



New Machinery Regulation Novelties and perspective in standardisation

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Introduction to EU Regulation 2023/1230 on Machinery

Introduction to EU Regulation 2023/1230 on Machinery

EU Machinery Regulation 2023/1230

- Machinery Regulation is the result of the revision of the Machinery Directive, 2006/42/EC
- This regulation is the core harmonized European legislation, for example
 - *Regulating machinery products from the design and manufacturing until the machinery is placed on the market*
 - *Setting obligations to manufacturers*
 - *Providing harmonized legislative safety requirements (Essential Health and Safety Requirements, EHSRs)*
 - *Defining Conformity Assessment Procedures to demonstrate the conformity of the products to the relevant EHSRs of the regulation*
- The Machinery Regulation covers wide range of products including
 - *Machinery*
 - *Partly completed machinery*
 - *Interchangeable equipment*
 - *Safety components*
 - *Lifting accessories and chains/ropes/webbing*
 - *Removable mechanical transmission devices*
 - *Lifting appliances*
- Machinery Regulation also covers new emerging technologies (AI, IoT, Robotics) and advanced machinery which has less dependency on human operators and has capabilities to learn and perform new actions

Introduction to EU Regulation 2023/1230 on Machinery

Relevance of the machinery regulation to the lift industry

- More than 50% of the essential health and safety requirements for lifts are defined by the Machinery Regulation
- Essential health and safety requirements and the Conformity Assessment Procedures for several products are fully covered by the Machinery Regulation
 - *Escalators and moving walks.*
 - *Lifting platforms*
 - *Building hoists*
 - *Goods only lifts*
 - *Stairlifts*
 - *Lifts used to access workplaces, such as lifts in wind turbines or in cranes*
- Borderline with the Lifts Directive
 - *The Machinery Regulation does not include definition for the borderline with the Lifts Directive 2014/33/EU*
 - *As the Lifts Directive is not changed, the borderline between the Machinery Regulation and the Lifts Directive remains unchanged.*
 - *Lifting appliances with speed greater than 0,15 m/s fall under the scope of the Lifts Directive.*
 - *Where relevant risk exists and not covered by the Lifts Directive, the EHSRs of the Machinery Regulation apply.*
 - *Therefore, new and changed EHSRs of the Machinery Regulation may also apply to lifts.*



New and changed requirements

New and changed requirements

Key changes compared to Machinery Directive

- Increased legal certainty, uniform application (e.g. substantial modification)
- Integration of Artificial Intelligence related provisions for safety functions
- Integration of Cyber Safety related provisions for safety control systems and compliance related software and data
- Autonomous and remote-controlled machinery
- Digitalisation of instructions for use, assembly instructions and EU Declaration of Conformity and Incorporation
- Mandatory Notified Body conformity assessment for 6 product categories
- Common specifications as a fallback option when suitable harmonised standards are not available
- Streamlined Safeguard Procedures, aligned with other legislation

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

- 1.1.6 “Ergonomics“: New requirements added
- New 1.1.9 “Protection against corruption“
- 1.2.1 “Safety and reliability of control systems“: Several modifications and new requirements
- 1.2.6 “Failure of the power supply or communication network connection“: Applies also to communication network connection
- 1.6.2 “Access to operating positions and servicing points“: Addition of requirements for emergency rescue
- 6.2 “Control devices” : Addition of conditions for using automatic stops instead of hold-to-run type control devices

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

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 the minimum possible, taking into account at least, the following ergonomic principles:

(a) allowing for the variability of the operator's physical dimensions, strength and stamina;

*(b) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity;**

* New requirement

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

1.1.9. Protection against corruption (excerpts)*

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.

A hardware [...] or access to software [...] that is critical for the compliance shall be designed so that it is adequately protected against accidental or intentional 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.

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.

* New requirement

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

1.2.1. Safety and reliability of control systems (excerpts)*

Control systems shall be designed and constructed in such a way that:

(a) they can withstand, where appropriate [...] reasonably foreseeable malicious attempts from third parties leading to a hazardous situation;

(d) the limits of the safety functions shall be established as part of the risk assessment performed by the manufacturer [...]

(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded [...] is enabled for five years after such upload [...]

Control systems of machinery or related product with fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:

(a) they shall not cause the machinery or related product to perform actions beyond its defined task and movement space;

(b) recording of data on the safety related decision-making process for software based safety systems ensuring safety function including safety components, after the machinery or related product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority;

* several changes and additions

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

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.

Particular attention shall be given to the following:

- (a) the machinery or related product shall not start unexpectedly;
- (b) the parameters of the machinery shall not change in an uncontrolled way when such change can lead to hazardous situations;
- (c) the machinery or related product shall not be prevented from stopping if the stop command has already been given;
- (d) no moving part of the machinery or related product or piece held by the machinery or related product shall fall or be ejected;
- (e) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded;
- (f) the protective devices shall remain fully effective or give a stop command.

* New title extending the requirements to the network connections

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

1.6.2. Access to operating positions and servicing points

Machinery or related products shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery or related product.

*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.**

* New requirement

New and changed requirements

New or modified EHSRs (Machinery Regulation, Annex III), relevant to lifts and escalators

6.2. Control Devices

Where safety requirements do not impose other solutions, the carrier shall, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices shall override any other devices controlling the same movement with the exception of emergency stop devices.

*The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices.**

* New requirement

New and changed requirements

Other new or changed requirements

Digital instructions (excerpt from various preambles and articles)

Instructions may be provided in a digital format. Upon request at the time of the purchase of the machinery, the instructions must be provided in paper format, free of charge.

When the instructions are provided in digital format, the manufacturer shall:

- (a) mark on the machinery and in an accompanying document how to access the digital instructions (e.g. QR code);
- (b) clearly describe which version of the instructions corresponds to the machinery product model;
- (c) present the instructions in a format that makes it is possible for the end user to download and save them on an electronic device so that those can be accessed or printed at all times, in particular during a breakdown of the machine. This applies also to a machinery where the instructions are embedded in the software of the machinery product.

When the instructions are provided in digital format online, those must be made available for the expected lifetime of the machinery and for at least 10 years after the placing on the market of the machinery. However, important safety information for non-professional users must be provided with every product in paper format.

Digital EU Declarations of Conformity document shall be made accessible online for at least 10 years after placing on the market.

New and changed requirements

Other new or changed requirements

Substantial modification (excerpt from various preambles and articles)

Substantial modification means a modification of a machinery which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery, 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;

Repair and maintenance operations which do not affect the machinery compliance with the relevant EHSRs should not be considered as substantial modifications.

The person that carries out the substantial modification should perform a new conformity assessment before placing the modified product on the market or putting it into service.



Implementation timetable

Implementation timetable

Publication

- Publication of the reference in the OJEU: **29 June 2023**
- Entered into force: **20 July 2023**
- Start application: **20 January 2027**
 - *The EU Member States and economic operators will have 42 months before the rules of the new Machinery Regulation applies starting from 20 January 2027, when the Machinery Directive 2006/42/EC is repealed*
- Voluntary application of the Machinery Regulation is not allowed before the application date
- However, relevant preparatory work and transitional arrangements may be started to be ready at the application date

Implementation timetable

Transitional arrangements

- Switching from the Machinery Directive to the Machinery Regulation happens when the Machinery Directive is repealed on 20 January 2027
 - *Voluntary application of the Machinery Regulation is not allowed before the application date.*
- Manufacturers and Notified Bodies can start relevant preparatory work and transitional arrangements to be ready at the application date
- Where the machinery complies with the requirements of both the Machinery Directive and the Machinery Regulation, the manufacturer could
 - *refer to the two in the EU Declaration of Conformity,*
 - *indicating the corresponding periods of application for each.*
- For example, the EU Declaration of Conformity could state
 - *'The object of the declaration is in conformity with the Directive 2006/42/EC (until 20 January 2027) and Regulation (EU) 2023/1230 (from 20 January 2027).'*



Standardization

Standardization

Impact to current standards and need for new harmonised standards

- Machinery Regulation requires review of all existing harmonised standards
- Current harmonised standards under the Machinery Directive will be assessed for their suitability of covering the relevant EHSRs of the Machinery Regulation
 - *If not impacted, the standard will be cited in the Official Journal of the EU (OJEU) under the Machinery Regulation*
 - *If impacted, the standard will be revised or amended by Q1 2026, before its citation in the OJEU*
- European Commission is preparing a new Standardization Request which will result in
 - *revision of all current harmonized standards*
 - *possibly new standards to cover new or revised EHSRs*
- Compliance to the new digitalization requirements, specifically Annex III 1.1.9 and 1.2.1, requires addressing the Cybersecurity (Cyber Safety) issues
 - *ISO 8102-20 (non-harmonized standard) published in August 2022 may provide the basis for addressing the cybersecurity for lifts and escalators*
- Work on new standards will be decided by CEN and ISO based on the needs for addressing the new technologies or for providing presumption of conformity to the legislative requirements



Thank you!