

## Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

This checklist was prepared following the format of Internal Regulations CEN/CENELEC Part 3 – Annex A “Checklist for writers and editors of document”. All CEN/CENELEC standards and deliverables shall follow the provisions of IR 3.

This checklist is applicable for all sectors, except construction.

This checklist shall be fulfilled 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, a new optional assessment after Formal vote (PUB 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 out and submitted to CCMC with the draft candidate harmonized standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018).

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

	<b><i>Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).</i></b>	<i>Check</i>
<b>General</b>	<p>Is this draft standard listed in a Standardisation Request / covered by a Mandate?                      Is this reflected in Projex-online database?  <i>NB: This information is normally already provided in the NWIP form.</i>  <i>NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)</i></p>	<p><input type="checkbox"/>  <input type="checkbox"/></p>

	<p>If the HAS assessment was performed (i.e. optional assessment at First Working Draft (FWD) stage or assessment at Enquiry stage), has the WG answered <u>all</u> comments from the HAS Consultant(s)?</p> <p><i>NB: 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>	<input type="checkbox"/>
	<p>If the text deals with requirements that are not linked to essential requirements of EU legislation, are these requirements in separate clauses, so that in Annex Z only the clauses covering essential requirements are identified?</p>	<input type="checkbox"/>
<b>European foreword</b>	<p>If the standard is a revision, are the significant changes with respect to the previous edition precisely defined?</p> <p><i>NB: 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.</i></p> <p><i>NB: 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.</i></p>	<input type="checkbox"/>
	<p>Does it include the following sentences "The standard has been prepared under a standardisation request given to CEN/CENELEC by the European Commission and the European Free Trade Association, and support essential requirements of EU Directive / Regulation. For relationship with EU Directive / Regulation, see informative Annex Z, which is an integral part of this document."?</p> <p><i>NB: Annex ZA in CEN and Annex ZZ in CENELEC.</i></p>	<input type="checkbox"/>
<b>Scope</b>	<p>Is the scope concise and clear? Is it worded as a series of statements of fact?</p>	<input type="checkbox"/>
	<p>Are the title, scope and annex Z consistent regarding exclusion / content covered by the standard?</p> <p><i>NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation.</i></p> <p><i>NB: The scope shall not include requirements, permission or recommendation (in line with IR 3).</i></p>	<input type="checkbox"/>
<b>Normative reference</b>	<p>Are the standards listed in the Normative references Clause 2 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> <p><i>NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i></p>	<input type="checkbox"/>
	<p>Are the normative references dated in Clause 2 and in all clauses of the draft standard?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

	<p>If not, is a justification for using undated normative references provided?</p> <p>Non-dated normative references are only possible if</p> <ol style="list-style-type: none"> <li>1. The normative reference is not relevant for compliance with essential requirements.</li> </ol> <p>or</p> <ol style="list-style-type: none"> <li>2. The normative reference is relevant for compliance with essential requirements but the implications of modifications to the referenced document for the compliance with essential requirements have been duly considered (to be explained in the justification).</li> </ol> <p><i>NB: Additionally, IR 3 requirements on normative references apply, i.e. the complete document is referenced, it will be possible to use all future changes of the referenced document for the purposes of the referring document and the reference will include all amendments to and revisions of the referenced document.</i></p> <p><i>NB: It is not enough to date the normative references in Clause 2 only; they need to be dated also within the main text. For series of standards the expression "all parts" is equal to undated normative references. The expression shall not be used unless a justification is provided.</i></p>	<input type="checkbox"/>
	<p>Are all the references used EN, ISO and IEC standards?</p> <p>If not, do suitable EN, ISO and IEC standards exist which could be used instead?</p> <p>If not,</p> <ul style="list-style-type: none"> <li>• Do the references comply with IR 3 conditions (see IR 3:2019 Clause 10.2)?</li> <li>• is the needed TC decision (in CEN) available?</li> <li>• is a justification provided (preferably to be included in the TC decisions)?</li> <li>• has provision been made to ensure the documents are available for the assessment by HAS Consultant/European Commission?</li> </ul> <p><i>NB: Guidance on the provision of supporting documents may be provided by the CCMC Project Manager</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	<p>Are all the normative references still active and published?</p>	<input type="checkbox"/>
<p><b>EU Legal text in the standard</b></p>	<p>Is the terminology (including definitions of terms in Clause 3) used in this standard in line or consistent with the relevant EU legislation?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

	<p>If not, where a definition differs from relevant EU legislation, is the difference indicated in the European foreword and in Annex Z?</p> <p><i>NB: The technical content of the document shall not</i></p> <ul style="list-style-type: none"> <li>• <i>contain requirements that contradict relevant EU legislation (e.g., fails to specify 'technical solutions', allows users of a document to decide on the specification);</i></li> <li>• <i>repeat legal requirements as part of its normative requirements.</i></li> </ul>	<input type="checkbox"/>
<b>Risk reduction</b>	<p><u>If</u> the standard is a product standard dealing with safety aspects, have the relevant hazards been identified and risks considered and adequately reduced?</p>	<input type="checkbox"/>
<b>Neutrality principle</b>	<p>Does the standard respect the neutrality principle?</p> <p><i>NB: The standard shall not contain 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).</i></p> <p><i>NB: The standard shall not contain clauses imposing first, second- or third-party assessment conformity.</i></p>	<input type="checkbox"/>
<b>Annex Z (ZA in CEN, ZZ in CENELEC)</b>	<p>Is the latest version of the template for the informative Annex Z used?</p> <p>Are the rows placed in order of the legal requirements?</p> <p><i>NB: 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).</i></p> <p><i>NB: If the standard covers different EU Directive / Regulation / Decision, separate annexes Z shall be prepared.</i></p>	<input type="checkbox"/> <input type="checkbox"/>
	<p>If a legal requirement is claimed as covered in the Annex Z, is this requirement clearly addressed by a clause / sub-clause of the standard?</p> <p><i>NB: Do not indicate in an Annex Z any references of other standards (or Technical Reports, Technical Specifications).</i></p> <p><i>NB: The Annex Z shall identify which clauses (or sub-clauses) of the standard support which requirements of the EU legislation.</i></p>	<input type="checkbox"/>