



FEM Bulletin

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Saving self-declaration of conformity

Whereas recent EU proposals on AI, Battery and Machinery extend third-party conformity assessment, FEM fights to maintain a successful model that allows manufacturers to self-declare the conformity of their equipment to EU legal requirements

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FEM News

#FollowFEM Campaign



We are pleased to announce that we will carry out a #FollowFEM campaign that aims to encourage people to learn more about:

- our channels,
- our association,
- our members,
- and the wide range of activities within FEM

In addition to providing graphic materials and draft texts that our members can use to help us disseminate the campaign, we will also introduce a range of short interviews with key personalities in our network, providing a personal insight into experiences and activities in our sector.

The campaign will be carried out through FEM's [Twitter](#) and [LinkedIn](#), kicking off on **6 October 2021**.

With your support we can continue to grow FEM and make our voice heard! STAY TUNED!



Task forces activities

Machinery Directive

Following the publication of the FEM official [position paper](#) on the Machinery Regulation proposal on 7 July, the Secretariat and members have been actively promoting the key messages in the paper towards the relevant decision-makers in the European Parliament and Council. As a reminder, FEM notably focused its advocacy messages on the following three points:

1. countering the mandatory third-party certification for high-risk machinery and requesting that self-assessment remains an option (as long as all the relevant harmonised standards are applied)
2. raising concerns about the empowerment of the Commission to adopt technical specifications in case harmonised standards are absent or not delivered by the European Standardisation Organisations
3. Calling on the EU decision-makers to ensure and maintain coherence between the Machinery proposal and the AI proposal throughout the legislative process

Since mid-July 2021, FEM has organised meetings with three additional permanent representatives in Brussels (France, Bulgaria and Poland) and also with the policy advisor of the EPP Secretariat in the European Parliament, responsible for the machinery file.

Due to the good cooperation with the office of the Rapporteur (Ivan Stefanec) and the IMCO Secretariat, FEM was invited to speak at a stakeholder workshop on the Machinery Regulation, moderated by the Rapporteur. FEM will particularly touch upon the arguments against the obligatory third-party certification for high-risk machinery.

Finally, the FEM Machinery Directive Task Force held two meetings in September 2021 to start preparing concrete proposals for changes to the legal text. Two additional meetings are planned in October, with the aim of finalising the work on the FEM amendments by the end of October.

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](#), 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, FEM published in July its [position paper](#). Overall, FEM acknowledges the need to modernise the EU legislation on batteries and supports the objectives to strengthen the Internal Market through a common set of rules, promote circular economy, and reduce environmental and social impacts of

batteries. In addition, FEM strongly believes that the legislation must strengthen the competitiveness and sustainability of the Union's economy, in the simplest, most efficient, and effective way possible, whilst avoiding overregulation and unnecessary administrative burdens, and finally be designed to facilitate its transposition and practical application.

In concrete terms, we suggest a series of changes to decision-makers, notably:

- Establish clear definitions to ensure a common understanding for the implementation and enforcement of the future legislation
- Differentiate the manufacturing of cells from other manufacturing activities to apply sustainability requirements where they have the biggest potential impact
- 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
- Impose a battery management system only to industrial batteries suitable for second life and exclude industrial batteries that do not have integrated management system

Moreover, FEM co-signed an [industry statement](#), together with 10 other associations, calling on the European Commission and the co-legislators to ensure a transition period for the implementation of the Batteries Regulation. This statement was sent to key EU decision-makers including all MEPs from the involved committees.

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.

For recall, on the side of the European Parliament, the procedure and allocation of competencies suddenly changed at the end of April. 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 Simona Bonafè (S&D, IT) instead of Antonius Manders (EPP, NL). Competences are shared in four Committees and we have been reaching out the four committees according to their responsibility, multiplying the contacts and work. In addition, each committee follows a different timeline.

Discussions and votes in the respective four Committees are ongoing, the Industry Committee being the first one [to vote and adopt its opinion](#). The vote in plenary session is now expected on 26 January 2022.

In the Council, lively discussions are taking place in the Working Party on Environment. Although Member States have discussed most provisions of the Commission's proposal, they did not find compromises. There are still many disagreements, especially on Chapter 3 (Labelling and information requirements) and 8 (Electronic exchange of information). The Environment ministers will not discuss about the draft battery regulation in October but only on 20 December, and they wish to adopt the Council position on that day. In the meantime, you are kindly invited to share the FEM position paper with your national authorities.

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

1- Activities of the Task Force

On 19th July, FEM published its [position paper](#) on the AI proposal. The position notably raises the following issues:

- 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 requirements of the future Regulation should be revised to make them proportionate, enforceable, and respectful of companies' IPRs
- 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

FEM had the opportunity of discussing these issues with Kilian Gross, Head of the DG CONNECT Unit which developed the AI proposal. The discussion notably highlighted the fact that mandatory third-party conformity assessment for high-risk machines in the machinery proposal probably has its source in the risk-based approach of the AI proposal, and more specifically the definition of high-risk AI. This makes it likely that other types of product legislation (e.g. RED, EMC, LVD) could experience the same generalisation of third-party conformity assessment.

The position paper was also sent to the Council (current and future Presidencies' Permanent Representations - Slovenia and France), and to all main actors in the European parliament (Rapporteur, Shadow Rapporteurs and Rapporteurs for Opinion) with whom meetings are being set up over the next weeks.

The AI proposal is now assessed by the European Parliament and Council. However, the European Parliament's legislative timeline is still unclear, as a result of discussions on the lead Committee. The process is therefore expected to carry on well into 2022.

FEM, working together with Orgalim, keeps a close eye on these developments, and in particular on the consistency with the Machinery Proposal.

2- Legislation

On 15 September, the European Commission presented a proposal for a "Digital Compass Policy Programme". This Policy Programme, named Path to the Digital Decade to deliver the EU's digital transformation by 2030, will:

- Impose an obligation for the Commission and the Member States to cooperate to achieve a set of digital targets on digital skills, digital infrastructures, digital transformation of businesses and of public services).
- Set up a governance structure for the achievement of these targets, including a monitoring and reporting system. The monitoring system will be based on an enhanced Digital Economy and Society Index (DESI), as well as annual report to the Parliament and the Council by the Commission.

- Create a mechanism to incentivise Member States to organise and work together on Multi-Country Projects to build Europe's capacities in critical areas and to accelerate large technological projects.
- Establish a stakeholder forum, composed of private and public actors, to gather technical input, conduct outreach activities and provide feedback on the necessary measures for accelerating digitisation in the EU.

As a reminder the digital targets for 2030 as defined in March 2021 are:

- **A digitally skilled population and highly skilled digital professionals:** at least 80% of those aged 16-74 have at least basic digital skills; at least 20 million information and communications technology (ICT) specialists are employed, with convergence between women and men;
- **Secure, performant and sustainable digital infrastructures:** all European households are covered by a Gigabit network, with all populated areas covered by 5G; the production of cutting-edge and sustainable semiconductors in the Union is at least 20% of world production in value; at least 10 000 climate neutral highly secure "edge nodes" are deployed in the EU, distributed in a way that guarantees access to data services with low latency (few milliseconds) wherever businesses are located; by 2025, the EU has its first computer with quantum acceleration, paving the way for being at the cutting edge of quantum capabilities by 2030. –
- **Digital transformation of businesses:** at least 75% of EU enterprises have taken up: cloud computing services, big data and artificial intelligence; more than 90% of EU SMEs reach at least a basic level of digital intensity; the EU grows the pipeline of its innovative scale ups and improves their access to finance, leading to at least doubling the number of unicorns;
- **Digitalisation of public services:** 100% online accessible provision of key public services for EU citizens and businesses; 100% of EU citizens have access to their medical records (electronic health records); at least 80% of EU citizens use a digital identification solution.



EU legislative issues

General Issues

New Legislative Framework

In the framework of the ongoing NLF evaluation study, FEM was invited to take part in an online interview with CSES (consultancy in charge of the study) which took place on 7 September.

FEM's general feedback on the NLF was positive, stressing that it has been an essential tool in support of a well-functioning Internal Market ensuring free movement of goods (via harmonised conformity assessment procedures, CE marking rules, common definitions etc.). FEM also outlined the benefits of harmonised standards but pointed out that there are current bottlenecks with the adoption and citation processes creating backlogs, which are generating difficulties and costs for the manufacturers.

It was also stressed that market surveillance could be improved, especially for B2B products. In terms of the link between digitalisation and NLF, FEM made the point that digital risks are already part of OEM's risk assessment and that one solution to facilitate administrative compliance is given by current provisions on digital documentation (e.g. electronic DoC). Regarding efficiency, the self-certification costs are clearly outweighed by the benefits of having a harmonised framework such as the NLF. On the other hand, there is a risk of incoherence that could be created by some provisions in the current Machinery proposal (third party certification for high-risk machines, technical specifications).

As for next steps, it is estimated that two online consultations (public and targeted) will be launched in October. The draft final report is then expected in January, and the final report, in March/April.

Whereas the Commission is preparing a new strategy on standardisation and at a time when the New Approach principles of self-assessment of conformity and use of harmonised standards are threatened in some recent proposals (Machinery, AI), the NLF evaluation is of utmost importance to preserve a model that has overall successfully supported European manufacturers.

Trade

EU-US

The EU-US Trade and Technology Council (TTC) met for the first time in Pittsburgh on 29 September. The meeting was a first occasion to touch upon the different topics identified back in June when the TTC was established.

EU and US call for appropriate enforcement mechanisms of their investment screening mechanisms on **Investment screening**. They have also determined shared principles and areas for **export control** cooperation.

On **AI**, the two sides affirm their willingness and intention to develop and implement AI systems that are innovative and trustworthy, and that respect universal human rights and shared democratic values.

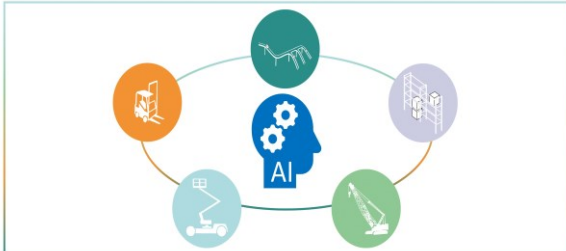
Moreover, EU and US commit to build a partnership on the rebalancing of global supply chains in **semiconductors** with a view to enhancing respective security of supply as well as their respective capacity to design and produce semiconductors.

Finally, on **Global trade challenges**, the two blocs intend to work closely together to address non-market, trade-distortive policies and practices, improve the effectiveness of their respective domestic measures that address those policies and practices, and explore ways to combat the negative effects of such policies and practices in third countries. The EU and the US also want to avoid new and unnecessary barriers to trade in new and emerging technologies.

For more information, see the [joint statement](#) and [factsheet](#).



Publications & events

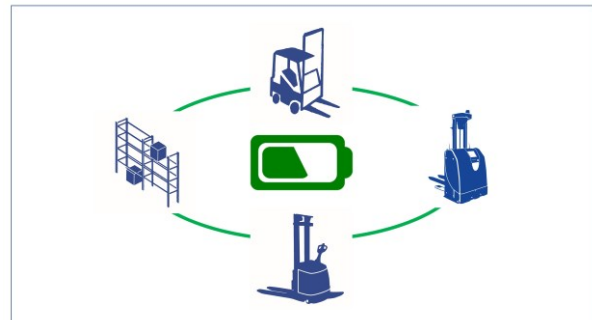


POSITION PAPER ON AI

On 19 July, FEM presented its position on the proposal for a Regulation on “A European Approach to Artificial Intelligence” presented by the European Commission in April 2021. A summary of our position and the full paper are available [HERE](#)

POSITION PAPER ON BATTERIES

On 13 July, FEM commented on the European Commission proposal for a Regulation on batteries and waste batteries and suggested a series of changes to decision makers. A summary FEM comments and the full paper are available [HERE](#)



JOINT INDUSTRY STATEMENT



FEM co-signed an industry statement, together with 10 other associations, calling on the European Commission and the co-legislators to ensure a transition period for the implementation of the Batteries Regulation. Click [HERE](#) for the full statement.

This newsletter is reserved to FEM members

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