

EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction, Machinery and Standardisation **Standards Policy**

Brussels, 4.7.2024

A Notification under Article 12 of Regulation (EU) No 1025/2012¹

Subject matter related to

	Annual Union Work Programme for European standardisation (Art. 12, point a)
\square	Possible future standardisation requests to the European standardisation organisations
	(Art. 12, point b)
	Formal objections to harmonised standards (Art. 12, point c)
	Identifications of ICT technical specifications (Art. 12, point d)
	Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12,
	point e)

Title of the initiative

Draft standardisation request to the European Committee for Standardization and to the European Committee for Electrotechnical Standardization as regards machinery and related products in support of Regulation (EU) 2023/1230 of the European Parliament and of the Council

Additional information

Legislative/Policy reference(s)	Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC, OJ L 165, 29.6.2023, p.1
EN reference(s)	-
Status	Draft
Other information	This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
Deadline for feedback	31.7.2024

Commission contact point for this notification

¹ OJ L 316, 14.11.2012, p. 12

Brussels, XXX [...](2024) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on a standardisation request to the European Committee for Standardization and to the European Committee for Electrotechnical Standardization as regards machinery and related products in support of Regulation (EU) 2023/1230 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the English, French and German texts are authentic)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

EN EN

COMMISSION IMPLEMENTING DECISION

of XXX

on a standardisation request to the European Committee for Standardization and to the European Committee for Electrotechnical Standardization as regards machinery and related products in support of Regulation (EU) 2023/1230 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the English, French and German texts are authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council¹, and in particular Article 10(1) thereof,

Whereas:

- (1) Regulation (EU) 2023/1230 of the European Parliament and of the Council² establishes a regulatory framework for the placing on the market of machinery, related products and partly completed machinery, so as to ensure a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment while guaranteeing the functioning of the internal market for these products. The essential health and safety requirements for such products are laid down in Article 8 of that Regulation and in its Annex III.
- (2) According to Article 8 Machinery Regulation (EU) 2023/1230 the essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety and environmental protection.
- (3) In accordance with Article 20(1) of Regulation (EU) 2023/1230, machinery and related products which are in conformity with harmonised standards or parts thereof,

OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj.

Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p.1, ELI: http://data.europa.eu/eli/reg/2023/1230/2023-06-29).

the references of which have been published in the *Official Journal of the European Union* are to be presumed to be in conformity with the essential health and safety requirements of that Regulation covered by those standards or parts thereof.

- (4) In 2006, the Commission adopted consolidated mandate M/396³, supporting Machinery Directive 2006/42EC of the European Parliament and of the Council⁴, which gave the terms of reference to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) to check the existing body of harmonised standards supporting Directive 98/37/EC of the European Parliament and of the Council⁵ and to ensure that harmonised standards would be available to cover the scope of the revised Directive, as well as to provide specifications, enabling manufacturers to comply with the relevant essential health and safety requirements of that Directive.
- (5) In addition, following the adoption Directive 2009/127/EC of the European Parliament and of the Council amending Directive 2006/42/EC with regard to machinery for pesticide application⁶ which introduced amendments to Annex I to Directive 2006/42/EC, the Commission adopted in 2010 the mandate M/471⁷ in the field of machinery for pesticide application.
- (6) To ensure high level of protection concerning health and safety of persons and, where appropriate, of domestic animals and property as well as environmental protection set by Machinery Regulation (EU) 2023/1230 repealing and replacing Directive 2006/42/EC, it is appropriate to allow the continuation of development of new or amended harmonised standards which contain detailed technical provisions to satisfy the essential health and safety and environmental requirements, with regard to the design and construction of machinery.
- (7) Harmonised standards help ensure a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property, and, where applicable, the environment throughout the Union and thus also contribute to the free movement of machinery and related products in the Union. Given that such standards are technology-neutral and performance-based, they also contribute to ensuring equal conditions of competition among relevant economic operators, in particular small and medium-sized enterprises. Indirectly, those standards will also contribute to lower development, production, operating and maintenance costs, benefitting consumers in particular.
- (8) The Machinery Regulation (EU) 2023/1230 introduces significant changes with regard to machinery and related products covered by Directive 2006/42/EC which it replaces, notably introducing provisions for safety functions with fully or partially self-evolving

Mandate M/396 to CEN and Cenelec for standardisation in the field of machinery of 19 December 2006

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) (OJ L 157, 9.6.2006, p. 24, ELI: http://data.europa.eu/eli/dir/2006/42/oj).

Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/37/oj).

Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (OJ L 310, 25.11.2009, p.29, ELI: http://data.europa.eu/eli/dir/2009/127/oj)

Mandate M/471 to CEN for standardisation in the field of machinery for pesticide application of 29 June 2010

behaviour using machine learning approaches, as well as protection against corruption of software and data that are critical for the compliance of machinery and related products.

- (9) On 15 September 2022, the Commission published a proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020 (hereinafter the "proposed Cyber Resilience Act"). The proposed Cyber Resilience Act sets out horizontal requirements for cybersecurity of products with digital elements placed on the European single market and its upcoming standardisation request should cover general provisions for products with digital elements ensuring the cybersecurity of such products.
- (10) This Decision requests CEN and CENELEC to develop specific standards covering machinery products, however, in case of Cyber-safety, taking into account the horizontal provisions of the proposed Cyber Resilience Act. This helps to achieve a coherent cybersecurity framework across the European market, avoiding duplication of efforts for specific product categories and facilitating compliance under both Acts, wherever products covered by the Machinery Regulation are also covered by the proposed Cyber Resilience Act. Following the risk-based approach, manufacturers of machinery products should carry out a risk assessment considering the relevant cybersecurity risks, which in the case of the Machinery Regulation refer to risk to health and safety. In this way, it is possible to tailor the harmonised standards addressing the essential requirements of the Cyber Resilience Act also to fit those of the Machinery Regulation. This synergy should therefore be emphasised in this request.
- (11) Similarly, on 21 April 2021, the Commission adopted the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (hereafter the "proposed Artificial Intelligence Act"). The proposed Artificial Intelligence Act covers requirements for the placing on the market and the putting into service of high-risk Artificial Intelligence systems. These requirements cover areas related to risk management, data quality and governance, technical documentation, record keeping, transparency and provision of information to users, human oversight, accuracy, robustness and cybersecurity. High-risk Artificial Intelligence systems are those considered to have a significant harmful impact on *inter alia* health and safety. In terms of machinery and related products, this translates into systems ensuring safety functions, with fully or partially self-evolving behaviour using machine learning approaches.
- (12) To ensure consistency and avoid an unnecessary administrative burden or unnecessary costs, this Decision requests CEN and CENELEC to develop specific standards covering machinery products, however, in case of Artificial Intelligence systems, taking into account the horizontal provisions of the proposed Artificial Intelligence Act. This helps providers of machinery or related products that contain high-risk Artificial Intelligence systems, to which the requirements of both Acts apply, to be flexible and efficient in their approach to ensure compliance.

COM(2022) 454.

⁹ COM(2021) 206 final

- (13) Moreover, new requirements are introduced to ensure 1) that the user of machinery or related products, where applicable, can test the safety functions, 2) avoidance of the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity, 3) avoidance of risk of contact in case of human-machine interaction or coexistence in a shared space, 4) adequate machine access dimensioning, 5) appropriate contents and format of instructions for use, 6) portable hand-held or hand-guided machinery or related products having exhaust fume provisions, 7) safety of autonomous mobile machinery, 8) safety belt reminder or inhibition of operating certain mobile machinery when the safety belt is not used, 9) filtration of hazardous substances for operators of ride-on mobile machinery applying such substances, as well as 10) inclusion of provisions covering reasonably foreseeable misuse.
- (14) Numerous harmonised standards have been drafted in support of Directive 2006/42/EC on the basis of standardisation mandates M/396 and M/471 to CEN and CENELEC concerning standards for machinery. A large proportion of the harmonised standards, however, need to be revised, amended or recast to take into account the new or updated essential health and safety requirements set out in Machinery Regulation (EU) 2023/1230.
- (15) The intention to request drafting of harmonised standards in support of Machinery Regulation (EU) 2023/1230 is stated in point 61 of the table in the Annex to the 2024 annual Union work programme for European standardisation¹⁰.
- (16) CEN and CENELEC have indicated that the work covered by this standardisation request falls entirely within their area of competence.
- (17) It is therefore necessary to request CEN and CENELEC to revise the relevant existing harmonised standards, to complete the work on the draft harmonised standards and to draft new harmonised standards in support of Machinery Regulation (EU) 2023/1230.
- (18) Moreover, given the extraordinary number of product categories and technological fields covered, as well as the related number of harmonised standards and European standardisation deliverables, it is appropriate to present the list of new harmonised standards and European standardisation deliverables, as well as the list of existing harmonised standards and European standardisation deliverables to be revised, amended or recast, based on a thematic list covering the relevant product categories and technological fields.
- (19) Harmonised standards should include detailed technical specifications, including appropriate test methods or equivalent verifiable and reproducible approaches, in support of the essential health and safety requirements set out in Machinery Regulation (EU) 2023/1230, especially with respect to the design, construction and manufacture of machinery and related products. They should also clearly indicate the correspondence between technical specifications and the essential health and safety requirements they aim to cover. They should also be based on risk assessment and risk reduction methodologies and reflect the generally acknowledged state of the art.

OJ C, C/2024/1364, 15.02.2024, ELI: https://eur-lex.europa.eu/eli/C/2024/1364/oj

- (20) Harmonised standards should be inclusive, so that they aim to ensure equal performance regarding all essential health and safety requirements set out in Machinery Regulation (EU) 2023/1230 across the Union's diverse population, i.e. regardless of gender, age, height as well as other anthropometric and biomechanical considerations. Moreover, harmonised standards should also consider persons with special needs, as appropriate.
- (21) Information as to which essential health and safety requirements are covered by a harmonised standard is necessary when assessing the compliance of the documents drafted by CEN and CENELEC in accordance with Article 10(5) of Regulation (EU) No 1025/2012. Such information is necessary for the publication of references of harmonised standards in the *Official Journal of the European Union* in accordance with Article 10(6) of Regulation (EU) No 1025/2012. In each harmonised standard, CEN and CENELEC should therefore specifically describe which essential health and safety requirements set out in Annex III to the Machinery Regulation (EU) 2023/1230 are relevant for the products covered by that harmonised standard and the extent to which it aims to cover those essential health and safety requirements. CEN and CENELEC should therefore also document which relevant essential health and safety requirements are not covered.
- (22) In accordance with Article 5 of Regulation (EU) 1025/2012, European standardisation organisations are expected to take the necessary steps to facilitate an appropriate representation and effective participation of relevant stakeholders, representative of all sectors covered by the scope of this request, including but not limited to EU small and medium-sized enterprises and societal stakeholders, including trade unions. Moreover, given the fundamental rights and data protection implications of the European standards and European standardisation deliverables requested, compliance with Union law on fundamental rights and Union data protection law should be also guaranteed.
- (23) The ESOs have agreed to follow the Guidelines for the execution of standardisation requests ¹¹. In addition, the Commission has provided different elements of guidance for the assessment of the deliverables. The addressees should verify that any deliverable is in line with the provided guidance.
- (24) To ensure transparency and facilitate the execution of the requested standardisation activities, CEN and CENELEC should prepare a work programme and submit it to the Commission.
- (25) To enable the Commission to better monitor the requested standardisation work, CEN and CENELEC should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardisation request and should report regularly on the execution of that request.
- (26) Experience shows that, during the execution of a standardisation request, it may be necessary to adjust the scope of the request or the deadlines set therein. CEN and CENELEC should therefore promptly report to the Commission if they consider that more time is required to draft the standards or the standardisation deliverables than

¹¹ SWD(2015) 205 final of 27 October 2015

- initially foreseen, or that it is appropriate to adapt the scope of the request, in order to allow the Commission to take appropriate action.
- (27) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, the standardisation request is subject to acceptance by the relevant ESO. It is therefore necessary to establish rules on validity of this request, if it is not accepted by CEN or CENELEC
- (28) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision.
- (29) In accordance with the judgement of the European Court of Justice of 5 March 2024, *Public.Resource.Org*, C-588/21, CEN and CENELEC recognise that the European standards adopted in response to this standardisation request may be subject to access to documents requests in accordance with Regulation (EU) 1049/2001 and, should that be the case, the access to the standards has to be granted.
- (30) Given that Directive 2006/42/EC is repealed with effect from 20 January 2027, it is appropriate to provide for the end of validity of standardisation mandates that have been issued by the Commission for drafting harmonised standards in support of that Directive.
- (31) The ESOs, the European stakeholders' organisations receiving Union financing and the Machinery Committee established by Article 48 of the Machinery Regulation (EU) 2023/1230 have been consulted.
- (32) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Regulation (EU) No 1025/2012,

HAS ADOPTED THIS DECISION:

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 complete the work on draft harmonised standards addressed in Table 1 to Annex I in support of Regulation (EU) 2023/1230, by the deadlines set out in that Annex.
- 2. CEN and CENELEC are also requested to revise or recast the standards and European standardisation deliverables addressed in Table 2 of Annex I, in support of Regulation (EU) 2023/1230, by the deadlines set in that Annex.
- 3. In the case where the harmonised standards referred to in Annex I to Commission Implementing Decision (EU) 2023/1586¹² are not revised or recast, CEN and CENELEC shall, by 20 January 2026, inform the Commission of the references of those standards and, when relevant, the reasons why they are not under preparation to be revised or recast.

-

Commission Implementing Decision (EU) 2023/1586 of 26 July 2023 on harmonised standards for machinery drafted in support of Directive 2006/42/EC of the European Parliament and of the Council (OJ L 194, 2.8.2023, p. 45, ELI: http://data.europa.eu/eli/dec_impl/2023/1586/oj).

- 4. The harmonised standards and European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.
- 5. CEN and CENELEC shall provide the Commission with the titles of the requested harmonised standards in all the official languages of the Union.

Article 2 Work programme

- 1. 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.
- 2. CEN and CENELEC shall submit the draft joint work programme to the Commission by [SG: insert date [dd] [month] [yyyy] 6 months after the notification of this Decision by the Commission] and shall inform the Commission of any amendments to the joint work programme.
- 3. 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.
- 4. CEN and CENELEC shall provide the Commission access to the overall project plan.
- 5. The project plan shall include arrangements ensuring cooperation with the Commission for the execution of the requested standardisation activities.

Article 3 Reporting

- 1. CEN and CENELEC shall report annually to the Commission on the execution of the request referred to in Article 1, indicating the progress made in implementation of the work programme referenced to in Article 2.
- 2. CEN and CENELEC shall submit the first joint annual report to the Commission by [SG: insert date [dd][month][yyyy] 18 months after notification of this Decision by the Commission]. Subsequent joint annual reports shall be submitted to the Commission [SG: insert date- the same [day] [month] as for the first annual report referred to in paragraph 2] each year.
- 3. CEN and CENELEC shall provide to the Commission the final report by [SG: insert date [dd][month][yyyy] 10 years after notification of this Decision by the Commission].
- 4. CEN and CENELEC shall promptly report to the Commission any major concerns relating to the scope of the request referred to in Article 1 or the deadlines set out in Annex I.

Article 4 Validity of the standardisation request

1. Where, in accordance with Article 10(3) of Regulation (EU) No 1025/2012, CEN or CENELEC indicate that they do not accept the request referred to in Article 1 of this Decision, that request may not constitute a basis for the standardisation activities referred to in that Article 1 of this Decision for the standardisation organisation concerned.

2. This Decision shall expire on [SG: insert date [dd][month][yyyy] 10 years after notification of this Decision by the Commission].

Article 5 Expiry of existing standardisation mandates

The following standardisation mandates shall expire on 20 January 2027.

- (a) M/396 of 19 December 2006; and
- (b) M/471 of 29 June 2010.

Without prejudice to the harmonised standards that shall be adopted by CEN or CENELEC in accordance with this Decision, in support of Regulation (EU) 2023/1230, the harmonised standards in support of Directive 2006/42/EC shall be drafted and adopted in accordance with the mandates referred to in the first paragraph and the last adoption date shall not be later than 1 March 2026.

Article 6 Addressees

This Decision is addressed to the European Committee for Standardization and the European Committee for Electrotechnical Standardization.

Done at Brussels,

For the Commission xxx

ANNEX I

Overview of new harmonised standards and European standardisation deliverables to be drafted and the list of domains covering standards and European standardisation deliverables to be revised or recast, as referred to in Article 1

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			adoption by CEN ENELEC
	technological fields	Phase 1 ¹	Phase 2 ²
1.	Standards and deliverables on horizontal matters of risk reduction and safety of machinery and related products, notably the standardisation of general principles, laying down terminology and methodology to be applied covering the associated risks of emerging technologies, as well as 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, as well as the identification and information provision regarding essential skills and competences necessary for the safe operation of the machinery and related products and services, and those necessary for the correct execution of the conformity assessment procedure	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
2.	Standards and deliverables covering various or unique product categories introducing specific provisions for machinery and related 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	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
3.	Standards and deliverables covering various or unique product categories introducing specific provisions ensuring that safety functions based on <i>inter alia</i> external connections, software or data are protected against corruption in case of accidental and intentional events, over the product lifetime	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
4.	Standards and deliverables covering various or unique product categories introducing specific provisions for autonomous mobile machinery and related products, with or without supervisory function	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the

Deadline for the priority deliverables in the form of new harmonised standards taking into account the new Essential Health and Safety Requirements of the Machinery Regulation vis-à-vis the Machinery Directive

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

			Commission]
5.	Standards and deliverables introducing specific provisions for product categories covered by the domains listed in Table 2 to this Annex that were not yet addressed in the existing harmonised standards	Not applicable	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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 revised or recast, and deadlines for their adoption

and E	erence information concerning harmonised standards European standardisation deliverables, covering various r unique product categories and technological fields	Deadline for the adoption by CEN and CENELEC	
		Phase 1 ³	Phase 2 ⁴
1.	Standards and deliverables on horizontal matters of risk reduction and safety of machinery and related products, notably the standardisation of general principles, laying down terminology and methodology to be applied for existing and new innovative product categories covering the associated risks of electrotechnical aspects, guards and protective devices, conventional and emerging technologies, predictive maintenance, ensuring, as appropriate, the health and safety of persons, in particular consumers and professional users with a broad degree of anthropometric characteristics, the environment, domestic animals and biodiversity, as well as the identification and information provision of essential skills and competences necessary for the safe operation of the machinery and related products, and those necessary for the correct execution of the conformity assessment procedure	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
2.	Standards and deliverables in the field of automation systems and technologies and their application and integration covering design, sourcing, manufacturing and delivery, support, maintenance and disposal of products	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

Deadline for the priority deliverables aligning existing or potential harmonised standards, as identified through an agreed gap-analysis, taking into account the Machinery Directive vis-à-vis the Machinery Regulation

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

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields		Deadline for the adoption by CE and CENELEC	
3.	Standards and deliverables covering various or unique product categories revising, amending and supplementing provisions for machinery and related 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 governed by fully or partially self-evolving behaviour using machine learning approaches	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
4.	Standards and deliverables covering various or unique product categories revising, amending and supplementing provisions with specific prescriptions ensuring that safety functions based on <i>inter alia</i> external connections, software or data are protected against corruption in case of accidental or intentional events, over the product lifetime	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
5.	Standards and deliverables covering various or unique product categories revising, amending and supplementing with provisions specific to autonomous mobile machinery and related products, with or without supervisory function	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
6.	Standards and deliverables in the field of ergonomics and human factors, namely - general ergonomics principles; - anthropometry and biomechanics; - ergonomics of human-system interaction, including aspects of psychical and psychological stress, cognitive workload, interface and communication; and - ergonomics of the physical environment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
7.	Standards and deliverables in the field of acoustics, including methods of measuring acoustical phenomena, and methods of noise reduction	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields			adoption by CEN ENELEC
8.	Standards and deliverables on safety and hygiene of machinery for use with foodstuffs and feed	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
9.	Standards and deliverables on safety and hygiene of machinery for pharmaceutical products and cosmetics	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
10.	Standards and deliverables on potentially explosive atmospheres: explosion prevention and protection	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
11.	Standards and deliverables on electrical apparatus for potentially explosive atmospheres	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
12.	Standards and deliverables on safety of measuring, control, and laboratory equipment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
13.	Standards and deliverables on aspects of machinery related to aspects of medical devices	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
14.	Standards and deliverables on safety requirements of equipment for making and shaping of metals	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
15.	Standards and deliverables on robotics, including robots for collaborative applications, service robots and wearable exoskeletons robots, including provisions for safety functions governed by fully or partially self-evolving behaviour using machine learning approaches	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
16.	Standards and deliverables on safety and environmental aspects of non-road mobile machinery, including automated and remote operation, as well as the methodology for measuring nominal power delivery	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
17.	Standards and deliverables on safety and environmental aspects of: - construction machinery for earth-moving, demolition, drilling and foundation, road-construction and road maintenance, tunnel-boring, concrete preparation and concrete handling; - building material machines for the production and treatment of concrete and calcium-silicate, ceramic, cement, lime, and gypsum, including crushing, screening, sizing and recycling; - machines for the production and treatment of glass; - machines for the production and treatment of natural stone; - mixing plants for asphalt, asphalt recyclates and concrete; - machines to process building materials (portable, hand-guided, support-mounted, on rails or self-propelled); - road operation machines; and - snow-grooming machines, including automated and remote operation, as well as the methodology for measuring nominal power delivery	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
18.	Standards and deliverables on safety aspects of specialised mining machinery and equipment for opencast mining (e.g. conveyors, high wall miners, rock drill rigs and continuous surface miners); underground mining machinery and equipment for the extraction of solid mineral substances (e.g. road headers, continuous miners, rock drill rigs, raise boring machines, shaft boring machines, mining auger boring machines, high wall miners, load-haul dumper, special refuge/rescue chambers as well as machinery and equipment for underground mine development); other machinery primarily designed for use outside mines but also intended for use underground; utility and support machines for underground use		[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
19.	Standards and deliverables on safety of crushing and screening machinery such as biomass screening machinery (e.g. woodchip and sawdust screens); waste recycling screening machinery (e.g. screens for recycled materials, excluding mineral and mining applications); biomass shredders/crushers (e.g. main or oversize crusher for biomass plant); waste shredders/crushers (e.g. shredders/crushers for recycled materials, excluding mineral and mining applications)	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
20.	Standards and deliverables on safety and sustainability aspects for electric motor-operated hand-held and transportable tools and electrical appliances for household and similar purposes	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
21.	Standards and deliverables on safety, environmental and sustainability aspects for machinery and related products used in the agriculture, horticulture, gardening and forestry	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
22.	Standards and deliverables on control and safety requirements for design, calculation, stability criteria for the construction, installation, security systems, maintenance and verification, as far as applicable, for: lifting devices; lifting platforms and mobile machines with one or more mobile elevating work platforms for the lifting of persons, which can be equipped with interchangeable equipment designed for handling of goods; lifting appliances (installed temporarily or permanently) such as cranes, power driven winches and hoists, and hand powered lifting machines for goods lifting and/or the lifting of persons; load manipulating devices; lifting accessories, such as non-fixed load lifting attachments, slings, shackles, eyebolts; lifting media for slings and lifting appliances, such as welded round steel link chains, steel wire ropes, textile ropes and webbing; continuous handling equipment; systems for unit loads and bulk materials; equipment and systems for pneumatic handling of bulk materials; as well as equipment for the storage of bulk materials	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields			adoption by CEN ENELEC
23.	Standards and deliverables for design, calculation, stability criteria for the construction, installation, maintenance and verification as well as control, safety and security systems for: lifts including service lifts, lifting appliances and lifting tables moving between fixed floors, carrying goods or passengers, installed temporarily or permanently; escalators, moving walks and passenger conveyors; and stairlifts	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
24.	Standards and deliverables for methods of test and specifications for conveyor and elevator belting and the preparation of practice codes, recommendations and specifications for the jointing, installation, safety, storage and transport of such belting.	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
25.	Standards and deliverables on machines used in drilling (e.g. well construction), production (i.e., production of hydrocarbons from a well) and processing of gas and liquid and gaseous hydrocarbons (i.e. refining crude oil and gas into commercial products) within the petroleum, petrochemical and natural gas industries	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
26.	Standards and deliverables on safety of power-operated windows, rooflights, roof hatches, doorsets, blinds and shutters, industrial/commercial garage doors and gates, pedestrian entrance control equipment and related safety devices	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
27.	Standards and deliverables on safety and environment, for the design, construction, installation, testing, operation, maintenance, repair and disposal of refrigerating systems used for cooling and/or heating	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
28.	Standards and deliverables in the field of welding by all processes, as well as allied processes, covering the terminology, definitions and the symbolic representation of welds on drawings, equipment for welding, raw materials (gas, parent and filler metals) welding processes and rules, inspection, testing and quality control, design and qualification of welding personnel, as well as safety and health.	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
29.	Standards and deliverables of systems and components and their use in the fields of lasers and photonics	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
30.	Standards and deliverables on optical radiation safety and laser equipment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
31.	Standards and deliverables of specific items of sports, playground and other recreational facilities and equipment with a special regard to terminology, safety requirements, operational requirements, service requirements, performance requirements, test methods, marking, consumer/user information, installation and maintenance	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
32.	Standards and deliverables on the design and manufacture in the field of safety of machines and tools for the processing of wood and similar materials and also of facilities and equipment for conditioning of wood	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
33.	Standards and deliverables on the safety of machine tools, their accessories and tools designed to form and to machine cold metal both with and without the removal of metal	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
34.	Standards and deliverables on safety of machines used for the preparation and processing of plastics and rubber	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
35.	Standards and deliverables on safety of machines and equipment used to prepare, not including the manufacture of packaging materials itself, to fill, to close, to assemble and to package containers of solids, liquids, powders and gases	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
36.	Standards and deliverables on safety of self-propelled and pedestrian-propelled industrial and rough-terrain trucks, including lift trucks, tractors, burden and personnel carriers, variable-reach trucks, straddle carriers, driverless trucks, platform trucks and trailers, as well as their components and attachments, and also safety of power-operated warehouse equipment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
37.	Standards and deliverables on integral lighting of machinery	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
38.	Standards and deliverables in the field of waste management, including public cleaning, taking into account technical and logistical aspects, covering in particular provisions for products and procedures including safety requirements for the collection, transport, storage and transfer of solid and liquid waste	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
39.	Standards and deliverables in the field of safety of equipment for industrial thermoprocessing equipment, inter alia industrial furnaces or kilns and other industrial heating equipment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
40.	Standards and deliverables of equipment and vehicles for rescue and firefighting, including automated and remote operation	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
41.	Standards and deliverables on compressors and vacuum pumps	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
42.	Standards and deliverables on Pumps	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
43.	Standards and deliverables on safety of machinery and equipment used for paper making, paper finishing, prepress, printing, post-press, print finishing, book binding, paper converting, including machinery for the manufacture and processing of corrugated board, cardboard and tissue; machinery for paper making and paper finishing; machinery for the preparation of raw materials; debarkers and their conveyors; wood grinders; plants for the production of pulp; de-wiring machines for bales and units; pulpers and their loading facilities; stock preparation machinery; digesters; thickeners; wire belt presses; sorters; beaters, chests; disintegrators and refiners; reel slitter; paper, board and cardboard making machines; tissue making machines; fibre board machines; coating machines; winder slitters and rereelers; plying machines; sheet-cutters; calenders in paper making; roll packaging machines as well as logistics and transport equipment in paper production and paper finishing	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
44.	Standards and deliverables in the field of safety of tannery machinery	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
45.	Standards and deliverables in the field of safety of manufacturing machinery leather and imitation leather goods and footwear	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
46.	European standardisation deliverables on textile machinery and accessories	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
47.	Standards and deliverables in the field of safety for machines and plants used in foundries for the production of castings in disposable and permanent moulds including shot blasting systems	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
48.	Standards and deliverables on health, safety and environmental sustainability in the field of furniture, including electrically operated furniture, covering test methods and requirements for end products, parts, components, surfaces, surface finishes and furniture hardware, as well as terminology and dimensioning	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
49.	Standards and deliverables of hand-held machines, using propulsive charges including safety requirements for the design, construction and use of cartridge operated tools, including fixing and hard-marking tools	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
50.	Standards and deliverables in the field of mechanical vibration and shock, including: methods for measuring and evaluating mechanical vibration and shock of machinery; methods for assessing human exposure to mechanical vibration and shock from machinery use; methods for reducing risks from exposure to mechanical vibration and shock from the design of machinery, including vibration isolation	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
51.	Standards and deliverables in the field of safety of non- electric hand-held power tools (including their use when mounted in fixtures) which can be both in one generic standard for aspects common to several types of tools, and standards for specific types of tools	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
52.	Standards and deliverables on all applications for all rail systems, in the field of heavy rail and urban rail (except electrical and electronic subjects) specifically intended for vehicles and fixed installations	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
53.	Standards and deliverables in the field of reciprocating and rotary displacement internal combustion engines, including definitions, performance/tests, nominal power delivery and special requirements, taking into account the relationship between engine and driven machinery and environment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
54.	Standards and deliverables in the field of non-internal combustion engine or hybrid propulsion systems, including definitions, performance/tests, nominal power delivery and special requirements, taking into account the relationship between propulsion system and driven machinery and environment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
55.	Standards and deliverables on the safety for the design and construction of machinery and installations used for surface treatment, covering the application of organic coating materials (paints, varnishes, adhesives and similar products) including cleaning and pre-treatment machines, application equipment, coating material supply systems, coating plants, dryers for organic coatings and thermal waste gas treatment systems, application of metal coatings (plating, electroplating), surface treatment by means of anodizing, and surface treatment by means of plasma processes (e.g. PVD, CVD, plasma nitriding, plasma activation)	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
56.	Standards and deliverables in the field of safety, function and performance requirements applicable to - Ground support equipment for passenger, baggage and cargo handling; - equipment for aircraft ground handling and servicing; and - airport facilities in respect of above	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
57.	Standards and deliverables in the field of safety requirements for roller brake testers and machines for mounting and demounting of vehicle tyres, applicable for road vehicles	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
58.	European standardisation deliverables of safety requirements and all other aspects for centrifuges having a kinetic energy of rotation of at least 200 Nm	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
59.	Standards and deliverables in the field of cycles, their components and accessories with particular reference to requirements for safety, testing methods and terminology	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
60.	Standards and deliverables on the safety, testing and performance requirements covering self-propelled vehicles and personal mobility devices that are not subject to EU type-approval	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
61.	Standards and deliverables of equipment for storage tanks and filling stations, including dispensers and submersible pumps	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
62.	Standards and deliverables on safety requirements of baling presses	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
63.	Standards and deliverables on safety of side curtain ventilation systems	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
64.	Standards and deliverables on turbines	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
65.	Standards and deliverables on sewing machines	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
66.	Standards and deliverables in the field of industrial equipment and installations intended for electroheating, electromagnetic processing of materials and electroheat based treatment technologies	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
67.	Standards and deliverables on safety of electrostatic painting and finishing equipment	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
68.	Standards and deliverables related to power electronics: equipment, their component parts, in particular electronic devices, and their extension to the system aspect	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
69.	Standards and deliverables on safety of automatic electrical controls, in particular electrical actuators and equipment for water house-hold application	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
70.	Standards and deliverables on equipment and tools for live working, i.e. work on or near live electrical systems or installations	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
71.	Standards and deliverables on additive manufacturing and additive manufacturing relevant equipment, including: - classification scheme for raw materials (e.g. aeronautic grade alloys, defence grade metals, food processing components, construction materials, ecological resins); - provisions to securely facilitate the traceability of manufactured parts; and - machines and supporting equipment related to aspects of security, defence and space utilisation	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
72.	Standards and deliverables on additive manufacturing supporting equipment related to aspects of security defence and space utilisation	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

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	
73.	Standards and deliverables on the design, manufacture and testing of entertainment technology equipment such as machinery, machinery installations, control systems, trusses, truss lifts, as well as devices, items and accessories for live events and broadcast applications	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
74.	Standards and deliverables on forced draught burners	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]
75.	Standards and deliverables on mobile machinery and related products, including: - restraint systems requirements in case of risk of roll or tip over; and - risk of contact with live overhead power lines	20 January 2026	[SG: insert date [dd][month][yyyy] 9 years after notification of this Decision by the Commission]

ANNEX II

Requirements for the harmonised standards and European standardisation deliverables referred to in Article 1

Part A

General requirements for harmonised standards and European standardisation deliverables, listed Tables 1 and 2 in Annex I

1. Legal requirements to be supported by the harmonised standards, whether new, revised, amended or meant to recast an existing harmonised standard or European standardisation deliverable

Harmonised standards and European standardisation deliverables shall support the application of the relevant essential health and safety requirements relating to the design and construction of machinery or related products, set out in Annex III to Regulation (EU) 2023/1230.

Harmonised standards shall provide detailed technical specifications in support of essential health and safety requirements relating to the design and construction of machinery or related products, including safety components for machinery and related products, to facilitate the presumption of conformity with relevant essential health and safety requirements.

Harmonised standards and European standardisation deliverables shall reflect the generally acknowledged state of art.

Each harmonised standard shall clearly indicate its product categories and technological fields, which fall under its scope.

Harmonised standards shall be inclusive, so that they aim to ensure equal performance regarding all essential health and safety requirements relating to the design and construction of machinery or related products, set out in Annex III to Regulation (EU) 2023/1230, across the Union's diverse population, i.e., regardless of gender, age, height as well as other anthropometric and biomechanical considerations. When equal performance for all is not possible, the advantages and disadvantages shall be fairly distributed. To this end, such standards shall be based on recent data that is representative of the Union's population, both for the design of products, processes and services as well as for testing them. In this context, preference shall be given to ranges rather than averages to describe product users or operators. Regarding anthropometric and biomechanical characteristics, all relevant body dimensions and physical capabilities representing body size, body structure, body composition, physical strength limits, operating postures and movements shall be considered. Moreover, harmonised standards shall also, where appropriate and reasonably practicable, consider persons with special needs, persons relying on ease of access, persons depending on ability aids and persons relying on assistance animals, taking into account the United Nations Convention on the Rights of Persons with Disabilities.

The requested harmonised standards shall not unduly restrict secure access to relevant maintenance and diagnostic data, whether stored and available locally or in a remote location, and related interfaces and tools, including software, needed during the lifetime of machinery and related products.

The structure of a harmonised standard shall be such that the clauses and sub-clauses of the standards, which need to be complied with to benefit from the presumption of conformity, are

easily identifiable. Clauses or sub-clauses of the standards that do not facilitate the presumption of conformity with an essential requirement, shall not compromise or prejudice the compliance with any of the clauses or sub-clauses that do facilitate the presumption of conformity.

The harmonised standards shall include a clear and precise description of the relationship between their content and the corresponding essential safety requirements set out in Annex III of Regulation (EU) 2023/1230 that they aim to cover. This shall be achieved through indication of the relationship between the clauses and the sub-clauses and the relevant essential health and safety requirements in the Annexes Zx to each harmonised standard. Such Annex shall also indicate which relevant essential requirements are not covered by the standard.

Each harmonised standard covering a certain product category shall identify and, to the greatest extent possible, cover all the essential health and safety requirements that are relevant to that machinery or related product. These essential requirements shall be taken into account from the beginning and throughout the process of developing of standards.

The requested harmonised standards shall not unduly inhibit a fair internal market and fair competition on the internal market, especially with respect to the implementation of those essential health and safety requirements necessitating technical specifications dealing with maintainability, serviceability, and related services of machinery and related products.

Therefore, harmonised standards shall be clear and succinct in terms of essential requirements covered by each standard to allow straightforward application of the standards by all relevant economic operators, especially by SMEs, in relation to their respective roles in ensuring compliance with all relevant essential health and safety requirements for a given product.

The harmonised standards shall give product category-specific provisions. They shall also provide services-specific provisions, where these are not beyond the manufacturer's capacity to control them and when they are pertinent to the relevant essential health and safety requirements being considered. These specific provisions shall include relevant methodologies to appropriately assess the potential compliance with those provisions. Based on this request, however, the harmonised standards shall not support any other legal requirements that are incompatible with those referenced in the first paragraph of this point, and in particular shall not:

- make any references to Regulation (EU) 2023/1230 or reproduce its requirements in their normative body, except in case of the latter where it is deemed unavoidable not to compromise the objective of the harmonised standard in question;
- modify any definitions set by Regulation (EU) 2023/1230 or define any legally relevant terms not defined by Regulation (EU) 2023/1230 itself;
- address any requirements, responsibilities, contractual arrangements or obligations, other than identification and information provision of pertinent skills, for any economic operator including notified or other bodies or market surveillance authorities; and
- contain any provisions concerning conformity assessment procedures, other than identification and information provision of pertinent skills, related documents or technical file as regulated by Regulation (EU) 2023/1230.

Each harmonised standard developed on the basis of the request referred to in Article 1 of this Decision shall refer to this Decision and shall be developed through consultation in an inclusive process that ensures transparency.

Standards to be developed should consider the ongoing and forthcoming work to be developed in response to the standardisation requests in support of the proposed Cyber Resilience Act and the proposed Artificial Intelligence Act. Those requests may contain both horizontal standards for cybersecurity as well as Artificial Intelligence systems and vertical standards for specific product categories, which may include certain 'important or critical products' or 'high-risk systems' as per relevant definitions in the respective Acts. The standards developed under this mandate shall be based on the harmonised standards that are developed in support of the proposed Cyber Resilience Act and Artificial Intelligence Act, and shall be prepared as specific standards covering the appropriate machinery product categories within the scope of the Machinery Regulation.

A harmonised standard shall not make conformity with that standard dependent on requirements of administrative or organisational nature like management system requirements for organisations, competence requirement for natural persons or through normative references to management system standards of any kind.

2. Legal requirements of a precise nature

Harmonised standards shall not provide any interpretation of essential health and safety requirements set out in Annex III to Regulation (EU) 2023/1230 applicable to machinery and related products, that diverges from the generally acknowledged objectives of those requirements.

3. Risk assessment and risk reduction to include safety aspects in harmonised standards

When harmonised standards are drafted or revised, the iterative process of risk assessment, risk elimination and risk reduction shall be applied by following the design principles set out in Regulation (EU) 2023/1230, Annex III, Part B, General principles, point 1, and by considering the operations of the machine for a wide range of users.

It shall include hazards that might arise during the lifecycle of the machinery or related product, when used as intended but also addressing reasonably foreseeable misuse. Moreover, it shall also address risk elimination or reduction through application of cognitive ergonomics principles, evaluating machinery properties and how they interact with humans and their cognitive abilities. Where appropriate, is shall also cover the evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy, and covering its continuous protection against corruption of safety functions that rely on *inter alia* external connections, software or data. Moreover, the risk assessment and risk reduction shall include risks resulting from interactions between machinery and related products in order to achieve the same end, that are arranged and controlled so that they function as an integral whole.

4. Normative references

Normative references included in a harmonised standard shall be specific and clear and ensure identification of all the essential health and safety requirements covered by the referenced standard. Where a harmonised standard refers to another standard, or a clause in that standard, and that standard or clause contains further normative references (i.e. normative reference chain), the whole normative reference chain shall be clear and specific. Normative reference chains shall however be limited whenever possible. Normative references to standards in the clauses, which by virtue of the normative referencing give presumption of conformity with

the essential health and safety requirements of Regulation (EU) 2023/1230 as applicable to machinery and related products, shall be dated.

Part B

Specific requirements for the revision of existing harmonised standards and European standardisation deliverables under the standardisation domains listed in Table 2 of Annex I

1. Requirements for all standards and European standardisation deliverables

Harmonised standards and European standardisation deliverables shall be periodically reviewed to continue to reflect the generally acknowledged state of art. This work shall be prioritised for cases where a harmonised standard covering a certain product category does not adequately identify and cover all the essential health and safety requirements that are relevant to that machinery or related product.

Such harmonised standards shall be established in particular by revising existing harmonised standards on machinery and related products, making them fit for purpose in the context of the design and construction of such machinery and related products, ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment.

Each revised harmonised standard shall contain clear information on significant changes introduced in that standard.

2. Normative references

Due care shall be taken concerning normative references and normative reference chains that are included in harmonised standards. Normative references that point to outdated, withdrawn or otherwise obsolete clauses shall be updated or removed, in particular when a later version of such referenced standard contains clauses that go against the essential health and safety requirements laid down in Regulation (EU) 2023/1230 or other relevant EU legislation, and that may be misunderstood or otherwise misconstrued as adequately addressing those essential health and safety requirements.

Part C

Requirements for specific harmonised standards and European standardisation deliverables listed in Annex I

1. International standardisation activities

Certain standards developed at international level by the International Organization for Standardisation (ISO) and the International Electrotechnical Commission (IEC), in relevant areas, may be adopted as European standards by CEN and CENELEC on the basis of the Vienna Agreement and the Frankfurt Agreement.

Appropriate modes of cooperation between CEN and CENELEC, ISO, IEC or other international standardisation organisations may be established to benefit from possible synergies with existing international standards or standards under development, provided that those modes ensure that harmonised standards or European standardisation deliverables produced as a result of this request are fully in line with the requirements set out in this Decision.

1.1. International collaboration

In the context of agreed objectives in bilateral or multilateral dialogues of the Commission with third countries or regions, CEN and CENELEC, when collaboration is needed and duly justified, collaborate under the framework of Vienna Agreement and Frankfurt Agreement with other standardisation organisations in such countries or regions to deliver standardisation deliverables that have a specific importance or strategic significance. Such a cooperation could be manifested by 'multi-logo' documents.

1.2. Standardisation areas of particular interest

Non-exhaustive list⁵ of reference information concerning specific harmonised standards and European standardisation deliverables listed in Annex I

- 1. Standards and deliverables covering various or unique product categories introducing specific provisions for machinery and related products:
 - with fully or partially self-evolving behaviour or logic that are designed to operate with varying levels of autonomy; and
 - whose safety functions are governed by safety components or systems with fully or partially self-evolving behaviour using machine learning approaches
- 2. 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 or intentional events, over the product lifetime
- 3. Standards and deliverables covering various or unique product categories introducing specific provisions for autonomous mobile machinery and related products, with or without supervisory function
- 4. Standards and deliverables on additive manufacturing and additive manufacturing relevant equipment, including:
 - classification scheme for raw materials;
 - provisions to securely facilitate the traceability of manufactured parts; and
 - machines and supporting equipment related to aspects of security, defence and space utilisation

.

Reference information concerning standards or deliverables that have already been established under the respective Vienna and Frankfurt agreements are not included, and standardisation activities following new agreements and covering further new areas of particular interest, may be encouraged, without amendment of the non-exhaustive list in the table