

European Standardization Organizations

CEN & CENELEC Update - EC MEG

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Harmonized standards in support of the Machinery Directive- State of play



Status: January 2025

- ► About **926 references (about 800 standards)** harmonized in support of the Machinery Directive 2006/42/EC cited in OJEU;
- ▶ Published // EN ISO + EN IEC ~ 49%
- ▶ Published Homegrown: **51%**
- ▶ Last publication of OJEU list: September 2024 (four new citations);
- ▶ 299 active work items under development MD & MR (some overlap);
- ▶ 91 active work items under development MR;

Impact of new / modified EHSRs (1/2)



- Modifications in some existing EHSRs (e.g. 2.2.1.1 on vibrations, 3.2.2 on seating)
 - ▶ impact on about 60%* of hENs
- new EHSR 1.1.9 on 'protection against corruption'
 - ▶ type-B standard to address this EHSR, <u>prEN 50742</u>, is being prepared by CLC/TC 44x
 - ► Status: ENQ draft under finalisation
 - ▶ impact on about 50 %* of type-C hENs (probably on even bigger number of standards)

^{*}acc. to CEN/CENELEC survey from 2022

Impact of new / modified EHSRs (2/2)



- ▶ New EHSR 3.2.4.:
 - 'Supervisory function' type-C hENs
 - ► Relevant for considerable number of hENs, e.g. on lifting equipment, construction machinery, agricultural machinery, mining, industrial trucks etc.
 - ▶ Interpretation of this EHSR is not clear for standard-drafters, e.g.:
 - ▶ What hazard is being addressed by this EHSR?
 - ► How to interpret "where relevant"?
- ▶ New EHSR 3.5.4:
 - 'Risk of contact with live overhead power lines' type-C hENs
 - ▶ Interpretation of this EHSR not fully clear for standard drafters:
 - ▶ What is to be considered an overhead powerline?
- ▶ Official guidance to standards developers essential for hENs on these





Sreq Machinery status (Mandate 605)

Chronology:



- ▶ 2023-10-20: CEN and CENELEC comments submitted to EC
- ▶ 2024-05-03: 2nd version draft standardization request
- ▶ 2024-06-06: deadline for SRAHG members to submit comments
- ▶ 2024-06-12: SRAHG meeting
- ▶ 2024-06-12: submission of CEN and CENELEC comments to EC
- ▶ 2024-09: EC confirmed that the interservice consultation phase if completed
- ▶ 2024-11-22: Committee on Standards vote (CoS)
- ▶ 2024-12-06: Final SRAHG 'Machinery' meeting
- ▶ 2024-12-12: CoS vote on the Sreq
- ▶ 2024-12-17: EC informed that the CoS delivered a positive opinion
- ▶ 2025-01-08: CCMC submitted to CEN & CENELEC BT the Sreq for decision
- ► 2025-02-04: voted positively by CEN & CENELEC BT (decision CEN/BT C011/2025 & CLC/BT D179/C067)
- ▶ 2025-02-13: CEN & CENELEC formal reply to the EC

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Deliverables & Deadlines

Article 1 Requested standardisation activities

1. The European Committee for Standardization ('CEN') and the European Committee for Electrotechnical Standardization ('CENELEC') are requested to draft new harmonised standards and European standardisation deliverables listed in Table 1 of Annex I to this Decision and to amend or revise the existing harmonised standards and European standardisation deliverables listed in Table 2 of Annex I to this Decision, in support of Regulation (EU) 2023/1230, for machinery, related products and partly completed machinery by the deadlines set out in that Annex.

EN 6 EN

- 2. If CEN and CENELEC do not amend or revise the harmonised standards referred to in Annex I to Commission Implementing Decision (EU) 2023/1586¹⁶, they shall, by 20 January 2026, inform the Commission of the references of those standards and, where relevant, of the reasons why their amendment or revision is not under preparation.
- The harmonised standards and European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.
- CEN and CENELEC shall provide the Commission with the titles of the requested harmonised standards in all the official languages of the Union.



2026 – 01 -20: deadline for Phase 1 Annex 1 Table 1 deliverables

2026 – 01 -20: deadline for Phase 1 Annex 1 Table 2 deliverables

2026 – 01 -20: deadline for not revising or amending the deliverables + justification needed (to be provided by TCs)

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

Judgement of the Court of Justice of 5 March 2024 Public Resource Org and Right to Know v. Commission and Others, C-588/21 P, ECLI:EU:C:2024:201.

ANNEX I

Overview of new harmonised standards and European standardisation deliverables to be drafted and the list of domains covering harmonised standards and European standardisation deliverables to be amended or revised, concerning machinery, related products and partly completed machinery ('machinery products')

Table 1: List of domains covering new harmonised standards and European standardisation deliverables to be drafted, and deadlines for their adoption

Reference information concerning new harmonised standards and European standardisation deliverables, covering various or unique product categories and		Deadline for the adoption by CEN and CENELEC		
	technological fields	Phase 11	Phase 22	
1.	Standards and deliverables on horizontal matters of risk reduction and safety of machinery products, namely: standardisation of general principles; laying down terminology and methodology to be applied, covering the associated risks of emerging technologies and new innovative product categories that are not covered by existing or potential harmonised standards; ensuring, as appropriate, the protection of operators and other persons with a broad degree of anthropometric characteristics, the environment, domestic animals and biodiversity; provisions identifying and informing on essential skills and competences necessary for the safe operation of the machinery products and services, and those necessary for the correct execution of the conformity assessment procedure	20 January 2026	20 January 2034	
2.	Standards and deliverables covering various or unique product categories introducing specific provisions for machinery products: - with fully or partially self-evolving behaviour or logic that are designed to operate with varying levels of autonomy; or whose safety functions are governed by safety components or systems with fully or partially self-evolving behaviour using machine learning approaches	20 January 2026	20 January 2034	
3.	Standards and deliverables covering various or unique product categories introducing specific provisions ensuring that safety functions based on inter alia external connections, software or data are protected against corruption in case of accidental and intentional events, over the product lifetime	20 January 2026	20 January 2034	
4.	Standards and deliverables covering various or unique product categories introducing specific provisions for autonomous mobile machinery products, with or without supervisory function	20 January 2026	20 January 2034	

Deadline for the priority deliverables in the form of new harmonised standards taking into account the new essential health and safety requirements set out in Regulation (EU) 2023/1230 compared to those set out in Directive 2006/4/DEC

2	Deadline for follow-up deliverables aligning new harm analysis, taking into account inter alia technical progress		
EN	2	E	N
5.	Standards and deliverables introducing specific profor product categories covered by the domains lister Table 2 to this Annex that were not yet addressed in existing harmonised standards	d in	

Table 2: List of domains covering standards listed in Annex I to Implementing Decision (EU) 2023/1586 or International or European standards in the same domain, as well as relevant European standardisation deliverables, to be amended or revised and deadlines for their adoption

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields		Deadline for the adoption by CEN and CENELEC	
		Phase 1 ³	Phase 2 ⁴
reducti standar termin and ne associa protect techno approp particu degree enviroo provisi and cor machir execut	rds and deliverables on horizontal matters of risk on and safety of machinery products, namely: disation of general principles; laying down ology and methodology to be applied for existing w innovative product categories, covering the ited risks of electrotechnical aspects; guards and ive devices; conventional and emerging logies; predictive maintenance; ensuring, as riste, the health and safety of persons, in lar consumers and professional users with a broad of anthropometric characteristics, the ament, domestic animals and biodiversity; ons identifying and informing on essential skills impetences necessary for the safe operation of the perturbation of the correct ion of the conformity assessment procedure	20 January 2026	20 January 2034
system integra	rds and deliverables in the field of automation is and technologies and their application and tion covering design, sourcing, manufacturing and y, support, maintenance and disposal of products	20 January 2026	20 January 2034

EN 4 EN



2034 − 01 -20: Phase 2

deadline for Annex 1 Table 2
deliverables

Deadline for the priority deliverables aligning existing or potential harmonised standards, as identified through gap-analysis, taking into account the new essential health and safety requirements set out in Regulation (EU) 2023/1230 compared to those set out in Directive 2006/42/EC.

Deadline for follow-up deliverables aligning existing or potential harmonised standards, as identified through gap-analysis, taking into account inter alia technical progress or other identified standardisation needs

Work Programme



- ►CEN & CENELEC prepare a Work Programme with all hEN deliverables in Annex I (Table 1 & 2).
- ►CEN & CENELEC submit the Work Programme by 2025-07-20

Article 2 Work programme

- CEN and CENELEC shall prepare a joint work programme indicating all the harmonised standards and European standardisation deliverables listed in Annex I, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadlines set out in that Annex.
- CEN and CENELEC shall submit the draft joint work programme to the Commission by 20 July 2025 and shall inform the Commission of any amendments to the joint work programme.
- The draft work programme shall take into account the priorities set out in Annex II
 for the execution of the request referred to in Article 1(1).
- CEN and CENELEC shall provide the Commission with access to the overall project plan.
- The project plan shall include arrangements ensuring cooperation with the Commission for the execution of the requested standardisation activities.



Reporting & Validity



- ▶ Report annually to EC the execution of deliverables (Article 1) and progress of the work programme (Article 2)
- ►Work programme shall be delivered by 2025-07-20 <a>⚠
- ▶1st Joint Annual report to be submitted to EC by 2026-07-20
- ► Yearly report to be sent by 202X-07-20
- ▶Final report to be submitted by 2035-01-20
- ► Validity of this Sreq (Art. 4) = 2035-01-20
- ►The following mandates shall expire by 2027-01-20 (Art. 5): M/396 and M/471

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Gap-analysis



- ▶ Gap Analysis exercise aims to support the EC and facilitate the future citation of harmonized standards in support of the MD into the OJEU under the MR.
- ► Exercise on all active hENs cited in OJEU for Machinery Directive (including parallel work)
- ▶ 1st Batch sent to EC: ~ 665 answers provided by the Technical Committees (TCs)
- ▶ 2nd Batch: As of February 2025, TCs working to input additional answers for the remaining standards
- ▶ Next steps: CEN & CENELEC will collect and send to the EC the remaining results

HAS assessments: status (EY report March 2024 - March 2025)



Total HAS requests under Machinery Directive and Machinery Regulation: 243

▶ Compliant assessments: 31

► Conditional compliance: 14

► Lack of compliance: 198

FV assessments: 58 (76% Lack of compliance)

LCA assessments: 60 (57% Lack of compliance – frequently minor issues easily resolved that lead to compliance and citation in the OJEU)

Horizontal Matters affecting hENs



Ongoing discussions about the future content and structure of the Annex Z

► Highly important to publish an official message from the EC to the stakeholders (CCMC)



Thank you!

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