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

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Final Report

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DG Enterprise and Industry

RPA
Risk & Policy Analysts

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DG Enterprise & Industry

by

Risk & Policy Analysts Limited,
Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT, United Kingdom
Tel: +44 1508 528465 Fax: +44 1508 520758
Email: post@rpaltd.co.uk

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Report Prepared by:	Pete Floyd, Director Meg Postle, Director Nigel Tuffnell, Senior Consultant Scott Marshall, Researcher Gill Pagluiuca, Denehurst Chemicals Terry Egginton, HPI Verification Services
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EXECUTIVE SUMMARY

Article 9 of the Pressure Equipment Directive (PED) separates 'fluids' into two groups based on their hazard classification under the Dangerous Substances Directive 67/548/EEC (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 requirements for the conformity assessment for compliance with the PED are generally more extensive for pressure equipment containing Group 1 fluids than for Group 2 fluids.

The Classification, Labelling and Packaging Regulation (CLP) was introduced to implement the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. The CLP will replace the DSD over a transitional period that will end on 31 May 2015. All downstream legislation that incorporates the DSD including the PED will need to be aligned to the CLP.

In relation to the PED, as the classification of hazardous properties for the CLP is different from that used for the DSD, it will be necessary to redefine what constitutes a 'dangerous fluid' in terms of the CLP classification in order to align the PED with 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 and codes used to identify the hazards, only a small number of fluids will change from one Group to another.*

*The transition from the DSD to the CLP for **health hazards** will not be as smooth as for the physical hazards. Under the CLP, there will be a greater number of hazard classes and categories and the boundaries do not often align with those of the DSD. Consequently, it is inevitable that a number of substances will need to change grouping under the PED.*

There is consensus from stakeholders that there is no requirement to change the PED in respect of 'dangerous fluids'. Rather the problem is that in some 'boundary areas', the classification of some substances under CLP may lead to some substances previously categorised as Group 2 fluids becoming Group 1 fluids and vice-versa. The overwhelming view from stakeholders is that the alignment needs to be as simple and as close to the current situation as possible.

With this in mind, it is proposed that the wording of Article 9 para 2.1 (which defines Group 1 fluids) is amended to refer to the Hazard Statements associated with the various hazardous properties. The current wording is presented overleaf with the suggested revision shown below.

Article 9 of the PED – Current Definition of Group 1 Fluids
2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or preparation covered by the definitions in Article 2 (2) of Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]). Group 1 comprises fluids defined as: explosive, extremely flammable, highly flammable, flammable (where the maximum allowable temperature is above flashpoint), very toxic, toxic, oxidizing.
([1]) OJ No 196, 16. 8. 1967, p. 1. Directive as last amended by Commission Directive 94/69/EC (OJ No L 381, 31. 12. 1994, p. 1).

Revised Article 9 for PED – Future Definition of Group 1 Fluids
2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or mixture covered by the definitions in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ([1]), Group 1 comprises fluids defined as: - explosive with Hazard Statements H200, H201, H202, H203, H204 and H205, - organic peroxides or self-reactive with Hazard Statements H240, H241 and H242, - flammable gas with Hazard Statements H220 and H221, - flammable liquids with Hazard Statements H224 and H225 and, where the maximum allowable temperature is above flashpoint, H226, - flammable solids with Hazard Statement H228, - pyrophoric liquids and solids with Hazard Statement H250, - contact with water emits flammable gases with Hazard Statements H260 and H261, - oxidising with Hazard Statements H270, H271 and H272, - acute toxicity – oral with Hazard Statement H300, - acute toxicity – dermal with Hazard Statement H310 (***Option 1 only)*** - acute toxicity – dermal with Hazard Statements H310 and H311 (***Option 2 only)*** - acute toxicity – inhalation with Hazard Statements H330 and H331, - specific target organ toxicity with Hazard Statement H370.
([1]) OJ L 353, 31.12.2008, p. 1.

The key differences between the current situation and future options are summarised in the table below.

Summary of Changes in Alignments for Options 1 and 2		
Hazard Class	**Hazard Statement**	**Comment**
Flammable Liquids	H225: Highly flammable liquid and vapour	Some substances with Flash Points from 21 to 23°C will now be automatically categorised as Group 1 fluids
Self-Reactive Substances and Mixtures *and* Organic Peroxides	H242: Heating may cause a fire	Theoretically, it is possible that some flammable substances (R10) may be reclassified as a self-reactive substance with the hazard statement H242
Acute Toxicity* (oral)	H301: Toxic if swallowed	Exclusion of H301 leads to some substances previously categorised as Group 1 being reclassified as Group 2 fluids

Summary of Changes in Alignments for Options 1 and 2		
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 vapours previously categorised as Group 2 being reclassified as Group 1 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 2 being reclassified as Group 1 fluids
Note: It is important to stress that, in relation Acute Toxicity, most substances will be unaffected. In other words, most substances which are currently categorised as 'very toxic' and 'toxic' under the DSD will remain Group 1 fluids but will be classified as Acute Toxicity Categories 1 and 2 under the CLP. Similarly, most substances which are currently categorised as 'harmful' will remain Group 2 fluids but will be classified as Acute Toxicity Category 4. As such, the area of interest concerns those substances which will be classified as Acute Toxicity Category 3 under the CLP with the associated Hazard Statements H301, H311 and H331.		

The most significant impacts (in terms of numbers of substances affected) are likely to be associated with the Hazard Statements H301, H311 and H331. However, further analysis indicates that the inclusion (under Option 1) or exclusion (under Option 2) of H311 makes very little material difference.

The costs of complying with the PED depend not only on the relevant Hazard Category for the equipment but also the compliance module(s) selected. Although there are few robust data available, it is estimated that the current compliance costs are probably of the order of €250m. These costs relate to pressure equipment placed on the EU market which was manufactured in the EU or imported into the EU.

In some cases, the compliance costs will increase after alignment with the CLP Regulation due to some substances being re-categorised as Group 1 fluids. Of course, compliance costs may decrease if a substance is re-categorised as a Group 2 fluid. In both instances where there is a change of fluid group, the equipment remains the same but the cost of the conformity assessment procedure is liable to change. In other words, the pressure equipment will still need to meet the same fundamental standards of design and construction. The only potential change will be the level of conformity assessment procedure (modules) and the extent of notified body involvement. These changes and their associated costs are considered to be the most significant impacts to industry resulting from the alignment of the PED with the CLP.

The costs of additional conformity assessments as a result of the PED aligning to the CLP have been estimated to be around €8.5 million per annum. There are no significant benefits beyond regulatory alignment, which is mandatory and a direct consequence of implementing the GHS by means of the CLP in the EU.

TABLE OF CONTENTS

1.	**INTRODUCTION**	**1**
1.1	Background	1
1.2	Study Aims	1
1.3	Structure of Report	2
2.	**PED AND CLP**	**3**
2.1	Pressure Equipment Directive	3
2.2	The CLP Regulation	11
2.3	PED and CLP	12
3.	**TRANSLATION OF PHYSICAL HAZARDS**	**15**
3.1	Introduction	15
3.2	Explosives	15
3.3	Flammable Substances	16
3.4	Oxidising Substances	20
3.5	Physical Hazards According to CLP	21
4.	**TRANSLATION OF HEALTH HAZARDS**	**23**
4.1	Introduction	23
4.2	Acute Toxicity – Overview	23
4.3	Specific Target Organ Toxicity	27
4.4	Summary	30
5.	**PROBLEM IDENTIFICATION & POLICY OPTIONS**	**31**
5.1	Evaluation of PED	31
5.2	Consultation with Stakeholders	32
5.3	Responses from Stakeholders	33
5.4	Problem Identification	36
5.5	Development of Policy Options	37
6.	**IMPACT ASSESSMENT**	**45**
6.1	Introduction	45
6.2	Numbers of Substances	46
7.	**COSTS OF ALIGNMENT**	**55**
7.1	Costs by Module	55
7.2	Compliance Costs to Industry	59
7.3	Costs of Alignment with the CLP Regulation	63
8.	**SUMMARY**	**67**

ANNEX 1: CORRELATION ON OF DSD AND CLP CLASSIFICATIONS

ANNEX 2: BOUNDARY TOXIC SUBSTANCES

Glossary

CEN	European Committee for Standardization
CLP	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EEA	European Economic Area
GHS	United Nations' Globally Harmonised System of Classification and Labelling of Chemicals
IA	Impact Assessment
(M)SDS	(Material) Safety Data Sheet
NLF	New Legislative Framework
PED	Pressure Equipment Directive 97/23/EC
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SEP	Sound Engineering Practice (under PED)
Seveso II	Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Seveso III	Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

1. INTRODUCTION

1.1 Background

Article 9 of the Pressure Equipment Directive (PED[1]) separates 'fluids' into two groups based on their hazard classification under the Dangerous Substances Directive 67/548/EEC (DSD[2]). 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 requirements for compliance with PED are generally more rigorous for Group 1 fluids than for Group 2 fluids

The DSD is now being replaced by the Classification, Labelling and Packaging Regulation (CLP[3]) over a transitional period that will end on 31 May 2015. As the classification of hazardous properties for CLP is different from that used for DSD, it will be necessary to redefine what constitutes a 'dangerous fluid' in terms of CLP classification in order to align the PED with CLP.

Under a framework contract with DG Enterprise and Industry, Risk & Policy Analysts Ltd. (RPA) has been commissioned to undertake a study to assess the impacts of redefining 'dangerous fluids' for PED.

1.2 Study Aims

The primary objective of the present study is to support the European Commission to carry out an impact assessment which will accompany a proposal on the alignment of the PED to both the New Legislative Framework (NLF) and the CLP Regulation. Since NLF alignment has already been considered in an earlier assessment[4], this study will focus on just the alignment of the PED to the CLP Regulation.

To fulfil the task specifications and prepare a robust impact assessment, it is necessary to examine the impact of the changes in classification of substances based on the CLP Regulation, compared to the current classification based on the DSD (only the hazard

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1 **Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the Approximation of the Laws of the Member States concerning Pressure Equipment** (OJ L 181, 9.7.1997, pp1-58), hereafter referred to as the Pressure Equipment Directive or PED.

2 **Council Directive 67/548/EEC of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions relating to the Classification, Packaging and Labelling of Dangerous Substances** (OJ 196, 16.8.1967, p1-98), hereafter referred to as the Dangerous Substances Directive or DSD.

3 **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No 1907/2006**, (OJ L 353, 31.12.08, pp1-1335), hereafter referred to as the Classification, Labelling and Packaging Regulation, the CLP Regulation or CLP.

4 **Commission Staff Working Paper: Impact Assessment Accompanying Document to the 10 Proposals to Align Product Harmonisation Directives to Decision No 768/2008/EC**, SEC(2011) 1376 final, dated 21.11.11.

categories listed for Group 1 fluids under the PED). It concerns, in particular, the physical and health related hazard classes and categories.

Against this background, RPA is expected to undertake analysis of the:

- current situation with regard to classification of substances under the PED; and
- the different options for aligning the PED to the CLP Regulation and their associated impacts.

1.3 Structure of Report

In order to provide the context for the study, Section 2 provides an introductory overview of the PED and the CLP Regulation. Sections 3 and 4 provide a detailed account of the correlation between the hazard categories under the PED and the CLP Regulation.

Thereafter the approach to the impact assessment elaborated by this study closely follows the European Commission's *Impact Assessment Guidelines*[5]. The key steps, therefore, in carrying out the assessment are:

- **Impact Assessment (IA) Step 1:** Identification of existing problems and objectives of legislative intervention;
- **IA Step 2:** Defining the policy options;
- **IA Step 3:** Identification of impacts that are relevant and key stakeholders that might be affected;
- **IA Step 4:** Initial assessment of the importance of these impacts based on their expected magnitude and on the likelihood of them occurring;
- **IA Step 5:** In-depth analysis of the most significant impacts;
- **IA Step 6:** Comparison of the policy options; and
- **IA Step 7:** Identification of the preferred policy option.

Section 5 of this report highlights the key problem areas associated with the planned alignment of the PED with the CLP Regulation and the possible policy options (IA Steps 2 and 3). This section takes account of targeted consultation which was undertaken for this study.

Section 6 provides an outline of the potential impacts and while Section 7 provides a detailed account of the costs of different options (to cover IA Steps 4 and 5). These sections take account of a stakeholder workshop to discuss this study held in November 2012. The final IA Steps 6 and 7 are presented in Section 8, which summarises the analysis with a recommendation for the preferred option.

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5 European Commission (2009): **Impact Assessment Guidelines**, SEC(2009) 92, dated 15 January 2009.

2. PED AND CLP

2.1 Pressure Equipment Directive

2.1.1 Purpose and Scope of Pressure Equipment Directive (97/23/EC)

The Pressure Equipment Directive (97/23/EC) has two main objectives. Firstly, it seeks to enable the free trade of pressure equipment and assemblies within the European Economic Area (EEA). This is achieved through the harmonisation of national systems with regards to hazards due to pressure for the design, manufacture, testing and conformity assessment of such products throughout the EEA. As a general rule, the manufacturer or his authorized representative will affix the CE mark to pressure equipment to demonstrate that it has complied with the provisions of the Directive.

The provisions of the PED do not prescribe specific technical solutions to problems to which designers and manufacturers must conform. Rather, within the provisions and Annexes are essential safety requirements that have been tailored for the range of pressure equipment that falls within the scope of the Directive. This approach allows designers and manufacturers to innovate and develop new pressure equipment. Not only does this approach encourage competition, it also ensures the second objective of the PED is met, namely, a high level of safety for pressure equipment.

As outlined under Article 1, the scope of the PED extends to pressure equipment (vessels, piping, safety accessories and pressure accessories) and assemblies with a maximum allowable pressure greater than 0.5 bar[6]. The PED therefore affects a wide range of equipment, including storage containers, water boilers, industrial pipe work, pressure safety devices, reaction vessels, and even domestic pressure cookers and fire extinguishers. The PED does not however cover the continued use of pressure equipment (subject to national in-service regulations) nor does it cover the wide range of pressure equipment listed below (Article 1(3))[7]

1. *Pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore).* However, it does apply to standard pressure equipment (e.g. in pressure reduction stations or compression stations).
2. *Networks for the supply, distribution and discharge of water and associated equipment and headraces.*
3. Simple pressure vessel equipment which is covered by Directive 87/404/EC;
4. Aerosol dispensers which are covered by Directive 75/324/EEC.
5. *Equipment for the functioning of vehicles* which is covered by Directives 70/156/EEC, 74/150/EEC or 92/61/EEC.
6. *Equipment classified as no higher than category I under Article 9* of the PED including:

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6 Note that 1 bar = atmospheric pressure = 100,000 Pa (N/m^2) = 14.7 psi

7 Text in italics are an exact quotations from the PED and other text summarises provisions of the Directive.

- new machinery covered by Directive 2006/42/EC (formerly Directive 89/392/EEC);
- lifts covered by Directive 95/16/EC;
- electrical equipment covered by Directive 2006/95/EC (formerly Directive 73/23/EEC);
- medical devices covered by Directive 93/42/EEC;
- appliances burning gaseous fuels covered by Directive 2009/142/EC (previously Directive 90/396/EEC);
- equipment and protective systems intended for use in potentially explosive atmospheres covered by Directive 94/9/EC.

7. Military equipment covered by Article 223 of the Treaty of Rome.
8. *Items specifically designed for nuclear use, failure of which may cause an emission of radioactivity.*
9. *Well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure.*
10. *Equipment comprising casings or machinery where … pressure is not a significant design factor.*
11. *Blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel and non-ferrous metals.*
12. *Enclosures for high-voltage electrical equipment.*
13. *Pressurized pipes for the containment of transmission systems.*
14. *Ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof.*
15. *Pressure equipment consisting of a flexible casing.*
16. *Exhaust and inlet silencers.*
17. *Bottles or cans for carbonated drinks for final consumption.*
18. *Vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar.*
19. Equipment covered by transport regulations (ADR, RID, IMDG and the ICAO Convention).
20. *Radiators and pipes in warm water heating systems.*
21. *Vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.*

In addition to the PED, the Commission has published formal guidance to ensure the coherent application of the PED[8] - hereafter referred to as the PED Guidelines. The PED Guidelines are developed and agreed by the Commission's Working Group "Pressure", which is composed of representatives of Member States, European federations, the Notified Bodies Forum and CEN.

[8] Guidelines related to the Pressure Equipment Directive 97/23/EC (PED), available from (http://ec.europa.eu/enterprise/sectors/pressure-and-gas/files/ped/ped-guidelines_en.pdf).

2.1.2 Classification of Pressure Equipment

To ensure that pressure equipment within the scope of the PED is safe when placed on the market and put into service, it must comply with the PED's Essential Safety Requirements. Compliance with these requirements is realised by subjecting the design and manufacture of pressure equipment to the appropriate conformity assessment procedure. The breadth of the conformity assessment procedure itself is dependent on the classification of the pressure equipment.

Equipment is classified under the PED using one of the nine tables (which, confusingly, are actually graphs) listed under Annex II. The correct table is determined by the type of equipment, state of contents (liquid or gas) and finally, where there are two conformity assessment tables to choose from, the grouping of the fluid (Group 1 or 2). Figure 2.1 and Table 2.1 provide an overview as to how the correct table is selected under the PED.

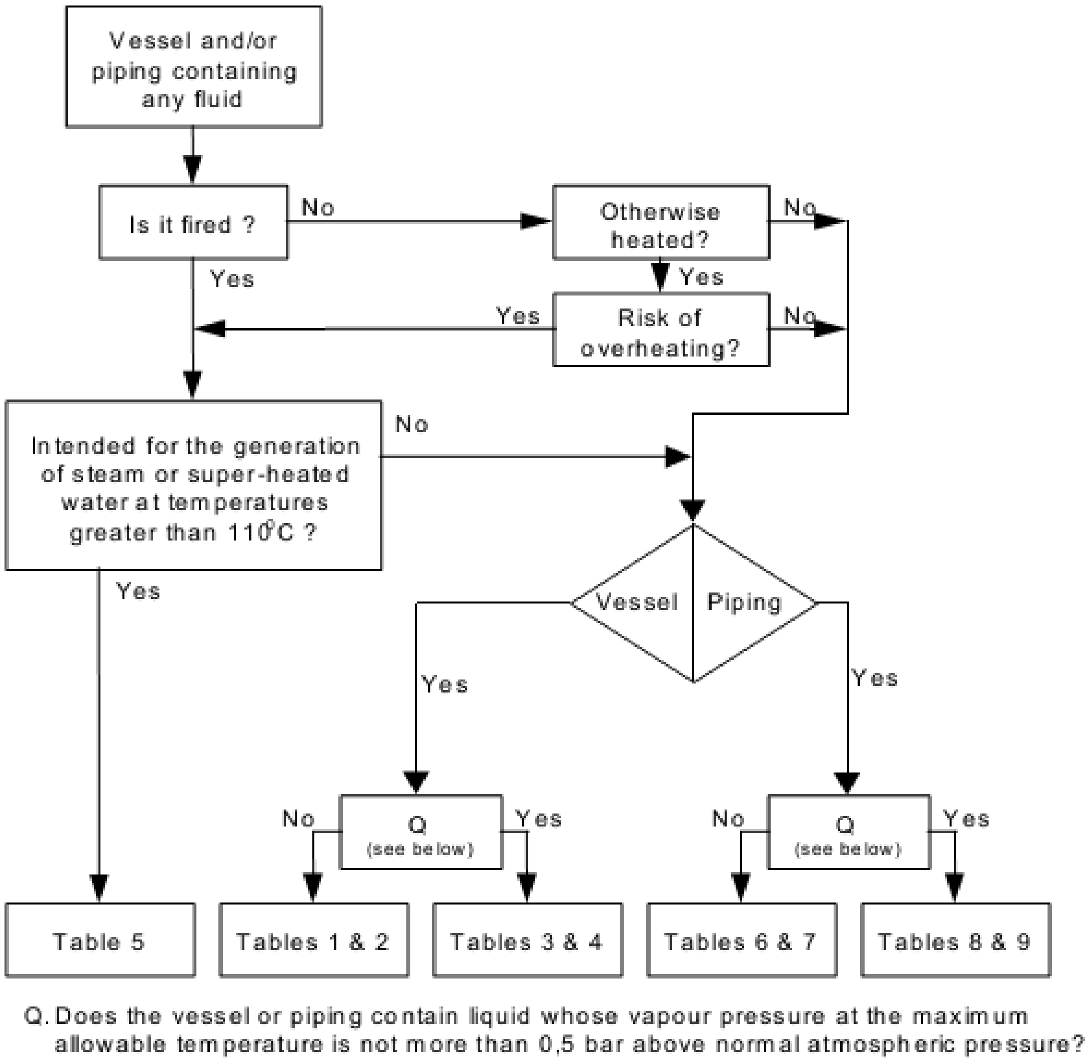

Figure 2.1: Classification of equipment under the PED[9]

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9 PED Guideline 2/13

Table 2.1: Determination of Applicable Category			
Equipment	**Classification**	**Group 1 Fluid**	**Group 2 Fluid**
Vessels	gaseous	Table 1	Table 2
	liquid	Table 3	Table 4
Piping	gaseous	Table 6	Table 7
	liquid	Table 8	Table 9
Pressure Accessories	volume	According to Tables 1 to 4	
	DN	According to Tables 6 to 9	
Safety Accessories	general	Category IV	
	specific	Category of respective equipment	
Assemblies	According to highest element (except safety accessories)		
Fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super-heated water			Table 5
Source: Commission presentation, February 2012			

The correct Conformity Assessment Table must be selected because the threshold values (allowable pressure and volume or nominal size) used to determine the category classification of the pressure equipment are markedly lower within the tables for Group 1 fluids as compared to the tables for Group 2 fluids. This can be illustrated with reference to Tables 3 and 4 for vessels containing liquids which have been reproduced as Figures 2.2 and 2.3

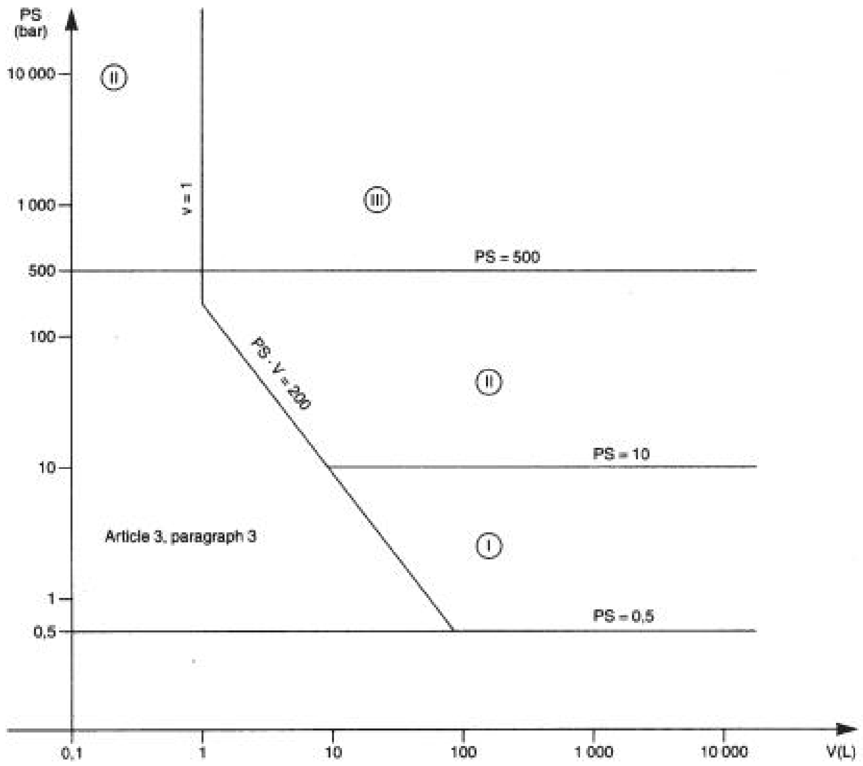

Table 3

Figure 2.2: Conformity Assessment Table 3 for Vessels (Liquid, Group 1)

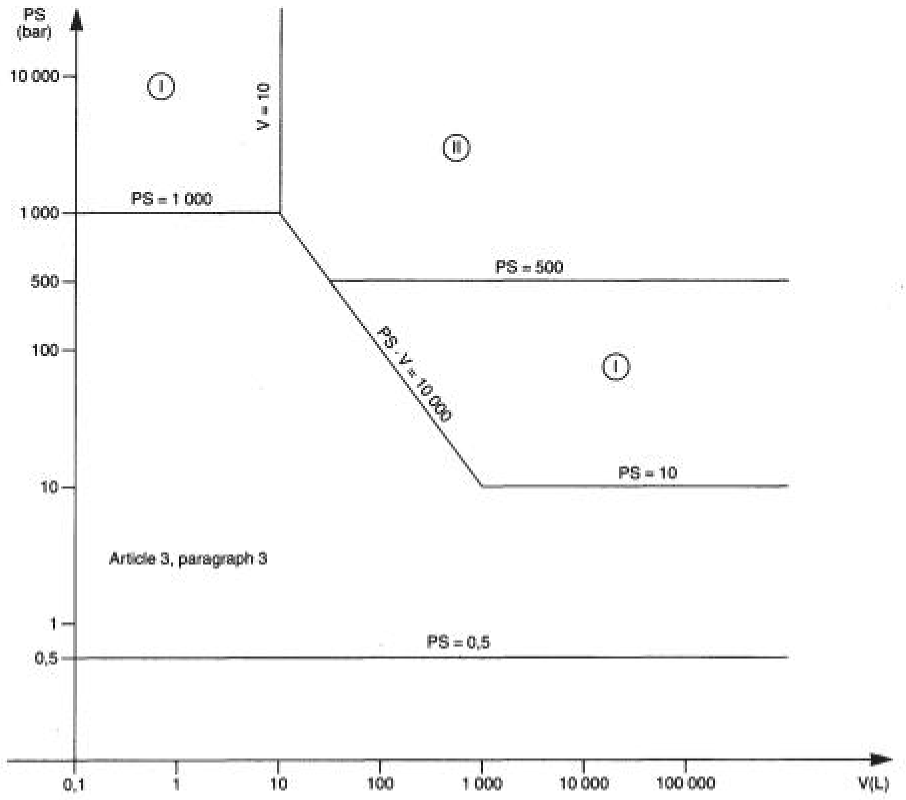

Table 4

Figure 2.3: Conformity Assessment Table 4 for Vessels (Liquid, Group 2)

By comparing Figure 2.2 (PED Conformity Assessment Table 3) and Figure 2.3 (PED Conformity Assessment Table 4), the potential impact of a substance moving Groups can be demonstrated. For example, Table 4 should be used to ascertain the hazard classification for a vessel that uses a Group 2 liquid fluid. By interpreting the table, it is clear that pressure equipment with a maximum allowable pressure of 450 bar and a volume of 10,000 litres, would need to fulfil the requirements of Hazard Category I.

Following the alignment of the PED to the CLP, if the substance were to move from Group 2 to Group 1, the vessel would now need to use Table 3 (see Figure 2.2) to ascertain the applicable hazard category. Due to the lower hazard thresholds of Table 3, the vessel operating at 450 bar and with a volume of 10,000 litres would now need to fulfil the requirements of Hazard Category II. Requiring the involvement of a notified body, this would increase the cost of complying with the PED.

In the above example, a substance moving from Group 2 to Group 1 resulted in the equipment it used moving into a higher hazard category bracket. However, it must be stressed that the changing of fluid group under the PED as a result of alignment to the

CLP will not always result in a change of hazard category. Indeed, whilst a substance may change group, it is possible that it will not change hazard class. For example, a comparison of Tables 3 and 4 indicates that a vessel with a volume of 1 litre and operating at 100 bar will need to fulfil the requirements of Sound Engineering Practice, irrespective of whether the fluid it uses is Group 1 or 2. If such equipment used a fluid that changed group under the PED, there would be no impact of the alignment to the CLP, as the PED compliance costs would remain the same.

More generally, pressure equipment using any of the Tables for Group 1 fluids is more likely to fall within a higher threshold bracket and thus have a higher category classification. The more demanding and more expensive conformity assessment procedure associated with a high category classification (discussed below) underscores the importance of ensuring fluids are assigned to the correct group.

2.1.3 Conformity Assessment Procedure

Thorough interpretation of the appropriate Conformity Assessment Table will classify the pressure equipment as belonging to one of five categories, with increasing levels of hazard associated with a higher category number. As outlined below, for each category, the PED sets out modules which, in combination, provide the route to conformity (PED assessment modules in brackets). Manufacturers may choose the module(s) which allows conformity to the PED and best suits them. For example, a manufacturer from Category III may elect to undertake B + E in combination, whilst another manufacturer would select modules B1 + D.

1. SEP (Sound Engineering Practice – no PED modules).
2. Category I (A).
3. Category II (A1, D1 and E1).
4. Category III (B1 + D, B1 + F, B + E, B + C1, H).
5. Category IV (B + D, B + F, G, H1).

The modules vary in the level of conformity assessment, ranging from Module A, which only details a process of self-certification, to Module H, which details full quality assurance, inspection and surveillance by a third party independently verified assessor (Notified Body) as summarised in Table 2.2 (overleaf). Evidently, the high category equipment conformity assessment procedure is comparably more extensive and thus financially more expensive than equipment deemed to pose less of a hazard.

However, it is important to note that irrespective as to the category (SEP and I to IV), the pressure equipment itself will remain the same, as will the Essential Safety Requirements. In other words, the pressure equipment will still need to meet the same fundamental standards of design and construction. The only potential change will be the level of conformity assessment procedure (modules) and the extent of notified body involvement. Clearly, the change of fluid grouping (from Group 2 to 1 or vice versa) could result in such changes.

Table 2.2: Modules Requirements under the PED		
Module	**Design**	**Production**
A	Technical documentation	Internal production control
A1	Technical documentation	Internal production control with monitoring of the final assessment
B	Type examination	
B1	Design examination	
C1		Monitoring of final assessment
D		Quality assurance for production, final inspection and test
D1	Technical documentation	Quality assurance for production, final inspection and test
E		Quality assurance for final inspection and test
E1	Technical documentation	Quality assurance for final inspection and test
F		Product verification
G	Unit verification	Unit verification
H	Quality assurance for design, manufacture, final inspection and test	
H1	Quality assurance for design, manufacture, final inspection and test with design examination and monitoring of final assessment	
DTI, Pressure Equipment, Guidance Notes on the UK Regulations – URN 05/1074 (April 2005)		

In addition to the Modules set out in the PED itself, Member States have agreed harmonised standards that set out the technical details needed to be sure of complying with the PED. These standards are not mandatory, but if they are not followed then a manufacturer shall have to demonstrate compliance with the essential safety requirements (ESR) of the PED. Pressure equipment in Categories I to IV must possess a CE mark, whilst equipment subject to Sound Engineering Practice is not allowed to possess a CE mark.

2.1.4 Grouping of Fluids

Article 9 of the PED separates 'fluids' into two groups based on their hazard classification under the Dangerous Substances Directive 67/548/EEC (DSD). For the purposes of the PED, a fluid is defined as:

> *gases, liquids and vapours in pure phase as well as mixtures thereof. A fluid may contain a suspension of solids*[10].

Thus, gas containing pieces of solids or drops of liquid will also be considered a fluid[11].

Group 1 comprises 'dangerous fluids', as classified by the DSD, whilst a Group 2 fluid is any other fluid. A fluid is only a Group 1 'dangerous fluid' if it possesses the

[10] PED Article 1 (2.7)

[11] PED Guideline 1/24.

properties cited in Article 9, paragraph 2 (2) of the PED. More specifically, dangerous fluids will have one or more of the risk phrases listed in Table 2.3.

Table 2.3: Hazard Class and R-Phrases	
Hazard Class	**Risk Phrase**
Explosive	R2 - Risk of explosion by shock, friction, fire or other sources of ignition R3 - Extreme risk of explosion by shock, friction, fire or other sources of ignition
Extremely Flammable	R12 - Extremely flammable
Highly Flammable	R11 - Highly flammable R15 - Contact with water liberates extremely flammable gases R17 - Spontaneously flammable in air
Flammable	R10 - Flammable (only if the intended maximum allowable temperature is above its flashpoint) [12]
O; Oxidising	R7 - May cause fire R8 - Contact with combustible material may cause fire R9 - Explosive when mixed with combustible material
T+; Very Toxic	R26 - Very toxic by inhalation R27 - Very toxic in contact with skin R28 - Very toxic if swallowed R39 - Danger of very serious irreversible effects
T; Toxic	R23 - Toxic by inhalation R24 - Toxic in contact with skin R25 - Toxic if swallowed R39 - Danger of very serious irreversible effects R48 - Danger of serious damage to health by prolonged exposure

It is noted that the PED makes no explicit reference to the Dangerous Preparations Directive 99/45/EC (DPD). However, the PED Guidelines[13] make it clear that where a DPD classification for a mixture exists, this classification should be used to determine the grouping of that mixture.

Due to the financial implications of assigning a fluid to the correct group (discussed above), a number of PED Guidelines further clarify whether fluids in particular states are Group 1 or Group 2.

If a solid is suspended in the fluid, its classification should take into account the group of the fluid, the group of the solid and, if known, the group of the mixture. If the mixture as a whole is classified as dangerous under the DPD, this should be used to determine its grouping. Otherwise, the classification (and grouping) should be that of the most dangerous solid or liquid[14]. It is therefore necessary to consider how the hazard classification of some solids may change in the transition from the PED to CLP.

12 PED Guideline 2/20 - The 'flash point' is the lowest temperature at which the vapour of a liquid can be made to ignite momentarily in air.

13 PED Guideline 2/24

14 PED Guideline 2/30

Conversely, if a non-suspended solid is blanketed by a Group 2 gas, or if the solid particles are big enough that they would not be expected to be released in the case of a pressure accident, classification will be undertaken with reference to Table 2 contained within the Annex of the PED[15]. Since the classification of a fluid may be influenced by the presence of a solid, this report must also consider how the introduction of CLP will impact the classification of such substances and mixtures.

If a chemical or physical reaction is likely to take place within the pressure equipment, the fluid which has the highest category will determine the classification of the final fluid. This will take account of starting, intermediate and final fluids and take into account all reasonably foreseeable conditions[16].

2.2 The CLP Regulation

The underlying objectives and purpose of The United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS)[17] within the European Union is outlined under Chapter 1:

a) enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
b) provide a recognized framework for those countries without an existing system;
c) reduce the need for testing and evaluation of chemicals; and
d) facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis[18].

The CLP Regulation was specifically introduced to implement the GHS and thus the overarching aim of the classification and labelling approach, as noted in the recital and Article 1 of CLP, is to:

> "*ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles…*".

This objective is fulfilled by harmonising the criteria for the classification of substances and mixtures according to health, environmental and physical hazards. Accordingly, the hazard communication element, which includes requirements for labelling and safety data sheets, is also harmonised. By identifying and communicating harmonised hazard criteria, the appropriate safety procedures and protective measures for health and the environment can be taken during handling, transport and use of chemicals.

15 PED Guideline 2/26

16 PED Guideline 2/27

17 GHS is intended to provide a global basis for a harmonised information provision system for hazardous substances and mixtures and a Plan of Implementation was adopted at the World Summit on Sustainable Development (WSSD) in Johannesburg in 2002; the first edition was approved by the Committee of Experts in December 2002 and published in 2003.

18 Chapter 1.1, 1.1.1.4

CLP will replace both the DSD and DPD over a transitional period that will end on 31 May 2015 (summarised in Figure 2.2 below).

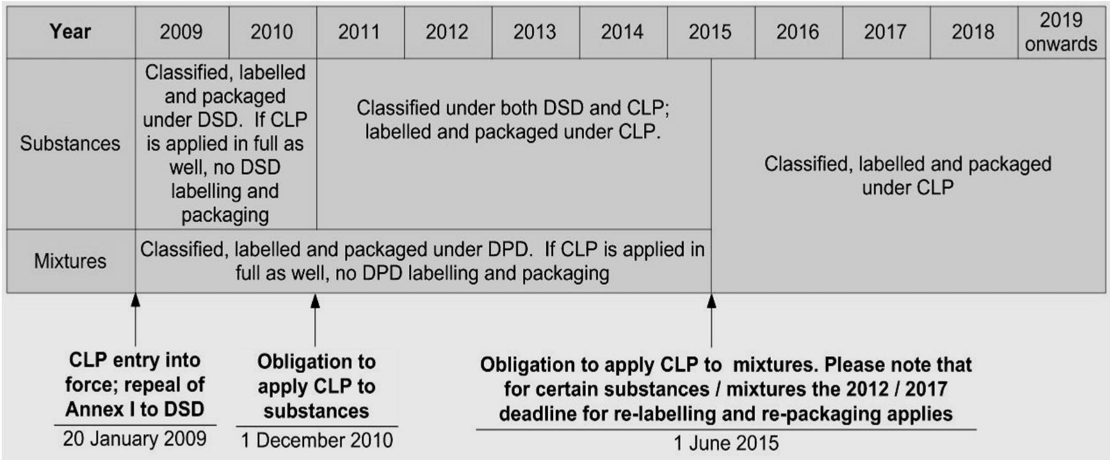

Figure 2.2: Summary of CLP Transitional Timetable

2.3 PED and CLP

From the discussion above, it can be seen that the objectives of the PED and CLP are different. The PED is concerned with the safety and functioning of the internal market in respect of pressure equipment whilst the CLP seeks to protect human health and the environment through identification of harmful substances and mixture.

Article 9 of the PED currently uses the DSD/DPD to classify substances and assign them to either Group 1 or Group 2. Since the DSD/DPD is to be repealed by CLP on 1 June 2015, the hazard categories currently employed by Article 9 must be replaced by the corresponding hazard classes, categories, and hazard statements of the CLP Regulation. However, a question remains as to the best way to align the PED to the CLP.

When aligning the PED to the CLP, it is important to ensure that the fundamental objectives of the PED (safety and functioning of the market) are not undermined. Furthermore, to ensure that the financial impact of the alignment is limited, where possible, the alignment should be simple and straightforward. This should ensure that all members of the pressure equipment industry, whether that is a large pressure equipment manufacturer or an SME that has only limited knowledge of the CLP, can understand and comply with the newly aligned PED. Fortunately, due to the similarities between the DSD and the CLP, the transition from the former to the latter should be relatively smooth. The relevant hazard classes for the DSD and CLP have been outlined in Table 2.4 (next page).

With regard to the physical hazards, the classification criteria for physical hazards under CLP have been aligned to GHS as have those of the UN Transport of Dangerous Goods Model Recommendations, which are then taken up through the various modal transport regulations such as ADR[19], RID[20], ADNR[21], IMDG[22], ICAO[23] and the EU Inland Transport Directive. It is expected that users will be familiar with the new ways that physical hazards may be described and that data from classification for the transport regulations will facilitate translation of classifications from DSD/DPD to CLP.

Table 2.4: Overview of Physical and Health Hazards translation from DSD to CLP	
Physical Hazards	
DSD Hazard Classes	**CLP Hazard Classes**
Explosive Oxidising Extremely Flammable Highly Flammable Flammable*	Explosives Oxidising gases Oxidising liquids Oxidising solids Flammable gases Flammable liquids Flammable solids Pyrophoric liquids Pyrophoric solids Substances and mixtures which, in contact with water, emit flammable gases Self-reactive substances and mixtures Self-heating substances and mixtures
*A *Flammable Fluid is only classified as a Group 1 Fluid if the intended maximum allowable temperature is above its flashpoint.*	
Human Health Hazards	
DSD Hazard Classes	**CLP Hazard Classes**
Very Toxic Toxic	Acute Toxicity STOT – Single Exposure STOT – Repeated Exposure

Following alignment with the CLP, there will still be a small number of physical hazard substances that that move from Group 1 to Group 2 and from Group 2 to 1. It is important to note that this change will not result in a substance falling out of the scope of the PED, for the substances will continue to be classified as either a Group 1 or Group 2 fluid.

For the human health hazard (Acute Toxicity), the division of this hazard class into several hazard classes and changes in the cut off values used to differentiate hazardous substances and mixtures within the hazard class, means that aligning the PED with CLP is not as simple or direct. As with physical hazards, this will not result in substances falling out of the scope of the PED. However, a number of substances will change Group under the PED.

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19 The European Agreement concerning the International Carriage of Dangerous Goods by Road

20 Regulations Concerning the International Carriage of Dangerous Goods by Rail

21 Regulations for the Carriage of Dangerous Substances on the Rhine

22 International Maritime Dangerous Goods Code

23 International Civil Aviation Organisation Technical Instructions

3. TRANSLATION OF PHYSICAL HAZARDS

3.1 Introduction

The transition from the DSD to CLP for physical hazards should be reasonably smooth. Whilst there will be a change in the terminology and codes used to identify the hazards, only a small number of fluids will change from one Group to another. The following tables provide a simplified and comprehensible overview of the translation from the DSD to CLP for the physical hazards. Consequently, they have not been drawn to scale and are figurative only. A more detailed description of the translation from the DSD to CLP for physical hazards can be found in Annex 1.

It should also be noted that the word 'substance' in the following discussion is used to mean any substance, mixture or explosive article that falls within the scope of the DSD, DPD or CLP Regulation.

3.2 Explosives

Table 3.1: Translation from the DSD to CLP (Explosive)							
DSD	E; Explosive R3			E; Explosive R2			
PED	Classified as 'Group 1' fluid under PED						
	Explosive						
CLP	Unstable	Div 1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
HS	**H200: Unstable Explosive**	**H201: Explosive; mass explosion hazard**	**H202: Explosive; severe projection hazard**	**H203: Explosive; fire, blast or projection hazard**	**H204: Fire or projection hazard**	**H205: May mass explode in fire**	**N/A**

Substances classified as explosive under the DSD will now be classified as unstable or within one of the five divisions (listed under Table 3.1). In addition, under CLP, there are Division 1.6 Explosives which are extremely insensitive **articles** that have a low probability of initiation and have been designed to avoid accidental detonation during storage and transportation (for example, warheads). Division 1.6 properties are tested for using Test series 7, and include tests such as the bullet impact test, as outlined in section 17 of the UN Manual of Tests and Criteria.

Since these articles will not be found in pressure equipment, it is proposed that these should not be classified as a Group 1 fluid under the PED. This approach benefits from simplicity and will assist industry with a smooth transition from the DSD to CLP.

Table 3.2: Translation from the DSD to CLP (Explosive)						
DSD	E; Explosive R2 / R3					
PED	Classified as 'Group 1' under PED					
CLP	**Organic Peroxide**			**Self-reactive**		
	Type A	Type B	Type C & D	Type A	Type B	Type C & D
HS	**H240: Heating may cause an explosion**	**H241: Heating may cause a fire or an explosion**	**H242: Heating may cause a fire**	**H240: Heating may cause an explosion**	**H241: Heating may cause a fire or an explosion**	**H242: Heating may cause a fire**

Some substances that were previously classified as E; Explosive (R2 / R3) according to the DSD will change hazard class according to CLP. The possible changes have been outlined above in Table 3.2. Type E and F have not been included in Table 3.2 because it is unlikely that substances previously classified as explosive under the DSD will be given either of these classifications under the CLP. This is because Type E substances will neither detonate nor deflagrate and show low or no effect when heated under confinement, whilst Type F is equally non-reactive, in addition to having low or no explosive power. It must however be stressed that substances which are classified as H242 Type E or F will be Group 1 fluids under the PED (see Table 3.5 and Table 3.10 below).

3.3 Flammable Substances

Table 3.3: Translation from the DSD to CLP (Extremely Flammable (gas))		
DSD	F +; Extremely Flammable R12	
PED	Classified as 'Group 1' fluid under PED	
	Flammable Gas	
CLP	Category 1	Category 2
HS	**H220: Extremely flammable gas**	**H221: Flammable gas**

Table 3.3 demonstrates that fluids previously classified as F +; Extremely Flammable (R12) will continue to be classified as a Group 1 fluid.

Table 3.4: Translation from the DSD to CLP (Flammable (Liquids))					
DSD	F +; Extremely Flammable R12	F; Highly Flammable R11	F; Flammable R10*		
* Substances classified as F; Flammable (R10) will be Group 1 if the intended maximum allowable temperature is above its flashpoint.					
PED	Classified as 'Group 1' fluid under PED				
FP °C	≤ 0	0 - 21	21 - 23	23 - 55	55 - 60
CLP	**Flammable Liquids***				
	Category 1	Category 2		Category 3**	
* As discussed further in Annex 1, the demarcation between Category 1 and 2 flammable liquids also takes account of the boiling point. Nevertheless, extremely flammable liquids (R12) under DSD will generally become Category 1 flammable liquids under CLP ** Substances classified as a Flammable Liquid, Category 3 will be a Group 1 fluid if the intended maximum allowable temperature is above its flashpoint.					
HS	**H224: Extremely flammable liquid and vapour**	**H225: Highly flammable liquid and vapour**		**H226: Flammable liquid and vapour**	

Table 3.4 shows that the most direct and simple translation from the DSD to CLP will be to classify only Categories 1 and 2 as a Group 1 fluid under the PED. The cut of values for a Group 1 fluid will thus increase from a flashpoint of 21°C to 23°C. Substances previously classified as F; Flammable (R10) under the DSD and have a flashpoint between 21 and 23°C will now be a Group 1 fluid, either Category 1 or 2. This will result in a small increase in the number of substances classified as dangerous fluids for the purposes of the PED (unless those substances were used in pressure equipment where the maximum allowable temperature was above their flashpoint).

To ensure congruity between the DSD and CLP, as occurred with substances classified as F; flammable (R10), substances with the hazard statement H226: Flam Liq. 3 will be classified as a Group 1 fluid if the intended maximum allowable temperature is above its flashpoint.

Table 3.5: Translation from the DSD to CLP (Flammable)					
DSD	F +; Extremely Flammable R12		F; Highly Flammable R11		F; Flammable R10*
* Substances classified as F; Flammable (R10) will be Group 1 if the intended maximum allowable temperature is above its flashpoint.					
PED	Classified as 'Group 1' fluid under PED				
CLP	**Self – reactive**				
	Type C	Type D	Type E	Type F	Type G
HS	**H242: Heating may cause a fire**				**N/A**

Some substances that are classified as flammable according to the DSD will move into the 'self-reactive' hazard class according to the CLP (see Table 3.5 above). Those previously classified as F+; Extremely Flammable (R12) and F; Highly Flammable (R11) will clearly remain within Group 1. In addition, a small number of substances classified as F; Flammable (R10) under the DSD will under CLP be classified as a Group 1 fluid. Whereas previously substances in this hazard class would only be classified as Group 1 if the maximum allowable temperature was above the flashpoint, those substances that move to Self-reactive Type F will by default be classified as dangerous fluids. For substances classified as Type G, then as there is no corresponding Hazard Pictogram, Signal Word or Hazard Statement for these substances classified as Type G, it is proposed not to include these in Group 1.

Type A and Type B substances have not been included in Table 3.5, as it is unlikely that a substance previously classified as Flammable under the DSD will fall within these classes. In other words, a substance classified as a Type A (or Type B) substance under CLP would have previously been classified as an 'explosive' under DSD (as opposed to being an 'extremely flammable' substance for example).

Table 3.6: Translation from the DSD to CLP (Highly Flammable (Solid))		
DSD	F; Highly Flammable R11	
PED	Classified as 'Group 1' fluid under PED	
CLP	**Flammable Solids**	
	Category 1	Category 2
HS	**H228: Flammable solid**	

Substances that are classified as F; Highly Flammable (R11) (solid) under the DSD and fulfil the definition of a fluid under CLP will continue to be classified as a Group 1 fluid.

Table 3.7: Translation from the DSD to CLP (Highly Flammable)		
DSD	F; Highly Flammable R17 (liquid)	F; Highly Flammable R17 (solid)
PED	Classified as 'Group 1' under PED	
CLP	**Pyrophoric Liquid**	**Pyrophoric Solid**
	Category 1	Category 1
HS	**H250: Catches fire spontaneously if exposed to air**	**H250: Catches fire spontaneously if exposed to air**

Substances that were previously classified as F; highly flammable (R17) according to the DSD are given a separate pyrophoric hazard class under CLP, with solids and liquids transferring accordingly. The scope of CLP is the same as DSD and these substances and mixtures that move hazard class will continue to be classified as a Group 1 fluid under the PED.

Table 3.8: Translation from the DSD to CLP (Highly flammable)

DSD	F; Highly Flammable R15		
PED	Classified as 'Group 1' under PED		
CLP	**Contact with Water Emits Flammable Gases**		
	Category 1	Category 2	Category 3
HS	**H260: In contact with water releases flammable gases which may ignite spontaneously**	**H261: In contact with water releases flammable gases**	

Substances previously classified as F; Highly Flammable (R15) according to the DSD will be classified under CLP as a water reactive substance, as the overall scope of this hazard class is the same. Although CLP has sub-divided this class into three categories, all substances that qualify for this hazard class will continue to be classified as a Group 1 fluid for the purposes of the PED.

3.4 Oxidising Substances

Table 3.9: Translation from the DSD to CLP (Oxidising)

DSD	O; Oxidising R8 (gas)	O; Oxidising R9 (liquid)	O; Oxidising R9 (solid)	O; Oxidising R8 (liquid / solid)		
PED	Classified as 'Group 1' fluid under PED					
CLP	**Oxidising (gas/liquid/solid)**					
	Ox. gas. Category 1	Ox liq. Category 1	Ox sol. Category 1	Ox. liq. / sol. Category 1	Ox. liq / sol Category 2	Ox. liq / sol Category 3
HS	**H270: May cause or intensify fire; oxidiser**	**H271: May cause fire or explosion; strong oxidiser**			**H272: May intensify fire; oxidiser**	

Those substances that are classified as O; Oxidising (R8 / R9) according to the DSD will be re-classified as displayed in Table 3.9 above. Although oxidisers are divided differently according to CLP, when compared to DSD, the overall scope of the hazard classes is the same under both systems (for gases and liquids they are identical, for solids the differences are very small). No issues have been identified with regard to the transition from the DSD to CLP.

Table 3.10: Translation from the DSD to CLP (Oxidising)

DSD	O; Oxidising R7			
PED	Classified as 'Group 1' under PED			
CLP	**Organic Peroxide**			
	Type C	Type D	Type E	Type F
HS	**H242: Heating may cause a fire**			

Organic peroxides that were previously classified as O; Oxidising (R7) are also given a separate hazard class under CLP. Those substances will also continue to be classified as Group 1 fluids for the purposes of the PED. Since it is unlikely that a substance previously classified as an oxidising substance (R7) under the DSD would be classified as a Type A or Type B organic peroxide, these have not been included in Table 3.7 (as they are included in Table 3.2).

3.5 Physical Hazards According to CLP

The preceding tables and discussion suggest that the impact of aligning the PED with CLP will be minimal and the transition should be smooth for physical hazards. In all but a few cases, substances that are classified according to the DSD as E; Explosive, F+; Extremely Flammable, F; Highly Flammable and O; Oxidising may change hazard class or category but will not change group under the PED.

Substances that were previously classified as F; Flammable (R10) under the DSD were not classified as dangerous fluids, unless the intended maximum allowable temperature was above its flashpoint. The transition from the DSD to CLP will result in some substances moving to higher categories as a result of the shift in the temperature parameters. In these instances, substances will now be automatically classified as dangerous fluids under the PED by default, irrespective of their maximum operating temperature.

4. TRANSLATION OF HEALTH HAZARDS

4.1 Introduction

The transition from DSD to CLP for health hazards will not be as smooth as for the physical hazards. As can be seen from Table 4.1 below, this hazard class is split into a greater number of hazard classes and categories and as will be explored in greater detail below, the parameters of these boundaries do not often align with those of the DSD. Consequently, it is inevitable that a number of substances will change grouping under the PED.

Table 4.1: Overview of Translation from DSD to CLP for Human Health Hazards

Group 1 fluid under DSD		Possible Group 1 fluid categories under CLP
T+; Very Toxic	R26 - Very toxic by inhalation; R27 - Very toxic in contact with skin; R28 - Very toxic if swallowed; and R39 - Danger of very serious irreversible effects.	Acute Toxicity – Oral, Categories 1/2/3/4 Acute Toxicity – Dermal, Categories 1/2/3/4 Acute Toxicity – Inhalation, Categories 1/2/3/4 STOT – Single exposure (SE) STOT – Repeated exposure (RE)
T; Toxic	R23 - Toxic by inhalation; R24 - Toxic in contact with skin; R25 - Toxic if swallowed; R39 - Danger of very serious irreversible effects; and R48 - Danger of serious damage to health by prolonged exposure.	

4.2 Acute Toxicity – Overview

4.2.1 Overview

As noted under Annex I, 3.1.1.2 of the CLP, the hazard class 'Acute Toxicity' differentiates substances according to route of exposure (Oral, Dermal and Inhalation) as well as severity of hazard. Due to the different physical forms that inhaled substances may take and the variable impact that each form has on toxicity, 'Acute Toxicity - Inhalation' is further defined so as to differentiate between 'Gas' 'Vapours' and 'Dusts and Mists', as outlined in Table 4.2 below.

Table 4.2: Acute Toxicity Categories and Acute Toxicity Estimates (ATE)

Exposure Route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg body-weight)	ATE ≤ 5	5 < ATE ≤ 50	50 < ATE ≤ 300	300 < ATE ≤ 2000
Dermal (mg/kg bodyweight)	ATE ≤ 50	50 < ATE ≤ 200	200 < ATE≤ 1000	1 000 < ATE ≤ 2000
Gases (ppmV*)	ATE ≤ 100	100 < ATE≤ 500	500 < ATE ≤ 2500	2 500 < ATE ≤20000
Vapours (mg/l)	ATE ≤ 0.5	0.5 < ATE ≤ 2.0	2.0 < ATE ≤ 10.0	10.0 < ATE ≤ 20.0
Dusts and Mists (mg/l)	ATE ≤ 0.05	0.05 < ATE ≤ 0.5	0.5 < ATE≤ 1.0	1.0 < ATE ≤ 5.0

Note: * *Gas concentrations are expressed in parts per million per volume (ppmV).*

Substances are classified using the values listed in Table 4.2 above, with each route of exposure considered. If the substance falls into multiple hazard categories, the most severe category will be used for the overall determination of label elements such as pictograms, signal words, etc.[24].

The transition from the DSD to CLP for the hazard class Acute Toxicity will not be smooth, for the DSD splits this hazard class into three categories (very toxic, toxic and harmful) whereas the CLP splits it into four categories (acute toxic 1,2,3 and 4), each subdivided into five exposure routes (oral, dermal, inhalation vapour, inhalation gas and inhalation dust and mist). These have been arranged in tables below which indicate the relative differences between each system using LD_{50} [25] and LC_{50} [26] values.

4.2.2 Acute Toxicity – Oral

<table>
<tr><th colspan="7">Table 4.3: Translation from the DSD to CLP (Acute Toxicity - Oral)</th></tr>
<tr><td>DSD</td><td colspan="2">T+; Very Toxic
R28</td><td colspan="2">T; Toxic
R25</td><td colspan="2">Xn; Harmful
R22</td></tr>
<tr><td>PED</td><td colspan="4">Classified as ‘Group 1’ fluid under PED</td><td colspan="2"></td></tr>
<tr><td>LD50</td><td>≤ 5</td><td>5 – 25</td><td>25 – 50</td><td>50 – 200</td><td>200 – 300</td><td>300 - 2000</td></tr>
<tr><td rowspan="2">CLP</td><td colspan="6">Acute Toxicity – Oral</td></tr>
<tr><td>Category 1</td><td colspan="2">Category 2</td><td colspan="2">Category 3</td><td>Category 4</td></tr>
<tr><td>HS</td><td colspan="3">H300: Fatal if swallowed</td><td colspan="2">H301: Toxic if swallowed</td><td>H302: Harmful if swallowed</td></tr>
</table>

Table 4.3 figuratively demarcates the Category boundaries of the DSD and CLP. As can be clearly seen, the boundary between toxic and harmful and the cut-off point for assigning a substance as a group 1 or group 2 fluid does not match the boundaries in CLP. A decision must be made whether to include Category 3 substances as Group 1 fluids under the PED.

To draw the boundary so as to include only Categories 1 and 2 would reduce the number of fluids deemed to be dangerous (Group 1 fluid) for the purposes of the PED. Conversely, if the boundary were to be drawn so as to include Categories 1, 2 and 3, additional substances would be captured and classified as a Group 1 fluid that were

[24] ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

[25] Lethal dose - the amount of material, given all at once or over a short period of time, which causes the death of 50% of a group of test animals (expressed as mg/kg bodyweight).

[26] Lethal concentration - concentration of the chemical that, in the air, will kill 50% of test animals in a given time (usually expressed as parts per million by volume (ppmV) or mg/litre).

previously deemed Xn; Harmful (R22) and' Group 2' according to the DSD. There is no justification for extending the scope so as to include Category 4.

4.2.3 Acute Toxicity – Dermal

Table 4.4: Translation from the DSD to CLP (Acute Toxicity – Dermal)					
DSD	T+; Very Toxic R27	T; Toxic R24		Xn; Harmful R21	
PED	Classified as 'Group 1' fluid under PED				
LD_{50}	≤ 50	50 - 200	200 - 400	400 - 1000	1000 - 2000
CLP	**Acute Toxicity – Dermal**				
	Category 1	Category 2	Category 3		Category 4
HS	**H310: Fatal in contact with skin**		**H311: Toxic in contact with skin**		**H312: Harmful in contact with skin**

Determining where the boundary will be drawn for the dermal exposure route will again be determined by a decision to either increase or decrease the fluids classified as 'Group 1' fluids under the PED. As is made clear in Table 4.4, the DSD classification T; Toxic (R24) intersects Category 3 (H311). Thus a decision must be made to either include Category 3 and potentially increase the fluids listed under 'Group 1', or exclude the Category and potentially decrease the number of fluids that are listed under Group 1.

4.2.4 Acute Toxicity – Inhalation (Dusts and Mists and Vapours)

Table 4.5: Translation from the DSD to CLP (Acute Toxicity – Dusts and Mists)					
DSD	T+; Very Toxic R26		T; Toxic R23		Xn; Harmful R20
PED	Classified as 'Group 1' fluid under PED				
LC_{50}	≤ 0.05	0.05 – 0.25	0.25 – 0.5	0.5 - 1	1 - 5
CLP	**Acute Toxicity – Dusts and Mists**				
	Category 1	Category 2		Category 3	Category 4
HS	**H330: Fatal if inhaled**			**H331: Toxic if inhaled**	**H332: Harmful if inhaled**

With regard to the exposure route 'Acute Toxicity – Dusts and Mists', alignment is simple and direct, with Category 3 (H331) aligning perfectly with the T; Toxic (R23) according to the DSD. Equally, Table 4.6 below demonstrates that Category 2 (H330) 'Acute Toxicity - Vapours' aligns perfectly with the T; Toxic (R23) according to the DSD.

Table 4.6: Translation from the DSD to CLP (Acute Toxicity – Vapours)				
DSD	T+;Very Toxic R26	T; Toxic R23	Xn; Harmful R20	
PED	Classified as 'Group 1' fluid under PED			
LC_{50}	≤ 0.5	0.5 – 2	2 - 10	10 -20
CLP	**Acute Toxicity – Vapours**			
	Category 1	Category 2	Category 3	Category 4
HS	**H330: Fatal if inhaled**		**H331: Toxic if inhaled**	**H332: Harmful if inhaled**

4.2.5 Acute Toxicity – Gas

Table 4.7: Classification for Gases under CLP				
LC50 (gases) (ppm V*)	≤ 100	100 - 500	500 - 2500	2500 - 20000
CLP	Category 1	Category 2	Category 3	Category 4
HS	**H330: Fatal if inhaled**		**H331: Toxic if inaled**	**H332: Harmful if inhaled**
*Note: *For a 'typical' gas with a molecular weight of 50 then concentrations of 100, 500 and 2500 ppmV would equate to around 0.2, 1.0 and 5.0 mg/l respectively.*				

It is not possible to produce an accurate comparison table for the hazard class 'Acute Gas Toxicity' because the criteria used to measure and classify substances are different according to the DSD and CLP. The DSD classification of a substance or mixture for the hazard class Acute Inhalation Toxicity is derived from the mass (mg/l) inhaled in a given volume. On the other hand, CLP classifies substances and mixtures using the volume concentrations (ppmV)[27].

[27] For the differences between gas concentrations by weight and volume, see, for example, http://www.epa.gov/apti/bces/module2/concentrate/concentrate.htm#major

4.3 Specific Target Organ Toxicity

Within CLP, substances which cause specific target organ toxicity (STOT) effects at doses lower than those causing acute lethal effects may be classified as STOT-SE (Single exposure) or in the case of chronic toxicity testing, STOT-RE (Repeated exposure). This report will not consider STOT-RE (equivalent to T; R48 and Xn; R48 under the DSD/DPD), as the release of dangerous fluid from pressure equipment following an accident will in all probability only occur once. Substances with this classification should therefore be listed as a Group 2 fluid by default.

Although STOT-SE is a new term in CLP, it is not a new concept since it was covered under the DSD. CLP defines this hazard class under Annex 1: 3.8.1.1 as "specific, non-lethal target organ toxicity arising from a single exposure to a substance or mixture". It includes all "significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed…"[28]. Where the criteria for STOT-SE and another hazard class are fulfilled, only the most appropriate hazard class may be assigned, thereby avoiding "double classification"[29]. This hazard class is applicable to any exposure route that is relevant for humans, although this will principally be oral, dermal or inhalation[30].

Substances that fall within the STOT-SE are classified using guidance value ranges outlined under Annex I, Table 3.8.2 of CLP. This approach is different to the strict threshold limits which are outlined elsewhere for the hazard class Acute Toxicity. Suppliers may vary their classification according to their expert judgement, provided there are valid scientific grounds for doing so.

Substances will be classified in either Category 1 or 2 for STOT-SE, depending on the nature and severity of the effect(s) observed. The hazard category STOT-SE 3, which is used to classify for the transient effects of respiratory irritation (R38) and narcotic effects (R67) has not been included below, as these were not previously considered under the PED and do not present an increased risk to justify inclusion within the aligned PED.

The following tables compare the classification of STOT-SE according to the DSD and CLP. As with the previous tables, they are primarily designed to highlight the different parameters and boundaries of the DSD and CLP. They are therefore not to scale and should not be used as an indicative guide to the number of substances contained within the various Categories.

There are three possible exposure routes, Oral Dermal and Inhalation (which is further divided to provide criteria for Gases, Vapours, and Dusts and Mists). For Gases it is not possible to produce an accurate translation table because the criteria used to measure and classify substances are different according to the DSD and CLP. The DSD classification of a substance or mixture for the hazard class 'Acute Toxicity –

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28 CLP Annex I, 3.8.1.1

29 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

30 CLP, Annex I, 3.8.1.5

Inhalation' is derived from the mass (mg/l) inhaled in a given volume. On the other hand, CLP classifies substances and mixtures for the STOT-SE gas exposure route using the volume concentration (ppmV)[31].

Table 4.8: Translation from the DSD to CLP (STOT-SE Oral)

DSD	T+; Very Toxic R39/28	T; Toxic R39/25	Xn; Harmful R68/22	
PED	Classified as 'Group 1' under PED			
Guidance Values (mg/kg-bw)	≤ 25	25 – 200	200 – 300	300 - 2000
CLP	**STOT-SE Oral**			
	Category 1			Category 2
HS	**H370: Causes damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**			**H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**

Table 4.9: Translation from the DSD to CLP (STOT-SE Dermal)

DSD	T+; Very Toxic R39/27	T; Toxic R39/24	Xn; Harmful R68/21	
PED	Classified as 'Group 1' under PED			
Guidance Values (mg/kg-bw)	≤ 50	50-400	400-1000	1000 - 2000
CLP	**STOT-SE Dermal**			
	Category 1			Category 2
HS	**H370: Causes damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**			**H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**

31 For the differences between gas concentrations by weight and volume, see, for example, http://www.epa.gov/apti/bces/module2/concentrate/concentrate.htm#major

Table 4.10: Translation from the DSD to CLP (STOT-SE Dusts and mists)			
DSD	T+; Very Toxic R39/26	T; Toxic R39/23	Xn; Harmful R68/20
PED	Classified as 'Group 1' under PED		
Guidance Values mg/l/4hr	≤ 0.25	0.25 -1.0	1.0 – 5.0
CLP	**STOT – SE Dusts and Mists**		
	Category 1		Category 2
HS	**H370: Causes damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**		**H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**

Table 4.11: Translation from the DSD to CLP (STOT-SE Vapours)				
DSD	T+; Very Toxic R39/26	T; Toxic R39/23	Xn; Harmful R68/20	
PED	Classified as 'Group 1' under PED			
Guidance Values mg/l/4hr	≤ 0.5	0.25 -2.0	2.0 – 10.0	10.0 – 20.0
CLP	**STOT – SE Vapours**			
	Category 1			Category 2
HS	**H370: Causes damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**			**H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**

Table 4.12: CLP Guidance Value Ranges for STOT-SE Gas		
Guidance Values ppmV/4h	≤ 2500	2500 > 20000
CLP	**STOT–SE Gas**	
	Category 1	Category 2
HS	**H370: Causes damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**	**H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)**
*Note: *For a 'typical' gas with a molecular weight of 50 then concentrations of 2500 and 20,000 ppmV would equate to around 5.0 and 40 mg/l respectively.*		

Collectively assessing the five tables (Tables 4.8 to 4.12 above), it is apparent that the classification of a Group 1 fluid must not include substances captured by STOT-SE Category 2 (H371). To do so would unnecessarily increase the number of substances classified as a Group 1 fluid. Thus for STOT-SE, only Category 1 fluids (H370) will, for the purposes of the PED, be classified as Group 1 fluids.

4.4 Summary

It has been demonstrated that the transition from the DSD to CLP will be relatively smooth for the physical hazards, with only a small number of substances changing fluid group. However, the alignment is not as smooth for the human health hazards and a decision will need to be made as to which categories under the Acute Toxicity hazard class will designated a substance as a dangerous fluid in the context of the PED.

These 'boundary areas' will form the focus of this Impact Assessment.

5. PROBLEM IDENTIFICATION & POLICY OPTIONS

5.1 Evaluation of PED

The PED has been the subject of a recently completed evaluation[32] which concluded, *inter alia,* that the PED:

- has been highly relevant for the improved functioning of the Internal Market;
- has led to a greatly improved and much more consistent regulatory framework for facilitating the free movement of pressure equipment;
- has opened up intra-EU trading opportunities; and, of particular relevance to this study
- has successfully combined market integration with maintaining the high levels of safety that Europe was already accustomed to.

The evaluation did not identify any past problems associated with the classification of fluids as Group 1 or Group 2 based on the DSD classifications cited in Article 9. However, it was noted that, in some cases, manufacturers may err on the side of caution and some small firms may find the compliance procedures complex (see Box 5.1).

Box 5.1: Experience of Group 1 Fluids
Where required compliance with the PED is carried out by the manufacturer of the pressure equipment (in certain cases users may have the capacity to perform this role), he has therefore to make certain assumptions, usually in dialogue with the user, but in cases where no agreement is reached the manufacturer has to presume that the fluid is 'hazardous' and the pressure equipment classified accordingly within Fluid Group 1. It may be the case that more stringent conformity assessment modules have had to be applied unnecessarily and costs increased. *It was mentioned that small firms may have particular difficulties in dealing with the framework, simply because procedures are relatively complex for products where there is the greatest hazard. However, it was generally felt that all pressure equipment had to be assessed based on common rules and aligned to common safety categories regardless of the size of the manufacturer.*
Source: Quoted from CSES (2012): ***Evaluation of the Pressure Equipment Directive***

As regards the future, the evaluation notes that there are some concerns over the alignment with CLP due to the changing classification but that *the intention with the alignment is to stay as close as possible to the current classification (Article 9 based on the Dangerous Substances Directive).*

[32] CSES (2012): **Evaluation of the Pressure Equipment Directive**, Final Report prepared for DG Enterprise, dated October 2012.

5.2 Consultation with Stakeholders

RPA undertook direct communications during September/October 2012 with a range of stakeholders which included:

1. Public authorities (policy and market surveillance);
2. Equipment manufacturers;
3. Equipment users;
4. Service providers (design offices, consultancies and system integrators);
5. Conformity assessment bodies (notified bodies and user inspectorates); and
6. Standardisation bodies.

A brief questionnaire was sent to over 340 relevant stakeholders with a reminder circulated to those who had not responded. Further assistance was also welcomed from the UK Department for Business, Innovation and Skills, which responded to the questionnaire and also forwarded it on behalf of RPA to additional stakeholders. With a view to engaging with the widest possible audience, particularly SMEs that may have otherwise been overlooked, RPA contacted relevant pressure equipment groups within *Linked-In*[33]. Where appropriate, we also contacted industry via the telephone to further increase the number of participants in this study. A more detailed questionnaire was sent to those stakeholders who expressed an interest in the study and a willingness to answer further questions, as summarised in Table 5.1.

Table 5.1: Stakeholder Response to Questionnaire

Stakeholder	No. of Responses	Respondents
Industry Association	7	German Engineering Federation The Expansion Joint Manufacturers Association The Swiss Mechanical and Electrical Engineering Industries The European Industrial Gases Association European Federation of Chemical Engineering UIC (French Chemical Association) Tank Storage Association
Member State Authorities, EU Technical Associations and other State Authorities	28	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Finland, France, Germany, Ireland, Italy, Latvia, Luxembourg, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Switzerland and United Kingdom
Private Companies	2	Italy, United Kingdom

Although the response rate was lower than anticipated, this may reflect the limited impact that aligning the PED with CLP will have. As has been noted, the alignment is relatively smooth for the physical hazards, with only a small number of substances changing Group. It should also be noted that manufacturers often by default design and manufacture equipment to comply with the more stringent modules. As one

33 These included the groups *Pressure Equipment Engineers* and *Pressure Vessel Association*, both of which have other 2,000 members via http://www.linkedin.com.

stakeholder noted, many UK manufactures use Module F or G irrespective of the category of the pressure equipment.

Another factor that will reduce the potential impact of the alignment is the industry practice of designing equipment as suitable for Group 1 fluids by default so as to appeal to the widest possible market which corresponds to the finding from the evaluation study reported Box 5.1.

A workshop was also arranged by the Commission in November 2012 to engage with stakeholders and allow the dissemination of potential problems associated with the alignment of the PED to CLP. Following the workshop, it became apparent that the low response rate may be attributed to the difficulty of stakeholders being able to accurately predict the impact of the alignment of the PED to CLP. By way of example, a user will specify which fluid(s) will be used in pressure equipment and will then provide the manufacture with the appropriate specifications.

If, for some reason, one or more fluids had become reclassified as a Group 1 fluid, the user may be faced with additional costs. However, it may be possible to avoid these costs by reducing the maximum allowable pressure or volume of the equipment used. Put differently, a manufacturer may adjust the design and operating parameters of pressure equipment so as to ensure that when the appropriate Conformity Assessment Table is applied, the conformity assessment procedures available to the manufacturer remain the same.

5.3 Responses from Stakeholders

5.3.1 Understanding of the DSD/DPD and Differences between the DSD and CLP

Industry associations and private companies were asked to express an opinion on their understanding of the current classification scheme (DSD/DPD) and the differences between CLP and the DSD. The results are displayed in Tables 5.2 and 5.3 (next page).

Table 5.2: Understanding of DSD/DPD

Stakeholder	Very Good	Good	Moderate	Poor	Very Poor	Not Applicable
Industry Association	2	4				1
Private Company[34]		1				

These results would suggest that the current regime used to classify fluids as a group 1 fluid under the (DSD/DPD) is well understood by industry. The responses were also accompanied by comments. The respondent who noted this question was not applicable commented that their members did not need to understand the DSD/DPD

[34] One of the private companies failed to complete this part of the questionnaire.

as users would provide them with the appropriate specifications, having already ascertained which Category of equipment they required. This view was also echoed by other respondent's as well industrial association attendees at the Commission workshop, who nevertheless noted they had a good understanding of the DSD.

Table 5.3: Understanding the Differences Between the DSD and CLP						
Stakeholder	**Very Good**	**Good**	**Moderate**	**Poor**	**Very Poor**	**Not Applicable**
Industry Association		4	1	1		1
Private Company[51]					1	

The responses suggest that whilst much of the industry is aware that the DSD will be replaced by CLP, efforts should still be made to widely communicate the upcoming changes. As with above, one of the respondents noted that their manufacturers will not need to be aware of the changes, as users will provide the appropriate specifications. Again, this view was echoed during the workshop held by the Commission on the alignment of the PED with CLP. Interestingly, the respondent who noted their members' knowledge of CLP was poor commented that it was possible that CLP could be introduced and manufacturers would not be aware of the change. This is because they would continue to manufacture goods as specified by users, without any knowledge that their users would be categorising equipment using CLP.

5.3.2 Concerns with regard to the Alignment of the PED with CLP

The responses outlined in Table 5.4 below reveal a relatively even split in respect of those concerned by the alignment of the PED with CLP. The subsequent table gives an overview of the specific comments made in respect of the proposed alignment. It should be noted that some respondents commented on interlinking aspects, meaning that they may be represented in multiple columns. For example, a respondent may have commented that they were concerned with a substance changing category classification and the resulting impact this would have on the cost of compliance.

Table 5.4: Do you have any concerns with regard to the alignment of the PED with CLP			
Stakeholder	**Yes**	**No**	**No clear position**
Industry Association	3	3	1
Member State Authorities, EU Technical Associations and other State Authorities	11	15	2
Private Companies			2

Considering the responses above, there is a relatively even split in respect of the concern expressed about the alignment of the PED with CLP. Most interestingly, it was difficult to ascertain a clear position from the private companies who responded to the questionnaire. This perhaps further reinforces the notion that information about CLP has yet to be fully communicated to downstream users.

5.3.3 Comments regarding the alignment of the PED to CLP

Table 5.5 below summarises the specific concerns expressed by stakeholders with regard to the alignment of the PED to CLP. Comments from the Commission workshop have also been included within the discussion below where appropriate.

Table 5.5: Outline of comments from those concerned with the alignment of the PED with CLP

Increased cost of compliance	Change in category classification	Align PED promptly provide clear guidelines	Simple alignment	Increased administrative effort	Safety
7	4	4	3	2	2

Increased Costs of Compliance & Change in Category Classification

The biggest concern that emerged from the consultation was the potential for increased cost of compliance as a result of substances moving from ‘Group 2’ to ‘Group 1’. One industry association objected to the possibility of increased costs on the basis of what they perceive to be a formal alignment, particularly given that no safety concerns have been expressed with regard to the categorisation of pressure equipment under the PED. Both the responses to the questionnaire and the recent evaluation of the PED (see Section 5.1) concur that there are few safety concerns related to the PED.

However, one respondent noted unease with Module A1, which requires notified body involvement only for the final assessment by means of unexpected visits. Thus it is possible for Category II equipment that contains a very toxic fluid to be PED compliant, with no involvement of a notified body during the design phase and without the need for the notified body to perform any inspections during manufacture. Indeed, it is also possible that pressure equipment containing very toxic fluids could be categorised under the PED as SEP, which permits the manufacturer to ensure compliance with the PED without the need for any notified body involvement.

As well as the immediate costs associated with certifying pressure equipment, stakeholders commented that they were concerned about the increased costs of ‘In Service Periodic Inspections’ as a result of change in the Grouping of a fluid (it is more expensive to periodically inspect pressure equipment in higher categories). Of course, the change in classification may result in a substance moving to a lower category, thus decreasing the cost of compliance. Interestingly, the concern about increased costs of ‘In Service Periodic Inspection’ costs also arose at the Commission workshop.

With regard to the increase of these costs, it is important to understand that the PED has harmonised the requirements for the ‘first placing on the market’ and the initial ‘putting in to service’ of pressure equipment. Regulating only these matters, it does not harmonise the ‘periodic inspections’ of pressure equipment, which is left to the discretion of Member States. Despite this, stakeholders have reported that the requirements for their 'periodic inspections' are based on the PED Conformity Assessment Tables in Annex II. Thus a change in the grouping of a fluid may well influence the costs of such periodic inspections. However, as this change is a result of national legislation that is not directly governed by the PED, any subsequent impacts are secondary and must not influence the final selection of the options.

Administrative effort

Stakeholders were also concerned about an increase in administrative effort that would be required following the alignment of the PED with CLP. Examples of additional activities include training teams to understand the new vocabulary and pictograms of CLP, as well as undertaking the necessary changes to their computer databases.

Simple Alignment and Guidelines

There was a preference for simple alignment from the responses to the questionnaire, a view echoed by almost all attendees to the workshop. A simple alignment should help to ensure full and complete comprehension following the transition from the DSD to CLP. Related to this point, notified bodies emphasised the importance of providing prompt Guidance Notes, as manufacturers will seek advice from notified bodies to ensure that they have complied with the amended PED.

Alignment of PED to CLP

With regard to specific comments on how the PED should be aligned, one stakeholder noted they were concerned that the PED would be aligned to CLP so as the parameter for Acute Toxicity would be set at Category 3 for all exposure routes (Oral, Dermal and Inhalation). The stakeholder disapproved of such an extension in scope as it would result in more of the equipment they operate using Group 1 fluids. However, the biggest impact of adopting this route of exposure for this particular stakeholder would arise from the 'In Service Periodic Inspections'. Whilst such concerns are valid, as has been explained above, such impacts must not influence the selection of options.

Another stakeholder suggested that the alignment of the PED for Acute Toxicity should mirror that adopted under Seveso III. If the PED were to adopt the same approach as Seveso III, this will be because it is the option that best aligns the PED to CLP. The current boundary delineations of Seveso III will not influence the final option selected for the PED.

5.4 Problem Identification

As outlined above, there is a general consensus that PED and the use of Group 1 and Group 2 fluids based on DSD classifications has not presented undue problems. The DSD is now being replaced by the CLP Regulation and will be fully repealed by 1st June 2015. As such, the PED has to be aligned to the CLP Regulation by that date.

There is consensus that there is no requirement to change the PED in respect of 'dangerous fluids'. Rather the problem is that in some 'boundary areas', the classification of some substances under CLP may lead to some substances previously categorised as Group 2 fluids becoming Group 1 fluids and vice-versa. The overwhelming view from stakeholders is that the alignment needs to be as simple and as close to the current situation as possible.

5.5 Development of Policy Options

5.5.1 Baseline

The baseline is the current situation based on Article 9 of the PED (see Box 5.2).

Box 5.2: Article 9 of the PED - Classification of Pressure Equipment
1. Pressure equipment referred to in Article 3 (1) shall be classified by category in accordance with Annex II, according to ascending level of hazard. For the purposes of such classification fluids shall be divided into two groups in accordance with 2.1 and 2.2. 2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or preparation covered by the definitions in Article 2 (2) of Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]). Group 1 comprises fluids defined as: - explosive, - extremely flammable, - highly flammable, - flammable (where the maximum allowable temperature is above flashpoint), - very toxic, - toxic, - oxidizing. 2.2. Group 2 comprises all other fluids not referred to in 2.1. 3. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.
([1]) OJ No 196, 16. 8. 1967, p. 1. Directive as last amended by Commission Directive 94/69/EC (OJ No L 381, 31. 12. 1994, p. 1).

Since the scope and intent is to be retained largely unchanged, paragraphs 1, 2.2 and 3 from Article 9 will remain unchanged. As discussed in Sections 3 and 4, the CLP Regulation has new hazard categories which require slightly more definition. In order to ensure simplicity, it is proposed that the categories are supplemented with relevant hazard statements as this will provide a clear guide to relevant stakeholders as to which precise categories would lead to a fluid being included in Group 1 or Group 2.

5.5.2 Option 1

The first option provides for a simple re-alignment from DSD to CLP – as shown in Box 5.3. As indicated above, paragraphs 1, 2.2 and 3 will remain unchanged from the current Article 9 of the PED. The relevant hazard statements for the 'boundary areas' are summarised in Table 5.6. From this, it will be seen that some substances will move from Group 2 to Group 1 and, in two cases, vice-versa.

Box 5.3: Revised Article 9 for PED – Option 1 (new text is underlined)

1. Pressure equipment referred to in Article 3 (1) shall be classified by category in accordance with Annex II, according to ascending level of hazard.
   For the purposes of such classification fluids shall be divided into two groups in accordance with 2.1 and 2.2.

2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or mixture covered by the definitions in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ([1]),

Group 1 comprises fluids defined as:

- explosive with Hazard Statements H200, H201, H202, H203, H204 and H205,
- organic peroxides or self-reactive with Hazard Statements H240, H241 and H242,
- flammable gas with Hazard Statements H220 and H221,
- flammable liquids with Hazard Statements H224 and H225 and, where the maximum allowable temperature is above flashpoint, H226,
- flammable solids with Hazard Statement H228,
- pyrophoric liquids and solids with Hazard Statement H250,
- contact with water emits flammable gases with Hazard Statements H260 and H261,
- oxidising with Hazard Statements H270, H271 and H272,
- acute toxicity – oral with Hazard Statement H300,
- acute toxicity – dermal with Hazard Statement H310,
- acute toxicity – inhalation with Hazard Statements H330 and H331,
- specific target organ toxicity with Hazard Statement H370,

2.2. Group 2 comprises all other fluids not referred to in 2.1.

3. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

([1]) OJ L 353, 31.12.2008, p. 1.

Table 5.6: Summary of Boundary Areas for Option 1

Hazard Class	Hazard Statement	Comment
Flammable Liquids	H225: Highly flammable liquid and vapour	Some substances with Flash Points from 21 to 23°C will now be automatically categorised as Group 1 fluids
Self-Reactive Substances and Mixtures *and* Organic Peroxides	H242: Heating may cause a fire	Theoretically, it is possible that some flammable substances (R10) may be reclassified as a self-reactive substance with the hazard statement H242 (see Table 3.5)
Acute Toxicity (oral)	H301: Toxic if swallowed	Exclusion of H301 leads to some substances previously categorised as Group 1 being reclassified as Group 2 fluids

Table 5.6: Summary of Boundary Areas for Option 1		
Hazard Class	**Hazard Statement**	**Comment**
Acute Toxicity (dermal)	H311: Toxic in contact with skin	Exclusion of H311 leads to some substances previously categorised as 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 2 being reclassified as Group 1 fluids

5.5.3 Option 2

The second option again provides for a simple re-alignment from DSD to CLP – as shown in Box 5.4. The only change from Option 1 is the inclusion of Hazard Statement H311. As before, the relevant hazard statements for the 'boundary areas' are summarised in Table 5.7. From this, it will be seen that some substances will move from Group 2 to Group 1 and, in just one case, vice-versa.

Box 5.4: Revised Article 9 for PED – Option 2 (change from Option 1 is underlined)

1. Pressure equipment referred to in Article 3 (1) shall be classified by category in accordance with Annex II, according to ascending level of hazard.

For the purposes of such classification fluids shall be divided into two groups in accordance with 2.1 and 2.2.

2.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or mixture covered by the definitions in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ([1]),

Group 1 comprises fluids defined as:

- explosive with Hazard Statements H200, H201, H202, H203, H204 and H205,
- organic peroxides or self-reactive with Hazard Statements H240, H241 and H242,
- flammable gas with Hazard Statements H220 and H221,
- flammable liquids with Hazard Statements H224 and H225 and, where the maximum allowable temperature is above flashpoint, H226,
- flammable solids with Hazard Statement H228,
- pyrophoric liquids and solids with Hazard Statement H250,
- contact with water emits flammable gases with Hazard Statements H260 and H261,
- oxidising with Hazard Statements H270, H271 and H272,
- acute toxicity – oral with Hazard Statement H300,
- acute toxicity – dermal with <u>Hazard Statements H310 and H311</u>,
- acute toxicity – inhalation with Hazard Statements H330 and H331,
- specific target organ toxicity with Hazard Statement H370,

2.2. Group 2 comprises all other fluids not referred to in 2.1.

3. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

([1]) OJ L 353, 31.12.2008, p. 1.

Table 5.7: Summary of Boundary Areas for Option 2		
Hazard Class	**Hazard Statement**	**Comment**
Flammable Liquids	H225: Highly flammable liquid and vapour	Some substances with Flash Points from 21 to 23°C will now be automatically categorised as Group 1 fluids
Self-Reactive Substances and Mixtures *and* Organic Peroxides	H242: Heating may cause a fire	Theoretically, it is possible that some flammable substances (R10) may be reclassified as a self-reactive substance with the hazard statement H242 (see Table 3.5)
Acute Toxicity (oral)	H301: Toxic if swallowed	Exclusion of H301 leads to some substances previously categorised as Group 1 being reclassified as Group 2 fluids
Acute Toxicity (dermal)	H311: Toxic in contact with skin	Inclusion of H311 leads to some substances previously categorised as Group 2 being reclassified as Group 1 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 2 being reclassified as Group 1 fluids

5.5.4 Discussion

Other Options

As previously indicated, the overwhelming view from stakeholders is that the alignment of PED to the CLP Regulation needs to be as simple and as close to the current situation as possible. Nevertheless, consideration was given to more novel ways in which this alignment could be achieved. For example, it was suggested at the workshop (held in November 2012) that the distinction of fluids (i.e. between Group 1 and Group 2 fluids) could be removed from the PED. If this were to be adopted, a decision would need to be made as to which conformity assessment tables under Annex II of the PED would be used to determine the category classification of pressure equipment.

Given that one of the primary objectives of the PED is to ensure a high level of safety for pressure equipment across the EU, one option would be that the tables for Group 1 fluids would be used to classify all pressure equipment. Alternatively, the tables could be merged, with the category cut-off values somewhere between those currently used for Group 1 and Group 2 fluids.

Such changes could have significant impacts and the results of the consultation and discussions during the workshop made it clear that stakeholders wanted the PED to be aligned to the CLP Regulation as simply and directly as possible. This approach would minimise the number of substances that would change fluid group and allow them to quickly adapt and comply with any changes made. With industry needing to comprehend and adapt to CLP, any proposed further changes such as the removal of the fluid grouping from the PED should be considered at a later date.

Inclusion/Exclusion of Toxic Substances

Nevertheless, there remain some 'boundary areas' where decisions need to be made - with particular regard to the inclusion/exclusion of substances with Hazard Statements H301, H311 and H331. Above all, the inclusion/exclusion of substances into Group 1 will be determined by the potential health hazards they pose to users in the event of a pressure equipment malfunction. This will ensure that the primary objective of the PED, the safety of pressure equipment, is respected and maintained. The financial implications of any changes on industry will therefore be a secondary consideration.

Acute Toxicity – Inhalation: Broad Approach

It will be recalled that Acute Toxicity – Inhalation, comprises of three exposure routes (dusts and mists, vapours, gas). A simple overview of how the CLP aligns to the DSD for this hazard class and three exposure routes has been provided below (for further detail see Section 4.2 above). If the sub-divided exposure routes are considered in isolation, then direct alignment is possible, with Group 1 fluids comprising of H331: toxic if inhaled for 'dusts and mists' (category 3) and H330: fatal if inhaled (category 2). Aligning the PED in this way is precise and would not result in any substances from these hazard classes changing fluid group. As previously noted, it is not possible to compare the DSD and CLP for Acute Toxicity – gas, because the criteria used to measure and clarify substances are different according to the DSD and CLP.

<table>
<tr><th colspan="10">Table 5.8: Translation from the DSD to CLP (Acute Toxicity – Inhalation sub-divisions)</th></tr>
<tr><td>DSD</td><td colspan="4">T+; Very Toxic</td><td colspan="3">T; Toxic</td><td colspan="2">Xn; Harmful</td></tr>
<tr><td>PED</td><td colspan="7">Classified as 'Group 1' fluid under PED</td><td colspan="2"></td></tr>
<tr><td rowspan="2">CLP</td><td colspan="9">Acute Toxicity – Dusts and Mists</td></tr>
<tr><td>Category 1</td><td colspan="4">Category 2</td><td colspan="2">Category 3</td><td colspan="2">Category 4</td></tr>
<tr><td>HS</td><td colspan="5">H330: Fatal if inhaled</td><td colspan="2">H331: Toxic if inhaled</td><td colspan="2">H332: Harmful if inhaled</td></tr>
<tr><td rowspan="2">CLP</td><td colspan="9">Acute Toxicity – Vapours</td></tr>
<tr><td colspan="2">Category 1</td><td colspan="5">Category 2</td><td>Category 3</td><td>Category 4</td></tr>
<tr><td>HS</td><td colspan="7">H330: Fatal if inhaled</td><td>H331: Toxic if inhaled</td><td>H332: Harmful if inhaled</td></tr>
<tr><td rowspan="2">CLP</td><td colspan="9">Acute Toxicity – Gas</td></tr>
<tr><td colspan="3">Category 1</td><td colspan="3">Category 2</td><td colspan="2">Category 3</td><td>Category 4</td></tr>
<tr><td>HS</td><td colspan="6">H330: Fatal if inhaled</td><td colspan="2">H331: Toxic if inhaled</td><td>H332: Harmful if inhaled</td></tr>
<tr><td colspan="10">Note: For further details on the category threshold limits, please see Tables 4.5, 4.6 and 4.7 for dusts & mists, vapours and gas respectively.</td></tr>
</table>

Whilst this approach for 'dusts and mists' and 'vapours' is direct, because the Hazard Statements are the same for the sub-divided exposure routes, the pressure equipment users/manufacturers would need to know which exposure route was being referred to. By way of example, the substance would be a Group 1 fluid if it had been classified as H331 for dusts and mists, but would be a Group 2 fluid if it had been classified as H331 for the vapour exposure route.

Pressure equipment users and manufacturers ascertain information on a substance from safety data sheets. These contain Hazard Statements and pictograms to convey the relevant information to the reader. Crucially, they will typically not provide any further information such as the sub-division of exposure routes for which it was classified. Thus without undertaking further work, a pressure equipment user/manufacture will only be able to determine from the safety data sheet that a substance has been designated as H331. It will not be known whether this was for the exposure route of dusts and mists or of vapours or of gas.

To prevent the transition from the DSD becoming overly complex and burdensome for manufacturers, the precise alignment has not been considered in the options. Rather, the same Hazard Statement (and, hence, category number) for classifying a substance as a Group 1 fluid will be assigned to all of the sub-divided inhalation exposure routes. Although this 'broad' approach is not as direct and some substances will change fluid group, it represents a practical solution designed to make the transition from DSD to the CLP less burdensome for industry.

Acute Toxicity – Inhalation: Inclusion/Exclusion of H331

Having ascertained that the 'broad' approach must be adopted, the decision as to whether substances classified as H331 should be a Group 1 fluid must be made. To include H331 will result in an increase in substances (Vapours in Category 3) whilst to exclude H331 will reduce the number of substances classified as a group 1 fluid (Dusts and Mists in Category 3). In essence, this decision hinges upon the inherent dangers presented by substances classified with this hazard statement and the potential for harm should there be a pressure equipment failure.

It is apparent that following a pressure equipment failure, substances classified as Acute Toxicity – Inhalation may pose a threat to those within the vicinity. For instance, pressure equipment could have an undetected minor leak that exposes workers to the substance. Equally, in the event of a catastrophic failure, a fluid may be rapidly dispersed and inhaled by those near to the operating pressure equipment. Taking these risks into consideration, there is a strong argument that H331 substances should be classified as Group 1 fluids.

Acute Toxicity – Oral (H301)

In the context of a pressure equipment failure, the dangers presented by substances which are toxic if swallowed (H301) are minimal. In the event of an undetected minor pressure equipment failure and a catastrophic incident, an individual is unlikely to orally ingest a significant quantity of these particular fluids.

For substances which are toxic if swallowed (H301), the threshold is an LD50 of 50 mg/kg of bodyweight (see Table 4.3). For a typical EU adult of 70 kg, this equates to 3.5 grams which is equivalent to a teaspoon. In the event of an incident involving pressure equipment, it is very unlikely that someone nearby would ingest such quantities of fluid. For this reason, it is not considered that substances classified as H301 present a significant hazard. As such, these substances have been excluded from the alignment under both Options 1 and 2.

Acute Toxicity – Dermal (H311)

In the context of a pressure equipment failure, the dangers presented by substances which are toxic in contact with skin (H311) may be significant. In the event of an undetected minor pressure equipment failure and a catastrophic incident, an individual may be exposed to a significant quantity of these particular fluids.

For substances which are toxic in contact with the skin (H311), the threshold is an LD50 of 200 mg/kg of bodyweight (see Table 4.4). For a typical EU adult of 70 kg, this equates to 14 grams which is equivalent to a tablespoon. In the event of an incident involving pressure equipment, it is possible (but not inevitable) that someone nearby would be sprayed or splashed with such quantities of fluid. For this reason, it is considered that substances classified as H311 may present a significant hazard. With this in mind, such substances have been excluded from the alignment under Option 1 but included under Option 2.

6. Impact Assessment

6.1 Introduction

6.1.1 The C&L Inventory

Given that the purpose of this report is to assess the impact of aligning the PED with CLP, efforts must be made to determine the number of substances used in pressure equipment that may move from one Group to another. The volume and prevalence of these substances will influence the resultant impacts with particular regard to the potential additional costs associated which could result from the application of more stringent compliance procedures.

The CLP Regulation established a classification and labelling inventory of substances which is maintained by the European Chemicals Agency (ECHA). The inventory is in the form of database which may be accessed online and currently has over 100,000 substances[35].

6.1.2 Harmonised Classifications

The inventory includes substances that are both harmonised and *not* harmonised. The distinction between the two classifications is important for the purposes of this report, as it is only a 'harmonised classification' and its assigned hazard statement that has been approved by regulators. Other classifications on the C&L Inventory have been self-assigned by industry and there is widespread acknowledgement that these self-classifications vary greatly in reliability. Unfortunately, only around 4,000 substances have been harmonised and therefore have reliable classifications on which to base further analysis. To ensure this report is based on robust data and not subject to challenge, this impact assessment must draw conclusions from the limited data that are currently harmonised.

The harmonised classifications can be found in two ways. Annex VI to the CLP Regulation can be consulted, making sure to check the 1st ATP[36], 2nd ATP[37] and 3rd ATP[38] to CLP. A search using the appropriate CAS number, EC number or substance name will help to identify the relevant substance. Alternatively, harmonised classifications (as listed in Annex VI to the CLP Regulation) can be found and downloaded in Excel format from the Institute for Health and Consumer Protection (JRC-IHCP)[39]. RPA elected to utilise the Excel database, as substances could be searched and filtered using the hazard statements relevant for this study[40].

35 http://echa.europa.eu/information-on-chemicals/cl-inventory-database

36 http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF

37 http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:FULL:en:PDF

38 http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:179:0003:0010:EN:PDF

39 http://esis.jrc.ec.europa.eu/clp/ghs/doc/Annex6_Table3-1.zip

40 It is accepted that the number of substances with harmonised classification has increased from 4,136 in the original Annex VI (and as listed in the Excel table) to 4,472 at the time of writing.

It should be noted that for some of the harmonised classifications, classes of compound and their salts have been registered under the harmonised classification database as a single entity (e.g. sodium, potassium and ammonia alkali fluorosilicates). For the purposes of counting the number of substances that may change fluid group, this report has considered such single entities a single substance.

6.2 Numbers of Substances

6.2.1 Overview

An initial indication of the prevalence of substances which have properties in the 'boundary areas' can be derived from the number of entries with these codes on the C&L Inventory database, as shown in Table 6.1. It will be seen that the percentage figures for those substances with harmonised classifications are similar to those for substances which have been self-classified.

Table 6.1: Number of Substances on ECHA's C&L Inventory with Hazard Statements in the 'Boundary Areas' (as of 5 November 2012)

Hazard Statement	All Substances		Harmonised Classification	
	Number of Entries[1]	% Total	Number of Entries[1]	% Total
H225 Highly flammable liquid and vapour	2,276	2.1%	132	3.2%
H242 Heating may cause a fire	204	0.2%	35	0.8%
H301 Toxic if swallowed	8,430	7.7%	321	7.8%
H311 Toxic in contact with skin	3,080	2.8%	187	4.5%
H331 Toxic if inhaled	3,142	2.9%	202	4.9%
H370 Causes damage to organs	480	0.4%	8	0.2%
All Substances	**109,120**		**4,136**	

Notes:
1) Substances may have more than one of these code or, indeed, other codes.

It is very important to stress that all of substances with these Hazard Statements would not change fluid group under PED. By way of example, only a small fraction of flammable liquids covered by H225 would previously not have been covered by the DSD 'highly flammable' categorisation (see Table 3.4)

With this in mind, it is likely that the greatest impact will be related to substances classified as Acute Toxicity, Category 3 with associated Hazard Statements H301, H311 and H331.

6.2.2 Identifying Boundary Substances

To identify those substances that may change group, the individual hazard statements of the boundary substances (H310, H311, H331, H225, H242, H370) were entered into the database. The results of this search are displayed in Table 6.1 under column 'Harmonised Classification'. Summing the numbers for each of these hazard statements might, at first sight, suggest that there are 885 boundary substances (Table 6.2). In fact some substances appear more than once under different hazard statements. By way of example, methanol appeared in entries with five different hazard statements H225, H331, H311, H301, H370 and, as such, appears five times in Table 6.2.

The substances were then checked to ensure they were not classified as a Group 1 fluid because of another inherent hazard. For example, potassium bromate (CAS No. 7758-01-2) has the hazard statements H301 (Acute 'Oral' Tox. 3), H350 (Carc. 1A) and H271 (Ox. Sol. 1). To consider only the hazard statement H301 would make Potassium Bromate a 'borderline' substance that may or may not be classified as a Group 1 fluid. However, for the purposes of the PED, the hazard statement H271 (Ox. Sol. 1) identifies this substance as a substance that should be classified as a dangerous fluid in any event. Thus, the grouping of this fluid will not be impacted as a result of the PED aligning with CLP, as irrespective of the inclusion/exclusion of H301 (Acute 'Oral' Tox. 3), this substance will remain a Group 1 fluid. The number of substances that continue to be classified as border substances has been listed under in numerical form in Table 6.2.

Table 6.2: Number of Substances that may be Included/Excluded as a Dangerous Fluid under Article 9 of the PED

Hazard Statement (HS)	Number of Entries[1]	Number of entries excluding those with a Group 1 Hazard Statement
H225 Highly flammable liquid and vapour	132	119
H242 Heating may cause a fire	35	33
H301 Toxic if swallowed	321	304
H311 Toxic in contact with skin	187	128
H331 Toxic if inhaled	202	169
H370 Causes damage to organs	8	7
Total	**885**	**760**

Notes:
1. From Table 6.1.

The number of boundary substances is then further reduced when those substances with the hazard statement H331 – Acute Toxic Inhalation are removed (Table 6.3 below). As has been discussed above, there is a strong argument that H331 substances should be classified as Group 1 fluids because of the inherent dangers they pose in the context of pressure equipment.

Table 6.3: Number of Substances that may be Included/Excluded as a Dangerous Fluid under Article 9 of the PED		
Hazard Statement (HS)	**Number of entries excluding those with a Group 1 Hazard Statement**	**Number of entries also excluding H331**
H225 Highly flammable liquid and vapour	119	109
H242 Heating may cause a fire	33	30
H301 Toxic if swallowed	304	174
H311 Toxic in contact with skin	128	40
H331 Toxic if inhaled	169	0
H370 Causes damage to organs	7	6
Total	**760**	**359**

It was possible to further reduce the number of substances that will be impacted by the alignment of the PED to the CLP by virtue of flashpoints (hazard statement H225) and specific hazard classifications (H242 Type F).

H225 – Highly Flammable Liquid and Vapour

The flashpoints of the 109 substances with the hazard statement H225 were then examined to identify those substances with flashpoints that fell within the parameters of 21°C to 23°C. Only four substances, listed in Table 6.4, are those that will now, by default, be classified as Group 1 fluids as a result of the PED aligning with the CLP.

Table 6.4: Boundary Substances with the Hazard statement H225		
Substance	**CAS No**	**Flashpoint °C**
ethyl methacrylate	97-63-2	21
tert-butyl propionate	20487-40-5	21
n-hexane	110-54-3	22
1-bromopropane; n-propyl bromide	106-94-5	22

H242 – Heating May Cause Fire

It will be recalled that the hazard statement H242 encompasses substances that are within the hazard class Self-reacting substances and Organic peroxides Type C, D, E and F. It is theoretically possible that substances may move from the DSD hazard class Flammable (R10) to Self-reacting Type F under the CLP. Of the potential 30 boundary substances, none fall within this boundary zone.

H301 - Toxic if Swallowed, H311 Toxic in Contact with Skin, H331 Toxic if Inhaled and H370 Causes Damage to Organs

Consultation of Tables 4.3, 4.4 and 4.8 through to 4.12 clearly show that the thresholds of the DSD intersect the CLP categories. Whilst it is possible to identify the substances that fall within the CLP categories that are intersected by the DSD thresholds, it is not possible to determine with certainty how many substances fall on each side of the intersection. It can only be acknowledged that within the total number of 'boundary' substances with 'boundary' hazard statements, a number would have previously been classified as a dangerous fluid under the PED and likewise, a number would not.

Overview

Table 6.5 below provides a summary of the boundary substances as a result of the alignment of the PED to the CLP. To reiterate, this reflects the impact of aligning the PED with CLP for those substances that have a harmonised classification.

Table 6.5: Numbers of Entries that may be Included/Excluded as a Dangerous Fluid under Article 9 of the PED

Hazard Statement (HS)	Number of 'boundary' Entries
H225 Highly flammable liquid and vapour	4
H242 Heating may cause a fire	0
H301 Toxic if swallowed	174
H311 Toxic in contact with skin	40
H331 Toxic if inhaled	169
H370 Causes damage to organs	6
Total	**393**

6.2.3 Substances Affected by Policy Options

The discussion of the options below considers only those contentious issues where a decision must be made as to whether include or exclude substances with a particular hazard statement. In other words, the inclusion of Categories 1 and 2 for all exposure routes within the Acute Toxicity hazard class[41] and Category 3 for Acute Toxicity – Inhalation[42] will not be discussed further.

Option 1

As outlined in Section 5.5.2, Option 1 leads to the removal of some substances which are toxic if swallowed (H301) and which are toxic in contact with the skin (H311) from being classified as Group 1 fluids. However, by including the hazard statement

41 Acute Toxicity – Oral (H300), Acute Toxicity - Dermal (H310) and Acute Toxicity – Inhalation (H330) and

42 Acute Toxicity – Inhalation (H331)

H331, additional substances will be classified as a Group 1 fluid. A numerical summary as to whether the identified boundary substances are a Group 1 or Group 2 fluid under Option 1 has been provided in Table 6.6 below. A full listing of substances with harmonised classifications H301, H311 and H331 is presented in Annex 2.

Table 6.6: Option 1 – Impact of Aligning PED with CLP		
Hazard Statement (HS)	**Substances Classified as a Group 1 fluid**	**Substances Classified as a Group 2 fluid**
Exclude H301 Toxic if swallowed	0	174
Exclude H311 Toxic in contact with skin	0	40
Include H331 Toxic if inhaled	169	0

Option 2

As outlined in Section 5.5.3, Option 2 leads to the removal of some substances which are toxic if swallowed (H301) from being classified as Group 1 fluids. However, Option 2 includes as Group 1 fluids those substances which are toxic in contact with the skin (H311) in addition to those that are toxic if inhaled (H331). A numerical summary as to whether the identified boundary substances are a Group 1 or Group 2 fluid under Option 1 has been provided in Table 6.7 below.

Table 6.7: Option 2 – Impact of aligning PED with CLP		
Hazard Statement (HS)	**Substances classified as a Group 1 fluid**	**Substances classified as a Group 2 fluid**
Exclude H301 Toxic if swallowed	0	135
Include H311 Toxic in contact with skin	40	0
Include H331 Toxic if inhaled	169	0

6.2.4 Nature of Impacts

The aim here is to establish the types of impacts that can be expected to occur and the stakeholders affected. This is achieved by reviewing the comprehensive checklist of potential economic, environmental and social impacts set out in Tables 1-3 of the Commission's Impact Assessment Guidelines and identifying any additional impacts. Both direct and indirect impacts are considered.

Based on the information collected, as a preliminary guide, the types of impacts that might be the most relevant to the alignment of PED to the CLP Regulation have been identified (see Table 6.8).

Table 6.8: Pre-screening of the Relevance of the Impacts	
Impact type	**Relevant?**
Economic Impacts	
Functioning of the internal market and competition	Not relevant
Competitiveness, trade and investment flows	Potentially relevant
Operating costs and conduct of business/SMEs	Potentially relevant
Administrative burdens on businesses	Potentially relevant
Public authorities	Potentially relevant
Property rights	Not relevant
Innovation and research	Not relevant
Consumers and households	Not relevant
Specific regions and sectors	Potentially relevant
Third countries and international relations	Potentially relevant
Macroeconomic environment	Not relevant
Social Impacts	
Employment and labour markets	Not relevant
Standards and rights related to job quality	Not relevant
Social inclusion and protection of particular groups	Not relevant
Gender equality, equality treatment and opportunities, non-discrimination	Not relevant
Individuals, private and family life, personal data	Not relevant
Governance, participation, good administration, access to justice, media and ethics	Not relevant
Public health and safety	Potentially relevant
Crime, Terrorism and Security	Not relevant
Access to and effects on social protection, health and educational systems	Not relevant
Culture	Not relevant
Social impacts in third countries	Not relevant
Environmental Impacts	
The climate	Not relevant
Transport and the use of energy	Not relevant
Air quality	Not relevant*
Biodiversity, flora, fauna and landscapes	Not relevant*
Water quality and resources	Not relevant*
Soil quality or resources	Not relevant*
Land use	Not relevant
Renewable or non-renewable resources	Not relevant
The environmental consequences of firms and consumers	Not relevant
Waste production/generation/recycling	Not relevant
The likelihood or scale of environmental risks	Potentially relevant
Animal welfare	Not relevant
International environmental impacts	Not relevant
* *Note that although some incidents may result in environmental impacts, this will not be directly affected by the alignment of PED to CLP as discussed further below.*	

As can be seen from Table 6.8, the impacts of the planned alignment will be primarily economic as outlined further below.

Impact on the Internal Market and Competition

Since the scope and intent of the PED remains essentially unchanged, there should be no significant impact on the internal market or competition.

Impact on Competitiveness, Trade and Investment Flows

Although the overall impact on trade should be minimal, it is conceivable that some specialist sectors might be impacted. For example, a particular specialist sector may rely on the use of a particular substance which is a Group 2 fluid which, after alignment with CLP, is reclassified as a Group 1 fluid with an associated increase in compliance costs which affects the competitiveness of that sector. It must be stressed that such sectors have not been identified in consultation with stakeholders.

Operating Costs and Conduct of Business/SMEs

The reclassification of some substances (and mixtures) may lead to additional compliance costs. While this would provide additional income to notified bodies, the cost would be borne by the manufacturers and installers of pressure equipment and their customers. Although there appear to be no reliable data on companies involved with pressure equipment, the recent evaluation report[43] notes that there are many SMEs within the sector. Although it is anticipated that the overall impact will be small, it is possible that some individual SMEs may be significantly impacted if their business is reliant on a substance which moves from Group 2 to Group 1 with significant additional costs (see Box 6.1).

Box 6.1: Change in Operating Costs & Conduct of Business
It could be argued that the greatest potential impact on individual businesses would occur when the exiting business was based entirely on a Group 2 fluid used in equipment covered by Sound Engineering Practice (SEP) for which there is no involvement of Notified Bodies or use of CE marking – such as vessels of 100l in volume under 20 bars pressure. Should the substance be moved to Group 1, this would place the same equipment under Hazard Category II necessitating additional compliance procedures, involvement of a Notified Body and affixing a CE mark with a potentially significant increase in costs. Of course, in response the company could also adapt by changing the operating pressure, the volume or the substance to keep within the SEP Hazard Category.

Although the Commission is, of course, committed to minimising the impacts of regulation on SMEs and micro-businesses in particular[44], there has been no suggestion that PED and/or the CLP Regulation should be relaxed in any way in respect of micro/small businesses. Similarly, while it is possible that some individual companies or, conceivably, specialist sectors could be impacted, the overall impact on trade and competitiveness is not expected to be significant. As such, it is not

43 CSES (2012): **Evaluation of the Pressure Equipment Directive**, Final Report prepared for DG Enterprise, dated October 2012.

considered necessary to undertake a more rigorous analysis of the sectoral competitiveness[45].

Administrative Burdens on Businesses

Changes would require that companies (including notified bodies) familiarise themselves with the new requirements and adapt their procedures. Of course, such familiarisation would be required in any event in order to understand the CLP Regulation. However, the functioning of PED in terms of its procedures would remain unchanged.

Public Authorities

Public authorities would incur costs of transposing any changes to the PED into national legislation and may incur an increased administrative burden due to the need to provide advice – although this may already be covered through the implementation of the CLP Regulation.

Property Rights

It is not anticipated that alignment of the PED to the CLP Regulation would have any impacts on property rights.

Innovation and Research

It is not anticipated that alignment of the PED to the CLP Regulation would have any significant impacts on innovation and research.

Consumers and Households

It is not anticipated that alignment of the PED to the CLP Regulation would have any significant impacts on consumers and households.

Specific Regions and Sectors

It is very unlikely that specific regions will be impacted by the planned alignment of PED with the CLP Regulation. However, as indicated above, it is conceivable that some specialist sectors could be impacted – but none have been identified.

Third Countries and International Relations

Although the overall impact on third countries and international relations should be small, any companies exporting from third countries into the EU will need to

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44 See, for example, European Commission (2011): **Minimizing Regulatory Burden for SMEs Adapting EU Regulation to the Needs of Micro-Enterprises**, COM(2011) 803 final dated 23.11.2011.

45 With reference to European Commission (2012): **Operational Guidance for Assessing Impacts on Sectoral Competitiveness within the Commission Impact Assessment System - A "Competitiveness Proofing" Toolkit**, SEC(2012) 91 final, dated 27.1.2012.

familiarise themselves with the new requirements for 'dangerous fluids' in the revised PED. As for businesses within the EU, it is possible that some individual companies may be significantly impacted if it is reliant on a substance which moves from Group 2 to Group 1.

Macroeconomic Environment

It is not anticipated that alignment of the PED to the CLP Regulation would have any significant impact on the overall macroeconomic environment.

Social and Environmental Impacts

In general, it is not anticipated that alignment of the PED to the CLP Regulation would have any significant social or environmental impacts (see Table 6.8). Clearly, the PED does affect two of the listed areas:

- Public Health and Safety; and
- The Likelihood or Scale of Environmental Risks.

It is, of course, acknowledged that a major incident involving a pressure equipment failure could impact upon the neighbouring environmental compartments (air, water, soil, etc.). However, the alignment of the PED to the CLP Regulation does not directly impact upon the likelihood or consequences of such incidents. This is because the alignment does not directly impact the engineering codes used for the design and construction of pressure equipment but will impact (in some cases) upon the associated procedures for verifying that the correct engineering codes have been applied. Of course, it can be argued that a more rigorous compliance regime should reduce the chances of sub-standard pressure equipment being placed on the market which, in turn, should reduce the chances of an incident which could adversely affect human health or the environment.

However there has been no suggestion that the risks associated with pressure equipment in general or with pressure equipment handling the 'boundary substances' in particular are a cause for concern.

With these points in mind, any impacts on public health and safety or environmental risks resulting from alignment of the PED to the CLP Regulation are likely to be insignificant.

The potential costs of the alignment are considered in more detail in Section 7.

7. COSTS OF ALIGNMENT

7.1 Costs by Module

7.1.1 Overview

The five Hazard Categories used in PED and their associated modules for demonstrating compliance are set out below. For some categories, there are multiple routes of compliance. Manufacturers can select the option that best reflects their scale of production and the extent of notified body involvement demanded by their customers. For example, a large chemical company may insist that an item of pressure equipment designated as Category 3 under the PED, complies with the Directive through adherence to the requirements listed under Module H. Alternatively, a SME may prefer that the same item of equipment conforms to the PED by fulfilling the requirements of Modules B and E.

It should be stressed that the prices below are indicative and represent an average across the Community. Thus for very complex equipment the fees are likely to be higher and for simple equipment the fees lower. With regard to the quoted fees, they reflect the direct cost of fulfilling the requirements of the relevant module and compliance with the PED.

The costs for sound engineering practice have been set at €0 so as to serve as a baseline against which other modules can be compared. It is acknowledged that, in practice, manufacturers would incur some costs when fulfilling these requirements.

7.1.2 Sound Engineering Practice

Pressure equipment and assemblies that are designed and manufactured in accordance with the principles of sound engineering practice need not comply with any of the internal PED modules and must not bear a CE mark. They do however need to be accompanied with adequate instructions for use and must bear markings that identify the manufacturer or his authorised representative established within the Community[46].

The manufacturer is responsible for the application of sound engineering practice and ensuring it is used safely during its intended life, when used in foreseeable or reasonably foreseeable conditions[47].

Table 7.1: Cost of Complying with PED Module (Sound Engineering Practice)

Module	Estimated cost in Euros (€) per annum, per manufacturer
N/A	€0

46 PED Article 3.3

47 PED Guideline 9/1

7.1.3 Category I

Module A (internal production control): This is a core module, the requirements of which also appear in subsequent modules. To assist with the comprehension of the modules below, these compliance measures have not been listed again for subsequent categories – although the associated costs of compliance have been included within the estimated costs. For an item of pressure equipment to comply with Category I, the manufacturer or his authorized representative must:

- prepare technical documentation (that addresses the Essential Safety Requirements (ESR) of the PED);
- ensure the item of pressure equipment conforms with the Essential Safety Requirements;
- ensure pressure equipment is CE marked;
- draw up a declaration of conformity; and
- retain all documents for 10 years

Table 7.2: Cost of Complying with PED Category I	
Module	**Estimated cost in Euros (€) per annum, <u>per product group</u>, per manufacturer**
A	€75

The costs of fulfilling the requirements listed under Category I will depend on the competence and knowledge of the manufacturer. Some manufacturers may be able to fulfil all of the requirements in-house without the need for a notified body (applying module A). The additional cost of compliance for these manufacturers will be relatively small. Conversely, manufacturers will contract a notified body to assess the technical documentation and confirm their products compliance with the ESR. For these manufacturers, the cost of compliance will be larger. The estimated figure represents the average cost of compliance, taking into consideration those who manufacturers who seek the assistance of notified bodies and those who perform in house compliance checks.

7.1.4 Category II

Module A1 (internal manufacturing checks with monitoring of the final assessment): This requires that:

- a notified body monitor the final assessment by means of unexpected visits.

Module D1 (production quality assurance): A notified body must assess quality assurance for production, final inspection and test. This comprises:

- of an assessment of the quality system of the manufacturer; and
- the manufacturer be subject to surveillance.

Module E1 (product quality assurance): A notified body must assess the quality assurance for final inspection and test, which requires:

- an assessment of the quality system; and
- the manufacturer be subject to surveillance.

Table 7.3: Cost of Complying with PED Module Category II	
Module	**Estimated cost in Euros (€) per annum, per manufacturer across the Community**
A1	€500
D1	€1000
E1	€1000

7.1.5 Category III

Module B1 (EC design-examination) and *Module B* (EC type-examination): Module B1 is concerned with technical documentation only, while Module B also requires that a Notified Body checks the manufacture of a sample production (representative example). The former is likely to be used for bespoke pressure equipment, the latter for serially produced pressure equipment. As is evident in Table 7.4 below, they must be used in conjunction with another module. Each module requires that:

- a notified body attests that the design of an item meets the applicable provisions of the PED (Module B1);
- a notified body attests that a representative example of production in question meets the applicable provisions of the PED (Module B). In this way, several versions of the pressure equipment can be covered, provided the differences between the versions do not affect the level of safety; and
- for both modules B and B1, the notified body must also check the technical documentation and assess the materials used, approve the joining of pressure equipment parts, verify the personnel undertaking welding and non-destructive tests.

Module C1 (conformity to type): As noted in Table 7.4 below, this Module can only be used with Module B (EC type-examination) which as discussed above, is used for serially produced items. Designed to monitor the final assessment, Module C1 is similar to A1, with the exception that this module is also used to verify that the representative example approved under Module B is tested in accordance with the PED.

Module D (production quality assurance): Module D must be used with Module B1 for Category III pressure equipment (Table 7.4) or Module B for Category IV pressure equipment (Table 7.5). Module D1 is similar to A1, establishing requirements for quality assurance for production, final inspection and test. Thus it requires a notified body to:

- assess the quality system of the manufacturer; and
- subject the manufacturer to surveillance.

Module E (product quality assurance): This module establishes requirements for quality assurance for final inspection and test. A notified body must:

- assess the quality system of the manufacturer; and
- subject the manufacturer to surveillance.

Module F (product verification): As with C1, this module must be used with either Module B1 for Category III pressure equipment (Table 7.4) or Module B for Category IV pressure equipment (Table 7.5), with module selection determined by the manufacturer. The manufacturer will take into consideration the number of units intended to be manufactured, whether serial production is envisaged and whether he has an approved quality assessment system. In addition to the requirements listed under Module A1, a notified body must also:

- verify the personal undertaking the permanent joining of parts and performing the non-destructive tests;
- verify the material certificates;
- review and approve non-destructive test reports;
- inspect the item during manufacture; and
- witness final inspection and examine any safety devices.

Module H (full quality assurance): This module has extensive notified body involvement, with the notified body tasks comprising the basic components of Module A as well as:

- quality assurance for design;
- quality assurance for manufacture; and
- final inspection and test.

Table 7.4: Cost of Complying with PED Category III	
Module	**Estimated cost in Euros (€) per annum, per product group, per manufacturer**
B1 + D	€1500 for B1 and €700 for D
B + E	€2000 for B, and €700 for E
H	€2000 for initial compliance, then €1200
Module	**Estimated cost in Euros (€) per annum, per item/per batch, per manufacturer**
B1 + F	€1500 for B1 and €700 ***per item*** for F
B + C1	€2000 for B and €700 ***per batch*** for C

7.1.6 Category IV

Module G (EC unit verification): This module is typically used for bespoke pressure equipment that is not serially produced. It is similar to B1 + F (Table 7.4), with the exception that a notified body must:

- examine the equipment during manufacture and perform the necessary tests where appropriate.

Module H1 (full quality assurance with design examination and special surveillance of the final assessment): In addition to the full assessment carried out under Module H, a notified body will undertake design assessment, additional surveillance and final assessment of the pressure equipment under Module H1.

Table 7.5: Cost of Complying with PED Module (Category IV)	
Module	**Estimated cost in Euros (€) per annum, per product group, per manufacturer**
B + D	€2000 for B and €1000 for D
Module	**Estimated cost in Euros (€) per annum, per item/per batch, per manufacturer**
G	€2000 per item
H1	€1500 per design, and €300 per batch
B + F	€2000 for B and €1000 for F, per item or batch

7.2 Compliance Costs to Industry

7.2.1 Estimated Number of Manufacturers Impacted

There are few reliable data on the pressure equipment industry sector. Indeed, a recent Commission Impact Assessment report[48] states:

> *Market data on these sectors is almost impossible to obtain. Information sources are restricted, as there is no single EU professional association representing the whole pressure equipment sector. Official statistical classification systems only reference a limited number of relevant products. Several attempts undertaken in the past to quantify the market for pressure equipment in Europe have failed.*

In the absence of robust data, some estimates have been made on the basis of available Eurostat data for 2009 and 2010 (2001 data are not yet available). The estimates were based on the following NACE (Rev 2) codes:

- 24.2 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel;
- 25.2 Manufacture of tanks, reservoirs and containers of metal;
- 25.3 Manufacture of steam generators, except central heating hot water boilers;
- 28.12 Manufacture of fluid power equipment;
- 28.13 Manufacture of other pumps and compressors; and
- 28.14 Manufacture of other taps and valves.

[48] Commission Staff Working Paper **Impact Assessment - Accompanying Document to the 10 Proposals to Align Product Harmonisation Directives to Decision No 768/2008/EC**, SEC(2011) 1376 final, dated 21.11.2011.

The available statistics for these codes suggests an industry of around 15,000 enterprises across the EU as shown in Table 7.6. The associated 'production value' is about €100 bn per annum.

Table 7.6: Numbers of Enterprises in the EU-27		
NACE Code	**2009**	**2010**
24.2 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	1,756	1,977
25.2 Manufacture of tanks, reservoirs and containers of metal	5,550	5,650
25.3 Manufacture of steam generators, except central heating hot water boilers	970	1,014
28.12 Manufacture of fluid power equipment	1,661	1,757
28.13 Manufacture of other pumps and compressors	2,551	2,523
28.14 Manufacture of other taps and valves	2,686	2,812
Totals	**15,174**	**15,733**
Source: Eurostat SBS Annual detailed enterprise statistics for industry (NACE Rev.2 B-E) [sbs_na_ind_r2]		

7.2.2 Imported Pressure Equipment

In addition to EU manufacturers, there will be companies exporting pressure equipment into the EU. For this analysis, two example product groups were taken from each of the above NACE codes in order to derive a ratio between the imported and produced quantities and values. The selected product groups are shown in Table 7.7.

Table 7.7: Example Product Groups	
Product Code	**Description**
24201310	Tubes and pipes, of circular cross-section, seamless, of stainless steel (excluding line pipe of a kind used for oil or gas pipelines and casing, tubing and drill pipe used for oil or gas drilling)
24202300	Tubes and pipes, welded, of an external diameter > 406,4 mm, of steel (excluding line pipe of a kind used for oil or gas pipelines and casing used for oil or gas drilling)
25291110	Iron or steel reservoirs, tanks, vats and similar containers for gases, of a capacity > 300 litres (excluding compressed or liquefied gas, fitted with mechanical or thermal equipment)
25291200	Containers for compressed or liquefied gas, of metal
25301150	Vapour generating boilers (including hybrid boilers) (excluding central heating hot water boilers capable of producing low pressure steam, watertube boilers)
25301170	Super-heated water boilers (excluding central heating hot water boilers capable of producing low pressure steam)
28121130	Hydraulic cylinders
28121450	Valves for the control of oleohydraulic power transmission for pipes, boiler shells, tanks, vats and the like
28132300	Compressors for refrigeration equipment

Table 7.7: Example Product Groups	
Product Code	**Description**
28133100	Parts of pumps for liquids and for liquid elevators
28141120	Pressure-reducing valves of cast iron or steel, for pipes, boiler shells, tanks, vats and the like (excluding those combined with lubricators or filters)
28141315	Process control valves for pipes, boiler shells, tanks etc excluding valves for pressure-reducing or oleohydraulic/pneumatic power transmissions, check, safety/relief valves, temp. regulators

The associated import and production values are shown in Table 7.8.

Table 7.8: Quantities (x1000) and Values (€m) of Imports and Production by Product Group

Product	Year	IMPQNT	IMPVAL	PRODQNT	PRODVAL	Ratio Q	Ratio V
24201310	2009	34704	248	375445	1681	9%	15%
	2010	40238	238	331577	1603	12%	15%
24202300	2009	150589	122	467174	480	32%	25%
	2010	102514	83	487040	522	21%	16%
25291110	2009	1326	6	112296	521	1%	1%
	2010	1459	10	103090	481	1%	2%
25291200	2009	52244	124	388363	1460	13%	9%
	2010	52295	133	367665	1358	14%	10%
25301150	2009	no data	67	27	576	no data	12%
	2010	no data	12	28	564	no data	2%
25301170	2009	no data	2	2	111	no data	1%
	2010	no data	1	3	118	no data	1%
28121130	2009	no data	87	4508	1317	no data	7%
	2010	no data	113	5547	1301	no data	9%
28121450	2009	8063	263	79586	1984	10%	13%
	2010	10352	317	92411	2727	11%	12%
28132300	2009	11576	710	33089	2086	35%	34%
	2010	15526	997	38370	2512	40%	40%
28133100	2009	0	815	no data	2541	no data	32%
	2010	0	1039	no data	2924	no data	36%
28141120	2009	1526	26	12719	226	12%	11%
	2010	1620	30	11000	228	15%	13%
28141315	2009	6440	156	150000	1600	4%	10%
	2010	7145	174	100000	2100	7%	8%

Source: Eurostat SBS - Statistics on the production of manufactured goods (prom)

As might be expected, the ratios vary from product group to product group but an overall estimate of around 15% seems to of the right order. On this basis it will be assumed that in addition to the 15,000 EU manufacturers, there will be a further 2,250 importers.

7.2.3 Estimated Manufacturers by Category

To determine the impact of any changes of aligning the PED to CLP, the distribution of pressure equipment manufactured within each of the five categories must be estimated. The estimates presented in Table 7.9 are centred on the overall number of manufacturers which has been estimated as 17,250. To facilitate the subsequent analysis, the estimates have been further divided into the choice of modules where appropriate. Clearly, these figures are uncertain but, nevertheless, provide a basis on which to derive some indicative costs.

Table 7.9: Number of Manufacturers that Construct Pressure Equipment

Hazard Category	PED Module	Estimates of the Numbers of Manufacturers		
		Low	Medium	High
SEP	N/A	12000	17250	22500
I	A	4500	5200	6000
II	A1, D1, E1	3500	4600	5750
III	(B1 +F) (B + C1)	2200	3350	4500
	(B1 + D) (B + E)	400	600	850
	H	100	200	300
IV	(B + D)	1000	2500	4000
	(G)	100	200	300
	H1	100	300	400
	B + F	100	300	400

7.2.4 Baseline Costs

By combining the numbers of manufacturers by category/module with the costs associated with each module (as derived in Section 7.1 above), it was possible to estimate the baseline costs of compliance with PED.

In order to derive these estimates, it was necessary to make some further assumptions:

- on average, each manufacturer has 40 product groups per category/module;
- limited runs are 500 items while bespoke runs are 15 items/year; and
- 'initial compliance costs' are spread over 5 years.

As can be seen from table 7.10 (next page), the total compliance costs of PED are estimated to be in the range €120m to €350m with a mid-estimate of €236m. As would be expected, the compliance costs increase with increasing hazard and the 'average' costs by Hazard Category are presented in Table 7.11 (next page).

Table 7.10: PED Compliance Costs (€m) by Hazard Category and PED Module				
Hazard Category	**PED Module**	**Low**	**Medium**	**High**
SEP	N/A	0.0	0.0	0.0
I	A	13.5	15.6	18.0
II	A1, D1, E1	13.4	17.6	22.0
III	(B1 +F) (B + C1)	3.7	5.4	7.1
	(B1 + D) (B + E)	11.9	17.9	25.3
	H	4.8	9.7	14.5
IV	(B + D)	42.0	105.0	168.0
	(G)	30.0	60.0	90.0
	H1	1.4	4.1	5.4
	B + F	0.7	1.1	1.3
Totals (€m)		**121.4**	**236.3**	**351.6**

Table 7.11: PED Compliance Costs (€m) by Hazard Category	
Hazard Category	**Mid Estimate**
SEP	0.0
I	15.6
II	17.6
III	32.9
IV	170.2

7.3 Costs of Alignment with the CLP Regulation

As discussed in Sections 3, 4, 5 and 6 most Group 1 fluids, as currently categorised according to the DSD classification, will remain Group 1 fluids when the PED is aligned to the CLP Regulation. There are, however, a number of substances in 'boundary areas' where changes in the group classification may occur. As explored in Section 6, the number of such substances will be less than 10% of the total[49].

The proportion of manufacturers which will be making equipment affected by such potential changes is difficult to estimate because of a lack of market data. Of course, many manufacturers will focus entirely on Group 2 fluids such as water/steam equipment manufacturers while others may manufacture equipment for a diverse range of fluids (such a pump manufacturer).

Using the 'best available knowledge', it has been cautiously estimated that 20% of manufacturers may be affected, although the true figure may indeed be less. However, of the 20% of manufacturers that are impacted, industry practice, the types of pressure equipment manufactured and the percentage of fluids that are Group 1 and Group 2 will mitigate any impacts of the PED aligning itself to the CLP.

49 Less than 400 of the 4136 substances with harmonised classification could potentially move fluid groups on alignment with CLP (see Tables 6.5, 6.6 and 6.7 for further detail).

It is common practice for pressure equipment to be designed and certified so as to be compatible with Group 1 fluids. This is especially prevalent for pressure equipment that is small and serially produced, particularly Category II equipment, as it ensures equipment will appeal to the widest possible market. Very expensive bespoke equipment will also be over engineered and designed and tested to be compatible with a Group 1 fluid to ensure that it can be used for any fluid during its entire life span (30 years is not exceptional). Taking this into account, of the manufacturers that supply pressure equipment that use substances that may change group, it has been estimated that 50% of pressure equipment will be compatible with Group 1.

Similarly, users of pressure equipment will often specify to manufacturers that they want an item of pressure equipment to be designed and manufactured to be compatible with a Group 1 fluid. This request will be submitted irrespective of whether the fluid to be used with the equipment is Group 1 or 2, with any difference in the cost of compliance absorbed in preference for adopting higher standards of safety. It has been estimated that around 25% of the manufacturers adopt this practice.

In summary, 20% of manufacturers use ‘boundary’ substances of which 50% already use Group 1 design by default and 25% are requested to design to Group 1 standards in any event. In other words, the potential changes may affect 25% of the 20% of manufacturers using ‘boundary’ substances which equates to 5% of all manufacturers. To provide a basis for further analysis, it has been assumed that the associated compliance costs would be 5% of the total. In other words, the compliance costs associated with those manufacturers handling ‘boundary’ substances form 5% of the total estimated costs for each PED Hazard Category.

If it is further assumed that the extra costs are associated with moving from one hazard category to the next (due to a substance moving from Group 2 to Group 1[50]), the costs of alignment can be estimated as shown in Table 7.12. Of course, there are no additional costs for equipment which is already considered hazard Category IV.

Table 7.12: PED Compliance Costs (€m) by Hazard Category

Hazard Category	Mid Estimate (€m)	5% of Current Costs (€m)	Costs of Moving up from Lower Category
SEP	0.0	0.00	n/a
I	15.6	0.78	0.78 (from SEP to I)
II	17.6	0.88	0.10 (from I to II)
III	32.9	1.65	0.77 (from II to III)
IV	170.2	8.51	6.87 (from III to IV)
		Alignment Costs	**€8.5m***

** The range can be estimated to be from €2.7m to €13.3m by carrying forward the figures from Table 7.10.*

50 Of course, in some cases, a change in group will lead to no change in the hazard category and, in a few cases, it is possible that there would be a change of two, or conceivably, three categories.

Given that the difference between Options 1 and 2 appears to be very small (compare Tables 6.6 and 6.7), there is no merit in further differentiating the costs, given the inherent uncertainties in the analysis.

In summary, the costs of aligning the PED to the CLP Regulation are estimated to be of the order of €8.5m per annum. Given the small number of 'boundary' substances that present physical hazards, the cost of alignment is largely influenced by the alignment of the health hazards, specifically Acute Toxicity. Of course, this figure could be further mitigated should manufacturers using a Group 1 fluid choose to change the operating parameters (volume of pressure equipment or maximum allowable pressure) so as to ensure the pressure equipment is categorised in the same way.

8. SUMMARY

The PED must be aligned with the CLP Regulation. This will require a revision to Article 9 of the PED which currently categorises fluids according to the DSD classification. The categorisation of fluids according to the CLP Regulation classification will, in the vast majority of cases, remain unchanged. However, there are some boundary areas in which substances may change fluid groups – depending on the precise alignment adopted.

Following consultation with stakeholders, it became clear that there was a lack of understanding amongst industry as to the consequences of aligning the PED to the CLP. To ensure a smooth transition, it was agreed that the prime aim of the alignment is to maintain the current regime of the PED, whilst ensuring that any changes are kept as simple as possible. With this in mind, we recommend that reliance be placed on the use of the new Hazard Statements.

The key differences between the current situation and future options are summarised in Table 8.1.

Table 8.1: Summary of Changes in Alignments for Options 1 and 2

Hazard Class	Hazard Statement	Comment
Flammable Liquids	H225: Highly flammable liquid and vapour	Some substances with Flash Points from 21 to 23^{o}C will now be automatically categorised as Group 1 fluids
Self-Reactive Substances and Mixtures *and* Organic Peroxides	H242: Heating may cause a fire	Theoretically, it is possible that some flammable substances (R10) may be reclassified as a self-reactive substance with the hazard statement H242
Acute Toxicity* (oral)	H301: Toxic if swallowed	Exclusion of H301 leads to some substances previously categorised as Group 1 being reclassified as Group 2 fluids
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 vapours previously categorised as Group 2 being reclassified as Group 1 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 2 being reclassified as Group 1 fluids

Note: It is important to stress that, in relation Acute Toxicity, most substances will be unaffected. In other words, most substances which are currently categorised as 'very toxic' and 'toxic' under the DSD will remain Group 1 fluids but will be classified as Acute Toxicity Categories 1 and 2 under the CLP. Similarly, most substances which are currently categorised as 'harmful' will remain Group 2 fluids but will be classified as Acute Toxicity Category 4. As such, the area of interest concerns those substances which will be classified as Acute Toxicity Category 3 under the CLP with the associated Hazard Statements H301, H311 and H331.

The most significant direct impacts (in terms of numbers of substances affected) are likely to be associated with the Hazard Statements H301, H311 and H331. It has proven difficult to provide an accurate assessment as to the exact number of substances will change fluid group following alignment to the CLP. To ensure the analysis was robust, only the harmonised classifications were assessed (4,000 of a possible 100,000 substances). Of the 4,000 harmonised substances, it is possible that 393 may change fluid group. Unfortunately, due to the way in which substances are classified using thresholds, it is not possible to provide a more accurate assessment that is not subject to challenge.

Interestingly, an indirect impact of changes in the PED relates to in-service inspections which are undertaken at national level and represent recurring costs throughout the lifetime of the equipment. These impacts are beyond the scope of this study, with associated increased costs not taken into account.

In some cases, where a substance is re-categorised as a Group 1 fluid, the compliance costs will increase after alignment with the CLP Regulation. The costs of complying with PED depend not only on the relevant Hazard Category for the equipment but also the compliance module(s) selected. Although there are few robust data available, it is estimated that the current annual compliance costs are probably of the order of €250m.

The additional costs of aligning the PED to the CLP have been estimated to be around €8.5 million per annum, with no significant benefits beyond regulatory alignment.

ANNEX 1:

CORRELATION OF DSD AND CLP CLASSIFICATIONS

<table>
<tr><th colspan="4">Annex 1.1: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Explosives)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="11">E; R2 Risk of explosion by shock, friction, fire or other sources of ignition
E; R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition (liquid)</td><td colspan="2">Annex I, 2.1.1.1 and 2.1.1.2 of CLP outline and define the relevant terms for substances, mixtures and articles that fall within the Explosive hazard class. Explosive substances, mixtures and articles that are not classified as unstable will be assigned to the appropriate division below, as determined by the hazard they present</td><td rowspan="11">Substances and mixtures that are currently classified as E; R2 or E; R3 according to the DSD are expected to be classified as explosive under CLP.

However because CLP divides physcial hazards into a greater number of hazard classes than DSD/DPD some substances may move from this hazard class and be classified under CLP hazard classes for organic peroxides or self-reactives (see relevant category below for more discussion).

CLP also classifies as explosive substances or mixtures that have been manufactured to produce an explosive or pyrotechnic effect, irrespective of how it may otherwise have been classified. Thus a small number of these ‘intentional explosives’ will be classified under CLP as explosive, which was not the case under the DSD.</td></tr>
<tr><td colspan="2">The Explosive Divisions under CLP</td></tr>
<tr><td>Division</td><td>Type of Hazard</td></tr>
<tr><td></td><td>Unstable explosives</td></tr>
<tr><td>1.1</td><td>Mass Explosion</td></tr>
<tr><td>1.2</td><td>Projection</td></tr>
<tr><td>1.3</td><td>Fire or minor blast/projection</td></tr>
<tr><td>1.4</td><td>No significant hazard, only a small hazard in the event of ignition or initiation</td></tr>
<tr><td>1.5</td><td>Insensitive substances or mixtures that have a mass explosion hazard</td></tr>
<tr><td>1.6</td><td>Extremely insensitive articles which do not have a mass explosion hazard</td></tr>
<tr><td colspan="2">CLP Annex I, 2.1.2.1</td></tr>
</table>

Annex 1.2: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Testing and Screening for Explosives)		
Current reference in Art. 9 and R-phrase according to PED Guideline 2/7	**Possible Group Hazard Classification under Article 9, PED after alignment with CLP**	**Explanatory Comments**
Regulation (EC) No. 440/2008 (Tests Methods Regulation): New substances that are suspected of possessing explosive qualities may be subsequently classified as explosive according to the results of test method A.14 (explosive properties) found under Regulation (EC) No. 440/2008 (former Annex V to DSD). Three tests are undertaken to determine whether a substance or mixture possesses explosive properties: • thermal sensitivity test (Koenen test); • mechanical sensitivity to impact (Fallhammer); and • mechanical sensitivity to friction (Friction apparatus)	The screening procedure identifies whether a substance or mixture possesses reactive groups that have the potential for rapid energy release and thus whether or not a substance mixture may be 'explosive' or 'unstable explosive'. This is outlined under: • CLP Annex I, 2.1.4.1; • Appendix 6 (Part 3) of the UN Manual of Tests and Criteria[51] identifies the substance/mixture as potentially having explosive effects will the test be necessary; and • Technical Guidance Document on the Information Requirements for REACH.[52] Thus there is a series of tests which have been divided into groups. By conducting Test series 1 – 4, it is possible to assess whether a substance/mixture has possible explosive effects. These tests may be undertaken in any order and indeed, for the safety of experimenters, it may be prudent to conduct test series 3 first[53]. In broad terms, Test series 1-4 assesses: • thermal sensitivity; • detonation behaviour; • deflagration behaviour; • mechanical sensitivity; • thermal stability; and • response to fire.	Under the DSD, if any of the tests undertaken for the purpose of identifying explosive properties (test method A.14) show a positive result, the substance/mixture will be classified as explosive. Whereas the DSD classification system only takes into account the intrinsic properties of a substance or mixture, CLP scheme also considers the packaged state of the substance or mixture. This change of approach could mean that some substances or mixtures that were previously classified as explosive according to the DSD, will no longer be classified as explosive under CLP if they are packaged in such a way that they do not meet CLP criteria. However, this is not an entirely new concept to CLP, as Note T to Annex I of the DSD includes a similar provision. Notably, the questions under Test series 3 for mechanical sensitivity differ slightly from the mechanical test undertaken for the purposes of the DSD and the criteria are also different. Specifically, the outcome of tests 3 (a) and 3 (b) determine whether a substance or mixture is too sensitive to mechanical stimuli, for which lower limits are stated. Conversely, upper limits were used in the A.14 test to determine whether a substance or mixture presented an explosive hazard[54].

51 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria *Fifth revised edition* United Nations: New York and Geneva, 2009 (ST/SG/AC.10/11/Rev.5)

52 Technical Guidance Document on the Information Requirements for REACH, Part 2 EWG 1-7, REACH Implementation Project (RIP) 3.3 Phase 2, chapter 7.1.11.3

53 This is because test series 3 uses relatively small sample sizes compared to other tests, thus reducing the risk to test personnel.

54 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

<table>
<tr><th colspan="4">Annex 1.3: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Flammable Gas)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="6">F+; R12 Extremely flammable (gas).

Flammable gases are defined in DSD as “gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.”

F+; R12 may also be used for liquids (see later discussion)</td><td colspan="2">For the purposes of CLP classification, ‘Flammable’ gases are defined as “a gas or gas mixture having a flammable range with air at 20°C and a standard pressure of 101,3 kPA”[55] (i.e. at atmospheric pressure).

Gases qualifying as flammable will then be sub-divided into one of two hazard categories as follows:</td><td rowspan="6">As the DSD has only one category for flammable gases, a direct translation to CLP is not possible. However, alignment is relatively simple as the breadth of the hazard class flammable gases under CLP remains the same as that of F+; R12 under the DSD. Substances or mixtures previously classified under the DSD as F+; R12 will simply be re-classified as either Category 1 or Category 2 flammable gases.

The exception to the classification procedure is Ammonia, which is currently classified as F; R10 according to the DSD. Under CLP, this will be classified as Flammable Gas Category 2.</td></tr>
<tr><td colspan="2">Criteria for Flammable Gases</td></tr>
<tr><td>Category</td><td>Criteria</td></tr>
<tr><td>1</td><td>a) are ignitable when in a mixture of 13% or less by volume in air; or
b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.</td></tr>
<tr><td>2</td><td>Gases, other than those of Category 1, which, at 20°C and a saturated pressure of 101,3 kPa, have a flammable range while mixed in the air.</td></tr>
<tr><td colspan="2">CLP Annex I, Table 2.2.1</td></tr>
</table>

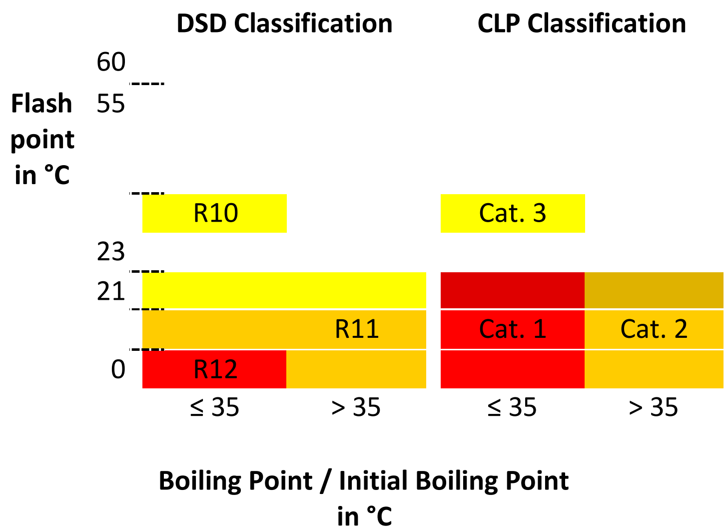
[55] CLP Annex I, 2.2.1.

<table>
<tr><th colspan="3">Annex 1.4: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Flammable Liquids)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th>Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr>
<td>F+; R12 Extremely flammable (liquid);
F; R11 Highly flammable (liquid); and
F; R10 Flammable (where it is intended to be used at maximum allowable temperature that exceeds its flashpoint).

The PED guidance confirms that flammable means any fluid “intended to be used at a maximum allowable temperature TS above its flashpoint”[56].

The current classification according to the DSD is up to a flash point of 55 °C.</td>
<td>For the purposes of CLP, ‘Flammable’ liquids are liquids “having a flash point of not more than 60°C”[57]. Such liquids are then further subdivided into three categories as outlined below:

<table>
<tr><th colspan="2">Label Elements for Flammable Liquids</th></tr>
<tr><th>Category</th><th>Criteria</th></tr>
<tr><td>1</td><td>Flash point < 23 °C and initial boiling point ≤ 35 °C</td></tr>
<tr><td>2</td><td>Flash Point < 23 °C and initial boiling point > 35 °C</td></tr>
<tr><td>3</td><td>Flash point ≥ 23 °C and ≤ 60°C*</td></tr>
<tr><td colspan="2">* It should be noted that flammable liquids of category 4 of the GHS are not implemented in the EU-CLP Regulation. However, CLP, gas oils, diesel and light heating oils that have a flash point between ≥ 55 °C and ≤ 75 °C are to be regarded as Category 3.</td></tr>
<tr><td colspan="2">CLP Annex I, Table 2.6.1</td></tr>
</table></td>
<td>A small number of additional substances and mixtures may be captured by CLP where their flashpoint falls between 55°C (the cut-off under DSD) and 60°C (the cut-off under CLP).



Comparison of Flashpoint / (Initial) Boiling Point[58] according to DSD and CLP[59]</td>
</tr>
</table>

56 PED Guideline 2/20

57 CLP Annex I 2.6.1.

58 The boiling point of a substance is the temperature at which the vapour pressure of the liquid equals environmental pressure (101, 325 kPa) surrounding the liquid

59 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

Annex 1.5: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Flammable Solids)		
Current reference in Art. 9 and R-phrase according to PED Guideline 2/7	**Possible Group Hazard Classification under Article 9, PED after alignment with CLP**	**Explanatory Comments**
F; R11 – Highly Flammable	As noted above, the grouping of a solid will influence the hazard classification of a mixture, where the fluid contains a suspension of a solid. This necessitates discussion of this hazard class. Flammable solids and mixtures are classified according to their burning behaviour and are defined under Annex I, 2.7.1.1. Since flammability is an intrinsic hazard within this hazard class, substances and mixtures classified as explosive, an organic peroxide, self-reactive, pyrophoric or oxidising solid should not be considered for classification as a flammable solid[60]. Flammable solids will be classified as either Category 1 or Category 2 depending on the results of the burning test outlined below: *Category 1: Substances and mixtures other than metal powders:* *(a) wetted zone does not stop fire and* *(b) burning time < 45 seconds or burning rate > 2.2 mm/s* *Metal powders: burning time ≤ 5 minutes* *Category 2: Substances and mixtures other than metal powders:* *(a) wetted zone stops the fire for at least 4 minutes and* *(b) burning time < 45 seconds or burning rate > 2.2 mm/s* *Metal powders: burning time > 5 minutes and ≤ 10 minutes*	Most solids and mixtures classified as 'F; R11' according to the DSD will translate into a flammable solid according to CLP. However, there may be some cases where substances or mixtures are better classified as self-reactive or possibly even, explosive according to CLP[61]. These will however, remain as Group 1 fluids. A conservative approach is adopted when it comes to classifying substances as Category 1 or Category 2, with Category 2 assigned only when the decision can be reasonably justified[62].

60 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

61 Ibid

62 Ibid

<table>
<tr><th colspan="4">Annex 1.6: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Pyrophoric Liquids)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="5">F; R17 – Spontaneously flammable in air.</td><td colspan="2">Pyrophoric Liquids are defined under Annex I, 2.9.1.

There is only one Category (Category 1) for pyrophoric liquids as outlined below:</td><td rowspan="5">The tests used to classify a substance or mixture as F; R17; and those used to determine whether a mixture or substance is a pyrophoric liquid are identical[63].

Equally, in a similar fashion to F; R17; CLP hazard class pyrophoric liquids contains only one Category. Furthermore, the classification criteria are also identical. The transition from the DSD to CLP in respect of these hazard classes is direct and simple.</td></tr>
<tr><td colspan="2">Criteria for Pyrophoric Liquids</td></tr>
<tr><td>Category</td><td>Criteria</td></tr>
<tr><td>1</td><td>The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min</td></tr>
<tr><td colspan="2">CLP Annex I, Table 2.9.1</td></tr>
</table>

[63] The DSD uses A.13 test in EC-Regulation 440/2008 whilst CLP methods N.3 as described in Part 3 Section 33 of the United Nations Manual of Tests and Criteria.

<table>
<tr><th colspan="4">Annex 1.7: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Pyrophoric Solids)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="4">F; R17 – Spontaneously flammable in air</td><td colspan="2">Pyrophoric Solids are defined under Annex I, 2.10.1, where it is noted that mixtures fall within this hazard class. As has already been noted, the grouping of a solid will influence the hazard classification of a mixture, where the fluid contains a suspension of a solid. This necessitates discussion of this hazard class.

There is only one Category (Category 1) for pyrophoric solids as outlined below:</td><td rowspan="4">The tests used to classify a substance or mixture as F; R17; and those used to determine whether a mixture or substance is a pyrophoric solid are identical[64].

Equally, in a similar fashion to F; R17; CLP hazard class pyrophoric solids contains only one Category. Furthermore, the classification criteria are also identical. The transition from the DSD to CLP in respect of these hazard classes is direct and simple.</td></tr>
<tr><td colspan="2">Criteria for Pyrophoric Solids</td></tr>
<tr><td>Category</td><td>Criteria</td></tr>
<tr><td>1</td><td>The solid ignites within 5 minutes of coming into contact with air.</td></tr>
</table>

[64] The DSD uses A.13 test in EC-Regulation 440/2008 whilst CLP methods N.3 as described in Part 3 Section 33 of the United Nations Manual of Tests and Criteria.

Annex 1.8: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Contact with water emits flammable gases)		
Current reference in Art. 9 and R-phrase according to PED Guideline 2/7	**Possible Group Hazard Classification under Article 9, PED after alignment with CLP**	**Explanatory Comments**
F; R15; Contact with water liberates extremely flammable gases.	CLP defines substances or mixtures which, in contact with water emit flammable gases under CLP Annex I, 2.12.1. These substances or mixtures will be classified in one of three categories: *Category 1: Any substance or mixture which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 litres per kilogram of substance over any one minute.* *Category 2: Any substance or mixture which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 litres per kilogram of substance per hour, and which does not meet the criteria for Category 1.* *Category 3: Any substance or mixture which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 litre per kilogram of substance per hour, and which does not meet the criteria for Categories 1 and 2.*	All substances and mixtures that are classified as F; R15 according to the DSD will be classified under CLP as a substance or mixture which, in contact with water emits flammable gases. Although under CLP the hazard class has been sub-divided into three categories, the breadth is comparable to the classification under the DSD. Consequently, this should be a straightforward alignment. CLP may however have an impact on pyrophoric substances or mixtures. As noted in CLP guidance document, if a substance or mixture was classified as F; R17 under the DSD, no additional classification in respect of F; R15; was required[65]. This is no longer the case under CLP, which mandates a UN N5. Test under nitrogen atmosphere for substances already classified as F; R17.

65 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

<table>
<tr><th colspan="4">Annex 1.9: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Oxidising Gases)</th></tr>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="5">O; R8 - Contact with combustible material may cause fire (gas)</td><td colspan="2">CLP defines an oxidising gas under Annex I, 2.4.1. There is only one Category under CLP, which is outlined below:</td><td rowspan="5">All oxidising gases classified according to the DSD as O; R-8 will be classified as a Category 1 Oxidising gas under CLP (Ox. Gas 1). Alignment is relatively simple.

The only slight difference is that under the DSD, a gas was classified as having oxidising potential O; R8 if it had an oxidising potential of at least 21%. Whereas under CLP, the oxidizing potential must be at least 23.5%. CLP also takes into account the fact that other gases in a mixture may have an inertising effect different from nitrogen[66].</td></tr>
<tr><td colspan="2">Criteria for Oxidising Gases</td></tr>
<tr><td>Category</td><td>Criteria</td></tr>
<tr><td>1</td><td>Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.</td></tr>
<tr><td colspan="2">CLP Annex I, Table 2.4.1</td></tr>
</table>

66 UK Department for Business Innovation & Skills (2010): *Adaptation of Art. 9 of the PED to CLP-Regulation with regard to physical hazards,* available from: http://www.bis.gov.uk/assets/biscore/business-sectors/docs/p/proposal-adaptation-article-9-ped-to-clp-regulation.doc

Annex 1.10: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Oxidising Liquid)		
Current reference in Art. 9 and R-phrase according to PED Guideline 2/7	**Possible Group Hazard Classification under Article 9, PED after alignment with CLP**	**Explanatory Comments**
O; R8 Contact with combustible material may cause fire (liquid); O; R9 Explosive when mixed with combustible material (liquid)	The definition for Oxidising liquids can be found under Annex I, 2.13.1. An oxidising liquid will be classified into one of three Categories of this class in accordance with test method O.2 in Part III, sub section 34.4.2 of the UN – Manual of tests and Criteria[67] as outlined below: *Category 1: Any substance or mixture which, in the 1:1 mixture, by mass, of substance (or mixture) and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of substance (or mixture) and cellulose is less than that of a 1:1 mixture, by mass, of 50 % perchloric acid and cellulose* *Category 2: Any substance or mixture which, in the 1:1 mixture, by mass, of substance (or mixture) and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40 % aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met* *Category 3: Any substance or mixture which, in the 1:1 mixture, by mass, of substance (or mixture) and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65 % aqueous nitric acid and cellulose; and the criteria for Category 1 and 2 are not met.*	Liquids that have been classified as O; R8 and O; R9 according to the DSD can be re-classified under CLP. Although CLP sub-divides the hazard class into three categories, its total coverage as defined by the cut-off limits corresponds to the previous classification under the DSD. Due to these similarities, transition from the DSD to CLP should be smooth in respect of substances in this hazard class[68].

67 CLP, Annex I, 2.13.2.1

68 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

Annex 1.11: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Oxidising Solid)

<table>
<tr><th>Current reference in Art. 9 and R-phrase according to PED Guideline 2/7</th><th colspan="2">Possible Group Hazard Classification under Article 9, PED after alignment with CLP</th><th>Explanatory Comments</th></tr>
<tr><td rowspan="6">O; R8 Contact with combustible material may cause fire (solid); and
O; R9 Explosive when mixed with combustible material (solid)</td><td colspan="2">The definition for Oxidising solids can be found under CLP Annex I, 2.14.1. It is necessary to consider this hazard class because the grouping of a solid will influence the hazard classification of mixture, where the fluid contains a suspension of a solid.

An oxidising solid will be classified into one of three Categories of this class in accordance with test method O.1 in Part III, sub section 34.4.2 of the UN – Manual of tests and Criteria[69] . The three categories are outlined below:</td><td rowspan="6">Solids that have been classified as O; R8 and O; R9 according to the DSD can be re-classified under CLP. Although CLP sub-divides the hazard class into three categories, its total coverage as defined by the cut-off limits corresponds to the previous classification under the DSD. The testing procedure under CLP is slightly different to that under the DSD but is expected to cover the same substances and mixtures. Due to these similarities, transition from the DSD to CLP should be smooth in respect of substances in this hazard class[70] .</td></tr>
<tr><td colspan="2">Criteria for Oxidising Solids</td></tr>
<tr><td>Category</td><td>Criteria</td></tr>
<tr><td>1</td><td>Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose</td></tr>
<tr><td>2</td><td>Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and the criteria for Category 1 are not met.</td></tr>
<tr><td>3</td><td>Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to are less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.</td></tr>
</table>

69 CLP, Annex I, 2.13.2.1

70 ECHA (November 2012) *Guidance on the Application of CLP Criteria* Available from http://echa.europa.eu/documents/10162/13562/clp_en.pdf

Annex 1.12: Translation Between Classification in Accordance with the DSD and CLP for Physical Hazards (Self-Reactive)		
Current reference in Art. 9 and R-phrase according to PED Guideline 2/7	**Possible Group Hazard Classification under Article 9, PED after alignment with CLP**	**Explanatory Comments**
E; R2 Risk of explosion by shock, friction, fire or other sources of ignition; E; R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition; F+; R12 for Extremely flammable; F; R11 Highly flammable	The definition for 'Self-reactive' substances or mixtures can be found under Annex I, 2.8.11 of CLP. These substances shall be classified in one of types for this class according to the results of Test Series A to G: • Test series A: determine if there is propagation of detonation; • Test series B: determine if there is detonation in the package; • Test series C: determine if there is propagation of deflagration; • Test series D: determine if there is rapid deflagration in the package; • Test series E: determine the effect of heating under confinement; • Test series F: determine the explosive power; • Test series G: determines the effect of a thermal explosion of a substance as packaged for transport As outlined under Annex I, 2.8.2.1, this procedure need not be applied if: • the mixture of substance does not contain any chemical groups with explosive or self-reactive properties; or for a single organic substance or homogenous mixture of organic substances, the self–accelerating decomposition temperature is greater than 75 °C for a 50 Kg package or the heat decomposition is less than 300 J/g.	The 'Self-reactive' substances and mixtures hazard class under CLP does not directly correspond to any of the hazard classes under the DSD. Thus it is a novel class, which will capture substances and mixtures that have previously been classified under other hazard classes according to the DSD. These hazard classes have typically been listed under Article 9 of the PED, meaning that substances and mixtures that will now be classified as 'Self-reactive' were previously classified as dangerous fluids under the PED For example, substances or mixtures that would qualify as 'Self-reactive' Test series A, B and in part C according to CLP, have been classified according to the DSD as Explosive (E; R2 or E; R3). Whilst substances or mixtures that would qualify as Test Series C to F have been classified according to the DSD as flammable (F+; R12, F; R11 and in some cases F; R10) . Specific examples of this include: • 3-Azidosulfonylbenzoic acid (currently E; R-2) • 2,2'-dimethyl-2,2'-azodipropiononitrile; ADZN (currently E; R2); and •Ammonium bis(1-(3,5-dinitro-2-oxidophenylazo)-3-(N phenyl carbamoyl)-2-naphtholato)chromate(1-) (currently F; R11)

ANNEX 2:

BOUNDARY TOXIC SUBSTANCES

Index Number	International Chemical Identification	H301	H311	H331
006-010-00-1	5,5-dimethyl-3-oxocyclohex-1-enyl dimethylcarbamate; 5,5-dimethyldihydroresorcinol dimethylcarbamate; Dimetan	1		
006-016-00-4	propoxur (ISO); 2-isopropyloxyphenyl N-methylcarbamate; 2-isopropoxyphenyl methylcarbamate	1		
006-018-00-5	aminocarb (ISO); 4-dimethylamino-3-tolyl methylcarbamate	1	1	
006-022-00-7	decarbofuran (ISO); 2,3-dihydro-2-methylbenzofuran-7-yl methylcarbamate	1	1	1
006-023-00-2	mercaptodimethur (ISO); methiocarb (ISO); 3,5-dimethyl-4-methylthiophenyl N-methylcarbamate	1		
006-028-00-X	dinobuton (ISO); 2-(1-methylpropyl)-4,6-dinitrophenyl isopropyl carbonate	1		
006-029-00-5	dioxacarb (ISO); 2-(1,3-dioxolan-2-yl)phenyl N-methylcarbamate	1		
006-035-00-8	pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	1		
006-037-00-9	promecarb (ISO); 3-isopropyl-5-methylphenyl N-methylcarbamate	1		
006-040-00-5	3-methylpyrazol-5-yl-dimethylcarbamate; monometilan	1	1	1
006-041-00-0	dimethylcarbamoyl chloride			1
006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	1		1
006-047-00-3	bufencarb (ISO); reaction mass of 3-(1-methylbutyl)phenyl N-methylcarbamate and 3-(1-ethylpropyl)phenyl N-methylcarbamate	1	1	
006-083-00-X	butocarboxim (ISO); 3-(methylthio)-2-butanone O-[(methylamino)carbonyl]oxime	1	1	1
006-088-00-7	benfuracarb (ISO); ethyl N-[2,3-dihydro-2,2-dimethylbenzofuran-7-yloxycarbonyl(methyl)aminothio]-N-isopropyl- β-alaninate			1
007-008-00-3	hydrazine	1	1	1

007-013-00-0	1,2-dimethylhydrazine	1	1	1
007-014-00-6	salts of hydrazine	1	1	1
007-025-00-6	(4-hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride	1		
009-004-00-7	sodium fluoride	1		
009-005-00-2	potassium fluoride	1	1	1
009-006-00-8	ammonium fluoride	1	1	1
009-007-00-3	sodium bifluoride; sodium hydrogen difluoride	1		
009-008-00-9	potassium bifluoride; potassium hydrogen difluoride	1		
009-009-00-4	ammonium bifluoride; ammonium hydrogen difluoride	1		
009-012-00-0	alkali fluorosilicates(Na); [1] alkali fluorosilicates(K); [2] alkali fluorosilicates(NH4) [3]	1	1	1
009-015-00-7	sulphuryl difluoride			1
009-018-00-3	magnesium hexafluorosilicate	1		
015-030-00-X	demeton-O-methyl (ISO); O-2-ethylthioethyl O,O-dimethyl phosphorothioate	1		
015-031-00-5	demeton-S-methyl (ISO); S-2-ethylthioethyl dimethyl phosphorothioate	1	1	
015-037-00-8	phenkapton (ISO); S-(2,5-dichlorophenylthiomethyl) O,O-diethyl phosphorodithioate	1	1	1
015-044-00-6	carbophenothion (ISO); 4-chlorophenylthiomethyl O,O-diethyl phosphorodithioate	1	1	
015-045-00-1	mecarbam (ISO); N-ethoxycarbonyl-N-methylcarbamoylmethyl O,O-diethyl phosphorodithioate	1	1	
015-046-00-7	oxydemeton-methyl; S-2-(ethylsulphinyl)ethyl O,O-dimethyl phosphorothioate	1	1	
015-047-00-2	ethion (ISO); O,O,O',O'-tetraethyl S,S'-methylenedi (phosphorodithioate); diethion	1		
015-048-00-8	fenthion (ISO); O,O-dimethyl-O-(4-methylthion-m-tolyl) phosphorothioate			1

015-049-00-3	endothion (ISO); S-5-methoxy-4-oxopyran-2-ylmethyl dimethyl phosphorothioate	1	1	
015-050-00-9	thiometon (ISO); S-2-ethylthioethyl O,O-dimethyl phosphorodithioate	1		
015-058-00-2	morphothion (ISO); O,O-dimethyl-S-(morpholinocarbonylmethyl) phosphorodithioate	1	1	1
015-059-00-8	vamidothion (ISO); O,O-dimethyl S-2-(1-methylcarbamoylethylthio) ethyl phosphorothioate	1		
015-064-00-5	bromophos-ethyl (ISO); O-4-bromo-2,5-dichlorophenyl O,O-diethyl phosphorothioate	1		
015-066-00-6	omethoate (ISO); O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate	1		
015-067-00-1	phosalone (ISO); S-(6-chloro-2-oxobenzoxazolin-3-ylmethyl) O,O-diethyl phosphorodithioate	1		
015-075-00-5	S-[2-(isopropylsulphinyl)ethyl] O,O-dimethyl phosphorothioate	1	1	1
015-077-00-6	2,2-dichlorovinyl 2-ethylsulphinylethyl methyl phosphate	1	1	1
015-078-00-1	demeton-S-methylsulphon (ISO); S-2-ethylsulphonylethyl dimethyl phosphorothioate	1		
015-084-00-4	chlorpyrifos (ISO); O,O-diethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate	1		
015-085-00-X	chlorphonium chloride (ISO); tributyl (2,4-dichlorobenzyl) phosphonium chloride	1		
015-086-00-5	coumithoate (ISO); O,O-diethyl O-,8,9,10-tetrahydro-6-oxo-benzo(c)chromen-3-yl phosphorothioate	1		
015-099-00-6	pirimiphos-ethyl (ISO); O,O-diethyl O-2-diethylamino-6-methylpyrimidin-4-yl phosphorothioate	1		
015-109-00-9	crotoxyphos (ISO); 1-phenylethyl 3-(dimethoxyphosphinyloxy) isocrotonate	1	1	
015-121-00-4	edifenphos (ISO); O-ethyl S,S-diphenyl phosphorodithioate	1		1
015-126-00-1	heptenophos (ISO); 7-chlorobicyclo(3.2.0)hepta-2,6-dien-6-yl dimethyl phosphate	1		
015-129-00-8	isofenphos (ISO); O-ethyl O-2-isopropoxycarbonylphenyl-isopropylphosphoramidothioate	1	1	
015-130-00-3	isothioate (ISO); S-2-isopropylthioethyl O,O-dimethyl phosphorodithioate	1	1	

015-131-00-9	isoxathion (ISO); O,O-diethyl O-5-phenylisoxazol-3-ylphosphorothioate	1	1	
015-132-00-4	S-(chlorophenylthiomethyl) O,O-dimethylphosphorodithioate; methylcarbophenothione	1	1	
015-136-00-6	trans-isopropyl-3-[[(ethylamino)methoxyfosfinothioyl]oxy]crotonate; isopropyl 3-[[(ethylamino)methoxyphosphinothioyl]oxy]isocrotonate; propetamphos (ISO)	1		
015-138-00-7	quinalphos (ISO); O,O-diethyl-O-quinoxalin-2-yl phosphorothioate	1		
015-140-00-8	triazophos (ISO); O,O-diethyl-O-1-phenyl-1H-1,2,4-triazol-3-yl phosphorothioate	1		1
015-168-00-0	fosthiazate (ISO); (RS)-S-sec-butyl-O-ethyl-2-oxo-1,3-thiazolidin-3-ylphosphonothioate	1		1
015-174-00-3	1-chloro-N,N-diethyl-1,1-diphenyl-1-(phenylmethyl)phosphoramine	1		
015-175-00-9	tert-butyl (triphenylphosphoranylidene) acetate	1		
015-193-00-7	triphenyl(phenylmethyl)phosphonium 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1)	1		
015-197-00-9	bis(2,4,4-trimethylpentyl)dithiophosphonic acid			1
016-009-00-8	disodium sulfide; sodium sulfide		1	
016-010-00-3	sodium polysulphides	1		
016-011-00-9	sulphur dioxide			1
016-012-00-4	disulphur dichloride; sulfur monochloride	1		
016-054-00-3	sodium 4-(2,4,4-trimethylpentylcarbonyloxy)benzenesulfonate			1
017-001-00-7	chlorine			1
017-002-00-2	hydrogen chloride			1
017-026-01-0	chlorine dioxide ... %	1		
028-011-00-6	nickel dichloride	1		1
033-001-00-X	arsenic	1		1
033-002-00-5	arsenic compounds, with the exception of those specified elsewhere in this Annex	1		1
033-004-00-6	diarsenic pentaoxide; arsenic pentoxide; arsenic oxide	1		1

033-005-00-1	arsenic acid and its salts with the exception of those specified elsewhere in this Annex	1		1
034-001-00-2	selenium	1		1
034-002-00-8	selenium compounds with the exception of cadmium sulphoselenide and those specified elsewhere in this Annex	1		1
042-002-00-4	tetrakis(dimethylditetradecylammonium) hexa-μ-oxotetra-μ3-oxodi-μ5-oxotetradecaoxooctamolybdate(4-)			1
048-003-00-6	cadmium diformate; cadmiumformate	1		1
048-005-00-7	cadmiumhexafluorosilicate(2-); cadmium fluorosilica	1		1
048-007-00-8	cadmium iodide	1		1
050-007-00-8	tripropyltin compounds, with the exception of those specified elsewhere in this Annex	1	1	1
050-008-00-3	tributyltin compounds, with the exception of those specified elsewhere in this Annex	1		
050-011-00-X	triphenyltin compounds, with the exception of those specified elsewhere in this Annex	1	1	1
050-021-00-4	dichlorodioctyl stannane			1
051-004-00-4	antimony trifluoride	1	1	1
056-004-00-8	barium chloride	1		
078-001-00-0	tetrachloroplatinates with the exception of those specified elsewhere in this Annex	1		
078-002-00-6	diammonium tetrachloroplatinate	1		
078-003-00-1	disodium tetrachloroplatinate	1		
078-004-00-7	dipotassium tetrachloroplatinate	1		
078-005-00-2	hexachloroplatinates with the exception of those specified elsewhere in this Annex	1		
078-006-00-8	disodium hexachloroplatinate	1		
078-007-00-3	dipotassium hexachloroplatinate	1		
078-008-00-9	diammonium hexachloroplatinate	1		
078-009-00-4	hexachloroplatinic acid	1		
080-008-00-9	phenylmercury nitrate; [1] phenylmercury hydroxide; [2] basic phenylmercury nitrate [3]	1		
080-009-00-4	2-methoxyethylmercury chloride	1		
080-011-00-5	phenylmercury acetate	1		
082-011-00-0	lead hydrogen arsenate	1		1

601-067-00-4	triethyl arsenate	1		1
602-002-00-2	bromomethane; methylbromide	1		1
602-005-00-9	methyl iodide; iodomethane	1		1
602-007-00-X	bromoform; tribromomethane			1
602-008-00-5	carbon tetrachloride; tetrachloromethane	1	1	1
602-010-00-6	1,2-dibromoethane	1	1	1
602-021-00-6	1,2-dibromo-3-chloropropane	1		
602-030-00-5	1,3-dichloropropene; [1] (Z)-1,3-dichloropropene [2]	1	1	
602-037-00-3	α-chlorotoluene; benzyl chloride			1
602-038-00-9	α,α,α-trichlorotoluene; benzotrichloride			1
602-042-00-0	1,2,3,4,5,6-hexachlorcyclohexanes with the exception of those specified elsewhere in this Annex	1		
602-043-00-6	lindane (ISO); γ-HCH or γ-BHC; γ-1,2,3,4,5,6-hexachlorocyclohexane	1		
602-044-00-1	camphechlor (ISO); toxaphene	1		
602-045-00-7	DDT (ISO); clofenotane (INN); dicophane; 1,1,1-trichloro-2,2-bis(4-chlorophenyl)ethane; dichlorodiphenyltrichloroethane	1		
602-046-00-2	heptachlor (ISO); 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene	1	1	
602-048-00-3	aldrin (ISO)	1	1	
602-058-00-8	α,α-dichlorotoluene; benzylidene chloride; benzal chloride			1
602-063-00-5	heptachlor epoxide; 2,3-epoxy-1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindane	1		

602-064-00-0	1,3-dichloro-2-propanol	1		
602-076-00-6	2,3,4-trichlorobut-1-ene			1
602-088-00-1	2,3-dibromopropan-1-ol; 2,3-dibromo-1-propanol		1	
603-018-00-2	furfuryl alcohol			1
603-026-00-6	1-chloro-2,3-epoxypropane; epichlorhydrin	1	1	1
603-063-00-8	2,3-epoxypropan-1-ol; glycidol; oxiranemethanol			1
603-066-00-4	1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	1	1	1
603-076-00-9	but-2-yne-1,4-diol; 2-butyne-1,4-diol	1		1
603-078-00-X	prop-2-yn-1-ol; propargyl alcohol	1	1	1
603-166-00-8	R-1-chloro-2,3-epoxypropane	1	1	1
603-185-00-1	2,4-dichloro-3-ethyl-6-nitrophenol	1		
604-001-00-2	phenol; carbolic acid; monohydroxybenzene; phenylalcohol	1	1	1
604-004-00-9	m-cresol; [1] o-cresol; [2] p-cresol; [3] mix-cresol [4]	1	1	
604-006-00-X	3,4-xylenol; [1] 2,5-xylenol; [2] 2,4-xylenol; [3] 2,3-xylenol; [4] 2,6-xylenol; [5] xylenol; [6] 2,4(or 2,5)-xylenol [7]	1	1	
604-011-00-7	2,4-dichlorophenol		1	
604-012-00-2	4-chloro-o-cresol;			1

	4-chloro-2-methyl phenol			
604-013-00-8	2,3,4,6-tetrachlorophenol	1		
604-015-00-9	2,2'-methylenebis-(3,4,6-trichlorophenol); hexachlorophene	1	1	
604-037-00-9	3,5-xylenol; 3,5-dimethylphenol	1	1	
605-001-00-5	formaldehyde … %	1	1	1
605-010-00-4	2-furaldehyde	1		1
605-014-00-6	chloral hydrate; 2,2,2-trichloroethane-1,1-diol	1		
605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	1		1
606-013-00-3	p-benzoquinone; quinone	1		1
606-016-00-X	pindone (ISO); 2-pivaloylindan-1,3-dione	1		
606-019-00-6	chlordecone (ISO); perchloropentacyclo[5,3,0,02,6,03,9,04,8]decan-5-one; decachloropentacyclo[5,2,1,02,6,03,9,05,8]decan-4-one	1	1	
606-107-00-4	8-azaspiro[4.5]decane-7,9-dione	1		
607-003-00-1	chloroacetic acid	1	1	1
607-055-00-5	endothal-sodium (ISO); disodium 7-oxabicyclo(2,2,1)heptane-2,3-dicarboxylate	1		
607-058-00-1	coumafuryl (ISO); fumarin; (RS)-3-(1-(2-furyl)-3-oxobutyl)4-hydroxycoumarin; 4-hydroxy-3-[3-oxo-1-(2-furyl) butyl]coumarin	1		
607-065-00-X	bromoacetic acid	1	1	1
607-068-00-6	iodoacetic acid	1		
607-070-00-7	ethyl chloroacetate	1	1	1
607-072-00-8	2-hydroxyethyl acrylate		1	
607-079-00-6	kelevan (ISO); ethyl 5-(perchloro-5-hydroxypentacyclo[5,3,0,02,6,03,9,04,8]decan-5-yl)-4-oxopentanoate;		1	

	ethyl 5-(1,2,3,5,6,7,8,9,10,10-decachloro-4-hydroxypentacyclo(5,2,1,02,6,03,9,05,8)dec-4-yl)-4-oxovalerate			
607-080-00-1	chloroacetyl chloride	1	1	1
607-090-00-6	thioglycolic acid	1	1	1
607-108-00-2	2-hydroxy-1-methylethylacrylate; [1] 2-hydroxypropylacrylate; [2] acrylic acid, monoester with propane-1,2-diol [3]	1	1	1
607-112-00-4	2,2-dimethyltrimethylene diacrylate; neopentyl glycol diacrylate		1	
607-117-00-1	2,3-epoxypropyl acrylate; glycidyl acrylate	1	1	1
607-120-00-8	2,2'-oxydiethyl diacrylate; diethylene glycol diacrylate		1	
607-138-00-6	butyl chloroformate; chloroformic acid butyl ester			1
607-150-00-1	endothal (ISO); 7-oxabicyclo(2,2,1)heptane-2,3-dicarboxylic acid	1		
607-151-00-7	propargite (ISO); 2-(4-tert-butylphenoxy) cyclohexyl prop-2-ynyl sulphite			1
607-158-00-5	sodium salt of chloroacetic acid; sodium chloroacetate	1		
607-166-00-9	medinoterb acetate (ISO); 6-tert-butyl-3-methyl-2,4-dinitrophenyl acetate	1		
607-168-00-X	dipropyl 6,7-methylenedioxy-1,2,3,4-tetrahydro-3-methylnaphthalene-1,2-dicarboxylate; propylisome		1	
607-181-00-0	3,5-dichloro-2,4-difluorobenzoyl fluoride			1
607-201-00-8	thiocarbonyl chloride			1
607-205-00-X	methyl chloroacetate	1		1
607-206-00-5	isopropyl chloroacetate	1		
607-214-00-9	N,N-hydrazinodiacetic acid	1		
607-246-00-3	allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester			1
607-256-00-8	azoxystrobin (ISO); methyl (E)-2-{}{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}}-3-methoxyacrylate			1
607-319-00-X	deltamethrin (ISO); (S)-α-cyano-3-phenoxybenzyl (1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate	1		1

607-332-00-0	cyclopentyl chloroformate			1
607-368-00-7	1-(N,N-dimethylcarbamoyl)-3-tert-butyl-5-carbethoxymethylthio-1H-1,2,4-triazole	1		1
607-417-00-2	3-chloropropyl chloroformiate			1
607-422-00-X	α-cypermethrin (ISO); racemate comprising (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	1		
607-431-00-9	prallethrin (ISO); ETOC; 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate			1
607-478-00-5	tetramethylammonium hydrogen phthalate	1		
607-504-00-5	diammonium 1-hydroxy-2-(4-(4-carboxyphenylazo)-2,5-dimethoxyphenylazo)-7-amino-3-naphthalenesulfonate	1		
607-534-00-9	ethyl 2-(3-benzoylphenyl)propanoate	1		
607-537-00-5	isopropylammonium 2-(3-benzoylphenyl)propionate	1		
607-565-00-8	3-ethyl 5-methyl 2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate	1		
607-615-00-9	reaction product of thioglycerol and mercaptoacetic acid consisting mainly of 3-mercapto-1,2-bismercaptoacetoxypropane and oligomers of this substance			1
608-002-00-9	trichloroacetonitrile	1	1	1
608-007-00-6	ioxynil (ISO); 4-hydroxy-3,5-diiodobenzonitrile	1		1
608-008-00-1	chloroacetonitrile	1	1	1
608-009-00-7	malononitrile	1	1	1
608-017-00-0	bromoxynil octanoate (ISO); 2,6-dibromo-4-cyanophenyl octanoate			1
608-018-00-6	ioxynil octanoate (ISO); 4-cyano-2,6-diiodophenyl octanoate	1		
608-034-00-3	chlorfenapyr (ISO); 4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile			1
608-043-00-2	3-(cis-3-hexenyloxy)propanenitril			1
608-055-00-8	fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile	1	1	1
608-058-00-4	esfenvalerate (ISO); (S)-α-cyano-3-phenoxybenzyl-(S)-2-(4-chlorophenyl)-3-methylbutyrate	1		1

608-063-00-1	(S)-α-hydroxy-3-phenoxy-benzeneacetonitrile	1		
608-066-00-8	salts of ioxynil with the exception of those specified elsewhere in this Annex	1		1
609-003-00-7	nitrobenzene	1	1	1
609-006-00-3	4-nitrotoluene	1	1	1
609-007-00-9	2,4-dinitrotoluene; [1] dinitrotoluene [2]	1	1	1
609-016-00-8	dinitrophenol (reaction mass of isomers); [1] 2,4(or 2,6)-dinitrophenol [2]	1	1	1
609-021-00-5	sodium salt of DNOC; sodium 4,6-dinitro-o-cresolate; [1] potassium salt of DNOC; potassium 4,6-dinitro-o-cresolate [2]	1	1	1
609-025-00-7	dinoseb (ISO); 6-sec-butyl-2,4-dinitrophenol	1	1	
609-026-00-2	salts and esters of dinoseb, with the exception of those specified elsewhere in this Annex	1	1	
609-028-00-3	dinex (ISO); 2-cyclohexyl-4,6-dinitrophenol	1	1	1
609-029-00-9	salts and esters of dinex	1	1	1
609-033-00-0	dinosam (ISO); 2-(1-methylbutyl)-4,6-dinitrophenol	1	1	1
609-034-00-6	salts and esters of dinosam	1	1	1
609-041-00-4	2,4-dinitrophenol	1	1	1
609-049-00-8	2,6-dinitrotoluene	1	1	1
609-050-00-3	2,3-dinitrotoluene	1	1	1
609-051-00-9	3,4-dinitrotoluene	1	1	1
609-052-00-4	3,5-dinitrotoluene	1	1	1
609-054-00-5	2,3-dinitrophenol; [1] 2,5-dinitrophenol; [2] 2,6-dinitrophenol; [3] 3,4-dinitrophenol; [4] salts of dinitrophenol [5]	1	1	1
609-055-00-0	2,5-dinitrotoluene	1	1	1
609-062-00-9	2-bromo-2-nitropropanol		1	

610-002-00-9	1,1-dichloro-1-nitroethane	1	1	1
610-003-00-4	chlorodinitrobenzene	1	1	1
610-005-00-5	1-chloro-4-nitrobenzene	1	1	1
610-008-00-1	2,6-dichloro-4-nitroanisole	1		
611-003-00-7	fenaminosulf (ISO); sodium 4-dimethylaminobenzenediazosulphonate	1		
611-020-00-X	tetrakis(tetramethylammonium) 6-amino-4-hydroxy-3-(7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo)naphthalene-2,7-disulfonate	1		
611-046-00-1	4,4'-diamino-2-methylazobenzene	1		
611-071-00-8	tris(tetramethylammonium) 5-hydroxy-1-(4-sulphonatophenyl)-4-(4-sulphonatophenylazo)pyrazole-3-carboxylate	1		
611-098-00-5	tetrakis(tetramethylammonium)3,3'-(6-(2-hydroxyethylamino)1,3,5-triazine-2,4-diylbisimino(2-methyl-4,1-phenyleneazo))bisnaphthalene-1,5-disulfonate	1		
612-008-00-7	aniline	1	1	1
612-009-00-2	salts of aniline	1	1	1
612-010-00-8	chloroanilines, with exception of those specified elsewhere in this Annex	1	1	1
612-012-00-9	o-nitroaniline; [1] m-nitroaniline; [2] p-nitroaniline [3]	1	1	1
612-015-00-5	N-methylaniline	1	1	1
612-016-00-0	N,N-dimethylaniline	1	1	1
612-023-00-9	phenylhydrazine; [1] phenylhydrazinium chloride; [2] phenylhydrazine hydrochloride; [3] phenylhydrazinium sulphate (2:1) [4]	1	1	1
612-024-00-4	m-toluidine; 3-aminotoluene	1	1	1
612-025-00-X	nitrotoluidines, with the exception of those specified elsewhere in this Annex	1	1	1
612-026-00-5	diphenylamine	1	1	1
612-027-00-0	xylidines with the exception of those specified elsewhere in this Annex; dimethyl anilines with the exception of those specified elsewhere in this Annex	1	1	1
612-028-00-6	p-phenylenediamine	1	1	1
612-029-00-1	benzene-1,4-diamine dihydrochloride;	1	1	1

	p-phenylenediamine dihydrochloride			
612-030-00-7	2-methyl-p-phenylenediamine sulphate [1]	1		
612-031-00-2	N,N-dimethylbenzene-1,3-diamine; [1] 4-amino-N,N-dimethylaniline; 3-amino-N,N'-dimethylaniline [2]	1	1	1
612-035-00-4	2-methoxyaniline; o-anisidine	1	1	1
612-039-00-6	2-ethoxyaniline; o-phenetidine	1	1	1
612-053-00-2	N-ethylaniline	1	1	1
612-054-00-8	N,N-diethylaniline	1	1	1
612-055-00-3	N-methyl-o-toluidine; [1] N-methyl-m-toluidine; [2] N-methyl-p-toluidine [3]	1	1	1
612-056-00-9	N,N-dimethyl-p-toluidine; [1] N,N-dimethyl-m-toluidine; [2] N,N-dimethyl-o-toluidine [3]	1	1	1
612-080-00-X	4-amino-N,N-diethylaniline; N,N-diethyl-p-phenylendiamine	1		
612-091-00-X	o-toluidine; 2-aminotoluene	1		1
612-099-00-3	4-methyl-m-phenylenediamine; 2,4-toluenediamine	1		
612-102-00-8	N,N-bis(3-aminopropyl)methylamine		1	1
612-109-00-6	bis(2-dimethylaminoethyl)(methyl)amine		1	
612-110-00-1	2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine)		1	1
612-116-00-4	C8-18alkylbis(2-hydroxyethyl)ammonium bis(2-ethylhexyl)phosphate			1
612-124-00-8	N,N,N-trimethylanilinium chloride	1	1	
612-125-00-3	2-methyl-p-phenylenediamine; 2,5-toluenediamine	1		
612-126-00-9	toluene-2,4-diammonium sulphate; 4-methyl-m-phenylenediamine sulfate	1		
612-133-00-7	(4-ammonio-m-tolyl)ethyl(2-hydroxyethyl)ammonium sulphate; 4-(N-ethyl-N-2-hydroxyethyl)-2-methylphenylenediamine sulphate	1		

612-137-00-9	4-chloroaniline	1	1	1
612-143-00-1	N5,N5-diethyltoluene-2,5-diamine monohydrochloride; 4-diethylamino-2-methylaniline monohydrochloride	1		
612-145-00-2	o-phenylenediamine	1		
612-146-00-8	o-phenylenediamine dihydrochloride	1		
612-147-00-3	m-phenylenediamine	1	1	1
612-148-00-9	m-phenylenediamine dihydrochloride	1	1	1
612-151-00-5	methyl-phenylene diamine; diaminotoluene; [technical product – reaction mass of 4-methyl-m-phenylene diamine (EC No 202-453-1) and 2-methyl-m-phenylene diamine (EC No 212-513-9)]	1		
612-160-00-4	p-toluidine; 4-aminotoluene; [1] toluidinium chloride; [2] toluidine sulphate (1:1) [3]	1	1	1
612-196-00-0	4-chloro-o-toluidine; [1] 4-chloro-o-toluidine hydrochloride [2]	1	1	1
612-197-00-6	2,4,5-trimethylaniline; [1] 2,4,5-trimethylaniline hydrochloride [2]	1	1	1
612-199-00-7	4,4'-oxydianiline and its salts; p-aminophenyl ether	1	1	1
612-202-00-1	3,4-dichloroaniline	1	1	1
612-210-00-5	5-nitro-o-toluidine; [1] 5-nitro-o-toluidine hydrochloride [2]	1	1	1
613-037-00-8	4-methylpyridine; 4-picoline		1	
613-044-00-6	captan (ISO); 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide			1
613-047-00-2	1-dimethylcarbamoyl-5-methylpyrazol-3-yl dimethylcarbamate; dimetilan (ISO)	1		
613-074-00-X	3-(3-methylpent-3-yl)isoxazol-5-ylamine	1		1
613-092-00-8	1,10-phenanthroline	1		
613-105-00-7	hexakis(tetramethylammonium) 4,4'-vinylenebis((3-sulfonato-4,1-phenylene)imino(6-morpholino-1,3,5-triazine-4,2-diyl)imino)bis(5-hydroxy-6-phenylazonaphthalene-2,7-disulfonate)	1		

613-112-00-5	octhilinone (ISO); 2-octyl-2H-isothiazol-3-one		1	1
613-133-00-X	etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole			1
613-149-00-7	pyridaben (ISO); 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one	1		1
613-159-00-1	fenazaquin (ISO); 4-[2-[4-(1,1-dimethylethyl)phenyl]-ethoxy]quinazoline	1		
613-167-00-5	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	1	1	1
613-173-00-8	fluquinconazole (ISO); 3-(2,4-dichlorophenyl)-6-fluoro-2-(1H-1,2,4-triazol-1-yl)quinazolin-4-(3H)-one	1		1
613-185-00-3	2,3,5,6-tetrahydro-2-methyl-2H-cyclopenta[d]-1,2-thiazol-3-one	1		
613-209-00-2	cis-1-(3-chloropropyl)-2,6-dimethyl-piperidin hydrochloride	1		
613-232-00-8	3-(benzo[b]thien-2-yl)-5,6-dihydro-1,4,2-oxathiazine-4-oxide			1
613-236-00-X	2-chloro-3-trifluoromethylpyridine	1	1	
613-266-00-3	2-chloro-5-chloromethylthiazole		1	
613-272-00-6	pyraclostrobin (ISO); methyl N-{2-[1-(4-chlorophenyl)-1H-pyrazol-3-yloxymethyl]phenyl}(N-methoxy)carbamate			1
613-275-00-2	3-(2-chloroethyl)-6,7,8,9-tetra-hydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one monohydrochloride	1		
613-283-00-6	ketoconazole; 1-[4-[4-[[(2SR,4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone	1		
614-022-00-9	digitoxin	1		1
614-025-00-5	ouabain	1		1
614-026-00-0	strophantin-K	1		1
615-002-00-2	methyl isothiocyanate	1		1
615-008-00-5	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate			1
615-009-00-0	4,4'-methylenedi(cyclohexyl isocyanate); dicyclohexylmethane-4,4'-di-isocyanate			1
615-010-00-6	2,2,4-trimethylhexamethylene-1,6-di-isocyanate; [1]			1

	2,4,4-trimethylhexamethylene-1,6-di-isocyanate [2]			
615-011-00-1	hexamethylene-di-isocyanate			1
615-013-00-2	cyanamide; carbanonitril	1		
615-018-00-X	2-(2-butoxyethoxy)ethyl thiocyanate	1	1	
615-019-00-5	dicyclohexylcarbodiimide		1	
615-021-00-6	1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione; TGIC	1		1
615-024-00-2	2-phenylethylisocyanate			1
616-003-00-0	acrylamide; prop-2-enamide	1		
616-013-00-5	butyraldehyde oxime		1	
616-033-00-4	cyprofuram (ISO); N-(3-chlorophenyl)-N-(tetrahydro-2-oxo-3-furyl)cyclopropanecarboxamide	1		
616-036-00-0	2-chloracetamide	1		
616-063-00-8	3-dodecyl-(1-(1,2,2,6,6-pentamethyl-4-piperidin)-yl)-2,5-pyrrolidindione			1
616-090-00-5	1-(1,4-benzodioxan-2-ylcarbonyl)piperazine hydrochloride	1	1	1
616-091-00-0	1,3,5-tris-[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione			1
616-124-00-9	lithium bis(trifluoromethylsulfonyl)imide	1	1	
650-005-00-2	(2R,6aS,12aS)-1,2,6,6a,12,12a-hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one; rotenone	1		
650-006-00-8	benquinox (ISO); p-benzoquinone 1-benzoylhydrazone 4-oxime	1		
650-008-00-9	drazoxolon (ISO); 4-(2-chlorophenylhydrazone)-3-methyl-5-isoxazolone	1		

Chemical name	CAS Number	H301	H311	H331
Beryllium	004-001-00-7	X		
Beryllium compounds with the exception of aluminium beryllium silicates, and with those specified elsewhere in this Annex	004-002-00-2	X		
Beryllium oxide	004-003-00-8	X		
5,5-Dimethyl-3-oxocyclohex-1-enyl dimethylcarbamate; 5,5-dimethyldihydroresorcinol dimethylcarbamate; Dimetan	006-010-00-1	X		
Propoxur (ISO); 2-isopropyloxyphenyl N-methylcarbamate; 2-isopropoxyphenyl methylcarbamate	006-016-00-4	X		
Aminocarb (ISO); 4-dimethylamino-3-tolyl methylcarbamate	006-018-00-5	X	X	
Decarbofuran (ISO); 2,3-dihydro-2-methylbenzofuran-7-yl methylcarbamate	006-022-00-7			X
Mercaptodimethur (ISO); methiocarb (ISO); 3,5-dimethyl-4-methylthiophenyl N-methylcarbamate	006-023-00-2	X		
Dinobuton (ISO); 2-(1-methylpropyl)-4,6-dinitrophenyl isopropyl carbonate	006-028-00-X	X		
Dioxacarb (ISO); 2-(1,3-dioxolan-2-yl)phenyl N-methylcarbamate	006-029-00-5	X		
Pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	006-035-00-8	X		
Promecarb (ISO); 3-isopropyl-5-methylphenyl N-methylcarbamate	006-037-00-9	X		
3-Methylpyrazol-5-yl-dimethylcarbamate; monometilan	006-040-00-5			X
Dimethylcarbamoyl chloride	006-041-00-0			X
Bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	006-046-00-8			X
Bufencarb (ISO); reaction mass of 3-(1-methylbutyl)phenyl N-methylcarbamate and 3-(1-ethylpropyl)phenyl N-methylcarbamate	006-047-00-3	X	X	
Butocarboxim (ISO); 3-(methylthio)-2-butanone O-[(methylamino)carbonyl]oxime	006-083-00-X			X
Carbosulfan (ISO); 2,3-dihydro-2,2-dimethyl-7-benzofuryl [(dibutylamino)thio]methylcarbamate	006-084-00-5	X		
Furathiocarb (ISO); 2,3-dihydro-2,2-dimethyl-7-benzofuryl 2,4-dimethyl-6-oxa-5-oxo-3-thia-2,4-diazadecanoate	006-087-00-1	X		
Benfuracarb (ISO); ethyl N-[2,3-dihydro-2,2-dimethylbenzofuran-7-yloxycarbonyl(methyl)aminothio]-N-isopropyl-β-alaninate	006-088-00-7			X
Hydrazine	007-008-00-3			X
Sodium nitrite	007-010-00-4	X		
Potassium nitrite	007-011-00-X	X		
1,2-Dimethylhydrazine	007-013-00-0			X
Salts of hydrazine	007-014-00-6			X
(4-Hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride	007-025-00-6	X		
Sodium fluoride	009-004-00-7	X		
Potassium fluoride	009-005-00-2			X
Ammonium fluoride	009-006-00-8			X

Chemical name	CAS Number	H301	H311	H331
Sodium bifluoride; sodium hydrogen difluoride	009-007-00-3	X		
Potassium bifluoride; potassium hydrogen difluoride	009-008-00-9	X		
Ammonium bifluoride; ammonium hydrogen difluoride	009-009-00-4	X		
Alkali fluorosilicates(Na); [1] alkali fluorosilicates(K); [2] alkali fluorosilicates(NH4) [3]	009-012-00-0			X
Sulphuryl difluoride	009-015-00-7			X
Magnesium hexafluorosilicate	009-018-00-3	X		
Dichlorvos (ISO); 2,2-dichlorovinyl dimethyl phosphate	015-019-00-X	X		
Demeton-O-methyl (ISO); O-2-ethylthioethyl O,O-dimethyl phosphorothioate	015-030-00-X	X		
Demeton-S-methyl (ISO); S-2-ethylthioethyl dimethyl phosphorothioate	015-031-00-5	X	X	
Phenkapton (ISO); S-(2,5-dichlorophenylthiomethyl) O,O-diethyl phosphorodithioate	015-037-00-8			X
Carbophenothion (ISO); 4-chlorophenylthiomethyl O,O-diethyl phosphorodithioate	015-044-00-6	X	X	
Mecarbam (ISO); N-ethoxycarbonyl-N-methylcarbamoylmethyl O,O-diethyl phosphorodithioate	015-045-00-1	X	X	
Oxydemeton-methyl; S-2-(ethylsulphinyl)ethyl O,O-dimethyl phosphorothioate	015-046-00-7	X	X	
Ethion (ISO); O,O,O',O'-tetraethyl S,S'-methylenedi (phosphorodithioate); diethion	015-047-00-2	X		
Fenthion (ISO); O,O-dimethyl-O-(4-methylthion-m-tolyl) phosphorothioate	015-048-00-8			X
Endothion (ISO); S-5-methoxy-4-oxopyran-2-ylmethyl dimethyl phosphorothioate	015-049-00-3	X	X	
Thiometon (ISO); S-2-ethylthioethyl O,O-dimethyl phosphorodithioate	015-050-00-9	X		
Morphothion (ISO); O,O-dimethyl-S-(morpholinocarbonylmethyl) phosphorodithioate	015-058-00-2			X
Vamidothion (ISO); O,O-dimethyl S-2-(1-methylcarbamoylethylthio) ethyl phosphorothioate	015-059-00-8	X		
Bromophos-ethyl (ISO); O-4-bromo-2,5-dichlorophenyl O,O-diethyl phosphorothioate	015-064-00-5	X		
Omethoate (ISO); O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate	015-066-00-6	X		
Phosalone (ISO); S-(6-chloro-2-oxobenzoxazolin-3-ylmethyl) O,O-diethyl phosphorodithioate	015-067-00-1	X		
S-[2-(isopropylsulphinyl)ethyl] O,O-dimethyl phosphorothioate	015-075-00-5			X
2,2-Dichlorovinyl 2-ethylsulphinylethyl methyl phosphate	015-077-00-6			X
Demeton-S-methylsulphon (ISO); S-2-ethylsulphonylethyl dimethyl phosphorothioate	015-078-00-1	X		
Chlorpyrifos (ISO); O,O-diethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate	015-084-00-4	X		
Chlorphonium chloride (ISO); tributyl (2,4-dichlorobenzyl) phosphonium chloride	015-085-00-X	X		
Coumithoate (ISO); O,O-diethyl O-,8,9,10-tetrahydro-6-oxo-benzo(c)chromen-3-yl phosphorothioate	015-086-00-5	X		
Pirimiphos-ethyl (ISO); O,O-diethyl O-2-diethylamino-6-methylpyrimidin-4-yl phosphorothioate	015-099-00-6	X		
Ethoprophos (ISO); ethyl-S,S-dipropyl phosphorodithioate	015-107-00-8	X		
Crotoxyphos (ISO); 1-phenylethyl 3-(dimethoxyphosphinyloxy) isocrotonate	015-109-00-9	X	X	
Edifenphos (ISO); O-ethyl S,S-diphenyl phosphorodithioate	015-121-00-4			X
Heptenophos (ISO); 7-chlorobicyclo(3.2.0)hepta-2,6-dien-6-yl dimethyl phosphate	015-126-00-1	X		
IPSP; S-ethylsulphinylmethyl O,O-diisopropylphosphorodithioate	015-128-00-2	X		

Chemical name	CAS Number	H301	H311	H331
Isofenphos (ISO); O-ethyl O-2-isopropoxycarbonylphenyl-isopropylphosphoramidothioate	015-129-00-8	X	X	
Isothioate (ISO); S-2-isopropylthioethyl O,O-dimethyl phosphorodithioate	015-130-00-3	X	X	
Isoxathion (ISO); O,O-diethyl O-5-phenylisoxazol-3-ylphosphorothioate	015-131-00-9	X	X	
S-(chlorophenylthiomethyl) O,O-dimethylphosphorodithioate; methylcarbophenothione	015-132-00-4	X	X	
Trans-isopropyl-3-[[(ethylamino)methoxyfosfinothioyl]oxy]crotonate; isopropyl 3-[[(ethylamino)methoxyphosphinothioyl]oxy]isocrotonate; propetamphos (ISO)	015-136-00-6	X		
Quinalphos (ISO); O,O-diethyl-O-quinoxalin-2-yl phosphorothioate	015-138-00-7	X		
Triazophos (ISO); O,O-diethyl-O-1-phenyl-1H-1,2,4-triazol-3-yl phosphorothioate	015-140-00-8			X
Isazofos (ISO); O-(5-chloro-1-isopropyl-1,2,4-triazol-3-yl) O,O-diethyl phosphorothioate	015-153-00-9	X		
Fosthiazate (ISO); (RS)-S-sec-butyl-O-ethyl-2-oxo-1,3-thiazolidin-3-ylphosphonothioate	015-168-00-0			X
1-Chloro-N,N-diethyl-1,1-diphenyl-1-(phenylmethyl)phosphoramine	015-174-00-3	X		
Tert-butyl (triphenylphosphoranylidene) acetate	015-175-00-9	X		
Triphenyl(phenylmethyl)phosphonium 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1)	015-193-00-7	X		
Bis(2,4,4-trimethylpentyl)dithiophosphonic acid	015-197-00-9			X
Disodium sulfide; sodium sulfide	016-009-00-8		X	
Sodium polysulphides	016-010-00-3	X		
Sulphur dioxide	016-011-00-9			X
Disulphur dichloride; sulfur monochloride	016-012-00-4	X		
Dimethyl sulphate	016-023-00-4	X		
Sodium 4-(2,4,4-trimethylpentylcarbonyloxy)benzenesulfonate	016-054-00-3			X
Chlorine	017-001-00-7			X
Hydrogen chloride	017-002-00-2			X
Chlorine dioxide ... %	017-026-01-0	X		
Chromium (VI) trioxide	024-001-00-0	X		
Potassium dichromate	024-002-00-6	X		
Ammonium dichromate	024-003-00-1	X		
Sodium dichromate	024-004-00-7	X		
Sodium chromate	024-018-00-3	X		
Nickel dichloride	028-011-00-6			X
Arsenic	033-001-00-X			X
Arsenic compounds, with the exception of those specified elsewhere in this Annex	033-002-00-5			X
Diarsenic pentaoxide; arsenic pentoxide; arsenic oxide	033-004-00-6			X
Arsenic acid and its salts with the exception of those specified elsewhere in this Annex	033-005-00-1			X
Selenium	034-001-00-2			X

Chemical name	**CAS Number**	**H301**	**H311**	**H331**
Selenium compounds with the exception of cadmium sulphoselenide and those specified elsewhere in this Annex	034-002-00-8			X
Potassium bromate	035-003-00-6	X		
Tetrakis(dimethylditetradecylammonium) hexa-μ-oxotetra-μ3-oxodi-μ5-oxotetradecaoxooctamolybdate(4-)	042-002-00-4			X
Cadmium diformate; cadmiumformate	048-003-00-6			X
Cadmiumhexafluorosilicate(2-); cadmium fluorosilica	048-005-00-7			X
Cadmium fluoride	048-006-00-2	X		
Cadmium iodide	048-007-00-8			X
Cadmium chloride	048-008-00-3	X		
Cadmium sulphate	048-009-00-9	X		
Fentin acetate (ISO); triphenyltin acetate	050-003-00-6	X		
Fentin hydroxide (ISO); triphenyltin hydroxide	050-004-00-1	X		
Tripropyltin compounds, with the exception of those specified elsewhere in this Annex	050-007-00-8			X
Tributyltin compounds, with the exception of those specified elsewhere in this Annex	050-008-00-3	X		
Triphenyltin compounds, with the exception of those specified elsewhere in this Annex	050-011-00-X			X
Azocyclotin (ISO); 1-(tricyclohexylstannyl)-1H-1,2,4-triazole	050-019-00-3	X		
Dichlorodioctyl stannane	050-021-00-4			X
Dibutyltin dichloride; (DBTC)	050-022-00-X	X		
Antimony trifluoride	051-004-00-4			X
Barium chloride	056-004-00-8	X		
Tetrachloroplatinates with the exception of those specified elsewhere in this Annex	078-001-00-0	X		
Diammonium tetrachloroplatinate	078-002-00-6	X		
Disodium tetrachloroplatinate	078-003-00-1	X		
Dipotassium tetrachloroplatinate	078-004-00-7	X		
Hexachloroplatinates with the exception of those specified elsewhere in this Annex	078-005-00-2	X		
Disodium hexachloroplatinate	078-006-00-8	X		
Dipotassium hexachloroplatinate	078-007-00-3	X		
Diammonium hexachloroplatinate	078-008-00-9	X		
Hexachloroplatinic acid	078-009-00-4	X		
Phenylmercury nitrate; [1] phenylmercury hydroxide; [2] basic phenylmercury nitrate [3]	080-008-00-9	X		
2-Methoxyethylmercury chloride	080-009-00-4	X		
Phenylmercury acetate	080-011-00-5	X		
Lead hydrogen arsenate	082-011-00-0			X
Triethyl arsenate	601-067-00-4			X
Bromomethane; methylbromide	602-002-00-2			X

Chemical name	CAS Number	H301	H311	H331
Methyl iodide; iodomethane	602-005-00-9			X
Bromoform; tribromomethane	602-007-00-X			X
Carbon tetrachloride; tetrachloromethane	602-008-00-5			X
1,2-Dibromoethane	602-010-00-6			X
1,2-Dibromo-3-chloropropane	602-021-00-6	X		
1,3-Dichloropropene; [1] (Z)-1,3-dichloropropene [2]	602-030-00-5	X	X	
A-chlorotoluene; benzyl chloride	602-037-00-3			X
A,α,α-trichlorotoluene; benzotrichloride	602-038-00-9			X
1,2,3,4,5,6-hexachlorcyclohexanes with the exception of those specified elsewhere in this Annex	602-042-00-0	X		
Lindane (ISO); γ-HCH or γ-BHC; γ-1,2,3,4,5,6-hexachlorocyclohexane	602-043-00-6	X		
Camphechlor (ISO); toxaphene	602-044-00-1	X		
DDT (ISO); clofenotane (INN); dicophane; 1,1,1-trichloro-2,2-bis(4-chlorophenyl)ethane; dichlorodiphenyltrichloroethane	602-045-00-7	X		
Heptachlor (ISO); 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene	602-046-00-2	X	X	
Aldrin (ISO)	602-048-00-3	X	X	
Dieldrin (ISO)	602-049-00-9	X		
A,α-dichlorotoluene; benzylidene chloride; benzal chloride	602-058-00-8			X
Heptachlor epoxide; 2,3-epoxy-1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindane	602-063-00-5	X		
1,3-Dichloro-2-propanol	602-064-00-0	X		
1,4-Dichlorobut-2-ene	602-073-00-X	X		
2,3,4-Trichlorobut-1-ene	602-076-00-6			X
2,3-Dibromopropan-1-ol; 2,3-dibromo-1-propanol	602-088-00-1		X	
Furfuryl alcohol	603-018-00-2			X
1-Chloro-2,3-epoxypropane; epichlorhydrin	603-026-00-6			X
2,2'-Bioxirane; 1,2:3,4-diepoxybutane	603-060-00-1	X		
2,3-Epoxypropan-1-ol; glycidol; oxiranemethanol	603-063-00-8			X
1,2-Epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	603-066-00-4			X
But-2-yne-1,4-diol; 2-butyne-1,4-diol	603-076-00-9			X
Prop-2-yn-1-ol; propargyl alcohol	603-078-00-X			X
R-1-chloro-2,3-epoxypropane	603-166-00-8			X
Ergocalciferol (ISO); Vitamin D2	603-179-00-9	X		
Colecalciferol; Vitamin D3	603-180-00-4	X		
2,4-Dichloro-3-ethyl-6-nitrophenol	603-185-00-1	X		
Phenol; carbolic acid; monohydroxybenzene; phenylalcohol	604-001-00-2			X

Chemical name	CAS Number	H301	H311	H331
Pentachlorophenol	604-002-00-8	X		
Sodium pentachlorophenolate; [1] potassium pentachlorophenolate [2]	604-003-00-3	X		
M-cresol; [1] o-cresol; [2] p-cresol; [3] mix-cresol [4]	604-004-00-9	X	X	
3,4-xylenol; [1] 2,5-xylenol; [2] 2,4-xylenol; [3] 2,3-xylenol; [4] 2,6-xylenol; [5] xylenol; [6] 2,4(or 2,5)-xylenol [7]	604-006-00-X	X	X	
2,4-Dichlorophenol	604-011-00-7		X	
4-Chloro-o-cresol; 4-chloro-2-methyl phenol	604-012-00-2			X
2,3,4,6-Tetrachlorophenol	604-013-00-8	X		
2,2'-Methylenebis-(3,4,6-trichlorophenol); hexachlorophene	604-015-00-9	X	X	
3,5-Xylenol; 3,5-dimethylphenol	604-037-00-9	X	X	
Formaldehyde … %	605-001-00-5			X
2-Furaldehyde	605-010-00-4			X
Chloral hydrate; 2,2,2-trichloroethane-1,1-diol	605-014-00-6	X		
Glutaral; glutaraldehyde; 1,5-pentanedial	605-022-00-X			X
Chloroacetaldehyde	605-025-00-6	X		
p-Benzoquinone; quinone	606-013-00-3			X
Pindone (ISO); 2-pivaloylindan-1,3-dione	606-016-00-X	X		
Chlordecone (ISO); perchloropentacyclo[5,3,0,02,6,03,9,04,8]decan-5-one; decachloropentacyclo[5,2,1,02,6,03,9,05,8]decan-4-one	606-019-00-6	X	X	
8-Azaspiro[4.5]decane-7,9-dione	606-107-00-4	X		
Chloroacetic acid	607-003-00-1			X
Endothal-sodium (ISO); disodium 7-oxabicyclo(2,2,1)heptane-2,3-dicarboxylate	607-055-00-5	X		
Coumafuryl (ISO); fumarin; (RS)-3-(1-(2-furyl)-3-oxobutyl)4-hydroxycoumarin; 4-hydroxy-3-[3-oxo-1-(2-furyl) butyl]coumarin	607-058-00-1	X		
Bromoacetic acid	607-065-00-X			X
Iodoacetic acid	607-068-00-6	X		
Ethyl chloroacetate	607-070-00-7			X
2-Hydroxyethyl acrylate	607-072-00-8		X	
Kelevan (ISO); ethyl 5-(perchloro-5-hydroxypentacyclo[5,3,0,02,6,03,9,04,8]decan-5-yl)-4-oxopentanoate; ethyl 5-(1,2,3,5,6,7,8,9,10,10-decachloro-4-hydroxypentacyclo(5,2,1,02,6,03,9,05,8)dec-4-yl)-4-oxovalerate	607-079-00-6		X	
Chloroacetyl chloride	607-080-00-1			X
Thioglycolic acid	607-090-00-6			X
2-Hydroxy-1-methylethylacrylate; [1] 2-hydroxypropylacrylate; [2] acrylic acid, monoester with propane-1,2-diol [3]	607-108-00-2			X
2,2-Dimethyltrimethylene diacrylate; neopentyl glycol diacrylate	607-112-00-4		X	

Chemical name	CAS Number	H301	H311	H331
2,3-Epoxypropyl acrylate; glycidyl acrylate	607-117-00-1			X
2,2'-Oxydiethyl diacrylate; diethylene glycol diacrylate	607-120-00-8		X	
Butyl chloroformate; chloroformic acid butyl ester	607-138-00-6			X
Endothal (ISO); 7-oxabicyclo(2,2,1)heptane-2,3-dicarboxylic acid	607-150-00-1	X		
Propargite (ISO); 2-(4-tert-butylphenoxy) cyclohexyl prop-2-ynyl sulphite	607-151-00-7			X
Sodium salt of chloroacetic acid; sodium chloroacetate	607-158-00-5	X		
Medinoterb acetate (ISO); 6-tert-butyl-3-methyl-2,4-dinitrophenyl acetate	607-166-00-9	X		
Dipropyl 6,7-methylenedioxy-1,2,3,4-tetrahydro-3-methylnaphthalene-1,2-dicarboxylate; propylisome	607-168-00-X		X	
3,5-Dichloro-2,4-difluorobenzoyl fluoride	607-181-00-0			X
Thiocarbonyl chloride	607-201-00-8			X
Methyl chloroacetate	607-205-00-X			X
Isopropyl chloroacetate	607-206-00-5	X		
N,N-hydrazinodiacetic acid	607-214-00-9	X		
Fenpropathrin (ISO); α-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate	607-239-00-5	X		
Allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester	607-246-00-3			X
Lambda-cyhalothrin (ISO); reaction mass of (S)-α-cyano-3-phenoxybenzyl(Z)-(1R)-cis-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S)-cis-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate (1:1)	607-252-00-6	X		
Azoxystrobin (ISO); methyl (E)-2-{}{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}}-3-methoxyacrylate	607-256-00-8			X
Deltamethrin (ISO); (S)-α-cyano-3-phenoxybenzyl (1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate	607-319-00-X			X
Cyclopentyl chloroformate	607-332-00-0			X
1-(N,N-Dimethylcarbamoyl)-3-tert-butyl-5-carbethoxymethylthio-1H-1,2,4-triazole	607-368-00-7			X
3-Chloropropyl chloroformiate	607-417-00-2			X
A-Cypermethrin (ISO); racemate comprising (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	607-422-00-X	X		
Prallethrin (ISO); ETOC; 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	607-431-00-9			X
Tetramethylammonium hydrogen phthalate	607-478-00-5	X		
Diammonium 1-hydroxy-2-(4-(4-carboxyphenylazo)-2,5-dimethoxyphenylazo)-7-amino-3-naphthalenesulfonate	607-504-00-5	X		
Ethyl 2-(3-benzoylphenyl)propanoate	607-534-00-9	X		
Isopropylammonium 2-(3-benzoylphenyl)propionate	607-537-00-5	X		
3-Ethyl 5-methyl 2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate	607-565-00-8	X		
Reaction product of thioglycerol and mercaptoacetic acid consisting mainly of 3-mercapto-1,2-	607-615-00-9			X

Chemical name	CAS Number	H301	H311	H331
bismercaptoacetoxypropane and oligomers of this substance				
Trichloroacetonitrile	608-002-00-9			X
Bromoxynil (ISO); 3,5-dibromo-4-hydroxybenzonitrile; bromoxynil phenol	608-006-00-0	X		
Ioxynil (ISO); 4-hydroxy-3,5-diiodobenzonitrile	608-007-00-6			X
Chloroacetonitrile	608-008-00-1			X
Malononitrile	608-009-00-7			X
Bromoxynil octanoate (ISO); 2,6-dibromo-4-cyanophenyl octanoate	608-017-00-0			X
Ioxynil octanoate (ISO); 4-cyano-2,6-diiodophenyl octanoate	608-018-00-6	X		
Chlorfenapyr (ISO); 4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile	608-034-00-3			X
3-(cis-3-Hexenyloxy)propanenitril	608-043-00-2			X
Fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile	608-055-00-8			X
Esfenvalerate (ISO); (S)-α-cyano-3-phenoxybenzyl-(S)-2-(4-chlorophenyl)-3-methylbutyrate	608-058-00-4			X
(S)-α-Hydroxy-3-phenoxy-benzeneacetonitrile	608-063-00-1	X		
Salts of bromoxynil with the exception of those specified elsewhere in this Annex	608-065-00-2	X		
Salts of ioxynil with the exception of those specified elsewhere in this Annex	608-066-00-8			X
Nitrobenzene	609-003-00-7			X
4-Nitrotoluene	609-006-00-3			X
2,4-Dinitrotoluene; [1] dinitrotoluene [2]	609-007-00-9			X
Dinitrophenol (reaction mass of isomers); [1] 2,4(or 2,6)-dinitrophenol [2]	609-016-00-8			X
Sodium salt of DNOC; sodium 4,6-dinitro-o-cresolate; [1] potassium salt of DNOC; potassium 4,6-dinitro-o-cresolate [2]	609-021-00-5			X
Dinoseb (ISO); 6-sec-butyl-2,4-dinitrophenol	609-025-00-7	X	X	
Salts and esters of dinoseb, with the exception of those specified elsewhere in this Annex	609-026-00-2	X	X	
Dinex (ISO); 2-cyclohexyl-4,6-dinitrophenol	609-028-00-3			X
Salts and esters of dinex	609-029-00-9			X
Dinosam (ISO); 2-(1-methylbutyl)-4,6-dinitrophenol	609-033-00-0			X
Salts and esters of dinosam	609-034-00-6			X
2,4-Dinitrophenol	609-041-00-4			X
2,6-Dinitrotoluene	609-049-00-8			X
2,3-Dinitrotoluene	609-050-00-3			X
3,4-Dinitrotoluene	609-051-00-9			X
3,5-Dinitrotoluene	609-052-00-4			X
2,3-Dinitrophenol; [1] 2,5-dinitrophenol; [2] 2,6-dinitrophenol; [3] 3,4-dinitrophenol; [4] salts of dinitrophenol [5]	609-054-00-5			X

Chemical name	CAS Number	H301	H311	H331
2,5-Dinitrotoluene	609-055-00-0			X
2-Bromo-2-nitropropanol	609-062-00-9		X	
1,1-Dichloro-1-nitroethane	610-002-00-9			X
Chlorodinitrobenzene	610-003-00-4			X
1-Chloro-4-nitrobenzene	610-005-00-5			X
2,6-Dichloro-4-nitroanisole	610-008-00-1	X		
Fenaminosulf (ISO); sodium 4-dimethylaminobenzenediazosulphonate	611-003-00-7	X		
Tetrakis(tetramethylammonium) 6-amino-4-hydroxy-3-(7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo)naphthalene-2,7-disulfonate	611-020-00-X	X		
4,4'-Diamino-2-methylazobenzene	611-046-00-1	X		
Tris(tetramethylammonium) 5-hydroxy-1-(4-sulphonatophenyl)-4-(4-sulphonatophenylazo)pyrazole-3-carboxylate	611-071-00-8	X		
Tetrakis(tetramethylammonium)3,3'-(6-(2-hydroxyethylamino)1,3,5-triazine-2,4-diylbisimino(2-methyl-4,1-phenyleneazo))bisnaphthalene-1,5-disulfonate	611-098-00-5	X		
Aniline	612-008-00-7			X
Salts of aniline	612-009-00-2			X
Chloroanilines, with exception of those specified elsewhere in this Annex	612-010-00-8			X
o-Nitroaniline; [1] m-nitroaniline; [2] p-nitroaniline [3]	612-012-00-9			X
N-Methylaniline	612-015-00-5			X
N,N-Dimethylaniline	612-016-00-0			X
Phenylhydrazine; [1] phenylhydrazinium chloride; [2] phenylhydrazine hydrochloride; [3] phenylhydrazinium sulphate (2:1) [4]	612-023-00-9			X
m-Toluidine; 3-aminotoluene	612-024-00-4			X
Nitrotoluidines, with the exception of those specified elsewhere in this Annex	612-025-00-X			X
Diphenylamine	612-026-00-5			X
Xylidines with the exception of those specified elsewhere in this Annex; dimethyl anilines with the exception of those specified elsewhere in this Annex	612-027-00-0			X
p-Phenylenediamine	612-028-00-6			X
Benzene-1,4-diamine dihydrochloride; p-phenylenediamine dihydrochloride	612-029-00-1			X
2-Methyl-p-phenylenediamine sulphate [1]	612-030-00-7	X		
N,N-Dimethylbenzene-1,3-diamine; [1] 4-amino-N,N-dimethylaniline; 3-amino-N,N'-dimethylaniline [2]	612-031-00-2			X
2-Methoxyaniline; o-anisidine	612-035-00-4			X
2-Ethoxyaniline; o-phenetidine	612-039-00-6			X
N-Ethylaniline	612-053-00-2			X
N,N-Diethylaniline	612-054-00-8			X
N-Methyl-o-toluidine; [1] N-methyl-m-toluidine; [2] N-methyl-p-toluidine [3]	612-055-00-3			X

Chemical name	CAS Number	H301	H311	H331
N,N-Dimethyl-p-toluidine; [1] N,N-dimethyl-m-toluidine; [2] N,N-dimethyl-o-toluidine [3]	612-056-00-9			X
Dimethylnitrosoamine; N-nitrosodimethylamine	612-077-00-3	X		
4-Amino-N,N-diethylaniline; N,N-diethyl-p-phenylendiamine	612-080-00-X	X		
o-Toluidine; 2-aminotoluene	612-091-00-X			X
4-Methyl-m-phenylenediamine; 2,4-toluenediamine	612-099-00-3	X		
N,N-bis(3-Aminopropyl)methylamine	612-102-00-8			X
Bis(2-dimethylaminoethyl)(methyl)amine	612-109-00-6		X	
2,2'-Dimethyl-4,4'-methylenebis(cyclohexylamine)	612-110-00-1			X
C8-18Alkylbis(2-hydroxyethyl)ammonium bis(2-ethylhexyl)phosphate	612-116-00-4			X
N,N,N-Trimethylanilinium chloride	612-124-00-8	X	X	
2-Methyl-p-phenylenediamine; 2,5-toluenediamine	612-125-00-3	X		
Toluene-2,4-diammonium sulphate; 4-methyl-m-phenylenediamine sulfate	612-126-00-9	X		
(4-Ammonio-m-tolyl)ethyl(2-hydroxyethyl)ammonium sulphate; 4-(N-ethyl-N-2-hydroxyethyl)-2-methylphenylenediamine sulphate	612-133-00-7	X		
4-chloroaniline	612-137-00-9			X
N5,N5-Diethyltoluene-2,5-diamine monohydrochloride; 4-diethylamino-2-methylaniline monohydrochloride	612-143-00-1	X		
o-Phenylenediamine	612-145-00-2	X		
o-Phenylenediamine dihydrochloride	612-146-00-8	X		
m-Pphenylenediamine	612-147-00-3			X
m-Phenylenediamine dihydrochloride	612-148-00-9			X
Methyl-phenylene diamine; diaminotoluene; [technical product – reaction mass of 4-methyl-m-phenylene diamine (EC No 202-453-1) and 2-methyl-m-phenylene diamine (EC No 212-513-9)]	612-151-00-5	X		
p-Toluidine; 4-aminotoluene; [1] toluidinium chloride; [2] toluidine sulphate (1:1) [3]	612-160-00-4			X
4-Chloro-o-toluidine; [1] 4-chloro-o-toluidine hydrochloride [2]	612-196-00-0			X
2,4,5-Trimethylaniline; [1] 2,4,5-trimethylaniline hydrochloride [2]	612-197-00-6			X
4,4'-Oxydianiline and its salts; p-aminophenyl ether	612-199-00-7			X
3,4-Dichloroaniline	612-202-00-1			X
5-Nitro-o-toluidine; [1] 5-nitro-o-toluidine hydrochloride [2]	612-210-00-5			X
4-Methylpyridine; 4-picoline	613-037-00-8		X	
Captan (ISO); 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide	613-044-00-6			X
1-Dimethylcarbamoyl-5-methylpyrazol-3-yl dimethylcarbamate; dimetilan (ISO)	613-047-00-2	X		
3-(3-Methylpent-3-yl)isoxazol-5-ylamine	613-074-00-X			X
Paraquat dichloride; 1,1-dimethyl-4,4'-bipyridinium dichloride; [1] paraquat dimethylsulfate; 1,1-dimethyl-4,4'-bipyridinium dimethyl sulphate [2]	613-090-00-7	X		

Chemical name	CAS Number	H301	H311	H331
1,10-Phenanthroline	613-092-00-8	X		
Hexakis(tetramethylammonium) 4,4'-vinylenebis((3-sulfonato-4,1-phenylene)imino(6-morpholino-1,3,5-triazine-4,2-diyl)imino)bis(5-hydroxy-6-phenylazonaphthalene-2,7-disulfonate)	613-105-00-7	X		
Octhilinone (ISO); 2-octyl-2H-isothiazol-3-one	613-112-00-5			X
Etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole	613-133-00-X			X
Pyridaben (ISO); 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one	613-149-00-7			X
Fenazaquin (ISO); 4-[2-[4-(1,1-dimethylethyl)phenyl]-ethoxy]quinazoline	613-159-00-1	X		
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	613-167-00-5			X
Fluquinconazole (ISO); 3-(2,4-dichlorophenyl)-6-fluoro-2-(1H-1,2,4-triazol-1-yl)quinazolin-4-(3H)-one	613-173-00-8			X
2,3,5,6-Tetrahydro-2-methyl-2H-cyclopenta[d]-1,2-thiazol-3-one	613-185-00-3	X		
Cis-1-(3-Chloropropyl)-2,6-dimethyl-piperidin hydrochloride	613-209-00-2	X		
3-(Benzo[b]thien-2-yl)-5,6-dihydro-1,4,2-oxathiazine-4-oxide	613-232-00-8			X
2-Chloro-3-trifluoromethylpyridine	613-236-00-X	X	X	
2-Chloro-5-chloromethylthiazole	613-266-00-3		X	
Pyraclostrobin (ISO); methyl N-{2-[1-(4-chlorophenyl)-1H-pyrazol-3-yloxymethyl]phenyl}(N-methoxy)carbamate	613-272-00-6			X
3-(2-Chloroethyl)-6,7,8,9-tetra-hydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one monohydrochloride	613-275-00-2	X		
Ketoconazole; 1-[4-[4-[[(2SR,4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone	613-283-00-6	X		
Nicotine (ISO); 3-(N-methyl-2-pyrrolidinyl)pyridine	614-001-00-4	X		
Digitoxin	614-022-00-9			X
Ouabain	614-025-00-5			X
Strophantin-K	614-026-00-0			X
Methyl isothiocyanate	615-002-00-2			X
3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate	615-008-00-5			X
4,4'-Methylenedi(cyclohexyl isocyanate); dicyclohexylmethane-4,4'-di-isocyanate	615-009-00-0			X
2,2,4-Trimethylhexamethylene-1,6-di-isocyanate; [1] 2,4,4-trimethylhexamethylene-1,6-di-isocyanate [2]	615-010-00-6			X
Hexamethylene-di-isocyanate	615-011-00-1			X
Cyanamide; carbanonitril	615-013-00-2	X		
2-(2-Butoxyethoxy)ethyl thiocyanate	615-018-00-X	X	X	
Dicyclohexylcarbodiimide	615-019-00-5		X	
Methylene dithiocyanate	615-020-00-0	X		
1,3,5-tris(Oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione; TGIC	615-021-00-6			X
2-Phenylethylisocyanate	615-024-00-2			X

Chemical name	CAS Number	H301	H311	H331
Acrylamide; prop-2-enamide	616-003-00-0	X		
Butyraldehyde oxime	616-013-00-5		X	
Cyprofuram (ISO); N-(3-chlorophenyl)-N-(tetrahydro-2-oxo-3-furyl)cyclopropanecarboxamide	616-033-00-4	X		
2-Chloracetamide	616-036-00-0	X		
3-Dodecyl-(1-(1,2,2,6,6-pentamethyl-4-piperidin)-yl)-2,5-pyrrolidindione	616-063-00-8			X
1-(1,4-Benzodioxan-2-ylcarbonyl)piperazine hydrochloride	616-090-00-5			X
1,3,5-tris-[(2S and 2R)-2,3-Epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	616-091-00-0			X
Lithium bis(trifluoromethylsulfonyl)imide	616-124-00-9	X	X	
(2R,6as,12as)-1,2,6,6a,12,12a-Hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one; rotenone	650-005-00-2	X		
Benquinox (ISO); p-benzoquinone 1-benzoylhydrazone 4-oxime	650-006-00-8	X		
Drazoxolon (ISO); 4-(2-chlorophenylhydrazone)-3-methyl-5-isoxazolone	650-008-00-9	X		