreeing on technical specifications given in standards which, when applied, could be of benefit to them and to the public. Typically, standards are set through an open and transparent process based on consensus between the interested parties who need or wish to apply them.

Standards may deal with any aspect of products, services or processes, depending on the needs of those who use them. In voluntary standardisation, the market-relevance of standards is determined by the markets and especially by those participating in or having access to the standardisation process.

As standardisation brings together experts from all domains, it is an appropriate and powerful tool for consolidating consensually a body of knowledge which is then reflected in technical specifications based on the ‘state of the art’. Standards should be reviewed regularly in line with technological developments.

Standards have also been used for many years to resolve challenges with societal dimensions, such as health and safety. In some cases, voluntary standards have contributed to safety in the absence of legal requirements and, in others, rather than developing voluntary specifications themselves, legislators have referred to standards or to technical specifications contained in standards, sometimes making them compulsory and integral to legal requirements.

Standards are ‘voluntary’ in that the application of standards in themselves and as published by standardisation organisations is always voluntary. Private standardisation organisations do not have the authority to claim that standards should be mandatory. This principle is usually applied in legislation when referring to standards. However, the legislator may decide to make standards, or parts thereof, compulsory, for example in order to ensure interoperability, to classify the performance of products or verify compliance against limit values laid down in legislation. Most commonly, however, standards become commercially binding on the basis of private agreements between economic operators.

The general role of voluntary standards is multifaceted and includes:

- enabling easier market access for products and services;
- improving business performance;
- facilitating or spreading innovation;
- supporting health and safety, interoperability or other legislation;
- supporting privacy, security and interoperability of ICT; and

- addressing major societal challenges such as climate change, sustainable resource use, innovation, population ageing, the integration of people with disabilities, consumer protection, workers' safety and working conditions.

On occasion, standards have been misused and care should be taken to prevent this.

National standardisation bodies (NSBs) typically contribute to the implementation of national industrial policies. In the European Union, these bodies have a dual role:

- they serve national stakeholders; and
- they cooperate with each other at European level to contribute to Union policies and the harmonisation of national standards through the work of the ESOs.

2. The Union's standardisation policy – a short historical background

The first major legislative act setting out the Union's standardisation policy was Directive 83/189/EEC, under which NSBs were obliged to notify the Commission, the ESOs and each other of their standardisation work programmes. The Directive also contained an article allowing the Commission to ask the ESOs to draw up European standards (for products) within a given time limit.

From the standardisation policy point of view, Directive 83/189/EEC paved the way for the 'new approach', a legislative technique to harmonise product requirements in legislation and use voluntary European standards (harmonised standards) as an important supporting instrument for harmonisation. The 'new approach' was approved by the Council of Ministers on 7 May 1985 in its Resolution on *A new approach to technical harmonisation and standards*.⁴⁷ Since revised by the 'new legislative framework' (NLF) in 2008,⁴⁸ the technique involves giving guidelines for restricting the content of product legislation to 'essential requirements', leaving the ESOs to set out the technical details for fulfilling these requirements in voluntary harmonised standards.

The 'new approach' led to a need to establish a European standardisation policy to support the new product harmonisation legislation and a need for a public-private partnership between the Union and the ESOs to ensure a common understanding on objectives supporting the functioning of the single market.

The method of referring to European standards in Union legislation, applied systematically for the first time in the 'new approach' directives, spread later to other fields. The approach was formally encouraged, in the first instance, by the Council Resolution of 18 June 1992⁴⁹ (points 17 and 21), which called on the Commission to apply it, where necessary, in future draft legislation.

The Resolution (point 17) also encouraged the use of European standards as an instrument for economic and industrial integration in the single market. This involves promoting European standardisation under its policies, even where they are not based on legislation, as in the field of new technologies.

⁴⁷ OJ C 136, 4.8.1985

⁴⁸ Decision No 768/2008/EC (OJ L 218, 13.8.2008).

⁴⁹ OJ C 173, 9.7.1992

In 1998, Directive 83/189/EEC was replaced by Directive 98/34/EC.

The Council Resolution of 28 October 1999⁵⁰ emphasises (point 10) ‘the role of European standardisation as a means to meet specific needs of the European market, to serve the public interest, in particular in support of the European policies, to provide standards in new domains...’.

In its Resolution of 10 November 2003,⁵¹ the Council acknowledged the importance of the ‘new approach’ as an appropriate and efficient regulatory model allowing technological innovation and enhancing the competitiveness of European industry, and confirmed the need to extend the application of its principles to new areas.

The Commission’s 2004 Communication on *The role of European standardisation in the framework of European policies and legislation*⁵² stressed that ‘the extension of making use of standards in areas of Community legislation beyond the Single Market is highly desirable, taking of course into account the specificities of the areas concerned, in accordance with the Commission proposals on governance and better regulation’.

In its Resolution of 21 October 2010 on the future of European standardisation (point 15),⁵³ the European Parliament ‘notes that the number of standardisation mandates supporting legislation in areas beyond those covered by the “New Approach” has increased in recent years, indicating that this model has been adopted across a broad range of EU policies; believes that it is desirable to extend the use of standards in other areas of Union legislation and policies beyond the single market, taking into account the specificities of the areas concerned, in accordance with the principles of better regulation’.

The successful use, in ‘new approach’/NLF legislation for products, of European standards developed on the basis of standardisation requests from the Commission gradually led to a wider use of European standards in support of other Union legislation and even in support of policies where no specific Union legislation existed. The process that started with Directive 83/189/EEC led to Regulation (EU) No 1025/2012 on European standardisation, under which European standardisation is a recognised policy tool for the Union.

The Regulation mainstreams the use of harmonised standards beyond ‘new approach’/NLF legislation for products. Harmonised standards can also be used to support the application of legislation on services. Also, for the first time, the Regulation creates a cross-cutting legal basis for using European standardisation, and issuing standardisation requests, in support of Union policies where no specific Union legislation exists.

⁵⁰ OJ C 141, 19.5.2000

⁵¹ Council Resolution of 10 November 2003 on the Communication of the European Commission *Enhancing the Implementation of the New Approach Directives* (OJ C 282, 25.11.2003, p. 3).

⁵² COM(2004) 674 final

⁵³ [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2010/2051\(INI\)](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2010/2051(INI)).

ANNEX II — REFERENCE DOCUMENTS ON THE UNION'S STANDARDISATION POLICY

- (1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardisation
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>
- (2) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers
<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0182>
- (3) Commission Communication on A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020 on a strategic vision for European standards (COM(2011) 311 final; 1.6.2011)
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0311:FIN:EN:PDF>
- (4) Commission staff working paper (SEC(2011) 671 final; 1.6.2011): Impact assessment – accompanying document to the Proposal for a Regulation of the European Parliament and of the Council on European standardisation (COM(2011) 315 final)
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011SC0671&from=EN>
- (5) New Legislative Framework — Union harmonisation legislation for products
http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm
- (6) General guidelines for the cooperation between CEN, Cenelec and ETSI and the European Commission and EFTA (28.3.2003)
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2003:091:0007:0011:EN:PDF>
- (7) 'Blue Guide' on the implementation of EU product rules⁵⁴
http://ec.europa.eu/growth/single-market/goods/building-blocks/index_en.htm

⁵⁴ See Chapter 4.1.2 *Conformity with the essential requirements: harmonised standards*.