

Proposal for a Regulation on Machinery Products

JBCE's position

Japan Business Council in Europe (JBCE) welcomes the proposal for the Regulation on Machinery Products, new legislative framework (NLF) and to reduce the costs of transposition with the choice of a Regulation.

To contribute to a clearer and more efficient Regulation, JBCE members would like the European Commission to consider the following recommendations:

Harmonisation & alignment with EU law

JBCE is satisfied to see the overall aim of enhancing harmonisation. Indeed, coherence and alignment must be guaranteed, not only with other Directives/Regulations under the NLF, but also with AI¹ and Cybersecurity-related legislative initiatives such as NIS2². By working towards a maximum harmonisation framework, the co-legislators indeed help provide legal certainty and to lower implementation costs or risks of diverging interpretation of the law between different enforcing authorities. This is very valuable for entities which operate in several Member States, as is the case for many JBCE members.

AI and Cybersecurity issues

On this topic, it is crucial to avoid overlaps and ensure alignment with the latest EU legislative initiatives.

- **On the topic of AI or human-robot collaboration:** JBCE believes that the Machinery Regulation is not the regulatory instrument to cover the safety of human-robot collaboration, AI or IoT. JBCE believes the Machinery Regulation should focus on essential health and safety requirements, which must themselves be set in a technologically neutral way, and independent from user cases.
- **On the topic of cybersecurity:** the Machinery Regulation focuses on the safety and the placing of products on the EU market - which is a very different objective than making products more secured against cyber-attacks. Therefore, for JBCE, the Machinery Regulation is not the appropriate legislative instrument to include mandatory cybersecurity requirements. Instead, JBCE recommends that cybersecurity requirements for manufacturers of machinery be implemented in the EU via voluntary certification and labelling, for instance through the Cybersecurity Act and be based on existing international standards (e.g. ISO 27001).

This concern on the application of AI and cybersecurity requirements in sectorial product safety legislation is valid for the proposal for a Machinery Regulation, but from a broader perspective **it is also valid for other pieces of NLF legislation**. NLF legislation should remain focused on safety, remain technology-neutral when possible, and not include cybersecurity or AI requirements. Indeed, the scope of each NLF Directive/Regulation is different and there is a high risk of diverging / conflicting rules for the same products, which further complexifies the inclusion of Cybersecurity or AI requirement in these individual texts. Instead, **a horizontal overarching framework such as the Cybersecurity Act** will therefore be more efficient than

¹ Input submitted by JBCE to “Artificial intelligence – ethical and legal requirements”, European Commission “Have your say” portal, September 2020 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F550904_en

² JBCE position on “NIS2”, JBCE website, March 2021 <https://www.jbce.org/digital-innovation/feedback-to-nis2/>

specifying cybersecurity requirements in each Directive/Regulation independently – thus minimising the room for divergence, contradiction and confusion for authorities and stakeholders alike.

Scope and definitions

JBCE welcomes the flexibility of the Regulation to cover innovations and new technologies, but wants to stress that it is important to keep technology-neutrality at the core of the Regulation.

The Machinery Regulation proposal adds a new indent in the definition of machinery that includes assembly missing only the upload of a software: the place of software update in the proposal is important for JBCE, as we believe that software is not always part of compliance, so it is not the right legislative vehicle to regulate software update in the framework of the Machinery Regulation; instead, it would work better if handled separately.

Conformity assessment

According to the new proposal, third-party conformity assessment is mandatory for high-risk machinery listed in Annex I, even when manufacturers apply the relevant harmonised standards.

On this topic, JBCE is concerned that mandatory third-party conformity assessment will increase costs, create more administrative burden for companies and authorities, and increase the time required to access the market. JBCE would be in favour of retaining the self-assessment option, which indeed has worked well for manufacturers under the previous Machinery Directive.

International standardisation

Art.17(2) of the Machinery Regulation proposal sets out that the Commission shall request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III. This can be supplemented in certain cases detailed in art.17(3) by technical specifications adopted as implementing acts – this scenario being envisaged as a “fall-back option to be used only in cases the standardisation bodies are not able to provide standards or provide standards that do not respond to the Commission standardisation request”.

The topic of standardisation is key for JBCE members. JBCE supports the preparation of harmonised standards in the Machinery Regulation and calls the Commission to work and align with international ISO/IEC standards when drawing up standardisation requests and recognising harmonised standards. This approach is helpful in ensuring a level-playing field in the EU without putting an excessive burden on some companies present in different markets. JBCE also calls on the Commission to refrain from adopting technical specifications as alternatives to harmonised standards, and to prioritise the adoption of harmonised standards in all situations.

Enforcement

JBCE welcomes in the new Regulation proposal the reduced paper-based requirements for documentation, and the openness for digital documentation and instructions. This flexibility is very much appreciated, especially in B2B transactions where many clients have varying requests depending on products. JBCE believes that introducing online or electronic manuals is a good method to reduce costs in the long term, even though there are variations per products.

However, JBCE members have flagged concerns about lack of clarity on the exact modalities of digital format:



- Under Annex III - 1.7.4 ((a), (b) and (c)), it is acceptable to provide instructions in a digital format, these paragraphs setting the more precise modalities. However, it is unclear if the EU Declaration of Conformity (as referenced in Annex V) may also be accepted in a digital format.
- In addition, there should be a clear confirmation in Annex III - 1.7.4.2 (c) that the “EU declaration of conformity” (which can be accessed from the internet address provided) refers to the EU declarations of conformity described in Annex V for machinery products and for partly completed machinery.

About JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.

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