



The changing legislation for machinery safety in Europe

Ian Murgatroyd – EMEA Product manager for safety components

David Main Reade – Global product standards & compliance

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Ian Murgatroyd

EMEA Product Manager Safety Components

- **Background in machinery safety for the last 28 years**
- **14 years – Rockwell Automation**
 - EMEA Product Manager for safety components
 - On machine safety components,
 - safety relays,
 - Configurable safety relays
 - TUV Rheinland Certified Machinery Safety Engineer – ID No: 3995/11



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David Main-Read – PM Standards & Regulations

22 years – Rockwell Automation

- Global standards specialist
- Participating on numerous International committees
 - IEC TC44 Machinery safety committee
 - ISO TC 199 Machinery safety committee
 - IEC TC 65 Industrial-process measurement, control and automation
 - ISO TC 299 Robotics
 - ISO TC 313 Packaging machinery

TÜV Rheinland Certified Machinery Safety Expert – ID No: 206/13



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Agenda



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The changing legislation for machinery safety in Europe

Agenda

- Machinery Directive 2006/42/EC
- Machinery Products Regulation
 - Dates
 - Overview – key considerations
- Considerations for machine builders and end users
- Questions



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Machinery Directive 2006/42/EC



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Machinery directive 2006/42/EC

Applicable since 29th December 2009

Applies to

- Machinery
- Interchangeable equipment
- Safety components
- Lifting accessories
- Chains ropes and webbing
- Removable mechanical devices
- Partly completed machinery



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Machinery directive 2006/42/EC

Who does it affect?

- Anyone that builds machinery or partly completed machinery covered by the directive, wanting to supply into the EEA
- OEMs
- End users building machinery for their own use – self supply
- Machines that are significantly modified – beyond original design limits
 - Speed, increased output,
 - addition of end of line robot
- Second hand equipment entering the European market for the first time



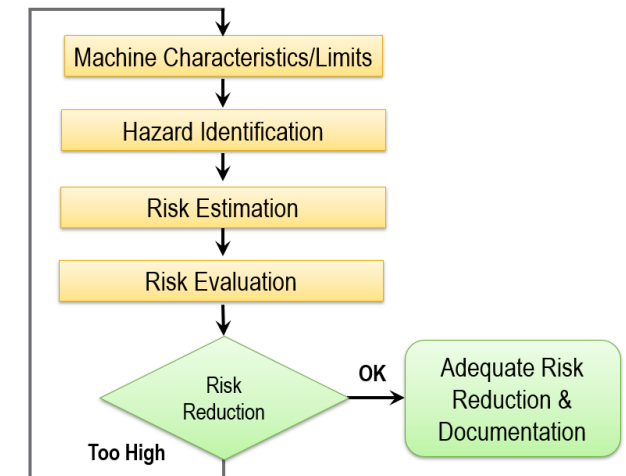
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Meeting the requirements - Overview

Meet the requirements of the relevant EHSRs in Annex I

- Risk assessment is the key to compliance
 - Identify the hazards and the associated risk for all tasks – (assemble, operate, maintain, cleaning, disposal)
 - eliminate or reduce the risks by using standards. (presumption of conformity)
- Produce the necessary documentation
 - Technical file
 - Declaration of conformity, or
 - Declaration of incorporation
- Affix CE mark
- Self certification process
 - With the exception of Annex IV machines which, depending on its type, will need additional evidence.



Machinery Products Regulation

Expected July 2023



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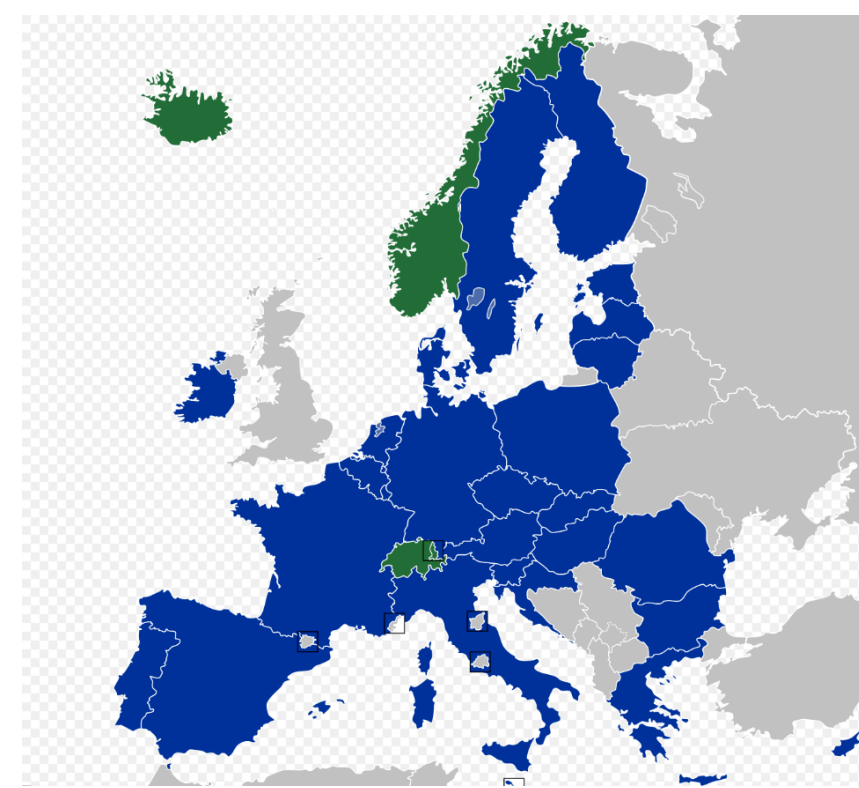


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Machinery Products Regulation

Applicable for the EU and EFTA countries

- Entry into force – expected July 2023.
- Transition period – 42 months.
- Application date – January 2027



- **How long does it take to design a new machine?**

It is no longer a Directive it is a Regulation.

- Will be adopted by all member states without modification, or change to date of entry



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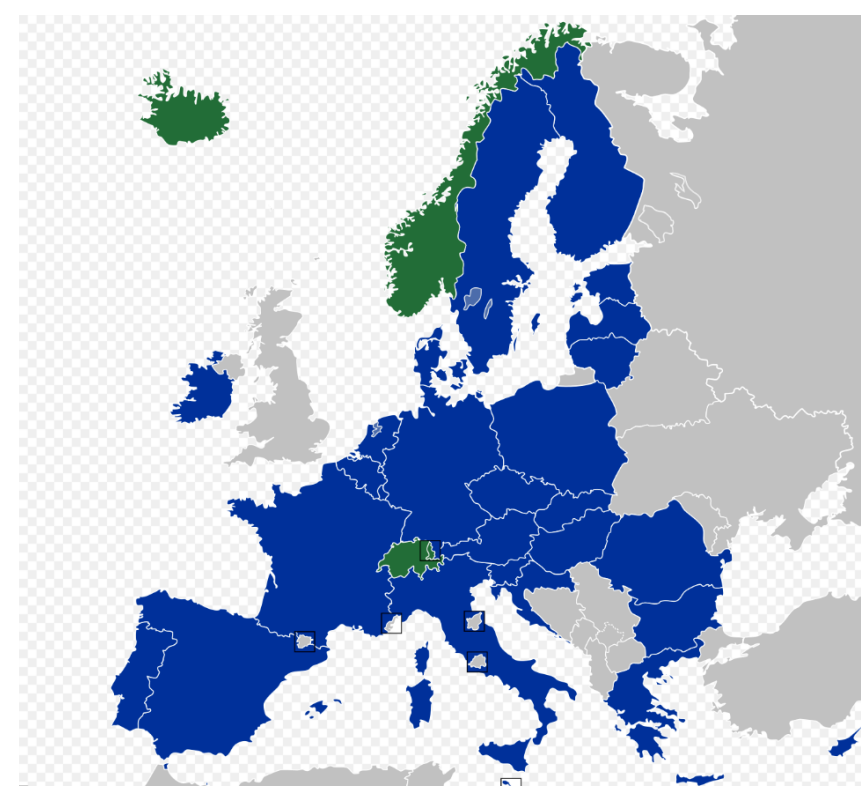


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Machinery Products Regulation

Compliance continues to be based around the use of harmonised standards.

- A challenge for the standards committees?



What about the United Kingdom?

United Kingdom continues with the Supply of Machinery Safety Regulations 2008 based on 2006/42/EC

- UKCA marking is required
- Under review.



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Overview of the major changes



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Machinery Products Regulation

Today's focus items

- New structure of the annexes
- Categories of machinery
- Indicative list of safety components
- Additions to the essential health and safety requirements.
- Conformity route
- Substantial modifications
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Structure of the Annexes



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New Annex Structure

- **Annex I** – Categories of machinery
- **Annex II** – Indicative list of safety components
- **Annex III** – Essential health and safety requirements relating to the design and construction of machinery
- **Annex IV** – Technical files / Technical documentation
- **Annex V** – Declarations
- **Annex VI** – Assessment of conformity with internal checks on the manufacture of machinery – module A
- **Annex VII** – EU type examination (module B)
- **Annex VIII** – internal production control – self assessment (module C)
- **Annex IX** – Full quality assurance – Annex IX (module H)
- **Annex X** – assembly instructions for partly completed machinery
- **Annex XI** – Correlation Table with Directive 2006/42/EC



More logical Flow to the Annexes

Annex I

Categories of machines or related products



Annex I – Categories of machines or related products

Annex I is split into two parts

Part A includes

Removable mechanical transmission devices including their guards

Guards for removable mechanical transmission devices

Vehicle servicing lifts

Portable cartridge operated fixing and other impact machinery

Procedure in Article 21 (2) shall be applied



Annex I – Categories of machines or related products

Annex I is split into two parts

Part A includes

NEW - Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions

NEW - Machinery embedding 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 to those systems.

Procedure in Article 21 (2) shall be applied



Annex I – Categories of machines or related products

Part B includes the remaining items from Annex IV 2006/42/EC, and includes

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics,
four types are defined
2. Hand-fed surface planing machinery for woodworking.
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics,
two types defined



Procedure in Article 21 (2A) shall be applied

Annex I – Categories of machines or related products

Part B includes the remaining items from Annex IV 2006/42/EC, and includes

5. Combined machinery of the types referred to in points 1 to 4 and in point 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 chain saws for wood-working

Procedure in Article 21 (2A) shall be applied



Annex I – Categories of machines or related products

Part B includes the remaining items from Annex IV 2006/42/EC, and includes

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 greater than 6mm, and a speed exceeding 30mm/s
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. Machinery for underground working. Two types defined.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.



Procedure in Article 21 (2A) shall be applied

Annex I – Categories of machines or related products

Part B includes the remaining items from Annex IV 2006/42/EC, and includes

17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.
19. Protective devices designed to detect the presence of persons.
20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.
21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).
23. Falling-object protective structures (FOPS).



Procedure in Article 21 (2A) shall be applied

Machinery Products Regulation overview

General provisions – Article 5 - Potentially high-risk machinery

The Commission shall assess the seriousness of the inherent potential risk for the purpose of adding a category of machinery or related product to Annex 1 or withdrawing a category of machinery or related product from Annex 1.

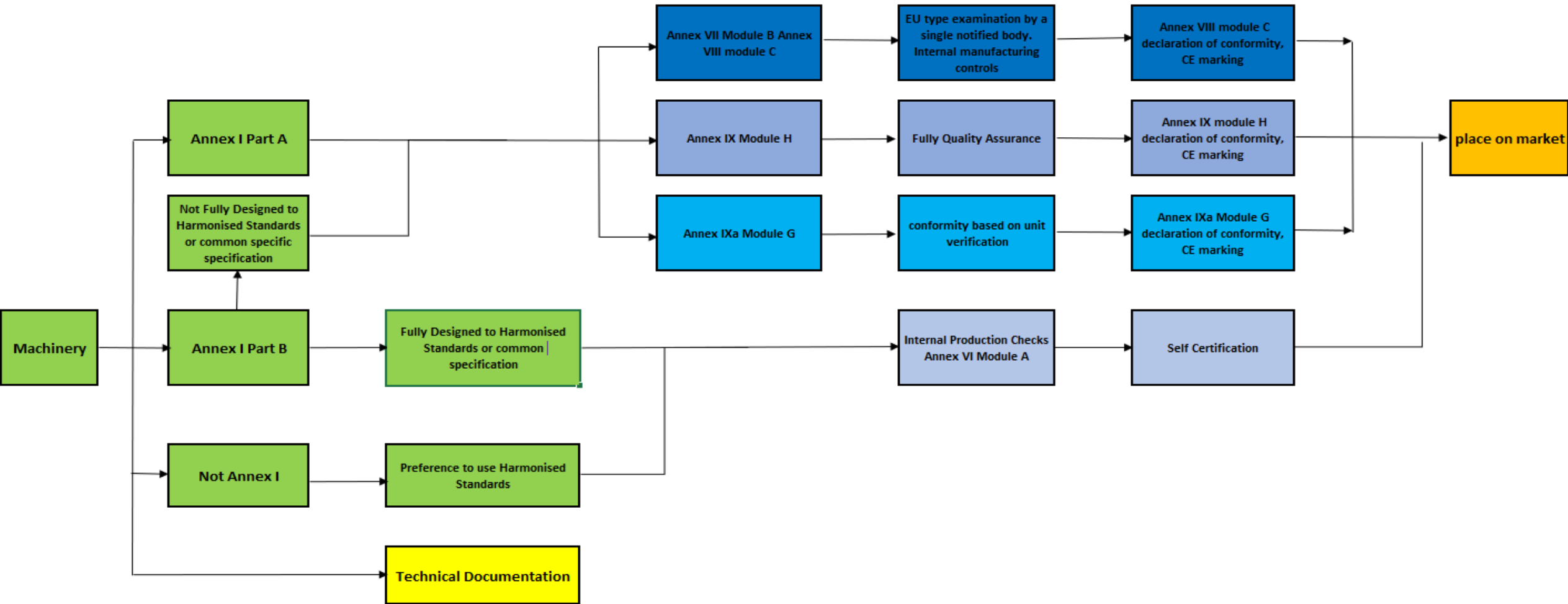
That assessment shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.

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Annex I – groups of machines and products are no longer fixed

Procedure for compliance



Annexe II

Indicative list of safety components



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Annex II – Indicative list of safety components

In general Annex II is the same as in 2006/42/EC

- 18. **NEW** - Software ensuring safety functions.
- 18a. **NEW** - Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions
- 19. **NEW** - Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.



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Annex II – Indicative list of safety components

In general Annex II is the same as Annex V in 2006/42/EC

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 &11 of Annex I.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for control of dangerous movements of machinery
6. Extraction systems for machinery



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Annex II – Indicative list of safety components

In general Annex II is the same as in 2006/42/EC

7. Guards and protective devices designed to protect persons against moving parts involved on the process of the machinery
8. Monitoring devices for loading and movement control in lifting machinery
9. Restraint systems to keep persons in their sets
10. Emergency stop devices
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges
12. Energy limiters and relief devices referred to in annex III
13. Systems and devices to reduce the emission of noise and vibrations.



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Annex II – Indicative list of safety components

In general Annex II is the same as in 2006/42/EC

14. Roll-over protective structure (ROPS)
15. Falling-object protective structures (FOPS)
16. Two hand control devices.
17. The following components for machinery designed for lifting and/or lowering persons between different landings
 - a. Devices for locking landing doors
 - b. Devices to prevent the load-carrying unit from falling or unchecked upwards movement
 - c. Overspeed limitation devices
 - d. Energy-accumulating shock absorbers, non-linear or with damping of the return movement
 - e. Energy-dissipating shock absorbers
 - f. Safety devices fitted to jacks of hydraulic power circuits and used to prevent falls
 - g. Safety switches containing electronic components



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Annex III

**Essential health and safety requirements relating
to the design and construction of machinery**



Annex III

Essential health and safety requirements relating to the design and construction of machinery

Key additions

Ergonomics

Protection against corruption

Control systems

Autonomous mobile machinery



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Annex III

Essential health and safety requirements relating to the design and construction of machinery

1.1.6 – Ergonomics

Under the intended conditions of use the discomfort, fatigue and physical and psychological stress faced by the operator shall be eliminated or reduced to a minimum possible.



Annex III

Essential health and safety requirements relating to the design and construction of machinery

1.1.6 – Ergonomics

NEW - Adapting the human machine interface to the foreseeable characteristics of the operators, including with respect to a machinery or related product with intended **fully or partially self-evolving behaviour** or logic that is designed to operate with varying levels of autonomy.



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Annex III

Essential health and safety requirements relating to the design and construction of machinery

1.1.6 – Ergonomics

- Where relevant, adapting a machinery or 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
 - verbally through words
 - non verbally through gestures, facial expressions or body movements
- and to communicate its planned actions (such as what it is going to do and why) to operators in a comprehensible manner.



Annex III

Essential health and safety requirements relating to the design and construction of machinery

With more machinery and products being integrated into SMART manufacturing lines, where industrial networks are commonplace, the need for **cybersecurity requirements** has been included in the EHSRs.



The first new European Regulation to include Cybersecurity !

Annex III

1.1.9. Protection against corruption

The machinery or related product 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.

Example – laptop

Example – Safety input device

Example – Motion system / drives



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Annex III

1.1.9. Protection against corruption

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 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.

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Annex III

1.1.9. Protection against corruption

Examples

Safety controller - modification of the safety task

Safety scanner - re-configuration of the safety fields

Motion system - increased through-put on the line



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Annex III

1.1.9. Protection against corruption

- **Software and data** that are critical for the compliance of the machinery or related product with the relevant 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

1.1.9. Protection against corruption

- 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
- The machinery or related product shall collect evidence of a **legitimate or illegitimate intervention** in the software or a modification of the software installed on the machinery or related product or its configuration.



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Annex III – 1.2 Control systems

1.2.1 – Safety and reliability of control systems

- Control systems shall be designed and constructed to prevent hazardous situations from occurring.
-they can withstand where appropriate to the circumstances and risks, the intended operating stresses and intended and unintended external influences, including reasonably foreseeable **malicious attempts** from third parties leading to a hazardous situation.



Annex III – 1.2 Control systems

1.2.1 – Safety and reliability of control systems

- The tracing log of the data generated in relation to an intervention, and of the versions of the 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 of the machinery or the related product with this annex, further to a reasonable request from a competent national authority



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Annex III – 1.2 Control systems

1.2.1 – Safety and reliability of control systems

Control systems with fully or partially self- evolving behaviour, or logic that is designed to operate with varying levels of autonomy

- They shall not cause the machinery or related product to perform actions beyond its defined task and movement space.
- Recording of data on the safety related decision making process for software based safety systems ensuring safety functions is enable and **retained for one year** after the machinery or related product is place on to the market or put into service.
- It shall be possible at all times to correct the machinery or related product in order to **maintain its inherent safety**



Annex III – 1.2 Control systems

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 the **communication network** connection to the machinery or related product shall not lead to hazardous situations.

including

- Shall not start unexpectedly
- Shall not change to an uncontrolled way when such change can lead to hazardous situations
- Shall not be prevented from stopping if the stop command has already been given



Annex III

3 – Supplementary essential health and safety requirements due to offset risks due to the mobility of machinery or related products

- **Definition** – mobile machinery that has an **autonomous mode**, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator.



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Annex III

3 – Supplementary essential health and safety requirements due to offset risks due to the mobility of machinery or related products

- 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 machine.
- **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.



Annex III

3 – Supplementary essential health and safety requirements due to offset risks due to the mobility of machinery or related products

- The movement of an **autonomous mobile machinery** shall take into account the risks related to the area where it is intended to move and work.
- **Autonomous mobile machinery** or related product shall comply, with one or both where necessary according to the risk assessment, of the following conditions
 - A) it shall move and operate in an enclosed zone fitted with peripheral protection system comprising guards or protective devices;
 - B) it shall be equipped with the 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 health and safety of persons or of domestic animals or to safe operation of the machinery or related products



Modification

- Machinery or related products should comply with the essential health and safety requirements when placed on to the market or put into service.
- Where such machinery products are **subsequently modified**, by **physical or digital means**, in a way that is not foreseen by the manufacturer and which affects the safety of such products by creating a new hazard or increasing an existing risk, **the modification should be considered as substantial** when new significant protective measures are required.
- Repair and maintenance operations which do not affect the machinery or related products compliance with the relevant essential health and safety requirements **should not be considered to be substantial modifications.**



SUMMARY

Considerations for machine builders and end users



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Machinery Products Regulation

- **Machine builders**

- Current date of application is January 2027
- Review the draft amended proposal
- Start early
 - Which changes affect you and your machinery?
 - If you have any form of network look at your cyber security requirements
-



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Machinery Products Regulation

- **End Users**

- **AUWED – Regulation 10**

- Employers providing work equipment for use in the workplace should ensure that it has been made to the requirements of the legislation implementing any product directive that is relevant to the equipment
 - Review and update your company's purchasing policy for machinery
 - For long term projects – Machinery will need to meet the new regulation



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Questions



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