

European Standardization Organizations

Standards in support of the Machinery Directive

Small Business Standards
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1. Introduction to CEN-CENELEC machinery sector



- ▶ At this moment there are approximately **800** harmonised standards (hEN) in support of machinery directive 2006/42/EC.
- ▶ About 50 Technical Committees involved
- ▶ **One of the largest** portfolio of hEN for a single NLF legislative act.

Classification of standards under Machinery Directive:

- type-A: basic concepts and general principles for design: EN ISO 12100
- type-B: deal either with one safety aspect or a safeguard used across a wide range of categories of machinery
- type-C: should preferably deal with all the significant hazards concerning one type of machine or one group of machines

Presumption of conformity with Machinery Directive

▶ Art. 7 (2) of Machinery Directive ‘Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard’.

▶ See also [the European Commission’s Guide to application of Machinery Directive, §110](#)

4. Annex ZA/ZZ

ANNEX ZA (informative)

All harmonised standards must include an **Annex ZA**, **Annex ZZ (for CENELEC)** demonstrating the relationship between the clauses of the standard and the regulatory requirements.

Relationship between this European Standard and the essential requirements of Directive 2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request "M/396 Mandate to CEN and CENELEC for Standardisation in the field of machinery" to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table Z...1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2. Principles of safety integration		
1.1.2 a)	4,5,6	
1.1.2 c)	4,5,6	
1.1.2 d)	4,5,6	
1.1.2 e)	4,5,6	
1.1.3. Materials and products	4.5.2; 4.5.3; 4.5.4; 4.9; 4.11; 4.14	
1.1.4. Lighting		Not covered
1.1.5. Design of machinery to facilitate its handling	4.3; 4.4; 4.5; 4.10; 4.13; 4.14	
1.1.6. Ergonomics	4.4; 4.13	
1.1.7. Operating positions		Not covered

5. Current status



Machinery Directive is under revision. CEN-CENELEC prepared a position that explains what are the key aspects for standardization (includes input from our members and technical committees - link [here](#))

- ▶ Elements of the EC proposal, which create an immediate impact for CEN & CENELEC:
 - EC implementing powers to develop technical specifications (Article 17.3 of the proposed Machinery Regulation);
 - the change in the conformity assessment procedure for high-risk machinery covered by the current Annex IV – i.e. the EC proposal to remove the internal check option in case of application of harmonized standards (Article 21.2);
 - the link between the Annex III of the proposed Machinery Regulation and the “high risk AI system” in the AI Regulation;
 - the multitude of changes in the Essential Health and Safety Requirements (EHSRs) (Annex III).

- ▶ CEN-CENELEC in the position on the revision of MD requested to:
 - Review the Implementing powers of EC to establish technical specifications because it is not in compliance with the NLF (see Article 3 of Decision 768/2008/EC);
 - Have adequate time for review of the whole portfolio of 800 hENs under MD and their formal and technical adaptation;
 - maintain the internal check option for high risk machinery (current Annex IV machinery);
 - review the relevant new/modified EHSRs so that they are in line with NLF concept and are not prescriptive;
 - avoid duplications in EHSRs and ensure consistent and concise requirements.

6. Implications of the revision of Machinery Directive

- ▶ Whole portfolio of 800 harmonized standards is expected to be reviewed;
- ▶ EC is expected to issue a new Standardization Request close to adoption of Machinery Regulation (MR) -> cooperation between CEN-CENELEC and EC on its content (SBS can participate and be involved during the SRAHG – partner organization);
- ▶ TCs are expected to start revisions / amendments/new work when text of MR will be more stable:
 - Standards impacted by changes in EHSRs will need to be revised;
 - All standards cited under new MR will need to have a detailed informative Annex Z ([Annex ZA for CEN](#) and [Annex ZZ for CENELEC](#));
- ▶ Timeframe to adapt: expected between 30 to 48 months – see Article 49 and 52 of draft MR). CEN-CENELEC request for 36 months as minimum

Mandated Standards Programme - Directive 2006/42/EC - Status October 2021

CEN:

787 references of standards* published - 30% EN ISO (VA)

200 work items* under development – 40% EN ISO (VA)

CENELEC:

209 references of standards* published – 35% EN IEC (FA)

104 work items* under development – 23% EN IEC (FA)

VA – Vienna Agreement on parallel work CEN-ISO

FA – Frankfurt Agreement on parallel work CENELEC - IEC

* Amendments and corrigenda are considered as separate references except for pure CEN standards where amendments are consolidated with main standards

OJEU situation - Status October 2021

Number of references of standards* cited in the OJEU: **859**

Number of standards offered and waiting for EC decision on citation: **33**

Last OJEU citation (Oct 2021): **29** references of standards* cited (**26** standards), one with a warning (EN 474-1:2006+A6:2019)

* Amendments are considered as separate references except for pure CEN standards where amendments are consolidated with main standards. The numbers on this slide do not include corrigenda: there are about 30 corrigenda cited in OJEU

8. Useful information/links

- ▶ For more information please check the webinar prepared by CCMC: ['Harmonized Standards under the Machinery Directive'](#)

9. Questions

Are there any questions?

Thank you!



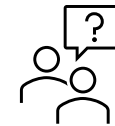
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Questions?



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