

Integration of pressure equipment into machinery: The relationship between the Pressure Equipment and Machinery legislation

Executive summary

In the context of discussions in the European Commission Working Group Pressure Equipment concerning the applicable regulatory framework and the relevant conformity assessment for the integration of pressure equipment into machines, Orgalim would like to set out its views and recommendations to ensure a level playing field and the necessary legal certainty for machinery manufacturers.

The two main relevant pieces of legislation are the Pressure Equipment Directive (2014/68/EU) and the Machinery Directive (2006/42/EC); the latter will be replaced by the Machinery Regulation (EU) 2023/1230 in 2027.

According to current practice, manufacturers apply conformity assessment according to the Pressure Equipment Directive for pressure equipment. However, when integrating pressure equipment in the final machinery, manufacturers apply the conformity assessment of the Machinery Directive. Furthermore, the current legal framework has proven to be effective, and the analysis of available data reveals a downward trend of incidents. In France, no machinery accident was attributed to pressure-related issues in the last years and most non-conformities are related to administrative issues rather than safety.

Given this evidence, we call on authorities to maintain the current interpretation and market practice, which has been successfully applied for over 20 years. Changing this practice, and consequently applying procedures required by the Pressure Equipment Directive to machinery integrating pressure equipment, would not enhance health and safety. Instead, such a change will put at stake well-established assessment processes, increase the administrative burden and raise conformity costs for manufacturers without any safety benefits.

Finally, to ensure a level playing field and legal certainty, we recommend issuing a new Guideline to clarify the assessment procedure and the applicable regulatory framework when pressure equipment is integrated into a machine, and, consequently, revising the C-13 Guideline.

In the last few years, the applicable regulatory framework and the relevant conformity assessment for the integration of pressure equipment into machines has been the subject of fierce debate. Today, Orgalim firmly believes that the discussions should focus on market practices, the notion of risk, and accident data to achieve the objective of the Pressure Equipment and Machinery legislation: the health and safety of the users.

Instead of engaging in an ideological debate, it is essential to focus on the two relevant pieces of legislation: the Pressure Equipment and Machinery Directives. Previous debates often ignored the definitions and scopes of these directives, and the principle that the manufacturer, “having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer” (recital 19 of the Pressure Equipment Directive).

Therefore, in view of the further discussions, this position paper aims to provide information about:

- The applicable legal framework
- Field practices
- Accident data

Recommendations

To ensure a level playing field and provide the necessary legal certainty to machinery manufacturers, we recommend authorities and the Commission’s Working Group Pressure Equipment to:

1. Maintain the current market practice for the conformity assessment of machinery integrating pressure equipment, which is based on the Machinery Directive and has been successfully applied for over 20 years.
2. Issue a new Guideline clarifying the assessment procedure and the applicable regulatory framework when pressure equipment is integrated into a machinery product or a partly completed machine; this new guideline should be based on the “notes” accompanying the current C-13 Guideline.
3. Revise the current C-13 Guideline on the integration of pressure equipment to remove the “notes” referring to the exclusion of certain pieces of equipment as PED assembly.

The adoption of a new Guideline on the integration of pressure equipment into machinery and the revision of the C-13 Guideline must be processed together. Revising the C-13 Guideline without adopting the new one would result in legal uncertainty, put at stake well-established assessment processes, and increase the administrative burden without any safety benefits.

The applicable legal framework

Scope and definitions

Regarding the integration of pressure equipment into machines, the first piece of the EU acquis to look at is the Pressure Equipment Directive (2014/68/EU). Indeed, it applies to “the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar” (PED Article 1.1). The Directive

defines pressure equipment and assemblies (Articles 2.1 and 2.6). The term “assemblies” is described as follows: “several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole”.

A second relevant piece of legislation is the Machinery Directive (2006/42/EU), which will be replaced by the Machinery Regulation (EU) 2023/1230 in 2027. It applies to machinery, partly completed machinery, and a series of related products as listed in Article 1.1 and defined in Article 2. Among these definitions, it is useful to highlight the definition of machinery in Article 2.a: “an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application”. We highlight that the definition of machinery, while encompassing the term 'assembly' in a general way, is not limited to it.

According to the scopes of these two directives and their definitions, the Pressure Equipment Directive does not apply to machinery, being limited by Articles 1 and 2. Consequently, it can only apply to pressure equipment, whether placed on the market assembled or isolated.

The case of hydraulic systems

Furthermore, the Pressure Equipment Directive provides a series of exclusions, which are listed in Article 1.2. It does not apply to:

1.2.j) “equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:

- (i) engines including turbines and internal combustion engines;
- (ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;”

It should be noted that the examples given in Article 1.2.j) points i) and ii) are indicative and not exhaustive. In addition, it is generally accepted that a hydraulic system corresponds to the definition provided in Article 1.2. j) and is therefore excluded from the scope of the Pressure Equipment Directive. The main reason is that the fundamental criterion for the design of a hydraulic cylinder is strength and not pressure. This approach is confirmed by various standards, including [EN ISO 4413](#) Hydraulic fluid power — General rules and safety requirements for systems and their components, [EN ISO 13849-1](#) Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design, and [ISO TS 13725:2021](#) Hydraulic fluid power — Method for evaluating the buckling load of a hydraulic cylinder.

Many countries, including Sweden, apply this exclusion provided by Article 1.2.j) to hydraulic systems. According to the Swedish market surveillance authorities, this exclusion allows the consideration of risks not covered by the Pressure Equipment Directive (see the contribution of the Swedish Work Environment Authority on the C-13 Guideline¹ in Annex 3 of this position paper). We fully support this interpretation and its conclusions.

¹ Contribution of Swedish Work Environment Authority was included in the Working Document “WG-2020.42 - (D, CH, DK, SE, ES, BG, CZ CEMA Comments on action point (6. PED Guideline C-13) updated 28042021.pdf” submitted to the EC Working Group Pressure and Machinery Working Group in April 2021.

Field practices

When integrating hydraulic systems into machines, manufacturers, following a risk analysis, ensure the management of pressure risk by applying harmonised standards, such as EN ISO 4413 'Hydraulic fluid power — General rules and safety requirements for systems and their components', and other European and international documents like ISO/TS 13725 'Hydraulic fluid power — Method for evaluating the buckling load of a hydraulic cylinder.'

According to manufacturers of machines with hydraulic systems, the actual risk in hydraulics is not related to the articulation of the two directives, but rather to the poor quality of materials or components, even those CE marked, that come from third countries. To mitigate this issue, most manufacturers ensure the traceability of critical parts. Subsequently, when integrating pressure equipment or assemblies that are not subject to the exclusion provided by Article 1.2.f) or 1.2.g), machine manufacturers apply Article 3 of the Machinery Directive and follow the guidelines of §91 of the Guide to Application of the Machinery Directive. It reads: "In accordance with Article 3, the PED is applicable, for the pressure hazards, to pressure equipment within its scope that is incorporated into or connected to machinery. If pressure equipment that has already been placed on the market is incorporated into machinery, the machinery manufacturer's technical file must include the EC Declaration of Conformity of that pressure equipment to the PED."

In this case, we would like to emphasise that pressure equipment and pressure assemblies higher than PED category I to be integrated into machines are subject to a conformity assessment according to Pressure Equipment Directive (2014/68/EU). Similarly, during integration of this pressure equipment into the final machine, manufacturers ensure that the pressure risk is properly considered. The final machine is subject to a conformity assessment procedure according to the Machinery Directive (2006/42/EU). These concepts and procedures are commonly applied and understood within our industry.

Accident data

Neither recent nor older data demonstrates that the current legal framework, its application and field practices pose any critical risk to the safety of pressure systems integrated into machinery.

Since 2019, the distribution of non-conformities in France has remained stable; almost all non-conformities are related to administrative rules, according to [Report No. 5 Edition 2023: Controls 2021 of the National Observatory of Pressure Equipment](#). In addition [the ARIA database](#) indicates that the total number of events involving pressure equipment in 2021 is the lowest since 2017; this marks a continued downward trend for the third consecutive year. The analysis of data from the French ARIA and [EPICEA](#) databases reveals that no machinery accident can be attributed to pressure-related factors. Given this evidence, we question the rationale for a regime change and the added value such a change might offer regarding health and safety. Furthermore, we recall that, in 2021, the Swiss market surveillance authorities highlighted non-conformities in hydraulic systems and other pressure assemblies integrated into machines and excluded from the Pressure Equipment Directive – including compressed air systems. Despite our earlier request, their examples and the list of identified non-conformities have not been thoroughly reviewed.

Therefore, the discussion surrounding the C-13 Guideline and the relationship between the two directives requires a detailed study of the elements used to provide a convincing case for the need for a revision or a regime change.

Conclusions

Given the above-mentioned elements, we refute the arguments for the revision of the C-13 Guideline. The reasons for the request to remove and revise the C-13 Guideline are not based on transparent accident or non-conformity data. The objective is rather to subject the machinery itself to the conformity procedure of the Pressure Equipment Directive to address implementation and market surveillance issues with a more restrictive regime. However, given the scopes and definitions of the two directives, this approach would be illegal if implemented.

Moreover, it is not apparent that such a regime would add value in terms of health and safety. On the contrary, manufacturers would need to allocate their limited resources and time to change their well-established processes and could therefore focus less on the safety of other aspects. Furthermore, it needs to be noted that the considerable additional effort for the manufacturers – which would be introduced for purely formal reasons – clearly contradicts the European Commission’s objective to reduce bureaucracy. It would rather result in a significant increase in the bureaucratic burden without any technical justification or safety benefits.

The current practice is beneficial for both manufacturers and machine users because under the existing regime everything necessary is done. Since there is no data to support a regime change, we call on authorities to maintain the existing articulation of the Pressure Equipment Directive with the Machinery Directive and current market practice, which has been successfully applied for over 20 years.

However, clarification of the C-13 Guideline is necessary to avoid further debates and to provide certainty to all stakeholders. Our proposal is annexed to this position paper.

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Annex 1 – Orgalim proposal for a new Guideline under PED 2014/68/EU

Category: C. Assemblies

Guideline C-XX

Pressure Equipment Directive PED 2014/68/EU Commission's Working Group "Pressure"

Guideline related to: Article 2(6), Article 4 paragraph 2(b), Article 14 paragraph 6

<p>Question</p>	<p>When one or several items of pressure equipment, that are CE-marked under the PED, are integrated into a product that is covered by the Machinery Directive 2006/42/EC or by the Machinery Regulation (EU) 2023/1230 (i.e. a machinery product or partly completed machinery), how is this integration to be assessed?</p>
<p>Answer</p>	<p>In the case described in the question above, the conformity assessment for the final product that is placed on the market is carried out in accordance with the Machinery Directive/Machinery Regulation. Individual items of pressure equipment, which have already been subject to a conformity assessment according to the Pressure Equipment Directive, are fully integrated in the conformity assessment of the final product, and consequently meet the essential health and safety requirements of the Machinery Directive/ Machinery Regulation.</p> <p>The integration of such items of pressure equipment into a machine as well as their potential connections between each other in that machine do not constitute an assembly in the sense of the PED, since such an assembly of pressure equipment is not made available on the market separately from the machine. They do not constitute a functional whole as a separate product, but gain a functional meaning only when they have become an integral part of the machine.</p> <p>Moreover, it is generally accepted that hydraulic systems correspond to the definition given by Article 1.2.j), as its dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability for which pressure is not a significant design factor – and thus these systems are excluded from the PED.</p> <p>Furthermore, complex machines with integrated items of pressure equipment, such as machine tools, earthmoving machinery, agricultural tractors, or mobile cranes (this list is not exhaustive) are not, as a whole, PED assemblies. Likewise, CE-marked items of pressure equipment that are integrated into these complex machines do not have to undergo an additional separate conformity assessment as PED assemblies.</p>

Annex 2 – Orgalim proposal for a revised C-13 Guideline under PED 2014/68/EU

Category: C. Assemblies

Guideline C-13

Pressure Equipment Directive PED 2014/68/EU Commission's Working Group "Pressure"

Guideline related to: Article 2(6), Article 4 paragraph 2(b), Article 14 paragraph 6

Question	When several items of pressure equipment are assembled by a manufacturer to constitute a functional whole, and when one or several of those items are excluded from the PED by Article 1 paragraph 2, is the resulting whole considered as an assembly covered by the PED?
Answer	<p>The definition of assemblies in Article 2(6) does not prohibit non PED pressure equipment (pressurised equipment excluded by Article 1 paragraph 2) to be included in an assembly covered by the PED.</p> <p>In the case of a PED assembly, the global conformity assessment required by Article 14 paragraph 6 does not include the assessment of non-PED items of pressure equipment.</p> <p>The assessment of</p> <ul style="list-style-type: none"> - the integration of the assembly - the protection of the assembly against exceeding the permissible operating limits <p>shall be conducted in the light by the highest category of PED items of pressure equipment included, but it shall also take account of the characteristics of the non-PED equipment.</p> <p>See also PED guideline C-12.</p> <p>For example, a refrigeration system is considered to be a PED assembly even if some of the pieces under pressure are excluded from PED.</p>
Note 1	<p>A hydraulic system of an item of machinery can meet the definition of Article 2(6), but as it is not intended to be put into service as such, it is not covered by Article 4 paragraph 2(b) (see PED Guideline C-10). On the other hand, a refrigeration system is considered to be a PED assembly even if some of the pieces under pressure are excluded from PED.</p>
Note 2	<p>In the sense of PED, an assembly is a pressurised system; a machine tool, an earthmoving machinery, an agricultural tractor, a mobile crane is not, as a whole, a PED assembly.</p>

Annex 3 – Contribution of Swedish Work Environment Authority

Extract of Working Document “WG-2020.42 - (D,CH, DK, SE, ES,BG,CZ CEMA Comments on action point (6. PED Guideline C-13) updated 28042021.pdf” submitted to the EC Working Group Pressure and Machinery Working Group in April 2021.

Comments on Question on

(PED guidelines C-13, Point 6 of the Agenda of the Machinery Working Group meeting 2 & 3 December 2019)

(....)

SWEDEN

The Swedish Work Environment Authority considers this to be an important guideline that **needs to stay as it is**. We find it as a clarifying and more thorough account of the exception in article 2 j) in directive 2014/68/EU.

The exception reads as follows:

(j) equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:

(i) engines including turbines and internal combustion engines;

(ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;

This text is being further developed through the notes 1 and 2 in Guideline C-13.

Note 1 says that even if a hydraulic system meets the definition of assemblies in article 2(6), but it is not intended to be put in use as such, then it is not covered by article 4 paragraph 2(b).

Further precision is made in **Note 2** where more examples are given, such as a machine-tool, an earthmoving machinery, an agricultural tractor and a mobile crane, these are not to be considered as PED assemblies.

This Guideline C-13 has not lead to problems in Sweden, quite the opposite, since it is a practical way to deal with hydraulic systems that are incorporated into machinery. The machine manufacturer is always responsible for the safety of the machine and that it fulfills all relevant requirements. Point 1.3.2, Annex 1 of the MD on the *Risk of break-up during operation*, aims to prevent the break-up of parts of the machinery during operation by means of the use of constituent materials and by means of the appropriate design and construction of components and assemblies in order to resist the stresses to which they are subjected during operation. Thus hydraulic systems incorporated in the machinery will correspond to higher demands than the PED requirements, due to its intended use.

Reasons:

Hydraulic systems are dimensioned for performing a task in the machine and this task gives rise also to other risks which the PED does not consider.

Example 1: There is an obvious risk of breakage caused by insufficient material thickness if the hydraulic cylinder is long and narrow.

Example 2: If the hydraulic system is designed and constructed to lift and tip a lorry platform, then it needs to be designed and constructed so that the risk of fatigue is minimized and safety is maintained throughout the machine's entire lifetime.

The dimensioning of such hydraulic systems is based on well-known construction principles that generally exceeds what a construction only according to the PED would result in. Thus it would neither increase safety nor will it be of benefit for the industry to have a hydraulic system to be constructed only to the PED.

If these hydraulic systems would be considered as assemblies according to the PED, this would mean both an increase in costs as well as an increased administrative burden for the industry, especially SMEs, and still not contribute to better and safer machines.

Conclusions:

We therefore **object to changing the Guideline C-13, without having any clear evidence that this Guideline results in unsafe products.**