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ScienceDirect
Journal of Hazardous Materials 157 (2008) 230–236
Journal of Hazardous Materials
www.elsevier.com/locate/jhazmat

Writing Seveso II safety reports: New EU guidance reflecting 5 years' experience with the Directive

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Received 26 July 2007; received in revised form 20 December 2007; accepted 23 December 2007
Available online 4 January 2008

Abstract

Since the coming into force of the Seveso II Directive, considerable experience has been acquired in regard to preparation of safety reports for establishments that fall under the requirements of this Directive. In light of this experience, the Amendment of the Seveso II Directive adopted by the European Parliament and the Council on 16 December 2003, gave the European Commission the mandate "to review by 31 December 2006 in close cooperation with the Member States, the existing Guidance on the Preparation of a safety report (EUR 17690)". As a result, a technical working group of Member States representing the Seveso competent authorities and the European Commission's Major Accident Hazards Bureau was established to review and re-examine the guidance. The new guidance maintains the high-level and overarching character of the older version, but improves the document through better definition of conceptual elements of the safety report and greater alignment with Annex II of the Directive, which describes the essential elements of the safety report. This paper describes the new guidance in terms of its contribution to developing a harmonized conceptual framework for preparing and reviewing safety reports within the context of Seveso II implementation. Overall, the aim of the guidance is to provide concrete advice to operators and competent authorities on the logic and expectations underlying the safety report, so as to make both preparation and review of the report a more efficient and useful exercise for all parties involved.

Keywords: Seveso Directive; Control of major accident hazards; Safety reports; Guidance documents; Industrial safety

1. Introduction

On 16 December 2003 the Seveso II Directive 96/82/EC [1] was extended by the Directive 2003/105/EC of the European Parliament and of the Council [2]. One particular provision of the amendment involved the European Commission's existing safety report guidance. Specifically, the amendment invited the European Commission "to review by 31 December 2006 in close cooperation with the Member States, the existing 'Guidance on the Preparation of a Safety Report'" [3]. By also coinciding with the end of the first phase of implementation of the safety report, it represented a unique opportunity to adjust the guidance with the benefit of hindsight from past experience and taking into account the particular needs of countries newly entering the Seveso regime with often vastly different histories and practices.

In accordance with this new obligation, the Major Accident Hazards Bureau (MAHB) of the European Commission's Joint Research Centre (JRC) led a Task Force on safety report Guidance. The task force consisted of representatives of Member State competent authorities with experience in enforcing safety report obligations, and was sponsored and supported by the European Commission's Directorate General-Environment, responsible for oversight of Seveso policy implementation in the EU. The work of the task force resulted in publication of revised guidance in 2005 by the Major Accident Hazards Bureau [4]. It was subsequently approved by the European Commission by common decision following an inter-service consultation [5]. The guidance was seen as a positive contribution to efforts for giving the safety report additional practical significance.

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doi:10.1016/j.jhazmat.2007.12.089

This paper describes the historical developments and discussions that led to strengthening the conceptual framework of the safety report guidance and on this basis, the important elements that have been newly introduced are explained.

2. Historical background

2.1. The significance of the safety report requirement

Safety technology and implementation strategy changed substantially in the years following the launching of the original Seveso Directive. As a result, the Seveso II Directive was eventually established, repealing the older version in order to introduce new concepts for managing industrial risks as a result of substantial changes in safety technology and implementation strategy since the first Seveso Directive was authorized in 1982 [6]. One of the major new advancements in industrial risk management that had been introduced in several EU countries prior to Seveso II was the safety report obligation [7]. Although this concept was embodied in a very general sense in the previous version of the Directive in notification requirements, the idea of structuring the main results and conclusions of the safety analysis in a separate report took on its own identity and became a leading edge concept in industrial risk management. This concept gradually gained substance in the years following the implementation of Seveso I and its purpose and implementing practices were further defined and detailed.

With the introduction of Seveso II, the safety report requirement is inextricably linked to the fundamental obligations of the Directive, described in Article 5. The safety report is one key piece of evidence for "*demonstrating*" that "*all measures necessary to prevent major accidents and to limit their consequences for man and the environment*" are in place.

The Seveso II Directive, in introducing the concept of the safety report, has formally obliged upper-tier operators to describe and defend the risk assessment process and the measures selected to prevent, control and limit major events. Moreover, the introduction of safety management systems and the linkage between competent authority obligations of land-use planning and external emergency planning signaled a new and elevated emphasis to a systemic approach to major accident control. Other provisions also augment the role of the competent authority in reviewing the report, including the time table for assessment established in the Directive and the enforcement obligations associated with the safety report [8].

As a result, the safety report requirement was considered an important new component of the Seveso regime with potentially significant benefits. More specifically, it was viewed as a mechanism that would drive companies toward a more systematic approach for assessing their major hazards and for selecting or confirming the necessary protection measures. It also was seen as a document that would offer the benefit to be '*auditable*' [9], and which would have been sufficiently complete and detailed to become a worthwhile piece of evidence such that the risks associated with the hazardous substances present on the site had been properly considered and addressed.

2.2. The safety report requirement and the EU guidance

In order to help EU Member States and operators to meet the safety report requirement, the Major Accident Hazard Bureau of the European Commission established a Technical Working Group of representatives of Member States and industry to assist with the development of safety report guidance. Anticipating the new requirement, the majority of this effort took place before the Directive was finalized. This fact explains why the guidance did not cover the various subtopics in the same sequence as Annex II of the Directive. Nonetheless, the information was quite consistent with the Annex II requirements, adequately reflecting the general scope and giving specific criteria for each subtopic.

The original guidance, created in collaboration with the Member States, was perceived as reasonably successful in finding the middle road between not enough detail and too much detail. Nonetheless, it was also recognized that the Seveso II Directive, and in turn, the various EU guidance documents created to support its implementation, were charting new territory. In this regard, there was some expectation that eventually various EU guidelines would need to be further modified in order to reflect actual implementation experience and perhaps even the Directive as such. In fact, as evidenced in this paper, both these situations have now already come to pass.

3. Revised EU guidance

3.1. Challenges associated with the safety report and similar goal-oriented requirements of the Directive

Consistent with a performance-oriented approach, the Directive purposely does not give specific directions concerning technical approaches that should be used to implement its requirement. As explained by Porter and Wettig, "The degree of prescription within the framework is limited as it is clearly recognized that the operators are best placed to comprehensively assess hazards/risks in detail and that it is not possible for authorities to prescribe a 'one-size fits all' solution". This situation makes the task of ensuring consistency of implementation somewhat of a challenge for goal-setting legislation and for the European Commission in particular [10]. Specifically, according to Article 9 of the Directive, the purpose of a safety report is to demonstrate that:

- a major accident prevention policy (MAPP) and a safety management system (SMS) have been put in effect,
- major-accident hazards have been identified and that necessary measures have been taken to prevent such accidents and to limit their consequences,
- adequate safety and reliability have been incorporated into the design, construction, maintenance and operation,
- internal emergency plans have been drawn up and supplying information have been provided for use in the external emergency plan, and
- sufficient information for land-use planning decisions has been given to the competent authorities.

Annex II of the Directive specifically lists the minimum data set and information that should be included in a safety report. These relate to: the organization of the establishment with regard to accident prevention, the environment of the establishment (internal and external), the hazardous installations, the processes therein, the methods applied to analyze risks associated with the presence of dangerous substances, and the measures of protection and intervention to limit the accident consequences.

Given these general instructions, the challenge of consistency in implementing the Directive is clearly two-fold. Firstly, some requirements of the Directive, such as the safety report, are not defined at a sufficient level of detail to be practically operational. In this case, there is the clear danger that requirements can be interpreted quite differently in the different Member States. As Mitchison notes, the guidance documents supporting the Directive were created largely to fill in this gap and to help to steer Member States towards common interpretations and good practice [11]. Secondly, the European Commission cannot take a position on technical and policy decisions about certain requirements when such details are not explicit in the Directive. For example, the European Commission cannot advise on the specific type of risk assessment method that should be used or the land-use planning process that should be implemented. For these aspects it was expected that Member States would use EU guidance to develop more detailed guidance at national level. However, the European Commission may promote consistency through technical exchange and by fostering co-operation among the Member States on technical matters, in particular facilitating common research and development of scientific methods and good practice.

3.2. Findings and conclusions from surveys and discussions to improve the safety report guidance

The idea of reviewing the existing safety report guidance was formally launched with the publication of the accident investigation report jointly prepared by the French Environmental Inspectorate, the French Explosives Inspectorate and 'L'Institut National de l'environnement industriel et des risques' (INERIS) [12]. This report strongly emphasised the need for better quality and harmonisation of safety reports across the regulated community. Subsequent to the amendment, The Major Accident Hazard Bureau of the European Commission surveyed the Seveso competent authorities concerning their use of EU and national guidance for preparation and review of safety reports and their opinions on potential improvements to the existing guidance. A workshop in Dublin, Ireland in May 2004 among Seveso competent authorities was held as a follow-up to the survey and aimed at consolidating Member State input to the review of the guidance.

The results of the survey and workshop showed that the fifteen responding countries (10 "EU 15", 4 new members, 1 EEA)[2] agreed on a number of general issues. In particular, they supported an emphasis on overarching principles that should guide safety report implementation and aligning the guideline structure more closely with the order and terminology used in the Seveso II Directive. However, there was significant disagreement concerning the level of detail. Countries that had produced their own guidance and implementation tools argued for limited EU guidance, which would remain largely conceptual and non-technical. Their main concern was to avoid a conflict between EU guidance and existing and in certain cases more detailed guidance that had been established at national level. However, in countries where good practice had not yet been established, more detailed EU guidance could be an efficient solution to the problem of lack of experience and bestow greater authority to regulators in their efforts to require operators to adhere to accepted good practices since the deadline for safety reports from existing establishments in most accession countries was some time after 2002 [13].

In the end, as a compromise, it was agreed that the existing guidance, though its high-level character, provided the proper level of detail and explanation concerning main concepts of implementation of the safety report requirement. Particular consensus was reached on the following issues:

- The content of the existing guidance should be aligned to correspond more closely with the structure of Annex II. Due to its different organization, the existing guidance was sometimes perceived as less clear and even incomplete concerning implementation of certain requirements.
- The guidance should be revised to include a coherent description of the purpose and scope of safety reports and their role in implementation and enforcement of the Directive. In particular the level of detail and minimum content required for seemed to vary somewhat in the Member States and even between different regions in the same country [14].
- Common definitions for key terms in Article 5, "General Obligations of the Operator", e.g., "demonstration" and "all necessary measures" were especially needed [15]. It was noted that lack of a uniform understanding of these terms posed a significant threat to consistency of implementation across the Member States. In some cases Member State definitions were being challenged by the regulated community.
- Risk assessment and its role in the safety report should be better defined. This aspect was of particular concern for new Member States, where risk assessment for major industrial hazards was a new concept and a clear understanding of good practice in this area was lacking [13].

In addition, several wishes were expressed by different countries to include more detailed guidance on specific topics, such as environmental effects, human factors and security. However, it was decided that these areas were too specific to be addressed in detail in a high-level guidance document, although they could be addressed in future collaborative work.

[2] The EU-15 refers to the countries belonging to the EU enlargement of 1 May 2004. Also, one non-EU member of the European Economic Agreement participated in the survey.

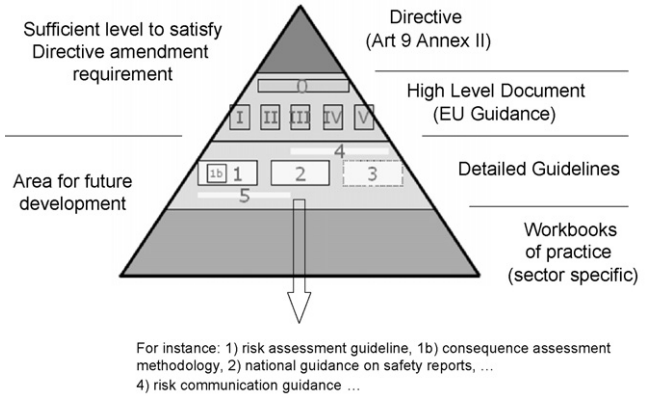

Fig. 1. Suggested general EU approach to provide guidance on the preparation of safety reports. The EU guidance described in the paper is a high level document (i.e., containing general principles (0), purpose of a safety report (I), scope (II), limitations (III),. . .). However, the proposed approach does not preclude some more specific guidance.

3.3. The revised document

The document gives further support to a harmonized philosophy for constructing and reviewing the safety report without precluding different technical approaches within the Member States, while maintaining the high-level and overarching character of the older version. This concept corresponds to the second to top layer of the triangle in Fig. 1, providing a conceptual framework for future development of more detailed guidance corresponding to the lower layers of the triangle.

Overall, the aim of the guidance is to provide concrete advice to operators and competent authorities on the logic and expectations underlying the safety report, so as to make both preparation and review of the report a more efficient and useful exercise for all parties involved. The document's conceptual improvements contributions can be summarized as a better definition of conceptual elements of the safety report in the Directive, including greater alignment with the essential elements of the safety report listed in Annex II. In addition, the document elaborates on certain key principles, such as:

- roles and responsibilities of the operator and the competent authorities, the central purpose and focus of the report,
- the relevance of the safety report in the context of the Seveso II Directive,
- specific obligations of the Directive related to the Directive, such as "demonstration", such as the obligation "to take all measures necessary to prevent major accidents and to limit their consequences for man and the environment,
- the kind of analysis and level of detail that might be necessary to characterize the risk at the facility, including the various approaches to risk assessment that are commonly used as a basis for safety reports in the European Union.

3.3.1. Modified structure of the guidance

The revised guidance is divided into three sections, two of which contain mostly new information compared to the original guidance. The first new section contains an elaborated description of the Seveso II obligations associated with safety reports and the second provides clear conceptual guidance on how to decide the content of the document. The original guidance is mainly incorporated into the third section with substantial changes mainly in the description of hazard identification and accidental risk analysis.

The safety report should demonstrate that all necessary measures to prevent, control and limit the consequences of a possible major-accident have been put in place and are fit for purpose.

- ***The Operator shall expect professional judgment from the assessor of a safety report and should base his demonstration on this assumption.***
- ***The demonstration must be "convincing". This means that the elements for the final conclusions on the completeness of the hazard identification study and the adequacy of the measures should be present in the safety report.***
- ***The demonstration should provide evidence that the process was systematic which means that it followed a fixed and pre-established scope.***

- ***The measures' efficiency and effectiveness should be proportionate to the risk reduction target (i.e. higher risks require higher risk reduction and, in turn, more stringent measures).***
- ***The current state of technical knowledge should be followed. Validated innovative technology might also be used.***
- ***The application of the measures should be acknowledged for the actual purpose (i.e., a clear link between the adopted measures and the accident scenarios should be present).***
- ***The feasibility of inherent safety should always be taken into account (i.e. hazards should always be removed or reduced at source, when feasible).***

Fig. 2. Guiding principles highlighted in the safety report.

3.3.2. Summary and explanation of Seveso II obligations

A new feature of the guidance, this section clarifies obligations of the operator versus obligations of the competent authorities associated with the safety report. Although no new information is presented here, it gives a succinct overview of all the relevant obligations, including time frames for submitting and reviewing reports and the conditions of Article 9.6 derogation. In particular, different related references in the Directive are identified to answer commonly asked questions such as: Who?, When?, How? and Why? Moreover, this section clarifies expectations regarding execution of the review and inspection responsibilities of the competent authority. A summary of conceptual modifications to the document is shown in Table 1.

3.3.3. General principles

This new section represents a substantial addition to the guidance (see Fig. 2). Notably, it summarizes the philosophy behind the safety report requirement in the following underlying principle:

> "The safety report should *demonstrate* that *necessary measures* to *prevent, control and limit* the consequences of a possible *major accident* have been put in place and are fit for purpose"

The particular aim of this section is to encourage focused safety reports, stripped of superfluous detail, but rich with infor-

Table 1
Summary of conceptual modifications to the EU safety report guidance

Modification	Explanation
Modified structure of the guidance	The guidance includes two new sections and the order of the existing content is changed to correspond to the order in Annex II
New section: Summary and explanation of Seveso II obligations associated with the safety report requirement	Operator obligations vs. competent authority obligations are separated and sometimes restated for further clarification
New section: General principles and definitions	The purpose and philosophy of the safety report is explained. "Guiding principles" are provided and key terms are also defined
Revised section: Essential elements of the safety report	This section unifies the main contents of the original safety report guidance and includes a conceptual framework for ordering and elaborating on particular elements. The order of the elements is presented in the same order as in Annex II
Revised content for the subsection on "identification and analysis of accidental risks"	The content was revised to include a discussion of different acceptable approaches to risk assessment in the EU. It also provides some general advice on the selection of scenarios and presentation of the results of risk analyses

mation necessary to judge the operator's mastery in identifying and managing hazardous substance risks present on the site. The vision of the safety report is presented here as a summarizing document, illustrating a systematic approach to safety with proportionate attention to risks on the basis of potential consequences. Three important themes are evoked in this vision:

- the "summarizing nature" of the safety report,
- "proportionality", i.e., the importance of balancing costs and technical complexity with severity of the risk,
- and a systematic and objective process for evaluating and controlling risks.

The guidance advocates applying these three underlying concepts to form the basis of a "harmonized approach" to application of safety report obligations in the Member States. Although technical approaches would still continue to differ, sufficient adherence to these principles could measurably reduce the various differences in criteria applied to judge the adequacy of safety reports across EU countries and their regions.

These three concepts were elaborated and emphasized precisely to address a number of criticisms on the practical problems associated with the process of devising and assessing a safety report, in particular, problems associated with assessing the adequacy of a safety report and defining how much documentation is enough. As noted by a Dutch competent authority in the early days of its experience with safety reports: "A major problem is the level of the report . . .. The official wants so much detail that, based on the report he can more or less reliably give an appraisal; the enterprise experience it as costly duplication of information which in addition can come in[to] the wrong hands" [16]. Competent authorities have also reported that the reverse situation also occurs, that is, too much documentation is provided.

3.3.4. Key definitions

The newly introduced definitions link the safety report requirement directly with the Article 5 obligations. Specifically, key terms within the article, "*demonstrate*", "*necessary measures*" and "*prevent, control and limit*" are each defined here (see Table 2) and associated with guiding principles. Article 5 is used as the basis for a number of these guiding principles offered in the discussions surrounding the terms "*demonstration"* and *"necessary measures*".

Issues associated with the practical application of the term "*necessary measures*" are also confronted. The guidance document pointedly addresses a common doubt expressed by assessors and inspectors: "Are the measures adequate?" and, at the same time, the complementary challenge faced by operators in trying to convince regulators that safety measures are adequate and appropriate. The systematic approach coupled with discreet application of the concept of proportionality as an approach is recommended to assist regulators and operators to reach common understanding about what constitutes "necessary measures" in specific situations.

Finally, this section also gives practical guidance in interpreting the term, "*major-accident scenarios*", that appears in Annex II. Both the term "major accident" and "accident scenario" are often considered as ambiguous terms, which is a barrier to harmonized approach in the Member States. For "*major accident*", the ambiguity is associated with the third criterion within the definition, indicating that a major accident "must lead to *serious danger* to human health, the environment or property". As has been noted by various competent authorities, the phrase "*serious danger*" can be interpreted in diverse ways, notably because of the subjective nature of the word "serious". To impose some clarity on this issue, the guidance suggests following the criteria in Annex VI. Criteria for the Notification of an Accident to the Commission as Provided for in Article 15 (1) that qualifies the term "*serious danger*" in the following ways:

- as potential life-threatening consequences to one human (on-site or off-site);
- potential health-threatening consequences and social disturbance involving a number of humans;
- as potential harmful consequences to the environment at a certain (larger) extent;
- as potential severe damage to property (on-site or off-site).

Table 2
Definitions provided in Section 2 of the revised guidance

Term	Definition in the Guidance
"Demonstrate"	". . . Intended in its meaning of: 'justify' or 'argue the case' but not 'provide an absolute proof' "
"Necessary measures"	To be "taken in order to prevent, control and limit the consequences of a possible major accident. In the context of the assessment of a safety report, in applying the identified measures, all risks of concern have been properly reduced according to current national practices"
"Prevent"	"To reduce the likelihood of occurrence of the reference scenario"
"Control"	"To reduce the extent of the dangerous phenomenon"
"Limit"	"To reduce the extent of the consequences of a major accident"
"Major accidents"	Following the definition in Article 3 of the Directive, three criteria must be fulfilled • the accident must be initiated by an 'uncontrolled development' • 'one or more dangerous substances' listed in Annex I of the Directive must be involved • the accident must lead to 'serious danger' to human health, the environment or property
"Accident scenario"	An undesirable event or a sequence of such events characterized by the loss of containment (LOC) or the loss of physical integrity and the immediate or delayed consequences of this occurrence

Table 3
An overview of the conceptual and practical differences between deterministic and probabilistic approaches to risk assessment

	Deterministic "consequence-based" approach	Probabilistic "risk-based" approach
Decision criteria	Consequences (harm, damage, etc., in absolute figures)	Risk of harm, damage, etc.
Initiating events	Pre-selected events; events beyond this closed list are not considered	Seeks to consider all potentially relevant events within the procedure
Failure description	Single failure postulated	Multiple failures considered
Operator behaviour	Qualitative case-by-case consideration	Diagnosis/execution errors considered numerically
Analysis characterization	"Conservative" (precautionary principle)	Seeks to be as realistic as possible
Account of uncertainty	Fixed "safety factor" (discrete value)	Numerical evaluation of risk (distribution of values)

In the same way, the concept of "accident scenario" is also clarified as follows:

> "For the specific purposes of safety reports in the context of Seveso II requirements, a scenario is always an undesirable event or a sequence of such events characterized by the loss of containment (LOC) or the loss of physical integrity and the immediate or delayed consequences of this occurrence".

preparing the way for more extensive discussion of risk analysis appearing later in Section 3.3.5 as discussed below.

3.3.5. Essential elements of a safety report

This section incorporates most of the elements of the original safety report guidance, organized and named in accordance with Annex II of the Directive. It is recommended to provide proportionately more detail on aspects of the site that are more closely linked to the site's major accident risk potential (see Fig. 3). Moreover, the key additions introduced by the safety report in this section are the discussion of the safety management system (SMS) and the major accident prevention policy (MAPP), and the elaborated section on accepted risk assessment practices for hazardous installations.

The SMS/MAPP explanation is aimed to make a connection between these two elements. It provides useful clarification for both establishments falling under columns 2 and 3 of Annex I, respectively, by explaining what is meant by each of the two terms and how they differ from each other. While the MAPP is a set of goals, the SMS is set of activities. In essence, the guidance explains that the SMS is what is needed to make the MAPP operational.

The subsection entitled "Identification and accidental risks analysis and prevention methods" represents a significant departure from the original guidance. The subject of risk assessment for Seveso applications has always been a sensitive topic and difficult to discuss at EU level outside the scientific community. Risk assessment approaches are often very carefully chosen by

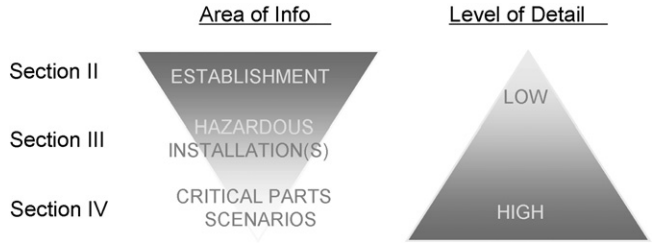

Fig. 3. Hierarchy of implementation tools and level of detail. The first triangle refers to the specific aspect of the plant for which the information has to be provided within the safety report. The second triangle refers to the level of detail of that is necessary for the information provided.

Member State policy makers to reflect a particular perception and tolerance of risk within their society, and such attitudes can vary considerably from country to country. Moreover, the selection and application of an approach may have historic roots and, what is even more critical, it may have required significant resources for development, implementation and communication. As a result, the original safety report guidance assumed that each country had more or less already decided or had been implementing a particular approach and it chose to remain at the sidelines of this discussion.

On the other hand, some countries, in particular the newly acceded Member States, have few preconceived notions about risk assessment and sometimes little experience in performing such analyses in the industrial sector. In particular, references, examples, and benchmarks are needed to help decide their policy direction in this area and to enable them to communicate a coherent definition of acceptable minimum practice that can be enforced in regulated establishments [17].

Hence, the guidance provides a succinct overview of the process of risk analysis (see an example in Table 3), the various types of methodologies in use (qualitative–quantitative, deterministic–probabilistic), and in what circumstances they may be commonly applied. Although the guidance does not take any position on which methodologies are preferred, it attempts to make clear the types of methods that are commonly used and the level of sophistication and depth of analysis that is expected. Furthermore, assembly and interpretation of a risk analysis is briefly explained and detailed lists of typical events, causes, and consequences are provided.

4. Conclusions

The amendment to the Seveso II Directive offered a unique opportunity to check initial assumptions about appropriate and necessary contents of the EU guidance. That such an opportunity would appear so soon after the implementation of the Directive was not evident. However, the importance of the safety report in government oversight has not been overlooked and in the relatively short period since implementation, considerable exchange on this topic has taken place between competent authorities and regulators and among Member States at EU level. It so happens that the new Member States have also joined the conversation since the Directive first became effective in 1999. Their voices have expressed additional needs and suggested new potential directions for joint activities in support of implementation. It is hoped that the revised guidance has responded effectively to concerns and unexpected needs arising from initial implementation of the Directive and made a contribution to harmonize the overall approach to its enforcement in the EU. In any case, there has been substantial benefit in exchanging experience at EU level with implementation of the safety report. One point that is very clear is that the effort must be ongoing to maintain consistency and a high level of performance in controlling major hazards. Moreover, as a result of the various discussions, there is some consensus on various aspects of implementation that should continue to be the focus of monitoring and implementation support at EU level.

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