



Review

The Seveso II experience in the application of generic substance criteria to identify major hazard sites

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ABSTRACT

Europe is currently in the process of finalising legislation to align its criteria for classifying and labelling dangerous substances with the new Globally Harmonised System of Classification and Labelling of Chemicals (GHS), replacing the criteria that have been in place within the European Union since the establishment in 1967 of Directive 67/548/EC on the Classification and Labelling of Dangerous Substances. The Seveso II Directive is potentially the piece of EU legislation most affected by this re-classification because coverage of sites under the Directive is determined to a large extent on the basis of the presence of certain generic categories of substances on site as defined by 67/548/EC. The European Commission in concert with the Member States has launched an initiative to review the current Seveso generic classifications with the view to adjusting these provisions as appropriate in light of the pending GHS-EU harmonisation. In doing so, it must foresee and take into account the inevitable inequalities that may result when the general conditions of a generalised approach are altered. This paper gives an overview of the Seveso qualifying criteria and corrective measures that have been used in the past to address its limitations in relation to specific substances and categories of substances. Adaptation of the criteria to the GHS classification is not likely to alter these limitations, but could generate new cases where they are again in evidence. Therefore, this analysis offers insight on what types of potential unforeseen and unintended consequences that changes to the current generic criteria (i.e., certain sites are inappropriately covered or not covered, as the case may be) may entail, while also highlighting how well different structural and administrative elements may function to address these situations.

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1. Background

The European Union now has over 10 years of experience implementing accident prevention legislation in which qualification for coverage principally relies upon generic categories of hazardous properties, supplemented by a named list of substances (and a few alternative categories). The EU approach is notable in that it includes generic criteria for a wide range of acutely dangerous properties. The generic criteria are widely accepted within the EU as an effective means for identifying major hazard sites for Seveso coverage. Therefore, changes in how dangerous substances are classified generically can also change which sites are covered by the Directive, depending on the quantity and type of substances generally present.

In the original Seveso Directive [2], which was replaced by Seveso II, the predominance was reversed and coverage was largely determined by named substances with only a few generic categories. The latter approach continues to prevail today in almost all non-European OECD countries, in which generic criteria are usually only applied for flammable substances and sometimes explosives. Europe is the only region known to have established site selection criteria for substances toxic to humans or the environment based on generic categories instead of a list of specific named substances [3].

The criteria have identified approximately 8500 sites that are covered under the Directive in the EU according to the most current data provided to the European Commission. (The coverage also extends to EEA countries, notably Norway and Iceland, whose sites are not included in this figure.) Fig. 1 shows the number of so-called Seveso “upper tier” sites (sites with dangerous substances in amounts exceeding the higher threshold quantity¹ established in the Seveso Directive) reported by EU Member States in 2005. The most highly industrialized countries in Europe have over 500 and even 1000 total sites. Sites fall into a diverse number of industrial sectors that use, handle or store chemical substances in significant volumes, including, for example, petroleum oil refineries, chemical processing (e.g., plastics, paints, dyes, adhesives, bulk chemicals) production and storage of fertilizers and pesticides, fuel storage and distribution, warehouses, explosives and pyrotechnics production, pharmaceutical manufacturers, hazardous waste incineration, and industrial gas plants (e.g., liquid petroleum gas, natural gas).

A subset of the categories, or “risk phrases”, established by the EU Directive 67/548/EC [7] on classification and labelling, mainly those related to acutely hazardous properties, forms the basis of the generic substance criteria used for site selection in the Seveso II Directive. As shown in Table 1, the generic criteria are essentially 10 categories (a few of which also are divided into subcategories) of acutely hazardous properties potentially harmful to humans and

the environment. Each category corresponds exclusively to one or more r-phrases of 67/548/EC (although the r-phrases belonging to each category are not specifically in the legislation).

However, this neat coupling of r-phrases with Seveso categories is soon to become obsolete. Europe has finalised legislation aligning its classification and labelling criteria for dangerous substances with the new Globally Harmonised System of Classification and Labelling of Chemicals (GHS) [8] and the r-phrase classification system is being replaced with a new set of hazardous classifications and hazard definitions. The GHS consists of harmonised criteria for classification and labelling of substances developed over a period of 12 years within the United Nations (UN) structure that was developed in order to facilitate worldwide trade. The so-called “CLP Regulation” (Regulation No. 1272/2008) [9] entered into force on 20 January 2009 and will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). The regulation establishes a period of transition from 1 December 2010 until 1 June 2015 in which substances shall be classified in accordance with both Directive 67/548/EEC and the CLP Regulation.

While the EU and GHS criteria match completely for some hazard classifications (e.g., flammables), differing criteria may apply to others. Fig. 2 shows that acute oral toxicity criteria differ substantially between the EU 67/548/EEC and the GHS classification. In addition, the GHS contains new classifications not represented as individual categories in 67/548/EEC (e.g., flammable aerosols). Also, the reverse situation exists (e.g., R29: contact with water liberates gas), but these categories have generally been directly adopted (without change) into the CLP Regulation. As a result of these discrepancies, it has become apparent that the substance criteria of the Seveso II Directive will also have to be modified to avoid confusion about how the new classifications should be applied and potentially significant gaps in coverage or overextensions.

The European Commission’s study of the impact of the new GHS-based classifications on down-stream legislation [11] confirms this view. According to this study, the Seveso II Directive is the piece of EU legislation most affected by the re-classification because of the direct link between the site selection criteria in Seveso II and the EU 67/548/EC categories. The study noted that, for various reasons, strict adaptation of the Seveso II Directive to the GHS categories could lead to an increased number of classified substances and mixtures which would then be covered by the Seveso II Directive in its current form. Therefore, using oral toxicity again as an example, the relevant r-phrase for the “Toxic” category of the Seveso II Directive is “R25: Toxic if swallowed”. As illustrated in Fig. 2, it does not align perfectly with a GHS category; rather, a fraction is covered by GHS Category 2 and the other fraction by Category 3. Therefore, assigning GHS Category 2 and 3 substances in their totality to the Seveso “toxic” category would reduce threshold quantities (and associated regulatory burden) for some substances (in GHS Category 2) because they would no longer be classified as “very toxic”. In the same way, this type of adaptation would also bring in

¹ The term “threshold quantity” is used interchangeably with “qualifying quantity” which is the term used in the Directive, to mean the minimum substance volumes triggering Seveso coverage. This paper will use both terms.

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