

FEM general comments – outcome of IA study and EC draft proposals to revise the MD

Brussels, 8 December 2020

FEM would like to thank the European Commission for being given the opportunity to provide comments on the draft proposals to revise the Machinery Directive (MD), as shared at the last Machinery Working Group of November 2020. In addition, we would like to highlight a number of main messages to complement the specific technical input which we are providing in the accompanying table of comments.

• New Legislative Framework alignment and conversion into a Regulation

First and foremost, FEM fully agrees with the intention to adapt the MD to the New Legislative Framework (NLF) as well as to convert the Directive into a Regulation. Both of these procedural changes would be highly beneficial for all parties, ensuring a coherent application of the Directive across the Member States and horizontal provisions (e.g. obligations of economic operators) which are consistent with the other NLF-aligned pieces of legislation.

Adapting Annex I to address challenges of new technologies

Many of the proposed modifications are related to new technologies, which reflects the Commission's preferred policy option 1 regarding the need to address challenges of new technologies by adapting Annex I. We believe that any of the proposed changes which alter the technology neutrality of the MD must not be endorsed in the process of preparing the revision proposal.

The MD poses no problem for materials handling manufacturers to develop technological solutions, like Al-driven innovations, without any compromise on safety. FEM does believe that the current MD text is fit for purpose in light of new technologies, so there is no need to modify the current text and include additional legal obligations.

Being technology neutral, the MD already covers different types of risks related to safety in Annex I, regardless of the origin of such risks. The current Annex I is robust enough to cover risks posed by new technologies. Details of technology solutions shall be left up to standardisation which plays a key role to set the state of the art, allowing the development of innovative solutions, and supporting manufacturers in overcoming challenges related to new technologies

To address specific challenges, for instance posed by AI or cybersecurity and to avoid a fragmentation of rules across the single market, proposing separate horizontal laws (for AI, cybersecurity) are recommended as the best way forward.

More generally, FEM would like to stress that any new concepts must not be introduced in the ESHR of MD without being defined by the legislator.



• Digital documentation

FEM generally agrees with the objective of allowing digital instruction manuals as one of the means to supply the instructions. However, adding another layer to the existing requirements, through the proposal of a paper safety manual, may be confusing for manufacturers. FEM requests further clarification of the actual goals of having both a safety manual and making available instructions by digital means – having both requirements may be conducive to more administrative burdens. We are fully supportive of the environmental objective of reducing paper waste and of the need to adapt current processes to embrace the growing digitalisation (in this case, through digital instructions). Therefore, the proposal should be simplified to go in that direction without an additional definition coupled with requirements for a secondary instruction manual (such as the safety manual).

PCM definition

FEM believes that the current definition for partly completed machinery is fit for purpose and does not need to be modified. The concept of 'specific application' is one of the core principles of the PCM definition. Keeping this concept is essential as it provides a clear and complementary link to the definition of Machinery in Article 2(a). Furthermore, there is a large consensus that "specific application" refers to an intended use of a machine as defined by the manufacturer at the design stage and that this notion corresponds to the final use (or end use) of a machine. A PCM only brings a function to machinery (or to an assembly of machinery) and does not have any final use. For example, during the lifetime of assemblies of machinery (e.g. intralogistics systems) it is necessary to sell to customers some new equipment for different reasons (e.g. belt conveyor). When such new equipment is placed on the market without any control system, the current interpretation is that they have to be considered as PCM, because this new equipment cannot in itself perform a specific application.

Modification of Annex IV

Last but not least, FEM strongly objects to any addition (e.g. machinery with AI) to the list of machinery in Annex IV and therefore also to a delegated act that would update this list. We also disagree with the removal of internal checks for Annex IV machines if all relevant harmonised standards to demonstrate compliance with the MD requirements have been used. More specific arguments are provided in the accompanying table containing FEM's input on the Commission proposals.