

Regulation on machinery products

2021/0105(COD) - 21/04/2021 - Legislative proposal

PURPOSE: to improve and adapt the existing Machinery Directive to the new needs of the market and risks origination from emerging technologies.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: as part of the Commission Work Programme 2020 under the priority ‘A Europe fit for the Digital Age’, the Commission plans to revise the [Machinery Directive](#) (‘the MD’, Directive 2006/42/EC). This revision contributes to both the digital transition and to the strengthening of the single market.

In order to boost the trust in new digital technologies such as direct human-robot (co-bot) collaboration, connected machinery, 3D printers, the MD needs to provide legal certainty as regards those technologies, existing gaps could hinder a level playing field for manufacturers, which would impact the efficiency of the MD.

The fact that the current machinery legislation is a Directive leaving Member States to choose the means to comply with the legislative objectives, has led to different interpretations of the MD provisions creating legal uncertainty and lack of coherence throughout the single market.

The Commission suggests that the proposal should take the form of a Regulation as this would better ensure that Member States do not impose national technical requirements that go beyond the safety requirements laid down in Annex I of the current Directive and/or contradict those safety requirements.

CONTENT: this draft regulation proposed by the Commission responds to market needs by bringing greater legal clarity to the current provisions, simplifying the administrative burden and costs for companies by allowing digital formats for documentation and adapting conformity assessment fees for SMEs, while ensuring coherence with the EU legislative framework for products.

The proposed new regulation will ensure the safe integration of artificial intelligence (AI) systems into machines and thus encourage innovation.

Specific provisions of the proposal

Scope and definitions

While the scope of the proposed regulation remains the same, the definition of safety component has been clarified to include non-physical components such as software. There is also a new definition of substantial modification to ensure that machinery, placed on the market and/or put into service, that suffers substantial modifications is in conformity with the essential health and safety requirements in Annex III.

Exclusions

The exemption of the means of transport on road is extended beyond the Union type approval legislation to increase the legal certainty. The reason is to prevent that vehicles not covered by that legislation are

covered by default by the machinery legislation, as this legislation is not meant to regulate risks other than those stemming from the machinery function (such as sawing, excavating, etc.), and not the risks exclusively related to its transport function of persons or goods.

High-risk machinery

The proposal sets up classification rules for high-risk machinery empowering the Commission to adopt delegated acts to adapt the list of high-risk machinery in Annex I. This list is obsolete and needs to be adapted to the technical progress and new type of machinery presenting high risks such as machinery with Artificial Intelligence ensuring safety functions.

Obligations of economic operators

The proposal incorporates obligations for manufacturers, importers and distributors to be aligned with the New Legislative Framework Decision.

Conformity assessment

The proposal keeps the manufacturer internal check option for machinery that is not classified as high risk. However, for high-risk machinery, considering that Annex I will be adapted to the technological progress when needed and the NLF alignment, only third-party certification will be accepted, even when manufacturers apply the relevant harmonised standards.

Notified bodies

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the New Approach system. Therefore, the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.