

Estimating possible impact of the Seveso III Directive for the UK to inform negotiation and implementation

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The Seveso III Directive entered into force on 13th August 2012 following several years of negotiation. Work is underway on its transposition into revised Control of Major Accident Hazard (COMAH) Regulations, which will come into force on 1st June 2015. The main driver for the new Directive was the change in classification system for chemicals within the EU, from the current Dangerous Substances Directive (implemented in the UK as the Chemical Hazards (Information and Packaging) (CHIP) regulations) to the new Classification Labelling and Packaging Regulation (CLP), also to be implemented in June 2015.

This paper discusses the main changes to be introduced by Seveso III, including scope changes and the requirement for increased public information. To inform the negotiation of the Directive a questionnaire was used to obtain information from UK COMAH sites. This allowed the effects of different alignment options for acute toxicity, between Seveso III and CLP, to be compared in terms of potential changes in numbers and types (top tier or lower tier) of UK COMAH sites. The analysis process and results are discussed. The negotiation was able to minimise the net number of new COMAH sites due to scope changes, although some 'churn' is expected with some sites leaving the COMAH regime and some new sites coming in. Classification changes may in future create new COMAH dangerous substances and nitric acid is an early example. Article 4 of Seveso III makes provision to remove substances from scope at EU level. Nitric acid solutions may be a suitable example to use as a test case in discussions on the implementation of Article 4.

Keywords: Seveso; COMAH; GHS; classification; toxicity; CLP; major accident

Introduction

The Seveso III Directive (EC, 2012) entered into force on 13th August 2012 following several years of negotiation. Work is underway on its transposition into the revised Control of Major Accident Hazard (COMAH) Regulations which will come into force on 1st June 2015. The main driver for the new Directive was the change in classification system for chemicals within the EU, from the current Dangerous Substances Directive (implemented in the UK as the Chemical Hazards (Information and Packaging) (CHIP) regulations) to the new Classification Labelling and Packaging Regulation (CLP) (EC, 2008), also to be implemented in June 2015.

The bulk of the Seveso III Directive will be transposed into regulations which will replace COMAH 1999, and be enforced by the COMAH Competent Authority (CA) (comprising the Health and Safety Executive (HSE), the Environment Agency (EA), the Scottish Environmental Protection Agency (SEPA), and Natural Resources Wales (NRW)). The Department for Communities and Local Government (DCLG), the Scottish Government and the Welsh Government have responsibility to implement the Directive's land use planning controls, which are a devolved matter, within the same timescales.

This paper first summarises the main changes between Seveso III and Seveso II. The remainder of the paper is concerned with the development of the technical evidence base which supported the negotiation of the Directive by the UK. This will form an input to the impact assessment for the revised COMAH regulations. This focuses on the change of scope of Seveso III due to alignment with the CLP Regulation. Ongoing issues due to classification changes are also discussed.

Seveso III main changes

Scope changes

As stated above, the main reason for the Seveso III Directive was the need to align with a different chemical classification system. The CLP Regulation is based on the UN-based Globally Harmonised System (GHS) of classification. There was a need for alignment of the Seveso II threshold quantities for top tier (TT) and lower tier (LT) sites, which were based on the classification system in the Dangerous Substances Directive (DSD) (EC, 1967), with the categories of the new classification system. Much of the work was carried out by a technical working group (TWG) (Gyenes, 2009). The aim was to minimise scope changes while maintaining existing levels of protection against major accident hazards. Any changes in the threshold quantities of existing dangerous substances or the introduction/removal of dangerous substances have the potential to change whether a site is within scope of the Directive and whether it is TT or LT.

Acute toxicity

This is the area with the greatest changes because the classification is different between the DSD and CLP. The DSD defines two categories for acute toxicity which align with the current Seveso II threshold quantities. These are 'toxic' (T) and 'very toxic' (T+). In addition, there is a 'harmful' (Xn) category which is out of scope of Seveso II. CLP uses the GHS acute toxicity categories 1, 2, 3 and 4. For both systems, categories can be defined according to the lethality response for the oral, dermal or inhalation exposure routes. Categories are determined by the LD₅₀ (dose which will kill 50% of a test population) or the 4h LC₅₀ (concentration which will kill 50% of a population given a 4 hour exposure). The physical form of the substance (vapour; liquid or solid; aerosol; or gas) is also taken into account for the inhalation route. For the inhalation of gases, the CLP categories are defined in units of ppm (parts per million), whereas in the DSD, this category was defined in units of mg/litre.

Figure 1 shows the relationship between these old and new categories. The blue dotted vertical lines represent where the T+/T and T/Xn boundaries were for the DSD. The shading shows the Seveso III alignment: dark blue for those CLP categories which are aligned with the current T+; and light blue for those which align with current T.

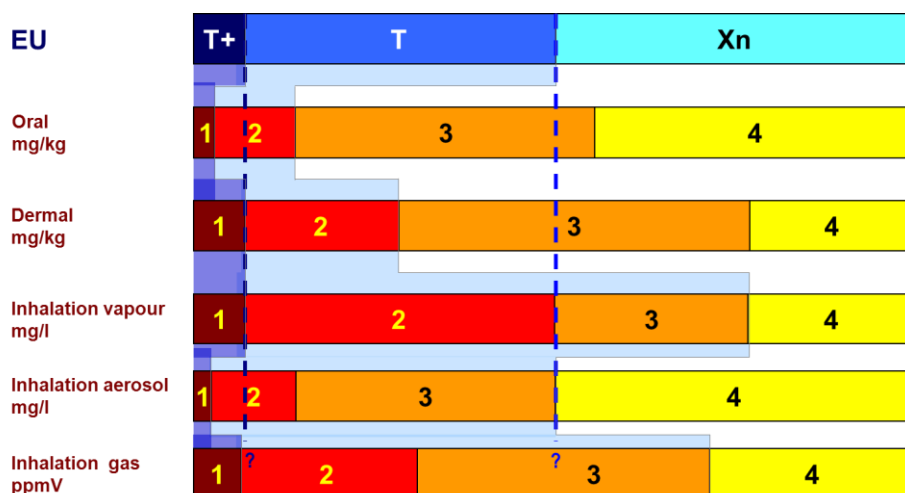


Figure 1: Comparison between Seveso II / DSD and Seveso III / CLP (GHS)

Key changes under this alignment option are:

- Some substances which are currently classified as T+ (oral and inhalation aerosol exposure routes) will become GHS Category 2 and given higher qualifying quantities equivalent to T. Their contribution to whether a site was top-tier, lower tier or out of scope of Seveso would therefore be reduced due to the change in classification.
- Many substances which are GHS Category 3 by the oral and dermal routes are currently classified as toxic, but under the current alignment they would fall out of scope.
- Some substances which are GHS Category 3 by the inhalation vapour route are currently classified as harmful (Xn). These would newly come into scope.
- Some substances which are GHS Category 3 by the inhalation gas route may newly come into or out of scope but the comparison is more complicated because of the different units (for CLP the categories are defined in units of ppm, whereas DSD used mg/litre; hence the question mark in Figure 1).

There is also a new category for specific organ toxicity (single exposure) (STOT) Category 1.

Physical chemical properties

The main changes are:

- New categories for flammable aerosols (aerosol canisters with flammable contents) and pyrophoric solids;
- Flammable liquids have changes to flash point definitions. There are also reduced threshold quantities for flammable liquids maintained at a temperature above the boiling point.

Environmental

There is no change to current threshold quantities. However CLP has introduced a new method for classification of mixtures (see Section 4 below).

New named substances

A number of new named substances have been added:

- Heavy fuel oils and alternative fuels have been added to the existing petroleum products named substance. The threshold quantities are unchanged. This provides higher thresholds for some heavy fuel oils which testing shows to have environmental toxicity (being a named substance takes precedence). The classification changes for heavy fuel oil applies to Seveso II from February 2014. HSE (2013) describes the CA position on this.
- Low molecular weight toxic gases (ammonia, hydrogen sulphide, boron trifluoride) which would otherwise have been reduced in scope due to the use of ppm units for alignment of gases for inhalation toxicity (Trainor 2008a, b).
- A number of new toxic named substances reduce the likelihood that the alignment for acute toxicity (see Section 2.1.1) will bring additional sites into scope.

- Mixtures of sodium hypochlorite containing less than 5% active chlorine are not classified as Aquatic Acute Category 1 (this prevents classification changes from bringing household bleach into scope in most cases).

Article 4

Article 4 makes provision for substances to be assessed at EU level with the possibility that they could be removed from the scope of the Directive. Potentially this is a means to address any anomalies that might in future be introduced by changes in the classification of substances (see also Section 4 below). The way that Article 4 will be implemented is still under discussion.

Public information

Seveso III has been brought in line with the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (UN, 1998). This is reflected in the public information article of Seveso III which requires information regarding sites and their hazards to be made permanently and electronically available to the public.

The main change for TT establishments is the requirement that the full safety report (subject to issues of security/commercial confidentiality) and inventory of substances be made available to the public on request. While this is actually a requirement in Seveso II, it has up until now been protected by a Secretary of State Direction since the terrorist attack on USA on 11th September 2001. That Direction will fall when the current COMAH regulations are replaced by revised regulations. Work is in progress (Durling, 2014) to develop guidance on the drafting of Non-Technical Summaries (NTS) by top tier sites of their safety reports. These would not include anything commercially sensitive nor with security implications, and could then be provided to the public on request to meet the Seveso III requirement.

Both TT and LT sites will have to provide information as set out in Annex V Part 1 of the Directive. This includes the name / trade of the operator and full address of the establishment; confirmation that the site is subject to the regulations; a simple explanation of the activity or activities undertaken; the common or generic names of the substances covered by Annex 1 Part 1, the generic name or the hazard classification of the relevant dangerous substances used at the establishment that could give rise to a major accident; general information about how the public concerned will be warned; the date of the last site visit by CA inspectors; and details of where more relevant information can be obtained. Making all of this information available is a new requirement for LT sites but for TT sites the only new requirement is providing details of the last site inspection.

Annex V Part 2 requirements are in addition to those in Part 1 but are for TT sites only. The additional requirements for TT sites are to provide a summary of major accident scenarios and the control measures to address them; and to indicate whether the site is close to the territory of another Member State with the possibility of a major accident with transboundary effects.

All of the above has to be available electronically and a CA project is working to develop an IT platform to deliver this requirement.

Notifications

It is anticipated that the majority of sites will have to re-notify because of the change from DSD to CLP. Existing establishments will have one year from 1st June 2015 to notify.

Emergency plans

There are some small changes to the requirements for external emergency plans due to the information requirements in Annex V. These are to:

- include responses to major accident scenarios from the safety report;
- consider possible domino effects;
- include the environmental impacts of domino effects;
- provide arrangements for providing neighbouring sites (not just domino sites) with information on accidents and actions to be taken.

Management of ageing equipment and corrosion

Management of ageing equipment and corrosion is now specifically required as part of the safety management system (SMS) detailed within Annex III of the Directive. This has always been covered within COMAH guidance and is the subject of a current COMAH national inspection project (COMAH Competent Authority, 2010).

Estimating the impact due to change of scope for acute toxicity

Methodology

Objectives

The initial aim was to provide evidence in terms of the numbers of UK sites expected to change COMAH status (to support the negotiations of the alignment for acute toxicity). A number of alignment options were in discussion during the negotiations. All of these options aligned the current qualifying quantities for 'very toxic' (T+) substances with GHS Category 1 substances. For the alignment with the current qualifying quantities for 'toxic' (T) substances, all options included GHS Category 2 substances, but there were different proposed options for which of the GHS Category 3 exposure routes to also include. The options are defined by Table 1.

The 'simple' alignment was discussed by Trainor (2008a, b). The E* and E alignment options were discussed by COWI (2010) in the impact assessment for the draft of the Seveso III Directive (EC, 2010), which was based on the E* alignment. The X, Y and Y* alignments were proposed during the course of the negotiations of the Directive. The final agreed directive (EC, 2012) was based on the E alignment.

Once the Seveso III Directive had been agreed, a further aim was to provide data for the impact assessment of the revised COMAH regulations.

Table 1: Alignment options during negotiation

Alignment option	Whether GHS Category 3 acute toxicity is within scope				
	Oral	Dermal	Inhalation		
			Vapour	Aerosol	Gas
Simple alignment	No	No	No	No	No
E* alignment	No	Yes	Yes	Yes	Yes
E alignment	No	No	Yes	Yes	Yes
X alignment	No	Yes	No	No	Yes
Y alignment	Yes	No	No	No	Yes
Y* alignment	No	No	No	No	Yes

UK survey of COMAH sites

COWI (2010) considered the impact in terms of the number of substances that could change scope, which does not necessarily equate to the number of sites changing status. Considerable data are needed to do this, specifically the substances and quantities held by each site. Moreover, there is a need to identify substances which could newly come into scope. Trainor (2008a, b) had attempted to do this by considering the substances in Annex 1 of the DSD and trawling high tonnage substances in the IUCLID database (OECD, 2012). It was, however, considered unlikely that all such substances had been identified, and there were also issues with the availability of toxicity data for many substances.

HSE commissioned ORC International to carry out a survey of UK COMAH sites (ORC, 2011). Two questions in the survey related to assessing the impact from acute toxicity alignment options. Question 7 asked for on-site tonnages of substances which Trainor (2008a) had already identified as being relevant. Question 8 asked for information and on-site tonnages of any other substances or mixtures which were classified as T+, T or Xn. In addition, material safety datasheets (MSDSs) were requested for each substance identified. This was to obtain the necessary toxicity data to allow the identified substances to be classified under GHS. Use of MSDS data was a compromise to reduce the burden on industry in supplying toxicity data and to be able to obtain results early enough to be useful to inform the negotiations. It was anticipated that the MSDS data would not be ideal but they were found to be worse than expected (Wilday, 2012).

Determination of GHS categories of identified substances

ORC International provided survey data to HSL in anonymised format with each site identified by a number. Approximately 1650 MSDSs were provided to HSL as hard copy. HSL carried out a partial analysis of the impact of different alignment options for the UK and this was reported by ORC (2011). However, the partial analysis was carried out to a tight time-scale which allowed analysis of only about 50% of the data. Furthermore, a simplistic analysis was carried out for mixtures, which were assumed to be solutions in water. More detailed subsequent analysis showed that this was not always the case.

The survey and MSDS data were collated into two spreadsheets, one each for responses to Question 7 and Question 8 of the survey. For Question 7, GHS categories for acute toxicity had been previously determined during the earlier analysis (Trainor, 2008a, b). For Question 8, the GHS category was determined, if permitted by the available data, based on the MSDS, using the methods in the CLP Regulation. For mixtures, sufficient data for a definitive GHS classification was rarely available.

The spreadsheets produced the following for each substance:

- Estimated GHS category for acute toxicity (for each physical state when the physical state had not been specified for the LC₅₀ for inhalation exposure), based on MSDS data;
- Whether the substance was potentially in any of the 'areas of interest' (A1 to A9), defined by Figure 2. These imply possible change to the scope of the substance;

- Category under the current DSD classification system;
- The existing (Seveso II) and new (Seveso III) qualifying quantities for each alignment option (this was inserted manually for named substances);
- Whether this implied any possible change in the substance’s treatment under Seveso, for each of the different alignment options;
- The tonnage held on site as a fraction of the qualifying quantity, for Seveso II and for each alignment option.

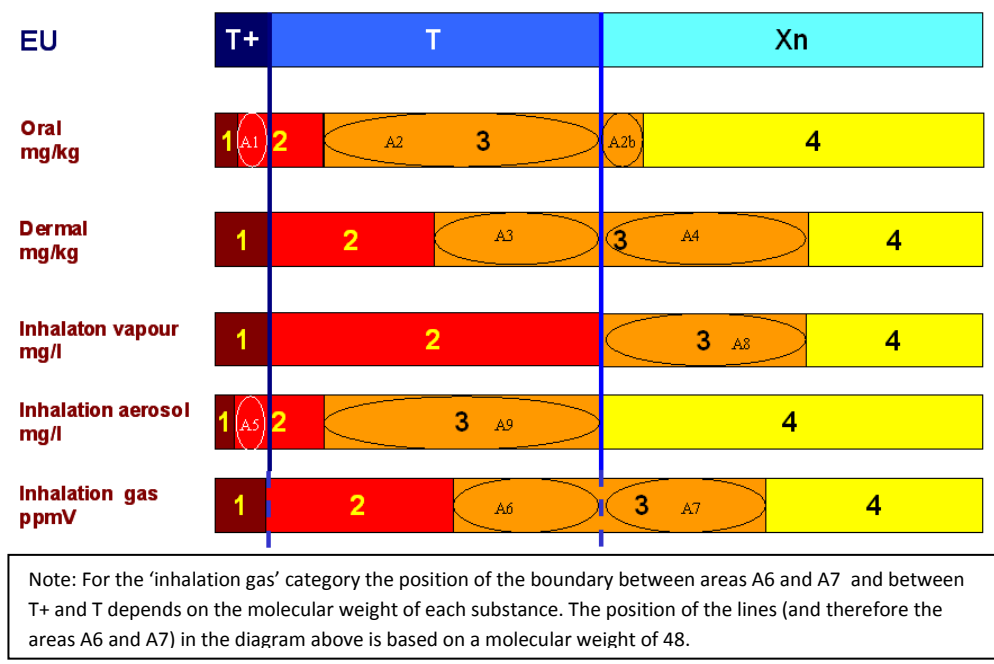


Figure 2: Definition of 'areas of interest' (A1-A9)

Estimation of impact on existing COMAH sites

The Seveso status of a site (TT, LT or non-Seveso) depends on whether the aggregated ratio of the tonnages held to the relevant qualifying quantities for each substance equals or exceeds 1, as defined in Schedule 1 of both Seveso II and Seveso III. Three aggregation calculations are carried out: for health hazards (acute toxicity), physical/ chemical hazards (flammability), and for environmental hazards. For the health hazards aggregation, information is needed on all the substances with acute toxicity classifications and their tonnages for any given site.

Data resulting from the Question 7 and Question 8 responses were combined and sorted by site in the spreadsheets. This allowed the data on all substances identified for each site to be viewed together. For most sites, this included a mixture of substances for which it had been possible to estimate the GHS category, and substances and mixtures for which it had not. Expert judgement assessed the potential change in Seveso status of the site as a whole, taking account of:

- which substance(s) at the site had been identified as potentially changing scope under Seveso III;
- which area(s) of interest were involved and hence the direction of the change(s) in scope;
- the tonnages of all relevant substances versus their qualifying quantities;
- the proportion of substances present at the site for which inadequate data were available from the survey;
- whether the status of the site would be dominated by the physical/chemical or environmental aggregation calculations, rather than that for health hazards.

Because of the inherent uncertainty in this analysis, each site was scored in terms of the likelihood of it changing its COMAH status, according to Table 2. The percentage of existing COMAH sites, which could change status in different ways, was then estimated based on the sample of sites for which sufficient data were available.

Table 2: Probabilities of sites changing their COMAH status

Likelihood of change	Probability
No change	0

Possible	0.1
Probable	0.6
Definite	1

Estimates of numbers of new COMAH sites

The identification of substances that could newly come into scope of COMAH was difficult and hence so was the estimation of numbers of new COMAH sites. Two approaches were used to estimate the number of new COMAH sites:

1. A crude assumption was made that the number of new sites would equal the number of sites which would have newly become top tier due to substance(s) which had newly come into scope, if the site had not already been top tier.
2. Substances which would newly come into scope were identified, as far as possible using the work of Trainor (2008a, b) and the results of the questionnaire analysis. The industrial uses of these substances were identified by internet search. Expert judgment was then made as to the possible numbers of new COMAH sites. This was done by an experienced process safety engineer.

Peer review

The lists of substances that could potentially change scope due to Seveso III were peer reviewed by an HSE toxicology specialist. This had the effect of removing more than 50% of the identified substances from the lists, largely a result of the poor quality of the MSDS data.

For the final agreed Seveso III alignment, all substances which were identified as changing scope were reviewed against the data in the Classification and Labelling (C&L) inventory on the European Chemicals Agency's web-site (ECHA, 2012). This contains both harmonised classifications under the CLP regulation (EC, 2008) and classifications notified under REACH (EC, 2006) but not peer reviewed. The data were only newly available at the time of the peer review. Not all substances were peer reviewed, rather just those identified as potentially changing scope. Therefore it is likely that some substances were determined as not changing scope when, in fact, they will change scope.

Expert judgments in terms of the number of new COMAH sites were independently reviewed by a second experienced process safety engineer.

Results

Alignment options considered during negotiation

The analysis was made on the basis of the results from 188 sites. This was the number of sites judged to have sufficient available data to allow conclusions to be drawn about the effects of the different alignment options. The estimated number of sites which would change their status (LT, TT or sub-COMAH), based on a total of 940 COMAH sites, is shown in Table 3. (Note that Table 3 and subsequent tables show fractions of sites to retain a higher number of significant figures. Obviously this is not physically realistic).

Table 3: Number of sites expected to change status for different alignment options

Alignment option	E	E*	X	Simple	Y	Y*
LT to TT	6.5	10.0	5.0	0	1.5	0
New COMAH sites	33.3	43.6	31.5	0	10.3	31.5
TT to LT	7.9	7.9	11.6	9.1	12.6	8.5
LT to sub-COMAH	18.5	18.5	18.5	22.0	10.0	10.5
<i>Net change in COMAH sites</i>	+14.8	+25.1	+13	-22.0	+0.3	+21.0

For the X, Y and Y* alignments, an additional issue was that they included only some of the physical states (vapour/aerosol/gas) for Category 3 inhalation. This would have posed a practical problem as the physical state would not necessarily be identified in safety data sheets and other sources of toxicity data.

The numbers of new COMAH sites in Table 3, for each alignment option, are based on the crude estimate that the number of new sites would equal the number of sites which (if the site had not already been top tier) would have newly become top tier due to substance(s) which had newly come into scope. For the E and E* alignments, an alternative estimate was made for the potential number of new COMAH sites, which involved identifying new substances which could come into scope and making an expert judgment on the number of new sites that this might bring in for each substance. The results are summarised in Table 4. The

alternative estimate had good agreement with the crude estimate for the E* alignment, but less so for the E alignment. Further details of this analysis are given by Wilday (2014).

Table 4: Estimates of numbers of new COMAH sites for the E and E* alignments

Estimation method	Estimated number of new COMAH sites	
	Final alignment (E)	Proposed alignment (E*)
Crude estimate (Table 3)	33	44
Expert judgment	10	50

It should be noted that all these estimates are approximate due to the assumptions which have had to be made at many stages in the analysis, as described above. Table 3 shows that there would also be a significant ‘churn’ of COMAH sites, i.e. sites going out of scope of COMAH and being replaced by new sites which were previously not in scope.

Potential new named substances identified for negotiation

To support the Seveso III negotiations, information was developed in terms of which substances could reduce the impact of proposed changes if they became new named substances.

Alignment options E and E* would increase the number of COMAH sites. Table 5 lists those substances which the UK survey indicated were of most importance for UK COMAH sites. They were all subsequently made new named substances with higher thresholds than the generic Seveso III thresholds for GHS Category 2 or 3, to minimise the impact.

Table 5: Identified substances with the most potential to increase the number of UK COMAH sites

Substance name	CAS number
methyl acrylate	96-33-3
diisopropylamine	108-18-9
tert-butyl acrylate	1663-39-4
3,5-dimethyl-1,3,5,2H-tetrahydrothiadiazine-2-thione (‘Dazomet’)	533-74-4
dipropylamine	142-84-7

It should, however, be noted that it was very difficult to identify substances that could potentially bring in new COMAH sites. While considerable efforts were made based on the survey results and previous work, it is nevertheless possible that some substances have not yet been identified which could bring in new COMAH sites.

Seveso III Directive final alignment and named substances

Table 6 summarises the results in terms of estimated changes in numbers of existing COMAH sites. There is uncertainty in these estimates and so both lower bound and upper bound estimates have been developed. The lower bound estimate was obtained by taking account of new named substances and reviewing the remainder that were in ‘areas of interest’ in Figure 2. As discussed in 3.1.6 above, it was not possible to review substances, that were not initially identified as being in the areas of interest in Figure 2, against harmonised classifications and REACH notifications. Therefore a number of substances previously thought to cause a change of scope were removed from the analysis, but there was no identification of additional substances which could cause a change of scope but were wrongly classified previously. An estimate of the upper bound maximum for the likely number of sites which could change status was based on the original survey analysis without removing substances due to their later harmonised classifications or REACH notification data. This is expected to provide a conservative upper bound.

The estimates of numbers of new COMAH sites in Table 6 was based on the crude assumption that the number of new sites would equal the number of sites which, if the site had not already been top tier, would have become top tier due to substance(s) which had newly come into scope. An alternative estimate was also made. This involved identifying new substances which could come into scope and making an expert judgment on the number of new sites that this might bring in. Further detail is provided by Wilday (2014). The results are summarised in Table 7.

Table 6: Number of sites expected to change status for final agreed Seveso III alignment

	Lower bound estimate	Upper bound estimate
LT to TT	0.5	7.5
New COMAH sites	1.5	25.5
TT to LT	10.9	19.9
LT to sub-COMAH	15.4	21.5
Overall net change in COMAH sites	-13.9	+4

Table 7: Estimates of numbers of new COMAH sites for final agreed Seveso III alignment

Estimation method	Estimated number of new COMAH sites	
	Lower bound estimate	Upper bound estimate
Crude estimate	1.5	25.5
Expert judgment	4.5	10

The analysis indicates that the net number of new COMAH sites is in the range -14 to +4, with some ‘churn’ of sites. There is considerable uncertainty in the number of new COMAH sites that could be brought in. The expert judgment suggests that the upper bound crude estimate of 25.5 new sites may be an overestimate. This would imply that the upper bound estimate of net numbers of new COMAH sites in Table 6 may also be an overestimate.

Classification change issues

While not an issue of alignment between Seveso III and CLP, changes in classification of substances can also have an impact on whether sites are in or out of scope of Seveso. Classification changes are usually a result of improved scientific data or analysis, with the REACH regulation acting as the primary stimulus for classification of substances. New harmonised classifications of substances may result from improved data and analysis. Two examples are given below.

M-factors for substances with environmental toxicity

The CLP regulation introduced the so-called M-factor method for determining the aquatic toxicity of mixtures. Aquatic toxicity Category 1 (either acute or chronic) applies when the LC_{50} is less than 1 mg/litre. An M-factor is assigned according to Table 8 and the effects of the substance in the mixing rule are multiplied by the M-factor. Therefore a very small concentration of a very toxic component can have a large effect on the classification of the mixture as a whole. It will therefore be necessary for COMAH sites and potential COMAH sites to take account of any changes in the environmental classification of mixtures.

Table 8: M-factors

4 hour LC_{50} (mg/litre)	M-factor
0.1 - 1	1
0.01 – 0.1	10
0.001 – 0.01	100
0.0001 – 0.001	1000

Nitric acid

The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) adopted proposals to change the harmonised classification and labelling of nitric acid on 31 May 2013 (ECHA 2013). This newly gives nitric acid the classification of Acutely Toxic by Inhalation Category 1. This change in classification of the pure acid has a consequential effect on dilute solutions as shown in Table 9.

Nitric acid is a strong mineral acid. It is usually manufactured by the oxidation of ammonia followed by distillation. Atmospheric distillation of the dilute acid gives a maximum concentration of 67%, which is often known as concentrated or technical grade acid. More concentrated forms of the acid are available. Red fuming nitric acid contains 83% acid, 17% oxides of nitrogen and 1-2% of water. The substance has a red-brown colouration due to the presence of the nitrogen oxides. White fuming acid is also available. This is essentially the anhydrous form of the acid without the oxides of nitrogen and is 98% pure.

Table 9: CLP classification for different dilutions of Nitric Acid

Concentration	Category	Acute Estimate (CLP)	Toxicity (under CLP)	LT threshold	TT threshold
≥ 40%	1	≤0.50 mg/l		5 tonnes	20 tonnes
≥ 10% - < 40%	2	>0.5 - ≤2 mg/l		50 tonnes	200 tonnes
≥ 2% - < 10%	3	>2 - ≤10 mg/l		50 tonnes	200 tonnes
≥ 2% - < 2%	4	>10 - ≤20 mg/l		Not in scope	Not in scope

Most nitric acid is used in the manufacture of ammonium nitrate fertiliser (75%). In the UK, there are only two companies manufacturing and supplying the acid, both of which are primarily fertiliser manufacturers. A number of industries and processes use the acid, including:

1. Chemical manufacture including polyamide and polyurethane production
2. Explosives manufacture
3. Metal treatment
 - a. Used in stainless steel pickling and passivation
 - b. In the aerospace industry
4. Surface cleaning used in
 - a. The dairy industry
 - b. Microelectronics manufacture
 - c. Other food preparation companies
 - d. Large scale farming
5. The nuclear industry – for dissolving fuel rods prior to reprocessing
6. Transport and storage.

Information from Trade Associations and chemical companies suggests that the classification change could lead to 40 – 80 sites coming within scope of COMAH for the first time, with most becoming lower tier sites and around 10% entering directly as top tier. Some 20 or so sites would be likely to move from being lower tier to top tier.

The accident history of nitric acid points to it being hazardous because it is strongly oxidising, with often violent reactions occurring when the acid comes in contact with metals and organic substances. These reactions lead to the evolution of copious quantities of brown fumes containing nitrogen dioxide and other oxides of nitrogen. For nitric acid to pose a major accident hazard solely from the toxicity of the vapour a sufficiently serious loss of containment event needs to occur that generates a vapour/gas cloud of sufficient size and concentration to put at risk employees and members of the public. At 20°C, the vapour pressures of white fuming nitric acid (WFNA) and red fuming nitric acid (RFNA) are 8,300 Pa and 14,000 Pa, respectively. In contrast 68% acid has a partial pressure of 390 Pa and a total vapour pressure of 730 Pa (NIOSH 1978). These figures suggest that quiescent pools of these fluids should not generate large vapour clouds. However, both fuming acids, and to a lesser extent the concentrated acid, will immediately react with any water present in the air or within a containment bund, generating nitrogen oxides. They will also react with the materials forming the surface of the bund emitting nitrogen oxide fumes from decomposition of the acid. Heat generated by the reaction will further increase vapour levels and oxide generation. As a result a large-scale leak of concentrated or fuming nitric acid could well create a sufficiently large cloud of acid vapour, aerosol droplets and nitrogen oxides to threaten both onsite and offsite populations.

More dilute acid, with concentrations in the range 15% - 40%, of the type used in industrial cleaning fluids and for metal treatment, will have lower vapour pressures at 20°C and, because of the level of dilution, leaks should not generate large quantities of acid vapour and oxides of nitrogen unless they react strongly with metallic or organic contaminants. These dilutions are less likely to pose a major accident hazard but remain hazardous because of the oxidising nature of the acid. In major hazard terms, therefore, the new classification may not justify a major hazards categorisation when applied to the more dilute concentrations of acid, e.g. 67% and

below, though this needs to be tested more rigorously. The testing would include a thorough search of the incident literature to identify any relevant accidents and a review of studies of the vapour pressure of the acid at different dilutions and temperatures.

For these reasons, nitric acid solutions appear to be good candidates to use as test cases during the discussions about the implementation of Article 4 of Seveso III.

Conclusions

The main changes introduced by the Seveso III Directive concern the scope of the Directive, particularly regarding substances with acute toxicity, and increased requirements for providing information to the public.

The analysis presented here was able to inform the UK negotiations of Seveso III and to reduce the impact on UK industry. Evidence is provided to support the selected alignment of Seveso III with CLP, and a number of new named substances. This gives significantly less impact on the UK than the original proposal for Seveso III.

Estimates for the net change in number of UK COMAH sites, as a result of the Seveso III alignment and new named substances for acute toxicity, range between a net decrease of 14 sites and a net increase of 4. The overall net effect is likely to be only a small change in the number of COMAH sites. There will, however, be some 'churn' in terms of some sites leaving the COMAH regime and some sites newly coming into COMAH. This needs to be taken into account in the impact assessment.

It was more difficult to identify substances which will newly come into scope of COMAH as a result of Seveso III than to assess the effects on substances which are already within scope. It cannot be guaranteed that all new substances have been identified and so there remains a small chance that more new COMAH sites will result than have been estimated.

Changes in classification, as a result of new data and knowledge, may cause additional substances to be identified as being in scope of COMAH, with potential to increase the number of COMAH sites. Nitric acid is a relevant example where it may be possible to argue that dilute solutions do not have major accident potential. Nitric acid could be used as a test case during discussions on the implementation of Article 4 of Seveso III, which is able to remove substances from scope at EU level if they do not have major accident potential.

References

- COMAH Competent Authority, 2010, Ageing Plant Operational Delivery Guide, <http://www.hse.gov.uk/comah/guidance/ageing-plant-core.pdf> (accessed 30/12/2013)
- COWI, (2010), Impact assessment study into possible options for adapting Annex 1 of the Seveso II Directive into the GHS, Final Report, February 2010, COWI A/S, http://ec.europa.eu/environment/seveso/pdf/Seveso%20IA_Final%20report.pdf (accessed 29/12/2013)
- Durling, J., Gaskarth, D., Whitfield, A., Ashcroft, A., McCann, R., 2014, Developing options for providing COMAH site information to the public under the Seveso III Directive, Hazards 24 Symposium, Edinburgh, May 2014
- EC, 1967, 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 (DSD Directive).
- EC, 2006, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on Registration, Evaluation, Authorisation and Restriction of Chemical substances. (REACH)
- EC, 2008, 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. (CLP regulation)
- EC, 2010, Proposal for a directive of the European parliament and of the council on control of major-accident hazards involving dangerous substances, http://ec.europa.eu/environment/seveso/pdf/com_2010_0781_en.pdf, (accessed 30/12/2013)
- EC, 2012, Directive of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, PE-CONS 22/2/12, 4 July 2012 (Seveso III Directive)
- ECHA Committee for Risk Assessment, 2013, Opinion proposing harmonized classification and labeling at EU level of Nitric Acid. <http://echa.europa.eu/documents/10162/a2003fc5-7363-4a1c-9500-cd25131311ff>, Accessed 17 October 2013
- Gyenes, Z., 2009, Technical Working Group on Seveso and GHS Interim Report, http://ec.europa.eu/environment/seveso/pdf/twg_report.pdf, (accessed 29/12/2013)
- ECHA, 2012, C&L inventory, <http://echa.europa.eu>, accessed July-August 2012, European Chemical Hazards Agency
- HSE, 2013, Competent Authority position on the COMAH regulation of Heavy Fuel Oil, <http://www.hse.gov.uk/comah/guidance/hfo-june-2013.pdf> (accessed 6/1/14)
- NIOSH, 1978, Occupational Health Guideline for Nitric Acid. September 1978. Accessed 12 December 2013 at <http://www.cdc.gov/niosh/docs/81-123/pdfs/0447.pdf>
- ORC International, 2011, HSE SEVESO III Impact Assessment Final Analysis, March 2011, (available from HSE, Merton Road, Liverpool L20 7HS, UK)

Trainor, M., Bosworth, D., Rowbotham, A., Wilday, J., Fraser, S., Saw, J.L., 2008a, 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. Proceedings of IChemE Conference `Hazards XX: Process Safety and Environmental Protection' 14-17 April 2008 Manchester UK

Trainor, M. T., Wilday, A. J., Moonis, M., Rowbotham, A. L., Saw, J. L., Bosworth, D., 2008b, Adapting the EU Seveso II Directive for GHS: initial UK study on acute toxicity to people, ESREL Conference, Safety Reliability & Risk Analysis: Theory Methods & Applications, Vol 3, pp2353-2361, ISBN 978-0-415-48513-5

UN, 1998, Convention on access to information, public participation in decision-making and access to justice in environmental matters, 25 June 1998, <http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf> (accessed 30/12/13)

Wilday, J., Fraser, S., Bailey, C., Stocks-Greaves, M., Ridgway, P., Ashcroft, S., 2012, The forthcoming Seveso III Directive: alignment with GHS classifications and data issues for acute toxicity, IChemE Symposium Series No 158, 379-386

Wilday, J., Fraser, S., Bailey, C., Stocks-Greaves, M., Fullam, B., 2014, Assessment of UK impact of possible alignment options between the Seveso III Directive and GHS classifications for acute toxicity, HSL report MH/13/235 (available from HSL, Harpur Hill, Buxton SK17 9JN, UK)

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