

Checklist for standards in response to a standardization request and to be offered for citation in the OJEU

Scope

The present horizontal checklist is the basis for ESOs and their Technical bodies for self-assessment of standards under a standardization request (SReq)/mandate to ensure fulfilment of a SReq/mandate, EU legislation requirements and other possible European Commission (EC) criteria.

All CEN/CENELEC standards and deliverables shall follow the provisions of CEN, CENELEC Internal Regulations, part 3 “Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2021, modified)”

All ETSI standards and deliverables shall follow the provisions of ETSI Directives.

The checklist is divided in three parts:

- **Part A:** It includes criteria for ESOs only
- **Part B.3:** It includes common criteria for EC/HAS and ESOs
- **Part C:** Administrative requirements for the HAS consultants

ESOs Technical Bodies need to complete Part A and B.3 when carrying out the self-assessment.

The Part B of this checklist covers the same content as in the HAS assessment report used by the HAS consultants when carrying out an assessment.

This checklist is applicable for all CEN and CENELEC sectors, except construction.

A dedicated checklist for the construction sector will be developed in cooperation with the European Commission.

NOTE: In very specific sectors, the applicable Standardisation Request may not require the Annex Z. In such cases, the criteria on Annex Z in Parts A and B of this checklist do not apply.

References

- CEN, CENELEC Internal Regulations, part 3 “Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2021, modified)”
- ETSI Directives
- EC Vademecum on European Standardisation ([Part I](#), [Part II](#) and [Part III](#))
- Guidance on normative references in harmonized standards (see [CEN](#) and [CENELEC](#) BOSS pages)

Part A - Criteria for ESOs only

Introduction

This checklist shall be filled in before dispatch for:

1. the First Working Draft for optional assessment (if any),
2. the draft for Enquiry,
3. the final draft for Formal vote,
4. In case of lack of compliance assessment at Formal Vote, a Last Confirmatory Assessment.

The Technical Committee secretary in CEN and the Technical body secretary / Reporting Secretariat in CENELEC are responsible for ensuring that the checklist below is filled in and submitted to CCMC with the draft candidate harmonised standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018). In CENELEC, the matrix of responsibilities shall be followed (see decision D169/006).

Guidance on the horizontal aspects to be considered when preparing harmonised standards in support of EU legislation can be found on CEN and CENELEC BOSS pages

It is strongly recommended to use the checklist for the drafting of harmonised standards in support of EU Legislation under VA and FA (with ISO or IEC lead).

If all the questions in the checklist can be positively answered, this increases the likelihood of receiving a compliant assessment and of being accepted by the European Commission.

Clarifications or justifications shall be given in the comment section.

- ETSI Directives demands ETSI Secretariat and ETSI Technical bodies chairs to send a copy of the mature draft standard (informal milestone between stable and final draft) to the EC for assessment and comments. This step is an equivalent of the Committee draft assessment request.
- It is imperative for ETSI TB(s) to complete the checklist before sending an EN(s) for HAS assessment(s).
- ETSI provides the possibility to trace all the changes made to its draft standards since the last assessment.
- ETSI Secretariat and responsible TB attach all the resolution reports from all the HAS assessments when sending published ENs to EC for publication of their titles in the OJEU.

Information on the project (to be filled in by the Technical Body):

Standard reference	
WI reference	
Stage	
Legislation supported indicate legal act reference(s), its short title (or acronym) and relevant articles and/or annexes supported	Indicate which is the legislation that is being assessed here (e.g. Directive/Regulation xxxx/xxxxx, Short title, Article X/Annex X) If the aspects assessed have a link with another legislation (e.g. electrical safety for LVD and RED) indicate whether a coordination took place or not
Standardisation request(s) give reference number and relevant point of a request	Indicate the Standardisation Requests/mandate corresponding to the legislation above (i.e. the one that is being considered in this assessment,) [e.g. M/xxx, Annex I point 3 of Table 1)
ESO technical body	Reference of the Technical Body
ISO/IEC parallel work	<input type="checkbox"/> No <input type="checkbox"/> Yes

1.1 Criteria for ESOs only	Compliance check	Comments/Justifications from Technical Body
1.1.1 The draft standard is listed in a Standardisation Request / covered by a Mandate supporting EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled	

<ul style="list-style-type: none"> • This is reflected in: <ul style="list-style-type: none"> ○ Projex-online database for CEN/CENELEC ○ Work Programme for ETSI <p><i>NOTE: This information is normally already provided in the NWI proposal form. If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (amended/revised) Standardisation Request. This is not applicable if the standard is covered by an old-format "open" Mandate (e.g. M/396 Machinery).</i></p>	<input type="checkbox"/> N/A	
<p>1.1.2 The TC/WG has answered to all the comments from the previous stage assessment of the HAS consultant(s)</p> <p><i>NOTE: The last column of the HAS Assessment Report ('Observations of the secretariat' at previous stage shall be filled in with the information on how the comments have been addressed.</i></p> <p><i>NOTE: The last column of the HAS Assessment Report ('Observations' for ETSI) at previous stage shall be filled in with the information on how the comments have been addressed.</i></p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
<p>1.1.3 If the standard is a revision, the significant changes with respect to the previous edition are precisely defined in the Foreword/Informative Annex</p> <p>NOTE 1: The list of the significant changes with respect to the previous edition is an important element of the useful information to the standard users. It should not be too vague but describe major changes.</p> <p>NOTE 2: When the list of significant technical changes is extensive, it may be included in an informative annex. A reference to that annex shall be included in the foreword, preferably after the generic sentence that refers to the superseded document.</p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
<p>1.1.4 The Foreword includes the following sentence:</p> <p>"This document has been prepared under a standardisation request addressed to [the relevant ESO] by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States. For the relationship with EU Legislation, see informative Annex Z, which is an integral part of this document."</p> <p>"The present document has been prepared under the {Commission's standardisation request [Full Commission Decision C-reference number when available]} to provide one voluntary means of conforming to the essential requirements of Directive [Reference numbers of legislation] [Full title]."</p> <p><i>NOTE: Annex ZA in CEN and Annex ZZ in CENELEC; hereinafter, "Annex Z"</i></p> <p><i>NOTE: Annex A in ETSI</i></p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
<p>1.1.5 The standards listed in the Normative references Clause 2 are normatively referenced within the text (i.e., are they cited in the text in such a way that some or all of their content constitutes requirements of the document, for instance with a "shall").</p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
<p>1.1.6 The CEN and CENELEC guidance on the use of normative references in harmonised standards was applied</p>	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	

NOTE: the guidance document on normative references in hENs is available on the CEN and CENELEC BOSS		
1.1.7 If the text deals with requirements that are not linked to essential requirements of EU legislation, these requirements are in separate clauses of the standard, so that in Annex A/Z only the clauses covering essential requirements are identified.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
1.1.8 The provisions are drafted in accordance with the requirements of the relevant standardisation request/mandate.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
1.1.9 The latest version of the template for the informative Annex A/Z was used. <ul style="list-style-type: none"> The rows were placed in order of the legal requirements. NOTE: The template is available in CEN BOSS / CENELEC BOSS (Reference material – Forms and templates) . The column with the Directive/Regulation requirements shall be the first one (on the left side). NOTE: ETSI templates are available at: https://portal.etsi.org/Services/editHelp/Standards-development/Drafting/Skeletons	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
1.1.10 If the standard covers different EU Directives/Regulations/Decisions, the standard contains a separate Annex Z/A for each of these EU Regulations	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	
1.1.11 The legal requirement claimed as covered in the Annex A/Z are clearly addressed by a clause / sub-clause of the standard. <ul style="list-style-type: none"> the Annex A/Z does not make reference to other standards (or Technical Reports, Technical Specifications) in the Table ZA.1. The Annex A/Z shall identify which clauses (or sub-clauses) of the standard support which requirements of the EU legislation. NOTE: each different part of a same family of harmonised standards shall have an Annex A/Z	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A	

Part B.1.: Summary of the assessment by the HAS consultant	
Responsible Commission service(s) DG/Unit	DG GROW/Unit XX or DG SANTE/Unit YY
Legislation supported indicate legal act reference(s), its short title (or acronym) and relevant articles and/or annexes supported	Indicate which is the legislation that is being assessed here (e.g. Directive/Regulation xxxx/xxxxx, Short title, Article X/Annex X) If the aspects assessed have a link with another legislation (e.g. electrical safety for LVD and RED) indicate whether a coordination took place or not
Standardisation request(s) give reference number and relevant point of a request	Indicate the Standardisation Requests corresponding to the legislation above (i.e. the one that is being considered in this assessment,) [e.g. M/xxx, Annex I point 3 of Table 1)

Regulated aspects covered by this assessment report	(1) <input type="checkbox"/> All aspects (2) <input type="checkbox"/> All other aspects except (give those excluded) _____ (3) <input type="checkbox"/> Only (give the aspect(s) assessed) _____
Main objective and purpose of the assessed document, including its relation to other standards within the ‘harmonised context’ describe briefly to set the context under which the assessment was carried out	Description of the standard or series of standards Short description of the scope of the standard Indication of any information or special circumstances affecting the assessment
Relevant normative references partly or fully verified and assessed give actual dated reference numbers of those standards checked or assessed as part of this assessment	Here we should include the normative references that have been verified and assessed If some normative references were not provided by the ESOs, this is a sufficient reason for lack of compliance, and this should be clearly flagged in the Assessment Report
Nature of the assessed document	New project / Revision of Harmonised standard or a standard that was cited under GPSD / Revision of a standard that was not cited If the draft amends a standard that was cited or non-cited under the relevant Union legislation, please provide information on this, in particular when Lack of Compliance is based on this situation

Part B.2.: Conclusion of the assessment by the HAS consultant

1. Consultant’s opinion

1.1 On the document’s compliance with the standardisation request(s) and suitability to support relevant EU legislation - i.e. sufficiency and suitability to initiate the intended ‘legal effect’ in relevant context based on a full verification and assessment as summarised below in 1.2 and 1.3 covering ‘Critical findings’ and on Part B

Compliance - no ‘critical findings’ are reported

Good or sufficient quality for a compliant document - no changes required and no critical findings

Minor or limited number of changes not affecting compliance – please indicate those changes in section 2 (other findings)

Conditional compliance - only in case of problems related to the dates of normative references¹ to other inter-linked standards²

Lack of compliance - quality not sufficient for a harmonised standard

Minor or limited number of changes are required – e.g. Annex A/Z – please see sections 1.2 and 1.3, Part B and template

Redrafting required - need for substantial changes to the document is reported – please see sections 1.2 and 1.3, Part B and template

Part B.3: Common criteria for EC/HAS and ESO

1.2 Common criteria	Compliance check	If not fulfilled: Clause/ Subclause/ § number	Comments/Justifications from HAS consultant	Observations of the secretariat / response from TC/ actions taken by TC
1.2.1 The terminology (including definitions) is consistent with relevant EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.2 The Foreword and the Introduction only contains appropriate information (e.g. they shall not contains requirements, legal or technical interpretations or information outside of the scope of the document).	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			

¹ Note: from this point onwards, with “**normative references**” it is intended the normative documents, **and chains thereof**, that are used in clauses that generate a legal effect after citation in the OJEU

² Typically from the same family of standards, or from standards that are being drafted in parallel whose final stable version is not available at the moment of the assessment. The conditional compliance of a draft document will read “lack of compliance” if the normative references of the final document still contains dated draft standards or undated final standards in clauses that generate a legal effect after citation in the OJEU

1.2.3 The Scope covers products, services or aspects concerned, at least in part, by the relevant legal requirements of EU legislation and the relevant standardisation request.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.4 The Scope does not set requirements.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.5 The Scope covers products, services or aspects not concerned by the relevant legal requirements of EU legislation or the relevant standardisation request, but the organisation/subdivision of technical content and the Annex A/Z allow to precisely identify the parts in support of the EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.6 The standard specifies <ul style="list-style-type: none"> • the intended use which it addresses; • the reasonably foreseeable use which it addresses, if foreseen by the related legislation; • the misuse which it addresses, if foreseen by the related legislation. 	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.7 The Scope includes products or aspects that are expected to be covered by the standard according to its title or Annex A/Z in order to support relevant EU legislation and standardisation Request. This means that there is consistence between the title, the scope and Annex A/Z.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.8 All the normative references are available at the time of the assessment.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.9 The document contains exclusively dated normative references or, if it does not, there is an accompanying acceptable justification for the use of specific undated normative references.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.10 The document contains limited and coherent chains of publicly available normative references that are needed when applying the harmonised part of the document.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.11 All the normative references reflect the state of the art (e.g. not withdrawn standards) and have a relevance for the compliance with EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.12 Standards which: <ul style="list-style-type: none"> • Are independently applicable; and • Cover different risks/products/services or do not concern legal requirements addressed by the document. are referred to as informative references in clauses that generate legal effect.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.13 The normative part of the document only contains requirements that are coherent with EU legislation (e.g. the technical content supports legal requirements, specifies 'technical solutions', or does not conflict with parallel applicable legislation)	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.14 The normative part of the document is written in a clear way so users will know which specification applies to address EU legal requirements and there is no room for arbitrary choices. Note: conditional choices are allowed as long as there is a clear, objective and reproducible criterion for each choice.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.15 The document avoids interpreting legal requirements (e.g. modifying them or suggesting that only some legal requirements are valid).	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.16 The document does not unsuitably repeat legal requirements.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			

1.2.17 The tests and/or assessment methods are reproducible and appropriate and they can be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner the technical specifications in support of the legal requirements, as indicated in Annex A/Z.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.18 The technological neutrality and performance-based principles are respected: the document avoids clauses imposing requirements or obligations on or between certain economic operators (e.g. requirements are set to an economic operator and its competence or resources instead of to product design and product properties).	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.19 The technological neutrality and performance-based principles are respected in requirements for verifications, sampling and testing (e.g. the clauses do not impose first, second- or third-party testing).	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.20 Risk assessment or identification of relevant risks is available or complete and/or there is evidence that all relevant risks were considered. The document clearly specifies in the Annex Z/A the relevant risks that it does not cover.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.21 The Annex A/Z is sufficiently detailed in describing which clauses or sub-clauses support relevant EU legislation with no ambiguity or need for interpretation. It is granular enough to support the risk assessment and mitigation in a precise manner.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.22 The Annex A/Z properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.23 The document is aligned with the guidance documents or checklist of the relevant EU legislation.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.24 The normative part of the document addressing the requirements of the EU legislation covers at least the same risks as previous standards ³ . If not, (i) an acceptable justification is provided or (ii) the removed risks are clearly stated in the Annex Z/A.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.25 The normative part of the document provides at least the same level of risk mitigation as previous standards ⁴ . If not, an acceptable justification is provided.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.26 The document avoids reproducing personal data.	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
1.2.27 Other findings				
1.2.28 Specific sectoral requirements if applicable (e.g. noise)	<input type="checkbox"/> Fulfilled <input type="checkbox"/> Not fulfilled <input type="checkbox"/> N/A			
...				

³ This case also includes mergers of standards, splitting them or creating a specific standard from a generic one

⁴ As above

Part C: Documents annexed and relevant for the assessment

The Assessment Report contains (tick the appropriate boxes):

1. Detailed assessment documents annexed

- template of comments on ESO commenting form (including assessment of the relevant normative references), duly numbered and identifying clearly the HAS Consultant
- noise assessment
- risk assessment file
- checklist as required by the corresponding EC sector unit
- assessed document with track changes (where relevant)
- previous assessment report or parts of it (where relevant)
- TC's answers to previous comments
- other (please indicate) _____

2. Other information given by the consultant and relevant for this report

- information on meetings or other communication with ESO before or during this assessment (where relevant)
- information on literature, other standards, studies etc. used during assessment to deliver this report (where relevant)]

3. Supporting documents produced by ESO and relevant for this report

- self-initiative ESO reports for the purposes of assessing or proving compliance (where relevant)
- extract(s) of a risk assessment (where relevant)
- documents describing ESO response on earlier assessment report(s) including challenged issues (where relevant)]