

Brussels, 20.1.2025 C(2025) 129 final

ANNEXES 1 to 2

# **ANNEXES**

# to the

# COMMISSION IMPLEMENTING DECISION

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

EN EN

# **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

st	Reference information concerning new harmonised standards and European standardisation deliverables, covering various or unique product categories and		e adoption by CEN ENELEC
	technological fields	Phase 1 <sup>1</sup>	Phase 2 <sup>2</sup>
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 <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	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 2006/42/EC.

\_

Deadline for follow-up deliverables aligning new harmonised standards, as identified through a gapanalysis, taking into account *inter alia* technical progress or other identified standardisation needs.

5.	Standards and deliverables introducing specific provisions	Not applicable	20 January 2034
	for product categories covered by the domains listed in		
	Table 2 to this Annex that were not yet addressed in the		
	existing harmonised standards		

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 CEI and CENELEC	
		Phase 1 <sup>3</sup>	Phase 2 <sup>4</sup>
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 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; provisions identifying and informing on essential skills and competences necessary for the safe operation of the machinery products, and those necessary for the correct execution of the conformity assessment procedure	20 January 2026	20 January 2034
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	20 January 2034

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.

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	
3.	Standards and deliverables covering various or unique product categories revising, amending and supplementing 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 governed by fully or partially self-evolving behaviour using machine learning approaches	20 January 2026	20 January 2034
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	20 January 2034
5.	Standards and deliverables covering various or unique product categories revising, amending and supplementing with provisions specific to autonomous mobile machinery products, with or without supervisory function	20 January 2026	20 January 2034
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	20 January 2034
7.	Standards and deliverables in the field of acoustics, including methods of measuring acoustical phenomena, and methods of noise reduction	20 January 2026	20 January 2034
8.	Standards and deliverables on safety and hygiene of machinery for use with foodstuffs and feed	20 January 2026	20 January 2034

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	
9.	Standards and deliverables on safety and hygiene of machinery for pharmaceutical products and cosmetics	20 January 2026	20 January 2034
10.	Standards and deliverables on potentially explosive atmospheres: explosion prevention and protection	20 January 2026	20 January 2034
11.	Standards and deliverables on electrical apparatus for potentially explosive atmospheres	20 January 2026	20 January 2034
12.	Standards and deliverables on safety of measuring, control, and laboratory equipment	20 January 2026	20 January 2034
13.	Standards and deliverables on aspects of machinery related to aspects of medical devices	20 January 2026	20 January 2034
14.	Standards and deliverables on safety requirements of equipment for making and shaping of metals	20 January 2026	20 January 2034
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	20 January 2034
16.	Standards and deliverables on safety aspects of non-road mobile machinery, including automated and remote operation, as well as the methodology for measuring nominal power delivery	20 January 2026	20 January 2034

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 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	20 January 2034
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		20 January 2034

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	20 January 2034
20.	Standards and deliverables on safety aspects for electric motor-operated hand-held and transportable tools and electrical appliances for household and similar purposes	20 January 2026	20 January 2034
21.	Standards and deliverables on safety aspects for machinery products used in the agriculture, horticulture, gardening and forestry	20 January 2026	20 January 2034
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	20 January 2034

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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034
27.	Standards and deliverables on safety, for the design, construction, installation, testing, operation, maintenance, repair and disposal of refrigerating systems used for cooling and/or heating	20 January 2026	20 January 2034
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	20 January 2034
29.	Standards and deliverables of systems and components and their use in the fields of lasers and photonics	20 January 2026	20 January 2034

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields			
30.	Standards and deliverables on optical radiation safety and laser equipment	20 January 2026	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034
34.	Standards and deliverables on safety of machines used for the preparation and processing of plastics and rubber	20 January 2026	20 January 2034
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	20 January 2034
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	20 January 2034
37.	Standards and deliverables on integral lighting of machinery	20 January 2026	20 January 2034

Reference information concerning harmonised standards and European standardisation deliverables, covering various or unique product categories and technological fields			
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	20 January 2034
39.	Standards and deliverables in the field of safety of equipment for industrial thermoprocessing equipment, <i>inter alia</i> industrial furnaces or kilns and other industrial heating equipment	20 January 2026	20 January 2034
40.	Standards and deliverables of equipment and vehicles for rescue and firefighting, including automated and remote operation	20 January 2026	20 January 2034
41.	Standards and deliverables on compressors and vacuum pumps	20 January 2026	20 January 2034
42.	Standards and deliverables on Pumps	20 January 2026	20 January 2034
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	20 January 2034
44.	Standards and deliverables in the field of safety of tannery machinery	20 January 2026	20 January 2034

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	
45.	Standards and deliverables in the field of safety of manufacturing machinery leather and imitation leather goods and footwear	20 January 2026	20 January 2034
46.	European standardisation deliverables on textile machinery and accessories	20 January 2026	20 January 2034
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	20 January 2034
48.	Standards and deliverables on health and safety 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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034

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	
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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034
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	20 January 2034

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	
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	20 January 2034
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	20 January 2034
61.	Standards and deliverables of equipment for storage tanks and filling stations, including dispensers and submersible pumps	20 January 2026	20 January 2034
62.	Standards and deliverables on safety requirements of baling presses	20 January 2026	20 January 2034
63.	Standards and deliverables on safety of side curtain ventilation systems	20 January 2026	20 January 2034
64.	Standards and deliverables on turbines	20 January 2026	20 January 2034
65.	Standards and deliverables on sewing machines	20 January 2026	20 January 2034
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	20 January 2034
67.	Standards and deliverables on safety of electrostatic painting and finishing equipment	20 January 2026	20 January 2034
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	20 January 2034
69.	Standards and deliverables on safety of automatic electrical controls, in particular electrical actuators and equipment for water house-hold application	20 January 2026	20 January 2034
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	20 January 2034

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	
71.	Standards and deliverables on additive manufacturing and additive manufacturing relevant equipment, including:	20 January 2026	20 January 2034
	<ul> <li>classification scheme for raw materials (e.g. aeronautic grade alloys, defence grade metals, food processing components, construction materials, ecological resins);</li> <li>provisions to securely facilitate the traceability of manufactured parts; and</li> <li>machines and supporting equipment related to aspects of security, defence and space utilisation</li> </ul>		
72.	Standards and deliverables on additive manufacturing supporting equipment related to aspects of security defence and space utilisation	20 January 2026	20 January 2034
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	20 January 2034
74.	Standards and deliverables on forced draught burners	20 January 2026	20 January 2034
75.	Standards and deliverables on mobile machinery 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	20 January 2034

# **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 in Tables 1 and 2 of 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 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 products, including safety components for machinery 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 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 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 Annex Zx to each harmonised standard. Such Annexes 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 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 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 shall consider the ongoing and forthcoming work to be developed in response to the standardisation requests in support of Regulation (EU) 2024/2847<sup>5</sup> and Regulation (EU) 2024/1689<sup>6</sup>. 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 the relevant definitions in those Regulations. The standards developed under this mandate shall take into account the harmonised standards that are developed in support of Regulation (EU) 2024/2847 and Regulation (EU) 2024/1689, and shall be prepared as specific standards covering the appropriate machinery product categories within the scope of Regulation (EU) 2023/1230.

A harmonised standard shall not make conformity with that standard dependent on requirements of administrative or organisational nature, such as 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 the essential health and safety requirements for machinery products set out in Annex III to Regulation (EU) 2023/1230 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 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 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 products in order to achieve the same end, that are arranged and controlled so that they function as an integral whole.

\_

Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: <a href="http://data.europa.eu/eli/reg/2024/1689/oj">http://data.europa.eu/eli/reg/2024/1689/oj</a>).

#### 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 for machinery products set out in Regulation (EU) 2023/1230, 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 product.

Such harmonised standards shall be established in particular by revising existing harmonised standards on machinery products, making them fit for purpose in the context of the design and construction of such machinery 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 Union 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 within the Vienna and the Frankfurt Agreements 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 list<sup>7</sup> 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 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
- 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 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 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.