



# FEM Bulletin

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## **AI & Machinery Directive Proposals**

*Supporting or obstructing innovation?*

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# FEM News

FEM Executive Committee and Board met on 6<sup>th</sup> July. The Executive Committee received a legislative update with a focus on the legislative files under revision: machinery, AI and battery. The secretariat also gave an advocacy report explaining the actions taken and the resources spent so far.

Whereas FEM Operating Rules are under revision, the Executive Committee decided to set up an ad hoc Task Force in order to prepare a final draft to be submitted to the general assembly at its next meeting on 9<sup>th</sup> November. The amendments relate to FEM financing, Product Group's financial management, and working groups' organisation.



## Task forces activities

### Machinery Directive

The proposal for a Machinery Regulation including the annex and the impact assessment report were [released](#) on 21 April, together with the Package on a European Approach for Artificial Intelligence. The proposed Machinery Regulation intends to address six issues identified during the evaluation of the current legislation, covering the following:

- Alignment with the New Legislative Framework (NLF) to ensure consistency with other EU product harmonisation legislation
- Conversion into a Regulation to address divergences in Member States' interpretations and ensure a uniform implementation in the EU
- New definitions proposed for further legal clarity (e.g. substantial modification, inclusion of software in the definition of safety components, AI systems – same definition as in the proposal for an AI Regulation)
- Exemptions extended to include all means of transport on road and electrical and electronic products integrating a wi-fi function (e.g. washing machine)
- New requirements to address risks stemming from new technologies (human-robot collaboration, connected machinery, software updates affecting the behaviour of the machine after placing on the market)
- Adaptation of the list of high-risk machines (Annex I – former Annex IV) to remove some of the existing machines that are no longer regarded as high-risk and include new ones (e.g.

machines embedding AI to ensure safety functions). A critical change is the removal of self-assessment/internal checks for high-risk machines.

- Move to a digital format of instructions to address administrative burdens and high economic and environmental costs due to extensive paper documentation, while ensuring that end-users and consumers can have access to a printed version free of charge, if they request it.
- Some specific changes to the essential health and safety requirements (Annex III – former Annex I) related to traditional machinery (e.g. installation of lifting appliances, slow speed lifts, seating, protection against hazardous substances, overhead power lines and vibration from portable handheld and hand guided machinery).

Following the publication of the Machinery Regulation proposal, the FEM TF Machinery Directive held five meetings to discuss the content of the proposal and prepare its position paper highlighting the core policy messages on this file. This position paper was adopted on 6 July. In short, FEM highlights its support to the NLF alignment, conversion into a Regulation and the shift to digital documentation, but raises concerns about the following issues:

- Removal of self-assessment option for high-risk machinery
- Consideration of machinery embedding AI system ensuring safety function as high-risk by default (inclusion in Annex I)
- EC empowerment to adopt technical specifications via implementing acts, if harmonised standards are not delivered by the European Standardisation Organisations
- The coherence between the Machinery Regulation and the AI Regulation
- New requirements related to digital technologies (cybersecurity, autonomous mobile machinery)

In parallel to the preparation of the position paper, FEM also launched its advocacy campaign on the Machinery proposal having set up meetings with the Council attachés from Portugal and Slovenian (outgoing and incoming Presidencies) as well as with the rapporteur in the European Parliament (Ivan Stefanec, EPP, SK) and one of the shadow rapporteurs (Svenja Hahn, Renew, DE).

## **Batteries Regulation**

In the last months, the revision process of the Battery Directive – to become a Regulation – keeps FEM and its TF Battery busy.

As a reminder, at the end of 2020, the European Commission published its proposal for a new Regulation on batteries and waste batteries (Annexes), which will be replacing and repealing the current Batteries Directive (2006/66/EC).

Through this new regulation, the European Commission aims that all batteries placed on the EU market become sustainable, high-performing and safe all along their entire life cycle. According to the proposal, the materials handling industry will be highly impacted since many new information and sustainability requirements will apply to industrial batteries – the relevant category for our equipment.

Therefore, in the last months, the FEM Task Force Battery finalised the analysis of this proposal and shaped the FEM position. The FEM position paper will be published in the coming days, allowing us to further engage with decision makers. We need FEM members to help performing this work.

Overall, FEM acknowledges the need to modernise this piece of legislation and supports the objectives: strengthen the Internal Market, promote circular economy, and reduce environmental and social impacts of batteries. However, the Task Force identified shortcomings and room for improvements in the Commission's proposal to support innovation and the global leadership position of our industry.

The Task Force identified four key requests to decision makers to improve the future regulation:

- 1) Establish clear definitions to ensure a common understanding for the implementation and enforcement of the future legislation;
- 2) Differentiate the manufacturing of cells from other manufacturing activities to apply sustainability requirements where they have the biggest potential impact;
- 3) Remove the systematic use of third-party verifications for sustainability aspects since it is neither necessary, nor proportionate or a booster for the circular economy;
- 4) Impose a battery management system only to industrial batteries suitable for second life and exclude industrial batteries that do not have integrated management system.

In addition, the FEM Task Force Battery has been closely following the legislative process in the Council and European Parliament, which started in early 2021.

On the side of the European Parliament, the procedure and allocation of competencies suddenly changed at the end of April – a very unusual process! The Parliament Committee on Environment, Public Health and Food Safety Committee (ENVI) was appointed as leading committee, instead of the Internal Market and Consumer Protection Committee (IMCO). In addition, the Internal Market (IMCO) and Industry (ITRE) Committees were assigned as 'associated committee'; the Transport and Tourism Committee (TRAN) remains for opinion.

About concrete consequences, this means that the Rapporteur for this file is now [Simona Bonafè](#) (S&D, IT) instead of [Antonius Manders](#) (EPP, NL). Competences are shared in four Committees: we will have to reach out the four committees according to their responsibility, multiplying the contacts and work. In addition, each committee follows a different timeline.

About the expected timeline, most discussions and votes in the respective four Committees have been postponed after the summer break. The vote in plenary session is now expected in February 2022.

In the Council, lively discussions are taking place in the Working Party on Environment. The status of discussion is explained in the [progress report](#) published by the Council Presidency on the occasion of the Environment Council in June. Although Member States have discussed most provisions of the Commission's proposal, they did not find compromises. While the Council position was initially foreseen in June, it has been postponed to December 2021.

The delay in both EU institutions will also postpone the finalisation of the future regulation, which is now expected for mid-2022. This raises concerns for its entry into force of this new regulation that is scheduled in January 2022.

# Digitalisation

## Artificial Intelligence

On 21 April, the European Commission published its AI package consisting of:

- A Communication
- A Review of the Coordinated Plan with the Member States
- A Proposal for a Regulation on AI

The AI proposal sets 2 main objectives: 1) addressing the risks associated with certain uses of this technology and build trust, and 2) promoting the uptake of AI, notably by SMEs. It builds on 4 categories of risk:

- unacceptable risk - AI systems falling in this category will be banned,
- 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,
- limited risks - AI systems will be subject to transparency rules,
- absence of risk where no rule is proposed

An analysis of the proposal highlighted several issues for European materials handling equipment manufacturers. The most significant one is 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. In parallel, the Proposal for a Machinery Regulation does indeed make third party certification mandatory for high-risk machines. This issue is therefore to be addressed in both legislative processes.

Other issue is the strict requirements for high-risk machines: risk management system, data and data governance (training, validation, and datasets testing) to minimise risks and discriminatory outcomes, technical documentation - including post market monitoring -, record-keeping of events (traceability), transparency and provision of information to users, appropriate human oversight measures to minimise risk, high-level of robustness, accuracy, and security.

FEM is in the final process of adopting its position paper and an advocacy plan is being drawn up. Advocacy activities will start after the summer, in close cooperation with Orgalim.

## Data

On 28<sup>th</sup> May, the European Commission published a [Roadmap](#) related to the Inception Impact Assessment (IIA) on the upcoming Data Act. Published on 28 May. The document also covers the review of Directive 96/9/EC on the legal protection of databases. The objective is to increase the use of and access to data, particularly non-personal data regulated by contract law in B2B situations. Several policy options are envisaged:

- Data sharing, transparency requirements and safeguards through legislation to bring greater clarity into the B2G data sharing context. This could include new rights for the public sector to access privately held data for a range of public interests.

- Transparency obligations for manufacturers of IoT in relation to the rights to access and use of non-personal data of such objects.
- A B2B fairness test to avoid unilaterally imposed unfair conditions for access to and use of data (complimented by model contract clauses).
- Data access and use rights for non-personal data, potentially based on fair, reasonable, proportionate, transparent and non-discriminatory terms.
- A legislative proposal is expected before the end of 2020.

## **Exhaust emissions**

As a reminder, FEM decided to not engage in a second round of advocacy activities to extend the Stage V 2021 deadlines in the NRMM Regulation.

On 24<sup>th</sup> June, [Regulation \(EU\) 2021/1068](#) was published, amending Regulation (EU) 2016/1628 as regards its transitional provisions for certain machinery fitted with engines in the power ranges greater than or equal to 56 kW and less than 130 kW, and greater than or equal to 300 kW, to address the impact of the COVID-19 crisis.

The amending Regulation postpones the transitional provisions as follows: a 6-month extension for the production of NRMM fitted with engines in the power ranges 56-130 kW and greater or equal to 300 kW, and a 9-month extension for the placing on the market. Such an extension had been requested mainly by the agricultural machinery industry.



# **EU legislative issues**

## **General Issues**

### **Standardisation Policy**

The European Commission has launched a [stakeholder consultation](#) on the Roadmap for its Standardisation Strategy.

The Roadmap acknowledges the strengths of the European Standardisation System (ESS) being based on inclusiveness, consensus-building, and transparency, but at the same time, notes that the system is not sufficiently equipped to deal with future standardisation needs (e.g. green/digital industrial transition).

The Standardisation Strategy is intended to modernize the ESS in order to:

- better anticipate standardisation priorities at political level
- strike the right balance between speed and quality (in that sense, a joint Task Force between the Commission and European Standardisation Organisations was established to address shortcomings of the current ESS and improve delivery mechanisms)
- make further improvements on governance, working methods and cooperation between all players in the standardisation community
- find solutions to incentivise coordination, efficiency and flexibility in the timely delivery of European standards

Other priorities relate to the need to ensure a coordinated approach to global standards-setting in areas of strategic EU interest, tackling gaps in standards-related education, skills and expertise, at both public and private levels; boost R&I in standardisation by making use of EU industrial resources.

Stakeholders are invited to provide feedback by 26 July, on the following three core aspects:

- 1) whether or not the current European standardisation system is fit for purpose to support European strategic interests;
- 2) how the EU can leverage and promote global leadership in standards-setting
- 3) whether or not changes in governance and working methods are required to improve the performance of the European standardisation system.

## **Road Circulation**

The European Commission organised a stakeholder workshop on the future Road Circulation Regulation. During the workshop the Commission presents the results of the public consultation, pointing out that the preferred policy option is that of a simplified type approval system (what was formerly called the hybrid approach, combining the EU type approval system with the New Legislative Framework model in terms of conformity assessment procedures). The workshop consisted of an open exchange between Member States and the industry on various technical aspects such as: maximum design speed, seats, goods' definition, masses & dimensions, borderline with other TA legislation, definition of type and variants . In terms of the policy architecture, the Commission intends to follow the structure of the Tractor Mother Regulation for the future Road Circulation Regulation. As far the approval procedures are concerned, the aim is to include the procedures suggested by the Industry Task Force (ITF), ranging from A to E, corresponding to the different technical requirements (for example, procedure A which requires a technical service to perform the test and issue the test report would apply for braking and steering, as these are considered critical in terms of road safety).

As for the next steps, the Commission intends to schedule a drafting meeting with Member States in the second half of 2021. COM will draft an impact assessment on this initiative which must forego scrutiny by the end of 2021. If it obtains political validation, the Commission Inter-service Consultation will be launched, and the new regulation could then be adopted in the first half of 2022.



## **BREXIT**

### **Trade and Cooperation Agreement (TCA)**

The TCA is now fully implemented. The final stage of the ratification process was completed when members of the European Parliament overwhelmingly voted to approve the deal on 27 April 2021. This completed the ratification process, with all relevant institutions having voted to approve.

### **Northern Ireland Protocol**

The 6-month transition period came to an end on 30 June 2021, after which the protocol is due to be fully implemented. This includes applying the Single Market border checks between Northern Ireland and Great Britain (GB). There is currently political tension as to the manner in which these border checks are to be applied, which could (in the worst case) result in the EU implementing infringement procedures against the UK.

### **Transition Engine Deadlines**

The EU recently approved to extend the transition engine deadlines for power categories 56kW to 130kW (see dedicated article above). However, since Great Britain is now fully outside of the EU Single Market, these extensions will not apply to the GB market. A separate act of UK parliament would be required in order to implement a similar extension, which is not foreseen. However, since Northern Ireland remains in the EU Single Market, the extension would be applicable in that market.

### **Type-Approval Legislation – Great Britain**

There is still no information from the UK government on what the type-approval process will be for NRMM engines from 1 January 2022. The current arrangement, whereby EU type-approvals are accepted in the GB market, expires on 31 December 2021 but there is currently no legislation to replace it. Numerous UK-based trade associations are strongly urging that the UK quickly advises its intentions and then swiftly implements the legislation in order to minimise disruption and turmoil for industry.

## **Trade**

### **Steel safeguard**

Despite a lot of opposition in the industry and less support within Member States, the EU has finally decided to [prolong the safeguard measure](#) currently in place on imports of certain steel products. The prolongation will apply from 1 July 2021. The initial safeguard measure was introduced in July 2018 to protect the Union steel market against trade diversion, following the US decision to impose, under its Section 232 legislation, duties on imports of steel into the US market. The US Section 232 measures are still in force.

The decision follows a Commission's investigation that found that the safeguard measure continues to be necessary to prevent or remedy serious injury to the EU steel industry, and that the EU industry is adjusting to a market situation in the EU with higher level of imports. The Commission will however closely monitor the situation and make adjustments if necessary.

In line with WTO rules, the duty-free import quotas of steel will also be increased by 3% annually. The Commission will also initiate a review if the US introduces significant changes to its 'Section 232' measure on steel.

## **EU-US**

On the occasion of President Biden's visit to Brussels, the EU and the US held a high-level summit on 15<sup>th</sup> June, that marked a relaunch of the transatlantic partnership in a post-Trump era. Expressing their joint commitment to common values and interests, EU and US leaders agreed on a number of new joint initiatives and actions.

First, the EU and the US found an [agreement on the Airbus/Boeing dispute](#), which will suspend the application of the countermeasures by each side for a period of 5 years.

In addition, the two sides launched a Trade and Technology Council (TTC), a forum to coordinate approaches to key global trade, economic, and technology issues and to deepen transatlantic trade and economic relations based on shared democratic values. Avoiding new technical barriers to trade, cooperating on key policies on technology, digital issues and supply chains, supporting collaborative research, cooperating on the development of compatible and international standards and facilitating cooperation on regulatory policy and enforcement feature among the main objectives. In addition to high-level political meetings, the TTC will operate with several working groups.

In parallel, the EU and the US have set up a Joint Technology Competition Policy Dialogue that will focus on developing common approaches and strengthening the cooperation on competition policy and enforcement in the tech sectors.

Other important deliverables from the summit include a [cooperation agreement between the European Commission's Joint Research Centre and the US National Institute of Standards and Technology](#), which aims to expand cooperation and support collaborative activities different fields, notably emerging ICT and AI.

With 42% of both global GDP and global trade in goods and services, the EU and US enjoy the largest bilateral trade relationship in the world.



## Publications & events



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