

Impact Assessment Study
on the Alignment of the
Pressure Equipment Directive
to the CLP Regulation

7th March 2013
DG Enterprise and Industry
Brussels



Disclaimer

The contents of this Presentation do not necessarily reflect the opinion or the position of the European Commission or any other organisation mentioned in this Presentation, but they are those of Risk & Policy Analysts Limited.



Background to the Study

- The Classification, Labelling and Packaging Regulation (CLP) will replace the Dangerous Substance Directive (DSD) over a transitional period that will end on 31 May 2015.
- All downstream legislation that incorporates the DSD, including the Pressure Equipment Directive, **must be** aligned to the CLP.



Objectives of the Study

- To examine the impacts of the alignment of the PED to the CLP.
- To focus on those substances with physical and health hazards that may change fluid group.



Pressure Equipment Directive - Article 9

- Article 9 of the PED separates 'fluids' into two groups based on their hazard classification under the Dangerous Substances Directive (DSD).
- Group 1 comprises 'dangerous fluids', as classified by the DSD, whilst a Group 2 fluid is any other fluid.
- To take account of the hazards associated with dangerous fluids, the conformity assessment procedure is generally more extensive for Group 1 fluids than for Group 2 fluids.



Definition of a Dangerous Fluid

- The definition of a dangerous fluid under Article 9 of the PED (which uses the DSD) is different from that used under the CLP.
- To align the PED to the CLP, the definition of a dangerous fluid under Article 9 must therefore be amended to reflect the CLP.



Physical Hazards: DSD to the CLP

- The transition from the DSD to the CLP for physical hazards should be reasonably smooth.
- Whilst there will be a change in the terminology used to identify hazards, only a small number of fluids will change from one fluid group to another.



Health Hazards: DSD to CLP

- The transition from DSD to the CLP for health hazards will not be as smooth as for the physical hazards.
- Under the CLP, there are a greater number of health hazard classes and categories. Furthermore, the boundaries of the CLP health categories do not align with those of the DSD.
- It is therefore **inevitable** that a number of substances will change fluid group as a result of the PED alignment to the CLP.



How to align the PED to the CLP

- Desk-based research and consultation with key stakeholders indicates that the PED conformity assessment procedure and concept of 'dangerous fluids' works well.
- The alignment therefore needs to be as simple and close to the current situation as possible.
- To ensure simplicity, CLP hazard statements have been recommended as a means to identify Group 1 fluids.



Physical Hazards – Amended Article 9

Hazard Class	Hazard Statement
Explosive	H200, H201, H202, H204 and H205
Organic peroxide or Self-reactive	H240, H241 and H242
Flammable gas	H220 and H221
Flammable liquids	H224 and H225 and, where the maximum allowable temperature is above flashpoint, H226
Flammable solids	H228
Pyrophoric liquids and solids	H250
Contact with water emits flammable gases	H260 and H261
Oxidising	H270, H271 and H272



Physical Hazards: Consequences of alignment

Hazard Class	Hazard Statement	Comment
Flammable liquids	H225: Highly flammable liquid and vapour	Some substances with flash points from 21°C to 23°C will now be automatically categorised as Group 1 fluids
Self – reactive	H242: Heating may cause fire	In theory, some flammable substances (R10) may be reclassified as a self-reactive substance with the Hazard Statement H242

- In short, the changes from DSD to CLP will only affect a small proportion of substances and the effects will be marginal.



Health Hazards – Amended Article 9

Hazard Class	Hazard Statement
Acute toxicity (oral)	H300
Acute toxicity (dermal)	H310 (Option 1 only)
Acute toxicity (dermal)	H310 and H311 (Option 2 only)
Acute toxicity (inhalation)	H330 and H331
Acute toxicity - Specific target organ toxicity	H370

- The only difference between Options 1 and 2 is the inclusion/exclusion of Acute toxicity (dermal) with Hazard Statement H311.



Health Hazards: Consequences of Alignment

Hazard Class	Hazard Statement	Comment
Acute toxicity (oral)	H301: Toxic if swallowed	Exclusion of H301 leads to some substances previously categorised Group 1 being reclassified as Group 2 fluids
Acute toxicity (inhalation)	H331: Toxic if inhaled	Inclusion of H331 leads to some vapours previously categorised as Group 2 being reclassified as Group 1 fluids
Acute toxicity (specific target organ toxicity)	H370: Causes damage to organs	Inclusion of H370 leads to some substances previously categorised as Group 1 being reclassified as a Group 2 fluid



Health Hazards: Consequences of Alignment

Hazard class	Hazard Statement	Comment
Acute toxicity (dermal)	H311: Toxic in contact with skin (Option 1 only)	Exclusion of H311 leads to some substances previously categorised as Group 1 being reclassified as Group 2 fluids
	H311: Toxic in contact with skin (Option 2 only)	Inclusion of H311 leads to some substances previously categorised as Group 2 being reclassified as Group 1 fluids

- The most significant impacts (in terms of numbers of substances affected) are likely to be associated with the Hazard Statements H301, H311 and H331.



Economic Impact of Alignment

- The current costs of complying with the PED is in the order of €250m per annum.
- The additional costs of aligning the PED to the CLP have been estimated to be:
 - €7.5 million per annum for **Option 1**; and
 - €9.5 million per annum for **Option 2**.



Economic Impact of Option 1 and Option 2

- The additional costs of aligning the PED to the CLP have been estimated to be:
 - €7.5 million per annum for **Option 1**; and
 - €9.5 million per annum for **Option 2**.



Assessment

- There is little difference between Options 1 and 2. They are effective in meeting the requirement to align the PED to the CLP and are coherent with other EU Directives.

- However, the additional costs associated with **Option 2** are not justified given the:
 - rare occurrence of pressure equipment failures; and
 - low level of risk associated with exposures to substances that are dermally toxic.

- **Option 1 is therefore the preferred option.**



Any Questions?

