

Brussels, 4th December 2013

Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of pressure equipment

Orgalime is pleased to table some general and specific comments on Ms. Rhoitova's draft report on the Commission's proposal of the European Parliament and of the Council on the harmonization of the laws of the Member States relating to the making available on the market of pressure equipment

1. Omission of the term "assemblies" in many paragraphs of the proposal.

The current directive and the Commission's proposal scope are very similar and refer to pressure equipment and assemblies. At the same time, the term 'assemblies' is defined in the Commission's proposal article 2, 6. Therefore we do not understand why, in many articles (see example of Article 3 and 5 for instance) the term 'assembly' has been deleted. This will lead to a situation where assemblies of pressure equipment are not treated like single unit of pressure equipment (which is the case with the current directive) in the EU market.

The current directive 97/23/EC indeed refers in its Article 4.1. to pressure equipment AND assemblies.

The first potential consequence of this deletion will lead to a situation where the free movement of pressure equipment in the EU market will not be guaranteed.

The second potential consequence is that in the end, the whole industry runs into the danger of seeing the whole concept of pressure assemblies abandoned definitely.

Orgalime members, who include into their constituencies many manufacturers of pressure equipment, request that the term "assembly" is re-introduced in all the articles and recitals where it has been deleted.

Orgalime, the European Engineering Industries Association, speaks for 38 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2012 accounted for some €1,840 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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2. Replacement of the term “hazard” with the term “risks” throughout the proposal.

Although Orgalime and its industries understand that this replacement results from an alignment with the New Legislative Framework, in the specific issue of Pressure equipment, it completely changes the concept of the current directive.

During meetings of the Working Group Pressure at the Commission, all stakeholders (manufacturers, users and notified bodies) urged the Commission to come back to the current situation (hazard analysis).

The term ‘risk’ and ‘hazard’ are not interchangeable. Indeed, a hazard is something that has the potential to cause harm whereas the term “risk” is the likelihood that the hazard will actually cause harm under prevailing conditions.

- A manufacturer of pressure equipment and/or assembly cannot under normal circumstances predict the extent of damage done by the detonation of pressure equipment as he/she has not enough information on the environment where the equipment will be placed.
- To give a probability for the failure of pressure equipment is against the whole concept of the directive. There is of course a ‘risk’ in operating pressure equipment but to accept to incorporate this risk in the design phase of pressure equipment is turning the whole philosophy upside down.

The main objective of the PED is to exclude any hazards as far as reasonably practicable and therefore only a HAZARD ANALYSIS can be used and required to the manufacturer.

Orgalime and its members understand that this request might be difficult to carry out in the light of the alignment requirements but they want to draw your attention to the fact that this mere alignment will lead to many technical changes of pressure equipment for the manufacturer.

3. Omission of the toxicity of gases in the new classification of substances.

The new classification of substances has omitted toxicity of gases. This implies that toxic non-flammable substances will be classified in group 2 whereas in the former directive, these were classified in group 1. This implies that the current proposal has not considered this risk when correlating with CLP. We suggest incorporating a new item in article 13.1a): xviii - toxic gases category 1, 2, 3 and 4.

Orgalime and its members recommend integrating the toxicity of gasses within the new classification of substances.

Orgalime also recommends taking the following remarks into consideration when drafting the report:

- **Recital 33**

Orgalime considers that this recital should be aligned with the one referred to in the Pyrotechnics Directive and should state as follows:

“To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity”.

2. Chapter 2 (Obligations of economic operators), Article 6, 2, 2

In order to allow the manufacturer to have the conformity assessment carried out by a third party body, we recommend using the wording of the Pyrotechnics directive: “have the relevant conformity assessment procedure referred to in Article xx carried out.”

3. Chapter 2 (Obligations of economic operators), Article 6, 6

Orgalime opposes this article as it obliges manufacturers who have a website address to add it to the product, while we consider that manufacturers should be allowed to choose among a physical and a web address.

The Pyrotechnics Directive states: *“Manufacturers shall indicate on the pyrotechnic article their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end- users and market surveillance authorities.”*



4. Article 14, 4

Orgalime would recommend using the wording “easily understood” instead of “EU Official language”.

5. Article 17 (new))

Orgalime agrees with this article but recommends integrating the requirements of the new recital 33 amended (see above).

6. Annex XV: EU DECLARATION OF CONFORMITY

Orgalime recommends deleting this provision and uses the following:

- Either a unique identification number of the Declaration of Conformity (DoC) itself as per EN 17050-1, instead of the products, because the Doc could apply to variations of the same product (e.g. same model, slightly different functionalities or colours).
- Or a number allowing the product's identification such as product, batch, type or serial number.

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