Machinery Working Group
Doc. WG-2020.42

Comments on Question on

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

GERMANY

GERMANY agrees with the considerations of the PED ADCO Chair (see attached document) about pressure equipment in machines (conformity assessment in assemblies according to the PED (Pressure equipment directive 2014/68/EC)) as presented i.a. in the Machinery ADCO Group.

The PED Guideline C-13 should be changed accordingly.

Description:

Note 1 of GL C-13 states that "a hydraulic system of an item of machinery can meet the definition of Art. 2 (6), but as it is not intended to be put into service as such, it is not covered by Art. 4 para 2 (b)".

In this respect the following should be considered:

A hydraulic unit does usually consist of a hydraulic cylinder (adjusting device) along with other (pressure) equipment (such as pump, piping, valve, regulator, fluid reservoir, pressure accumulator), either in a machine or even as a standalone machine.

Such a combination of pressure equipment meets - as mentioned in sentence 1 of note 1 of GL C-13 - the criteria of an assembly according to Art. 2 (6) PED, where-by it can either have been assembled by a supplier or by the manufacturer of a final machine.

Such an assembly would have to fulfil the corresponding requirements of Annex I of the PED if the relevant assembly manufacturer (either supplier or manufactur-er of the final machine) had determined that it would be made available on the market and would be ready for putting into service (cf. Art. 4 (2b) PED). Although, this would certainly depend on the degree of equipment or the intended use of the assembly.

In case of doubt, it would be the manufacturer of the final machine who would make the complete and thus usable assembly (e.g. hydraulic unit) available on the market and who would intend it for putting into service - perhaps only after it has been installed in his machine.

If this is the case, such an assembly would then have to undergo the global con-formity assessment according to Art. 14 (6) PED.

As mentioned above, the relevant assembler would be responsible for this; again - in case of doubt - it would be the final machine manufacturer.

Reasoning:

Art. 3 of the Machinery Directive 2006/42/EC (MD) states that hazards arising from a machine, which are at the same time covered more precisely by another Community Directive, must be taken into account specifically by this directive -> in this case the MD is not applicable.

It should be clear that the more concrete provisions of the PED (and not those of the MD) must be applied to pressure equipment in machinery (generally starting from pressure equipment category II).

Since, however, pressure-related hazards / risks can also arise from an assembly / a combination of pressure equipment (e.g. because of insufficient compatibility, poor mounting and/or safeguarding etc.), with reference to Art. 3 MD, this would have to be considered by the more specific PED; i.e. a global conformity assess-ment according to Art. 14 (6) PED is necessary.

Thus, in case of a pressure equipment assembly used / installed in a machine, the PED and not the MD is relevant for assessing that assembly regarding pressure assemblies in machinery related hazards / risk.

The provisions of the MD for machinery remain unaffected by that.

Proposal for a decision:

1. Endorsement by PED-AdCo Group

2. Informing Machinery AdCo and asking for comments

3. Informing WPG and asking to delete note 1 of PED-GL C-13

4. Informing WGP

SWITZERLAND

Switzerland **agrees with the considerations of the PED ADCO Chair** and supports the German statement in Machinery Working Group Doc. WG-2020.42. Additionally, we would like to emphasize that Note 1 of Guideline C-13 does neither give an answer nor a clarification to the initial question and therefore – if it should be kept at all – it should be placed in Guideline C-10 dealing with the questions of assemblies and Article 4 para 2 b).

In this context, we would like to remind that the question of responsibility for the conformity assessment has not been addressed and discussed yet accordingly: Even if the manufacturer of a hydraulic systems who fulfills the definition of an assembly, with respect to Art. 4 para 2 b) doesn't need to carry out a conformity assessment, who will have to do this (if at all), when the assembly - as part of a machine - is placed on the market and put on the market? Or was it the intention of the legislator to exclude such situation from the PED and shift this responsibility entirely to the MD? How would this view correspond with Article 3 MD?

Even if the current situation has not led to a general safety risk of hydraulic systems, a legal clarification seems important in order to allow the Market Surveillance Authorities (MSA) to carry out their tasks on a sound legal basis. Market surveillance activities in Switzerland have shown, that this current "regime" with hydraulic systems is also applied to other pressure-assemblies being integrated into machines (e.g. autoclaves, compressed air systems). Therefore we would highly appreciate such clarifications.

With regard to Article 4 para 2 b) PED and Article 3 MD, Switzerland is of the opinion, that for hydraulic systems or any other assembling of pressure equipment fulfilling the definition of assembly being integrated into a machine, a conformity assessment according to PED has to be carried out, either by the manufacturer of the hydraulic system/assembly itself or the manufacturer of the machinery containing the hydraulic system/assembly.

DENMARK

Revision of PED guideline C-13

In relation to PED guideline C-13, Denmark are supporting a revision. If PED equipment are integrated in equipment covered by other directives, a conformity assessment according to PED should be performed, to ensure that the product is safe to use by the end user, and to ensure that a notified body is used as demanded in PED.

Denmark acknowledge that the manufacturers of machinery has been handling the PED equipment in their risk analysis, and that no data has been provided to document that this practice has been causing a risk to the end user. But to ensure a consistent procedure for PED equipment integrated in equipment cov-ered by other directives and to ensure a high level of safety for the end user, Denmark believes that a conformity assessment according to PED has to be performed when the product is covered by the machinery directive.

Thus, a revision of PED guideline C-13 is needed.

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 unsufficient 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**.

CEMA

Subject: Deletion of note 1 of the PED Guideline C-13

Following the discussions held during last Machinery Working Group meeting (19 and 20 February 2020) on the deletion of note 1 of Pressure Equipment Directive (PED) Guideline C-13, CEMA would like **to strongly oppose for the following reasons**:

- Machinery Directive, Annex I, EHSR 1.3.2. "Risk of break-up during operation" covers already the risk related to pressure. This is taken into account as a result of the necessary risk assessment made on the machinery. In this respect, the Machinery Directive considers as an assembly the risks generated by pressure equipment components.
  The application guideline of the Machinery Directive (version 2.2) confirms this interpretation in §91, when it comes to the application of PED 2014/68/EU.
- In this respect, there are no clues to state that a machinery containing PED components should be considered as a PED assembly. We would like to know what is the base for this change of interpretation: are there accident data? What is the technical background to legitimate this change of approach?
- We would like to stress also the fact that this deletion would generate a financial increase in the development costs as well as an additional administrative burden for manufacturers.

CEMA is the association representing the European agricultural machinery industry. With 11 national member associations, the CEMA network represents both large multinational companies and numerous European SMEs active in the sector. CEMA companies produce a large range of machines that cover any activity in the field from seeding to harvesting, as well as equipment for livestock management.

SPAIN (after WGP meeting of 12 March 2020)

Spain agrees with the German position.

Bulgaria (after WGP meeting of 12 March 2020)

BG suggests **redrafting MD, PED, or including new essential requirement of MD addressing in particular the risk of explosion due to pressure**.

However, BG asks for an Impact Assessment (no data, no cost-benefit to decide)

(in agreement with PED WG members)

We are of the opinion that the issue raised by Germany with regard to deleting a note in the PED Guidelines C-13, although starting from a minor point of insisting on deletion in the Guidelines, in fact represents a very serious case. It definitely needs a wider and deeper further discussion and wider consultation with stakeholders. All the arguments should be given due consideration and an impact analysis is needed.

So far BG market surveillance authorities have not encountered any specific problem with the situation in question. Also, with no sufficient data available, at this stage we do not have any strong position.

Considering all the related documents we are of the opinion that a change maybe needed but in any case it could have significant further effects in terms of extra costs for manufacturers and potential reorganisation of the production process.

Basically the interpretation given in Note 1 of C-13 distinguishes assemblies based on the fact they are not intended to be placed on the market alone but are designed to be incorporated into a machine, which is their intended use in fact.

We consider that there is a good reasoning in the position of Germany but we should look for a balanced and working solution, taking into account the fact that in any case an extra burden for the manufacturers would be expected.

Taking into account that these products technically meet the definition of assemblies set out in PED, it could rather be relevant to consider redrafting or including new essential requirement of MD addressing in particular the risk of explosion due to pressure.

The other option could be to include clear reference with regard to the interrelation of scopes of PED and MD but in a way so as to avoid overlapping and properly deal with the pressure related risks.

Bulgaria has always been in favour of having clear provisions in the basic legal act – Directive, Regulation, rather than leaving unclear cases to Guidelines. The latter leaves the door too open for interpretation and the interpretation issue may lead to an extremely opposite situations. The guidelines even intended as a supplementary flexible instrument, often make the problem deeper. The legal text is always the leading one.

The deletion of Note 1 in C-13 or its keeping will not solve the problem itself since both MD and PED texts remain unchanged. So, it is the time now to reconsider the MD EHSR in view of their possible change, e.g enhancing the safety aspect. The change in a guide is in any case an easier task than the change in a legislative text.

Czech Republic (after WGP meeting of 12 March 2020)

Czech Republic - Comments on Question on the PED guidelines C-13

As far as the PED guidelines C-13 is concerned, we do not agree with its revision. We support the statements and arguments of Sweden expressed in the document WG-2020.42. We also accept the explanatory texts of Orgalim.

OTHERS