



OPINION

European Economic and Social Committee

Machinery

Proposal for a Regulation of the European Parliament and of the Council on machinery
products
[COM(2021) 202 final – 2021/0105 (COD)]

INT/952

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Referral	Council of the European Union, 09/06/2021 European Parliament, 07/06/2021
Legal basis	Articles 114 and 304 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	02/09/2021
Date adopted in plenary	22/09/2021
Plenary session No	563
Outcome of vote (for/against/abstentions)	226/0/7

1. Conclusions and recommendations

- 1.1 The machinery products sector is a key economic sector in the European Union. The capabilities of machinery and the areas in which it is used are expanding rapidly as a result of new technical and engineering possibilities. It is high time that greater account is taken of digital technologies such as artificial intelligence, the Internet of Things and robotics. Consequently, regulatory requirements must also be adapted to health and safety conditions relating to machinery. Against this backdrop, the proposal for a regulation is also highly relevant to the internal market. The EESC has already addressed the issue of the Machinery Directive¹ of 2020.
- 1.2 The EESC stresses that in any move to set EU-wide standards for machinery, lay down legally binding requirements and ensure the consistent enforcement thereof, EU companies, manufacturers and operators of machinery should not be overlooked. This does not only apply to large companies, but also and in particular to small and medium-sized ones. Mechanical engineering is an international business and EU product regulation needs to be able to promote quality, safety and competitiveness and help businesses develop innovative approaches without being hampered by regulation.
- 1.3 The EESC welcomes the fact that the proposal for a regulation continues to focus on operators of machinery products and other workers involved, as their health and safety protection remains a key issue. Moreover, changing the original Machinery Directive into a regulation brings with it the advantage of more uniform interpretation across Member States. This will make it even easier to detect and remedy safety deficiencies in the future, which will especially benefit people operating the machinery.
- 1.4 The EESC presents the following recommendations to the Commission:
 - 1.4.1 The transitional provisions to the new machinery regulation need to be specified in order to provide legal certainty for all stakeholders.
 - 1.4.2 The EESC sees a need to adapt the structure and substance of the annexes to the proposal for a regulation. The nature of the numbering, the allocation of types of machinery and overlaps with adjacent EU regulation still raise questions.
 - 1.4.3 In the EESC's view, it must be clear that machinery must be safe at the time it is placed on the market and throughout its lifetime.
 - 1.4.4 Increasingly sophisticated machinery requires special training for users so that workers are not exposed to unnecessary risks². Mechanisms are also needed that allow clear responsibility to be attributed in the event of accidents. Workers' representatives should be enlisted in the procedure for the purchase and installation of new machinery.

¹ [Information report "Revision of the Machinery Directive"](#).

² See also [OJ C 240, 16.7.2019, p. 51](#).

- 1.4.5 The deployment of artificial intelligence requires a specifically defined security framework in which the operation of such systems can take place.
- 1.4.6 The mandatory involvement of notifying bodies in the production of conformity assessments for machinery must continue to be affordable for undertakings.
- 1.4.7 The EESC sees the need for continuous monitoring of legislation on machinery products, in coordination with the relevant stakeholders, in order to respond to technological innovations and challenges for producers and the protection of workers' physical and mental health.

2. **Background to the opinion, including the legislative proposal concerned**

- 2.1 In 2018, the machinery sector recorded a turnover of EUR 700 billion, production of EUR 670 billion, and value added of EUR 230 billion. Total EU machinery and equipment exports amounted to EUR 517 billion, of which around 50% were exported to EU Member States (i.e. intra-EU exports) and the rest were exported to countries outside the EU (extra-EU exports)³.
- 2.2 The Commission proposal for a new regulation on machinery products is part of a wider "Artificial intelligence package". The specific proposal on machinery is a revision of the Machinery Directive (the "MD", Directive 2006/42/EC). This revision is a contribution to both the digital transition and the strengthening of the single market. The Machinery Directive is part of legislation on product safety. It aims to ensure a high level of protection for workers, consumers and other exposed persons by focusing on the inherent safety of the machinery. It obliges machinery manufacturers to take safety into account when designing and constructing machinery ("Safety by Design").
- 2.3 The proposal has six specific objectives:
1. Limiting new risks related to digital emerging technologies;
 2. Ensuring consistent interpretation of the scope and definitions and improving safety for traditional technologies;
 3. Reassessing machines considered to be high risk and reassessing related conformity procedures;
 4. Reducing paper-based documentation requirements;
 5. Ensuring consistency with other New Legislative Framework (NLF) legislation; and
 6. Reducing possible divergences in interpretation derived from transposition into national law.
- 2.4 As part of an impact assessment, the Commission has considered various options for dealing with the Machinery Directive, which goes back as far as 2006, i.e. already 15 years, and is based on 1989 regulations. Given the rapidity of technical and engineering development, this is a very long time. Against this background, a revision has been opted for, with the aim of boosting competitiveness by minimising the burden on manufacturers and also increasing safety by

³ Source: https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en.

means of clearer and/or additional requirements. It is accepted that there will be additional compliance costs.

- 2.5 The change from a directive to a regulation is intended to avoid divergent transposition in the Member States. In this way, the Commission expects to increase and ensure overall consistency in the interpretation and enforcement of the legislative act.

3. **General comments**

- 3.1 Unlike many other directives, the Machinery Directive in force to date has not yet been adapted to the New Legislative Framework (NLF). In this respect, the EESC welcomes the fact that the rules are now being updated and adapted to the changed context of EU regulation. Clarifications on scope, in particular the delineation from the Low Voltage Directive, the Pressure Equipment Directive and other directives, as well as the specification of definitions such as partly completed machinery, are deemed to be important.
- 3.2 The EESC appreciates that the revision proposal tackles a subject that is important for many businesses, workers and other relevant groups in the EU. The proposed rules form the central legal framework for any company that designs, constructs or operates machinery. The safety of workers operating machinery depends crucially on consistent enforcement and monitoring of the requirements in the Member States.
- 3.3 It is in keeping with the principle of equality in the EU that health and safety requirements relating to machinery must be the same in all Member States and apply equally to all manufacturers, distributors and operators in those countries. For the EESC, it is clear that if these requirements are met, products may be freely traded between all the Member States.
- 3.4 The EESC welcomes the fact that the proposal preserves the central aim of the directive in force to date: to establish basic Europe-wide rules on safety, health and the free movement of goods – relating to machinery. The main objectives remain safety, on the one hand, and removing barriers to trade, on the other, although they now also cover current and future technical and engineering innovation in the machinery sector.
- 3.5 The EESC stresses the need for transparent, appropriate and comprehensible transitional provisions in the move from the Machinery Directive to the new Machinery Regulation. Article 50 of the proposal needs to be more specific. It is unclear what rules apply to machinery produced or placed on the market during the 30-month transition phase and how this machinery is distinguished from products from before the transition phase. Manufacturers and importers need a suitable lead time. For example, a useful solution would be to stipulate that Member States may not impede the placing on the market of machinery produced in accordance with Directive 2006/42/EC before the date of its repeal until 42 months after the entry into force of the new regulation.
- 3.6 The current proposal on machinery products further widens the range of very different types of machinery that need to be covered by such a regulation. In the EESC's view, this is logical in order to create a comprehensive and clear set of rules. For manufacturers, exporters and also

purchasers of machinery in particular it is important for the integration of artificial intelligence (AI) systems into machinery to be regulated. This global approach to regulation means that businesses only have to carry out one conformity assessment in each case.

- 3.7 The EESC sees a need to adapt the structure and substance of the annexes to the proposal for a regulation. There is no reason to change the numbering of the related annexes to the proposal for a regulation (Annex IV is now Annex I, etc.). Changes should be restricted to instances where there is a clear need. At the same time, given their potentially high risk, it is right that certain safety components from Annex II, such as ROPS, FOPS and software ensuring safety functions, also be included in the list of high-risk machinery products set out in Annex I. Discrepancies with other existing EU legislation applicable to machinery should also be avoided, such as in the case of the Low Voltage Directive. Conformity assessment procedures should be carried out only once. This would be relevant, for instance, to certain health and safety requirements listed in Annex III of this proposal which are linked to risks (e.g. the Radio Equipment Directive (RED) 2014/53/EU or the Pressure Equipment Directive (PED) 2014/68/EU). In this case, only the conformity assessment procedures for placing on the market or putting into service provided for in this proposal for a regulation should apply.
- 3.8 The EESC considers the protection of workers' health and safety to be an essential element. Machinery manufacturers and planners are responsible for the basic safety of machinery. If safety cannot be ensured, machinery must not be put into operation. People who operate machines on a daily basis must not in doing so be exposed to any dangers that are avoidable. Specifically, this means that machinery must be safe at the time it is placed on the market and throughout its lifetime. Compliance with safety rules must be checked regularly. Machinery must be safely operable and all safety and protective devices must be constructed in such a way that they cannot be easily bypassed or switched off. In addition, all residual risks that cannot be eliminated by design must be clearly pointed out to users and operators through markings and technical documentation, in particular operating instructions. The EESC recommends that the Commission include a recommendation in the proposal for a regulation on the need to consult workers' representatives and safety representatives in the workplace. In addition, the responsibilities of natural or legal persons in the event of an accident should be clearly stipulated, especially where the use of artificial intelligence is concerned.
- 3.9 The EESC draws attention to its 2019 opinion on the *Coordinated Plan on Artificial Intelligence*⁴. This pointed out that in order to lessen the risks to which people might be exposed when using machines, workers need to be trained individually in the use of AI and robots so they can work safely with them and turn them off in an emergency (the "emergency brake" principle). This is especially true where people and machinery are operating in particularly close proximity. The International Organisation for Standardisation (ISO) has adopted a standard on robots addressed to manufacturers, distributors and users. This standard provides guidelines for the design and organisation of work areas in order to diminish risks in the workplace.
- 3.10 The EESC would prioritise the use of digital operating instructions. At the request of customers, manufacturers may provide operating instructions in paper format. However, we know from

⁴ [OJ C 240, 16.7.2019, p. 51.](#)

industry that in many cases customers are already asking for operating instructions in digital format.

- 3.11 Everyday use of machinery shows that the diversity of uses and associated risks scarcely makes it possible to apply blanket and supposedly simpler rules, such as simply "banning" the presence of sharp metallic edges, because these are sometimes an integral part of the function of the machine concerned. For many types of machinery, such as presses or laser cutting systems, the hazards for machine operators are inextricably linked to the intended function of the machine. It is the responsibility of manufacturers to minimise such injury risks by taking appropriate protective measures.
- 3.12 The EESC considers it appropriate that the proposed regulation now also and in particular includes machinery that is more advanced and therefore less dependent on human operators. The share of these technologies in the overall European market for machinery is expected to grow strongly in the coming years. In particular, there is a need for uniform standards for machines that are capable of independent learning, of becoming progressively more autonomous and thus of carrying out new actions and operating steps. It is virtually self-evident that digital technologies such as artificial intelligence, the Internet of Things and robotics will bring new challenges in terms of product safety. It is precisely the deployment of artificial intelligence that requires a specifically defined security framework in which the operation of such systems can take place.
- 3.13 The EESC stresses that, in addition to protecting the (physical and mental) health of machinery operators, environmental aspects and the impact on the climate must also have a significant influence on whether a machine is safe. The manufacture and operation of machines and the question of sustainability must be considered in tandem and assessed in terms of human and environmental impacts. A machine that permanently harms the climate can hardly be deemed safe. The proposal in hand addresses the environmental impact. This concerns in particular what happens when machinery products are subsequently modified by physical intervention or digitally, in ways that may not have been foreseen by the manufacturer. This could mean that essential health and safety requirements are no longer met and that the conformity assessments used are no longer valid. When looking broadly at the role of machine manufacture and operation in environmental and climate protection, there needs to be a coherent link with other EU legislation (e.g. on product sustainability).
- 3.14 The Commission proposal stipulates that, for high-risk machinery subject to assessment, even when harmonised standards are applied, the option should be removed in future for manufacturers to carry out the conformity assessment procedure fully in house. However, many of the machines in question are produced in small series or as individual items, so the involvement of a third party assessor in these cases would not be suitable in practice. The EESC therefore recommends that the current rules be maintained in duly justified individual cases – for example, if the share of artificial intelligence relates only to static software that cannot evolve on its own or make decisions. In addition, the question arises as to whether the mandatory involvement of a notifying body in order to carry out a conformity assessment does not entail significant costs, taking a heavy toll not least on small and medium-sized enterprises. This happens in exactly those cases where only a small part of the machine is equipped with

artificial intelligence, but this necessitates it being fully tested and notified as a high-risk machine. It is precisely when it comes to individual components, where no appropriate test standard can be applied, that the question of the efficiency of an external notifying body arises.

- 3.15 The EESC welcomes the fact that the Commission can draw up its own technical specifications in the event of a lack of appropriate harmonised standards. To this end, all relevant stakeholders must be involved in advance.
- 3.16 With reference to uniform testing and notification procedures, the EESC recommends the introduction of a European certificate for companies to demonstrate the reliability of trustworthy artificial intelligence systems⁵.
- 3.17 The proposal provides that machinery products may only be made available on the market or put into service if they are properly installed, maintained and used for their intended purpose. In addition, the essential health and safety requirements set out in Annex III must be complied with (Article 7). However, partly completed machinery does not need to be put into service and should therefore be exempted from the provisions relating to doing so. A separate provision could be made, for example, for partly completed machinery only to be made available on the market if it complies with the essential health and safety requirements set out in Annex III, for which the manufacturer has declared conformity in the declaration of incorporation.
- 3.18 With a view to the most coherent implementation of the Machinery Regulation, the EESC believes continuous monitoring is needed for the European Commission and all relevant stakeholders. This requires coordinated consultation processes between DGs GROW, EMPL and CONNECT. Specifically, for example, a board for continuous coordination could be created, made up of the Administrative Cooperation Groups (AdCos) on the machinery sector and the Committee of Senior Labour Inspectors (SLIC) for safety and health at work and funded by the Commission.

Brussels, 22 September 2021

Christa Schweng
The president of the European Economic and Social Committee

⁵ See also [OJ C 240, 16.7.2019, p. 51](#).