

ETUC position paper on the EC proposal for a regulation on machinery products

Political and legislative context

1. The proposal for a regulation on machinery products was published by the European Commission in April 2022. According to the ordinary legislative procedure, the European Parliament is working on a report and discussions at the level of the Council have started. The leading Committee is the Internal Market and Consumer Protection. A number of amendments that have been tabled so far risk to demean significant sections of the Commission's revision, as they either get away with the definition of high-risk, or exclude the third-party assessments for high-risk machinery. ETUC pledges to contribute to this process by promoting the principles set out in this document.
2. In the annex, ETUC presents a series of amendments aimed at contributing to the mentioned report of the European Parliament's Committee on Internal Market and Consumer Protection on the proposal for a regulation on machinery products (more concretely, to the draft compromise amendments dating of December 17th).
3. ETUC appreciates the European Commission willingness to update the Machinery Directive 2006/42/EC with a view to take stock of the latest technological developments and, among other objectives, better protect workers from risks associated to artificial intelligence technologies.
4. ETUC welcomes the Commission proposal to upgrade the Directive into a Regulation, as this will contribute to a further harmonisation across the European Union and take account of the challenges that new and emerging technologies pose for workers.

Third-party certification: An extra layer of security to protect the safety and health of workers

5. The proposal for a regulation on Machinery products keeps the manufacturer internal check option (Module A, set out in Annex VI) for machinery that is not classified as high risk. However, for high-risk machinery, third-party certification is now required after the application by manufacturers of the relevant harmonised standards.
6. ETUC supports the proposal to keep the category of high-risk machinery products (Annex IV under machinery directive, Annex I under the proposal for a regulation on machinery products) for which the administration of third-party conformity assessments is made compulsory because it will provide for an enhanced protection of workers' health and safety. Furthermore, third-party conformity assessments make manufacturers liable in case of accidents or diseases associated to the use of machinery products.
7. ETUC recalls that third-party conformity assessments were mandatory under the Machinery Directive before the revision enacted in 2006. From this latest revision and up until today (and as far as the new regulation is not completely adopted

and implemented), third-party conformity assessments were made optional to businesses as an extra layer of protection after the self-assessment done by the manufacturer with the application of the relevant harmonized standards. Third-party conformity assessment consists in the examination of the compliance of the relevant harmonised standards and the adequacy of the technical design of the machinery product to verify the conformity of the machinery product with the corresponding essential health and safety requirements. Third-party conformity assessments are carried out by notified bodies appointed by Member States, which must be neutral and independent from the manufacturer. ETUC calls on the European Commission to guarantee that trade unions convey their demands for the methodological criteria of the functioning of Notified Bodies, all the more considering that a number of new methodologies will be needed to guarantee the health and safety of workers when operating with AI technologies.

8. It is worth mentioning that the impact assessment produced by the European Commission in view of launching the proposal for a regulation on machinery products found that many manufacturers – including SMEs – continued making use of third-party conformity assessment on a voluntary basis after the above-mentioned revision of 2006, either for reputational reasons to reassure their customers that their products are safe, due to lack of means e.g. laboratories/expertise or for competitiveness reasons.
9. ETUC supports the capacity granted to the European Commission to issue delegated acts to amend the list of high-risk machinery products [annex 4 of the Machinery Directive (new annex 1 under the regulation on machinery products)]. By virtue of the application of delegated acts, the list can be adapted to take stock of the technical progress or new scientific evidence, by withdrawing or including new items, based on data provided by Member States and stakeholders. ETUC calls on the European Commission to spell out the participation of trade unions in these consultations. ETUC recalls that the machinery products included in list of high-risk machinery products are not unmovable. These products are on the list because empirical evidence have shown that they pose a high risk in terms of safety and health for its users, including workers. Any a significant technological leap, new evidence, or new and well-reasoned finding which can proof that a given product on the list should no longer be considered as high risk will result on the removal of that product from the list.

The risks brought by AI technologies

10. Advanced machines using Artificial Intelligence pose new and unknow risks during their lifecycle. Besides, these machines will be subject to software updates and other revisions which will also affect its safety. For this reason, ETUC appreciates that the new legislation regulates software ensuring safety functions based on AI (inter alia by including it in the mentioned annex I) by subjecting it to third-party conformity assessment, thus enhancing a coherent approach with the AI act. In the light of this argument on enhanced security, ETUC therefore supports the addition of the machinery products included in the annex IV of the Machinery Directive into the annex I on high-risk machinery products enshrined in the regulation. Since AI decisions may imply risk situations at a later stage of its use or automated behaviour, it is equally relevant to consider the classification of all AI technologies as high risk, and not only when they entail safety functions.

11. Considering the increased risks posed by AI-enabled systems, ETUC endorses the fact that the essential health and safety requirements (set out in Annex III) have become more specific. These include inter alia considerations of the life cycle of the systems under the manufacturer liability as well factors appertaining to mental stress (cognitive workload caused by the interaction between humans and machines). At the same time, the principle of technological neutrality is met, since the specifications included in annex III refer to protection objectives which can be subsequently underpinned by standards.
12. The impact assessment issued by the European Commission and the market surveillance activities performed by Member States found problems with manufacturers which have not duly applied the harmonized standards, either because of errors in the application, incomplete administration of the tests, or wrongdoing. Accidents and casualties of workers caused by machines operated with AI which did not comply with the safety obligations of the current machinery directive have also been reported. ETUC believes that the addition of a third-party conformity assessment to the application of harmonized standards will prevent potential defects in the hardware or the software which may lead to hazardous situations.

Standards will continue to be relevant under the new regulation

13. ETUC will continue engaging in the standardisation processes for machinery products. Under the new regulation, third-party conformity assessment will be an added level of protection for high-risk machinery and its outcomes will be legally binding and therefore subject to Parliamentary scrutiny. ETUC welcomes this strengthened role for the legislator in the control of the safety of machinery products. Harmonized Standardization has the role to underpin and specify the legislation in detail and it is an essential element of the New Legislative Framework legislation.¹

Position of the industry

14. The position of the industry supports the argument that machines placed in the market should be subject to a conformity assessment and certification procedure to be carried out by the manufacturers (internal check option following Module A) and not by a notified body or any other third-party certification. They therefore advocate to maintain the current situation in which manufacturers are allowed to carry out the conformity assessment procedure autonomously for machinery covered by Annex IV of the Directive 2006/42/EC with existing harmonised standards. They allege that undertaking this third-party certification would create undue additional costs for companies, particularly SMEs.

¹ *The new proposal of the European Commission to make technical specifications itself through implementing acts is not in competition with the standardisation system and is to be welcomed. This should be regarded as a fallback option in the event that no standards exist, or they are not (yet) fit for purpose drawn up or they are not drawn up properly (according to the assessment of Harmonized Standard consultants, HAS). In these cases, the regulatory gap should be filled by technical specifications and all relevant stakeholders, including social partners, should be involved in this process.*

Annex I: Proposals of ETUC to the compromise amendments of the IMCO Committee report on the proposal for a regulation on machinery products

ETUC and the ETUC affiliated organisations are particularly concerned about some of the amendments proposed by the rapporteur in the draft compromise from 17/12/2021.

A

Proposal for a regulation Recital 19

The proposed compromise suggests to replace the broadly accepted and clearly defined category of ‘high-risk’ systems with a more vague wording of systems ‘that pose significant risks to the health and safety of persons’.

ETUC is of the opinion that this proposal will pose a problem to the overall systematic legal coherence. ‘High-risk’ is a precise, well established and systematically important term in the New Legislative Framework (NLF). Annex I in the EU Commission’s draft defines the category in the context of the Machinery products regulation in more detail. “Significant risk”, by contrast, is a weak terminology in the context of this legislation and would require additional specifications, i.e. how exactly “significant” would be defined, how the data is collected, and how the “significance” is actually calculated. The clear definition of “high-risk” as proposed by the European Commission is more helpful here and provides legal clarity.

ETUC further thinks that an ambitious legislation such as the Machinery products regulation should build on strong and reliable definitions. In that sense, it is important to have a clear definition of the different categories at stake, i.e. to know clearly which products fall in which category. Having an obscure product category newly introduced, without clear criteria how to assess the products in place, and without a reliable definition of what, for example, “significant” means in the context of this legislation, only leads to difficulties in the implementation and brings a harmonised application of the Regulation at risk.

ETUC recommends to leave recital 19 as proposed by the European Commission.

B

Proposal for a regulation Article 5 – paragraph 1

The proposed amendment contributes further to the confusion described in our concerns regarding the proposed amendments for *Recital 19*. It makes no sense to drop a, in the NLF well-established, terminology and to introduce a more obscure wording instead. It is important to maintain coherence with NLF terminology and legislation, but also the draft AI act, which builds on a risk-based approach and includes a category of “high-risk” products.

ETUC recommends to leave article 5 – paragraph 1 as proposed by the European Commission.

C

Proposal for a regulation Article 5 – paragraph 2

1. ETUC agrees with the rapporteur to include a stakeholder consultation in the process towards a delegated act adopted by the Commission. Social partners, and trade unions in particular, should be granted the right to contribute meaningfully in these consultations.
2. ETUC reiterates the reservations against dropping well established categories.

ETUC recommends to maintain the initially proposed wording, i.e. "...in the list of high-risk machinery products..."

3. ETUC thinks that the proposal to have the delegated acts applied only after 36 months after their entry into force is dangerous. Since we are talking about products that are of potential high-risk, any undue delay is not acceptable. Although we think that the delegated acts should apply without delay after their entry into force, we accept that there might be well-founded objections by manufacturers who may need more time to adapt to legislative developments.

ETUC recommends to introduce a transition period of six months as this is a realistic timeframe and should be acceptable to all.

D

Proposal for a regulation

Article 5 – paragraph 3 – subparagraph 1

ETUC reiterates the reservations against dropping well established categories. The Machinery products regulation should not refer to a "list of categories of machinery products", as this implies various risk categories which are not clearly defined. This bears the risk of ending up with different risk categories that were not intended by the legislator, and it will most certainly lead to additional confusion, especially for SMEs with a wide range of products.

ETUC recommends to leave article 5 – paragraph 3 – subparagraph 1 as proposed by the European Commission.

E

Proposal for a regulation

Annex I - subheading 1

ETUC reiterates the reservations against dropping well established categories.

ETUC recommends to leave Annex I – subheading 1 as proposed by the European Commission.

F

Proposal for a regulation

Annex I – point 25

ETUC is of the opinion that machinery should always be assessed as a sum. Machinery entities should never be divided and assessed in parts, except in the sense of partly completed machinery as proposed by the European Commission. This is of particular relevance when discussing machinery ensuring safety functions.

ETUC recommends to leave Annex I – point 25 as proposed by the European Commission.

G

Proposal for a regulation

Recital 21

ETUC reiterates its call for clear definitions and the use of well established categories. Especially when discussing risk categories, the term “potentially” only leads to confusion where legal clarity is needed. A clear definition of “high risk” machinery, and of machinery that would fall into any other risk category, will facilitate the placing on the market of new types of machinery. The list of “high risk” machinery should be clear and well-reasoned. Introducing a category of “potentially posing a high risk” will only place undue burden on the manufacturer, which should be prevented by clearly defining which machinery poses a “high risk”, and which not.

ETUC recommends to leave Recital 21 as proposed by the European Commission.

H

Proposal for a regulation

Recital 45

ETUC reiterates its call for clear definitions and the use of well established categories.

ETUC recommends to leave Recital 45 as proposed by the European Commission.

I

Proposal for a regulation

Recital 45a (new)

AI and software ensuring safety functions in general lack robustness. It is therefore important to continue to work with a broad definition of both, as proposed by the Commission. This amendment would, in the worst case, lead to all products existing today being excluded from the high-risk definition in the sense of the Commission’s proposal and, consequently, leave the status quo untouched. This would render vast parts of the current revision useless.

ETUC recommends to decline Recital 45 a (new) altogether.

J

Proposal for a regulation

Article 21 – paragraph 2 – introductory part

ETUC reiterates its call for clear definitions and the use of well established categories.

ETUC recommends to leave Article 1 – paragraph 2 – introductory part as proposed by the European Commission.

K

Proposal for a regulation
Article 21 – paragraph 2 – point -a (new)

ETUC thinks that the Commission's proposal for a third party assessment performed by notified bodies is well-reasoned and timely. It is based on an impact assessment and aims at ensuring the legal coherence with the risk-based approach in the New Legislative Framework. Most of the EU product safety legislation for CE marking have already integrated respective provisions. Mandatory third party assessment is already required in the personal protection equipment regulation or the lifts directive. Decision NO 768/2008/EC ensures the robustness and reliability of the third party certification system.

ETUC recommends to decline Article 21 – paragraph 2 – point -a (new) as this provision would allow for self-certification of high-risk machinery by the manufacturers, which the Commission aims at excluding. The provision would leave the status quo untouched and render vast parts of the current revision useless.

L

Proposal for a regulation
Article 21 – paragraph 3

ETUC reiterates its call for clear definitions and the use of well established categories.

ETUC recommends to leave Article 21 – paragraph 3 as proposed by the European Commission.

M

Proposal for a regulation
Article 50 – paragraph 1

ETUC thinks that 60 months would be too long, especially in the context of high risk machinery. 42 months, as proposed by the European Commission, is already long enough given the justified security needs of workers and could be the compromise position, although a period of 12 months would probably be enough for manufacturers to adapt to the requirements of the Regulation.

ETUC recommends to leave Article 50 – paragraph 1 as proposed by the European Commission.

N

Proposal for a regulation
Article 51 – paragraph 2 – point b

ETUC reiterates its call for clear definitions and the use of well established categories.

ETUC recommends to leave Article 51 – paragraph 2 – point b as proposed by the European Commission.

O

Proposal for a regulation
Article 52 – paragraph 2

ETUC thinks that 48 months would be too long. 30 months, as proposed by the European Commission, is already long enough given the justified security needs of workers and could be the compromise position, although an even shorter period of 24 months would probably be enough for manufacturers to adapt to the requirements of the Regulation.

ETUC recommends to leave Article 52 – paragraph 2 as proposed by the European Commission.

P

Proposal for a regulation

Recital 65

ETUC reiterates its call for clear definitions and the use of well established categories.

ETUC recommends to leave Recital 65 as proposed by the European Commission.