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Vademecum on European standardisation in support of Union legislation and policies

PART III

Guidelines for the execution of standardisation requests

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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 III) gives guidelines for the execution of standardisation requests to establish coherent practices for developing, publishing and revising Commission-requested deliverables and an agreed level of communication between the Commission and the ESOs.

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 sets out guidelines for the execution of standardisation requests ('mandates')⁴ which have been accepted by the European standardisation organisations (ESOs). It is addressed to the ESOs and their technical bodies or equivalent drafting entities and should be applied consistently during execution of all requests.

The approach taken and the underlying principles are aimed at:

- enabling efficient and timely **drafting** and **adoption** of standardisation requests and thus prompt **availability** of European standards or European standardisation deliverables as requested and of an appropriate **quality**;
- promoting effective project **planning**, transparent **reporting** and efficient **follow-up** during the execution of requests;
- ensuring transparent **access to requested-work programmes**;⁵
- setting conditions for **amending requested-work programmes**;
- promoting **transparent, market-relevant and SME-friendly harmonised standards and standardisation processes taking account of the public interest**;
- **promoting confidence in the requested-work programmes**;
- ensuring coherent **reporting on the basis of Articles 10(5) and 24(1)(a) of the Regulation (EU) No 1025/2012**; and
- ensuring that the **Commission has all the requisite information available** when applying Article 10(6) to harmonised standards.

The principles for developing and revising harmonised standards also apply generally to other European standards, such as those within the meaning of Article 4 of Directive 2001/95/EC on general product safety,⁶ which support the application of Union legislation through indirect referencing, where the references of such standards should be published in the *Official Journal of the European Union*. Therefore, when there is reference made to harmonised standards in this document, the text should also apply to standards developed in support of the above mentioned general product safety legislation.

2. GUIDELINES FOR THE EXECUTION OF STANDARDISATION REQUESTS

2.1. Introduction to general principles

The principles set out in this document provide guidance for those executing standardisation requests that have been accepted by the ESOs. The guidance helps to ensure compliance with requirements in the requests and is twofold:

⁴ Article 10(1) to (5) of the Regulation.

⁵ 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.

⁶ OJ L 11, 15.1.2002, p. 4.

- (i) procedural guidance, e.g. concerning the appropriate level of communication between the ESOs and the Commission during execution; and
- (ii) general development guidance on the expected content of harmonised standards in order to ensure the quality of requested deliverables and especially of harmonised standards.

2.2. Information on project planning

Project plan(s) containing information on the execution of the standardisation request should be available to the Commission. Such plans should identify as appropriate:

- the relevant project manager(s) or other contact points;
- required or available resources (including any other bodies contributing to the work), main tasks and essential milestones during the project;
- the categories of stakeholders that should/will participate in the development of the requested deliverables; and
- in general terms, any foreseeable control in place to ensure that the requirements of a request can be fulfilled.

2.3. Establishment of the requested-work programme

The information on deliverables in the requested-work programme should contain at least a tentative title and scope.

The deliverables may include standards or other deliverables already adopted or under development by the ESOs or by other bodies.

The programme should indicate clearly whether the deliverables proposed are also linked to other standardisation requests.

2.4. Agreement on and availability of the requested-work programme

The ESO(s) should always seek agreement with the Commission⁷ on the requested-work programme to be executed when providing information in the context of the first sentence of Article 10(5) of the Regulation.

Ideally, the ESO should make this specific work programme available to interested parties after any updates.

2.5. Updates to the requested-work programme

Whenever the subject matter or deliverables covered by a requested-work programme are split, merged or removed from the programme, the Commission should be informed and given an explanation.

Unlike a revision to a deliverable already covered by a request, the inclusion in the programme of a new subject for standardisation requires a new request under

⁷ Usually, the Commission simply takes note of the requested-work programme established on the basis of a request. However, it may also draw attention to its priorities or make other comments to ensure correct interpretation of its initial request.

Article 10(1) and (2) of the Regulation, unless the original request contains a procedure⁸ for initiating new work not originally covered by the programme.

2.6. Reporting

Annual reporting on the execution of a request should continue until the request is completed (i.e. all subjects for standardisation or deliverables identified in the initial requested-work programme, possibly as amended, have been adopted⁹ as European standards or European standardisation deliverables), is repealed, expires or is replaced by another request.

Where an individual request does not set a deadline for the final report, the ESO should indicate clearly that the last annual report is the final report.

As regards requests for harmonised standards, reporting should continue for the validity period of the request and cover any amendments to and revisions of the standards in question.

Annual reporting should enable the Commission to monitor progress on the execution of the request and should at least:

- identify the reasons for any deviations from the work programme;
- indicate whether measures taken on the basis of Article 5 of the Regulation have encouraged and facilitated appropriate representation and effective participation of all relevant stakeholders or any barriers that have been identified, and list the categories of stakeholders who participate actively in the Commission-requested standardisation work;
- describe, in general terms, any specific measures taken to ensure that harmonised standards under development or revision comply with the relevant request(s);
- identify any harmonised standards not submitted to the Commission to allow publication of the references in the *Official Journal* and explain the reasons for non-submission;
- indicate any conflicting national standards that have not been withdrawn in line with Article 3(6) of the Regulation within deadlines set by the relevant ESO after publication of a harmonised standard; and
- contain, or allow access to, the requested-work programme.

2.7. Coherence in the requested standardisation work

In the CEN-CENELEC-ETSI Basic Cooperation Agreement,¹⁰ the three ESOs ‘have agreed to provide the public with a complete and consistent set of standards and other consensus documents to maximise the efficient use of scarce resources, by:

- preventing duplication of work by CEN, CENELEC and ETSI;
- identifying any gaps in the work programmes;

⁸ See the relevant provisions of the request in question.

⁹ In this document, ‘adoption’ refers to the relevant ESO making a European standard or a European standardisation deliverable available to its members or the public.

¹⁰ Annex C to CEN/CENELEC Internal regulations, Part 2.

- clarifying responsibilities;
- providing a guideline for common activities.’

2.8. Specific guidance for developing harmonised standards¹¹

2.8.1. Measures for ensuring that a harmonised standard complies with a standardisation request

The ESOs are primarily responsible for ensuring that the accepted request is executed properly and that the resulting harmonised standards comply with it. Commission and ESO measures on the basis of Article 10(5) of the Regulation do not affect this primary responsibility and commitment.

The ESOs should take appropriate measures to ensure that all harmonised standards comply with the terms of relevant standardisation requests.

2.8.2. Guidance for developing provisions for harmonised standards

A harmonised standard always aims to support the application of Union harmonisation legislation. Standardisation request(s) will indicate the legal requirements which should be supported by the use of a requested harmonised standard. The ESOs should ensure that technical bodies or other entities responsible for developing harmonised standards have sufficient knowledge of all requirements addressed in the relevant request.

EXAMPLE: The responsible technical body should be aware that it is expected to provide information on the essential requirements aimed to be covered by a harmonised standard (see section 2.8.4).

A harmonised standard developed in response to a request may cover subject matter not covered by the request or covered by other requests. However, if this is the case, a distinction should be made, as far as possible, between normative elements in response to the relevant request(s) and other normative elements not responding to any request(s).

EXAMPLE: In a harmonised standard, safety-related normative elements (aiming to support essential requirements) should as far as possible be separated from non-safety-related normative elements (not supporting essential requirements), so that this same distinction can be made when indicating the essential requirements covered by a harmonised standard (see section 2.8.4).

The Union harmonisation legislation referred to in a relevant request should be the reference point for developing provisions contained in a harmonised standard. As a general rule, a harmonised standard should specify means to support essential or other legal requirements given in relevant Union harmonisation legislation.

EXAMPLES:

Simply repeating legal requirements in a harmonised standard does not provide means.

¹¹ The guidance in this section is based on experience of the content of harmonised standards and has already been applied by the ESOs in certain technical sectors.

Neither do non-specific references to other standards, if the users of a harmonised standard need to establish for themselves the means of applying the standard referred to.

Harmonised standards cannot amend legislative definitions or provisions, i.e. a precise legal requirement (such as compulsory markings on a product).

It is for the relevant ESO(s) to decide whether a harmonised standard should cover one or more or all essential (or other legal) requirements applicable to a given product or service. Provisions that aim to support legal requirements in line with a relevant request should always take the form of normative elements in a harmonised standard.

EXAMPLES:

Provisions given in an informative annex cannot be linked to essential requirements, as compliance with a harmonised standard should be possible without reference to its informative annexes.

Similarly, “Foreword” (an informative element) to a harmonised standard cannot contain provisions or normative references to other standards.

In line with the spirit of European standardisation, provisions should:

- not create conditions for unfair competition; and
- be technology-neutral and performance-based to ensure that a harmonised standard does not unfairly discriminate against certain products, services or economic operators, in particular SMEs.

2.8.3. *Guidance for selecting normative references in harmonised standards*

When selecting normative references for use in a harmonised standard, the ESOs should always try to achieve limited and controlled reference chains.

Normative references form an integral part of a harmonised standard, but do not need to be harmonised standards or even requested by the Commission. For that reason, the ESOs should pay particular attention to evaluating the suitability of each normative reference, by considering its availability at national level, for example — including the possibility of having national language versions.

For harmonised standards, the following principles are important in order to avoid the risk of normative references leading to non-compliance with the initial request:

- 1) As a general rule, reference should be made to EN or ISO/IEC standards;
- 2) The requirements of a relevant request should not be contradicted by provisions contained in normatively referenced clauses of a referenced standard;
- 3) Undated references should be avoided, as they may prevent references being published in the *Official Journal*.¹²

¹² If undated normative references are subsequently changed, conformity with a harmonised standard could be lost. In turn, the presumption of conformity would also be lost if users of the harmonised standard do not immediately adapt their products or services in line with the relevant changes. In such cases, the Commission does not (and cannot) apply Article 10(6) of the Regulation and the users of the harmonised standard are unable easily to establish when the changes become applicable and there

- 4) Particular attention should be paid to making normative references to the latest editions available during the adoption of a harmonised standard;
- 5) References to a clause of a standard with known or alleged deficiencies (e.g. subject to formal objection) should be avoided;
- 6) All normative references should be publicly available when a harmonised standard is published. If this is not possible, the relevant ESO should delay submission of the references of that harmonised standard to the Commission until they are publicly available; and
- 7) Legal acts can never be used as a normative reference.¹³

2.8.4. Indication of the legal requirements aimed to be covered by a harmonised standard

All information on legal requirements aimed to be covered by a harmonised standard, and only that information, should preferably be set out in an informative annex to the harmonised standard. This information should also contain a reference to the relevant Commission implementing decision(s) (i.e. standardisation request(s)).

The information should be drafted in parallel with the provisions given in the harmonised standard and should be available during the public consultation stages in order to facilitate assessment of the draft harmonised standard according to Article 10(5) of the Regulation. Where a harmonised standard aims to support the application of a number of directives/regulations, the information should make clear which provisions support which act.

All ESOs should apply harmonised principles for the wording and format of this information, preferably using a dedicated table format. In the application of these principles, it should be evaluated – on the basis of the legal requirements supported and other information given in a harmonised standard – how detailed correspondence can be indicated between the normative elements of the harmonised standard and the legal requirements aimed to be covered.

The ESOs should have suitable means of verifying and amending this information, in particular on the basis of assessments according to Article 10(5), before a harmonised standard is published.

The ESOs together with the national standardisation bodies (NSBs), should seek suitable ways of making publicly available the information which indicates the legal requirements aimed to be covered by a harmonised standard e.g. in abstracts of harmonised standards, in particular for the benefit of SMEs.

2.8.5. Harmonised standards developed by other bodies

The ESOs may cooperate with other standardisation bodies to develop, amend or revise harmonised standards covered by a standardisation request. The requirements of the initial request are equally valid when a standard, which should become a harmonised standard, is developed by other body. In such cases, the relevant ESO should inform the

are no specific transitional arrangements to ensure that the presumption of conformity (although not indispensable) can be maintained without interruption.

¹³ Only informative references to legal acts are possible, e.g. in an informative annex (see section 2.8.4).

other body of the requirements of the relevant standardisation request and of the requirements in Article 5 of the Regulation.

Where a harmonised standard is developed, amended or revised by other body, the relevant ESO should pay particular attention to the drafting of the information referred to in section 2.8.4 and its timely availability during public consultation stages.

Independently of measures to be initiated with the Commission under Article 10(5) of the Regulation, the ESOs should have appropriate means of verifying whether a harmonised standard developed by other body can be fully or partly used in response to a relevant Commission request.

2.9. Adoption of requested European standards and European standardisation deliverables by the ESOs

The ESOs should make available to the Commission, in their official language(s), the texts of requested European standards and European standardisation deliverables and, on request, information on the sources of all normative references.

When the references of harmonised or other European standards are to be published in the *Official Journal*, the relevant standardisation request asks the ESOs to submit these references to the Commission. The ESOs should do this without delay and in line with their annual planning after they have adopted the standards in question.

Where the relevant ESO considers that a harmonised or other European standard does not comply with the initial standardisation request, it should not submit the references to the Commission and should report on the reasons, on the basis of the means it has established in line with section 2.8.1 or an assessment under Article 10(5) of the Regulation.

2.10. Revision of requested European standards and European standardisation deliverables

2.10.1. Validity of a standardisation request

The requirements given in a standardisation request, together with any subsequent amendments, continue to apply where requested European standards and European standardisation deliverables are revised, unless the request is repealed, expires or is replaced by another request.¹⁴

2.10.2. State of the art reflected by a harmonised standard

ESOs should have suitable means and procedures to initiate revision of a harmonised standard to ensure that its provisions given in such a harmonised standard continue appropriately to reflect the generally acknowledged ‘state of the art’.

¹⁴ See also section 6.3 in Part I.

2.10.3. Restricting the scope of a harmonised standard

Where the revised version of a harmonised standard is intended to be narrower in scope than the superseded standard, the ESO in question should inform, and explain this to the Commission before publishing it.¹⁵

2.10.4. Access to information indicating significant changes in a harmonised standard

The ESOs together with the NSBs should seek suitable means for making publicly available information indicating significant changes in a revised or amended harmonised standard, e.g. in abstracts of harmonised standards, in particular for the benefit of SMEs.

2.11. Standstill during preparation of harmonised standards

ESO acceptance of a standardisation request triggers a ‘standstill’ referred to in Article 3(6) of the Regulation concerning national standardisation activity within the scope of the relevant request.

2.12. Obsolete harmonised standards

The ESOs should inform the Commission if they intend to withdraw a harmonised European standard referred to in the *Official Journal* on the basis that it no longer reflects the ‘state of the art’ or has become obsolete and they do not intend to revise it or publish a new harmonised standard to supersede it.¹⁶

Article 3(6) will apply until the Commission withdraws the references to the standard in question from the *Official Journal*, even if it has been withdrawn as a European standard.

2.13. Cooperation with other bodies and international relevance

Where a requested European standard or a requested European standardisation deliverable is developed, revised or amended by other bodies, the relevant ESO should verify that the development processes are based on the principles recognised by the World Trade Organisation in the field of standardisation (the WTO TBT Annex 3 principles).¹⁷

When executing requests, the ESOs should, as far as possible, take into account relevant existing international standards and globally used technical specifications developed by other standardisation organisations in line with the WTO TBT Annex 3 principles.

2.14. Liaison with the Commission

The ESOs should liaise with the Commission department responsible for the standardisation request throughout the period of execution.

¹⁵ This enables the Commission to consider whether specific action is needed as regards products or services no longer covered by the standard. This is a specific case where the ESO partly stops executing the standardisation request.

¹⁶ This enables the Commission to set the last date for the presumption of conformity for products, services or other subjects no longer covered by the harmonised standard. This is a specific case where the ESO partly stops executing the request.

¹⁷ https://www.wto.org/english/res_e/booksp_e/analytic_index_e/tbt_02_e.htm#ann_3

Any questions on the interpretation of the requirements given in a standardisation request should be addressed to that department and the standardisation unit in DG GROW should be kept informed.