

Orgalim review of options for PED Guideline C-13

Executive summary

Orgalim is fully committed to maintaining the current market practice. We believe that an enhanced option 3 would be the most effective solution to address legal clarity for the PED: introducing a provision in the Machinery Products Regulation that would modify the PED. As a fall-back option, if the enhanced Option 3 is not feasible, we could accept Option 2, provided that the new guideline is adopted before the deletion of the notes to the current PED Guideline C-13.

Option 1	Option 2	Option 3
<ul style="list-style-type: none"> Remove notes 1 and 2 from PED Guideline C-13 Decision to be taken by WGP in upcoming meeting <p>[current PED ADCO position]</p> <p>5</p>	<ul style="list-style-type: none"> Remove notes 1 and 2 from PED Guideline C-13 Decision to be taken by WGP in upcoming meeting Develop <u>new</u> PED Guideline specifically addressing global conformity assessment for machinery including items of pressure equipment higher than Category I under PED Need to ensure coherence with PED Article 1 §2 j) exclusion for machinery Requires PED and MD experts discussion in WGP 	<ul style="list-style-type: none"> Modification to Machinery Regulation (MR) Aim at single conformity assessment under MR including global conformity assessment related to <ul style="list-style-type: none"> integration of items of pressure equipment in machinery protection against exceeding permissible operating limits (pressure) involvement of a third party (NB under machinery legislation) for high risk machinery products involving items > cat. I under PED

Figure 1: Options presented by the European Commission for a solution to the discussion on PED Guideline C13 (presented at Machinery Expert Group on November 10, 2021)

1. Introduction

Orgalim represents Europe's technology industries – comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics and ICT, and metal technology branches. Our constituency represents both machine and pressure equipment manufacturers. In this context, different Orgalim members made an analysis of the possible impacts that a change in the conformity assessment practices related to the integration of PED equipment with CE-marking into machinery products would have on their industries¹. According to our data collection, we estimate a significant impact on machinery manufacturers without enhancing the safety of the machines. Therefore, Orgalim calls for maintaining the current market practice.

1.1. Option 1

Orgalim cannot support this option. This decision would disproportionately impact machinery manufacturers and would create an inconsistency with the machinery legislation. Under the Machinery Directive 2006/42/EC, the relation to specific product directives does not apply to the final machinery product even if certain integrated elements bear a CE-mark under a different piece of legislation. If a safety component, in the sense of the Machinery Directive, is integrated into a PCM, this PCM does not itself become a safety component, and equipment covered by the Low Voltage Directive 2014/35/EU (LVD) integrated into a machine does not make the assembly into an electrical equipment – nor is there an additional conformity assessment under LVD for this integration process. The consequences would greatly increase the administrative burden without enhancing the safety of the machines².

1.2. Option 2

In principle, Option 2, making use of the exclusion in Article 1.2(j) of the PED, could uphold the current interpretation of the legislation. However, for this solution to be implemented correctly the following preconditions must be fulfilled:

1. A new guideline must be drafted, specifically addressing the integration of items of pressure equipment with CE-marking into machinery and highlighting that the machinery manufacturer is responsible for the conformity assessment procedure of the final product – the machinery with the integrated pressure equipment
2. The conformity assessment carried out by the machinery manufacturer for the entire machine must not result in a duplication of the conformity assessment procedure according to the PED
3. The C-13 notes must NOT be removed until the new guideline is approved and ready for application

The current market practice, which has successfully been applied for over 20 years, is based on Article 5(1) of the Machinery Directive 2006/42/EC. According to this article, machinery manufacturers need to carry out a conformity assessment procedure for the entire machine. This includes a risk assessment which takes into account all the elements that make up a machine, including those elements that work under pressure, such as hydraulic systems, commonly used within machinery. The manufacturer of the pressure equipment intended for integration foresees the safe integration of their equipment into the final product (main machine). The pressure equipment is CE-marked under the PED. When that pressure equipment is combined with a machine, the manufacturer of the final machine must analyse the combination of pressure equipment in terms of safety through their own conformity assessment procedure of the machine, comparable to the conformity assessment under the PED Art. 14(6), but applying the provisions of Article 5(1) of the Machinery

¹ See the letter and Annexes sent to Ms Barbara Bonvissuto on 10 March 2020

² There is no data on accidents linked to this issue

Directive or the provisions of the EU-Regulation Machinery Products. This concept is commonly applied and understood within industry.

1.3. Option 3

In our past correspondence we have suggested that, as stipulated in Option 3, a provision to address this issue can be introduced in the new Machinery Products Regulation. However, upon closer examination this solution as proposed by the Commission could easily lead to unwanted changes in the current practice. Furthermore, the provision in the Machinery Products Regulation would not address the legal clarity for the PED unless the provision also modified the PED. Finally, we believe that the third bullet point in the description above “involvement of a third party (...) under PED” is not necessary. Orgalim understands that the current market practice and legal requirements already address the issue of the safe integration of pressure equipment into machines. Machinery manufacturers have the technical know-how and experience to ensure the safety of the machinery as a whole. The involvement of a third party beyond what is currently foreseen under the Machinery Directive will not improve the safety of the machines, as the Notified Bodies use the same standards and instructions in their check as the manufactures. Therefore we cannot support Option 3 as drafted by the Commission.

1.4. Enhanced Option 3

Our preferred solution would then be an enhanced Option 3. The enhancement would be:

- to delete the bullet point related to Notified Bodies, or, at least
- to limit the number of new indents to Annex I of Machinery Regulation. This means that only very specific machines, for which the overall risk analysis shows that pressure is a significant risk, should be added to Annex I. Also, it should be clarified that their inclusion in Annex I is motivated by the pressure risk only.
- the Commission develops guidance on what part of the conformity assessment procedure would be subject to the mandatory involvement of a Notified Body.

In this option, we also propose to address the issue of legal clarity for the PED, through a provision in the Machinery Products Regulation that would also modify the PED. A precedent for this exists in the Machinery Directive, where Article 24 amends Directive 95/16/EC. The enhanced Option 3 would allow a simplified approach conformity module A instead of a PED higher module.

Orgalim proposal for amending the Directive 2014/68/EU, through a new paragraph following the list of exclusions in Article 1(2):

"If one or more items of pressure equipment with CE marking or covered by PED article 4(3) are to be incorporated into a machinery product, the manufacturer of the machinery product shall carry out a conformity assessment procedure in accordance with Article 21(3) of the EU Machinery Products Regulation for the machinery product with the incorporated pressure equipment. When carrying out the conformity assessment procedure, the manufacturer of the machinery product shall take into account the information for the incorporation of the pressure equipment, in particular the information on the intended use of the pressure equipment. If pressure equipment is to be used outside its intended use, the required conformity assessment procedure in accordance with the Pressure Equipment Directive must be carried out for this purpose."

2. Conclusion

In conclusion, for Orgalim it is clear that the current market practice, which has successfully been applied for over 20 years, fully supports the safe integration of components into machinery products. Any change to legislation or guidelines needs to be carefully considered. Orgalim is convinced that an enhanced Option 3, or Option 2 (provided that the new guideline comes before the deletion of the notes to current C-13) as a fall-back solution), would be the most effective solutions to the legal issue while also taking business needs and safety into consideration.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

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