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Machinery Proposal: Mandatory third party certification is a step backwards

The mandatory third party certification of so-called "high-risk" machines is unjustified and disproportionate

Today, when harmonised standards cover all relevant essential health and safety requirements, manufacturers of so-called 'high-risk'¹ machinery can either self-assess conformity or use a third party (known as a 'Notified Body') to do so.

The proposed new Machinery Regulation removes the self-certification possibility, making third party certification mandatory for all machinery products listed in Annex I.

However, the supporting arguments in the European Commission [Impact Assessment](#) mainly rely on subjective assumptions not confirmed by any data, and an incomplete measurement of the effects. The proposal is therefore unjustified and disproportionate, as demonstrated below.

Are third party certified machines safer and of better quality? **No**

- There is no data showing more accidents with 'high-risk' self-certified vs third party certified machines
- The quality level of the machine has nothing to do with the type of conformity assessment

¹ [The Machinery Products Regulation](#) proposal introduces the term 'high-risk' for the machines listed in Annex I. Orgalim considers the designation inappropriate. Such a term 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 legal provisions, which have been successfully applied 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 find it disturbing that some products are now being called 'High-Risk Machinery Products'. Such a designation is misleading for customers and damaging to the reputation of the European manufacturer and the industry in general.

Do third party certified machines show better conformity? **No**

- There is **no data showing less conformity** with 'high-risk' self-certified vs third party certified machines
- Notified Bodies use the **same standards** as manufacturers to meet the requirements of the legislation

Does the cost of third party certification only represent 1% of the total machine price as argued by the Impact Assessment²? **No**

- The 1% estimation does not cover the **additional cost of resources, logistics, planning, or the additional lead time** (10-15 weeks, or more depending on availability and resources at test houses)
- The **increased time-to-market delay** would have a detrimental impact, especially for machines produced in series and for seasonal use
- In some industry sectors, the cost of an EC type certification process can range between **€10,000 and €40,000**, depending on the choice of Notified Body
- For OEMs that offer tailored solutions (e.g. switchboards tailored to individual customer requests) the cost can reach between **5% and 40%** of the value of the machine
- There is the risk of an accumulation of **several assessment procedures** before the product is assembled as a safely functioning whole

Does third party certification reduce the need for market surveillance? **No**

- Third party certification is about *assessing* conformity and is **not a substitute for enforcement and control** by market surveillance authorities
- Third party certification does **not guarantee conformity**: some machines certified by Notified Bodies are also found to be non-compliant by other authorities
- Notified Bodies' levels of competence and knowledge vary considerably.

Would mandatory third party certification support innovation? **No**

- Third party certification **increases time-to-market**, which is incompatible with faster innovation cycles and the seasonal character of certain machinery products
- Manufacturers' experience shows that Notified Bodies often **struggle to risk-assess** or support the development of appropriate new safety concepts for **new technologies** (such as AI) or new types of products

² European Commission Staff Working Document (2021) 82 Impact Assessment for the Machinery Products Regulation proposal.

Would mandatory third party certification undermine the harmonised standard system?

Yes

- There will be no added value for manufacturers to conform to the standard, resulting in **increased divergences between products**
- Industry experts will have no market motivation to produce standards, which will result in **lower technical quality and decreased market relevance of new standards**
- Mandatory third party certification would be a return to the concept of external control, an approach which was popular in the 1980's. Since then, European legislation has evolved in the direction of greater responsibility for the manufacturer

Does third party certification support SMEs? No

- SMEs want to **retain the business choice** to self-assess or use a Notified Body according to their business needs and resources

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