

COMAH 2015: classification issues in determining whether establishments are in scope

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The new Seveso III Directive will come into force on 1 June 2015. The implementation of the European Directive led to a revision of the existing COMAH regulations, which will also come into force on 1 June 2015. A major change is the hazard classification system used to define the scope. Therefore, operators in the UK will need to take action to understand any changes to their COMAH status (defined as upper tier, lower tier or non-COMAH establishments) as well as to make all the necessary changes to comply with the requirements of the COMAH 2015 status. COMAH 2015 hazard categories will refer to the international Globally Harmonised System (GHS) for the classification of chemical substances and mixtures, which is the basis of the European Classification, Labelling and Packaging Regulations (CLP) that replaces Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP). Operators therefore need to determine CLP classifications for their inventory and this has the potential to influence the COMAH status of the establishment via the aggregation calculations.

This paper is based on experience gained when providing technical support to the Health and Safety Executive (HSE) on the implementation of COMAH 2015 regulations in the UK, and on recent work to develop a tool to implement the hazard classification of mixtures according to CLP regulations by using available data on the ingredients. The paper describes a number of issues that were identified and suggests possible solutions to succeed in the classification of substances and mixtures present in an establishment and in the application of the aggregation calculations and hence the determination of the COMAH status.

KEYWORDS: Seveso III, COMAH 2015, GHS, classification, CLP, aggregation

Introduction

The introduction of a new Globally Harmonised classification System (GHS) has led to the development of new European Classification, Labelling and Packaging Regulations (CLP) (EC, 2008), which are progressively replacing the existing CHIP Regulations (Chemicals (Hazard Information and Packaging for Supply)) (HMG, 2009). This new classification system includes new hazard classes (e.g. flammable aerosols) and introduces new categories for the categorisation of some hazard classes (e.g. acute toxicity). While there are some changes for the other hazard classes (physical hazards and environmental), the changes are most fundamental for acute toxicity. The changes in the classification system led to the new Seveso III Directive (EC, 2012), which will come into force on 1 June 2015. The existing COMAH regulations will be updated to implement Seveso III. Thus, COMAH 2015 will also come into force on 1 June 2015. The main changes were described by Wilday (2014). A public consultation on the draft revised COMAH 2015 Regulations took place during 2014 (HSE, 2014a).

The changes in the classification system may have a direct impact on establishments resulting in them moving in or out of COMAH 2015 scope. Establishments may also change their COMAH status and continue being within scope (lower tier establishments might become upper tier establishments and vice versa). The COMAH requirements, as at present, will be different for the two types of establishment (upper tier or lower tier), in particular with upper tier establishments required to produce a safety report. Therefore, operators in the UK will need to understand and take action to comply with the requirements before the new regulations come into force, and certainly before the deadline of 1 June 2016 for notification under COMAH 2015 (HSE, 2014b).

To find out what the new COMAH status will be (upper tier, lower tier or non-COMAH establishments), the hazard classification for the inventory present onsite must be determined. In previous publications, HSL presented different methods for the determination of the hazard categories for acute toxicity under the new classification system using LD_{50} and LC_{50} data from different toxicity databases (Wilday, 2012) and an overview of other classification changes and the estimation of the impact of the changes in Seveso III scope in the UK (Wilday, 2014). In that publication it is highlighted that the overall net effect is likely to be a small change in terms of the overall number of COMAH sites, but with the potential for a higher number of sites to be affected (some going out of scope and others newly coming into scope). Furthermore, this number could become higher if some substances are identified as being in scope due to new data becoming available, leading to new or revised European harmonised classifications.

The authors extended their experience of classification and aggregation by providing technical support to the Health and Safety Executive (HSE) in the negotiation of the Seveso III Directive and its implementation in the COMAH 2015 regulations in the UK (Wilday, 2012, 2014). This previous work highlighted:

- The importance of basing classifications on the most reliable data, including harmonised classifications where available;
- The difficulties posed by the classification of mixtures, for which experimental data for the mixture as a whole are rarely available and it is often difficult to source data for every ingredient.

Discussions with colleagues from industry have also highlighted that Seveso/COMAH aggregation calculations are an area of potential confusion, even though these are essentially unchanged by the new Directive. Aggregation calculations are described below

and are required to determine whether the aggregate quantity of all dangerous substances held on a site exceed the thresholds for lower tier or upper tier.

In subsequent work, a tool was developed to implement classification and subsequent COMAH aggregation, making efficient use of available data. In particular, the tool implements mixture calculations from the CLP Regulation and associated guidance (ECHA, 2013) to calculate the classification of a mixture from the hazardous properties of the ingredients. The tool has been tested using industrially relevant mixtures provided by a major company.

This paper will describe a number of issues that were identified during this work. Some of these concerns may affect the operators' ability to determine the COMAH 2015 hazards classification of the inventory in an establishment. Possible solutions are suggested to succeed in the classification of substances and mixtures present in an establishment and in the application of the aggregation calculations and hence the determination of the COMAH status.

COMAH aggregation

The key point to define the COMAH status of an establishment is the maximum amount of dangerous substances that are likely to be present in it. Dangerous substances are defined by COMAH together with their qualifying quantities for both lower and upper tier; these can include both pure substances and mixtures. The definition for COMAH 2015 includes certain classifications from the CLP regulation together with a number of 'named substances' which have different qualifying quantities from those of the generic classification. The qualifying quantities for named substances override those for any of the classifications that the dangerous substance has. If the maximum amount of a dangerous substance is greater than or equal to the upper tier threshold for that substance as a named dangerous substance or otherwise for the generic hazards of the substance, then the establishment will be classified as an upper tier establishment.

When none of the dangerous substances are present in an establishment in quantities equal to or greater than the relevant upper tier qualifying quantities, the concept of aggregation should be applied to define the COMAH status of the establishment. Aggregation calculations determine the overall hazard of the whole inventory present in the establishment; thus, the role of aggregation is the addition of the maximum amount of each dangerous substance likely to be present onsite in comparison to the corresponding COMAH qualifying quantities. The first step is to determine whether an establishment should be classified as an upper tier establishment. For this purpose, equation (1) (EC, 2012) should be used:

$$\frac{q_1}{Q_{U1}} + \frac{q_2}{Q_{U2}} + \frac{q_3}{Q_{U3}} + \frac{q_4}{Q_{U4}} + \frac{q_5}{Q_{U5}} + \cdots \quad (1)$$

where q_x is the quantity of a substance present in the establishment and Q_{UX} is the upper tier qualifying quantity for the substance.

If the result of equation (1) is greater than or equal to 1, then the establishment has to be considered as an upper tier establishment. However, if the result of the aggregation calculation is lower than one it would be necessary to determine if the establishment should be counted as a lower tier establishment. In this case, equation (2) (EC, 2012) should be used:

$$\frac{q_1}{Q_{L1}} + \frac{q_2}{Q_{L2}} + \frac{q_3}{Q_{L3}} + \frac{q_4}{Q_{L4}} + \frac{q_5}{Q_{L5}} + \cdots \quad (2)$$

where Q_{LX} is the lower tier qualifying quantity for the substance.

If the result of equation (2) is greater than or equal to 1, then the establishment will be considered a lower tier establishment. However, if the result of this calculation is also below 1 the establishment will be out of scope of COMAH regulations.

Because there are three different types of hazard (physical, health and environmental hazards) that potentially trigger the application of the regulations, this process needs to be applied three times, one for each type of hazard. When carrying out the calculations it must be remembered that some substances will exhibit more than one category of hazards. Where this is the case the substance will appear in more than one of the sums. In terms of the COMAH status of an establishment, only one of the calculations needs to be greater than or equal to 1 to define the COMAH status.

Clearly the CLP classifications for all substances and mixtures held in the establishment need to be known so that the aggregation calculations can be carried out. Schedule 1 of COMAH 2015 defines which CLP classifications need to be considered for the physical (P), health (H) and environmental (E) aggregations. Within each of these categories (P, H and E) the classification with the lowest qualifying quantity should be used. For example, consider a substance that is classified, within the overall Physical category, both as:

- P5c (Flammable liquid) with qualifying quantities of 5000 tonnes lower tier and 50,000 tonnes upper tier; and
- P6b (Self reacting substance) with qualifying quantities of 50 tonnes lower tier and 200 tonnes upper tier.

In this case, the P6b qualifying quantities should be used in the aggregation calculation unless, as already stated, a substance is a named substance within Schedule 1 when the named substance qualifying quantity should be used.

Possible concerns in determining the COMAH status

Classification of harmonised substances

CLP regulation includes a harmonised substances catalogue in Annex VI which contains a list of those substances for which the hazards classifications have been agreed by the EU. If a substance has been harmonised, operators can use the harmonised classification for that substance. A point that can cause confusion concerns those cases where a harmonised substance does not have a category for a specific hazard. Operators may think that this could mean either that the hazard was considered and it was decided that the substance was harmless for that hazard or that there was not enough data for that hazard at the time that the substance was harmonised, in which case a re-evaluation would be necessary for the substance.

For all the substances that have already been harmonised and included in the harmonised substances catalogue all types of hazard have been considered; therefore, the hazard categories which are not included in the catalogue are considered harmless.

There is a European process in place to regularly amend the harmonised substances catalogue to take account of advances in technical progress (ATP). The COMAH aggregation needs to use the current version so that there is a continuing requirement to maintain awareness of the content of new ATPs and to revise the COMAH aggregation calculations accordingly.

Interpretation of Note 7 Seveso III – Annex I

Some issues were raised when trying to apply Note 7 in Annex I, which affects the category acute toxic (H2). Category H2 includes acute toxicity category 2 by all exposure routes and category 3 by the inhalation exposure route. Note 7 states: "Dangerous substances that fall within Acute Toxic Category 3 via the oral route (H301) shall fall under entry H2 ACUTE TOXIC in those cases where neither acute inhalation toxicity classification nor acute dermal toxicity classification can be derived, for example due to lack of conclusive inhalation and dermal toxicity data."

Note 7 is relatively straightforward for pure substances or if the toxicity of a mixture was obtained by measurement. It uses a hierarchy in terms of the relevance of the route of exposure to major accident hazards, for which inhalation is most relevant. It also takes into account that in terms of availability of data, there are most for oral, then dermal and least for inhalation. The interpretation of Note 7 is more complex for mixtures when the classification is to be determined by calculation based on the hazardous properties of the ingredients.

Four issues about the use of Note 7, the first three related to mixtures, are discussed below:

1. *What amount of data is deemed sufficient for dermal and inhalation exposure routes? At what percentage of missing data does it become insufficient and Note 7 would then be implemented?*

According to CLP, if $\geq$1% of data is missing/unknown a definitive classification cannot be given based on use of mixture calculations. This percentage also correlates with the CHIP regulations, where if a substance was classified as very toxic under CHIP and included at $\geq$1% in a mixture which otherwise would have a hazard category of harmful or lower, the mixture would have been regarded as toxic.

The percentage of a mixture that would bring a substance into H2 category was estimated. This was done using the point estimates, these are estimated values for each category for use when a category is available but data are not, they are provided in Table 3.1.2 of the CLP regulation, (EC, 2008). The point estimates were used to calculate the percentage content that would bring a mixture into scope for the dermal and inhalation exposure routes. The percentage that would potentially bring a substance into scope ranged from approximately 1% for dermal to 0.04% for inhalation of vapours. As explained, it should be noted that for these estimates, point estimate values were used; which is not necessarily the worst case, so the percentages would be even smaller in a worst case scenario. It would seem that the CLP criterion of $\geq$1% is a pragmatic choice. It would make a difference to the COMAH status of a mixture only if the unknown ingredients had extremely high toxicity. After some deliberation, it is considered that Note 7 should be implemented if $\geq$1% of dermal and inhalation data are missing. It would be impractical to use a lower cut-off value. Although 1% appears to be a small amount, if the missing data were for substance(s) with very high toxicity, then it could make the difference between the mixture being in or out of scope of COMAH 2015.

2. *Note 7 is open to interpretation because of the wording used. Does this statement mean that both dermal and inhalation data have to be inadequate to implement Note 7?*

It is understood that Note 7 will only be implemented in those cases where there is a lack of both inhalation and dermal toxicity data, but not if just one of them is missing, This is because, as already mentioned above, inhalation and dermal exposure routes are more relevant than oral for major accident hazards. Oral exposure would only be expected in the case of release of a cloud of particulates which entered the mouth and were subsequently swallowed.

3. *Note 7 assumes that there will be sufficient oral data, which may not be true for all substances and mixtures. Many substances will be lacking in oral data as well as dermal and inhalation data. Therefore, for mixtures it is possible that there is ≥ 1% missing for the oral, dermal and inhalation toxicity data. Should Note 7 apply in these circumstances?*

It is considered that Note 7 should be implemented for mixtures even when the oral toxicity data is lacking. In these circumstances, a statement should be made alongside the provisional classification quantities to make clear that "Note 7 has been implemented but there is x% of the oral data of unknown toxicity, if more data become available the classification may change".

In such cases, sensitivity analysis could be conducted to consider the effect of the classification of the mixture(s) in question on the aggregation calculations for the establishment. This would be to determine whether the classification of the substance could make any difference to the COMAH status for the establishment. If this were the case, further work to resolve the classification could be appropriate, or else the worst case assumed.

4. *Does Note 7 apply to named substances?*

Most of the named substances in Schedule 1 Part 2 of COMAH 2015 are harmonised under the CLP regulation so that their classifications have been agreed at European level and are readily available. However, for any named substances where a classification is needed to decide how it should be treated for aggregation (see below), then Note 7 would apply.

Named substances as ingredients in a mixture

Annex I in Seveso III and Schedule 1 of COMAH 2015 state the qualifying quantities of dangerous substances for the application of lower tier/upper tier requirements. They are split in two parts: Part 1 lists the generic hazard categories that are considered in scope. Part 2 contains the qualifying quantities for specific substances, which are defined as named dangerous substances.

For the classification of mixtures, it is not clear which threshold values should be used in the aggregation calculations in those cases where a named dangerous substance is one of the ingredients of a mixture. Three different approaches would be possible:

1. The named dangerous substance dominates over the rest of the ingredients. In this case the threshold values that apply would be the same as for the named substance;
2. Where a named dangerous substance is in a mixture above a certain concentration, the qualifying quantities for the named substance could be used for the whole mixture;
3. The mixture could be classified according to its hazards and the threshold values for these hazards used.

It is considered that item 3 above generally applies, i.e. that the qualifying quantities that apply for mixtures are those that reflect the hazards based on the classification of the mixture itself regardless of the concentration of any named dangerous substances that could be part of the mixture, as in this case the mixture is not a named substance. However, if the item on the list in Annex I/ Schedule 1 (part 2) states a specific concentration limit for the consideration of the substance as a named substance then this cut-off value will apply, e.g. formaldehyde ≥ 90%.

Item 2 above may sometimes apply, for example where the concentration is close to 100% and corresponds to a standard industrial grade that approximates to the pure substance. It would not meet the intent of the named substance list to use generic qualifying quantities from Part 1 if Schedule 1 of COMAH 2015 due to a small percentage of impurities.

Qualifying quantities in the aggregation calculations for named substances

Three aggregation calculations need to be performed in order to determine the COMAH status of an establishment, one for each type of hazard (physical, health or environmental hazards).

Named substances may only be dangerous for one or two types of hazard. Operators might not know whether to consider the qualifying quantities for the substance in all three aggregation calculations or just need to take into account those aggregations that represent the hazards of the substance.

Where a named substance does not have a relevant physical, health or environmental hazard classification (i.e. one which is mentioned in Part 1 of Schedule 1), the substance should not be counted in the aggregation calculations for that hazard category. To do otherwise would result in a hazard that does not exist being aggregated, e.g. the hazards of chlorine gas are acute toxic (H2) and hazardous to the aquatic environment in category acute 1 or chronic 1 (E1). In this case, the qualifying quantities for chlorine should be applied in two out of three addition calculations (health and environmental hazards) but not for the calculation of the physical hazards aggregation.

Conclusions

Classification of substances under the CLP regulation is fundamental to determining whether they fall within scope of Seveso III and COMAH 2015 as dangerous substances. HSL noticed some issues that might concern operators on the application of COMAH 2015criteria to determine the hazard classification and the aggregation calculations.

1. If a substance already has a harmonised hazard classification and it does not have a hazard category for a specific hazard class, that hazard will be considered as harmless for that substance and discounted.
2. Note 7 in Seveso III Annex I should be applied if ≥1% of the toxicity data is missing for both dermal and inhalation exposure routes. This should be independent of the available oral toxicity data.
3. For mixtures containing substances included in the named dangerous substances list, the qualifying quantities that will apply are those representing the generic hazards for the mixtures, unless the substance has a concentration above a specific cut-off value for the consideration of qualifying quantities or its concentration is close to 100%.
4. The threshold values for a named dangerous substance should be applied only for those hazards that represent the hazards of the substance.

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