



**European Materials Handling Federation**

**European Commission proposal for a “Regulation on  
a European Approach for Artificial Intelligence” (COM(2021) 206 final)**

**FEM position paper**

**19/07/2021**

**Executive Summary**

- While not in favour of any specific piece of legislation on AI systems in the industrial field, FEM agrees with the need to have a harmonisation piece of legislation preventing Member States from enacting diverging pieces of legislation that would threaten the free circulation of our products in the EU Internal Market.
- The risk-based approach proposed by the European Commission should be much better fine-tuned by providing a better definition of AI, and of the notion of AI system affecting a safety function, considering the current legislation in place and the industrial environment. Most industrial AI application use cases have entirely different ethical implications compared to consumer-oriented AI solutions for end-consumers. Therefore, in most of the cases industrial AI should not be considered as a high-risk AI. The possibility given to the Commission to extend the list of high-risk AI systems should be counterbalanced by a proper consultation of stakeholders
- Most requirements of the future Regulation should be revised to make them proportionate, enforceable, and respectful of companies’ IPRs, notably with regards to data and data governance, technical documentation, record-keeping of events, transparency, and provision of information to users, appropriate human oversight measures to minimise risk and high-level of robustness, accuracy, and security
- A balance has to be found whereby the companies' right to protect their know-how shall only be infringed in cases where such sharing of information has a substantial and indisputably necessary effect on safety or on the personal right to protect personal data.
- The respective roles and responsibilities of providers and users have to be clarified
- Standardisation and harmonised standards and not “common specifications” must remain the tool of choice to develop technical specifications offering compliance with essential requirements
- A single Declaration of Conformity (DoCs) for the final product, even composed of several DoCs, should be established
- Cybersecurity aspects should be dealt with in a dedicated horizontal legal act.
- The European AI Board should be supported by an advisory group of industry experts

**Introduction**

On 21 April, the European Commission presented a “package” of policy papers related to Artificial Intelligence (AI), consisting of a Communication, a review of the Coordinated Plan with the Member States, and a Regulation proposal, which the European material handling industry represented by the FEM has carefully read.

As underlined in our preliminary [statement](#) following the publication of the proposal, the largest part of our industry’s competitiveness relies on our manufacturers’ capacity to bring in digital development, and particularly industrial AI, where for the moment our European companies are in a position of leadership globally. Digitalisation in our industry focuses on information management, space optimisation, human-to machine cooperation and



## European Materials Handling Federation

improvement of decision and prediction. Our members develop and use systems described in Annex 1, and the proposed Regulation is therefore of direct interest to them.

This first ever proposal tabled by the European Commission on AI covers two fundamental aspects of the EU policy on AI: addressing the risks associated with certain uses of this technology and build trust, and to a lesser extent, promoting the uptake of AI, notably by SMEs. Our comments will focus on the first aspect. The promotion of the AI uptake, notably by industry, is covered in other pieces of EU legislation or programmes and very partially in the current proposal.

### 1. Interest of a specific legislation on AI.

In our [Manifesto](#) "Supporting the digital transformation of the European Materials Handling Industry" of February 2021, the FEM stated that the current legislative framework as concerns safety requirements for the free circulation of material handling equipment within the EU Internal Market is fit for purpose, including for the deployment of AI. The pieces of legislation based on the New Legislative Framework (NLF) - Machinery Directive, Radio Equipment directive (RED), Low Voltage Directive and Electromagnetic Compatibility Directive - completed by horizontal pieces of EU legislation (e.g., on product liability or on general safety of products) or by general principles of law such as the freedom of contract, provide in our view a very solid corpus of EU legislation.

On the other hand, we understand that having a specific piece of legislation on AI will guarantee the coherence of the EU Internal Market against Member States temptation to enact national rules. Moreover, we welcome the Commission choice of a Regulation and the use of article 114 of the Treaty as well as the alignment with the NLF principles, all elements further guaranteeing the free circulation of our products. In the context of AI in particular: it is crucial that non-EU manufacturers comply with the same rules when they place their solutions on the EU market, meaning that market surveillance has to play a key role.

Beyond ensuring free circulation of machinery and equipment, cooperation between Member States is crucial, not only at academic level but also between the States themselves. The 2021 review of the "Coordinated Plan on Artificial Intelligence", though limited, should be fully used as catalyser of national and EU efforts, particularly as regards high impact sectors "robotics" and "mobility".

### 2. Risk-based approach

The legal regime established by the Regulation proposal is based on the concept of risk and classifies AI systems in four categories: a) unacceptable risk - AI systems falling in this category will be banned, b) high-risk AI systems, including safety components of products, subject to strict obligations before they can be placed on the market or put into service, c) limited risks - AI systems will be subject to transparency rules and d) absence of risk where no rule is proposed.

Whereas the FEM takes note of the limited scope of prohibited AI practices, which, in its current phrasing, does not directly affect our industry, we very much regret the automatic qualification as high-risk of AI machines or components with a safety function if they are submitted to third party certification under harmonised legislation such as the Machinery, ATEX, Pressure Equipment, or Radio Equipment Directives. Moreover, if we consider a situation where humans and AVs are collaborating on a given task, safety component does come into picture. If that component is relying on ML/AI based techniques (e.g., to interpret the gesture or intent of a human), but still has other means to ensure safe distance, would it qualify as high-risk AI system?

A cross-reading of this proposal with the proposal for a Machinery Products Regulation aimed at replacing the current Machinery Directive (tabled by the European Commission at the same time) seems to indicate that third



### European Materials Handling Federation

party certification will be made compulsory for all products whose safety component is the AI system, or where the AI system itself is a product.

This is adding costs, administrative burden, and delays for OEMs without any safety gain: AI is not a new technology in the B2B and particularly the machinery sector. In this respect, FEM regrets the equivocal use of the terms "risk" and "high risk" throughout the proposal and the lack of verifiable criteria for classifying a product as "high risk", with the consequence that any AI system affecting a safety function could be considered as such, regardless of whether or not it is able to evolve autonomously out of the machine limits established by the manufacturer during the risk assessment. A better definition of a safety function under the AI regulation has to be included in the final text: for example, can an assistant system be considered as a safety component/safety function? This definition could refer to the one used in EN ISO 12100, clause 3.30, and should also be added in the Machinery Products Regulation under preparation.

More generally, a clearer definition of AI and AI system should be provided in the final text of the Regulation.

In any case, the current broad scope creates a serious obstruction on innovation, as any future AI machinery could be potentially covered, depending on how the concept of safety function will be interpreted. FEM strongly recommends the definition to be narrowed to consider the existence of fall back/other levels of safety.

Moreover, FEM is concerned by the power granted by the Commission to update by means of delegated acts the list of high-risk systems contained in Annex III, even if this power is framed by article 7. Stakeholders should systematically be consulted on these updates.

### 3. Requirements

Non-compliance with the requirements of the future Regulation will be submitted to heavy fines, and this is why not only the scope of the legislation but also the requirements to companies, especially SMEs, have to be proportionate and enforceable to allow them to comply with the rules with reasonable expenses. In particular:

- Data and data governance (training, validation, and datasets testing) to minimise risks and discriminatory outcomes)
  - The rules should not be overprotective, only restricted as needed,
  - Stakeholders shall be free to agree the ownership and the use of data of the results/inventions achieved in joint activities within the EU data spaces by private contracts.
- Technical documentation, including post market monitoring
  - The technical information to be provided and listed is too prescriptive; requirements should follow general good AI practice developments such as MLOps
- Record-keeping of events (traceability)
  - Requirements are too prescriptive. The text is too vague and may lead to multiple interpretations. Moreover, it is advisable to clarify the obligations, which need to become feasible to fulfil the requirements.
- Transparency and provision of information to users
- Appropriate human oversight measures to minimise risk
  - As regards the reporting of serious incidents and malfunctioning: more flexibility, on the timing is needed. FEM proposes an alignment with the GDPR, art. 33 in this respect.
- High-level of robustness, accuracy, and security
  - These aspects in particular need to be proportionate and enforceable

### 4. Obligations of AI systems providers and users



## European Materials Handling Federation

FEM is very concerned about the large amount of information that has to be inserted in the database, and therefore made available to the public: while we understand that it only applies to Annex III types of AI systems,

Annex III itself can be modified by delegated acts. This could threaten the right for companies to protect the confidentiality of their know-how, patented or not, and their trade secrets. Furthermore, providing details on companies' cybersecurity measures could result in a higher vulnerability because of the disclosure of such sensitive information to third parties.

A balance has to be found whereby the companies' right to protect their know-how shall only be infringed in cases where such sharing of information has a substantial and indisputably necessary effect on safety or on the personal right to protect personal data.

Moreover, there are topics to be further specified and clarified during the legislative process:

- The articulation of these different obligations could imply that a manufacturer integrating an AI system into its machinery product becomes the user of that system, while assuming the obligations of the provider (Article 24).
- The combination of Article 15-3 on resilience with Article 29 on users' obligations creates confusion about the responsibilities of each interested party and would require clarification.
- Legal consequences and liabilities for the user in case he/she becomes a provider and vice versa.

### 5. Standardisation

FEM strongly supports the development and the boosting of harmonised standards that remain of a voluntary nature, represent the state of the art and can in more details finetune the notions of "high/low level risk" in a proportionate manner.

It is concerned by the right granted to the Commission in article 41 to establish common specifications by means of implementing acts. In many use-cases of AI, there are no existing standards or technical requirements yet due to the innovative field of action which is under development. It is therefore fundamental to keep industry very closely involved with the development of such specifications and that the principles of harmonised standards (involvement of all stakeholders, transparency, consideration of the state of the art, voluntary approach, etc.) are respected throughout the preparation of such common specifications.

### 6. Declaration of conformity

FEM proposes to replace the unique EU Declaration of Conformity (DoC) for AI systems integrated/embedded into a machinery by allowing that a single DoC for the final product can be composed of several DoCs. In any case, a duplication of third-party certification under the AI regulation must be avoided when embedding CE marked AI software to a new component or product. It must be ensured that existing conformity assessment results under this regulation are passed on along every integration stage in the value chain.

### 7. Cybersecurity

The FEM considers that cybersecurity risks should be dealt with by a dedicated horizontal legal act. Also, safety can also be strengthened through the work of the European Cybersecurity Agency (ENISA) in the area of industry automation.



## **European Materials Handling Federation**

For these reasons, we strongly object to any cybersecurity specific requirements in the AI Act.

### **Conclusion**

Overall, while FEM continues to strongly promote the concept of technology neutrality, which has proven to function well over the years and is a pillar of the NLF system, we invite the European Parliament and the EU Council to, during their examination of the Commission proposal, keep in mind:

- The B2B specificities of any AI legislation, where human to machine interactions are very limited
- The need to promote innovation, particularly in our sector of the European Materials Handling Industry where AI is a vector of innovation and global competitiveness
- The role played by contracts in B2B company interactions.

Last but not least, we strongly encourage the European Parliament and the EU Council to amend the proposal in such a way to involve much more closely industry and technical experts, notably at the level of the European AI Board which should be supported by an advisory group of experts designated by the Commission.