

Position paper

Articulation between the Pressure Equipment Directive and the Machinery Directive: revision of C-13 orientation

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Introduction

FIM has followed and contributed to the debates about the C-13 orientation since their inception. We regret that these debates, both in 2019 and today, deviate from the applicable legal framework, field practices, the notion of risk, and the objective sought by the Pressure Equipment and Machinery Directives: the health and safety of the user. Indeed, these debates have become ideological, to the point of ignoring the definitions and scopes of the cited directives, the accident data, and the principle that the manufacturer, “due to the detailed knowledge they have of the design and production process, is best placed to implement the conformity assessment procedure” (see recital 19 of Directive 2014/68 concerning the making available on the market of pressure equipment). We hope that this position paper will help anchor the discussion around:

- Applicable legal framework
- Field practices
- Accident data.

Applicable legal framework

Scope and definitions

The Directive 2014/68 concerning the making available on the market of pressure equipment applies, according to its Article 1.1, to “the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar”. The directive defines pressure equipment and assemblies (Articles 2.1 and 2.6). The latter are described as follows: “2.6) “assemblies”: means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole”.

On the other hand, the Directive 2006/42 on machinery applies to machinery, partly completed machinery, and a series of related products listed in Article 1.1 and then 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 application of the two directives and their definitions, it is clear that the Pressure Equipment Directive does not apply to machinery, being limited by its 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 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;”

Note that the examples given in Article 1.2.j points i) and ii) are indicative and not exhaustive. It is generally accepted that a hydraulic system corresponds to the definition in point j) and is therefore excluded from the scope of the Pressure Equipment Directive. To illustrate why, we recall that the fundamental criterion for the design of a hydraulic cylinder is strength and not pressure. This approach is confirmed by the following standards: [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 -2, 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. The Swedish market surveillance authorities even state that this exclusion allows for the consideration of risks not covered by the Pressure Equipment Directive (see the contribution of the Swedish Work Environment Authority on the C-13 orientation topic).

We fully adhere to this interpretation and its conclusions.

Field practices and considerations

When integrating hydraulic systems into machinery, manufacturers, following a risk analysis, ensure the management of pressure risk by applying harmonized 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 our manufacturers of machinery with hydraulic systems, the real danger in hydraulics is not related to the articulation of the two directives, but to the poor quality of materials or components, even those CE marked, that come from third countries. To combat this phenomenon, 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, machinery manufacturers apply Article 3 of the Machinery Directive and follow the guidelines of §91 of the Machinery Application Guide.

“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 emphasize that it is evident that pressure equipment and pressure assemblies >cat. 1 to be integrated into machinery are subject to a conformity assessment according to Directive 2014/68. Similarly, during integration, manufacturers ensure that pressure risk is taken into account. However, the final machine will be subject to a conformity assessment according to Directive 2006/42.

Accident data

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

We note that since 2019, the distribution of non-conformities in France has remained stable, with almost all non-conformities being related to administrative rules, according to [Report No. 5 Edition 2023: Controls 2021 of the National Observatory of Pressure Equipment](#).

Similarly, the total number of events involving pressure equipment in [the ARIA database in 2021](#) is the lowest since 2017 for the third consecutive year.

According to the French ARIA and [EPICEA](#) databases, no machinery accident can be attributed to pressure factors. In this context, we can question the validity of a regime change and the added value in health and safety it could bring.

Furthermore, we recall that in 2021, 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. Our request to review their examples in more detail and possibly the list of identified non-conformities has not been satisfied.

Therefore, the debates around the C-13 orientation and more broadly the articulation between the directives mentioned here must be accompanied by the study of the elements used to convince of the need for a revision or a regime change.

Conclusions

Given the presented elements, we refute the official arguments for the revision of the C-13 orientation. The reasons for the request to remove and revise the C-13 orientation 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, in order 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, such a regime would not add value in terms of health and safety. On the contrary, manufacturers would need to allocate more resources and time to place their machinery on the market.

The current practice is beneficial for both manufacturers and machine users. Since there is no data to support a regime change, we ask to maintain the current articulation of the Pressure Equipment Directive with the Machinery Directive.

However, we do consider that clarification of the C-13 orientation is necessary to put further debates to rest and to reassure all stakeholders. Our proposed revision is here attached.

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	<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>
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>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. This includes in particular the integration of items of pressure equipment, most of which have been subject to a conformity assessment according to the Pressure Equipment Directive.</p> <p>The integration of such items of pressure equipment into a machine as well as their potential connection among each other on that machine does not constitute an assembly in the sense of the PED. They do not constitute a functional whole as a separate product, but they only gain a functional meaning 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</p>

	<p>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 (list not exhaustive) are not, as a whole, PED assemblies nor do CE-marked items of pressure equipment that are integrated into these machines have to undergo an additional separate conformity assessment as PED assemblies.</p>
Reason	
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>

Les industries mécaniques, premier employeur industriel de France, fournissent tous les secteurs de l'économie :

- Pièces mécaniques issues d'opération de fonderie, forge, usinage, formage, décolletage, traitement de surface, etc.
- Composants et sous-ensembles intégrés dans les produits des clients
- Équipements de production (machines, robots, etc.) et équipements mécaniques (pour la santé, l'agriculture, les TP, le bâtiment, la restauration, la lutte contre l'incendie, l'approvisionnement en eau, la production d'énergie, la mesure, ...)
- Produits de grande consommation (arts de la table, outillage, ...)