

# EU Machinery Legislation: Current and Proposed Product Regulation

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## About The Author



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Alex also consults on international equivalents to these laws and works on product policy studies for clients including the European Commission and the UK Government.

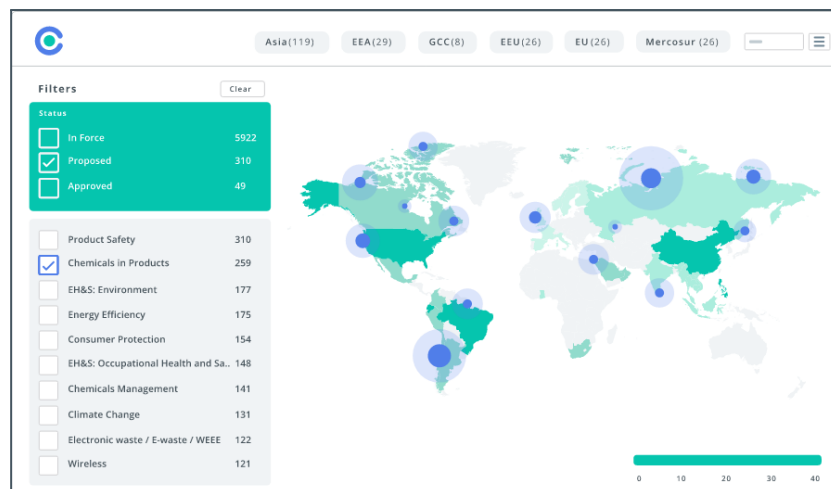
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## 1. Introduction

At present, Directive 2006/42/EC regulates the placing on the market – and putting into service – of machinery in the EU. This legislation is, however, on the cusp of change. The Directive will soon be replaced by a new EU law, the proposed Machinery Products Regulation.

This whitepaper introduces and summarises the scope and requirements of Directive 2006/42/EC before discussing how the proposed Machinery Products Regulation will likely build upon Directive 2006/42/EC.

As a whitepaper, this document is not intended to offer comprehensive guidance. If queries arise when reading what follows, please feel free to raise these either with the author at [alex.martin@rina.org](mailto:alex.martin@rina.org) or Compliance & Risks.

## 2. The Current EU Machinery Directive

In the EU, most machinery has been subject to a product safety law – the Machinery Directive – for the last 30 years.

The original Directive dates to 1993 while the requirements of the current Directive, Directive 2006/42/EC, have applied since 29 December 2009.

In broad terms, Directive 2006/42/EC seeks to harmonise machinery safety requirements to achieve a high level of protection of health and safety while also ensuring the free circulation of machinery on the EU Single Market for Goods. Under the Directive, machinery is to be designed and constructed such that it is safe and “can be operated, adjusted and maintained without putting persons at risk”. This applies “throughout the foreseeable lifetime of the machinery” (e.g., during transport, assembly, dismantling, disabling and scrapping). Assessment of the safety risk entails

consideration of the machinery's intended use as well as conditions of "reasonably foreseeable misuse"<sup>1</sup>.

## Scope

The current Machinery Directive applies to:

- Machinery
- Interchangeable equipment
- Safety components
- Lifting accessories
- Chains, ropes and webbing
- Removable mechanical transmission devices
- Partly completed machinery<sup>2</sup>.

Machinery is defined as "an assembly... of linked parts or components, at least one of which moves, and which are joined together for a specific application".

A wide-ranging definition, it encompasses a great many machines, from simple hand-held power tools through to complete automated production lines. Among the industrial machinery that is captured within the scope of this definition is food processing machinery and food service equipment; semiconductor manufacturing equipment; sawmill, woodworking and paper making machinery; and commercial and industrial refrigeration equipment. These are just a few examples though.

Certain items are excluded from scope. Exclusions apply to:

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<sup>1</sup> Directive 2006/42/EC defines this term as "use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour".

<sup>2</sup> This is "...an assembly which is almost machinery but which cannot in itself perform a specific application... Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment". Partly completed machinery is not discussed in detail in this white paper, although it should be noted that Article 13 of Directive 2006/42/EC outlines a procedure that partly completed machinery manufacturers (or their authorised representatives) must adhere to before placing such machinery on the EU market.

- Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery
- Specific equipment for use in fairgrounds and/or amusement parks
- Machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity
- Weapons, including firearms
- Certain types of transport, for example agricultural and forestry tractors, motor vehicles and their trailers, and motor vehicles exclusively intended for competition
- Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units
- Machinery specially designed and constructed for military or police purposes
- Machinery specially designed and constructed for research purposes for temporary use in laboratories
- Mine winding gear
- Machinery intended to move performers during artistic performances
- Household appliances intended for domestic use, audio and video equipment, IT equipment, ordinary office machinery, low-voltage switchgear and control gear and electric motors when they fall in scope of the EU Low Voltage Directive<sup>3</sup>
- High-voltage switchgear and control gear
- High-voltage transformers.

In addition, it is worth noting that the current Directive only specifies requirements for machinery manufacturers<sup>4</sup> and their authorised representatives<sup>5</sup>. The Directive does not place any obligations upon EU-based importers or distributors of machinery.

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<sup>3</sup> Directive 2014/35/EU.

<sup>4</sup> According to Directive 2006/42/EC, a “manufacturer” is “any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by [Directive 2006/42/EC] and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use”.

<sup>5</sup> According to Directive 2006/42/EC, an “authorised representative” is “any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive”.



## Requirements

Article 5 of Directive 2006/42/EC states that machinery manufacturers or their authorised representatives shall ensure that:

- Their machinery satisfies relevant essential health and safety requirements
- A technical file is available
- The necessary information (e.g., instructions) is provided
- The appropriate procedures for assessing conformity are carried out
- The EC Declaration of Conformity is drawn up and that it accompanies the machinery
- The CE marking is affixed to their machinery.

Concerning relevant **essential health and safety requirements (EHSRs)**, these are listed in the Directive's Annex I. It is organised into several parts. The first part has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Regardless, machinery manufacturers or their authorised representatives are instructed to examine the whole of Annex I to be sure of meeting all applicable EHSRs.

Machinery manufacturers or their authorised representatives are to identify the safety hazards that their products exhibit and then to assess the risks that these hazards present to users. In turn, machinery must be designed and constructed to account for the results of the risk assessment. Manufacturers or their authorised representatives are to adhere to five steps, which consist of:

- Determining the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof
- Identifying the hazards that can be generated by the machinery and the associated hazardous situations
- Estimating the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence

- Evaluating the risks, with a view to determining whether risk reduction is required
- Eliminating the hazards or reducing the risks associated with these hazards by application of protective measures.

Regarding **conformity assessment**, the design and construction of machinery can be internally checked (i.e., self-certified) by most machinery manufacturers or their authorised representatives prior to it being placed on the EU market / put into service. In other words, provided the Directive's requirements are met, a manufacturer or an authorised representative can perform all of the assessment and develop all of the corresponding documentation in-house; there is no need for third party certification.

This said, there are around 25 types of machinery (e.g., circular saws, vehicle servicing lifts) that may necessitate a manufacturer or an authorised representative engaging a notified body to perform third party certification. The applicable machinery is listed in the Directive's Annex IV while the Directive's Article 12 substantiates the circumstances under which third party certification is required.

Turning to the **technical file**, this is to comprise of:

(a) A construction file including:

- A general description of the machinery
- The overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery
- Full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the EHSRs
- The documentation on risk assessment demonstrating the procedure followed, including:
  - a list of the EHSRs which apply to the machinery

- the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery
- The standards and other technical specifications used, indicating the EHSRs covered by these standards
- Any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative
- A copy of the instructions for the machinery
- Where appropriate, the Declaration of Incorporation for included partly completed machinery and the relevant assembly instructions for such machinery
- Where appropriate, copies of the EC Declaration of Conformity of machinery or other products incorporated into the machinery
- A copy of the EC Declaration of Conformity.

(b) For series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The technical file does not have to be held in the EU but must be capable of “being assessed and made available” by the person designated on the EC Declaration of Conformity.

The **EC Declaration of Conformity** must contain the following:

- The business name and full address of the manufacturer and, where appropriate, his authorised representative
- The name and address of the person authorised to compile the technical file, who must be established in the EU
- A description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name
- A sentence expressly declaring that the machinery fulfils all the relevant provisions of Directive 2006/42/EC and, where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with

which the machinery complies. These references must be those of the texts published in the EU Official Journal

- Where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in the Directive's Annex IX and the number of the EC type-examination certificate
- Where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in the Directive's Annex X
- Where appropriate, a reference to the harmonised standards used, as referred to in the Directive's Article 7(2)
- Where appropriate, reference to other technical standards and specifications used
- The place and date of the EC Declaration of Conformity
- The identity and signature of the person empowered to draw up the EC Declaration of Conformity on behalf of the manufacturer or his authorised representative.

Having introduced and summarised the current EU Machinery Directive's scope and requirements, this whitepaper now considers the likely legislative changes that the proposed EU Machinery Products Regulation will bring in. At the time of writing, the proposed Regulation<sup>6</sup> was nearing adoption as a new EU law. It is expected that this law will be published in the EU Official Journal in the second half of 2023.

### 3. Changes on the Horizon

Poised to replace Directive 2006/42/EC, the proposed Machinery Products Regulation is anticipated to enhance current EU machinery legislation in the following ways:

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<sup>6</sup> Note that an EU Regulation is different to an EU Directive. Unlike Directives, Regulations are binding and must be applied in their entirety across the EU. Regulations also apply directly, without needing to be transposed into national legislation (as is the case with Directives).

- **Alignment with the New Legislative Framework (NLF).** The NLF is a package of measures that were adopted by the EU to both improve the functioning of the European Single Market for Goods and strengthen conformity assessment for certain products. While 23 pieces of EU legislation are aligned with the NLF (e.g., the Low Voltage, Electromagnetic Compatibility and Radio Equipment Directives), this is not the case for Directive 2006/42/EC. The proposed Machinery Products Regulation adapts current Machinery Directive provisions to incorporate NLF references. For instance, the proposed Regulation introduces some NLF definitions absent from the current Directive (e.g., what is meant by an “importer” and “distributor”), specifies economic operator<sup>7</sup> obligations, and carries over NLF provisions on the notification of conformity assessment bodies.
- **Making provision for the digitisation of documentation.** The proposed Regulation specifies that instructions can be provided either digitally or on paper. They must, however, be provided free of charge in paper format upon the purchaser’s request, at the time of the purchase of the machinery product (this may be especially helpful for users who lack internet access in certain environments like forests and woodland).
- **Introducing greater clarity to the law’s scope as well as definitions in use.**
  - The proposed Regulation seeks to clarify some exclusions. For example, electrical and electronic equipment listed in the current Directive’s Article 2(2) would be excluded insofar as they fall under the Low Voltage or Radio Equipment Directives. As a second example, the proposed Regulation clarifies that “means of transport” that operate to transport people or goods (e.g., electric-power-assisted bicycles or hoverboards) are excluded from scope.
  - The proposed Regulation adapts some definitions or introduces new ones. “Partly completed machinery” (PCM) is a machinery product that must undergo further construction to be able to perform its specific

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<sup>7</sup> This is a collective term applied to product manufacturers, manufacturers’ authorised representatives, importers, distributors and fulfilment service providers.

application. Not all requirements of the current Machinery Directive apply to PCM. The proposed Regulation clarifies the definition of PCM, as the current definition has been variably applied by manufacturers and this is believed to have led to some incorrect classifications of products as components instead of PCM, and to incorrect CE marking of PCM. To take into account the growing use of software in machinery, the proposed Regulation adds a new indent in the definition of machinery. Specifically, it is suggested that Article 3(1)(b) states that an assembly missing only the upload of a software intended for its specific application is machinery and not PCM (meaning that, for instance, non-pre-programmed robots are machinery). The proposed Regulation also adds a definition of “substantial modification” of machinery to avoid different interpretations across the EU.

- Driverless mobile machines – autonomous or remotely controlled – are to be explicitly addressed through the amendment of the current Directive’s Annex III. The definition of a driver is to include a person who may remotely supervise the autonomous mobile machinery product regardless of the distance and the means of control communication.
- **Improving the safety of traditional machinery.** The proposed Regulation adapts or introduces various EHSRs concerning the design and construction of traditional machinery products. For example, the proposed Regulation updates the EHSRs for ride-on mobile machinery to specify that a visual or audible signal must be provided at the driving position alerting the driver when the restraint system is not active. Furthermore, a new EHSR on risk of contact with live overhead power lines has been added, as several accidents linked to mobile machinery hitting such power lines have occurred in recent years.
- **Better addressing the modification of a piece of machinery.** Directive 2006/42/EC does not address situations where machinery is modified by distributors without the manufacturer’s knowledge and agreement. The machinery may then no longer be in conformity with EHSRs. To address this, the proposed Regulation introduces a definition for “substantial modification”.

This is when machinery products are modified by physical or digital means in a way that is not envisaged by the manufacturer, and that may imply that it no longer is in conformity with an EHSR. In the proposed Regulation, the person that carried out the substantial modification becomes the manufacturer and is required to perform a new conformity assessment before placing the modified machinery product on the EU market / putting it into service.

- **Empowering the European Commission to develop technical specifications.** The proposed Regulation empowers the Commission to adopt technical specifications for EHSRs. The Commission would only use this power if harmonised standards were absent (e.g., when the standard request had not been accepted by a European Standardization Organisation or when the standardization process was blocked).
- **Introducing new provisions for high-risk machinery products.** For certain types of machinery presenting a higher risk (i.e., those listed in Annex IV of Directive 2006/42/EC), a stricter certification procedure applies. The proposed Regulation aims to reinforce the provisions for these machinery products. Furthermore, the proposed Regulation updates the list of high-risk machinery, adding two new items: 1) software ensuring safety functions, including Artificial Intelligence systems; and 2) machinery embedding Artificial Intelligence systems ensuring safety functions. The proposed Regulation also empowers the Commission to adopt delegated acts to update this list. This is a change to what is currently the case, where updates could only be achieved through legislative revision under the EU's ordinary legislative procedure<sup>8</sup>. Of additional note is that the proposed Regulation introduces the obligation to involve a third party in the conformity assessment for all high-risk machinery.
- **Expanding hazard identification in risk assessments that relate to new digital technologies:**

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<sup>8</sup> This is the standard decision-making procedure used in the EU, unless EU treaties specifically state one of the special legislative procedures is to be applied to a particular subject. See: <https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/overview>

- The proposed Regulation updates the general principles in the current Directive's Annex on EHSRs. Specifically, when carrying out risk assessments to select applicable EHSRs, a machinery product manufacturer must identify the hazards that may be generated from evolving behaviour or logic, as a result of a machinery product operating with some degree of autonomy.
  - Furthermore, to take into account changes in human-machinery interaction arising from the emergence of digital technologies, the proposed Regulation updates a number of EHSRs. For instance, for EHSR 1.3.7 on risks related to moving parts and psychological stress, an update is suggested to include mention of the need for machines with an evolving behaviour and a certain degree of autonomy to respond to people and to communicate on their planned actions.
- **Identifying software ensuring safety functions as safety components.** Software ensuring safety functions, including Artificial Intelligence systems placed independently on the market, are to be added to the indicative list of safety components under the proposed Regulations Annex II (this is Annex V of Directive 2006/42/EC). The proposed Regulation also empowers the European Commission to use delegated acts to adapt the indicative list of safety components in Annex II, to take into account technical progress and new knowledge or scientific evidence.
- **Providing for the mitigation of safety issues linked to cyber-attacks.** Safety issues linked to cyber-attacks are addressed in the proposed Regulation with the introduction of a new EHSR (1.1.9) on protection against corruption. Manufacturers are to design machinery products so that connection to them by another device does not lead to a hazardous situation. A hardware component for connection must be designed so that it is protected against corruption. The proposed Regulation also clarifies EHSR 1.2.1 on safety and reliability of control systems. Machinery products that have been certified or for which a statement of conformity has been issued under a relevant cybersecurity scheme adopted



in accordance with the EU Cybersecurity Act<sup>9</sup> would be presumed to be in conformity with EHSRs 1.1.9 and 1.2.1.

## 4. Conclusion

This whitepaper introduced and summarised the scope and requirements of the current EU Machinery Directive before discussing how the proposed Machinery Products Regulation is set to strengthen EU machinery legislation.

Various changes are on the horizon, including alignment with the New Legislative Framework, provision for machinery manufacturer documentation to be digitised, improvements in traditional machinery safety, regulation of the substantial modification of machinery products, and stricter regulation of high-risk machinery products.

It is anticipated that the proposed Machinery Products Regulation will be adopted as an EU law in the second half of 2023.

## 5. Update: June 29, 2023

On 29 June, the new EU Regulation on Machinery was published in the Official Journal of the European Union as Regulation (EU) 2023/1230.

Regulation (EU) 2023/1230 constitutes the new legal framework applicable to machinery, related products and partly completed machinery in the European market. Compared to the Machinery Directive 2006/42/EC, it provides more clarity on the products in scope and redefines the essential health and safety requirements for machinery, taking into account digital transition and risks arising from new technologies.

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<sup>9</sup> Regulation (EU) 2019/881.

The new Regulation will enter into force on 19 July 2023 (on the twentieth day following that of its publication) and will apply from 20 January 2027, date on which Directive 2006/42/EC will be repealed.

A whitepaper will be published soon to highlight the novelties of the EU Regulation. To keep updated with further regulatory developments, join 30,000+ compliance professionals and sign up to our [monthly regulatory compliance newsletter](#).

## 6. Further Reading

- For a general introduction to EU machinery legislation, please [click here](#).
- The current Machinery Directive (Directive 2006/42/EC) is accessible to read at [32006L0042 - EN - EUR-Lex](#)
- The proposed EU Machinery Products Regulation can be [downloaded here](#).
- The European Commission's Guide to the Application of the Machinery Directive 2006/42/EC can be [downloaded here](#).