EUnited feedback on the proposed machinery products regulation COM(2021) 202 final

16 August 2021

Introduction

EUnited welcomes the opportunity to provide feedback on the proposed machinery products regulation COM(2021) 202 replacing the Machinery Directive 2006/42/EC. The Machinery Directive (MD) is a cornerstone and key reference for all industry sectors represented by EUnited. Furthermore, the MD has created legal certainty and a high level of harmonisation for our manufacturers over decades when selling into the European Single Market.

Therefore, the proposed machinery products regulation is equally important for the future of our industry in Europe and will determine whether the European Single Market will remain an attractive marketplace for our sectors to invest as well as to deliver jobs, growth and continued innovation.

The harmonised access to the Single Market and legal requirements in the proposed regulation will impact on how the EU compares to other regions in the world at a time when the twin transition towards the green and digital economy transforms our industries. Combined with the impact of the pandemic and economic recovery plans it is of paramount importance to ensure that the machinery products regulation continues to provide first and foremost legal certainty and continued proportionate market access requirements based on Harmonised Standards and presumption of conformity.

In particular Small and Medium Enterprises represented by EUnited, often market leaders in their field, cannot afford to substantially change established procedures and processes that have ensured the highest level of safety and compliance of their equipment over the last decades, unless there are justified and substantial reasons to do so.

Please find below EUnited's feedback on the proposed machinery products regulation:

Harmonisation, modernisation and alignment to the New Legislative Framework

EUnited welcomes the proposal to turn the MD into a regulation which is directly applicable in national law; this is likely to eliminate many issues occurring during the transposition of European directives into the national bodies of law. It is also likely to increase the level of harmonisation and thus legal certainty when marketing machinery products in the Single Market, a key condition for a well-functioning and attractive European marketplace.

In this context, the alignment of the MD to the New Legislative Framework is equally welcome as it will further harmonise the terminology used and applicable procedures as well as accompanying guidance which is crucial for creating certainty for economic operators and market surveillance authorities. Furthermore, EUnited supports the proposal towards the digitalisation of instructions and the new Essential health and safety Requirements (EHSR) in order to promote a level playing field.

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Harmonised Standards vs. Technical Specifications

The European Standardisation System (ESS) is the cornerstone of the Single Market for products, including machinery. Harmonised Standards have played over decades a crucial role to provide clarity on how to meet the essential requirements for selling into the Single Market and are the most important tool to provide presumption of conformity for manufacturers.
The use of Harmonised Standards allows manufacturers to ensure compliance of their machines and to self-declare that their machine is meeting all essential health and safety requirements to be marketed in the Single Market.

While recent years have seen for several sectors significant delays and issues with the availability of Harmonised Standards industry strongly recommends to continue using standards provided by the European Standardisation Organisations (ESO) or international standardization organisations rather than allowing the European Commission to mandate European technical specifications that have an equal legal standing to Harmonised Standards.

The implementation of such specifications creates double standards and undermines and devalues the well-functioning ESS and relevant international standardisation work; ultimately even leading to a potential disconnect of the Single Market from internationally recognised standards representing the state-of-the art.

Recommendation:
Deletion of Article 17 (3) that empowers the European Commission to adopt implementing acts establishing technical specifications for the essential health and safety requirements set out in Annex III.

Self-assessment vs mandatory 3rd party certification

European engineering industries are often global leaders in their domains and as such key innovators that constantly improve their products. So far the MD has thus provided a balanced and well-functioning framework for marketing machinery in the EU.

Based on this positive experience and compliance record it is hard to follow the European Commission's reasoning for why to break with the past by removing the option for manufacturers to self-ass and to declare compliance. Instead the European Commission introduced mandatory third-party certification for all machines in Annex I; under the MD these machines could instead be self-assed and declared compliant provided that the applicable Harmonised Standards were used.

One needs to keep in mind that the manufacturer is the only economic actor that is responsible for the machine and actually makes the product safe, not a third-party. Hence, third-party certification should remain a tool at disposal of the manufacturer as it is essentially a commercial choice, and thus should remain voluntary. Furthermore, there is also no difference in regard to the standards manufacturers and third-parties usually rely on for assessing compliance, namely again Harmonised or equivalent international Standards. However, mandatory third-party certification is clearly a relevant cost driver for manufacturers and in particular SMEs, it also adds time and complexity to marketing a product in the Single Market.

Finally, third-party certification is not a remedy for a lack of chronically under-resourced Market Surveillance in many EU Member States which is key for ensuring a level-playing field for all economic operators. Additional burdens and requirements before being able to sell in Europe will not eliminate unsafe products, but likely increase costs for diligent manufacturers and complexity for SMEs that cannot afford the extra legal advice, additional testing or certification while still having to sell at a competitive price in an increasingly globalised market.

Recommendation:
The provisions in articles 5 and 21 for machinery referred to in Annex I, should maintain the option to self-assess the machine and declare compliance provided that the machine has been manufactured in accordance with the applicable Harmonised Standard cited in the OJEU.

"High-risk" machinery

The machinery products listed in Annex I of the proposal are essentially copied from the machinery directive Annex IV with the addition of AI enabled machines. Such machinery is now all over sudden listed as "High-Risk Machinery Products". This terminology and categorisation is misleading as it suggests that products that have been legally marketed for years, would when the new regulation becomes applicable suddenly turn into high-risk products.

Unfortunately, this change may be caused by wanting to "align" the proposed regulation to the proposed AI ACT which mainly regulates "High-Risk AI". However, it is equally questionable whether most AI applications or embedded AI used in machinery today, really constitute a high-risk AI/machine. Furthermore, the two proposals may have involuntarily created a "loop situation" whereby the mandatory 3rd party certification for many, so-called high-risk machinery (even when Harmonised Standards are applied) may mean that embedded AI will automatically have to be 3rd party assessed under the AI Act and separately declared, thus qualifying it as High-Risk AI. In return any embedded high-risk AI under the definition of the AI Act may turn a non-high-risk machinery by default into a high-risk machinery and again require a third-party certification under the machinery products regulation.

Finally, we need to avoid a situation whereby the conformity assessment made by the AI provider needs to be repeated by the machinery manufacturer. A unnecessary duplication of conformity assessments undermines the foundations of marketing products in the Single Market, while adding significant burdens for manufacturers without improving the safety of the machine.

In conclusion, it is unclear how the relationship between high-risk obligations and conformity assessment procedures under the AI Act and machinery products regulation would be handled in practice in future. This may unfortunately have additional unforeseen and unintended consequences that may significantly raise the bar for marketing machinery in the Single Market. The related uncertainty in the marketplace, cost increase and burdens of such new obligations may be too much for SMEs to internalise in a highly competitive environment.

Recommendation:
Remove the title of Annex I and replace it with a neutral title. Remove in article 5 the mandatory third party certification obligation, by reintroducing the option of self-assessment based on applicable Harmonised Standards. Clarify the relationship between the AI Act and machinery products regulation.

Managing the transition from machinery directive to a regulation

The proposal establishes that 30 months after its entry into force the new Regulation will be applicable without any transitional period for products being placed on the Single Market.
This would constitute a sharp "cut-off" date from one day to another that will effectively create lots uncertainty in the marketplace and is a worst case scenario for manufacturers, in particular SMEs that will struggle to manage such an anomaly in their business. This situation would be aggravated if the proposed mandatory third-party certification would be included, not to talk about the necessary revision and new citation of hundreds of new Harmonised Standards under the new regulation. The foreseen 12 months transition period for making products available already placed on the Single Market is equally far too short for the B2B market.

Hence, SMEs will need to be able to manage the transition over a sufficient period of time of at least 3 years during which manufacturers can choose whether to place machinery products on the market according to the obligations in MD or according to the new Machinery Products Regulation. It is of utmost importance that the Harmonised Standards are ready at the moment when manufacturers need to apply the new Regulation, namely at the beginning of the transitional period, otherwise a managed transition will not be possible.

Recommendation:
Allow in article 49 and 50 for a sufficient time for manufacturers to adapt to their new legal obligations, including 3 years for transitioning from the MD to the regulation; hence, EU Member States shall not impede the placing on the market or putting into service of machinery products which were in conformity with Directive

2006/42/EC and which were placed on the market or put into service before 66 months after the date of entry into force of the new Regulation.

Substantial modification definition

The proposed definition of 'substantial modification' in article 3 is in EUnited's view too broad and may deter owners from making modifications to their machinery, which could otherwise improve user safety, performance or extend the lifespan of the machinery product.

Recommendation:
To amend article 3(16) as follows: *'substantial modification' means a modification of a machinery product, **except partly completed machinery,** by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements ~~**maybe be**~~ **is** affected.*

Specific comment on annex III, 2.2.1.1: supplementary EHSRs

Under 2.2.1.1. in the ESHR EUnited members are concerned that that the proposed changes concerning vibrations (2.2.1.1 intro as well as point a), b) and c) would lead to confusion as well as legal uncertainty and would not increase the safety of workers.

With the changes proposed, the Machinery Regulation would no longer be aligned with 2002/44/EC. Article 3 of the 202/44/EC Directive sets the daily exposure action value at 2.5 m/s², standardised at a reference period of 8 hours. The reference to manufacturers' data is made in Annex A (hand-arm vibrations): "The assessment of exposure may be carried out by means of an estimate based on the manufacturer's data concerning the level of vibration caused by the work equipment used... or by measurement." These declared values would be useless for workplace risk assessments:

- For vibration values measured below 2.5 m /s², the uncertainty in many cases will be higher than the declared/measured value.
- The proposed requirement would mean that for all hand-held and hand-guided machines both values would have to be declared, but not all machines show repeated shock events (e.g. a screwdriver does not show repeated shocks).
- Repeated shock is not defined concerning frequency and duration. This would lead to high level of legal uncertainty for manufacturers on what is covered and not.
- There is no epidemiological evidence for equal treatment of vibration and single impact (shock) concerning the effects on a human hand arm system.
- For repeated shocks, there is no harmonized EN standard available how to measure. This would lead to incomparable data and legal uncertainty.

If new scientific data should underpin the need, a revision of vibration regulation 2002/44/EC should be prioritized, before reforming this aspect at product level. This would have the advantage of guaranteeing consistency and providing enough time to create/adapt necessary measuring standards to comply with new requirements.

Recommendation:
Keep the existing text on 2.2.1.1 of 2006/42/EC, namely:
The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:
- the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s2. Where this value does not exceed 2,5 m/s2, this must be mentioned,
- the uncertainty of measurement.

Specific comment on annex III, 3.2.4. Supervisory control function: supplementary EHSRs

This generalised introduction of a supervisory control function on autonomous mobile machinery products does not take into account that especially smaller, lighter, slow moving autonomous mobile machinery without dangerous exposed moving parts (like robotic lawn mowers, cleaning robots, service robots, all typically used in areas open to the public) are easily controllable by touching control elements placed directly on the machinery product if necessary.
Such a requirement for special applications could be defined in standardisation, but should not become part of the legal text.

Recommendation:
Deletion of annex III, 3.2.4.

About EUnited

EUnited connects machinery and equipment companies in one association to improve awareness and understanding among decision-makers and policy actors in the European Union institutions. Equipment suppliers are the mainstay of advanced manufacturing, increasingly recognized as indispensable for the basic every day needs of European citizens.

We speak for companies that design and produce specialist machinery and equipment operated in advanced factories all over the word to produce, to automate and monitor, to transport, to recycle, to power, or for cleaning and maintenance purposes. A vast range of industrial and consumer goods and innumerable processes along complex supply chains (from extraction to re-use) depend on advanced manufacturing equipment, which largely determines performance in terms of productivity, energy and resource utilisation.

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