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GROW H2/ VPC

## **Commission proposal for a Regulation on machinery products**

### **Rationale to remove manufacturers' self-assessment for high-risk machines**

#### **Background**

Annex I of the proposed Regulation on machinery products contains 25 items considered as high-risk products. The list is the same as in the current Machinery Directive 2006/42/EC, except for two new items on software ensuring safety functions, including AI systems, and machinery embedding AI systems ensuring safety functions.

This list can be adapted in view of technical progress or new scientific evidence, by withdrawing or including new items, based on data provided by Member States and stakeholders, through the empowerment conferred to the Commission in Article 45.

As for the conformity assessment of the products in Annex I, the proposal has removed the manufacturers' self-assessment (on the condition that the relevant harmonised standards are applied) in favor of third-party certification.

Hereafter we detail the reasons for this change and the outcomes of the impact analysis on stakeholders.

#### **A. Reasons for a mandatory third-party certification**

The Commission, based on an impact assessment and extensive discussions with Member States and stakeholders, made such proposal aiming at ensuring the legal coherence with the Decision No 768/2008/EC, which has been integrated in the proposed Regulation on machinery products and at enhancing the safety of certain category of products that present higher risks.

##### **1. Ensure legal coherence – the risk-based approach drives the New Legislative Framework.**

The New Legislative Framework, Decision No 768/2008/EC, lays down a 'horizontal menu' of conformity assessment modules, based on a risk approach. Most of the EU product safety legislation for CE marking (approx. 25 legal acts) have already integrated the relevant modules. Based on this menu, the most appropriate procedure for high-risk products is to have a third-party certification. In the mechanical engineering sector, a mandatory third party is also required for example in the personal protection equipment regulation, the pressure equipment directive or the lifts directive.

An important element stemming from the New Legislative Framework is the role of the notified bodies for third party certification. Decision No 768/2008/EC sets up a comprehensive framework to ensure the robustness and reliability of the third party certification system. In particular, notified bodies must ensure an independent conformity assessment of the machinery from the organisation or the product it assesses and must comply with an exhaustive number of competences that are not requested to manufacturers. In addition, the conformity assessment requirements are more stringent and detailed when the notified bodies intervene. This means that the conformity assessment performed by notified bodies is not only about applying the relevant harmonised standards or checking whether the relevant harmonised standards referred to in the technical documentation have been applied. For example, the notified bodies must assess the adequacy of the technical design of the machinery product and carry out their own appropriate examinations and tests to verify the conformity of the machinery product with the corresponding essential health and safety requirements.

## **2. Enhance safety**

Member States have found during their market surveillance activities that some manufacturers that followed the self-declaration conformity assessment by using standards, either wrongly applied their specifications or incompletely used those standards, thus not addressing all the machinery risks and consequently placing unsafe products on the market.

For example, French authorities provided data on incompliances and accidents, including fatal ones, caused by high-risk machinery products assessed through self-certification route. To give some examples, in a market surveillance action for refuse collection vehicles (machinery point 13 of Annex I), all manufacturers who carried out the self-assessment on the basis of the applicable standard<sup>1</sup> did not apply a relevant requirement of that standard<sup>2</sup>. As a result, 100% of these machines self-assessed by the manufacturers have been unduly placed on the market. Another example can be given from a joint enforcement action (10 MS) in 2016-2017 on vehicle servicing lifts (machinery point 16 of Annex I) where serious non-conformities have been found with these products. Large part of the non-conforming machines were self-certified. For injection moulding machines (machinery point 10 of Annex I), some manufacturers of vertical electric axis machines have self-certified machines on the basis of a wrong harmonized standard<sup>3</sup>.

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<sup>1</sup> EN 1501-1+A1: 2015

<sup>2</sup> §5.10.3.3.4: "the detection devices and associated parts of the chassis cab [are] at least of the required performance level (PLr)c"

<sup>3</sup> EN 201 specifically excludes these products from the scope of this standard.

## **B. Impact on stakeholders**

Before taking the decision, the Commission assessed its impact on stakeholders and in particular on SMEs also by analysing the market practices with conformity assessment choices for high risk products.

### **1. Existing practices on the market**

Today, the conformity assessment of half of high-risk machines in the list is already done with third party involvement. Despite the fact that a mandatory third party assessment was removed from the current version of the Directive as compared to its previous version, this change did not necessarily lead to a sudden reduction in demand for third party services. Manufacturers of the high-risk machinery products included in Annex I of the proposed Regulation are often SMEs. Many manufacturers/SMEs have continued to use the services of third parties “voluntarily” 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.

### **2. Costs**

According to the evaluation of the Machinery Directive 2006/42/EC, high-risk machinery represents only 20% of the whole machinery sector. Costs for third party involvement are estimated at EUR 202 million one-off overall costs (EUR 2 500 per company in average, EUR 25 000 or more for certain machine types).

For example, the costs for third party conformity assessment for the production of 50 to 100 of presses (high-risk machines) varies between 0, 07% to 0, 13% of the machine price. For some unique high-risk machines which can cost up to 1M€, the third party conformity assessment represents up to 1% of the machine price. There are other examples for machines with selling price between 3k€ to 5k€ where the third party costs are less than 0.33%.

In order to reduce costs for SMEs, the proposal includes provisions requiring notified bodies to take account of SMEs specific interests when setting up the conformity assessment fees.