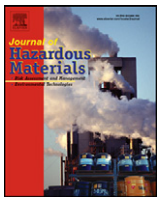
Journal of Hazardous Materials 171 (2009) 16–28

Contents lists available at ScienceDirect

Journal of Hazardous Materials

journal homepage: www.elsevier.com/locate/jhazmat



Review

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

Maureen Heraty Wood*

European Commission, Joint Research Centre, Institute for the Protection and Security of the Citizen, Major Accident Hazard Bureau, Ispra Establishment, 21020 Ispra (VA), Italy

ARTICLE INFO

Article history:
Received 30 September 2008
Received in revised form 20 May 2009
Accepted 25 May 2009
Available online 6 June 2009

Keywords:
Seveso
Substance criteria
Threshold quantities
Qualifying quantities
Control of major accident hazards
Generic criteria
Major hazard sites
Named substances
Industrial safety

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.

Contents

* Tel.: +39 0332 789140; fax: +39 0332 785032.
E-mail address: maureen.wood@jrc.it.

0304-3894/$ – see front matter © 2009 Elsevier B.V. All rights reserved.
doi:10.1016/j.jhazmat.2009.05.110

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 quantity[1] 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).

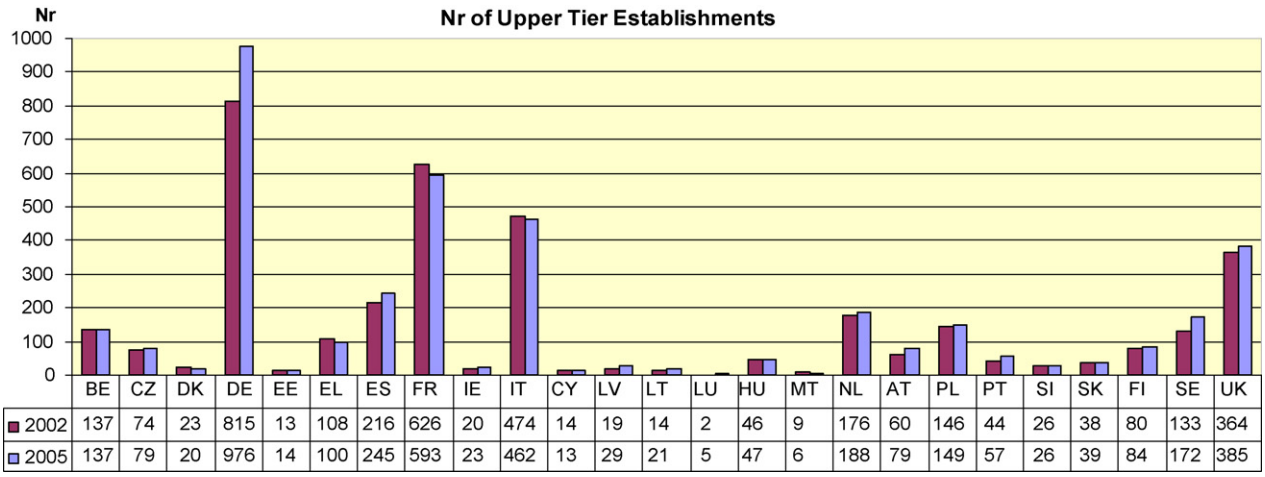
A subset of the categories, or "risk phrases", established by the EU Directive 67/548/EC [7] on classification and labelling, mainly those related to acutely hazardous properties, forms the basis of the generic substance criteria used for site selection in the Seveso II Directive. As shown in Table 1, 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.



	BE	CZ	DK	DE	EE	EL	ES	FR	IE	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	SI	SK	FI	SE	UK
2002	137	74	23	815	13	108	216	626	20	474	14	19	14	2	46	9	176	60	146	44	26	38	80	133	364
2005	137	79	20	976	14	100	245	593	23	462	13	29	21	5	47	6	188	79	149	57	26	39	84	172	385

Fig. 1. Distribution of 3949 upper tier establishments in the EU-25 [4,5].

Table 1
Typical substances found on major hazard sites in Europe and their Seveso classifications.

Category	Risk phrase	Qualifying quantities Article 6 and 7/Article 9	Examples of substances falling in these categories [6]
1. Very toxic	R26; R27; R28. Also in combination with R39	5/20	Hydrogen cyanide, hydrogen fluoride, hydrogen sulphide
2. Toxic	R23; R24; R25. Also in combination with R39 or R48	50/200	Ammonia, nitrogen dioxide, sulphur dioxide
3. Oxidising	R7; R8; R9	50/200	Nitric acid, sodium peroxide, potassium chlorate
4. Explosive	UN/ADR Division 1.4	50/200	Ethyl nitrate, mercury difulminate
5. Explosive	UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3	10/50	Lead azide, display fireworks (most)
6. Flammable liquids	R10	5000/50,000	Styrene, cyclohexylamine
7a. Highly flammable liquids	R17; and R10 and R11, 2nd indent: under particular processing conditions	50/200	Zinc powder, aluminium alkyls
7b. Highly flammable liquids	R11, 2nd indent	5000/50,000	Toluene, ethanol
8. Extremely flammable gases and liquids	R12	10/50	Carbon monoxide, methane, furan
9(i). Dangerous for the environment	R50; R50/53	100/200	Ethyl mercaptan, sodium hypochlorite (≥)
9(ii). Dangerous for the environment	R51/53	200/500	Chlorobenzene
10(i). Any classification: reacts violently with water	R14; R14/15	100/500	Lithium, sodium, potassium
10(ii). Any classification: contact with water liberates toxic gas	R29	50/200	Thionyl dichloride

sites with higher quantities of substances (from GHS Category 3) previously classified in the EU as only "harmful".

Therefore, in anticipation of these potential impacts, the Commission in concert with the Member States has launched an initiative to review the substance criteria in the Seveso II Directive with the view to adjusting these provisions as appropriate in light of the pending changes to substance classification criteria in the EU. It is a complicated task. One particular challenge will be to foresee and take into account the inevitable inequalities that will result when the boundaries and definitions of the generic criteria change slightly. Even small changes to a criterion that defines a classification can have substantial impact on which sites are regulated and which are not regulated under the Directive. In addition to substances that are marginally qualified or unqualified for particular qualifications, the generic criteria also have difficulty in properly characterising some dangerous substances (as intended by the Directive) in the face of wide variation or idiosyncrasies in chemical behaviour and when confronted with important factors that cannot be described in terms of physico-chemical properties, such as process conditions, accident history, social and economic costs, and public perception.

The EU already has experience with applying various legal and administrative mechanisms for mitigating the disadvantages associated with generic criteria. For the OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved In Accidental Releases (October 2006, Varese, Italy), the Major Acci-

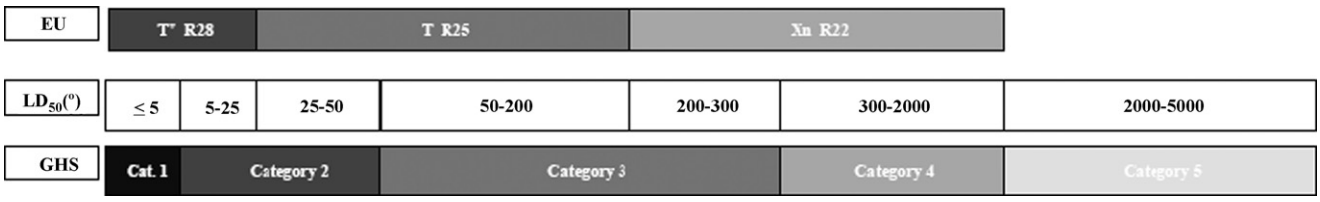


Fig. 2. Comparison of acute oral toxicity criteria between 67/548/EEC and the GHS classification [10].

dent Hazards Bureau (MAHB) of the European Commission's Joint Research Centre undertook to review and present an analysis of these mechanisms and the conceptual structure and scientific underpinnings of the Seveso criteria approach. The study aimed, in particular, to determine how substances that are considered exceptions to the generic criteria, for whatever reason, may be managed such that, over time, the scope of the Directive remains consistent with the goals of the legislation and relevant for the vast number of sites to which it is intended to apply. As Hervé-Bazin wrote, weaknesses of any particular approach should be examined to improve the system, in particular "to perceive more clearly the relevance of a criterion and ways of taking it into account; to clearly establish fields for further or action or research"; and "to avoid arbitrarily leaving difficult or special cases out of account with a risk that they may be precisely those cases which will subsequently pose the most acute problems because they are unusual or unexpected." [12] Therefore, it was considered important to elaborate the analysis further in anticipation of its usefulness in critical evaluation of various proposals to adapt the Seveso II substance criteria to the GHS. This article presents the results of this elaborated study.

The analysis reviews the major design aspects of Seveso II coverage, namely:

- the primary use of generic categories of acutely hazardous properties and limitations that can result in overcoverage (false positive), undercoverage (false negative) or ambiguous coverage,
- the use of a named substance list and the use of threshold quantities associated with both generic categories and named substances to make relative and practical adjustments in coverage, and
- additional supplementary measures that are aimed to correct limitations not addressed by using the named substance list or threshold quantities. The paper finishes with some general conclusions about the criteria and potential future adaptations resulting from this analysis.

It is worth noting here that the CLP Regulation should not be confused with EU Regulation No. 1907/2006, known as "REACH" (Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals) [13]. REACH replaced the procedures outlined in 67/548/EC for classifying and labelling substances in Europe. Amongst other objectives, REACH aims to establish a significantly more transparent and comprehensive process for assigning risk classifications to dangerous substances than its predecessor legislation. By contrast, the CLP Regulation does not affect the process for assigning classifications in the EU but changes the names and criteria used for substance classification. Although REACH does not change the substance classifications per se, its broad substance coverage and information dissemination mandate may magnify considerably the impact of the CLP Regulations re-classification on businesses and consumers. (For information on both pieces of legislation, see http://ec.europa.eu/enterprise/reach/index_en.htm).

Finally, it must be stressed that the point of view of this paper is retrospective and it cannot be excluded that additional limitations to the generic criteria come to light or are introduced with implementation of the GHS Regulation.

2. The selection of a predominantly generic approach over a named substance list in Seveso II

The generic approach was deliberately chosen as the dominant approach in the Seveso II Directive due to experience with the named list approach in the original Seveso Directive. The original Seveso Directive was primarily based on a list of 180 named substances (and industry sectors). The named list approach has one particular advantage in that it is extremely clear in terms of which substances are covered and which are not. However, it can be hard work scientifically and very contentious politically to maintain an accurate and complete list on an ongoing basis. In addition, this approach generates concerns about who bears the cost of maintaining an accurate list (usually government), and about lack of transparency in the criteria used to create the list [12].

Smeder justifies the choice of a generic approach in Seveso II based on the experience with the original Seveso's named list of substances as follows:

> "In the Seveso II Directive (Council Directive 96/82/EC), generic criteria are as far as possible used as the basis for the inclusion of substances under the Directive, since the current extensive listing of substances has been found inflexible and inappropriate. The assignment of substances into one of the categories in Part 2 of Annex I is based on classification systems addressing the intrinsic properties of substances and established in the Directives 67/548/EEC, 88/379/EEC and 78/631/EEC." [14]

Nonetheless, as discussed later on in this paper, the named list approach has certain advantages that, when coupled with the generic approach, can introduce some precision in site coverage. In particular, it can take into account important safety or other factors (e.g., economic) that the generic criteria ignore.

2.1. Advantages of the generic criteria approach

The non-discriminatory nature of this system is by far the most distinct and important advantage to using generic categories of substances. This system requires the inclusion of any substances with dangerous properties within the legally defined categories. Therefore, it provides a uniform objective criteria that do not discriminate across state/national lines, facilitating a harmonised approach to accident prevention. The generic criteria are consistent across industry sectors and do not take into account economic importance of the subject, local issues, influence of the industry in policy making, or other subjective factors.

In addition, experience has shown that there are three other important advantages to using generic categories:

- The system does not assume that a hazardous substance can be discounted solely if it has a relatively benign accident history.
- The criteria can account for new data and scientific and practical knowledge. As substances are re-evaluated and re-classified, the system automatically accounts for the re-classification without any need for new legislation.
- Political controversy over the addition and subtraction of substances from coverage is limited. What controversy arises is usually managed in the classification arena with reference only to the hazardous properties and in isolation from potential impacts on other legislation because of re-classification. It is only very occasionally that the classification of a particular substance is controversial in a Seveso context. The analysis of the disadvantages of these criteria highlights some situations where this can occur.

2.2. Disadvantages of a generic approach

Prior to the proposal of a second Seveso Directive, a report was published in 1986 by Hervé-Bazin of the French National Institute of Research and Safety (INRS) in which an approach based on generic criteria was advocated [12]. Hervé-Bazin observed that the typical generic procedure "is never entirely satisfactory" from a qualitative standpoint. Even with relatively simple parameters (e.g., volatility), there is almost always a problem with a lack of data for particular substances, quantification of a particular property, and overgeneralisation. These limitations can sometimes lead to situations where

Table 2
Summary of substance-related scope issues raised at EU level.

Substance or condition	Problem description	Coverage problem	Corrective mechanism	Comments
Carcinogens [15]	Limited data and scientific methods to establish carcinogenicity	Lack of data and agreed analytical methods (under or overcoverage)	Named list of substances	Expert group convened to reach consensus reached on how to establish reasonable list within scientific limitations Significant gaps in science remain. Very precautionary approach taken in establishing thresholds
Petroleum products [14,16]	Substances acutely dangerous to the environment is a very broad category	Overgeneralisation of hazardous properties	Named substance with different threshold	Renamed and redefined "automotive petrol and other spirits" as "petroleum products" and re-defined
	Lower thresholds appropriate for some substances in this category would also bring in petrol stations and retail establishments into the scope	Failure to account for economic and social factors (overcoverage)		The new thresholds actually reduced the threshold for automotive petrol itself
Ammonium nitrate [17]	Named substance description does not distinguish between different compositions with different hazard potential Named substance description does not include all compositions with hazard potential	Overgeneralisation of hazardous properties (undercoverage)	Named substance with differentiated thresholds for four categories instead of two	
Potassium nitrate fertilizers [17]	Similar properties as ammonium nitrate fertilizers; not covered by generic or named substance categories	Overgeneralisation of hazardous properties (undercoverage)	Named substance with differentiated thresholds for two categories. Previously treated as generic Category 3 – oxidising	Generic classification 3 used for similar non-fertilizer potassium nitrate compositions
Explosive and pyrotechnic objects [18]	Generic categories do not adequately define important subcategory	Overgeneralisation of hazardous properties	Additional qualifying criteria for generic categories of explosives (Note 2 in the amendment)	
		Preparation/mixture (undercoverage)		
Hazardous waste [19]	Difficult to classify when composition of waste changes frequently	Preparation/mixture (under or overcoverage)	Case-by-case expert judgment using information about the origin of the waste, practical experience, testing, transport classification or classification according to the European waste legislation	Solution must often be pragmatic
Contaminated soil [19]	Sometimes difficult to classify because composition is unknown	Preparation/mixture (under or overcoverage)	Same solution as hazardous waste	Solution must often be pragmatic
Chromic (VI)trioxide (Cr03) [19]	Definition of toxic substances does not account for factors limiting exposure potential. Change from T to T+ brings in sites with questionable risk potential	Overgeneralisation of hazardous properties	For upper tier sites, on a case-by-case basis an Article 9.6 derogation could be applied. No relief for lower tier sites	
		Unanticipated change in EU classification (overcoverage)		

coverage or lack of coverage is clearly inappropriate in a safety context. In other instances, they simply generate an ambiguity and even conflict in regard to certain substances whose inclusion or exclusion by the criteria cannot be fully justified by factual evidence.

The EU experience with the Seveso II Directive not only confirms this analysis but also offers specific examples of how such systemic weaknesses can be manifested and how the structure can respond when one of these weaknesses is perceived to cause a significant error in coverage, or "false positives" and "false negatives" as Hervé-Bazin termed them.

Table 2 summarises the substance and substance categories that have been recognised as challenges at EU level to the Seveso scope since the Directive came into effect in 1997. This list does not pretend to cover all challenges to the substance criteria that may have been noted in the Member States since its implementation, but only those that have been deemed important enough to seek an EU level response. A few additional cases were raised at the Seminar on Chemical Substance Classification Issues in the Context of the Seveso II Directive (Vienna, Austria, January 2006), but case-by-case resolution of these issues has been more or less overtaken by the process of revising the substance criteria to adapt to the GHS, during which such cases have been or will be further discussed for possible resolution within the revised criteria. As such they have not been officially recognised and discussed at EU level and thus cannot be included in the table, although some are mentioned as examples elsewhere in this paper.

The table does not include substances and categories that were recognised as challenges in the original Seveso II legislative process. Specific considerations in composing the original Seveso II named substance list and generic criteria have been largely summarised by M. Smeder in 1999. Moreover, the establishment of the original Seveso II criteria faced additional special situations regarding certain substances as a legacy of Seveso I and for this reason certain Seveso I criteria protocols influenced Seveso II solutions. However,

this paper occasionally cites specific examples from the original legislation to illustrate that limitations of the generic approach were clearly foreseen in establishment of the criteria and that corrective measures to compensate for these limitations were transparently applied.

The research for Seveso II as well as subsequent experience suggests the following categories to describe the main limitations of a generic approach.

2.2.1. Lack of data and agreed analytical methods

The objective criteria are only as strong as the underlying data and analysis that supports the classification. In particular, for toxic substances, classification can be based on limited or incomplete data, or analytical methods may not be considered adequate for reliably quantifying the hazardous property of a substance in a majority of cases. Analytical methods particularly come into question when considering various types of "delayed dangers" that could result from exposure to certain substances, in particular, carcinogenicity, mutagenicity and reprotoxicity. Analytical methods to quantify the acute aspects of these properties are still in development.

A particularly illustrative example concerns the named category "carcinogens". During discussions over the new Seveso II Directive in Council, it was agreed that carcinogens should be covered but only the limited number for which some evidence existed of a carcinogenic effect after a single exposure. Therefore, the Council, when adopting the Seveso II Directive, requested the Commission, in co-operation with the Member States, to carry out a detailed examination of the list provided in the Directive. A technical working of international experts on the subject was convened by the commission. The group's final report clearly describes the scientific challenge of identifying so-called "one-shot" carcinogenic substances (i.e., those demonstrated to provoke a carcinogenic effect after one exposure). In the first place, data on carcinogens are sparsely available, particularly for short exposure times. In the second place, it could not even be confirmed with any certainty that substances with known carcinogenic properties could be "one-shot carcinogens". The group eventually based its recommendations on a correlation between high-potency carcinogens (a small quantity of substance produces a proportionally large effect) and carcinogens for which a 'one-shot' effect was suspected, coupled with evidence of some persistence of the substance in the human body. On the basis of these and other relevant considerations, 73 substances were screened by the technical working group and of these seven substances were selected and eventually added through an amendment to the named carcinogens list of the Seveso II Directive [15].

For physical dangers, testing protocols and qualifying limits are not always agreed by scientists. Moreover, testing protocols may not account for some circumstances for handling and using a substance, that is, circumstances which may substantially reduce or increase the risk. The GHS classification is a significant step forward towards harmonisation of analytical methods for classification of dangerous substances by hazard at a global level. Nonetheless, practical considerations limit a harmonious adaptation in countries and regions like the EU who must make exceptions to the GHS due to a vast regulatory structure based on an existing classification system built on other accepted analytical approaches. It is likely that a number of analytical questions will always remain unsettled, particularly in areas where new methods are in development, or for applications for which factors other than inherent properties must be (always or occasionally) considered in evaluation of the hazard.

2.2.2. Borderline substances

The fairness of scientific criteria comes into question when one considers substances that fall just above or below the dangerous threshold limits. For substances falling within the margins of these limits (whether flammable, toxic or explosive), these threshold limits are perhaps not adequate as the sole criterion. For example, risk phrase R12 (EU Classification and Labelling System) includes the following definition of an extremely flammable substance:

> "Liquid substances and preparations which have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C" [1]

Pentane, a high production volume substance in Europe, is a particularly famous lurker in the border region between extremely and highly flammable, with some forms and tests realizing a 35 °C boiling point vs. others which produce a boiling point of 36 °C. Officially, it is classified as R12 (extremely flammable) but material safety data sheets can be found that classify it as R11 on the assumption of a 36 °C boiling point.

This situation poses the question as to how much less flammable is a substance of this nature with a boiling point of 36 °C? Or conversely is "highly flammable" substance with a boiling point of 35 °C that much more dangerous than a similar ("extremely flammable") substance with a boiling point of 36 °C? Yet in the Seveso Directive, this 1 °C can be significant in terms of regulatory burden, since 50 tonnes of an extremely flammable substance on site guarantees coverage under Seveso with upper tier status vs. 5000 tonnes for highly flammable substances.

It can sometimes be difficult to rationalise these marginal differences. Over the last 10 years a few situations involving substances, notably pentane, have been cited, yet no scientific arguments no matter how robust can change the legal status. One has to accept that, short of creating an extensive list of exceptions, these cut-offs, though sometimes questionable and even "unfair", are necessary for pragmatic reasons. Furthermore, if they can be shown to be particularly impractical and unmerited they may be treated as exceptions by other means within the Directive.

2.2.3. The problem of overgeneralisation

2.2.3.1. Overgeneralisation of hazardous properties. The EU categories of dangerous properties are specifically designed to be multi-purpose, and applied in such diverse fields as consumer protection, environmental protection, occupational health, civil protection, fire protection, and various other arenas. In some cases, this generalised criteria may be inadequate for industrial risk control, leading to a false negative (undercoverage) or a false positive (overcoverage) because details that reduce or increase the risk associated with the substance in this context are not considered. In particular**,** process conditions and density of gases and vapours can play a fundamental role in potential for release and dispersion.

The explosive categories of the Seveso II Directive are an example of this problem, which, prior to 2003, were defined as equivalent to R1 and R2 risk phrases under 67/548/EC. Following the explosion at Enschede, the Netherlands, on 13 May 2000, experts indicated that the 67/548/EC risk phrases did not precisely address the specific hazards associated with explosive and pyrotechnic substances in transportation or storage [16]. The UN/ADR Hazard Division 1 (HD1) classifications provide a much broader assessment of hazards associated with explosive substances and articles alike under different conditions. Hence, the UN/ADR HD1 classification scheme was incorporated to rectify this particular limitation in the original scope.

2.2.3.2. Preparations and mixtures. A similar problem with overgeneralisation is reflected in application of generic categories to mixtures and preparations. Generalised methodologies for calculating the dangerous properties of preparations are contained in the Directive for the Classification and Labelling of Dangerous Preparations (1999/45/EC) [20]. As a generic approach, they do not always result in an accurate approximation of the hazard or its severity across the range of possible preparations and mixtures.

In particular, the generalised approaches may not reflect accurately whether the mixing of a dangerous substance with a non-dangerous substance will reduce the significance of the original hazard or not. Moreover, sometimes a new substance may be generated from the mixing of substances, with different properties all together, but this situation may remain unrecognised or undetected.

Automotive fuels are just one example of substances where this problem occurs and was addressed in the original Seveso II Directive as follows:

> "Most petroleum types are complex mixtures that are difficult to characterise in detail, and therefore many definitions used to describe petroleum and its products lack precision, and terms can even be used in different ways by different sectors of the petroleum industry. Definitions of materials often are given in terms of the processes used to obtain them. Many petroleum products are blended, or modified from primary stocks as they come from the refining units. Trade names are not necessarily the refiner's names, and one product may have more than one trade name, depending on the use." [14]

Direct testing of preparations and mixtures can also be conducted to correct any error in classification imposed by the methodology. However, this solution is not always satisfactory. Notably, analytic methods to assign a proper classification to a mixture or substance are sometimes not available. For example, concerning fireworks, the following has been noted:

> "Member States have identified three types of situations involving composite articles or mixtures of substances for which no generally accepted rules exist to adequately identify the magnitude of the risk, and therefore the threshold level that should apply." [16] This concern was highlighted by the investigation following the Enschede incident, which indicated that the lack of a standard for calculating such percentages could lead to an underestimation of the hazard. To address this concern, Annex I, Part 2, Note 2 was introduced by the 2003 amendment, requiring that, for explosive or pyrotechnic objects, the entire weight of the object should be used in Seveso II threshold calculations when the percentage of explosive content or net explosive content (NEC) is not known.

A similar case was put forward by Borgonjon in 2006 who indicated that lack of proper testing methods was also a barrier to excluding sites using alloy metals in solid form [21].

2.2.4. Failure to account for important economic and social factors

An approach that uses generic categories defined by their hazardous properties cannot take into consideration economic and social factors associated with a particular substance. For instance, the costs of imposing obligations on handling and usage of certain substances (in a manner consistent with other substances of an equally hazardous nature) may be economically or socially unacceptable. Automotive fuels are a case in point: it would be economically infeasible for petrol stations around Europe to implement the full requirements of the Seveso II Directive for storage of a flammable liquid, if the threshold quantities for the category to which this substance were actually applied. Such criteria also ignore exposure potential, for example, handling and equipment that may reduce or increase exposure or reduced or the location of a site in reference to a population centre or other vulnerable receptor.

2.2.5. The criteria cannot be changed in reaction to new information except through legislation

Adjustments to the substance criteria can only be enabled through the legislative process. There is always a risk that technical adjustments to coverage, based on new information on hazardous substances or processes, might be ignored in a period where re-opening the Directive is politically unviable. Any change of a substance's EU classification into or out of a category used by Seveso can also trigger a change in establishment coverage. In particular, entry into the scope through a new or revised classification can occur unexpectedly to industries unprepared or unused to coming under the strict requirements of the accident prevention legislation.

For example, following the 29th Adaptation to Technical Progress (ATP) of the EU Classification and Labelling Directive [22] some stakeholders argued that the re-classification of chromium trioxide (VI) from T to T+ in the 29th ATP could potentially bring numerous sites in the electroplating industry into the purview of the Directive that did not represent major hazards in actuality. However, whether or not these arguments held true on examination was irrelevant because the Seveso Directive gives no authority to modify the status of coverage of a particular substance from its generic classification outside new legislation. It was also argued that the assignment of new classifications to triclosan solutions and zinc oxide in the 29th ATP could bring some sites into the Seveso regime that are not, in true process safety terms, high priority hazards [23].

In the short term, the coming into force of the REACH requirements [13] may exacerbate the rate at which new substances are classified into or out of Seveso-relevant categories. Some of these substances, by virtue of the volume of usage in particular processes, could cause an important alteration in Seveso coverage of a certain industry. Although many of these changes could be anticipated and often welcomed, there may be a small subset that causes distortions in coverage deemed inappropriate by Member States in proportion to the actual risks present at these sites.

In the long term, the potential for new classifications and changes to classifications emanating from REACH should stabilise to a much lower level, and REACH is expected to resolve some past problems associated with Seveso's dependence on underlying EU substance classifications to define its scope. For example, the self-classification provision of the 67/548/EC classification system led to some ambiguities in classification and raised the potential for inconsistency across Member States. In addition, Trainor et al. also pointed out that Annex I, 67/548/EC has a number of erroneous classifications in relation to acute toxicity [24]. It is expected that implementation of REACH will eliminate such inaccuracies.

3. Supplementary features of the criteria: the named list of substances and the establishment of threshold quantities

Seveso substance criteria incorporate two additional important and complementary features to the generic categories. These are the named list of substances and the assignment of threshold quantities to all generic categories and named substances. These features are additional tools for targeting resources appropriately in the spirit of the Directive. The named list of substances is particularly a corrective measure that compensates for weaknesses in the generic category approach. The assignment of threshold quantities is mainly a strategy for targeting resources to sites with the highest hazard potential but it also can be used as a corrective measure.

3.1. The named list of substances

Generic categories of hazardous substances are supplemented by a list of approximately 50 named substances in Annex 1, Part 1 of the Seveso II Directive. The named substance list is used to adjust threshold quantities for specific substances, differentiating subsets of generic substances from the generic categories, or adding specific substances that may not otherwise be covered by the generic categories.

Table 3
Qualifying quantities for select named Seveso II substances in comparison to their corresponding generic categories.

Substance	Seveso threshold quantity (t) Article 6–7/Article 9	Qualifying quantity (t) for applicable generic category with lowest thresholds [6]	Reason for difference [14]
Chlorine	10/25	50/200 (toxic)	Accident history
Ethylene oxide	5/50	10/50 (extremely flammable)	Political reasons
Ethyleneimine	10/20	5/20 (very toxic)	Pragmatic reasons
Diesel fuel (gas oil)	2500/25,000	5000/50,000 (flammable)	Petroleum product
Fluorine	10/20	5/20 (very toxic)	Pragmatic reasons
Formaldehyde (concentration ≥90%)	5/50	50/200 (toxic)	Seveso (I) thresholds
Hydrazine	–/0.001	50/200 (toxic)	Carcinogen
Hydrogen	5/50	10/50 (extremely flammable)	Accident history
Hydrogen chloride (liquefied gas)	25/50	50/200 (toxic)	Accident history
Lead alkyls	5/50	5/20 (very toxic)	Seveso (I) thresholds
Methanol	500/5000	50/200 (toxic)	Pragmatic reasons
Methylisocyanate	–/0.15	5/20 (very toxic)	Accident history (Bhopal)
Natural gas	50/200	10/50 (extremely flammable)	Pragmatic reasons
Petrol (gasoline)	2500/25,000	10/50 (extremely flammable)	Petroleum product
Phosgene	0.3/0.75	5/20 (very toxic)	Unique properties/political
Propylene oxide	5/50	10/50 (extremely flammable)	Political reasons

Smeder describes the main reason for the inclusion of a named list of substances as follows:

> "... for some substances it is desirable to establish higher or lower thresholds than they would have according to their category. The reasons for this may be a combination of technical ones (since the classification system address the intrinsic properties of substances rather than the potential to cause a major accident), industrial or pragmatic (a reasonable number of establishments to be covered)." [14]

Table 3 gives examples of specific named substances, comparing actual threshold quantities to the threshold quantities that would have applied if generic categories had been used and the rationale for not using them.

3.2. The assignment of qualifying or "threshold" quantities to categories and substances

The "threshold quantity" is a cut-off value, in this case it represents the minimum quantity that must be present on site to trigger lower or upper tier coverage under the Directive. Under the Directive, "lower tier" sites are associated with lower quantities of hazardous substances and a lower regulatory burden; "upper tier" sites are associated with higher threshold quantities and a higher regulatory burden. The establishment of a minimum quantity and two levels of obligation is a mechanism that allows Seveso to target coverage more precisely according to severity of the hazard.

3.3. Advantages associated with the named substance list and threshold quantities

3.3.1. Higher obligations can be imposed on sites with the most serious hazards present

In theory, the system allows resources to be concentrated on the establishments that pose the highest risk. According to Porter and Wettig:

> "... the Directive can be viewed as inherently providing for three levels of 'proportionate' controls in practice, where larger quantities mean more controls. A company who holds a quantity of dangerous substance less than the lower thresholds given in the Directive is not covered by this legislation but will be proportionately controlled by general provisions on health, safety and the environment provided by other legislation which is not specific to 'major-accident hazards'. Companies who hold a larger quantity of dangerous substance, above the lower threshold contained in the Directive, will be covered by the 'lower tier' requirements. Companies who hold even larger quantities of dangerous substance, above the upper threshold contained in the Directive, will be covered by all the requirements contained within the Directive." [25]

Quantities for some categories, as well as named substances, can be established at lower or higher levels, if their risk potential relative to other hazardous substances is perceived as lower or higher than another category or substance. A threshold quantity may also be purposely increased or lowered to take account of other influential factors, such as economic burden or public perception.

The differentiation between upper tier and lower tier sites especially affects safety report and inspection obligations. In particular, for lower tier sites, obligations assigning production (by the operators) and review (by the authorities) of the safety report are eliminated and rules for scheduling and defining inspection of lower tier sites are not specified.

It should be noted that for some Member States the differentiation between upper and lower tier sites does not seem to be advantageous. However, at this moment it does not appear that this perception is universally shared.

3.3.2. Regulatory status and obligations can be differentiated for sites with substances whose hazardous character is not adequately captured by the generic categories

Exceptions to the generic categories are made to correct threshold quantities associated with particular substances or groups of substances. The threshold quantity for generic categories is a generalised minimum and creates the possibility for gross underestimates or overestimates of the potency of certain substances. For some substances a higher or lower threshold quantity has been applied on the basis of accident history, or because expert opinion or public perceptions judge that the generic categories do not adequately reflect the hazard potential of a particular substance. An example of this is chlorine. Based on generic criteria ("toxic"), thresholds would have been 50/200 tonnes (lower/upper tier). However, its thresholds were lowered to 10/25 tonnes because it is widely used and history has shown that it has a high major accident potential [14].

In addition, certain substances may have physical and behavioural elements affecting hazard severity that are overlooked by the generic categories and are therefore not adequately reflected in threshold quantities. Ammonium nitrate is an example of a substance whose unique nature creates hazards of quite different levels in various conditions. A review of its hazardous nature following the accident in Toulouse, France of 21 September 2001 produced the following recommendation for coverage in the Seveso II Directive

"... the Seveso Directive [should] be expanded to cover all ammonium nitrate, ammonium nitrate compounds, simple ammonium nitrate-based fertilisers, and composite fertilisers (e.g., NPK), even if nitrogen content as a result of the ammonium nitrate is less than 28% by weight ... In addition, [there exists] the possibility for maintaining higher thresholds for packaged products (sacks, big bags), in the assumption that they are much less susceptible to contamination, therefore less likely to encourage detonation, than loose product." [17]

The 2003 amendment (2003/105/EC) included a revision of the ammonium nitrate categories as indicated in the named substance list of the Directive as shown in Table 2 [26].

3.3.3. Regulatory status and obligations can be differentiated for sites on the basis of practical considerations associated with particular substances

The Commission has consistently maintained that threshold quantities are not precise estimates of risk, and practical considerations or other policy goals can justify raising or lowering threshold quantities in some circumstances. As an example, "liquefied petroleum gases and natural gas" were excluded from the generic category, "extremely flammable". Instead, thresholds for liquefied petroleum gas (LPG) were set specifically with economic considerations in mind as noted here:

Based on generic criteria, thresholds would be 10/50 tonnes ("extremely flammable"). The original Commission proposal was to list "LPG (including propane and butane)" and "Natural gas or other combustible gases" in Part 1 (thresholds 50/200 tonnes in order not to include too many sites). This would however lead to unfair competition for sites using other liquefied gases. Thus, the two entries were changed and combined to read "liquefied extremely flammable gases (including LPG) and natural gas" (50/200 tonnes)" [14].

3.4. Disadvantages associated with the named substance list and threshold quantities

3.4.1. Threshold quantities of generic categories are highly imperfect proxies for hazard potential

The difficulty of calculating threshold quantities based on scientific criteria was well understood based on experience already gained with the original Seveso Directive. It is often complicated to do so for individual substances; it can be enormously difficult to do so on a generic basis. For this reason, the Commission insisted on a transparent and consistent process for establishing threshold quantities, even though the establishment of threshold quantities for some substances, and even some categories, proved quite challenging scientifically.

For generic substances, the threshold quantity is calculated on the basis of the severity of the hazard and the likelihood of it causing a major accident. In his study for the Commission, Marshall defines threshold quantities more precisely as "the mass of substance that must be present for it to acquire the potential for a major-accident hazard". [27] He notes that the chief difficulty in calculating a threshold is the definition of "potential of a hazard" and that "there is no single figure which can be used to express the potential of a hazard." In other words, the necessity of reducing hazard potential to one number involves some sacrifice of scientific rigour. Significant expert judgment is required especially in the case of substances or dangerous properties where the data and knowledge base are limited. Moreover, even when one accepts this compromise as inevitable, it can be difficult to find a suitable methodology and data for calculating the potential of a hazard associated with each hazardous property. In some cases, such as carcinogens, even the most basic methodology and data are lacking [15].

In general, with some exceptions, the threshold quantities for the generic flammable and explosives categories in the Directive can be more or less traced back to Marshall's recommendations. Marshall's approach uses historical data in combination with hazard severity measures as the basis for his recommendations (whereas Bello uses deterministic methodologies in the first instance and historic data to validate results). However, the methodologies proposed by Marshall and Bello for calculating the threshold quantities for toxic substances are rather complex and more or less designed for analysis of individual substances [27,28]. The hazard potential of substances with toxic properties is very difficult to capture in a generic way since the characteristics that can influence severity are several (e.g., concentration, exposure time, exposure route, persistence, type of effect) and vary between substances or subgroups of substances (e.g., pesticides). Bello noted that identifying the critical mass that must be present to produce a major accident "implies the use of quite sophisticated dispersion simulation codes, whose results are not only "substance-dependent", but also "scenario-dependent", i.e., their results are a function of the physico-chemical properties of the released substance (molecular mass, density, viscosity, etc.) and of the parameters describing the micro-scenario (i.e., micrometeorology, terrain roughness, presence of obstacles, etc.)" [28]. For this reason, calculation of threshold quantities is problematic and sometimes controversial for substances and generic categories of substances that are toxic and very toxic to human health. Furthermore, similar complexities for assigning thresholds have been pointed out for substances classified in Seveso as dangerous for the environment [16].

As such there is no clear explanation for the threshold quantities that were established for the generic categories of toxics and toxic substances. However, a plausible assumption is that the thresholds were established in a precautionary way, reflecting expert judgment concerning "average minimum" quantities for a number of important toxic and very toxic substances. Accident history associated with a number of toxic substances or possibly minimum container size may have had some influence.

Since the Bello report in 1989, little further work has been done on any of these models per se. It is possible that the models could be refined with findings from more recent work. However, thus far the Enschede accident has posed the only challenge to the definition of specific categories (the explosives categories) and the threshold change resulting thereof was by and large derived through expert judgement rather than modeling.

3.4.2. Limits of data and precise knowledge undermine the certainty of definitions and thresholds associated with some substances on the named substance list

Expert opinion and often accident history justified the placement of several substances and groups of substances on the named substance list. While these factors are a reasonable and widely accepted basis for identifying substances for accident prevention regulation, they provide only limited scientific evidence to establish specific qualifying quantities for each substance on the basis of hazard potential. Moreover, when the named substance is actually a group of substances, the named substance list runs into the same problem with generalisation as when generic categories are applied.

4. Other corrective measures for managing exceptions and imperfections associated with the generic categories approach

On a more limited basis, there are additional measures that are available and have been applied to adjust or clarify coverage for

certain installations or types of installations (short of amending the Directive). These measures are generally intended for cases where coverage has been deemed inappropriate, either on the basis of actual risk posed by a substance, or simply for practical reasons, e.g., overlap with other legislation or regulatory regimes.

4.1. Other legislative measures

The following additional corrective measures have been used to address both types of coverage problems in the legislation:

- *Addition of supplementary criteria to re-specify generic categories or named substances.* The Seveso II Directive inserts supplementary criteria for some generic categories and named substances to ensure that the criteria remain focused on substances that pose a serious risk and associate them with the appropriate level of obligation (represented by threshold quantities). In particular, the generic "Explosive" categories are qualified through the assignment of UN ADR categories and generic "Flammable" categories are qualified with additional specifications relating to process conditions (pressure and temperature). The named substance list includes specific suspected carcinogenic substances covered under the Directive and, as mentioned in Section 2.4.1, differentiates between various categories of ammonium nitrate and potassium nitrate compounds.
- *Exemptions of industry sectors.* Certain activities are currently exempted from Seveso requirements by Article 4. These activities include military and nuclear installations, transport of dangerous goods by any means including pipeline, ports and marshalling yards, off-shore facilities, and mining and waste land-fills with the exception of operational tailing facilities.

In general, both the supplementary criteria and the allowance for exempted industries are simple mechanisms for adjusting coverage if suitable situations are uncovered. Sometimes a precise description of the new criteria or exempted industry sector for legislative purposes is not available and some work is required to develop an agreed and scientifically sound solution. However, the narrow focus of these mechanisms limits the complexity of such tasks.

4.2. Discretionary measures

For Member States, the most powerful discretionary tool resides in Article 176 of the Treaty on the European Communities, often referred to as "minimum harmonisation". This article established the right of each Member State to introduce more stringent environmental protection measures provided they do not contradict any principles embodied in the Treaty or other EU legislation [29]. This article allows Member States to increase coverage and obligations associated with implementation of any Directive in its territory, although Member States cannot reduce coverage or obligations in any way except as allowed within the Directive itself.

In essence, Member States have broad scope to expand coverage under the Directive on the basis of EU principles but no authority to reduce coverage. There are two other somewhat limited discretionary measures that can provide relief in specific situations where coverage is deemed inappropriate or ambiguous.

- *Article 9.6 Derogation from the full safety report requirement for qualifying establishments.* Article 9.6 of the Seveso II Directive allows Member States to grant such a derogation when the presence of a particular Seveso-covered substance on site is demonstrated to be "incapable of creating a major hazard". In this case, the safety report can be limited to "those matters which relevant to the prevention of residual accident hazards". In essence, Article 9.6 applies only to upper tier sites (because lower tiers sites are not obliged to submit a safety report under the Directive) and if approved for a derogation, they may only "limit the information required in safety reports to those matters which are relevant to the prevention of residual major-accident hazards and the limitation of their consequences for man and the environment" [1]. As noted by Wettig and Mitchison, the term "residual major-accident hazards" relates to "dangerous substances present at the establishment, other than those for which the dispensation has been granted (either different substances or the same substance under different circumstances)" [30]. Therefore, in practical terms, a safety report must still be provided and only some information on prevention of major accident hazards may be eliminated. Moreover, the derogation only relates to the safety report and does not release the operator or the competent authority from other obligations of the Directive, including inspections.

As such, the regulatory relief obtained from applying this derogation has been perceived as quite limited to some Member States since applying the derogation often results in a marginally reduced burden for operators (at most) with no reduction at all in responsibilities of competent authorities. (As of the date of this publication only 12 derogations have been approved in the Member States).

- *Consensus process to interpret complex or ambiguous situations within the context of the Directive.* The European Commission has established a process by which Member States can request clarification of Seveso requirements in situations of exceptional technical complexity or ambiguity. In many cases, these questions have involved application of the criteria for coverage. After consensus is reached on a technical analysis, the "suggested interpretations" are published in the MAHB Q&A tables [19]. This process of suggesting interpretations for ambiguous or complex situations functions well as long as consensus can be reached.
- *Case-by-case expert judgement.* In some cases no immediate systemic solution can be found when it is judged that the accident risk potential of a specific substance or group of substances (or its social acceptability) differs from that assigned to the generic category. In this instance the local experts are responsible for making a decision after weighing the various options and legal justifications.

5. Summary analysis and implications for future changes to the Seveso II Directive and its qualifying criteria

Table 4 summarises the findings of this study in regard to advantages and disadvantages of the Directive's substance criteria and mechanisms for addressing potentially unintended coverage or gaps in coverage. Based on this summary analysis, the following can be concluded:

- This study indicates that the main limitations of the generic approach were recognised in the establishment of the criteria. The named list of substances and threshold quantities, as well as other corrective measures allowed in the structure and administration, offers a quite flexible means to compensate for deficiencies of a generic approach. Indeed, there are both systemic solutions, e.g., altering the definition of a category to capture the targeted set of substances more precisely, and case-by-case solutions built into the structure.
- Lack of data and knowledge will always be a problem. The only solution is to accept this limitation and work with the data and methods that are available, while at the same time continuing

Table 4
Advantages and disadvantages associated with specific corrective measures.

Corrective measure	Advantages	Disadvantages	Application
Named list of substances	Differentiation of substances and groups of substances on the basis of hazardous properties or practical considerations	Identifying and characterising groups of substances that should be treated as exceptions to generic categories can require additional analysis and data. Complex situations can yield imperfect solutions (and cause overcoverage or undercoverage) Exceptions and new data that surface after the Directive becomes official EU law, cannot be managed without new legislation	In combination with threshold quantities, this mechanism can accommodate scientific complexities. Can be applied to any substance or substance category where there is justification to treat it differently from the generic category
Threshold quantities	Higher obligations can be imposed on sites with the most serious hazards present	Estimating and averaging the proper cut-offs for Seveso coverage of toxic substances can require considerable expert judgement. Moreover, data and models are sometimes inadequate to establish a minimum quantity that represents severe accident potential with any degree of certainty. The potential may vary widely from substance to substance depending on its release pathway and the nature and severity of the physiological effect	Used to differentiate categories and subcategories of hazardous substances in terms of severity. In combination with named substances can adjust the criteria for any substance or substance category where there is justification to treat it differently from the generic category
	Differentiation of substances and groups of substances on the basis of hazardous properties or practical considerations Minimum quantities and cut-offs representing accident risk potential can be reasonably estimated from scientific data for explosives and flammables		
Industry sector exemptions	Allows exclusion of industry sectors that would meet Seveso coverage criteria but are deemed inappropriate for Seveso coverage for practical reasons	Identifying and properly qualifying subsectors that are to be treated as exceptions can require additional analysis and data. Complex situations can yield imperfect solutions (and cause overcoverage or undercoverage, or heavy reliance on expert judgment in local situations)	In general used to exempt activities but on occasion can also filter out substance categories (e.g., nuclear materials)
Additional qualifying criteria for generic categories	Differentiation of generic categories with additional criteria (e.g., Notes 2 and 3 of Annex I Part 2) to make coverage of hazards more complete and distinguish severity levels more accurately	Defining additional criteria may require additional analysis of varying scientific difficulty. Moreover, additional criteria can further confuse the identification of substances that fall in or out of Seveso	Used to make technical differentiations related to major accident potential within the generic categories
Reduction in safety report obligations (Article 9.6)	Specific upper tier establishments can be allowed reduced safety report obligation if lower risk can be demonstrated	Relief is limited to upper tier installations	Applied on a case-by-case basis to individual sites where lower accident potential can be demonstrated
		Demonstration to justify this reduced obligation can require significant resources It cannot be applied on an EU wide basis to similar facilities, but on a case-by-case basis	
Q&A	Can manage small technical and linguistic ambiguities without requiring legislation	The only authority is the consensus basis of the interpretation suggestions. Complex or controversial questions cannot be managed by this mechanism	Used for narrowly focused interpretations
	Can impose uniform interpretation of complex or ambiguous situations		

to seek and develop new sources of data and improve analytical tools. There is hope that the new REACH regulation may produce more data for judging the proper classification and hazard potential of numerous substances. However, many of the challenges posed by lack of adequate analytical or testing methods may not be resolved so easily. Some of these gaps remain simply due to the scientific difficulty of finding a proper solution (e.g., carcinogenicity). In other cases, such as identifying hazards associated with certain preparations, the search for a solution will only be prioritised if it is expected to yield significant social or economic benefits for citizens or for the affected industries.

- There are cases where data and methods are available and the generic classification is correct but the criteria nonetheless produce a false positive or false negative when applied. This situation generally occurs due to either specific inherent properties (e.g., volatility) or process conditions that influence major accident hazard potential in that they affect the release and dispersive capacity of the inherent hazard. No mechanism currently exists for adjusting criteria for particu-

larly important false positives or negatives outside of re-opening the entire Directive for re-legislation. The first few years of implementation of REACH will almost certainly provide good evidence as to whether the lack of such discretionary powers is a minor or serious inconvenience in Seveso terms. Depending on this experience, it could be worth reviewing whether there should be more flexibility to revise the substance criteria outside the context of a major legislative revision.

- Derogation for specific sites under Article 9.6 has been criticised for offering regulatory relief that is too limited to be considered worthwhile in most cases where the scope of the Seveso Directive may have mistakenly identified a site as a major accident hazard. The possibility of modifying the derogation provisions under Article 9 (6) to address these concerns could be explored.
- Threshold setting is admittedly an imperfect mechanism for distinguishing between high priority sites, medium priority sites, and low priority major hazard sites. The most difficult thresholds to establish from a scientific perspective are arguably carcinogens, toxic and very toxic to human health and dangerous to the environment. Nonetheless, the thresholds of these generic categories remain virtually unchallenged thus far except in the case of a few specific substances in recent years. Aware that the generic criteria are imperfect, these substances are normally handled as exceptions than as criticisms of the current criteria. However, should new methodologies or data emerge in this regard that can substantially improve the efficiency of the criteria, it is likely that they will be given serious consideration. In several instances, the EU legislative bodies have shown themselves to be open to modifying thresholds when new information is presented and the impact seems important.

6. Conclusion

Every system has its weaknesses. In Europe, it is well understood that the application of strict criteria can sometimes unintentionally exclude sites intended for coverage and bring in sites that were not intended for coverage by the Directive, or otherwise impose disproportionately light or heavy obligations on sites in comparison to their risk potential. Nonetheless, this approach has been well-supported within the EU as providing a fair and objective means to ensure that all high risk sites are indeed required to employ a rigorous safety regime to prevent industrial accidents. Where no perfect solutions can be found, the precautionary principle will always prevail, and without a doubt, the current definition of the scope of accident prevention regulations, with all its imperfections, remains preferable to ignoring potentially high risks against the will of the society subject to that risk.[2]

References

[1] Council Directive 96/82/EC (“Seveso II”) concerning the control of major-accident hazards involving dangerous substances, Official Journal of the European Communities, L 10/13, Brussels, 14.1.97. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0082:20031120:EN:PDF.

[2] Council Directive 82/501/EEC of 24 June 1982 on the major-accident hazards of certain industrial activities, Official Journal of the European Communities, P 196, Brussels, 16.8.67. http://mahbsrv.jrc.it/downloads-pdf/Seveso1-LEG-EN.pdf.

[3] Report of the OECD-EC Workshop on Risk Assessment Practices for Hazardous Substances Involved in Accidental Releases (16–18 October 2006, Varese, Italy), OECD Environment Directorate. OECD Environment, Health and Safety Publications Series on Chemical Accidents, No. 16, Paris, 2007, ENV/JM/MONO, p. 29.

[4] Report on the Application in the Member States of Directive 96/82/EC on the Control of Major-Accident Hazards involving Dangerous Substances for the Period 2003–2005, European Commission. http://ec.europa.eu/environment/seveso/implementation.htm.

[5] Report on the Application in the Member States of Directive 96/82/EC on the Control of Major-Accident Hazards involving Dangerous Substances for the Period 2000–2002, European Commission. http://ec.europa.eu/environment/seveso/implementation.htm.

[6] Ex-European Chemicals Bureau ClassLab Database, European Commission, Joint Research Centre. http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab/.

[7] 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, Official Journal of the European Union, L 10/13, Brussels, 14.1.97. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:NOT.

[8] UNECE, Globally Harmonized System of Classification and Labelling of Chemicals (GHS), First published in 2003. http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

[9] 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, Official Journal of the European Union, L 353/1–1355, Brussels, 31/12/2008. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

[10] Comparison between EU and GHS Criteria Human Health and Environment Draft version, European Commission, December 2007. http://ec.europa.eu/enterprise/reach/docs/ghs/ghs_comparison_classifications_dec07_en.pdf.

[11] Analysis of the potential effects of the proposed GHS regulation on its EU downstream legislation, European Commission, August 2006. http://ec.europa.eu/enterprise/reach/docs/ghs/ghs_sc_study_final_110806.pdf.

[12] B. Hervé-Bazin, A Review of the Directive on the Major-Accident Hazards of Certain Industrial Activities (82/501/EC), Review of Annex IV, Institut National de Recherche et de Securité (INRS), Final Report, 1986.

[13] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Official Journal L 396 of 30 December 2006. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF.

[14] M. Smeder, Substances covered by Part 1, Annex I, of the Seveso II Directive, Major Accident Hazards Bureau, Joint Research Centre, European Commission, EUR 18705 EN, 1999. http://mahbsrv.jrc.it/Framework-Seveso2-Annex1.html.

[15] M. Christou (Ed.), Carcinogens in the context of Council Directive 96/82/EC report by Technical Working Group 8, Major Accident Hazards Bureau, Joint Research Centre, European Commission, EUR 19650 EN, 2000. http://mahbsrv.jrc.it/downloads-pdf/wg7-Final-Report-1.pdf.

[16] M. Christou (Ed.), Substances Dangerous for the Environment in the Context of Council Directive 96/82/EC, Report by Technical Working Group 6, Major Accident Hazards Bureau, Joint Research Centre, European Commission, EUR 10651 EN, 2000. http://mahbsrv.jrc.it/downloads-pdf/wg7-Final-Report-1.pdf.

[17] M. Wood, S. Duffield, Ammonium Nitrate Safety: Summary Report of the Workshop Held on 30 January–1 February 2002, Ispra, Italy, Major Accident Hazards Bureau, Joint Research Centre, European Commission, Special Publication No. I.02.116, August 2002.

[18] M.H. Wood, S. Duffield, Pyrotechnic and explosive substances in the context of the Seveso II Directive, A Summary Report from Seminars held on 27 September 2000 (Marseille, France) and 28–29 March 2001 (Ispra, Italy), Major Accident Hazards Bureau, Joint Research Centre, European Commission, Special Publication No. 1, 02.115. http://mahbsrv.jrc.it/downloads-pdf/Fireworks-Proceedings-FinalWebPublication.pdf, 2001.

[19] Council Directive 96/82 – Questions and Answers, Major Accident Hazards Bureau, Joint Research Centre, European Commission, May 2007 Version.

[20] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, Official Journal L 200, 30/07/1999 P. 0001–0068. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0045:EN:HTML.

[21] I. Borgonjon, Practical experiences with classification problems, Presentation at the Seminar on Chemical Substance Classification Issues in the Context of the Seveso-II-Directive, Organised by the Austrian Competent Authorities and the Major Accident Hazards Bureau of the European Commission, Vienna, Austria, 18 January 2006.

[22] Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. http://ecb.jrc.it/documents/Classification-Labelling/DIRECTIVE_67-548-EEC/ATPS_OF_DIRECTIVE_67-548-EEC/29th_ATP.pdf.

[2] These are representative examples using relatively well-known and widely used substances (and preparations). Many substances fall in more than one Seveso category. Example substances are linked to the Seveso category that has the lowest Seveso threshold quantities among all the categories to which they belong.

[23] A. Wilson, Dangerous substances to the Seveso II Directive, Presentation by the UK Health and Safety Executive at the Seminar on Chemical Substance Classification Issues in the Context of the Seveso-II-Directive. Organised by the Austrian Competent Authorities and the Major Accident Hazards Bureau of the European Commission, Vienna, Austria, 18 January 2006.
[24] M. Trainor, P. Ridgeway, R. Macbeth, J. Wilday, H. Balmforth, A methodology to prioritise substances for possible further development of Acute Exposure Threshold Levels (AETLs), Prepared by the Health and Safety Laboratory for the Health and Safety Executive, Research Report 426, 2006.
[25] S. Porter, J. Wettig, Policy issues on the control of major accident hazards and the new Seveso II directive, J. Hazard. Mater. 65 (1999) 1–14.
[26] Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003 amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances, Official Journal of the European Communities L 345, Brussels, 31.12.2003.
[27] V.C. Marshall, Implementation of the Directive on Major Accident Hazards of Certain Industrial Activities (82/501/EEC) Article 19 – Review of Annexes I, II, and III, University of Bradford, England – on a contract of the Commission of the European Communities, 1985.
[28] G. Bello, T. Moraes de Amorim, E. Galatola, Revision of the Directive No. 82/501 (Seveso Directive), Eidos Studi Associati. on a contract of the Commission of the European Communities, Lodi (Italy), June 20th 1989.
[29] Treaty Establishing the European Community, Consolidated Version, Official Journal C 325, 24 December 2002.
[30] J. Wettig, N. Mitchison (Eds.), Seveso II Article 9(6): Explanations and Guidelines, Major Accident Hazards Bureau, Joint Research Centre, European Commission, EUR 18124 EN, 1999. http://mahbsrv.jrc.it/downloads-pdf/Twg6-en.pdf.