White paper

The new Machinery Regulation (EU) 2023/1230

Safety of machinery and systems in the European Economic Area

Learn more about:

- What the new EU Machinery Regulation is
- Who it affects
- What changes are coming
- Practical tips: What you need to do now

Introduction

The digital transformation, the increasing emergence of new technologies, collaborative forms of work between people and machines, and the resulting impact on safety regulations were key drivers for the revision of the Machinery Directive 2006/42/EC. The new EU Machinery Regulation is the result of this development – also referred to in the following as "MR".

As part of a white paper on artificial intelligence, the EU Commission published the "Commission Report on safety and liability implications of AI, the Internet of Things and Robotics" back in February 2020. This report analyzed the impact of new technologies and the challenges they pose for the European Union's safety regulations. According to the report, the (still) current product safety legislation has a number of gaps. One goal of the new MR is therefore to close these gaps.

On April 18, 2023, the European Parliament approved the final legal text for the new MR. After it comes into force (listing in the Official Journal of the European Union), it will become legally effective 42 months later, on January 20, 2027. The MR will then apply directly and mandatorily in all EU member states, without transposition into national law.

This white paper describes the background and objectives of the new MR without claiming to be complete or legally binding. In addition, it explains which companies, economic operators, and machines are affected by the new regulation. Read on to learn how the structure of the new MR differs from that in the current Machinery Directive 2006/42/EC and what the main changes and extensions to the content are.

The white paper provides you with helpful, practical tips and recommendations for action to successfully prepare for upcoming changes in the field of safety of machinery.

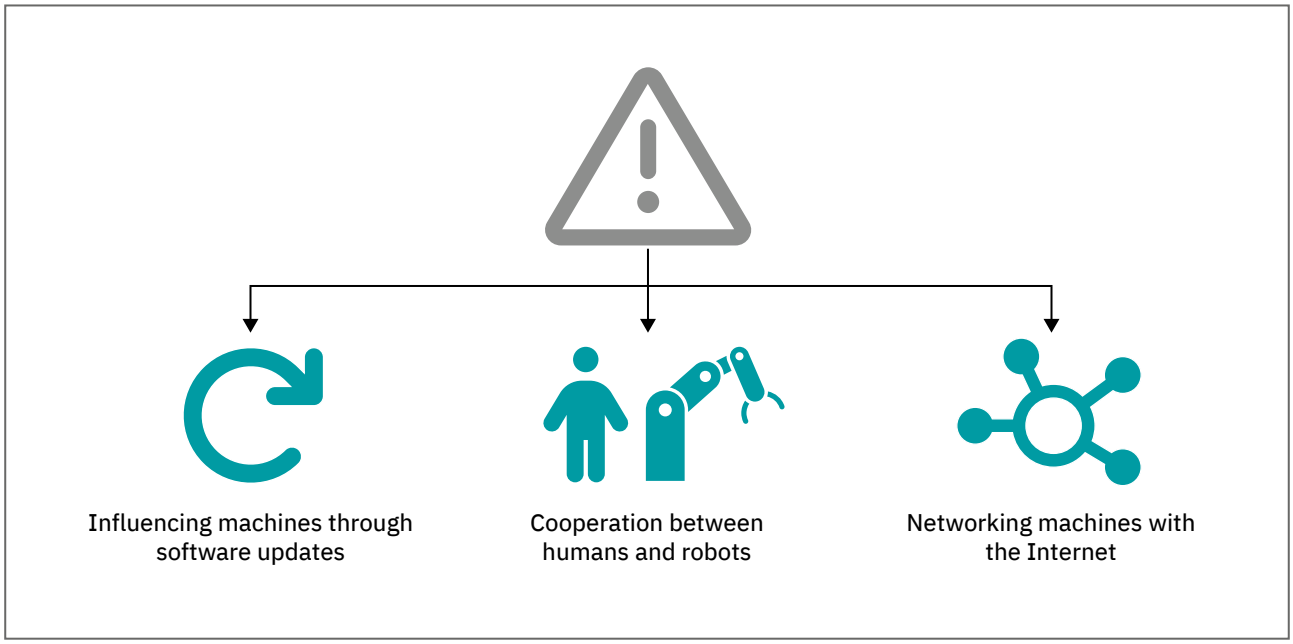
Contents

1 Reason, content, and objectives of the new MR

Machinery Directive 2006/42/EC and the new MR are applicable regulations within the EU for the safety of machinery. The aim of each document is to achieve a uniform safety level with regard to accident prevention on machines. They regulate the binding basic safety and protection requirements for providing and placing machines on the market. In addition, the regulations serve to reduce trade barriers for the free movement of goods within the EU.

1.1 Further development based on state-of-the-art technology

The intention of replacing the Machinery Directive 2006/42/EC with the MR is to bring the requirements on the safety of machinery in line with the current state of the art. Digital technologies open up new opportunities, but also create new risks. In the context of machines connected to the Internet, for example, for software updates or remote monitoring, security aspects and cybersecurity threats have taken on a whole new meaning. Machines with special risk potentials require separate consideration with regard to their safety. Artificial intelligence (AI), which is making machines and robots increasingly self-learning and autonomous, also brings entirely new challenges in terms of functional safety. This is particularly evident in collaborative human-machinery work scenarios. At the same time, the Internet and advancing digitalization are opening up new options. These include, for example, requirements on machinery documentation and, in particular, the possibility of making the provision of operating instructions and CE attestations of conformity paperless. This reduces costs and effort and conserves resources. These and other developments,



Risk gaps

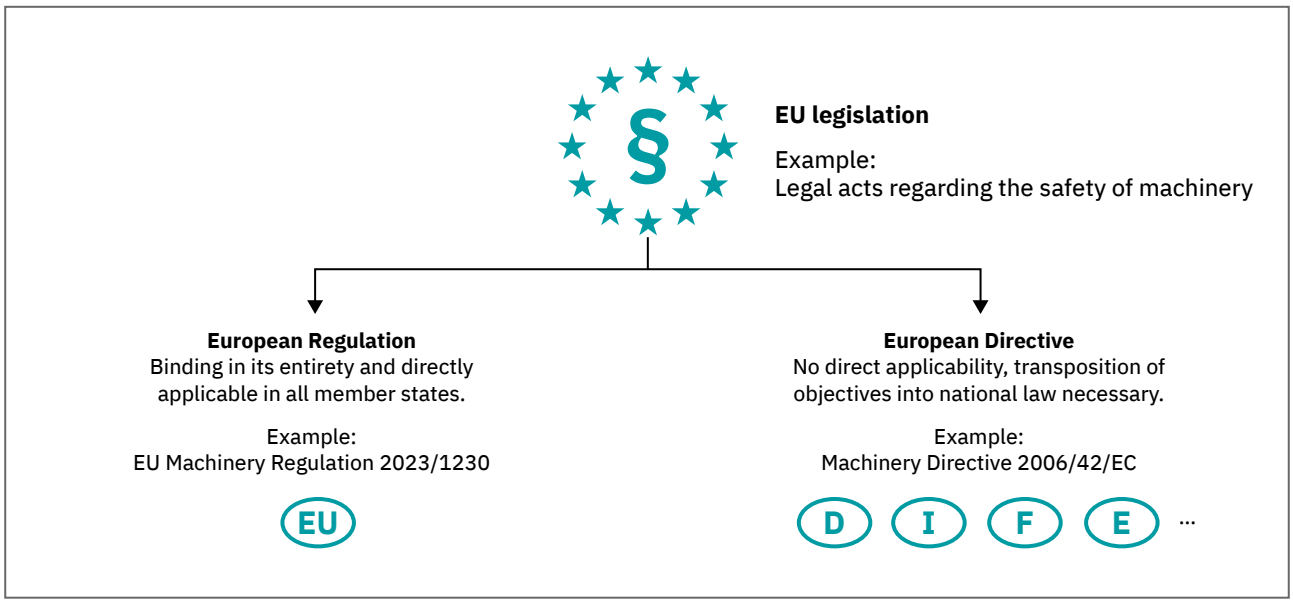
which have changed the machinery market worldwide in the last decade and will continue to change it in the future, are not or only inadequately reflected in the current Machinery Directive.

It is precisely these gaps in the safety assessment of machines that the new MR closes. At the same time, throughout the EU it ensures a consistent and legally secure interpretation and application of the requirements it contains.

1.2 Legal distinction between MR and Machinery Directive

Machinery Directive 2006/42/EC and the MR differ in one essential point: their legally binding nature. As with all directives based on the EC Treaty, the Machinery Directive was initially not directly effective and binding. This required transposition into national law in each EU member state. The MR, on the other hand, which will regulate the EU-wide provision, sale, and import of machinery after it comes into force and the resulting date of legal effectiveness, adopts direct legal force as a legal instrument of the EU.

Companies should become familiar with the upcoming changes that the new MR will bring compared to the Machinery Directive 2006/42/EC as early as possible. The new requirements of the new Regulation must be satisfied by the time it comes into force on January 20, 2027.

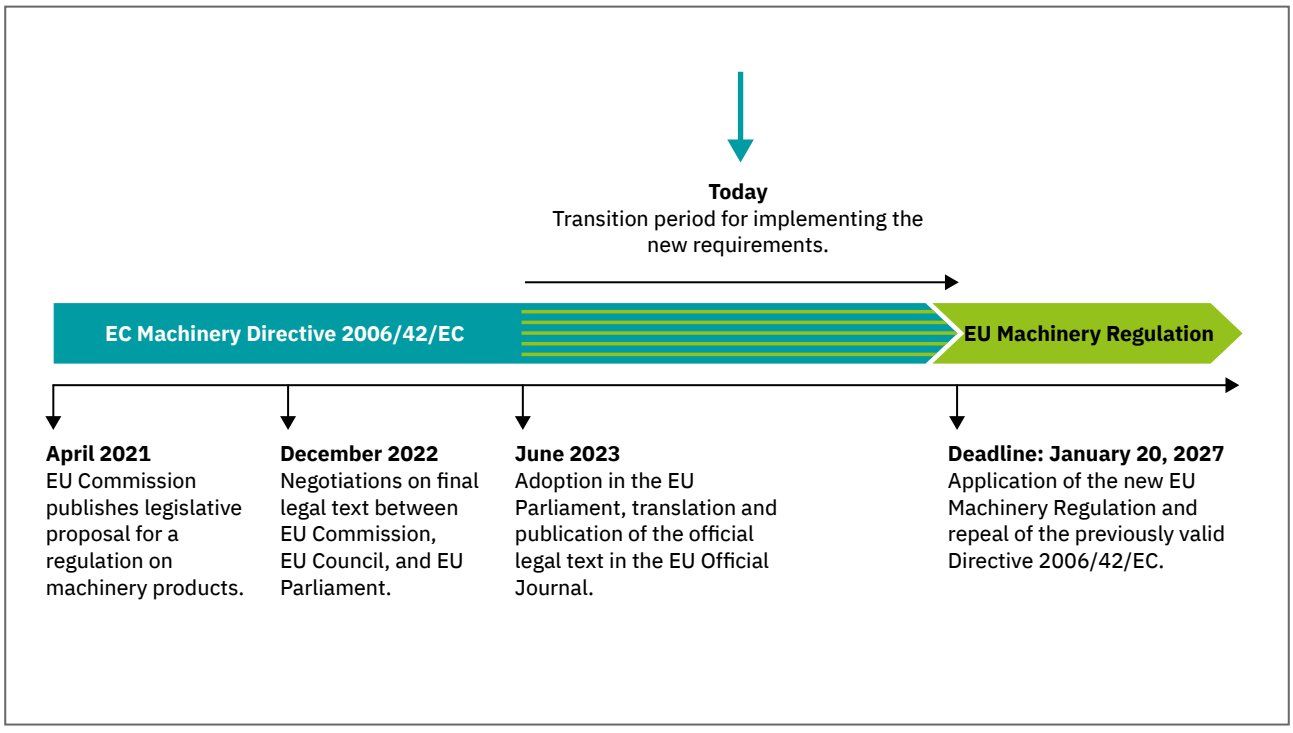


The EU legislation regarding the new Machinery Regulation (EU) 2023/1230

1.3 Scope, inception, and transition periods

The MR applies directly to all economic operators in all member states of the EU. It is published in the Official Journal of the European Union and acquires direct legal force as an EU legal instrument on the 20th day following its publication. Member states and economic operators have 42 months to apply the rules of the new regulation.

There will not be a floating transition period with parallel application of the current directive and the new regulation.



Replacement of EC Machinery Directive 2006/42/EC by the new Machinery Regulation

2 Area of application: What and who does the MR apply to?

2.1 Machinery affected

The MR will apply to the machinery designated therein. These are:

- Machinery, including partially completed machinery
- Replacement parts, interchangeable equipment
- Removable mechanical power transmission devices
- Safety components
- Load-carrying accessories
- Chains, ropes, coils, and webbing

It does not apply to a number of named machines, including:

- Replacement parts for safety products
- Office machines and information technology equipment
- Certain vehicles and sea vessels
- Machines for research purposes
- Certain electrical and electronic products insofar as they fall within the scope of Directive 2014/35/EU or Directive 2014/53/EU, e.g., household electrical appliances (so-called “white goods”), low-voltage switching and control devices, electric motors, and certain high-voltage electrical products

CE marking on machines

2.2 Companies and economic operators affected

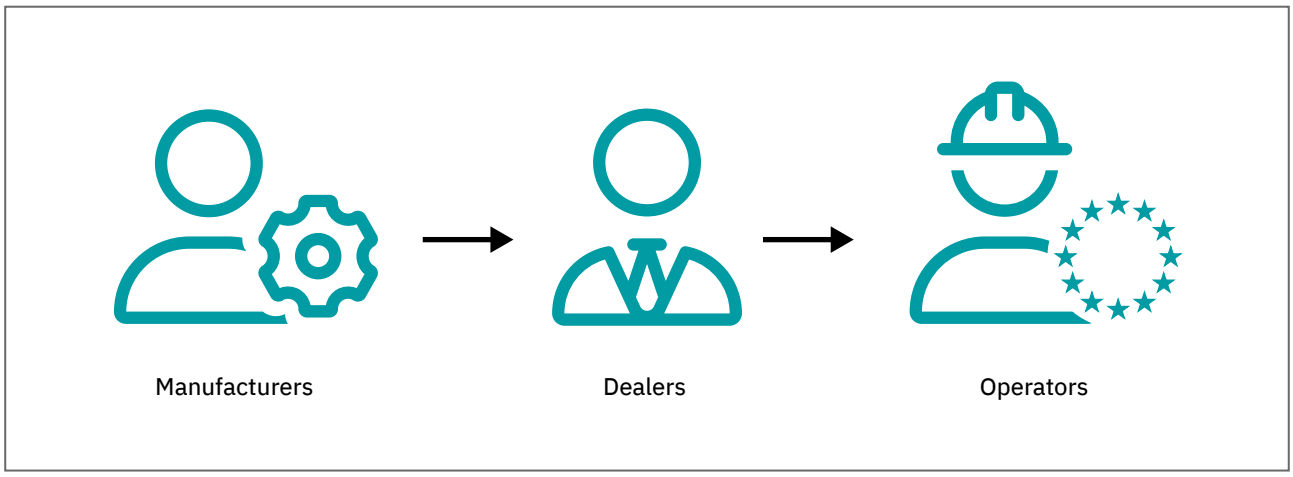
The requirements of the MR apply to the companies and economic operators responsible for the machines mentioned in 2.1 on the EU market because they:

- Manufacture them
- Make them available
- Place them on the market
- Commission them

This group of affected economic operators explicitly includes:

- Dealers – also online dealers
- Importers from outside the EU
- Authorized representatives

These are required to obtain the correct CE marking for the machines concerned within the scope of their economic activity(activities) mentioned above. In doing so, they declare compliance with the MR as a legal text and, if applicable, other standards and guidelines.



Economic operators affected

3 Structure of the MR

Compared to the Machinery Directive 2006/42/EC, the new Machinery Regulation has been adapted in terms of content as well as structure.

3.1 Topics of the Machinery Regulation

Divided into separate chapters with a total of 52 articles, the MR covers a total of nine topics:

1. General provisions with scope, terminology, definitions, and requirements
2. Economic operators and their obligations
3. Conformity of machinery, presumption of conformity through specifications, and requirements through EU legal act
4. Conformity assessment procedure in accordance with five modules defined in accordance with risk factors
5. Notification of conformity assessment bodies, including an overview
6. Union market surveillance, control of imported machinery, taking protective measures
7. Delegated powers and committee procedures
8. Confidentiality and sanctions
9. Transitional and final provisions

3.2 Adjusted order of the annexes

The annexes of the MR have been reordered compared to the Machinery Directive 2006/42/EU. Machinery and related products with a special conformity assessment procedure are of greater importance from the point of view of the EU Commission.

The new order takes this assessment into account:

- Annex I: Machines and related products with special conformity assessment procedure (previously Annex IV)
- Annex II: Indicative list of safety components
- Annex III: Essential health and safety requirements relating to the design and construction of machinery (previously Annex I)
- Annex IV: Technical documentation for machinery

In particular, in the period up to the coming into force of the new MR, affected economic operators should clarify when referring to annexes in the case of machinery relevant to the regulation whether the numbering of annexes refers to the Machinery Directive 2006/42/EC or to the MR.

4 Changes in the MR compared to the Machinery Directive

4.1 Machinery and related products with special conformity assessment procedure

In Chapter 1, Article 6, in connection with Annex I, the MR defines the so-called "machinery and related products with relevant conformity assessment procedures", hereinafter referred to as "Annex I machines". These pose a particular risk to human health in terms of their design and intended use. With a view to the digitalization of machinery, machinery controllers, software updates, and machinery connected to the Internet, Annex I machinery also includes, among others, AI systems that perform safety functions. These also include machinery using machine learning approaches, which in turn perform functional safety tasks. For machines and related products that are not Annex I machines, the manufacturer can, as before, carry out an internal production inspection to demonstrate conformity with the relevant health and safety requirements and declare this via CE marking (see Section 4.3).

The list of Annex I machines is not exhaustive and may be adapted to the state of development of the technology.

CNC folding machinery with special risk

New risk-bringing machines can be included, and those that no longer pose a particular risk can be removed. In addition, the EU Commission has delegated the power to adopt delegated acts to adapt the list of high-risk machinery. This makes it possible to adapt Annex I to technical progress and the state of knowledge or new scientific findings with reference to the listed classification rules.

Monitoring the list of "Annex I machinery" and its adaptations is an additional task for machinery manufacturers. It is possible that machines manufactured in accordance with harmonized standards also require an additional EC-type examination. This situation is a new challenge for every machinery manufacturer.

4.2 Substantial modification

In Chapter 1, Article 3, (16), the MR introduces the concept of a "substantial modification" of machinery. This refers to a physical or digital modification to machinery after it has been placed on the market or commissioned, which was not foreseeable by the manufacturer and which may affect the conformity of the machinery with the relevant essential health and safety requirements. Economic operators are thus obliged to objectively evaluate the modification of machinery. In the event of a substantial modification, a new conformity assessment procedure must be carried out in order to obtain the CE marking for the modified machinery.

Conveniently, the definition of substantial modification is largely consistent with the European Commission's Guide to the Implementation of EU Product Regulations (Blue Guide) and the EU General Product Safety Regulation (GPSR).

4.3 Designation of products subject to third-party authorization

Within the framework of the MR, the EU Commission has divided machinery into 25 groups, of which six product groups fall under the third-party obligation. These are listed in Annex 1, Part A:

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 behavior using machine learning approaches ensuring safety functions
6. Machinery that has embedded systems with fully or partially self-evolving behavior using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems

Involving notified bodies at an early stage is recommended. A list of designated third-party bodies is available here:
View the list now.

This regulation takes into account the fact that some Member States and stakeholders consider conformity assessment by third parties, so-called notified bodies such as TÜV, conformity assessment bodies, DGUV,

VDE, etc., to be better suited to cover the high risks posed by certain groups of machines. This applies even to manufacturers who work in accordance with the relevant harmonized standards.

The remaining 19 product groups are defined in Annex I, Part B. They are only subject to third-party authorization if harmonized standards are not available or if they are not applied.

4.4 Approval of digital operating instructions and declarations of conformity

In accordance with general legal opinion, operating instructions must be provided in paper form. However, this increases both costs and administrative burdens for economic operators and also has a negative impact on the environment. The new MR will allow manufacturers of business-to-business machinery to provide operating instructions and declarations of conformity in digital form as well in the future. The manufacturer must show access to the data, which in turn must be printable, downloadable, and storable on end devices. In addition, the digital data must be available on the market for at least ten years after the machinery has been made available.

Upon request, the manufacturer must provide both the operating instructions and the declaration of conformity of machinery in paper form up to one month after sale. For business-to-consumer machines, operating instructions and attestations of conformity must still be enclosed in printed form so that they are also accessible to purchasers that do not have the Internet.

In principle, the same content requirements apply to digital operating instructions as those applying to paper-based operating instructions. The objective is that machinery can be operated safely in every phase of its life, based on a previously conducted risk analysis. The information provided in operating instructions must be able to guarantee this.

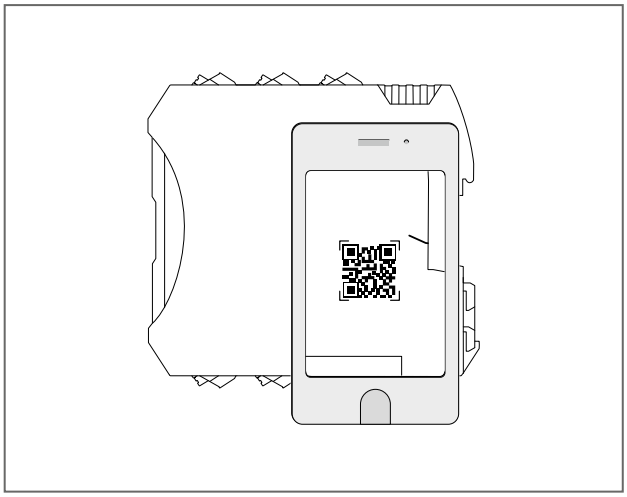
Annex III, 1.7.4 of the MR defines the mandatory content requirements for digital as well as printed operating instructions (instructions for use) and declarations of conformity.

The way in which operating instructions and declarations of conformity are provided digitally is not specified in concrete terms. They can be provided by affected economic operators directly in the machinery, as a PDF file on a data carrier, on the user interface of a machinery terminal, or provided in a cloud as a downloadable file, for example. From there, they can be downloaded, for example, via the ID of the machinery's digital twin (often a QR code on the machinery or component).

4.5 Extension of the manufacturer's specifications

The MR extends the scope of the machinery manufacturer's specifications. In addition to the name, trade name, and postal address, a website, email, or other digital contact information will also have to be provided in the future.

A QR code can be used for providing machine-readable digital contact information.



Additional information on the product

4.6 Safety and security

As a general rule, machinery must be designed and built in such a way that neither a connected device itself nor a remote device communicating with the machinery can lead to a hazardous situation. This applies to hardware and software, both in the case of intended use of the machinery and in the case of possible manipulation. The MR describes new essential health and safety requirements for this in 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. 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. 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. 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 must be designed such that connection or communication via remote access devices, such as routers, cannot lead to dangerous situations. Safety-relevant components with which other equipment is connected must be constructively protected against unintentional or deliberate manipulation.

The lawful intervention in the machinery during its intended use must be documented with the same evidentiary reliability as the unlawful intervention in the hardware component.

The evidence-based documentation of actions can be achieved, for example, by storing and backing up log data on mass storage devices.

Software installed on machinery necessary for it to operate safely operation must be identified and this information must be made readily available at all times. When it comes to ensuring that the machinery complies with the health and safety requirements of the MR, software and data must be designated as such and protected against manipulation of any kind. In analogy to the manipulation of machinery, the machinery must also collect and document appropriate evidence of a legitimate or illegitimate intervention in the software. The same applies in the event of a modification of the software installed on the machinery or its configuration.

The security level varies depending on the application and cannot be determined by the machinery manufacturer alone. In addition to the purely technical solution, organizational measures must also be implemented. Therefore, when it comes to security, a holistic approach and coordination between component manufacturers, machinery manufacturers, and end users is necessary.
The IEC 62443 standard should be drawn upon to increase the IT security of the products. The secure development process in accordance with IEC 62443-4-1 includes all elements from the security qualification of the participants to verification, validation, and release. The necessary measures can be determined based on the standard parts -3-3 and -4-2.

4.7 Safety of controller hardware and software

The requirements for the safety and reliability of control systems, especially in connection with software, play an important role in the MR. Control systems must provide protection against intended and unintended external influences. The same applies to external attempts through which the machinery creates hazardous situations. Errors in control circuit logics or defects in hardware and/or software must not cause hazardous situations. This also applies in the event of a wireless controller communication failure or a faulty connection. The controller for autonomous mobile machines must independently fulfill safety functions prescribed by the MR. Even when actions of the machines are triggered via a remote monitoring function. In the event of intervention by the market surveillance authorities, it must be possible to make the traceability log of the data generated in this context available to the relevant national authorities as proof of the conformity of the machinery for up to five years thereafter.

This also applies to versions of safety software uploaded to the machinery after it has been placed on the market or commissioned. Data on safety-related decision-making processes must be recorded after placing on the market or commissioning. It must be stored for one year to prove the conformity of the machinery to the relevant national authorities.

Machinery-specific safety-related application software will not be considered a safety component in practice if the conformity assessment is performed within the scope of the machinery. Nevertheless, it is also subject to the requirements for the safety-related parts of the control system.

The MR also specifically lists safety-related software as a safety component. All formal requirements that are also imposed on machinery thus apply to the software. If the software meets the requirements of a harmonized standard, such as EN ISO 13849-1, the CE marking must also be applied and a declaration of conformity issued. However, these requirements are only relevant if the software is marketed separately. Typically, this involves software libraries that support safety functions or perform parts of safety functions, provided that they are made available to the market independently of the hardware product.

For this reason, the use of a harmonized standard is also recommended for this safety-related application software (EN ISO 13849-1, Section 4.6). Through this, it can be ensured that the health and safety requirements of the Machinery Directive 2006/42/EC and the future EU Machinery Regulation 2023/1230 are met in the context of the presumption of conformity with these standards.

In any case, proof must be provided and documented that the protection objectives are achieved by the methods used. In 2023, the new version of the EN ISO 13849-1 standard was adopted by a majority at the European and international level. It will be listed in the Official Journal under the current Machinery Directive 2006/42/EC.

4.8 Safe coexistence and interaction of humans and machinery

The number of collaborative robots (cobots) designed to work with human workers is growing exponentially. For this reason, the occupational health and safety requirements for machinery formulated in the Machinery Directive 2006/42/EC have been supplemented in Annex III, 1.1.6 with the ergonomic aspects of work methods. Specifically, these include those methods in which humans and machines at least share the same workspace, right through to those where they interact and collaborate. Principles include designing interfaces between humans and learning and/or autonomous machines to the predictable traits of the operators. Furthermore, these machines, for their part, must be designed in such a way that they communicate planned actions, such as movements or handling, to the operators in good time and in a comprehensible form. Such machines must also respond appropriately in interaction with humans when people ask them to act verbally through speech or nonverbally through gestures or facial expressions.

The application of the standard EN ISO 13849-1 “Safety of machinery – Safety-related parts of control systems” provides supplementary support for the relevant economic operators in the appropriate design of such machinery.

4.9 Risks due to moving parts of machines and psychological stress

Adapted and supplemented health and safety requirements concerning risks that may arise from moving parts of machinery or due to psychological stress caused by possible contact and shock situations during interaction with the machinery are formulated in the MR in Annex III, 1.3.7. In this context, special attention should be paid to the coexistence of humans and machinery in a workspace and to interactive collaboration between humans and robots. The principles listed in 4.8 are to be applied. As before, hazardous moving parts of machinery must be designed such that there is no risk of accidents when touching such parts. If this is unavoidable from a machinery-technology perspective, the machinery parts must be assessed in terms of their risk potential and provided with separating or electro-sensitive protective equipment. In addition, all necessary measures must continue to be taken to safely prevent the unintentional blocking of moving parts. If this is not possible, special safety equipment and tools must be included with the machinery to enable any blockages to be released without risk or danger. In this case, there is a corresponding obligation to provide information in the operating instructions and, if possible, also directly on the machinery.

4.10 Risk and safety considerations for autonomous machinery behavior

In principle, the MR stipulates that machinery must be assessed in terms of the risks with regard to the protection of health and safety. A new addition in comparison to the Machinery Directive 2006/42/EC is that, in the case of machinery characterized by evolving and autonomous behavior, risks must also be anticipated and taken into account that may arise after the machinery has been placed on the market as a result of this same evolving and autonomous behavior. Continually learning machinery must therefore have no influence on safety functions.

The need for safety in applications with AI arises, for example, in automated guided vehicle systems when making predictions or routing decisions in dynamic factory environments. The autonomous vehicles can be diverted in a safety-relevant manner to prevent collisions with operators or other road users. Relevant data must always be recorded and stored for autonomous machinery. The behavior must comply with the design principles of functional safety and be protected against manipulation from the outside.

4.11 Safety aspects for machinery with artificial intelligence (AI)

Artificial intelligence is capable of endowing machinery with autonomously evolving capabilities and developing them further. This also applies to the potential perception of safety functions through AI. As such, this brings new challenges in terms of functional safety and associated liability issues. Therefore, the principles set out in 4.7, 4.8, and 4.9 regarding essential health and safety requirements must also be applied to machinery with evolving capabilities, so-called AI systems. In addition, the EU Regulation on Artificial Intelligence (EU AI Act) – which may come into force as early as 2023 – will also define four graded risk classes for AI systems in the future and thus regulate the placing on the market, commissioning, and use of such machines.

The risk assessment for machinery with evolving capabilities includes an obligation to consider whether an AI system is designed to improve itself in operation. In this case, all potential risks that may arise from the expected degree of autonomy must be weighed. This assessment must consider the entire life cycle of the machinery.

4.12 Machinery safety standards, presumption of conformity, and delegated legal acts until the MR comes into force

By the time the MR comes into force in January 2027, all standards currently listed in the Machinery Directive 2006/42/EC must have been revised both in form and in terms of content. This is necessary to bring them up to the current state of the art. This applies in particular to:

- Risk and safety aspects for human-machinery collaboration
- Machinery connected to the Internet
- Effects of software updates
- Machinery with evolving and autonomous behavior

In the absence of corresponding harmonized standards to ensure presumption of conformity, the EU Commission is empowered to issue technical specifications through so-called delegated legal acts.

This will be particularly the case if standardization bodies are unable to provide standards that comply with the Commission's standardization mandate and the essential health and safety requirements in Annex III of the MR.

Affected economic operators can then use the specifications drawn up by the Commission as a substitute for the presumption of conformity in place of the non-existent – non-harmonized – standards.

Relevant standards and links

The European Commission’s website lists all currently applicable CE directives and regulations related to the MR under Harmonized Standards:

europa.eu

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Authors:

Carsten Gregorius
Manager Strategic Product Marketing Safety
cgregorius@phoenixcontact.com

Torsten Gast
Director Competence Center Services
Functional Safety Expert (TÜV Rheinland #220/13)
IT Security Consultant (TÜV Rheinland)
torsten.gast@phoenixcontact.de

3011200924