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European Association of the Machine Tool Industries
and related Manufacturing Technologies

▶ POSITION PAPER

Proposal for a Regulation of the European Parliament and of the Council on Machinery Products

Brussels, 28.08.2021



Introduction: Revision of the Machinery Directive

CECIMO, representing the machine tool industry and related manufacturing technologies, welcomes the opportunity to share its position on the European Commission's proposal for a Regulation on Machinery Products – hereafter referred to as the “Regulation”. The current Machinery Directive 2006/42/EC¹ is the core legislation regulating the mechanical engineering industry, and in our view, it is a sound piece of legislation whose revision should be characterized by continuity rather than revolutionary changes. In the context of the ongoing revision of the Machinery Directive, we had expressed in a previous position paper² our great satisfaction with the text, which represented an example of successful European Union legislation on harmonization, providing a high level of safety and ensuring the free flow of goods within the Single Market.

Therefore, it is important for our sector that the future legislative framework continues to support harmonization within the Single Market and the development of standards to promote innovation. In this regard, CECIMO has actively engaged in various policy discussions with the aim of coordinating actions and exchanging views with other European Associations on the Commission's Machinery Regulation Proposal. Throughout this process, we have identified a series of major threats in the draft Regulation, which could potentially create significant hurdles and lead to additional burdens and costs for machine tool manufacturers.

Major Threats Identified in the Machinery Regulation Proposal

Definition of High-Risk Machinery

In our view, the current definition of “High-Risk Machinery Products” outlined in the draft Regulation risks creating confusion and could negatively impact European machine tool manufacturers. The definition suggests that the machines covered under Article 5³ and listed in Annex I, which also include some types of machine tools (Most importantly machine presses), would pose a significant health and safety risk during use. Nevertheless, we contest such definition, since the existing legislation already forbids the sale of machinery products that pose a high risk. In fact, according to the current legal provisions, which have been successfully applied in practice since 1 January 1993, only machines whose risks have been eliminated or minimized to the lowest possible level may be marketed.

Henceforth, we reject the concept that certain machine tools would be labelled “High-Risk” under the draft Regulation, as this would be misleading for customers and potentially damaging to the reputation of European manufacturers. For this reason, we advocate for a clearer definition of the machinery products that would be covered by Article 5, especially considering that the Commission will have the power to amend Annex I on the basis of technical progress. In this regard, the Commission will need to establish clear criteria in order to better understand the process by which new machinery types will be added to Annex I, while fostering transparency and enhancing stakeholder involvement in this process.

To this end, we propose to change the title of Article 5 to “Machinery Products that may be intended for certain conformity assessment procedures” and to add clear criteria to help identify the types of machines that this article should be applicable to.

Third-Party Certification for High-Risk Machines

The current Machinery Directive offers three possible conformity assessment procedures, outlined under Annex IV⁴ for machine tool manufacturers to demonstrate the safety of machines, one of which is to use internal production controls (Module A as defined in Decision 768/2008). The Module A conformity assessment certifies that a machine has been manufactured in accordance with a harmonized standard (Based on the Official Journal of the European Union) and that the manufacturer has applied all the relevant Essential Health and Safety Requirements (EHSRs).

Harmonized standards provide a guideline to implement technical solutions that comply with the state of the art while the EHSRs, laid out in Annex I of the Directive (Annex III⁵ of the draft Regulation), provide concrete safety requirements that all machines have to adhere to. This assessment procedure, as outlined in Article 12⁶ of the Machinery Directive, is by far the most common and efficient procedure that is utilized in our sector.

Nonetheless, the draft Machinery Regulation aims to introduce the requirement for third-party certification (Module B + C or Module H) to all machinery products listed in Annex I, which would be a fundamental shift away from the current Module A conformity assessment procedure (Internal production controls). In our view, imposing such a requirement on manufacturers would not necessarily enhance the health and safety levels of their machinery. In fact, there is no definitive market evidence indicating that third-party certifications increase the health and safety of machinery products. The conformity assessments performed by third parties (Notified bodies) are based on the same harmonized standards and EHSRs that manufacturers apply when performing internal production controls (Module A).

Furthermore, performing third-party conformity assessments would undoubtedly result in increased costs and lead times for manufacturers, particularly for SMEs, which make up roughly 80% of our sector. The costs of using a third party for conformity assessments are real and extensive, and thus could lead to an excessive economic burden for the manufacturers operating in our sector. Besides its direct costs, we fear that third-party certification would present both manufacturers and notified bodies with significant logistical and administrative challenges, thereby increasing lead times. Significantly higher lead times could have devastating effects on manufacturers, since the ability to bring products to market in an agile manner is an essential success factor for any kind of manufacturer.

For these reasons, we feel that the extension of third-party certification to all the machinery products listed under Annex I could be deeply counterproductive in terms of increased health and safety, as well as detrimental for the market performance of machine tool manufacturers. As Europe's manufacturing sector continues to struggle to recover from the Covid-19 crisis, increasing costs, lead times and red tape without achieving any particular benefits in terms of health and safety would likely undermine our sector's ability to compete globally. Thus, we feel that the draft Regulation should maintain the option of applying the Module A conformity assessment for machines listed in Annex I, as set out in the existing Machinery Directive under Article 12.

Definition of Substantial Modification

Modifications made to machinery products after being placed on the market may present new risks in terms of health and safety. According to the concept of substantial modification, if these risks were not present during the original conformity assessment, then the modification is considered substantial, and a new assessment must be undertaken by the entity that carries out the modification.

Although CECIMO welcomes the draft Regulation's proposal for an actual definition of substantial modification, we feel that there is definitely room for improvement. The definition needs to be clearer in order to limit the cases where a modification becomes "substantial", and ultimately avoid a discretionary implementation of the Regulation. The current text is highly ambiguous, particularly with regards to the phrase "the compliance of the machinery product with the relevant essential health and safety requirements may be affected," which implies a possibility rather than a certainty.

Such ambiguity would likely deter manufacturers from carrying out modifications to their machinery that could otherwise improve user safety and performance, or even extend their lifespan.

Moreover, the Regulation should establish legal clarity on who is liable for the regulatory consequences in the case of a substantial modification. In this regard, we welcome the fact that dealers, importers and subcontractors performing substantial modifications would bear the responsibility for the modification and face the obligation to carry out new conformity assessments (Art 14⁷ & 15⁸), according to the draft Regulation. Nonetheless, modifications usually consist of two main phases: an engineering/design phase and a work phase to carry out the actual modification. Given that it is fundamental to assign responsibility for a substantial modification where it is due, we believe that the ultimate legal responsibility should be defined contractually within the respective work agreements.

Hence, considering the lack of legal clarity, we propose to change the current definition of substantial modification to "a modification (...) as a result of which the compliance *is* affected" in order to introduce greater clarity through the use of a direct verb – *is* rather than *may* be. With regards to the legal liability of substantial modification, we suggest amending Article 15 to allow the use of contractual obligations to determine the responsible party for the regulatory consequences of a substantial modification.

Harmonized Standards vs. Technical Specifications via Implementing Acts

The draft Machinery Regulation proposes an alternative to the use of harmonized standards, in the form of technical specifications developed through implementing acts by the European Commission. These technical specifications would be applied to assess the conformity of machinery products in cases where harmonized standards are unavailable or delayed.

While we recognize the Commission's intention to create a level playing field by applying uniform conditions for implementation, we deem the introduction of technical specifications through implementing acts to be an unnecessary change, for various reasons.

First of all, the development of technical specifications requires specific technical know-how on the state of the art, which would largely be unavailable within the Commission. On the other hand, the European Standardization Organization does possess this know-how, as it can draw on a wide range of stakeholders including users, market surveillance authorities, notified bodies, academia, and industry.

Secondly, the procedures to develop technical specifications through implementing acts have not yet been clearly established and defined. By hiring technical experts to elaborate these technical specifications, the Commission would risk creating a parallel system within the existing standardization mechanisms that could impact the inclusiveness and transparency of standardization processes.

Thirdly, the development of technical specifications through implementing acts could lead to a misalignment with the technical solutions provided by international standardization bodies, thereby eroding over time the market relevance of European standardization.

Even though technical specifications are voluntary in their application, like harmonized standards, history shows that they are perceived as being de facto mandatory by manufacturers. Henceforth, based on the aforementioned considerations and the available evidence, we propose to delete Article 17⁹ altogether from the draft Regulation proposal.

Conclusion

While the objectives of the draft Machinery Regulation are fundamentally correct in principle, the measures outlined in the text would likely undermine our sector's ability to compete globally, inevitably penalizing the smaller manufacturers that represent 80% of machine tool manufacturers. Henceforth, CECIMO firmly believes that the proposals advanced in this position paper would significantly contribute to establish a clearer regulatory environment for this important industrial sector. We strongly look forward to continuing working with all the relevant stakeholders to construct a legislative text that can provide a high level of safety while ensuring the free flow of goods in Europe's machine tool manufacturing sector.

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.
2. CECIMO Position Paper: "Is the Machinery Directive fit for purpose?" (14 July 2020).
3. Article 5 ("High-risk machinery products") of the Proposal for a Regulation of the Parliament and of the Council on machinery products.
4. Annex IV ("Categories of Machinery to which one of the procedures referred to in Article 12 must be applied") of the Directive 2006/42/EC of the European Parliament and of the Council.
5. Annex III ("Essential Health and Safety Requirements relating to the design and construction of machinery products") of the Proposal for a Regulation of the Parliament and of the Council on machinery products.
6. Article 12 ("Procedures for assessing the conformity of machinery") of the Directive 2006/42/EC of the European Parliament and of the Council.
7. Article 14 ("Cases in which obligations of manufacturers apply to importers and distributors") of the Proposal for a Regulation of the Parliament and of the Council on machinery products.
8. Article 15 ("Other cases in which obligations of manufacturers apply") of the Proposal for a Regulation of the Parliament and of the Council on machinery products.
9. Article 17 ("Presumption of conformity of machinery products") of the Proposal for a Regulation of the Parliament and of the Council on machinery products.

CECIMO is the European Association of the Machine Tool Industries and related Manufacturing Technologies. We bring together 15 national associations of machine tool builders, which represent approximately 1500 industrial enterprises in Europe (EU + UK+ EFTA + Turkey), over 80% of which are SMEs. CECIMO covers 98% of the total machine tool production in Europe and about 33% worldwide. It accounts for approximately 150,000 employees and a turnover of around 20 billion euros in 2020. More than three quarters of CECIMO production is shipped abroad, whereas half of it is exported outside Europe.

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