



**European Materials Handling Federation**

## **FEM Position Paper on the Proposal for a Machinery Regulation**

FEM, the European Materials Handling Federation, represents the European manufacturers of materials handling, lifting and storage equipment. FEM speaks for sixteen members representing more than 1,000 companies employing 160,000 people directly and with an annual turnover of more than €60 billion.

The Machinery Directive is arguably the single most important piece of legislation for our manufacturers. Since its adoption, it has been an effective and successful internal market legislation. Not only has it provided the highest level of machinery safety in the world, but it has also enabled the material handling industry to continue innovating, thriving and taking the lead in many segments.

In this context, our industry's very first priority is to ensure that the future Regulation maintains such a balance between safety and innovation whilst offering the necessary predictability for manufacturers and users alike. With this in mind, FEM would like to make the following comments on the proposal.

### **Executive summary**

#### **Positive Aspects:**

- Conversion of the Machinery Directive into a Regulation and its alignment with the New Legislative Framework
- Digital documentation (both instructions and Declaration of Conformity)

#### **Developments of concern:**

- **Mandatory third-party certification for high-risk machinery** and extension of Annex I to items 24 (software ensuring safety functions) and 25 (machinery embedding AI ensuring safety functions): The obligatory third-party conformity assessment is unjustified and disproportionate in the absence of any identified safety need nor gains of third-party certification compared to self-assessment.  
➔ FEM calls for the removal of this new requirement.
- **Interplay between the AI Regulation and Machinery Products Regulation**  
➔ FEM draws attention to the need for continued coherence between the two pieces of legislation throughout the legislative process.
- **The Commission empowerment to adopt technical specifications via implementing acts**  
➔ FEM calls for the reconsideration of this clause and ensuring the process of adopting these specifications is subject to scrutiny by all relevant stakeholders, including the industry, and is built on the principle of transparency.
- **New essential health and safety requirements for emerging technologies (cybersecurity, autonomous mobile machinery) and adapted requirements for traditional technologies (seating):**  
➔ FEM recommends that the specificities on these technologies should be laid down in standards and/or a horizontal legal act, instead of the Machinery Regulation, to ensure the latter remains technology neutral.



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### I- Positive developments

#### ***Conversion from a Directive to a Regulation and NLF alignment***

FEM fully supports the conversion of the Directive into a Regulation and the alignment with the New Legislative Framework (NLF). These changes are essential to ensure a uniform application across the Member States, and a common legal framework for the marketing of machinery products. Particularly in terms of simplification benefits, we welcome the adoption of the NLF provision allowing a single Declaration of Conformity (DoC) dossier compiling all the relevant DoCs for a machinery product.

#### ***Digital documentation***

At the same time, the move to digital documentation for both instructions and the DoC is a positive change that will pave the way towards making the Machinery Regulation fit for the digital age.

### II- Developments of concern

A number of the new or adapted requirements in the proposal have the potential to hamper the innovation and competitiveness of the European machinery sector, while they may affect technology neutrality which has always been and must remain a core principle of the Machinery Directive (MD).

#### **High-risk machinery**

FEM fundamentally disagrees with the mandatory third-party certification for all (so-called) high-risk machines. This is a disproportionate measure that unjustifiably modifies the current practice of application of internal checks (as long as all relevant harmonised standards have been used), which has worked for more than twenty years without raising any safety concerns.

This new obligation would undermine the importance and credibility of harmonised standards when used by machine manufacturers to meet the essential health and safety requirements. It will also be detrimental to the involvement and motivation of the industry to develop or maintain harmonised standards if the latter cannot be used to demonstrate the conformity of high-risk machinery products. As a result, the outdated harmonised standards could infringe the state-of-the-art for high-risk machinery products. Furthermore, the lack of harmonised standards will lead to divergences in the application of essential health and safety requirements, resulting in products being placed on the market with different safety levels.

A mandatory third-party certification for all (so-called) high-risk machines is unjustified because:

- There is no evidence available reporting accidents or lack of compliance associated with self-certification, although AI-driven innovation has already been implemented for several years.



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- There is no safety gain for using third-party certification as compared to self-certification. Notified bodies carry out the conformity assessment using the same harmonised standards based on the same technical requirements. Moreover, our manufacturers have an extensive experience in the field of Notified Body involvement under the Outdoor Noise Directive with no evidence of safer products being placed on the market. In addition to the lack of safety gains, the additional costs that will be borne through an obligatory third-party involvement will place a burden on European consumers too.
- A third-party certification may lead to an "innovation brake", because even changes to the software are at least notifiable and/or require a re-examination. Developments in AI are moving at a fast pace, so comprehensive risk reduction and fast integration into the field are needed. In our experience, it is important to support a close cooperation for development, testing and risk assessment.
- Moreover, as an example, with an inherently safe system, where only a sublayer that has no influence on the safety concept has been integrated, the full system remains safe, although (so-called) high risk AI is used.

Ultimately, in the absence of an identified lack of safety when using self-assessment (e.g. because more accidents are reported) and whereas third-party certification does not provide any additional benefits compared to self-assessment, there is no justification for making third-party certification mandatory. This drastic change would be completely disproportionate with a negative impact on European industry's competitiveness, while the costs incurred would eventually add burdens to the European consumer. Moreover, if Notified Bodies would have to certify all new machinery products listed in Annex I in general, this would be an obstacle to innovation and generate additional lead time.

➔ For all these reasons, FEM strongly requests that self-assessment must continue to be allowed for high-risk machinery as well, in addition to the third-party conformity assessment, as long as the manufacturer has used all the applicable harmonised standards.

### Inclusion of items 24 and 25 in Annex I

We are also particularly concerned about the **inclusion of item 25 (machines embedding AI systems with a safety function) in Annex I**, which imposes third-party certification on the complete machine if the latter contains AI systems ensuring safety functions. This would adversely impact on automation, making it more cumbersome and costly whereas automation is clearly a process that increases the level of safety.

Concerning **item 24 (inclusion of software ensuring safety function)** this is added in both Annex I and Annex II, to make the link with the definition of safety components which now comprises software. The inclusion of this item adds uncertainty to the meaning of safety components in relation to third-party intervention. Moreover, we see no meaning in adding 'digital component' in the definition of safety component as software always needs hardware to become a safety component.



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- FEM calls on the legislators to restore the definition of safety components as set out in the MD, while ensuring that the condition of ‘independently placed on the market’ is preserved.

With regard to the **empowerment of the Commission to amend Annex I**, the conditions for the inclusion and removal of equipment from Annex I further clarification is needed on what can be considered the threshold to include and remove high-risk machinery from the Annex. Arguably, any machine poses some kind of risk to human health, so this criterion alone is not sufficient to justify the addition of machines under Annex I. Besides, as the criteria given in article 5.3 are unclear, we suggest using instead the well-known notion of “*product presenting a serious risk*”, from the Regulation (EU) 2019/2010.

### Coherence with the AI Act

Given that the Machinery and AI proposals follow two parallel legislative processes, it is not clear how full coherence would be guaranteed throughout the legislative process. It is crucial that the co-legislators align the two texts specifically on the definition of AI systems and the interplay between the two pieces of legislation in terms of the scope and conformity assessment procedures, to avoid that at the end of the process the two Regulations are not consistent with each other.

The Regulation should clarify that it covers only the safety related part of the AI integrated in a machine whereas the AI systems themselves fall under the Artificial Intelligence Act. One specific gap is the lack of legal clarity on what machine learning is, as well as the different levels of autonomy that are considered when it comes to machines with evolving behaviour. A clarification on the concept of safety function in both pieces of legislation is advisable bearing in mind the state-of-the-art and the technological progress. As an example, assistance systems can have a positive effect on safety without being safety systems as such.

- FEM calls on the co-legislators to ensure as much coherence as possible between the Machinery Regulation and the AI Regulation, notably concerning the definition of AI systems, and also to provide further clarity on the concepts of ‘machine learning’ and ‘safety function’.

### Presumption of conformity

FEM would like to express its concerns about the empowerment of the Commission to adopt technical specifications giving presumption of conformity outside the European standardisation process.

The adoption of these technical specifications, even if considered a last-resort option, generates distrust in the NLF system, in which the principle of harmonised standard is enshrined. Moreover, it would effectively undermine the current consensus-based system and a balanced representation of stakeholders in a transparency process, ensured with the public enquiry. Most importantly, this is not an industry-driven process, whereas this is a backbone feature of the EU standardisation process.

Last but not least, these technical specifications are likely to adversely impact European competitiveness and innovation because the process for revision and amendment will inevitably be



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less agile in following the development of the state-of-the-art than the European standardisation process. Given that the Machinery Regulation covers a multitude of complex machines, these technical specifications will further add to the complexity of this legislation rather than support it, due to the lack of sufficient manufacturers' involvement. Instead, the Commission should resolve the current delays in development of harmonised standards by investing in the pro-active involvement of HAS consultants in the drafting process.

- FEM calls on the co-legislators and the European Commission to reconsider the adoption of technical specifications outside the EU standardisation system, and instead work together with the standardisation community to improve shortcomings in the current system (such as for example, delays in the development and citation of harmonised standards). If activated, the process of adopting these technical specifications should undergo formal scrutiny by all relevant stakeholders, to avoid soft legislation being developed in parallel.

### Autonomous mobile machinery

Most of the new requirements for “Autonomous Mobile Machinery” are disproportionate because Automated Guided Vehicles (AGVs) are already safe today under the Machinery Directive with the use of standards. The new Essential Health and Safety Requirements (EHSRs) add unjustified burdens to the OEM's and the users/customers without adding safety and obstruct European manufacturers' competitiveness in the global markets. Industrial producers would be encouraged to move their production sites outside Europe where automation can be developed in a practical and a competitive manner. One outstanding example relates to the requirement to implement live remote supervision, which would obliterate the business cases for customers to buy AGVs. Investing in both automation and live human supervision is not state-of-the-art and does not increase the level of safety.

Moreover, the wording in the regulation implies there are different levels of autonomy but there is no definition given, nor adjustments in the corresponding EHSR.

- FEM requests that specific technical solutions and requirements for autonomous mobile machinery should be elaborated in product specific standards, instead of the Machinery Regulation.

### Cybersecurity

Concerning the cybersecurity requirements EHSR 1.1.9 and 1.2.1 (a) (f) FEM has always stated that any future cybersecurity/security requirements must be taken into account under a separate horizontal legislation and not under the Machinery Directive for which the primary goal is to ensure safety of machines.

The proposed text seems to take into account cyberattacks when referring to all unintended external influences. Further explanation is provided below.



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- External influences typically refer to the intended environment where a machine is operated (e.g. vicinity with an overhead power line for road operation machinery). The requirement for protection against unintended external influences will regularly lead to a "shut-down-functionality" if such influences are detected.
- This may create additional risks if the control system "detects" a malicious attempt, shuts off, although the circumstances of the operation have created the "impression", e.g. high unwanted dynamics during a crane operation shall not lead to a shut off; instead, the possibility shall exist that the lift is finished prior to inspection. It would require proprietary systems and components (and their supply as spare part) and the service/repair only from the OEM.
- Moreover, the proposal implies that all unintended external influences shall be considered at the design stage, which is entirely an unacceptable ask to the manufacturer who cannot be expected to know all these influences in advance.

We would like to stress that cyberattacks are not considered a foreseeable misuse but a malicious use of the product. Therefore, these aspects should not be covered by the Machinery Regulation and would be best addressed in a horizontal cybersecurity legislation.

The proposed text in 1.2.1 does not specify if every software that performs safety functions have to log the data mentioned in this section or it is only the one using AI in future. Software updates already exist today, but the proposal does not make a clear distinction between "classic" software and AI software. Our concerns are given in detail below.

- Regarding the points f) and g) in 1.2.1, machine manufacturers are not responsible for the logging after they have brought the machine in the market. After the placing on the market, the owner is responsible for the remaining life cycle of the machine. A machine builder cannot log data of a machine that they sold without consent of the new owner of the machine.
- The requirement to record all data on the safety related decision-making process after the machinery product has been placed on the market or put into service might lead to extensive data storage, depending on the required way to fulfil this criterion

➔ FEM calls on the co-legislators to remove over-prescriptive cybersecurity requirements from the Machinery Regulation as these should be laid down in a separate horizontal cybersecurity legislation.

### Other concerns

The new requirement added to **EHSR 3.2.2 (seating)** is too design restrictive. The scope of this draft wording is too generic, whereas the requirement as such is far too specific and detailed.

➔ FEM recommends that these details are left out from the legal text and elaborated in harmonised standards. Harmonised standardisation (machine type specific C-Type standardisation) is the only possible and most appropriate measure to make sure that all kinds



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of mobile machinery are safe and this is practical to use as the state-of-the-art of mobile machinery evolves.

### **Conclusion**

FEM welcomes the steps taken to achieve further harmonisation via the alignment with the New Legislative Framework and the conversion of the Directive into a Regulation. We also fully support digital documentation which is another important step in adapting this legislation to the digital age. However, FEM raises strong concerns about specific changes in the Machinery Regulation proposal such as the mandatory third-party certification for all high-risk machinery (including machines with AI systems ensuring safety function) which will hamper innovation and create distrust in the industry's ability to safely place machines with AI innovations on the market without third-party involvement.

We call on the European Parliament and Council to address the issues outlined above during the decision-making process, to achieve a balanced Machinery Regulation which rightfully integrates digital innovation in the legal framework while continuing to preserve European industry's competitiveness.