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| **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)"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)"
* EC Vademecum on European Standardisation ([Part I](https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations), [Part II](https://ec.europa.eu/docsroom/documents/13508/attachments/1/translations) and [Part III](https://ec.europa.eu/docsroom/documents/13509/attachments/1/translations))
* Guidance on normative references in harmonized standards (see [CEN](https://boss.cen.eu/media/BOSS%20CEN/ref/guidance_normative_references_hens.pdf) and [CENELEC](https://boss.cenelec.eu/media/BOSS%20CENELEC/ref/guidance_normative_references_hens.pdf) BOSS pages)
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| **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](https://boss.cen.eu/media/CEN/formtemp/matrix_responsibilities.pdf) shall be followed (see decision BT C081/2018). In CENELEC, the [matrix of responsibilities](https://boss.cenelec.eu/media/matrix_responsibilities_harmonizedeniec.pdf) 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](https://boss.cen.eu/developingdeliverables/pages/en/pages/enforojeu/) and [CENELEC](https://boss.cenelec.eu/fadel/pages/eniec/eniecforojeu/) BOSS pagesIt 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. |
| **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** | [ ]  No [ ]  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.* This is reflected in Projex-online database for CEN/CENELEC

*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).* | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.2 The WG has answered to all the comments from the previous stage assessment of the HAS consultant(s) *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.* | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.3 If the standard is a revision, the significant changes with respect to the previous edition are precisely defined in the Foreword.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.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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.4 The Foreword includes the following sentence:“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." NOTE: Annex ZA in CEN and Annex ZZ in CENELEC; hereinafter, “Annex Z” | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 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”). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.6 The CEN and CENELEC guidance on the use of normative references in harmonised standards was appliedNOTE: the guidance document on normative references in hENs is available on the [CEN](https://boss.cen.eu/media/BOSS%20CEN/ref/guidance_normative_references_hens.pdf) and [CENELEC](https://boss.cenelec.eu/media/BOSS%20CENELEC/ref/guidance_normative_references_hens.pdf) BOSS | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 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 Z only the clauses covering essential requirements are identified. | **☐ Fulfilled****☐ Not fulfilled****☐ N/A** |  |
| 1.1.8 The provisions are drafted in accordance with the requirements of the relevant standardisation request/mandate. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.9 The latest version of the template for the informative Annex Z was used.* 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). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.10 If the standard covers different EU Directives/Regulations/Decisions, the standard contains a separate Annex Z for each of these EU Regulations | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |
| 1.1.11 The legal requirement claimed as covered in the Annex Z are clearly addressed by a clause / sub-clause of the standard.* the Annex Z does not make reference to other standards (or Technical Reports, Technical Specifications) in the Table ZA.1.
* The Annex 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 Z | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |

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| **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) [ ]  All aspects (2) [ ]  All other aspects except (give those excluded)\_\_\_\_(3) [ ]  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 standardsShort description of the scope of the standardIndication 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 assessedIf 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 citedIf 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 references[[1]](#footnote-1) to other inter-linked standards[[2]](#footnote-2)  |
| [ ]  **Lack of compliance** - quality not sufficient for a harmonised standard |
|  [ ]  **Minor or limited number of changes are required – e.g. Annex A/Z –** pleasesee 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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.4 The Scope does not set requirements. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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 Z allow to precisely identify the parts in support of the EU legislation. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.6 The standard specifies * 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.
 | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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 Z in order to support relevant EU legislation and standardisation Request. This means that there is consistence between the title, the scope and Annex Z. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.8 All the normative references are available at the time of the assessment. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.12 Standards which:* 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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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)  | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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.  | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.15 The document avoids interpreting legal requirements (e.g. modifying them or suggesting that only some legal requirements are valid). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.16 The document does not unsuitably repeat legal requirements. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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 Z. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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). | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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 the relevant risks that it does not cover.  | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.21 The Annex 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. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.22 The Annex Z properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.23 The document is aligned with the guidance documents or checklist of the relevant EU legislation. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **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]](#footnote-3). If not, (i) an acceptable justification is provided or (ii) the removed risks are clearly stated in the Annex Z. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.25 The normative part of the document provides at least the same level of risk mitigation as previous standards[[4]](#footnote-4). If not, an acceptable justification is provided. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.26 The document avoids reproducing personal data. | [ ]  **Fulfilled**[ ]  **Not fulfilled**[ ]  **N/A** |  |  |  |
| 1.2.27 Other findings  |  |  |  |  |
| ...  |  |  |  |  |

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| **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)] |

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 [↑](#footnote-ref-1)
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 [↑](#footnote-ref-2)
3. This case also includes mergers of standards, splitting them or creating a specific standard from a generic one [↑](#footnote-ref-3)
4. As above [↑](#footnote-ref-4)