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Technical Working Group on Seveso and GHS

Interim report

Draft

Edited by Zsuzsanna Gyenes

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This report has been developed by Zsuzsanna Gyenes, the scientific secretary of the TWG on Seveso and GHS in close collaboration with the members of Technical Working Group on Seveso and GHS, appointed by the Committee of Competent Authorities for the Seveso II. Directive. The editor would like to thank all the members of TWG (see composition below) for their constructive comments and suggestions throughout the process of preparing this report.

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Applied abbreviations

DG ENV	Directorate-General Environment
GHS	Globally Harmonised System of classification and labelling of substances and mixtures
SEVESO	Council Directive 105/2003/EC SEVESO II. Directive
MAHB	Major Accidents Hazards Bureau
DSD	Dangerous Substances Directive 67/548/EC
CLP	Regulation on classification, labelling and packaging of substances and mixtures
MSDS	Material Safety Data Sheets
TWG	Technical Working Group "Seveso and GHS"
STOT	Specific Target Organ Toxicity

1. Introduction

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) provides a harmonized basis for globally uniform physical, environmental, health and safety information on dangerous substances and mixtures.

The European Commission and the EU Member States have endorsed the UN recommendation to implement the GHS in domestic law. The recommendation was also supported by stakeholders from industry and non-governmental organizations.

On 16th of December 2008 the European Parliament and the Council adopted a new Regulation on classification, labelling and packaging of substances and mixtures (CLP) which aligns existing EU legislation to the GHS. It was published in the Official Journal 31 December 2008. This directive enters into force on 20 January 2009. The deadline for substance classification according to the new rules will be 1st of December 2010 and for mixtures 1st of June 2015. The CLP Regulation will ultimately replace the current rules on classification, labeling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after a transitional period.

At the 15th plenary meeting of the Committee of Competent Authorities (CCA) for Seveso II. Directive on 18-20th of January in 2006, members of the committee decided to establish a new expert group; a clear remit should be identified since other GHS classification initiatives are ongoing. The main objectives of the new group are to review the potential impact of GHS classification rules in a Seveso context; also it has been decided to adopt a Technical Working Group – a Technical Working Group "Seveso and GHS".

The first meeting was held in Brussels 19th of May 2006 - where the main purpose and the need of this working group was discussed. The first official meeting of the TWG was settled in 2008.

2. Methodology

The Technical Working Group made a differentiation in investigation, between physical, health and environmental hazards in GHS categories in order to find the best way for alignment to the Seveso II. Directive.

The philosophy of the work was to find the best and most appropriate way to make the GHS consistent through the DSD with the Seveso II. Directive. To implement this aim a technical working group was established with many experts on this issue.

The working group's main objectives are given below:

Objective 1:

- No reduction of the level of protection achieved by existing Seveso II. Directive scope (e.g. no significant changes for the thresholds of relevant substances already in scope).

Objective 2:

- No unnecessary and significant extension of the scope of Seveso II. Directive as a consequence of the GHS alignment in order to avoid increasing the burden on industry and administration, i.e. no increase unless the risk of major hazard is significant.

At the first official meeting of the Technical Working Group in Ispra (20^{th}-22^{nd} of February, 2008) two subgroups were formed. One subgroup discussed work to be done from the point of view of physical hazards, while the other subgroup focused on health hazards.

After these preliminary actions, at following meetings the whole group faced all types of hazards and was not divided into two subgroups.

3. Physical hazards

There are 16 types of physical hazards currently covered by the second revised "The Globally Harmonized System of Classification and Labelling of Chemicals" [GHS] which are the followings:

1. Explosives (chapter 2.1)
2. Flammable gases (chapter 2.2)
3. Flammable aerosols (chapter 2.3)
4. Oxidizing gases (chapter 2.4)
5. Gases under pressure (chapter 2.5)
6. Flammable liquids (chapter 2.6)
7. Flammable solids (chapter 2.7)
8. Self-reactive substances and mixtures (chapter 2.8)
9. Pyrophoric liquids (chapter 2.9)
10. Pyrophoric solids (chapter 2.10)
11. Self-heating substances and mixtures (chapter 2.11)
12. Substances and mixtures which, in contact with water emit flammable gases (chapter 2.12)
13. Oxidizing liquids (chapter 2.13)
14. Oxidizing solids (chapter 2.14)
15. Organic peroxides (chapter 2.15)
16. Corrosive to metals (chapter 2.16)

The group launched the work with investigation on these groups and made final decisions for most of these substance groups.

As it was mentioned before, at the first official meeting of the Technical Working Group in Ispra two subgroups were formed. One subgroup discussed work to be done from the point of view of physical hazards, while the other subgroup focused on health hazards.

The subgroup responsible for physical hazard analysis, studied each of the different GHS categories related to physical hazards and established all the necessary actions.

After this pre-analysis at the following TWG meetings the whole group attempted to finalize the investigation on physical hazards in order to establish what kind of substance groups will extend the scope of Seveso and which do not.

3.1 SUBSTANCE GROUPS WHICH ARE NOT INVOLVED IN SEVESO II. DIRECTIVE

Based on the investigations carried out by the TWG some of the physical hazards are completely taken out of scope of Seveso due to certain justifications.

1. Gases under pressure: means gases contained in a receptacle at a pressure of 200 kPa or more, or which are liquefied or liquefied and refrigerated. It's a new hazard class since this category of substances was not included previously in Seveso and it's not been found relevant to the scope of Seveso.
2. Flammable solids: means solids which are really combustible, or may cause or contribute to fire through friction. In Seveso there are 3 types of flammability; flammable, highly flammable and extremely flammable. Following on from their definition it's clear that these substances are gases and liquids but not solids. Although flammable solids in powder form may be relevant to (external) safety, this group of substances is not covered by Seveso at the moment. Most of the flammable solids are already covered by other categories of Seveso or are not dangerous substances. The generic group of powdered flammable solids may be of concern because of their sensibility to dust explosions. TWG agreed not to involve this category in Seveso.
3. Self-heating substances: a self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).
4. Corrosive to metals: means a substance or mixture which by chemical action will materially damage, or even destroy, metals. It's a new hazard class and not involved in Seveso because it's not relevant for Seveso.

3.2 SUBSTANCE GROUPS WHICH ARE INVOLVED IN SEVESO II. DIRECTIVE

3.2.1 One-to-one translation

1. Oxidising gases: an oxidizing gas is any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does. It is agreed that this category should be involved with a one-to-one translation with Seveso group "oxidizing". Oxidizing gases, Category 1 with thresholds 50 & 200 tonnes.
2. Oxidizing liquids: means a liquid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other materials. Straight translation. Liquids with R9 and R8 in DSD correspond to Oxidizing liquids Category 1, 2 and 3 in CLP. Oxidizing liquids, Category 1, 2 and 3 – thresholds of 50 & 200 tonnes.
3. Flammable gases: means a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa. Flammable gases, Category 1 or 2; thresholds are of 10 & 50 tonnes. Straight translation for Note 3(c) (2) F+; R12 gases in DSD correspond to Flammable gases Category 1 and 2 in CLP. *Text still has to be added to cover the current Note with regard to the "supercritical state". A proposal has been put forward. It has been agreed to omit the definition of a gas, since it is in the CLP.*

3.2.2 Substance groups included within the scope of Seveso with modifications

1. Explosives:
   (1) Where the substance, mixture or article falls under GHS hazard class Explosives, unstable explosives or divisions 1.1, 1.2, 1.3, 1.5 or 1.6 with thresholds of 10 & 50 tonnes. The current entry is already harmonized with CLP through use of the ADR-classification. Unstable Explosives have been added, which is a category which does not occur in ADR (since they may not be transported). It has been agreed to take out the definition of Explosives since it exists in the CLP. *Note has to be rephrased and checked carefully.*
   (2) Where the substance, mixture or article falls under GHS hazard class Explosives, Division 1.4 and is packaged as for transport, with thresholds of 50 & 200 tonnes (see note 1).

The current entry is already harmonized with CLP through use of the ADR-classification. In the proposal a clarification is added that unpacked or repacked Explosives of Division 1.4 may no longer be Division 1.4, (see 2.1.3 in Annex I. Part 2 of the CLP). It has been agreed to remove the definition of Explosives since it exists in the CLP. *Note has to be rephrased and checked carefully.*

note 1: If explosives of division 1.4 are unpacked or repacked, they must be assigned to entry x[1] unless the hazard is shown to correspond still to this hazard division.

2. Flammable aerosols: meaning aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid or gaseous state.

– Option 1: a common entry (or possibly two) for Category 1 and Category 2, where the appropriate qualifying quantities still have to be agreed:

(1) Flammable aerosols, Category 1, 2 with flammable propellant with thresholds of 150 & 500 tonnes. *Further investigation is needed.*

(2) Flammable aerosols, Category 1, 2 with non-flammable propellant with thresholds of 5.000 & 50.000 tonnes. *Further investigation is needed.*

If the two entries are specified depending on whether the propellant is flammable or not, the advantage is that it probably divides flammable aerosols better according to the hazard they actually pose. However, the practical implementation will be more problematic due to the required information in the supply chain which cannot always be ensured.

– Option 2: separate entries for Category 1 and Category 2:

1. Flammable aerosols, Category 1 with thresholds of 75 & 300 tonnes. *Further investigation is needed.*

2. Flammable aerosols, Category 2 with thresholds of 250 & 1.000 tonnes. *Further investigation is needed.*

[1] This reference shall be to the other entry for explosives (comprising unstable explosives and explosives of the divisions 1.1, old entry no. 5.

The advantage of this solution is that problems due to insufficient communication of the components of flammable aerosols in the supply chain are avoided because the qualifying quantity is directly linked to the classification.

The disadvantage is that the distinction between category 1 and category 2 is based on tests that are aimed at the end-user (and that are not really Seveso-relevant). However, the average content of flammable contents of category 1 aerosols will be lower than that of category 2, so it is still better than having only one entry for flammable aerosols.

3. Flammable liquids:

    1. Flammable liquids

        - Flammable liquids, Category 1 or
        - Flammable liquids, Category 2 or flammable liquids with a flash point up to and including 60 °C maintained at a temperature above their boiling point

with thresholds of 10 & 50 tonnes.

Translation from F+; R12 in DSD to Flammable liquids Category 1 in CLP, which is not completely straight (increase of the upper limit of the flash point from 0°C to 23°C) but this is not of practical relevance (because liquids with a boiling point below 35°C do not have such a high flash point). It is the best possible translation and in practice has few consequences.

Translation for liquids is F; R11 → Category 2 and R10 → Category 3 in CLP, which is not straight (slight increase of the upper limit of the flash point for both categories) but the best possible and with few consequences. Category 3 Flammable liquids are liquids with flash points ≥ 23 and ≤ 60°C. However, the wording ”or flammable liquids with a flash point up to and including 60°C” is used in the proposal. This has the effect of including the liquids that have been excluded from Category 3 (for the purposes of CLP) due to not supporting combustion according to 2.6.4.5 in Annex I Part 2 of the CLP. This is necessary because under these conditions (above the boiling point) the results of the sustained combustibility test L.2 are not relevant.

    2. Flammable liquids, Category 2 or flammable liquids with a flash point up to and including 60 °C where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards – with thresholds of 50 & 200 tonnes.

The proposal corresponds to Note 3(b)(1) second indent:

Translation for liquids is F; R11 → Category 2 and R10 → Category 3, which is not straight (slight increase of the upper limit of the flash point for both categories) but the best possible and with few consequences. Category 3 Flammable Liquids are liquids with flash points ≥ 23 and ≤ 60°C. However, the wording ”or flammable liquids with a flash point up to and including 60°C” is used in the proposal. This has the effect of including the liquids that have been excluded from Category 3 (for the purposes of CLP) due to not supporting combustion according to 2.6.4.5 in Annex I Part 2 of the CLP. This is necessary because under these conditions (elevated pressure/temperature etc.) the results of the sustained combustibility test L.2 are not relevant.

3. Flammable liquids, Category 2 or 3 with thresholds 5.000 & 50.000 tonnes.

Translation for liquids is F; R11 → Category 2 and R10 → Category 3, which is not straight but the best possible and with few consequences. Category 3 thus corresponds to current entry 6 FLAMMABLE, and Category 2 to current entry 7b HIGHLY FLAMMABLE Note 3(b) (2).

According to 2.6.4.5 in Annex I of the CLP, liquids with flash points above 35°C need not be classified in Category 3 if they do not support combustion. Such liquids are therefore not Flammable Liquids Category 3 and as such do not fall under this entry. Hence the last condition in the current Note 3(a), ”supporting combustion”, is already included in the condition on Category 3 in CLP, and can therefore be omitted.

4. Self-reactive substances and mixtures and organic peroxides: these GHS hazard categories are discussed under the same group because their classification tests and criteria are the same. Self-reactive substances and mixtures are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). Organic peroxides are liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivates of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals.

(1) Self-reactive substances and mixtures, Type A or B or organic peroxides Type A or B – thresholds are of 10 & 50 tonnes.

Organic peroxides and Self-reactives Types A and B in CLP are always classified as E; R2 or E; R3 according to DSD. Hence this is a straight translation from E; R2 or E; R3 in DSD to Self-reactives or Organic peroxides Types A or B in CLP.

(2) Self-reactive substances and mixtures, Type C, D, E or F or organic peroxides Type C, D, E or F – thresholds are of 50 & 200 tonnes.

Organic peroxides are classified O; R7 in DSD, unless they are R2 or R3. Straight translation is from O; R7 in DSD to Organic Peroxides Type C, D, E or F in CLP.

Self-reactives are a new hazard class in CLP that has no direct correspondence in DSD. DSD-assignment for Types C, D. E and F can be F+;R12, F;R11, R10, possibly none or in a few cases E;R2.

They therefore may fall under diverse entries (mainly 6, 7a, 7b, 8) in the current Annex I Part 2, or fall out completely. The classification scheme for Self-Reactives in CLP and ADR is exactly the same as for Organic peroxides, and thus also the hazards are the same. For this reason Self-Reactives have been treated in the same way as Organic peroxides in this new entry.

Organic peroxides and Self-reactives Type G are exempted from ADR and have no hazard communication elements in CLP. They have therefore also been exempted here.

5. Pyrophoric liquids: are liquids which, even in small quantities, are liable to ignite within five minutes after coming into contact with air. There is a straight translation for the first indent of current Note 3(b) (1), since F; R17 corresponds directly to Pyrophoric liquids Category 1. Pyrophoric liquids, Category 1 – thresholds are of 50 & 200 tonnes.

6. Pyrophoric solids: means solids which, even in small quantities, are liable to ignite within five minutes after coming into contact with air. Pyrophoric solids are currently not included in Seveso. Pyrophoric solids, Category 1 – thresholds are of 50 & 200 tonnes. *Inclusion of Pyrophoric solids is an open issue that is still under discussion.*

7. Oxidizing solids: means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other materials.

For solids O; R9 and O; R8 in DSD correspond almost directly to Oxidizing solids Category 1, 2 and 3 in CLP. No significant impact is expected due to the slight discrepancy, which is due to somewhat different test methods (A.17 in DSD and O.1 in CLP). Oxidizing solids, Category 1, 2 and 3 with thresholds of 50 & 200 tonnes.

3.3 ANY CLASSIFICATION IS NOT COVERED

Substances and mixtures which, in contact with water, emit flammable gases: This category means any classification not covered by those given above in combination with hazard statement EUH014 (including EUH014/GHS hazard class "Substances which in contact with water emit flammable gases"). EUH014 is a remaining EU-hazard statement in CLP, and is a straight translation from R14 in DSD. Substances and mixtures which contact with water emit flammable gases, Category 1, 2 or 3 in CLP correspond to R15 in DSD – thresholds are of 100 & 500 tonnes. Normally those in Category 1 should also be assigned R14.

It still has to be clarified what the purpose of the wording "Any classification not covered by those given above" is and whether it is justified.

4. Environmental hazards

There is a direct match between the previous classification system and the GHS for environmental hazards, so a direct alignment is suggested which has been accepted by the group.

(1) Hazardous to the Aquatic Environment Category Acute I, Chronic I: where the substance or mixture falls under the GHS hazard class Acute Category 1 and Chronic Category 1 – thresholds are of 100 & 200 tonnes. It means straight translation form R50 and R50/53 in DSD to GHS Aquatic Acute Category 1 and to GHS Aquatic Chronic Category 1, respectively.

(2) Hazardous to the Aquatic Environment Category Chronic II: where the substance or mixture falls under the GHS hazard class Chronic Cat 2 with thresholds of 200 & 500 tonnes. Straight translation from R51/53 in DSD to Aquatic Chronic Category 2.[1]

Wastes: according to discussions the TWG agreed on that this category should be taken into consideration at the procedure of implementation of mixtures.

[1] Unless the chronic toxicity NOECs of relevant organisms are >1 mg/l

5. Health hazards

Members of the TWG have developed alternative options for alignment of health hazards from GHS. The working group had two main objectives relating to health hazards:

Objective 1:

- No reduction in the level of protection achieved by existing Seveso II. Directive scope (e.g. no significant changes for the thresholds of relevant substances already in scope).

Objective 2:

- No unnecessary and significant extension of the scope of Seveso II. Directive as a consequence of the GHS alignment in order not to increase the burden on industry and administration, i.e. no increase unless the risk of major hazard is significant.

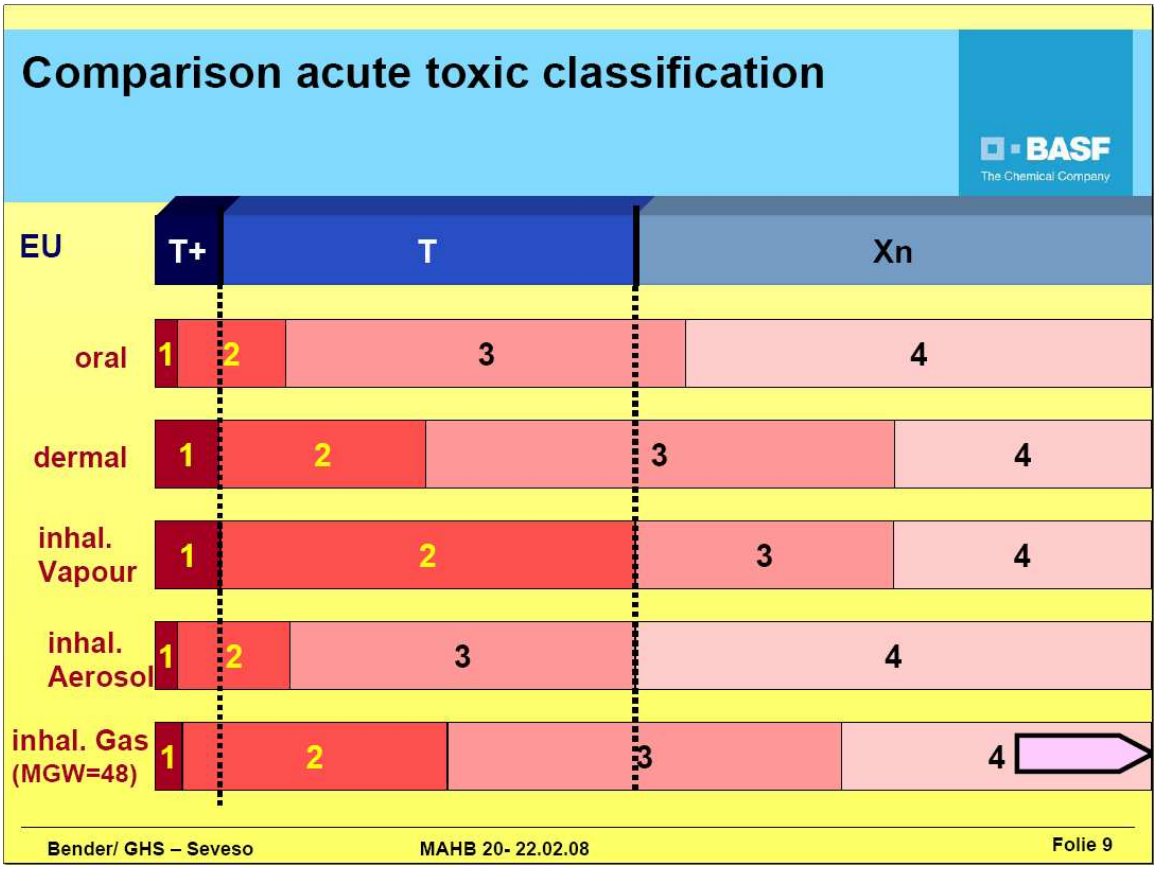


Figure 1: Comparison of EU and GHS toxicity categories depending on intake route

After the 2nd meeting of the TWG on Seveso and GHS the group carried out a more precise approach with 3 possible alternatives. These are referred to as Option 1, Option 2 and Option 3. The TWG had a general agreement that T+ should be equal to Category 1 and T to Category 2, but as illustrated by the graph above, this would imply a decrease in the scope of the Directive that will need more T-named substances (Category 3 substances).
Each option has its differences and the following points will highlight some of these.

Option 1:

- Suggests a simple alignment with an addition of named substances. Furthermore the option is characterised by suggesting a screening tool that should consider whether a given substance should be included, based on whether it is in Category 3, on its exposure route, and on its LD/LC50 values, etc. Briefly it means that T category substances under Seveso aligned with Category 2 substances + named substances and/or use of screening tool to screen in (see Figure 3).

Option 2:

- Aims to maintain the scope of Seveso, however, supports a slight increase in scope for substances in oral test areas and a slight increase for gases. According to this proposal new T category for Seveso includes Category 3 substances for oral, inhalative dust and inhalative gas intake routes; it also includes Category 3 substances for dermal intake, but only for those cases that are not classified as Category 3 for inhalative vapour.

Option 3:

- Suggests a slight decrease in scope of Seveso with taking out of scope Category 3 substances in oral, dermal and inhalation vapours and gases (except those which should be included based on screening tools). It means that the new T category for Seveso includes Category 3 substances only for inhalative dust + use screening tool for inhalative gas Category 3.

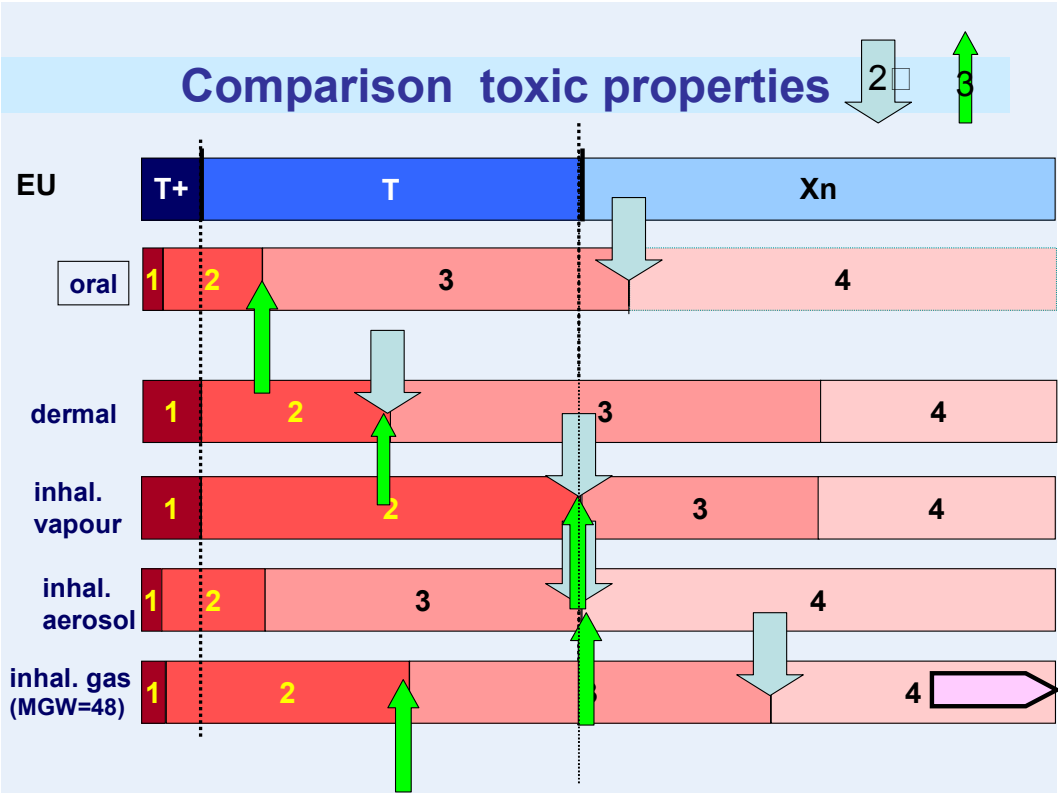
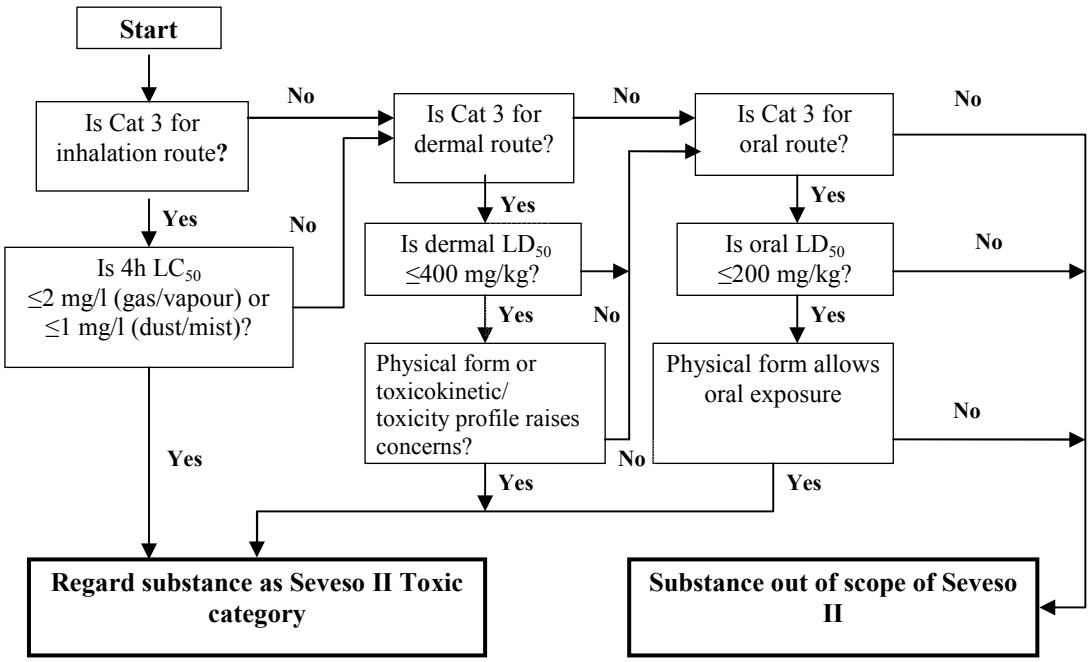


Figure 2: Comparison of EU and GHS toxicity categories depending on intake route based on the 2nd – 3rd meeting discussions

Figure 3: Screening tool for substances with overall GHS acute toxicity classification of Category 3 according to Option 1



At the 4th meeting of the TWG one option has become the so-called "Decision tree" approach, this is referred to as Option 4.

Option 4: "Decision tree" approach.

- According to this suggestion T+ also means Category 1 substances. As for T substances there is a priority concerning the intake route. According to this approximation the first intake route is acute toxic inhalative, since it can contribute to the occurance of major accidents. Dermal and oral intake routes have a lower rating, since they are not involved in triggering major accidents as frequently as the inhalation route.

  It means that if no data is available for inhalation intake route for vapours and gases Category 2, neither for aerosols Category 2 and Category 3, then it needs to go to the next level. The next step signifies the dermal intake route Category 2. In that case if there is no data available, then we should go forward to oral intake route Category 2 and Category 3. *This option needs checking.*

At the 4th meeting the other 3 options had changed and finally converged with each other. The latest version of the 4 options are visible below in Figure 3.

Column 1	Column 2	Column 3
Categories of dangerous substances	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of	
	Article 6 and 7	Article 9
ACUTE TOXIC where the substance or mixture falls under GHS hazard class: Acute toxic, category 1	5	20
ACUTE TOXIC where the substance or mixture falls under GHS hazard class: 1. Acute toxic, inhalative route: vapour and gases category 2 Aerosols categories 2 and 3 2. If no inhalative data are available: Acute toxic, category 2 via dermal route 3. If neither inhalative and dermal data are available: Acute toxic categories 2 and 3 via oral route	50	200

Table 1: Decision tree approach

Final agreement after the 4th meeting:

Option 1 means that T category substances under Seveso aligned with Category 2 substances + named substances and/or use of screening tool to screen in according to the figure of screening tool (see Figure 3).

Options 2-3-4 mean the new T category for Seveso includes Category 3 substances for oral and inhalative aerosols intake routes; it includes Category 2 only for dermal route, inhalative vapour and gases intake routes. Inhalative gases Category 3 is not included.

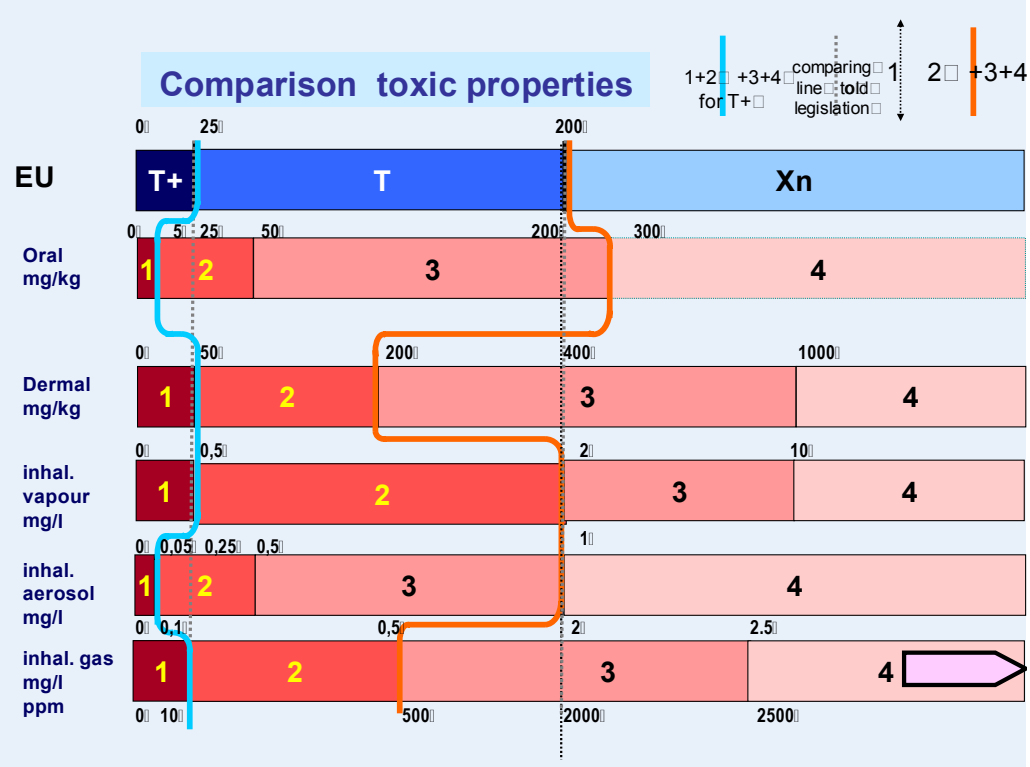


Figure 4: Comparison of EU and GHS toxicity categories depending on intake route based on the 4 options

STOT's: At the 4th meeting there was a discussion on the alignment of STOT's substances. It was agreed by the TWG that these substances should be included in the Seveso with one-to-one translation. It means that STOT's Category 1 substances are included in Seveso with thresholds of 50 & 200 tonnes. The TWG agreed that further investigations are needed in this issue.

R29 substances [EUH029]: means substances which are contact with water liberates toxic gas. (in contact with water or damp air evolve gases which are classified for Acute Toxicity, Category 1, 2 or 3 in potentially dangerous amounts) (old 10 ii R29 in Seveso) with proposed thresholds of 50 & 200 tonnes. *It's needed to check.*

6. Conclusions and final decisions according to the 4th meeting

6.1 PHYSICAL HAZARDS

- Flammable gases:
    - Check note 2.
    - Check named entry - extremely flammable gases (LPG).
- Flammable liquids:
    - Agreement on rephrased notes but final check is needed.

- Explosives:
    - Check notes in the draft Annex I. part 2.

- Pyrophoric solids:
    - Further investigation is welcomed – in or out – about which substances are involved.

- Flammable aerosols:
    - Further investigation is needed on the new options (Option1 and Option2).

- "Any classifications are not covered"
    - Final check the wording for EUH014 and EUH029 substances.

6.2 HEALTH HAZARDS

- Alignment options:

    - STOTs Cat.1: Further research and reviews are needed – threshold of 50/200?

  Actions:
    - Decision tree approach needs checking.
    - Substance list is needed for dermal exposure route values in Category 3 LD50 values between 200 and 400 mg/kg.

- Oral exposure route Cat 3 should be in - especially for LD50 values between 200 and 300 mg/kg. Investigation is needed.
- Take into consideration gases Category 1 and Cat 2 - 5 substances should take into account the group of named substances (NH3, SO2, sulphuryl-difluoride with thresholds of 50/200 and CO, H2S with appropriate thresholds for toxic and flammable properties. 2 substances, the boron-trifluoride and the methyl-mercaptan are to be checked.

6.2.1 Proposal for named substances

Take into consideration gases Category 1 and Category 2 - 5 substances should take into account the group of named substances:

Name	**CAS number**
ammonia	7664-41-7
sulphur-dioxide	7446-09-5
sulphuryl-difluoride	2699-79-8

with thresholds 50/200.

carbon-monoxide	630-08-0
hydrogen-sulphide	7783-06-4

with appropriate thresholds for toxic and flammable properties.

boron-trifluoride	7637-07-2
methyl-mercaptan	74-93-1

to be checked.

Appendix

TABLE I: SEVESO II. DIRECTIVE PROPOSAL FOR ANNEX I. PART 2 AFTER TWG MEEITNG 4 FOR PHYSICAL HAZARDS WITH MOTIVATIONS

Draft proposal after TWG4			**Corresponding current text**		**Motivation/Comment**
Column 1	Column 2	Column 3			
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of		Entry #	Denotation	
	Article 6 and 7	Article 9			
EXPLOSIVES (see note 1) where the substance, mixture or article falls under GHS hazard class: Explosives, Unstable explosives or divisions 1.1, 1.2, 1.3, 1.5 or 1.6	10	50	5	EXPLOSIVE (see note 2) where the substance, preparation or article falls under any of: UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3	The current entry is already harmonized with CLP through use of the ADR-classification. Unstable Explosives have been added, which is a Category that does not occur in ADR (since they may not be transported). *Note has still to be reworded and carefully checked. It has been agreed to take out the definition of Explosives since it is in CLP.*
EXPLOSIVES (see note 1) where the substance, mixture or article falls under GHS hazard class: Explosives, Division 1.4 and is packaged as for transport	50	200	4	EXPLOSIVE (see note 2) where the substance, preparation or article falls under UN/ADR Division 1.4	The current entry is already harmonized with CLP through use of the ADR-classification. In the proposal a clarification is added that unpacked or repacked Explosives of Division 1.4 may no longer be Division 1.4, see 2.1.3 in Annex I Part 2 of the CLP. *Note has still to be reworded and carefully checked. It has been agreed to take out the definition of Explosives since it is in CLP.*
OXIDIZING GASES Oxidizing gases, Category 1	50	200	3	OXIDIZING	Straight translation from O;R8 in DSD (Dangerous Substances Directive) to Oxidizing Gases Category 1.
OXIDIZING LIQUIDS AND SOLIDS Oxidizing solids and liquids, Category 1, 2 and 3	50	200	3	OXIDIZING	For liquids: Straight translation. O;R9 and O;R8 in DSD correspond exactly to Oxidizing Liquids Category 1, 2 and 3 in CLP. For solids: O;R9 and O;R8 in DSD correspond

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3			
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of		Entry #	Denotation	
	Article 6 and 7	Article 9			
					almost directly to Oxidizing Solids Category 1, 2 and 3 in CLP. No significant impact is expected due to the slight discrepancy, which is due to somewhat different test methods (A.17 in DSD and O.1 in CLP).
FLAMMABLE GASES ~~(see note 2)~~ Flammable gases, Category 1 or 2 ~~(and falls within the definition in note 2~~?)	10	50	8	EXTREMELY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (c)) Note 3(c)(2): "(c) extremely flammable gases and liquids: 2. gases which are flammable in contact with air at ambient temperature and pressure (risk phrase R12, second indent), which are in a gaseous or supercritical state, and"	Straight translation for Note 3(c)(2). F+;R12 gases in DSD correspond to Flammable Gases Category 1 and 2 in CLP. *Text still has to be added to cover the current Note with regard to the "supercritical state". A proposal has been put forward. It has been agreed to omit the definition of a gas, since it is in the CLP.*
Option 1 for FLAMMABLE AEROSOLS Flammable aerosols, Category 1 and Category 2 with flammable propellant Flammable aerosols, Category 1 and Category 2 with non-flammable propellant	150? 5.000?	500? 50.000?	8 or 6, 7a, 7b	Flammable aerosols are considered based on their individual contents using the summation rule. In the vast majority of aerosols, the driving gas is LPG, which is a flammable gas	If the two entries are specified depending on whether the propellant is flammable or not, the advantage is that it probably divides flammable aerosols better according to the hazard they actually pose. However, the practical implementation will be more

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
				with F+;R12 classification in DSD. Aerosols frequently also contain flammable liquids. The direct assignment of an individual entry in the current Annex I of the Seveso-Directive is not possible; entries 6, 7a, 7b and especially 8 are all involved, as is the named entry of LPG in Part 1 of the Annex.	problematic due to the required information in the supply chain which cannot always be ensured. *There is agreement that Flammable Aerosols should be included as a separate entry, but precisely how to do that and with which qualifying quantities has not been settled yet. There is no direct correspondence in DSD to the Flammable Aerosols in CLP, so no direct translation is possible.*
Option 2 for FLAMMABLE AEROSOLS Flammable aerosols, Category 1 Flammable aerosols, Category 2	75? 250?	300? 1.000?	8 or 6, 7a, 7b	Flammable aerosols are considered based on their individual contents using the summation rule. In the vast majority of aerosols, the driving gas is LPG, which is a flammable gas with F+;R12 classification in DSD. Aerosols frequently also contain flammable liquids. The direct assignment of an individual entry in the current Annex I of the Seveso-Directive is not possible; entries 6, 7a,	The advantage of this solution is that problems due to insufficient communication of the components of flammable aerosols in the supply chain are avoided because the qualifying quantity is directly linked to the classification. The disadvantage is that the distinction between category 1 and category 2 is based on tests that are aimed at the end-user (and that are not really Seveso-relevant). However, the average content of flammable contents of category 1 aerosols will be lower than that of category 2, so it is still better than having only one entry for flammable aerosols.

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3			
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of		Entry #	Denotation	
	Article 6 and 7	Article 9			
				7b and especially 8 are all involved, as is the named entry of LPG in Part 1 of the Annex.	*There is agreement that Flammable Aerosols should be included as a separate entry, but precisely how to do that and with which qualifying quantities has not been settled yet. There is no direct correspondence in DSD to the Flammable Aerosols in CLP, so no direct translation is possible.* *Currently a split entry with 75t/300t qualifying quantities for Category 1 and 250t/1000t qualifying quantities for Category 2 is suggested and further investigated.*
FLAMMABLE LIQUIDS - Flammable liquids, Category 1 or - Flammable liquids, Categories 2 or ~~(3?)~~/ flammable liquids with a flash point up to and including 60 °C, maintained at a temperature above their boiling point	10	50	8	EXTREMELY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (c)) Note 3(c)(1) and (3): "(c) extremely flammable gases and liquids: 1. liquid substances and preparations which have a flash point lower than 0 ºC and the boiling point (or, in the case of a boiling range, the initial boiling point) of which at normal pressure is	Translation from F+;R12 in DSD to Flammable Liquids Category 1 in CLP, which is not completely straight (increase of the upper limit of the flash point from 0°C to 23°C) but this is not of practical relevance (because liquids with a boiling point below 35°C do not have such a high flash point). It is the best possible translation and in practice has few consequences Translation for liquids is F;R11 → Category 2 and R10 → Category 3, which is not straight (slight increase of the upper limit of the flash point for both categories) but the best possible

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
				less than or equal to 35 ºC (risk phrase R 12, first indent), and" […] "3. flammable and highly flammable liquid substances and preparations maintained at a temperature above their boiling point."	and with few consequences. Category 3 Flammable Liquids are liquids with flash points ≥ 23 and ≤ 60°C. However, the wording "or flammable liquids with a flash point up to and including 60°C" is used in the proposal. This has the effect of including the liquids that have been excluded from Category 3 (for the purposes of CLP) due to not supporting combustion according to 2.6.4.5 in Annex I Part 2 of the CLP. This is necessary because under these conditions (above the boiling point) the results of the sustained combustibility test L.2 are not relevant.
FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or ~~(3)~~ flammable liquids with a flash point up to and including 60 °C where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards (?)	50	200	7a	HIGHLY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (b) (1)) Note 3(b) (1), second indent: " (b) highly flammable liquids: — substances and preparations which have a flash point lower than 55 ° C and which remain liquid under pressure, where particular processing	The proposal corresponds to Note 3(b)(1) second indent: Translation for liquids is F;R11 → Category 2 and R10 → Category 3, which is not straight (slight increase of the upper limit of the flash point for both categories) but the best possible and with few consequences. Category 3 Flammable Liquids are liquids with flash points ≥ 23 and ≤ 60°C. However, the wording "or flammable liquids with a flash point up to and including 60°C" is used in the proposal. This has the effect of including the liquids that have been excluded from Category 3 (for the purposes of CLP) due to not supporting combustion according to 2.6.4.5 in

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
				conditions, such as high pressure or high temperature, may create major-accident hazards;"	Annex I Part 2 of the CLP. This is necessary because under these conditions (elevated pressure/temperature etc.) the results of the sustained combustibility test L.2 are not relevant.
FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 ~~(see note 3)~~	5.000	50.000	6 and 7b	FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (a)) Note 3(a): "(a) flammable liquids: substances and preparations having a flash point equal to or greater than 21 ºC and less than or equal to 55 ºC (risk phrase R 10), supporting combustion;" HIGHLY FLAMMABLE liquids (where the substance or preparation falls within the definition given in Note 3 (b) (2)) Note 3(b)(2): "substances and preparations having a flash point lower than 21 ºC and	Translation for liquids is F;R11 → Category 2 and R10 → Category 3, which is not straight but the best possible and with few consequences. Category 3 thus corresponds to current entry 6 FLAMMABLE, and Category 2 to current entry 7b HIGHLY FLAMMABLE Note 3(b)(2). According to 2.6.4.5 in Annex I of the CLP, liquids with flash points above 35°C need not be classified in Category 3 if they do not support combustion. Such liquids are thus not Flammable Liquids Category 3 and therefore do not fall under this entry. Hence the last condition in the current Note 3(a), "supporting combustion", is already included in the condition on Category 3 in CLP, and therefore can be omitted.

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
				which are not extremely flammable (risk phrase R 11, second indent);"	
SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES Self-reactive substances and mixtures, Type A or B or organic peroxides, Type A or B	10	50	5	EXPLOSIVE (see note 2) where the substance, preparation or article falls under any of: UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3	Organic Peroxides and Self-Reactives Types A and B in CLP are always classified as E; R2 or E;R3 according to DSD. Hence this is a straight translation from E;R2 or E;R3 in DSD to Self-Reactives or Organic Peroxides Types A or B in CLP.
SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES Self-reactive substances and mixtures, Type C, D, E or F or organic peroxides, Type C, D, E, or F	50	200	3	OXIDIZING	Organic peroxides are classified O;R7 in DSD, unless they are R2 or R3. Straight translation is from O;R7 in DSD to Organic Peroxides Type C, D, E or F in CLP. Self-Reactives are a new Hazard Class in CLP that has no direct correspondence in DSD. DSD-assignment for Types C, D. E and F can be F+;R12, F;R11, R10, possibly none or in a few cases E;R2. They therefore may fall under diverse entries (mainly 6, 7a, 7b, 8) in the current Annex I Part 2, or fall out completely. The classification scheme for Self-Reactives in CLP and ADR is exactly the same as for Organic Peroxides, and thus also the hazards are the same. For this reason Self-Reactives have been treated in the same way as Organic Peroxides in this new entry.

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
					Organic Peroxides and Self-Reactives Type G are exempted from ADR and have no hazard communication elements in CLP. They have therefore been exempted also here.
PYROPHORIC SOLIDS AND LIQUIDS Pyrophoric solids, Category 1, or Pyrophoric liquids, Category 1	50	200	7a	HIGHLY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (b) (1)) Note 3(b) (1), first indent: " (b) highly flammable liquids: 1. — substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy (risk phrase R 17),"	For liquids: Straight translation for the first indent of current Note 3(b)(1), since F;R17 corresponds directly to Pyrophoric Liquids Category 1. For solids: Pyrophoric Solids are currently not included in Annex I Part 2. *Inclusion of Pyrophoric Solids is an open issue that is still under discussion.*
ANY CLASSIFICATION not covered by those given above in combination with hazard statement EUH014 (including EUH014 / GHS hazard class "Substances which in contact with water emit flammable gases")	100	500	10	ANY CLASSIFICATION not covered by those given above in combination with risk phrases: (i) R14: 'Reacts violently with water' (including R14/15)	EUH014 is a remaining EU-hazard statement in CLP, and is a straight translation from R14 in DSD. Substances and Mixtures which in Contact with Water Emit Flammable Gases, Category 1, 2 or 3 in CLP correspond to R15 in DSD. Normally those in Category 1 should also be assigned R14.

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	Column 2	Column 3	Entry #	Denotation	
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of				
	Article 6 and 7	Article 9			
					It still has to be clarified what the purpose of the wording "Any classification not covered by those given above" is and whether it is justified. There may be problems with this wording.

Notes

1. An “explosive” means:

   ~~(– a substance, mixture or article covered by the hazard class "explosives" of the CLP-Regulation, Unstable explosives or Divisions 1.1, 1.2, 1.3, 1.4, 1.5 or 1.6.)~~ ?

   If explosives of division 1.4 are unpacked or repacked, they must be assigned to entry x[1] unless the hazard is shown to correspond still to this hazard division.

   (~~Included in this definition are pyrotechnics, which for the purposes of this Directive are defined as substances (or mixtures of substances), designated to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions.~~

   ~~Included in this definition are also explosive or pyrotechnic substances or mixtures contained in articles. In the case of articles containing explosive or pyrotechnic substances or mixtures, if the quantity of the substance or mixture contained is known, that quantity shall be considered for the purposes of this Directive. If the quantity is not known, then, for the purposes of this Directive, the whole article shall be treated as explosive~~.) ?

This Note on Explosives still has to be carefully checked and reworded.

2. ~~(A flammable gas means: a gas or gas mixture having a flammable range with air at 20°C and a standard pressure of 101.3 kPa and which is in a gaseous or supercritical state.) ?~~

The supercritical condition has to be taken care of in this Note,

[1] This reference shall be to the other entry for explosives (comprising unstable explosives and explosives of the divisions 1.1, old entry no. 5.

(~~3. According to 2.6.4.5 of Annex I of the CLP-Regulation liquids with a flash point of more than 35°C need not be classified in Category 3 if negative results have been obtained in the sustained combustibility test L.2, Part III, section 32 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.~~)

TABLE II: SEVESO II DIRECTIVE, PROPOSAL FOR ANNEX I, PART 2 AFTER TWG MEETING 4 FOR ENVIRONMENT HAZARDS

Draft proposal after TWG4			Corresponding current text		Motivation/Comment
Column 1	**Column 2**	**Column 3**			
Categories of dangerous substances and mixtures	**Qualifying quantity (tonnes) of dangerous substances as delivered in Article 3 (4) for the application of**		**Entry #**	**Denotation**	
	Article 6 and 7	**Article 9**			
Substances Hazardous to the Aquatic Environment			9	Dangerous for the Aquatic Environment risk phrases:	
i) Hazardous to the Aquatic Environment, Category Acute I, Chronic I	100	200		i) R50: "Very toxic to aquatic organisms (including R50/53)	Straight translation from R50 and R50/53 in DSD (Dangerous Substances Directive - 67/548/EC) to Aquatic Acute Category 1 and to Aquatic Chronic Category 1, respectively.
ii) Hazardous to the Aquatic Environment, Category Chronic II	200	500		ii) R51/53: "Toxic to aquatic organisms. May cause long term adverse effects in aquatic environment"	Straight translation from R51/53 in DSD to Aquatic Chronic Category 2.[1]

[1] Unless the chronic toxicity NOECs of relevant organisms are >1 mg/l

8. References

[1] Report on the 15th CCA meeting held in Austria

[2] European Commission, JRC-IPSC MAHB TWG on Seveso and GHS working documents on website: http://mahbsrv.jrc.it/sevesoandghs

[3] Draft minutes and lists of actions on the 1st meeting of TWG on Seveso and GHS - Ispra, 20-22nd of February 2008.

[4] Draft minutes and lists of actions on the 2nd meeting of TWG on Seveso and GHS - Ispra, 12-13th of June 2008.

[5] Draft minutes and lists of actions on the 3rd meeting of TWG on Seveso and GHS - Ispra, 6-7th of November 2008.

[6] Draft minutes and lists of actions on the 4th meeting of TWG on Seveso and GHS Ispra, 5-6th of March 2009.

[7] Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

[8] European Commission, [COM(2007) 355 final] for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006.

[9] EC Council Directive 105/2003/EC SEVESO II. Directive

[10] EC Council Directive, 67/548/EC Dangerous Substances Directive

[11] CLP Regulation on classification, labelling and packaging of substances and mixtures

[12] European Commission JRC- IHCP EX-ECB website: http://ecb.jrc.ec.europa.eu