

Regulation on machinery products

2021/0105(COD) - 29/06/2023 - Final act

PURPOSE: to ensure that machinery placed on the market meets the requirements to provide a high level of protection of the health and safety of persons and, where appropriate, domestic animals and property.

LEGISLATIVE ACT: Regulation (EU) 2023/1230 of the European Parliament and of the Council on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.

CONTENT: the new legislation updates the 2006 Machinery Directive and transforms it into a Regulation.

Subject matter and scope

The new regulation lays down **health and safety requirements for the design and construction of machinery, related products and partly completed machinery** to allow them to be made available on the market or put into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment. It also establishes rules on the free movement of products within the scope of this regulation in the Union.

The regulation applies to machinery and the following related products: (a) interchangeable equipment; (b) safety components; (c) lifting accessories; (d) chains, ropes and webbing; (e) removable mechanical transmission devices.

It also applies to partly completed machinery.

Conformity requirements

The regulation makes conformity assessment by a third-party compulsory for six categories of machinery (listed in Annex I, Part A) with a higher risk factor, namely:

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 behaviour using machine learning approaches ensuring safety functions.
6. Machinery that has embedded 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 of those systems.

The Commission will assess the seriousness of the inherent potential risk presented by a category of machinery or related product for the purpose of determining whether to add that category of machinery or related product to Annex I or to withdraw that category of machinery or related product from Annex I.

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

When conducting the assessment, the Commission will consider the following elements:

- indications of harm that have been caused in the past by machinery or related products which have been used for their intended use or following any reasonably foreseeable misuse;
- information about safety defects detected in the course of market surveillance, and material possibly available in the information systems administered by the Commission;
- information about known accidents and serious ‘close calls’, including the characteristics of those accidents or ‘close calls’;
- data on accidents or damage to health caused by the machinery or related product for at least the preceding four years.

A category of machinery or related product will be included in Annex I, Part A, if, according to the assessment and taking into account the available information, it presents a serious inherent potential risk, and if specific conditions are fulfilled.

Common technical specifications

The Commission will be able to adopt implementing acts laying down common specifications for the essential health and safety requirements of the Regulation, provided that in doing so it duly respects the role and functions of standardisation organisations, as an **exceptional fall back solution** to facilitate the manufacturer’s obligation to comply with those health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards.

Documentation requirements

Safety information will need to be provided for each product but, in line with the digital transition, the regulation states that **digital instructions will be the default option**. Paper instructions will remain an option for customers who request them.

Economic operators will ensure that all relevant documentation, such as the instructions for use, while containing precise and comprehensible information, is **easily understandable** and available in a language which can be easily understood by users, as determined by the Member State concerned, takes into account technological developments and changes to user behaviour, and is as up to date as possible.

No later than 14 July 2028 and every four years thereafter, the Commission will present a report on the evaluation and review of the Regulation to the European Parliament and the Council. The reports will be made public.

ENTRY INTO FORCE: 19.7.2023.

APPLICATION: from 14.1.2027.