

ADAPTING THE EU SEVESO II DIRECTIVE FOR THE GLOBALLY HARMONISED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) IN TERMS OF ACUTE TOXICITY TO PEOPLE: INITIAL STUDY INTO POTENTIAL EFFECTS ON UK INDUSTRY

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Within the EU, the risks of major accidents from chemical installations are regulated under the 'Seveso II' Directive. This paper describes an initial study into potential implications for regulation of UK installations arising from changes to the classification of acute toxicity to people when the EU adopts the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The study's aim was to identify a means of adapting the Seveso II Directive for GHS that: will not increase the Directive's scope and attention unless this increases safety from major accidents; will not increase the risk of a major accident by creating gaps in the regulation of installations; and will be transparent and straightforward for industry to apply. The outcome was to identify a possible option, the 'Simple Alignment', whereby references to the EU classifications Very Toxic and Toxic are replaced by GHS acute toxicity hazard Category 1 and Category 2 respectively for all exposure routes and physical states. To prevent regulatory gaps, the adapted Seveso II Directive would include further Named Substances, such as the lower molecular weight gases ammonia and sulphur dioxide, which have a less severe GHS acute toxicity category but are currently in the Seveso II regime and correspond to installations with major accident hazard potential that would not otherwise fall within the scope of the Directive. These substances would be identified using Technical Criteria that could, for example, be used by an EU Technical Committee to include further Named Substances in future. The other options considered were rejected either because of cost or because of the potential to significantly increase the scope of Seveso II. The outcome of this initial study, together with work by the German and Dutch Seveso II regulatory authorities, is being taken forward through an EU Technical Working Group.

KEYWORDS: GHS, Seveso II Directive, acute toxicity, major accident

INTRODUCTION: THE SEVESO II DIRECTIVE AND THE GLOBALLY HARMONISED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

In the EU, the risks of major accidents[1] from chemical installations are regulated through the 'Seveso II' Directive (96/82/EC as amended) for the Control of Major Accident Hazards Involving Dangerous Substances [ECC, 1997 & 2003]. The Directive covers accident prevention and mitigation.

Seveso II applies to establishments where dangerous substances may be present or generated in quantities in excess of specified threshold tonnages – the 'Qualifying Quantities'. The status of regulated establishments is either 'lower-tier' (Directive Articles 6 and 7 apply) or the more highly regulated 'top-tier' (Article 9 additionally applies) depending on whether lower or higher Qualifying Quantities apply. The Qualifying Quantities differ according to which of the Seveso II 'Dangerous Categories' the dangerous substances fall into *on the basis of their classification* and whether they are Seveso II 'Named Substances'. There are ten Dangerous Categories, they relate either to substances': physico-chemical properties such as flammability and explosivity, toxicity to people, or toxicity to the aqueous environment.

This simple threshold tonnage approach operates as an approximate screen to determine the appropriate degree of regulation of establishments under Seveso II. The screen is approximate since off-site risk in the vicinity of any specific installation depends on factors such as: a substance's packaging or containment and inherent physical properties such as vapour pressure; the process and storage conditions; and the geography of the local area. The approximate nature of the screen is explicitly recognised in Seveso II in so far as an installation may be granted a 'derogation' exempting the operator from preparing a full Seveso II 'safety report' if there is no major accident hazard potential.

At present, the basis of classification of substances and mixtures (preparations) is the EU's classification system according to the provisions of The Classification, Packaging and Labelling of Dangerous Substances Directive, CPL (67/548/EEC as amended) and The Classification, Packaging and Labelling of Dangerous Preparations Directive (99/45/EC as amended) [ECC, 1967 & 1999]. Approximately five thousand substances are listed in Annex 1 of CPL with a 'harmonised classification' that is legally binding in the EU. Other substances must be self-classified by the supplier or Seveso II installation operator.

The EU is replacing this classification system by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) [ECC 2007], [UN, 2005]. At an international level, it is anticipated that major benefits of adopting GHS will include:

[1]Major accident `shall mean an occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive, and leading to serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances' [ECC, 1997].

reducing classification costs to industry by having a single system in use; increasing the consistency and transparency of those public protection levels that are based on classification of chemicals [ECC, 2006a]; and reducing animal testing [UN, 2005].

The adoption of GHS at EU level is a major endeavour because there is not a one-to-one correspondence between GHS and the current EU classification system. Seveso II is only one of over twenty regulations that will potentially be affected. A proposed regulation on `Classification and Labelling of Substances and Mixtures based on the Globally Harmonised System' was published in August 2006 [EEC, 2006a] and updated in June 2007 [EEC, 2007] following stakeholder consultation. The currently proposed EU timescales for the adoption of GHS are for classifications of substances to be mandatory from Dec 2010 and of mixtures from June 2015 [Bierman, 2007].

The timescales for GHS are being coordinated with those for the introduction of the new EU regulatory framework for chemicals called REACH (Registration, Evaluation and Authorisation of Chemicals) under which enterprises that manufacture or import more than one tonne of a substance per year will be required to register it in a central database [European Commission, EIDG & EGD, 2007]. The registration process will include regulatory scrutiny of the substance classifications submitted by enterprises.

An EU 'ad hoc Technical Working Group on Seveso II and GHS' (TWG) is considering the implications for Seveso II when GHS is adopted. Essentially, the differences between the EU and GHS classification systems mean that if GHS classifications are used there is a potential for changes to:

- the *scope* of Seveso II where establishments move between being regulated under Seveso II and not being regulated under Seveso II, or vice versa; and
- the *regulatory attention* of Seveso II where establishments move between lower-tier and the more highly regulated top-tier status or vice versa.

AIMS OF INITIAL STUDY INTO IMPLICATIONS FOR UK INDUSTRY OF THE OPTIONS FOR SEVESO II IN TERMS OF ACUTE TOXICITY TO PEOPLE WHEN GHS IS ADOPTED

This paper describes an initial study into the implications for UK industry of the options for Seveso II in adopting GHS substance classifications for acute toxicity to people. (The study's remit did not include classification of mixtures or classification for toxicity to the aquatic environment and physico-chemical properties.) The study was carried out by the Health and Safety Laboratory, HSL, working with, and on behalf of, the Health and Safety Executive, HSE, which is the lead UK Competent Authority (regulator) for those aspects of Seveso II which relate to harm to people. The objective was to inform the considerations of a group of interested EU Member State Competent Authorities drawn from the EU TWG.

The overall aim of this initial study was to identify a means of adopting GHS for the Seveso II Directive in terms of acute toxicity to people that:

- will not increase the Directive's scope and regulatory attention unless this increases safety from major accidents since this would pose a needless cost burden on the chemical industry[2] and dilute the UK regulatory effort;
- will not increase the risk of a major accident by creating gaps in the regulation of installations; and
- will be transparent and straightforward for industry to apply.

THE OPTIONS FOR SEVESO II WHEN GHS IS ADOPTED AND APPROACHES USED TO STUDY THEM

At EU level, two approaches are under consideration for Seveso II in terms of acute toxicity to people when GHS is adopted:

- The first approach, the 'Dual Classification Option', is to continue to use the current EU classification system to determine the Seveso II Dangerous Category of a substance, whilst requiring industry to classify by GHS under other EU legislation. This option was proposed in [ECC, 2006b]. It is of interest because there would be no change to the regulation of installations under Seveso II.
- The second approach is to replace the EU classification system by GHS using one of the possible 'Alignment Options' whereby references in Seveso II to EU classifications are replaced by references to specified GHS classifications.

HSE's view is that the above long-term Dual Classification Option is not acceptable for Seveso II because using two classification systems in parallel would present an additional cost to both industry and EU Member State regulators compared to using GHS classifications alone.

To assess the possible Alignment Options, a two-part approach was used. The primary approach was to analyse the implications for UK installations based on consideration of: the operation of the Seveso II Aggregation Rule and Qualifying Quantities; and the differences between the EU and GHS classification systems for acute toxicity to people. The second, supplementary, approach was an initial study into the implications at a substance-by-substance level; it is limited by two confounding factors:

1. lack of knowledge of the GHS classifications that will be in use for individual substances within the EU since these will be made, at a future date by industry[3]; and

[2]The costs to UK industry of complying with Seveso II (which is implemented in the UK through the 'COMAH' Regulations) are estimated in [Brazier, 2003]. For example: the cost of analysis and safety report writing starts at about £35k (approximately 50k euros) for storage and warehouse installations, rising to about £220k (approximately 300k euros) for petroleum refineries; and for a fifth of companies considered, Seveso II safety report preparation diverts resources away from other safety activities.

[3]Under the proposed GHS regulation [ECC, 2007] enterprises would classify substances on the market by the end of the transitional period for substances; this is currently proposed to be Dec 2010 [Bierman, 2007]. This GHS classification does not require substance testing: it would be *notified* to the EU Chemicals Agency

2. the extreme difficulty of identifying substances that are not currently within the Seveso II regime[4] in terms of acute toxicity to people, but may be brought in depending on how Seveso II is adapted for GHS, since at present they have no Seveso II regulatory significance and are therefore not listed in any Seveso II related database.

INSTALLATIONS FALLING IN THE SCOPE OF SEVESO II IN TERMS OF SUBSTANCE CLASSIFICATIONS FOR ACUTE TOXICITY TO PEOPLE

Two of the ten Seveso II Categories of Dangerous Substance relate to acute toxicity to people: the Toxic and Very Toxic Categories. A substance falls in these categories if its *overall* EU classification (the most severe of the classifications for the oral, dermal and inhalation exposure routes) is Toxic (T) or Very Toxic (T^+).

Table 1 shows the Seveso II Qualifying Quantities for these Categories of Dangerous Substances. Dangerous substances present at an establishment in quantities greater than 2% of the relevant Qualifying Quantity need to be considered - the 'Aggregation Rule'. The Aggregation Rule also applies to Seveso II Named Substances for the relevant Categories of Dangerous Substances. Table 1 also shows the Qualifying Quantities for two examples of Named Substances that are acutely toxic.

In practice, in the UK many of the Seveso II installations that meet the Qualifying Quantity conditions for the Toxic or Very Toxic Categories of Dangerous Substances, do so on the basis of the Aggregation Rule. For example, installations manufacturing pharmaceuticals or agrochemicals tend to produce a range of substances with overall classification as T or T^+. Similarly, some installations also fall within the scope of Seveso II because they meet the Qualifying Quantity conditions for one or more Categories of Dangerous Substances relating to physico-chemical properties such as flammability: examples include refineries, and some manufacturing plants using toxic substances as intermediates.

Hence, for many UK Seveso II installations, any potential for a reduction in regulatory status and attention arising from a reduction in the severity of the acute toxicity classification of some substances, will in practice be offset by the operation of the Aggregation Rule and their Seveso II status for Dangerous Categories relating to physico-chemical properties. However, the converse is not the case: increases in the regulatory status of installations may arise from an increase in the severity of the acute toxicity classification

unless a substance has already been *registered* through the REACH legislation. Thereafter, the classification may change, for example when a substance is newly registered through REACH (when the classification will be subject to regulatory scrutiny). `It is anticipated that for some substances the classifications will vary. Over time, it is expected that notifiers and registrants will agree on a single entry [classification]' [ECC, 2007].

[4]For ease of reference, we refer to any substances that either fall into one of the Seveso II Dangerous Categories, or are named in Seveso II, as 'falling within the Seveso II regime' whether or not they lead to installations falling within the scope of Seveso II.

Table 1. Seveso II qualifying quantities for: the toxic and very toxic categories of dangerous substances not named in the directive, and two examples of named substances

	Qualifying quantity in tonnes of dangerous substances	
Dangerous substances	Lower-tier (Seveso II Articles 6 and 7 apply)	Top-tier (Seveso II Article 9 additionally applies)
Very Toxic Category	5	20
Toxic Category	50	200
Phosgene (a Very Toxic Named Substance)	0.3	0.75
Chlorine (a Toxic Named Substance)	10	25

of some substances, and in some instances this effect may be amplified by the operation of the Aggregation Rule.

OVERVIEW OF THE EU AND GHS CLASSIFICATION OF ACUTE TOXICITY TO PEOPLE

Conceptually, the EU and GHS classification systems are broadly similar in terms of acute toxicity to people *except* in the treatment of inhalation exposures to substances classified as gases under GHS.

Both systems assign substance classifications based on their acute toxicity following exposure via the oral, dermal and inhalation routes. For inhalation exposures, the physical state of a substance is taken into account: that is to say whether it is classified as a gas or vapour, or as an aerosol or particulate. Both systems rank the acute inhalation toxicity of substances classified as vapours, and as aerosols or particulates, in terms of the *mass* inhaled in a given volume. However, unlike the EU system, the GHS system makes a classification distinction between vapours and gases. For inhalation exposures to those substances classified as gases under GHS[5], the EU and GHS systems are fundamentally different:

- the EU system is set up to rank acute inhalation toxicity in terms of the *mass* inhaled in a given volume, whereas
- the GHS system is set up to rank acute inhalation toxicity in terms of the number of *molecules* inhaled in a given volume.

[5]Substances classified as gases under GHS are those for which the test atmosphere is a gas or a vapour near the gaseous state [UN, 2005]. A `vapour near the gaseous state' is not defined. No reason is given for classifying gases and vapours (gases in contact with the liquid or solid state) differently.

Table 2. 4hr LC_{50} and LD_{50} acute toxicity classification boundaries used under the GHS and EU classification systems for each exposure route/ physical state combination

Exposure route/physical state		Definitions of 4hr LC_{50} or LD_{50} (with units) used to set acute toxicity classification boundaries	Classification boundaries	EU classification	GHS classification
Oral		LD_{50} mass fraction (mg/kg)	<5	T^+	1
			5 to 25		2
			25 to 50	T	
			50 to 200		3
			200 to 300	Xn	
			300 to 2000		4
Dermal		LD_{50} mass fraction (mg/kg)	<50	T^+	1
			50–200	T	2
			200–400		3
			400–1000	Xn	
			1000–2000		4
Inhalation	Aerosols & Particulates (GHS terminology mists & dusts)	4hr LC_{50} mass fraction (mg/l)	<0.05	T^+	1
			0.05–0.25		2
			0.25–0.5	T	
			0.5–1		3
			1–5	Xn	4
	Vapours	4hr LC_{50} mass fraction (mg/l)	<0.5	T^+	1
			0.5–2	T	2
			2–10	Xn	3
			10–20		4
	Gases (EU as for vapours)	4hr LC_{50} mass fraction (mg/l) **EU only**	<0.5	T^+	
			0.5–2	T	
			2–20	Xn	
		4hr LC_{50} *volume* fraction (ppmV)* **GHS only**	<100		1
			100–500		2
			500–2500		3
			2500–5000		4

* For individual substances the conversion factor is: 4hr LC_{50} mg/l = 4hr LC_{50} ppmV × Molecular Weight g/mol ÷ 24,450 .

Table 2 shows the LD_{50} and 4hr LC_{50}[6] boundaries used to classify a substance under the EU system as T^+, T, or the less severe 'Harmful' (Xn), and under GHS as Category

[6]For a particular species, the LD_{50} is the dose that will kill 50% of the exposed population whilst the LC_{50} is the equivalent airborne concentration for a specified exposure period.

(Cat) 1, 2, 3 or 4 of which Cat 1 is the most severe. It can be seen that the correspondences between the boundaries fall into three groups:

1. For inhalation exposures to substances classified as vapours, the boundaries for the EU T and T+ and GHS Cat 1 and Cat 2 classifications are identical.
2. There is a straightforward shift in some boundaries for dermal and oral exposures and for inhalation exposures to aerosols. Therefore, for these exposures, an alignment can either be chosen for which substances may move to a less severe classification but not a more severe one, or alternatively where substances may move to a more severe classification but not a less severe one.
3. There is a correspondence depending on molecular weight for inhalation exposures to substances classified under GHS as gases but as vapours/gases under the EU system; this is illustrated in Figure 1. It can be seen that some lower molecular weight substances that have inhalation classification as T or T+ in the EU system, will not have a severe GHS classification (GHS Cat 1 or 2). Examples are the industrially important substances ammonia, sulphur dioxide, and ethylene oxide (a Seveso II Named Substance). Conversely, some higher molecular weight gases that are not classified as T or T+ in the EU system will have a relatively severe GHS classification (GHS Cat 2).

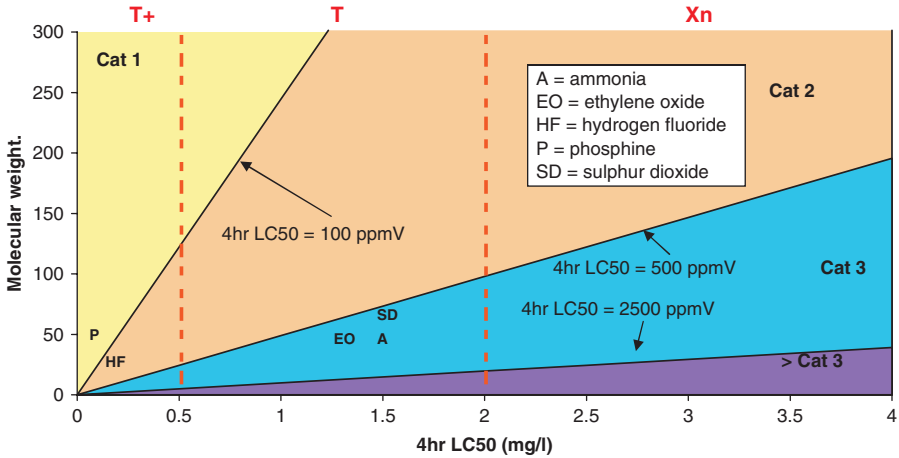

Figure 1. The 4hr LC_{50} boundaries used to define acute toxicity inhalation classifications for substances classified in the EU system as gases/ vapours but as gases under GHS: shown by dashed lines for EU T+, T and Xn, and by full lines for GHS Cat 1, 2, 3 or 4. Also shown are the 4hr LC_{50} values of four example lower molecular weight substances

OUTCOME OF PRIMARY ANALYSIS: THE SIMPLE ALIGNMENT OPTION WITH TECHNICAL CRITERIA

Based on the above, we considered the suitability of various alignments including the 'CPL' and 'Precautionary' Alignments discussed below. We identified a possible option that meets the study's aims, the:

- 'Simple Alignment' where references to the EU T^+ and T classifications are replaced by GHS acute toxicity Cat 1 and Cat 2 for all exposure routes and physical states. We refer to this as GHS Cat 1 being GHS T^+-equivalent, and GHS Cat 2 being GHS T-equivalent. This is supplemented by
- Technical Criteria to be used to retain other substances with a less severe GHS category that are currently within the Seveso II regime and correspond to installations with major accident hazard potential that would otherwise fall outside the scope of the Directive. This could, for example, be implemented by the addition of extra Named Substances in the Directive, and the use of an EU Technical Committee to include further Named Substances thereafter.

Our reasoning for this option, in order to best meet the UK aims stated above for adapting Seveso II for GHS, and assuming the EU uses the GHS classification distinction between gases and vapours, is as follows:

1. This alignment is the same for all physical states for inhalation exposures. Therefore, knowledge of the physical state used for classification is not needed thus maximising both the ease of use and transparency of this alignment.
2. This alignment minimises the potential for substances to move to a more severe equivalent classification, hence minimising the potential for increases in scope and oversight of Seveso II. This potential arises only for some higher molecular weight substances classified under GHS as gases where changes from T to GHS T^+-equivalent, or Xn to GHS T-equivalent are possible. (We are considering whether further technical criteria could be used to address this.)
3. With the exception of these higher molecular weight gases, this alignment means that substances may move to a less severe equivalent classification but not to a more severe one. Hence, with this exception, the regulatory scope and attention of Seveso II cannot increase. The opportunity for gaps in regulation to arise is limited by the operation of the Aggregation Rule and Dangerous Categories of Substances relating to physico-chemical properties. The use of the Technical Criteria as described above would act as a safety net to ensure that such gaps cannot arise.

PRIMARY ANALYSIS OF THE CPL AND PRECAUTIONARY ALIGNMENTS

We also considered the suitability of two other Alignments Options that have been of interest at EU level: the 'CPL Alignment' and the 'Precautionary Alignment'.

The CPL Alignment Option was the initial EU proposal for classification and labelling purposes [ECC, 2006a]. It differs from the Simple Alignment in aligning T with

GHS Cat 2 and 3 for the oral route and inhalation exposures to aerosols. It has the drawback of requiring knowledge of the physical state used for inhalation classifications. It also has significant potential to increase the regulatory scope and oversight of Seveso without increasing safety from major accidents, by bringing Xn substances into the Seveso II regime through GHS classifications for the oral route. The proposal has now been dropped pending review [ECC, 2007]; we do not consider it further.

The Precautionary Alignment Option aligns Seveso T^+ with GHS Cat 1 and Cat 2, and Seveso T with GHS Cat 3 for all exposure routes and physical states. It is of interest because it is the most straightforward alignment that would not result in a reduction in the scope of Seveso II because substances could not, in practice, move out of the Seveso II regime. Like the Simple Alignment, it has the advantage that the alignment is independent of the physical state for inhalation exposures.

However, this alignment does not meet the UK's aims because it has significant potential to increase the regulatory scope and oversight of Seveso without increasing safety from major accidents. For example, from Table 2 and Figure 1, it can be seen that Xn substances may be newly brought within the Seveso II regime as GHS-T equivalent through GHS classifications for the oral and dermal routes and inhalation exposures to vapours and higher molecular weight gases, or as GHS T^+-equivalent through GHS classifications for higher molecular weight gases.

INITIAL SUPPLEMENTARY STUDY INTO IMPACT ON UK INDUSTRY: SUBSTANCES, CLASSIFICATIONS, AND ASSESSMENT OF IMPACT ON INSTALLATIONS FORMING BASIS OF STUDY

The initial supplementary study into potential impact on UK installations considered two groups of substances:

1) Substances currently classified as T or T^+ that are important in the UK in terms of Seveso II - the 'UK Seveso T and T^+ substances'.
2) Substances that are not currently classified as T or T^+ but could newly be brought into the Seveso II regime under the Simple or Precautionary Alignment Options. To attempt to identify candidates, we trawled the EU High Production Volume Chemicals, HPVCs. These are the approximately 2,500 chemicals that were on the European market before September 1981 and are produced or imported in quantities exceeding 1,000 te per year. Data provided by manufacturers and importers on HPVCs such as tonnage and toxicity is held on the IUCLID database [Hansen, 1999]. HPVCs do not include all the substances of interest (examples are low production substances such as intermediates and reagents, or substances that have only been high production volume since 1981). We trawled approximately 1,300 HPVCs: all those with an EU harmonised classification that means they may potentially be brought within the Seveso II regime; and the approximately 40% of highest production volume[7].

[7]We used a list provided by the European Chemicals Bureau, ISPRA, in October 2006 of HPVCs ordered in groups of descending tonnage volume using latest reported volumes from manufacturers.

A confounding factor in identifying the second group of substances, and in using both groups for the study, is lack of knowledge of the GHS classifications that will be made by EU industry subject. We assigned relatively rapid *informal* GHS substance classifications (see Appendix) which without doubt will differ from the detailed industry GHS classifications for some substances. The informal GHS classifications were assigned to:

- 71 (30%) of the 238[8] UK Seveso T, T^+ substances. This was done using readily available toxicological data. (See Appendix for the data sources used and the constraints on substances that could be included.)
- 29 candidate substances that may be newly brought into the Seveso regime under the Precautionary Alignment. This was done using industry toxicity data from the IUCLID database. Substances with an EU harmonised classification that is inconsistent with this data were excluded from the study. No candidates were found that would be brought in under the Simple Alignment.

The regulatory impact on UK installations arising from classification changes to these substances was considered in a series of three meetings with HSE specialists. These were informed by Internet information on industrial use of the substances, together with HSE information on tonnages at specific UK installations for some substances. The aim was to identify changes to the scope or regulatory attention of Seveso II. We did not aim to, and could not, identify borderline establishments such as those which are borderline top-tier and would become borderline lower-tier. We do not consider that such cases have regulatory significance given that the Seveso II Qualifying Quantities act as an approximate screen only.

INITIAL STUDY INTO IMPACT ON UK INDUSTRY OF PRECAUTIONARY ALIGNMENT OPTION: OUTCOME

Two of the candidate Xn substances that may be newly brought into the Seveso II regime under the Precautionary Alignment based on industry toxicity data in IUCLID were found to have UK regulatory significance:

- sodium dodecyl sulphate [CAS 131-21-3] which is used in detergents and foamy personal hygiene products like shampoo, shaving foam and bubble bath;
- calcium diproprionate [CAS 4075-81-4] which is used as a mould inhibitor in processed foods such as cheeses, non-alcoholic drinks, confectionaries and some meat products, as well as in livestock and poultry feeds.

As a result, some UK formulators of processed foods, animal feeds, detergents or frothy personal hygiene products might become Seveso II sites. (A formulator blends ingredients to make final products: therefore a site may have stock tanks or other relatively large storage of ingredients.)

[8]See list at http://www.hse.gov.uk/hid/haztox.htm. HSE uses this in connection with: the assessment of Seveso safety reports, and the provision of advice on land-use planning in the vicinity of installations.

Our trawl of candidate substances from IUCLID will only have identified a small fraction of the substances that might be newly brought into the scope of Seveso. Hence, whilst the GHS classification assigned by industry in future may differ for these two example substances, our view is that this initial study confirms the potential for the Precautionary Alignment to widen the scope of the Seveso II Directive without giving an increase in safety from major accidents.

INITIAL STUDY INTO IMPACT ON UK INDUSTRY OF SIMPLE ALIGNMENT OPTION: OUTCOME

For the 71 UK T, T^+ substances considered, the effect of the Simple Alignment on overall classification is that:

- between 29% and 43% of overall T^+ classifications drop to overall GHS T-equivalent (between 15 and 22 substances out of 51); and
- between 30% and 45% of overall T classifications drop to overall GHS-equivalent classification less than T – we refer to this as 'GHS sub-T equivalent' (between 6 and 9 out of 20 substances).

We quote a range because for some substances the overall classification is dependent on the physical state assumed for inhalation exposures. No examples were found of substances moving from T to GHS T^+-equivalent. Table 3 gives the classifications for example substances and their current proposed EU harmonised GHS classification[9].

The classification changes were only found to have regulatory significance for two substances: the lower molecular weight gases ammonia and sulphur dioxide. As a result of their overall classification change from T to GHS sub-T equivalent, UK installations with major accident hazard potential would fall outside the scope of Seveso. To address this, they would be made Named Substances.

No other adverse regulatory impact was found. For one substance, it was found that there would be a reduction in the scope of Seveso but that this would be beneficial as the reduction applies to installations with no major accident hazard potential to people[10]. For one substance, information on inventories at UK installations is limited but there is none to suggest that there would be an unacceptable regulatory impact. For the remaining

[9]The current proposal [ECC, 2007] is that EU harmonised acute toxicity classifications would be translated to *minimum* GHS classifications except for T^+ for dermal exposures which translates directly to GHS Cat 1. Industry would increase the classification over this minimum where appropriate. An alternative proposal of interest at EU level is *maximum* harmonised GHS classifications that industry would decrease where it can be demonstrated that this is appropriate.

[10]Potassium dichromate: some UK surface engineering industry establishments are brought into the scope of Seveso II solely on the basis of this substance's inventory. Under the Simple Alignment they would be out of scope. http://www.hse.gov.uk/surfaceengineering/comahguidance.pdf gives an HSE analysis showing that there is no off-site major accident hazard potential in terms of acute toxicity to people for the quantities of potassium dichromate typically stored.

Table 3. Effect of simple alignment on the overall classification for example substances with breakdown by Oral (O), Dermal (D), and Inhalation (I) routes. Listed are the: current EU classification; *informal* GHS classification followed by its EU equivalence under the simple alignment; and proposed harmonised (H) GHS classification marked * where a minimum

Substance name	Substance CAS No.	Classification	O	D	I	Over-all	Effect of simple alignment on overall classification
Anhydrous ammonia	7664-41-7	EU	—	—	T	T	Change: EU T to GHS
		GHS	—	—	3	3	Xn- equivalent based on
		GHS-equiv	—	—	Sub-T	Sub-T	*informal* GHS classification
		H-GHS	—	—	3*	3*	
Ammonium dichromate as CrVI	7789-09-5	EU	T	Xn	T^+	T^+	Change: EU T^+ to GHS T-
		GHS	3	4	2	2	equivalent based on *informal*
		GHS-equiv	Sub-T	Sub-T	T	T	GHS classification
		H-GHS	3*	4*	2*	2*	
Methylene dithio-cyanate	228-652-3	EU	T	—	T^+	T^+	No change: EU T^+ to GHS T^+-
		GHS	3	—	1	1	equivalent based on *informal*
		GHS-equiv	Sub-T	—	T^+	T^+	GHS classification
		H-GHS	3*	—	2*	2*	

substances, there is no change in regulatory attention or scope of corresponding installations due to the operation of the Aggregation Rule and the Dangerous Categories related to physico-chemical properties.

No substances were found that would be newly within the Seveso remit. As described above, the potential for this to occur is limited, arising only through GHS inhalation classifications for some higher molecular weight gases.

Our view is that this initial supplementary study supports the conclusion that the Simple Alignment with Technical Criteria is a suitable option and identifies ammonia and sulphur dioxide as examples of substances that would need to be Named Substances in the adapted Seveso II Directive. Further work is underway at HSL to develop the Technical Criteria.

STATUS OF STUDY AND NEXT STEPS

In March 2007, this initial UK study was disseminated to the group of interested Member States drawn from the EU TWG. Together with studies from the Netherlands and Germany it formed the basis of discussion on acute toxicity at the group's 2nd meeting in September 2007. It is anticipated that at the 3rd meeting in November 2007, an agenda will be mapped out for technical sub-groups to consider the issues for toxicity to people, the aqueous environment and physico-chemical properties in order to facilitate data sharing and pooling of expertise between Member States.

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GLOSSARY

Aerosol (mist): liquid droplets of a substance or mixture suspended in a gas (usually air) [UN, 2005].
Particulate (dust): solid particles of a substance or mixture suspended in a gas (usually air) [UN, 2005].
ppmV: parts per million by volume (cm^3/m^3).
Vapour: the gaseous form of a substance or mixture released from its liquid or solid state [UN, 2005].

APPENDIX: ASSIGNMENT OF INFORMAL GHS CLASSIFICATIONS

For the purposes of this study, informal GHS classifications were assigned without carrying out the detailed checks and data gathering that would, for instance, form part of the work of EU harmonised classification assignment. For example: we did not check that data came from valid well-performed tests; where information was incomplete we did not request further details from the source; and we only considered data on the notional 'preferred test species' rather than carrying out a full evaluation of all available experimental animal data. For those substances that have an EU harmonised classification, we generally could not use the corresponding LC_{50} and LD_{50} as this information was not retained in the earlier years of the programme. (The need to publish the scientific motivations of classifications was proposed in [Ruden, 2003] which discusses the accuracy of harmonised classifications.) For inhalation exposures, assigning the physical state of the test atmosphere appropriately is non-trivial for substances that are liquids at ambient conditions: it may not be specified in the available account of the test, and testing may have been conducted using a mixture of physical states. Therefore, we considered all possible physical states. For instance, based on the manufacturer's toxicity data in IUCLID, tridemorph (CAS 24602-86-6), has overall GHS acute toxicity Cat 4, Cat 3, or Cat 2 according to whether the aerosol, vapour or gas state is assumed.

For the UK T, T^+ substances, the data sources used were toxicological reviews including: CICADS[11], ATSDR[12], OECD SIDS[13], EU Risk Assessment Reports on HPVCs under regulation 793/93/EEC [ECC, 1993], WHO Environmental Health Criteria reports[14], draft Technical Support Documents prepared by HSE for the EU ACUTEX project [Wood, 2006]; and UK Pesticide Safety Directorate substance evaluations carried

[11]CICADS: `Concise International Chemical Assessment Documents' International Programme on Chemical Safety IPCS Co-operative Programme of WHO/ILO/UNEP.
See http://www.inchem.org/pages/cicads.html.
[12]ATSDR: US `Agency for Toxic Substances and Disease Registry', US Department of Health and Human Services. See http://www.atsdr.cdc.gov/2p-tox-substances.html.
[13]SIDS: `Screening Information Dataset for High Production Volume Chemicals', Organisation for Economic Co-operation and Development (OECD). See: http://www.inchem.org/pages/sids.html.
[14]See: http://www.who.int/ipcs/publications/ehc/ehc-numerical/en/index.html.

out[15] under the EU 'Pesticides' Directive 91/41/EEC on Plant Protection Products [ECC, 1991]. Additionally, confidential HSE records were accessed, discussions were held with HSE toxicologists involved in the EU harmonised classification process to clarify the basis of decisions taken for some substances and, where no other information was available, Manufacturer's Material Safety Data Sheets were used. Only 30% of the UK T, T^+ substances were considered. For the remainder either: data were not available for all exposure routes or were not in a format that would allow a comparison with classification criteria; the overall EU harmonised classification is not supported by the data regardless of the physical state assumed for inhalation classifications; or the EU harmonised classification is corrosive but not T or T^+ although there are data to support the latter. (Inconsistencies with corrosive substances can arise because of priorities, unrelated to Seveso II, within the administrative system for agreeing the EU harmonised classifications.)

[15]Evaluations carried out by the UK Pesticide Safety Directorate Advisory Committee on Pesticides, see: http//www.pesticides.gov.uk/psd_evaluations_all.asp.