Regulation on machinery products

2021/0105(COD) - 18/04/2023 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 595 votes to 7, with 30 abstentions, a legislative resolution on the proposed for a regulation of the European Parliament and of the Council on Machinery products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Subject matter

This 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.

In order to ensure that the scope of this Regulation is sufficiently clear, a distinction should be made between machinery, related products and partly completed machinery. Moreover, related products should be understood as comprising interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, and removable mechanical transmission devices, which are all products within the scope of this Regulation.

Scope of application

The purpose of this Regulation is to address the risks stemming from machinery function and not from the transport of goods, persons or animals. Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks although it should still apply to the machinery mounted on those means of transport.

Means of transport by road that are not yet covered by a specific Union legal act should be regulated by this Regulation except in respect of risks that might arise from circulation on public roads. This means that vehicles, including e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under Regulation (EU) No 167/2013 of the European Parliament and of the Council or Regulation (EU) No 168/2013 of the European Parliament and of the Council or approval under Regulation (EU) 2018/858 of the European Parliament and of the Council(10) are covered by this Regulation.

Protection of persons during installation or use of machinery or related products

Member States may lay down requirements to ensure that persons, including workers, are protected when installing or using machinery or related products, provided that such rules do not allow for the modification of machinery or a related product in a way that is not compatible with this Regulation.

List of products

The new Regulation changes the structure of the list of machinery or products, which is set out in Annex I of the Commission proposal. Machinery and related products falling under the categories listed in Annex I, Part A and Part B should be subject to **specific conformity assessment procedures**. The European

Commission, after consulting the relevant stakeholders, should adopt delegated acts to **update** this list of products.

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

When conducting the assessment, the Commission should 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 should 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 certain conditions are fulfilled.

Common technical specifications

The Commission should adopt **implementing acts** laying down common specifications for the essential health and safety requirements of the Regulation, provided that it respects the role and functions of the standardisation organisations, as an **exceptional fall back solution** to facilitate the fulfilment of the manufacturer's obligation to comply with those requirements, where the standardisation process is blocked or where there is a delay in establishing appropriate harmonised standards. If such a delay is due to the technical complexity of the standard in question, the Commission should take this into account before contemplating the establishment of common specifications. The Commission should involve relevant stakeholders in the process.

Instructions

The new Regulation strikes a balance between digital and paper documentation. Manufacturers should ensure that machinery or related products are accompanied by the instructions and information set out in Annex III. The instructions should be provided in **digital format**. These instructions and information must clearly describe the product model to which they correspond.

When the instructions for use are provided in digital format, the manufacturer should make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product. However, at the request of the user at the time of the purchase, the manufacturer should **provide the instructions for use in paper format free of charge within one month**.

The instructions for use, the safety information and the information set out in Annex III should be in a language which can be easily understood by users, as determined by the Member State concerned, and shall be clear, understandable and legible.