

The new Machinery Regulation (EU) 2023/1230 - Requirements for embedded software, artificial intelligence and digital operating instructions

A whitepaper from Saskia Wittbrodt and Karin Potel.

Initial situation

On 21.04.2021, the European Commission's proposal for a [Machinery Regulation](#) (Machinery Regulation)¹ was published, which was adopted by the Council of the European Union on 22.05.2023 and published in the Official Journal of the European Union on 29.06.2023. The new Machinery Regulation (EU) 2023/1230 with its new regulatory regime has now been in force since 19.07.2023. The stricter legal regulations, which are found in more and more legal areas due to the increasing digitalisation and networking of products in the Internet of Things (IoT) or through smart applications, should not be a "stumbling block" for the European economy. The aim of European legislators is therefore to create competitive conditions that ensure international competitiveness and, at the same time, a high level of safety and protection for users of machinery and third parties, while promoting consumer and user confidence in digital innovative technologies. In addition, specific objectives of the revision are to address risks arising from the application of new technologies, AI in particular. Legal clarity is to be increased with regard to the scope of the regulation, definitions and

terminology through the long-overdue alignment with the NLF and the establishment of coherence with other legal acts. At the same time, the economic and business burdens on economic actors are to be cushioned by enabling digital documentation.

The fundamental changes to the Machinery Regulation and their impact on the integration of software and AI systems in machinery as well as the legal framework for digital instructions for use are outlined below.²

Regulation instead of a directive

The recast of the [Machinery Directive](#) (MRL) is ([as reported](#)) a regulation. By designing it as a regulation, the aim is to achieve more unified and efficient implementation serving to reduce national divergences. This is because the requirements of the Machinery Regulation are, in contrast to the MRL, directly applicable in the member states due to the elimination of national implementation requirements.

¹ Proposal for a Regulation of the European Parliament and of the Council on machinery, 2021/202 final.

² Machinery Regulation (EU) 2023/1230, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1230>

Structural changes

Compared to the MRL, the Machinery Regulation contains a large number of changes, which form the subject of this white paper. At variance with the original draft of the Machinery Regulation, the change of the term "machinery" to "mesh products" was rejected, as the Council of the European Union already criticized in its opinion³ of 18.11.2021 that legal clarity would be lost by changing the terminology and that this could lead to translation problems.

Among the other structural changes:

- The essential health and safety requirements previously regulated in Annex I of the MRL will in the future be found in Annex III of the Machinery Regulation.
- Annex I of the Machinery Regulation contains a list of machines and related products of Classes A and B (previously: high-risk machinery), most recently regulated in Annex IV of the MRL.
- Annex II of the Machinery Regulation now contains a non-exhaustive list of safety components. This was previously found in Annex V of the MRL.
- Annex V of the Machinery Regulation regulates requirements, previously regulated in Annex II of the MRL, for the preparation of an EU declaration of conformity.

Clarification of the scope

In the past, manufacturers repeatedly complained about the lack of precision regarding the scope of application of the MRL and

the lack of coherence with other harmonised legal acts, especially when combining machinery and low-voltage components and radio interfaces. In this constellation, the applicable legal framework can only be derived in a roundabout way via the exclusion criteria of Article 1(2)(k) MRL and Article 1(4) of Radio Equipment Directive 2014/53/EU (RED)⁴, which often leads to difficulties and misinterpretation in practice. Article 2(2)m of the Machinery Regulation now specifies that the scope of the Machinery Regulation should not apply to electrical and electronic products specifically defined in the Regulation if they are subject to the [Low Voltage Directive](#) (LVD) or the [Radio Equipment Directive](#) (RED). However, according to Annex III, Item 1.5.1. of the Machinery Regulation, the protection-related objectives of the LVD must continue to be taken into account in the design and construction of machinery.

There was a need for further clarification with regard to the exclusion of certain means of road transport from the scope of application of the MRL, particularly in relation to the provisions on type-approval pursuant to Regulation (EU) 2018/858 and Regulation (EU) 168/2013. Here, Article 2 (2) (e) of the Machinery Regulation provides, by reference to the intended use of the vehicles, that motor vehicles, two-, three- and four-wheeled vehicles, agricultural and forestry tractors and their systems, components and separate technical units are to be excluded from the scope of the Machinery Regulation, with the exception of machinery mounted on these vehicles.

Furthermore, inconsistencies arose from the definitions of complete and partly

³ Council of the European Union, Opinion, 18 November 2021, 2021/0105(COD), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=consil:ST_13569_2021_REV_1

⁴ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (Text with EEA relevance).

completed machinery in the terms of Article 1(1) a and b of the MRL, particularly when it was only necessary to install the control or functional software in order for the machine to perform a specific function. Article 3(1)1f now closes this loophole in the law and, as a complete machine, now also covers such complete units for whose specific application only software, possibly from another manufacturer, needs to be installed.

Definition of a substantial modification

The Machinery Regulation codifies the term "*substantial modification*" for the first time, the meaning of which was previously only derived from an [interpretation paper](#) by the Federal Ministry of Labor and Social Affairs. According to Art. 3 Para. 16 Machinery Regulation, a substantial modification in this sense means a physical or digital change to machinery or an associated product after it has been placed on the market or put into service that was not foreseen or planned by the manufacturer, that impairs safety by creating a new hazard or increasing an existing risk and that requires additional protective measures. This applies, for example, to the installation of non-manufacturer software or subsequent design changes, insofar as these result in risks that were not covered by the manufacturer's conformity assessment. The obligation to perform a new conformity assessment always falls on the person who makes the substantial modification.

Duties in the case of substantial modifications

Unlike § 2(10) of the Equipment and Product Safety Act (GPSG) (old version),⁵ the Machinery Regulation, like the MRL before

it, dispenses with the legal fiction that the person making a substantial modification is deemed to be the manufacturer in the legal sense. Instead, the Machinery Regulation imposes on this person the obligations of a manufacturer, particularly to reassess conformity. However, according to the will of European legislators, in order to avoid disproportionate burdens, these obligations should in principle only apply to the modified part and not in relation to the entire machine. The situation is only different if the modification has an effect on the machine as a whole, which is likely to be the case as a rule with respect to safety-relevant modifications.

Category A and B machines

The Machinery Regulation defines new classification rules for machinery and associated products, taking into account the state of the art and the risks arising from the use of new technologies such as AI. According to Annex I of the Machinery Regulation, Class A machinery includes machinery and safety components that are considered to be particularly hazardous and are equipped with fully or partially self-developing behavior using machine learning approaches, as well as portable cartridge-operated fastening and other impact machinery. Pursuant to Annex III, No. 18, safety components also include software with safety functions and certain AI applications, regardless of whether the software is "embedded" or not. As in the [proposal for a Regulation on General Product Safety](#), Software is thus recognised as a product in principle.

The list of Class B machines coincides with the list of high-risk machines in accordance with Annex IV of the MRL. In order to avoid a rigid scope of application for the

⁵ § 2 GPSG was valid from 13 July 2005 to 30 November 2011.

Machinery Regulation, the European Commission remains empowered to issue delegated acts supplementing Annex I to adapt it to technical progress as required.

Conformity assessment

Also within the scope of the Regulation, the presumption of conformity for machinery manufactured in accordance with harmonised standards or parts thereof is to continue to apply according to Article 20(1) of the Machinery Regulation. These machines are presumed to comply with the essential health and safety requirements in Annex III of the Machinery Regulation.

Pursuant to Article 25(2) of the Machinery Regulation, the conformity assessment for Class A machinery may only be carried out with the involvement of notified bodies on the basis of the following modules:

- Module B (EU type examination procedure) pursuant to Annex VII and subsequent conformity to type based on internal production control (Module C) pursuant to Annex VIII
- Module G (conformity assessment on the basis of unit verification)
- Module H (conformity based on full quality assurance)

When assessing Class B machinery, the manufacturer will in future be free to apply Module A (internal production control) in addition to the aforementioned assessment modules, but only on condition that the manufacturer designs and builds the machine or associated product in accordance with specific harmonised standards or specifications covering all relevant essential health and safety requirements. Otherwise, the manufacturer is required to use one of the procedures prescribed for Class A machines.

For traditional machines not listed in Annex I, there is still the possibility to carry out the conformity assessment by means of

internal production control pursuant to Module A.

Requirements for digital operating instructions in accordance with the Machinery Regulation

As long demanded by industry representatives and environmental protection players, the Machinery Regulation implements the first basic features of the permissibility of digital operating instructions. In contrast to the Machinery Directive, Article 10(7) of the Machinery Regulation explicitly allows manufacturers for the first time to make operating instructions available strictly in digital form. Only at the explicit request of the end customer must manufacturers continue to provide operating instructions in hardcopy form. If a manufacturer provides the operating instructions digitally, it must:

- indicate on the machine or - if this is not possible - on the packaging or an accompanying document how the digital operating instructions can be accessed;
- clearly describe the version of the operating instructions corresponding to the machine or related product.

German legal rulings (cf. among many: [District Court of Potsdam, Judgement of 26 June 2014 - Case 2 O 188/13](#); [Higher Regional Court of Frankfurt, Judgement of 28 February 2019 - Case 6 U 181/17](#)) have so far also presupposed a certain embodiment for electronic instructions. For example, the courts recognised the inclusion of a CD-ROM or the e-mailing of a PDF document. More practical electronic alternatives (such as offering QR codes or download options) were previously excluded under this so-called "embodiment doctrine". Clarifying these previously existing legal uncertainties, the Machinery Regulation makes it clear that the digital operating instructions must be provided in a format that enables the user to download the operating

instructions and save them on an electronic device. This is to ensure the availability of the manual even in the event of a machine failure - especially if the operating manual has been embedded in the machine's software.

So far, there is no corresponding equivalent in other EU harmonisation acts with regard to the provision of digital operating instructions. The approach chosen in the Machinery Regulation is in line with the efforts of European legislators to digitalise product documentation as far as possible (cf. digital product passport according to the [Draft Ecodesign Regulation](#)), but legislators could not be persuaded to completely abandon paper-based documentation within the scope of the Machinery Regulation. However, the cost savings and reduced administrative burden are likely to achieve the goals of the [Green Deal](#) of a modern, resource-efficient and competitive economy by 2050.

Use of software in machines

The scope of application of the Machinery Regulation has been extended by Article 3(1)f, the term "machinery" also including an entity in which only the installation of software intended for the specific application of the machine is missing. This clarification is intended to avoid uncertainties with regard to the distinction between a complete and an incomplete machine in the terms of Article 1(1) a and b MRL. In this way, European legislators want to prevent manufacturers from placing such machines on the market as partly completed machines.

In future, software will fall under the definition of a safety component within the meaning of Art. 3(3) Machinery Regulation. Related to this, Annex III, Item 1 of the Machinery Regulation regulates iterative risk assessment procedures that must be observed for the safety of machinery in design and construction. Within this framework, manufacturers must in the future also

determine and evaluate those hazards that result from the intended change in behaviour or a variable logic within the scope of the design for autonomous operation.

According to the will of European legislators, machines connected to the Internet must be specially protected against falsification (cf. Annex III, Item 1.1.9 of the Machinery Regulation). This also applies to software and data that are essential for the conformity of the machine or related product with the applicable health and safety requirements. Accordingly, the machinery or the related product must be designed and constructed in such a way that the connection of another device via any function of the connected device itself or via a remote device communicating with the machinery or the related product does not lead to a hazardous situation. Evidence of lawful or unlawful interference with the machine's software must be collected by machine. Reference is also made to software in connection with the safety and reliability of control systems. Pursuant to Annex III, Item 1.2.1b of the Machinery Regulation, control systems must be designed in such a way that a defect in the software does not lead to hazardous situations.

Summary

The Machinery Regulation takes up the aspects of the MRL that require revision and adapts the existing legal framework to the new technical possibilities due to the advancing digitalisation and networking of machinery. In doing so, it sets an important course for the integration of software and AI systems in machines and is thus in line with the planned AI Regulation. In addition, it takes into account the demands for resource savings depicted in the "Green Deal" through the possibility of digital documentation. It remains to be seen whether the possibility of providing digital instructions for use will also find its way into other European harmonisation legislation to a comparable extent and whether it will be

possible to dispense entirely with hardcopy instructions in the future.

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