

The new machinery regulation Status – Problems - Standards

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CD – Research & Development

2024 – 11 – 13



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- › Over 50 subsidiaries worldwide
- › Around EUR 2,3 billion sales in 2023
- › More than 12.000 employees

- › Your speaker : Otto Görnemann
- › Since 1995 employee of SICK AG
- › Functional Safety Trainer
CFSA E Trainer (SGS - TÜV Saar #13)
- › **Chairperson of ISO/TC199 – Safety of Machinery**
- › **Chairperson of CEN/TC114 – Safety of Machinery**
- › Nominated Expert at TC299 - TC110 - IEC/TC44...



The new machinery safety regulation

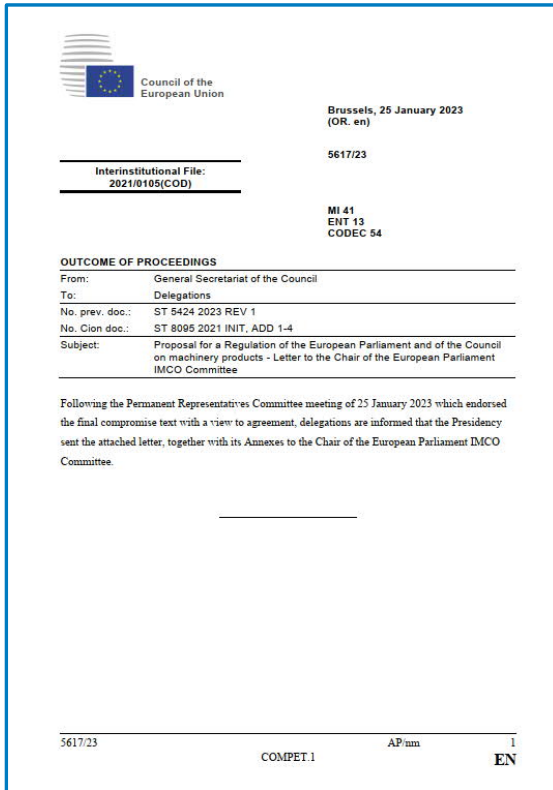
Goals of the revision of the Machinery Directive (2006/42/EC)

- › Keep ensuring the well-functioning of the single market
- › Create a level playing field for economic operators and preserve the competitiveness of the machinery sector in global markets
- › Establish a high level of trust in digital innovative technologies for consumers and users
- › Adapt to the risks of emerging digital technologies & boost innovation
- › Reduce costs for the industry, in particular SMEs, save natural resources, ...
- › Adopt digital instructions and Conformity / EU Declarations
- › Support regulation through Essential Health and Safety Requirements by harmonised standards cited in the EU OJ
- › ... this all requires an 11 Pages long argumentation with #86 rationales.....
(previously 3 Pages with 30 rationales)



The new machinery safety regulation

Key dates



Council of the European Union

Brussels, 25 January 2023
(OR. en)

5617/23

MI 41
ENT 13
CODEC 54

Interinstitutional File:
2021/0105(COD)

OUTCOME OF PROCEEDINGS

From: General Secretariat of the Council
To: Delegations
No. prev. doc.: ST 5424 2023 REV 1
No. Clon doc.: ST 8095 2021 INIT, ADD 1-4
Subject: Proposal for a Regulation of the European Parliament and of the Council on machinery products - Letter to the Chair of the European Parliament IMCO Committee

Following the Permanent Representatives Committee meeting of 25 January 2023 which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annexes to the Chair of the European Parliament IMCO Committee.

5617/23 COMPET.1 AP/um 1 EN

- › Publication in the Official Journal 29 June 2023
- › Entry into force 20 days after publication
- › The transitional period for the Regulation is 42 months (application)
- › **No application of the Machinery Regulation before the application date (by the member states !)**
- › Application date : 20 January 2027
(Except for certain provisions that will apply before)
 - Reporting obligation for Member States (after 24 months)
 - Safeguard Procedures (upon entry into force)



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Fundamental changes (?)

- › Increased legal certainty, uniform application (e.g., substantial modification)
- › Adoption of digital instructions for use, assembly instructions and EU Declarations of Conformity and Incorporation
- › Mandatory Notified Body conformity assessment for 6 product categories
- › Streamlined Safeguard Procedures, aligned with other legislation
- › The Commission is empowered to adopt common specifications as a fallback option when suitable harmonised standards are not available



The new machinery safety regulation

Fundamental changes (?)

- › Increased legal certainty, uniform application (e.g., substantial modification)
- › Adoption of digital instructions for use of EU Declarations of Conformity
- › Mandatory M...
6 pr...

**FOR LEGAL QUESTIONS AND INTERPRETATIONS:
DO NOT ASK THE SPEAKER !
ASK YOUR LEGAL DEPARTMENT !**

- › ...to adopt common specifications as a fallback
harmonised standards are not available



The new machinery safety regulation

Fundamental changes

- › Provisions for the integration of **Artificial Intelligence** related to safety functions
- › Integration of **Cyber-Safety** related provisions for safety control systems and compliance related software and data
- › Increased requirements for **Autonomous and remote-controlled** machinery including protection in case of **contact with power lines**
- › Requirements for **collaborative applications**
- › **Digitalisation** of the related documentation



The new machinery safety regulation

Structure of the Legal / Formal section



- › General provisions
 - › Obligations of economic operators
 - › Conformity of products within the scope of this regulation
 - › Conformity assessment
 - › Notification of conformity assessment bodies
 - › Union market surveillance and union safeguard procedures
 - › Delegated powers and committee procedure
 - › Confidentiality and penalties
 - › Transitional and final provisions
- ... with a total of 54 Articles in 28 Pages

(previously 29 Articles in 8 Pages)



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Structure of the Annexes

- › Annex I **Categories of machinery or related products to which one of the procedures referred to in § 25(2) and (3)**
- › Annex II Indicative list of safety components
- › Annex III **essential health and safety requirements relating to the design and construction of machinery or related products**
- › Annex IV Technical documentation
- › Annex V EU declaration of conformity and EU declaration of incorporation
- › Annex VI Internal production control (Module A)
- › Annex VII EU type-examination (Module B)
- › Annex VIII Conformity to type based on internal production control (Module C)
- › Annex IX Conformity based on full quality assurance (Module H)
- › Annex IX a **Conformity based on unit verification** (Module G)
- › Annex X Assembly instructions for partly completed machinery
- › Annex XI Correlation table between Machinery Directive (2006(42/EC) and the new Regulation



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Definitions (I)

Related to the scope

- 1. Machinery**
2. Interchangeable equipment
3. Safety component
4. Safety Function
5. Lifting accessory
6. Chains
7. Ropes
8. Webbing
9. Removable mechanical transmission device
10. Partly completed machinery



Related to actions and duties

- 11. Making available on the market**
12. Placing on the market
13. Putting into service
- 14. Essential health and safety requirements**
- 15. Union harmonisation legislation**
- 16. Substantial modification**
- 17. Instructions for use**

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Definitions (II)

Related to addressed stakeholders

- 18. Manufacturer
- 19. Authorised representative
- 20. Importer**
- 21. Distributor**
- 22. Economic operator**

Related to regulation enforcement

- 31. Market surveillance authority**
- 32. Recall**
- 33. Withdrawal**
- 34. Lifetime**



Related to conformity processes

- 23. Technical specifications**
- 24. Harmonised standards
- 25. CE marking**
- 26. Accreditation**
- 27. National accreditation body**
- 28. Conformity assessment**
- 29. Conformity assessment body**
- 30. Notified body**

Other terms

- 35. Source code**
- 36. Professional user**

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Scope of the regulation

Products within the scope of the regulation

› Machinery

› Related products

- Interchangeable equipment
- Safety components
- Lifting accessories
- Chains, ropes and webbing
- Removable mechanical transmission devices

› Partly completed machinery

Revision of the definition of “Machine” adding:

- f) an assembly as referred to in points (a) to (e) **missing only the uploading of the software** intended for the specific application foreseen by the manufacturer;



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In & Out – Applicability

The regulation does **not apply** to

- a) **safety components** that are intended to be used **as spare parts** to replace identical components and are **supplied by the manufacturer** of the original machinery, **related product or partly completed machinery**;
- c) machinery and related products specially designed for use within or used in a **nuclear installation and whose conformity with this Regulation may undermine the nuclear safety of that installation**;
- f) **aeronautical products**, parts and equipment that fall within the scope of Regulation (EU) 2018/1139 of the European Parliament and of the Council, and the definition of machinery under this Regulation, insofar as Regulation (EU) 2018/1139 covers the relevant essential health and safety requirements set out in this Regulation;



The regulation **applies to**

- p) (iv) ordinary office **machinery for additive printing** to produce three-dimensional products;



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The economic operators



manufacturers - authorized representatives - importers - distributors

- › **“manufacturer”** means any natural or legal person who:
 - a) manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets those products under its name or trademark; or
 - b) manufactures products within the scope of this Regulation, and puts those products into service for its own use
- › **“authorised representative”** means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks
- › **“importer”** means any natural or legal person established within the Union who places a product within the scope of this Regulation from a third country on the Union market
- › **“distributor”** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product within the scope of this Regulation available on the market



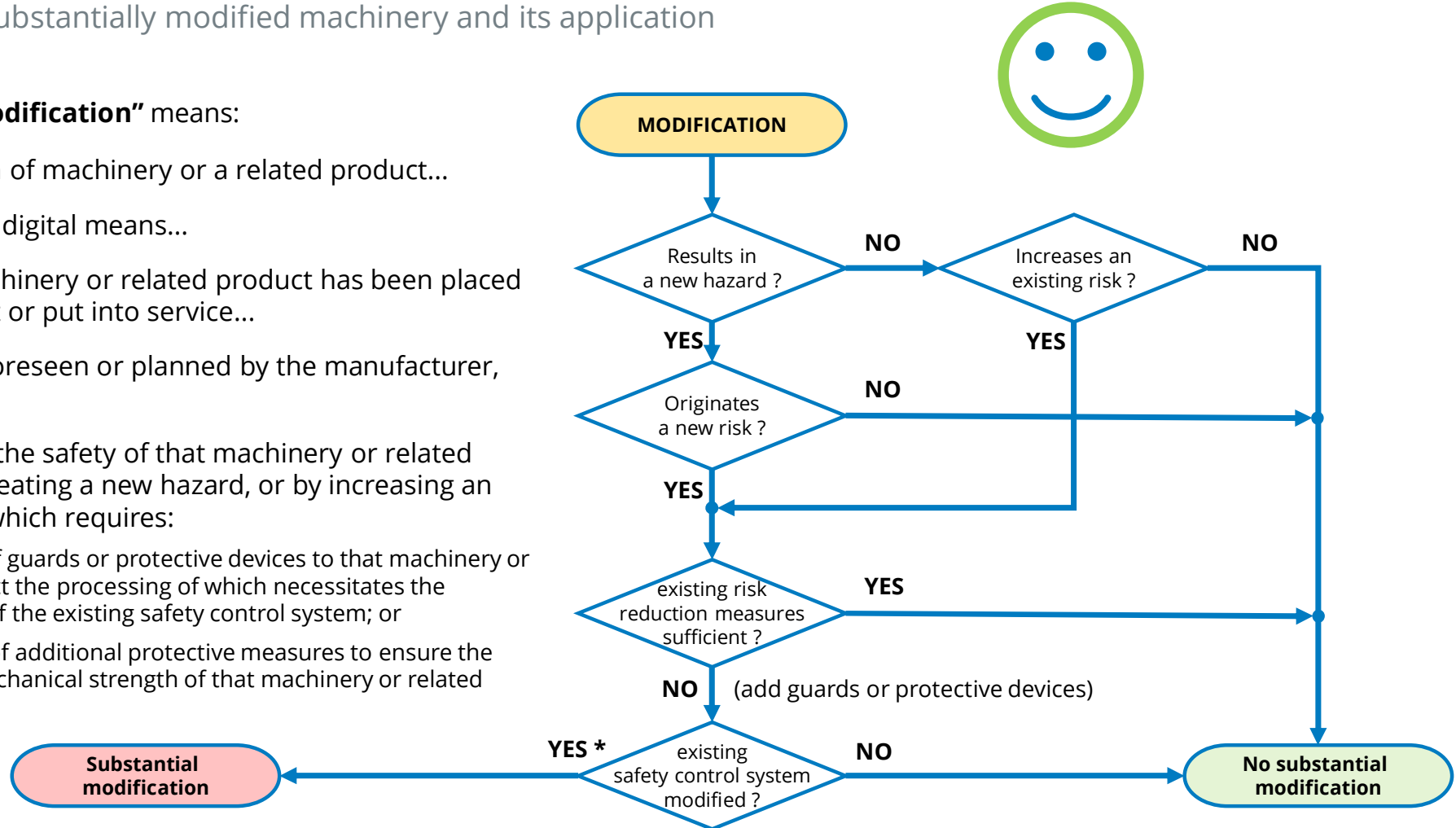
NOTHING NEW !

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Definition of substantially modified machinery and its application

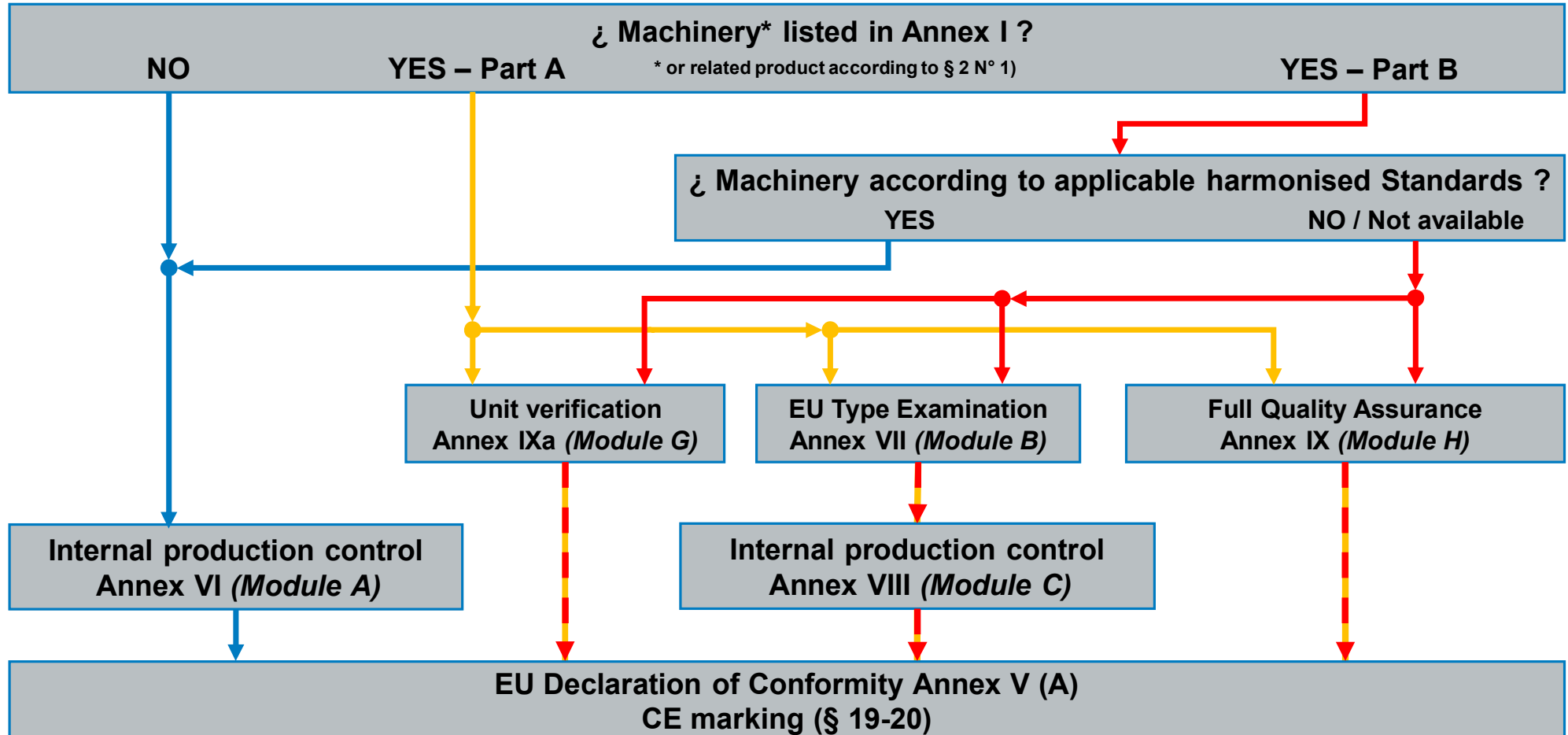
“substantial modification” means:

- › a modification of machinery or a related product...
- › by physical or digital means...
- › after that machinery or related product has been placed on the market or put into service...
- › which is not foreseen or planned by the manufacturer, and
- › which affects the safety of that machinery or related product, by creating a new hazard, or by increasing an existing risk, which requires:
 - a) the addition of guards or protective devices to that machinery or related product the processing of which necessitates the modification of the existing safety control system; or
 - b) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;



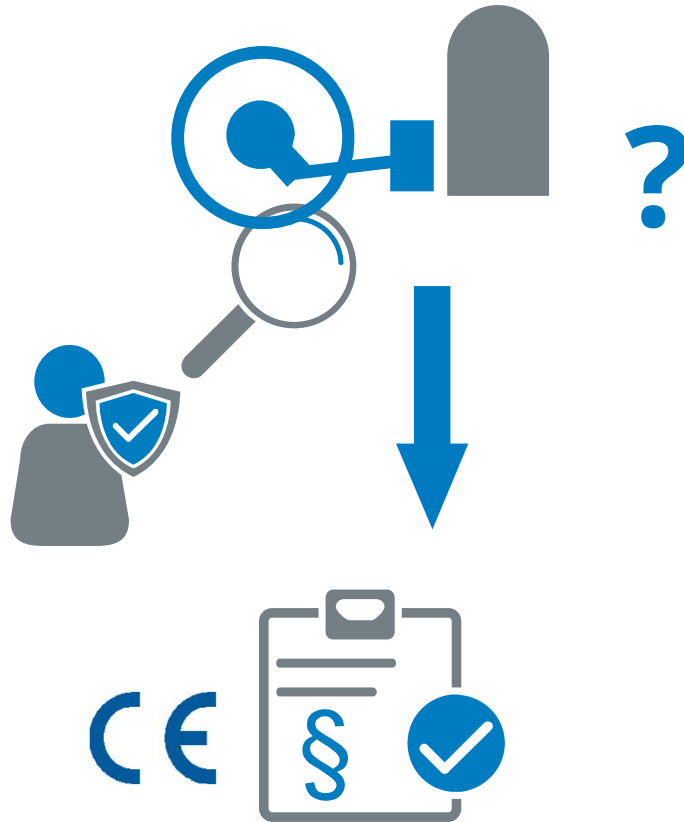
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Conformity procedure. § 25



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Annex I – Part A



Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied:

1. Removable mechanical transmission devices including their guards.
2. Guards for removable mechanical transmission devices.
3. Vehicle servicing lifts.
4. Portable cartridge-operated fixing and other impact machinery.
5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.
6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems.

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Annex I – Part B (Simplified text) Points 1 to 9

1. Certain circular saws (single- or multi-blade) for wood, meat or material with similar physical characteristics
2. Hand-fed surface planing machinery for woodworking
3. Thicknessers with mechanical feed device & manual loading/unloading for woodworking
4. Certain band-saws with manual loading/unloading for wood, meat or material with similar physical characteristics
5. Combined machinery of the types 1 to 4 and 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

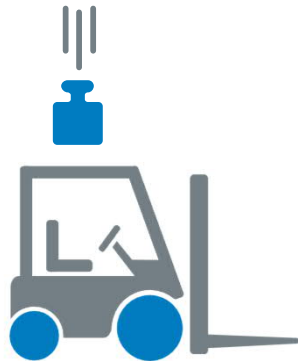


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Annex I – Part B (Simplified text) Points 10 to 19



NOTHING NEW !



10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Locomotives, brake-vans and hydraulic-powered roof supports for underground working
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Devices for lifting persons or persons and goods involving a hazard of falling from a vertical height of more than 3 m.
15. ...
16. Power-operated interlocking movable guards designed to be used as safeguards in machinery according to points 9, 10 and 11.
17. ...
18. Roll-over protective structures (ROPS).
19. Falling-object protective structures (FOPS).

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Annex I – Part B Inconsistency between items #15 and #17



15. Protective devices designed to detect the presence of persons.

- This includes all sensors and sensor systems that are intended to detect people to reduce risks.
- This is independent of any (imaginative) naming

17. Logic units to ensure safety functions.

- This refers to hardware components
- With or without embedded software (operating system) or application program
- › Software that performs safety function(s) is a safety component (listed in Annex II) but does not require a special conformity assessment procedure according to §25 (2, 3).
- › **It is technically not understandable why the "hard-wired logic" of a safety module shall meet higher requirements than the "freely programmable logic" of a safety related PLC**

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Annex II – Indicative list of safety components

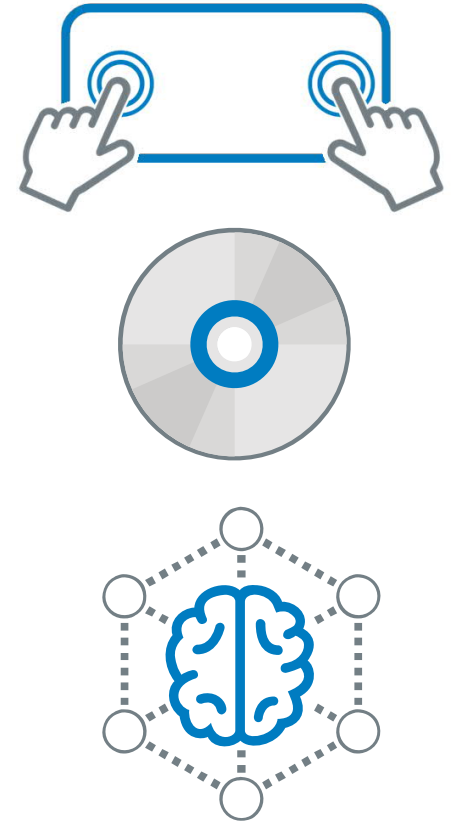
1. Guards for removable mechanical transmission devices
- 2. Protective devices designed to detect the presence of persons**
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Annex I, Part B.
- 4. Logic units to ensure safety functions**
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery
6. Extraction systems for machinery emissions
7. Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery
8. Monitoring devices for loading and movement control in lifting machinery
9. Restraint systems to keep persons in their seats
- 10. Emergency stop devices**



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Annex II – Indicative list of safety components

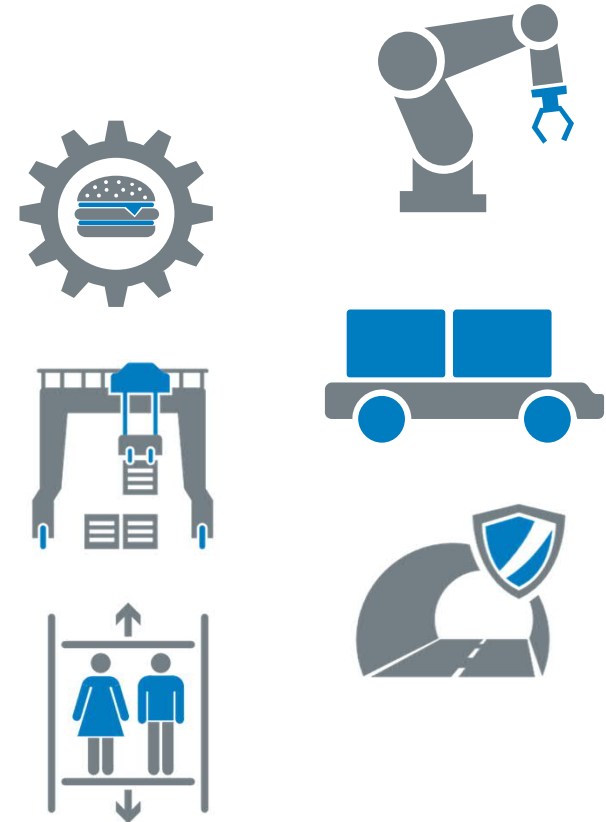
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III
13. Systems and devices to reduce the emission of noise and vibrations
14. Roll-over protective structures (ROPS)
15. Falling-object protective structures (FOPS)
- 16. Two-hand control devices**
17. Certain components for machinery designed for lifting and/or lowering persons between different landings:
- 18. Software ensuring safety functions**
- 19. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.**
20. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including plant protection products , and filters for such filtration systems.



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Structure of Annex III – Problematic areas

- › Section A Definitions
- › Section B General principles
 - **Chapter 1** Essential Health and Safety Requirements (ESHR's)
 - Chapter 2 Supplementary ESHR's for certain categories of machinery and related products
 - **Chapter 3** Supplementary ESHR's to offset risks due to the mobility of machinery or related products
 - Chapter 4 Supplementary ESHR's to offset risks due to lifting operations
 - Chapter 5 Supplementary ESHR's for machinery or related products intended for underground work
 - Chapter 6 Supplementary ESHR's for machinery or related products presenting particular risks due to the lifting of persons

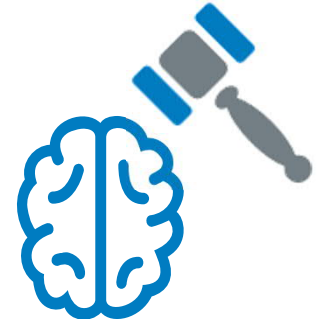


The new machinery safety regulation – Annex III

Part B – General principles – Applicability of the ESHR's

- › **The obligations laid down by the essential health and safety requirements only apply**
 - **when the corresponding hazard exists for the machinery or related product in question**
 - when it is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations.

- › **However, in all cases the following applies:**
 - the principles of safety integration (section 1.1.2)
 - the obligations concerning marking of machinery or related products (section 1.7.3)
 - the requirements for instructions for use (section 1.7.4).

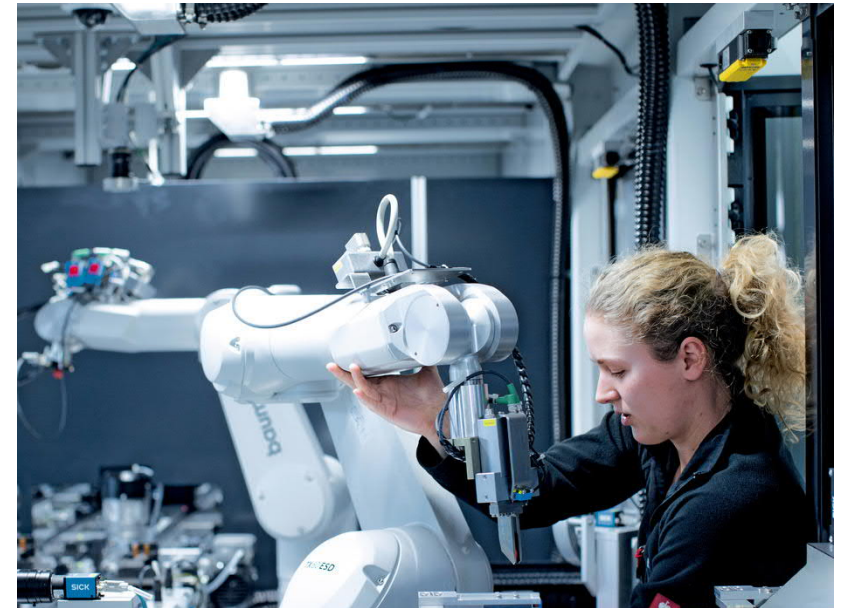


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Chapter 1 – General principles – Collaborative applications – New requirements ?

1.1.6. Ergonomics

- g) where relevant, adapting machinery or a related product with intended fully or partially self-evolving behaviour or logic** that is designed to operate with varying levels of autonomy
- **to respond to people adequately and appropriately** (such as verbally through words and non-verbally through gestures, facial expressions or body movement) and
 - **to communicate its planned actions** (such as what it is going to do and why) to operators in a comprehensible manner.



**The requirement bears a high risk of information overload.
Therefore, it should be limited to safety-related actions.**



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Annex III – Chapter 1 – General principles – Control systems

1.2.1. Safety and reliability of control systems (i)

Control systems shall be designed and constructed in such a way that: they can withstand...

- › where appropriate to the circumstances and the risks,
- › the intended operating stresses and
- › intended and **unintended external influences**,
- › including **reasonably foreseeable malicious attempts from third parties** leading to a hazardous situation;

**Question: what is an unintended external influence ?
(e.g., a flood in the Sahara desert, a meteor shower ?)**



Recital Nr. 14:

In order to ensure legal certainty, the scope of this Regulation should be set out in a clear manner and the concepts relating to its application should be defined as precisely as possible.

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Annex III – Chapter 1 – General principles (Cyber-security)

1.1.9. Protection against corruption (Related to software)

- › The machinery shall be designed and constructed so that the **connection to it of another device**, via any feature of the connected device itself or via any remote device that communicates with the machinery or related product **does not lead to a hazardous situation**.
- › The machinery or related product shall **identify the software installed** on it **that is necessary for it to operate safely** and shall be able to provide that **information at all times in an easily accessible form**.
- › **Software and data** that are **critical** for the compliance of the machinery or related product with the relevant essential health and **safety** requirements **shall be identified** as such **and** shall be **adequately protected against** accidental or intentional **corruption**.



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Annex III – Chapter 1 – General principles (Cyber-security)



1.1.9. Protection against corruption (Related to **hardware**)

- › A **hardware component** transmitting signal or data, **relevant for connection or access to software that is critical for** the compliance of the machinery or related product with the relevant essential health and **safety** requirements **shall be** designed so that it is **adequately protected against accidental or intentional corruption**.
- › The machinery or related product **shall collect evidence of a legitimate or illegitimate intervention in that hardware component, when** relevant for connection or access to software that is critical for the compliance of the machinery or related product and to the software **or a modification of the software or its configuration**.

Cyber-attacks are designed to remain undetected !

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Annex III – Chapter 1 – General principles – Formal requirements as ESHR's !



1.2.1. Safety and reliability of control systems (tracing)

- › (ii) The **tracing log** of the data generated in relation to an **intervention and of the versions of safety software uploaded** after the machinery or related product has been placed on the market or put into service is enabled for **five years** after such upload, **exclusively to demonstrate the conformity**

This is NOT an ESHR (See definition #14 in § 3)

- › (iii) The **record of data on the decision-making process of software-based safety systems** including safety components, after the machinery has been placed on the market or in service, **must be kept for one year after its collection**, **exclusively to demonstrate the conformity of the machinery**

This is also not an ESHR and only applicable for self evolving logic !

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Annex III – Chapter 1 – General principles



1.2.6. Failure of the power supply or communication network connection

- › The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply **or communication network connection** to the machinery or related product shall not lead to hazardous situations.

1.6.2. Access to operating positions and servicing points

- › In the case of machinery or related products into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be **dimensioned and adapted for the use of rescue equipment** in such a way that an emergency rescue of the persons is possible.

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Annex III – Chapter 2 – Supplementary ESHR's for certain categories of machinery

2.1 Machinery for foodstuffs (including potable water), cosmetics or pharmaceutical products

- › Requirements are included for all materials and surfaces that come into **contact with water intended for human consumption.**



2.2 Portable hand-held or hand-guided machinery or related products

- › They shall be provided with a connected exhaust device or system, or with an extraction connection outlet or an equivalent system to capture or reduce emissions of hazardous substances.
- › This requirement does not apply:
 - if it gives rise to a new danger
 - when the main function of the machinery is the application of hazardous substances
 - to emissions from internal combustion engines;



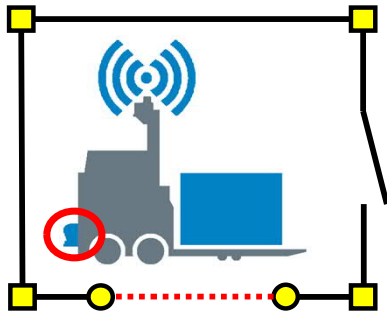
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Annex III – Chapter 3 – Supplementary ESHR's to offset risks due to the mobility of machinery



3.2.2 Seats

- › Machinery shall be equipped with a **restraint system to keep people in their seats.....**
- › When there is a **significant risk** of tipping or overturning and the **restraint system is not used, it shall not be possible for the machinery to move.**
- › Restraint systems or devices shall take ergonomic principles into account and not be installed if they increase the risk



3.3.3. Travelling function

- › Autonomous mobile machinery shall **comply, with one or both** where necessary according to the risk assessment, **of the following conditions:**
 - i. it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;**



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Annex III – Chapter 3 – Supplementary ESHR's to offset risks due to the mobility of machinery

3.3.3. Travelling function (autonomous mobile machinery...)



- › (ii) it shall be equipped with devices intended to detect any human, **domestic animal or any other obstacle in its vicinity**, where those obstacles could give rise to a risk to the health and safety of persons or domestic animals or to the safe operation of the machinery or related product.



- › The movements of mobile machinery or a related product connected with one or more trailers or towed equipment, including autonomous mobile machinery or a related product connected with one or more trailers or towed equipment, shall not give rise to risks for persons, **domestic animals or to any other obstacle** in the danger zone of such machinery or related product and trailers or towed equipment.



Question: what is a domestic animal... any other obstacle... vicinity ?

Recital Nr. 14:

In order to ensure legal certainty, the scope of this Regulation should be set out in a clear manner and the concepts relating to its application should be defined as precisely as possible.

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Annex III – Chapter 3 – Supplementary ESHR's to offset risks due to the mobility of machinery

3.2.4 Supervisory function

- › **Where relevant, (?)** autonomous mobile machinery or related products shall have a **supervisory function specific to the autonomous mode.**
- › This function shall allow the supervisor to remotely receive information from the machinery. The supervisory function shall **only allow actions to stop and to start remotely the machinery or move it to a safe position** and a safe state to avoid causing other risks.
- › It shall be designed and constructed to allow those actions only when the supervisor can see directly or indirectly the machine's movement and working area and **the protective devices are operational.**



The last requirement should not apply for stop commands, otherwise on a failure of protective devices or functions the intended risk reduction cannot be achieved !

This should be considered as a major and dangerous flaw of the regulation !



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Annex III – Chapter 3 – Supplementary ESHR's to offset risks due to the mobility of machinery

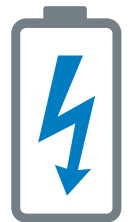
3.3. Control systems

- › For autonomous mobile machinery the control system shall be designed to **perform the safety functions by itself** as set out in this section, **even when actions are ordered by** using a remote **supervisory function**.
- › For autonomous mobile machinery, a **failure in the steering system shall not have an impact on the safety of the machinery.** (should read “shall not lead to a hazardous situation”)



3.5.1. Batteries

- › Batteries with automatic charging for mobile machinery must be designed to **prevent mechanical and electrical hazards** as well as the risks of contact or collision of the machinery with a person or other machinery **when moving autonomously to the charging station.**



Why only when the machine moves autonomously to the charging station ?

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Annex III – Chapter 3 – Supplementary ESHR's to offset risks due to the mobility of machinery

3.5.4 Risk of contact with live overhead power lines

- › Depending on their height mobile machinery or related products shall, where relevant, be designed, constructed and equipped, so as to **prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc** between any part of the machinery or an operator driving the machinery and an energised overhead power line.
- › When the risk to the persons operating machinery incurred by the contact with an energised overhead power line cannot be fully avoided, mobile machinery or related products shall be designed, constructed and equipped so as **to prevent any electrical hazards**.



The new machinery safety regulation

Digitalization of documentation



- › Currently, the instructions are required in paper format, following the Application Guide of the Machinery Directive 2006/42/CE
- › For most users it can be assumed that they have the means of accessing and reading instructions supplied in electronic form.
- › **Therefore, instructions and declarations in digital form will be allowed in future**
- › Digital instructions and declarations will help achieve savings of €16.6 billion in printing costs each year, and will significantly reduce environmental impact.
- › Articles 10 to 15 contain the related obligations for economic operators.
- › The technological and content requirements are:
 - for instructions for use in Annex III, Part B, sections 1.7.4. to 1.7.4.2.
 - for EU Declarations of Conformity/Incorporation in Annex V
 - for the assembly instructions of partly completed machines in Annex XI



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Digitalization of documentation – General rules for digital instructions for use

- › How to access these must be indicated directly on the machinery (for example, QR code)
- › If this is not possible, it is acceptable for the access information to be on the accompanying document or on the packaging.
- › They must be downloadable and printable (also when integrated into the machine)
- › If it is on a network (Internet) , it must be available for at least 10 years after its commercialization
- › At the user's request at the time of purchase, a paper copy must be provided, free of charge and within a month.
- › For machinery with foreseeable use by non-professional users, important safety information must be attached to the machine or product in printed format.



2D



The new machinery safety regulation

Impact on Standardisation I



› Harmonized standards

Adaptation required ?

- Yes, because the Commission only accepts dated cross-references to other standards

› Transition period

Sufficient ?

- No, because for every type of safety standard, 18 months is the shortest project time
- First EN ISO 12100 must be revised, then Type-B standards, and then Type-C standards
- The regulation may be challenged if not sufficient harmonized standards are available (The EHC-Curia has declared Harmonized Standards as part of the EU legislation)



› Current standards projects

Two ZA annexes ?

- Yes, intended for old MRL and new MVO in the transition period.
- Previously rejected by the Commission

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Impact on Standardisation II



- › HAS Consultants, can they assess timely ? Very unlikely.
 - The backlog of standards to be assessed is enormous
 - The EU Commission is also not able to timely list already assessed standards
 - It is unclear if the Commission will provide sufficient funds to the service provider (E+J)

- › Technical specifications Who should draft them ?
 - It is very likely that industry will challenge specifications drafted by inexperienced authors
 - There is a large risk that such specifications will follow ideologies instead of scientific knowledge and technical principles



- › Application Guide to the Machinery Regulation Why required ?
 - CEN/CLC Machinery Sector has volunteered to support the Commission in drafting technical content
 - Nevertheless, it should be noted that an Application Guide would not be required if the Regulation had been properly drafted (see also Recital #14)

Thank you for your kind attention

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