POSITION PAPER

Brussels, 16 August 2021

Orgalim's input to the European Commission Consultation on the proposal for a new Machinery Products Regulation "Machinery Directive Revision"

Executive summary

Orgalim represents Europe's technology industries, a dynamic and highly competitive sector that relies on European Union harmonisation legislation for its success. Orgalim also acts as an industry platform (our Machinery Task Force includes stakeholders from outside our membership) and adviser to the European Commission on the machinery topic. Our industries welcome the Commission's proposal for a Regulation on machinery products (hereafter "the Regulation"), but also have a number of concerns. This input into the Commission's consultation addresses key points for our industry.

We welcome:

- Alignment to the New Legislative Framework (NLF) and transposition into a Regulation
- Digitalisation of instructions, EU Declaration of Conformity and technical documentation

We call for changes on the following points:

- Preserve module A for Annex I machinery manufactured in accordance with harmonised standards
- Remove the misleading description "high-risk machinery" in favour of a more neutral term and better rules for the amendment of the list in Annex I
- Ensure coherence between the AI and Machinery Regulations for conformity assessment
- Clarify the characteristics of substantial modification
- Ensure essential health and safety requirements that are technology-neutral
- Remove the Commission's power to develop technical specifications via implementing acts instead of relying on harmonised standards
- Extend the use of digital formats to the declaration of incorporation and assembly instructions
- Amend provisions for entry into force and the transition period

1. Introduction

Orgalim, representing Europe's technology industries, welcomes the opportunity to comment on the European Commission's proposal for a Regulation on Machinery Products (hereafter, "the Regulation"). The current Machinery Directive 2006/42/EC is the core legislation regulating the mechanical engineering industry. In our view the current Machinery Directive represents an example of successful European Union harmonisation legislation, providing a high level of safety and ensuring the free flow of goods within the Single Market.

It is important that the future legislative framework continues to support harmonisation within the Single Market and the development of standards to promote innovation. Orgalim has provided input on possible policy directions over the past years, including most recently our comments to the Commission's indicative proposal which we submitted to the Commission's Machinery Working Group on 9-10 November 2020. This paper aims to share our key observations and asks on the draft Regulation.

2. Aspects to be welcomed

We welcome the transposition into a Regulation to ensure unified applicability. We support the legal clarifications that the proposal brings to some of the current provisions through the alignment of the Regulation to Decision 768/2008 (NLF). One example of this is the alignment of the definitions in Article 3. It will also be important to ensure that no new legal uncertainties and inconsistencies between new and existing legislation arise during the revision. For example, the definition of Artificial Intelligence should remain consistent across relevant EU legislation.

We also welcome the shift to increased digitalisation of the instructions and the EU Declaration of Conformity. However, as outlined below, more is needed.

3. Focus areas during the legislative process

3.1. High-risk machinery

We consider that the designation "High-Risk Machinery Products" risks creating confusion and impacting the position of European manufacturers. Such a designation suggests that machines covered by Article 5 and listed in Annex I would pose a high risk during use. However, this is not the case, as the legislation forbids the sale of machinery that poses a high risk. According to the current legal provisions, which have been successfully applied in practice since 1 January 1993, only machines whose risks have been eliminated or reduced to the lowest possible level on the basis of the state of the art may be marketed.

We therefore find it problematic that some products would be labelled "High-Risk" under the draft Regulation. Such a designation would be misleading for customers and damaging to the reputation of European manufacturers. Furthermore, we believe a clear definition of the machinery designated in Article 5 is necessary. This is especially important as the Commission will have the power to amend Annex I in view of technical progress. Clear criteria are necessary to better understand the process by which new machinery types will be added, and to foster transparency and stakeholder involvement in this process.

Therefore, we propose to change the title of Article 5 to "Machinery Products that may be intended for certain conformity assessment procedures" and to add clear criteria to identify the types of machines that this article refers to.

3.2. Conformity assessment for high-risk machines

In the current Machinery Directive, one of the three possible conformity assessment procedures for manufacturers to demonstrate the safety of machines referred to in Annex IV is to use internal production controls (Module A as defined in Decision 768/2008). When a manufacturer applies a Module A conformity assessment, this means that the machinery has been manufactured in accordance with a harmonised standard (that has been cited in the Official Journal of the European Union) and the manufacturer has ensured that the relevant Essential Health and Safety Requirements (EHSRs) are applied. This is outlined in the Machinery Directive, Article 12 (3). Module A is currently the most used and efficient procedure for our industry.

The EHSRs laid out in Annex I of the Directive (Annex III of the draft Regulation) provide concrete safety requirements that all machines have to adhere to[1] and harmonised standards provide a recipe to implement technical solutions that comply with the state of the art.

The draft Regulation requires third party certifications (module B+C or module H) for machines listed in Annex I. This fundamentally changes the current practice and would have massive implications for the affected machinery manufacturers, in particular SMEs, due to increased costs and lead times:

- Module A offers the same level of safety as the conformity assessment procedures supported by a third party (e.g. a notified body) given that these third parties perform the conformity assessment using the same harmonised standards and assess the EHS requirements based on the same Regulation. There is no concrete market evidence that would support a hypothesis that such third-party certifications increase safety. However, the costs of using a third party for conformity assessment are real and extensive.
- We also fear increasing lead times as both manufacturers and notified bodies will be faced with additional logistical challenges, due to a potentially significant increase in demand. An essential success factor for any manufacturer, and particularly for seasonal businesses, is the ability to bring products to market in an agile manner.

Adding costs, delays and red tape without a discernible benefit for product safety, at a time when the industrial backbone of Europe's economy is still struggling to recover from the Covid-19 crisis, would be deeply counterproductive and risks undermining European industries' ability to compete globally.

Removing the possibility of internal production controls would also significantly decrease the added value of harmonised standards for manufacturers, which in turn risks affecting the participation and motivation of European companies to develop and maintain quality standards for high-risk machinery through the European Standardisation System.

We therefore propose that Articles 5 and 21 for machinery referred to in Annex I should maintain the option of applying module A, as set out in the current Machinery Directive's Article 12 (3), reverting to the current language of the Machinery Directive.

[1] see an analysis of how the current Annex 1 (EHSR) of the MD continues to meet the objectives regarding safety for new technologies in our past paper

3.3. Coherence between the Regulations on AI and Machinery Products

The Regulation was released in a package with a proposal for an Artificial Intelligence (AI) Regulation. As the proposals will be following separate legislative procedures, it will be essential to ensure coherence to maintain a stable and harmonised legislative framework. To that end, we propose improvements regarding the AI Regulation that will also be important for the Regulation:

1. The current definition of "AI systems" is very broad and does not provide legal certainty for the future development of AI systems. Orgalim proposes the definition of AI outlined in our previous position papers:

   AI refers to computer systems based on algorithms designed by humans that, given a complex task, operate by processing the structured or unstructured data collected in their environment according to a set of instructions, determining the best step(s) to take to perform the given task, via software or hardware actuators. AI computer systems can also adapt their actions by analysing how the environment is affected by their previous actions.

   This definition is similar to the one given by the Commission's High-Level Expert Group on AI, of which Orgalim was a member. It insists on the human origin of any AI and highlights the fact that a machine can only perform an action assigned from the outset by a human – whether a designer, computer specialist or manufacturer. This "narrow AI" has been deployed effectively and safely in manufacturing for many years.

2. We are also concerned about the inclusion of item 25 (machines embedding AI systems with a safety function) in Annex I. We believe that this category needs to be clarified to ensure that only those AI applications that are intended to provide safety functions are covered. This criterion is especially important to prevent the need for the conformity assessment made by the AI provider to be repeated by the machinery manufacturer. Such a duplication of conformity assessment efforts would contradict the good functioning of the CE system, adding to the manufacturer's burden without benefitting the safety of the machine.
3. Finally, the requirement of Article 9 of the AI Regulation implies a continuous risk management system run throughout the entire life cycle of a high-risk AI system, which goes beyond the current provisions of the NLF. The current legislative framework requires manufacturers to make sure that the product will remain safe throughout its life cycle at the moment it is placed on the market (sold for the first time on the EU market)[2]. After that, the product falls under other EU legislation, such as the Product Liability Directive 85/374/EEC or the Use of Work Equipment Directive 2009/104/EC unless a substantial modification is made (see below).

We believe that the conformity assessment procedure for machines (including those that integrate AI systems) should be limited to one instance and should happen before they are placed on the market.

[2] Sold for the first time in the EU - Article 3 (12) of the proposal;

3.4. Concept of substantial modification[3]

When modifications are made to a product after they are placed on the market, new risks may occur. If these new risks were not present during the original conformity assessment, the modification is considered substantial and a new conformity assessment should be undertaken by the entity that carries out the modification for the parts that were modified.

Orgalim welcomes the proposal for a definition of substantial modification in the draft Regulation. However, the definition needs to be clearer to limit the cases where a modification becomes "substantial" and to avoid discretionary implementation. In particular, the phrase "as a result of which the compliance of the machinery product with the relevant essential health and safety requirements *may be* affected" implies a possibility rather than a certainty. As drafted, the Regulation would leave as the only unambiguous criteria the fact that the modification was not foreseen by the manufacturer. In order to take into account the approach of the Blue Guide, new or increased risks should be clearly indicated as the criteria. We also consider that the proposed broad definition would deter owners from making modifications to their machinery which would otherwise improve user safety or performance, or would extend the lifespan of the machinery product.

Furthermore, it is important to have clarity on who is responsible for the regulatory consequences in the case of a substantial modification. We consider it positive that dealers, importers and subcontractors performing substantial modifications would have the responsibilities of manufacturers (obligation to carry out new conformity assessment and take responsibility for the modification) in accordance with Articles 14 and 15. However, it is important to assign the responsibility for a substantial modification where it is due. Modifications usually consist of two phases: an engineering/design phase and a work phase to carry out the actual modification (for example: the activities in the workshop, uploading the software). The ultimate responsibility should be contractually assigned within the work agreement.

Therefore, we propose to use a direct verb in the definition "a modification (…) as a result of which the compliance (…) *is* affected". To improve clarity with regard to responsibility we suggest amending Article 15 to allow contractual obligations to define the responsible party for the regulatory consequences of the modification.

3.5. Maintaining technology neutrality

The technology neutrality of the current Machinery Directive has helped our companies to become undisputed global leaders in their fields, while maintaining the highest level of safety for their machines.

The introduction of new essential health and safety requirements for digital technologies into the legislative text (especially on cyberattacks, cybersecurity when impacting safety, human-machinery interaction, machines with evolving capacity, the supervision function on autonomous machinery etc.) risks undermining the Regulation's continued technology neutrality. We recognise that these are important topics but believe that they should be addressed in standards that are voluntarily applicable. Setting broad requirements in the legislative provisions will limit these evolving technologies.

We recommend that the new requirements in Annex III should be technology-neutral according to the philosophy of the current legislation.

Specific proposals will be provided in the upcoming Orgalim proposals for amendments.

[3] The Orgalim position on substantial modification is not aligned with that of our member association FIM.

3.6. Commission empowerment to develop technical specifications

The draft Regulation puts forward an alternative to the use of harmonised standards, in the form of technical specifications developed via implementing acts. These technical specifications would grant presumption of conformity in cases where harmonised standards are unavailable or delayed.

We believe that the introduction of a parallel process to developing harmonised standards is unnecessary, for the following reasons:

- The release of technical specifications requires specific technical know-how of the state of the art that might not be available within the Commission. The European Standardisation Organisations, in contrast, possess this know-how, because they can draw on the expertise of a wide range of stakeholders including users, market surveillance authorities, notified bodies, academia and industry.
- The procedures to develop technical specifications through implementing acts are not clearly established. If the Commission intends to hire technical experts to elaborate such technical specifications, it will lead to a parallel system with the existing standardisation system and would impact inclusiveness and transparency.
- Although technical specifications adopted via implementing acts are voluntary in their application, like harmonised standards, we believe that these specifications are likely to be seen as being de facto mandatory by the manufacturers. This would disrupt the underlying idea of the NLF that requirements are defined in the legislation, while details are developed in the standards. Furthermore, manufacturers could find it difficult to deviate from the technical specification, negatively impacting product innovation processes.
- Finally, the developing of technical specifications through implementing acts risks leading to a misalignment with the technical solutions provided by international standardisation organisations and the erosion of the market relevance of European standardisation.

To that end, we propose to delete Article 17(3) of the proposal.

3.7. Digital formats to be used exclusively and extended to partly completed machinery

As already mentioned, we welcome the flexibility that the proposal introduces, allowing instructions and declarations of conformity (if a copy is included in the instructions) to be accessible through digital formats – at least as a default option.

However, we would prefer the advanced status of digitalisation in the EU to be fully taken into account, and the instructions to be made available exclusively in digital format.

Furthermore, the possibility to provide instructions and the declaration of conformity in digital format needs to be extended to the declaration of incorporation and the assembly instructions for partly completed machinery. This is important to maintain consistency and improve information flow.

To that end, we propose to add a paragraph in Annex X to specify that the declaration of incorporation and the assembly instructions for partly completed machinery should be made available in a digital format.

3.8. Provisions for entry into force and the transition period

With regard to the proposed transitional provisions according to Article 50, we have the following concerns:

1. The current proposal for the transition period in Article 50 seems to confuse the concept of **placing on the market**[4] (i.e. sold for the first time on the EU market) and **making available** (i.e. any sale other than the first)[5]. According to the current wording, machines manufactured in accordance with 2006/42/EC could no longer be made available at all "42 months after the date of entry into force". This will effectively stop the sales of second-hand machinery on the EU market.
2. Given the significant changes to the conformity processes proposed by the new Regulation, and building on our experience in other legislative revision processes, the industry needs a period to prepare for the application of the new regulation. Therefore, we welcome the 30 month period **preceding** the application of the new Regulation to align the harmonised standards, for manufacturers to prepare their industrial processes, and for national authorities to adapt to the new requirements.
3. However, a transition period of at least **24 months** is needed during which manufacturers can choose whether to continue to place products on the market according to Directive 2006/42/EC or according to the new Regulation. A drastic cut-off, as proposed in the draft Regulation, is impossible to work towards, as manufacturers cannot prepare products with such a precise timeline and resellers would be left with a large amount of unsold stock. Therefore, we suggest to amend Article 49 to "54 months", so that Directive 2006/42/EC is not repealed on the same day that the new Regulation becomes applicable.

Therefore, we suggest to modify Articles 49 and 50. Specific proposals will be provided in the upcoming Orgalim proposals for amendments.

4. Conclusion

Orgalim believes that the proposals suggested in this position paper would contribute to a clearer regulatory environment for this important industrial sector. We look forward to working with all stakeholders involved to build a future Regulation that provides both a high level of safety and ensures the free flow of goods in one of the most dynamic and competitive sectors of Europe's industry.

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[4] Article 3 (12) of the proposal: "placing on the market" means the first making available of a machinery product on the EU market;
[5] Article 3 (11) of the proposal "making available on the market" means any supply of a machinery product for distribution or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge;

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