# JRC Scientific and Technical Reports

## **Seveso Lower Tier Establishments**

# Implementation of Article 7 of the Seveso II Directive in the European Union

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**EUR XXXXX EN** 





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#### **Executive Summary**

The European Union has approximately 8500<sup>1</sup> industrial sites that are considered to present major hazards due to the potential accident risk associated with the presence of dangerous substances as defined by the Seveso II Directive<sup>2</sup>. Approximately, half of these sites are classified as so-called lower tier sites because the quantity of the dangerous substances exceeds the lower threshold quantity stipulated in the Directive. Theoretically, the Seveso II Directive imposes a lower regulatory burden on lower tier sites than upper tier sites, whose quantity of dangerous substances exceeds the higher threshold quantity given in the Directive. This lower burden is manifested particularly in Article 7, designed to apply exclusively to lower tier sites. In 2008-2009, on behalf of the Committee of Seveso Competent Authorities (CCA), the European Commission's Joint Research Centre (JRC) undertook a study of Seveso implementation in lower tier sites, through administration of a survey of competent authorities and subsequently co-organization of a seminar on the topic with DG-Environment and the Czech Republic, which took place in Prague on 22 April 2009. This paper summarises the results of this study.

The regulatory burden imposed by the Directive on lower tier sites ("LT sites") is intended to be less than that imposed on upper tier sites ("UT sites") on the basis that they generally represent a lower hazard (although not in all cases, a point discussed later in this paper). Most notably, in lieu of a safety report, Article 7 of the Directive requires LT sites to develop a Major Accident Prevention Policy (MAPP). Lower tier sites are exempt from the Article 9 obligation to produce a safety report and demonstrate the existence of a safety management system. Lower tier sites are also exempt from obligations imposed by Article 11 and 13 (see Table 1 on p. 1). Annex III of the Directive also introduces the "proportionality principle" such that "The requirements laid down in the document referred to in Article 7 should be proportionate to the major-accident hazards presented by the establishment".

#### The MAPP Requirement

The requirement of a MAPP is built on the model established by the international standard community and that had already been applied to management systems for controlling risks to environment health and safety. As shown in Figure 2 (next page) policy is only one part of a management system. For example, the major requirements of an environmental management system under ISO 14001 include a policy statement that describes the company's commitments to prevent pollution, to continually improve the environmental management system, and to comply with all applicable statutory and regulatory requirements.

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<sup>&</sup>lt;sup>1</sup> According to Commission data as at March 2009

<sup>&</sup>lt;sup>2</sup> Currently defined as substances with specific toxic, flammable, explosive and other reactive properties in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

According to the Seveso II Directive, lower tier sites are only explicitly responsible for establishing the policy part of the Safety Management System (SMS), which is the MAPP. Annex III indicates that implementation of the remainder of the SMS "should be proportionate to the major-accident hazards presented by the establishment". This approach allowed simplification of SMS requirements on lower tier sites on an individual site basis in relation to the hazard. Member States, being responsible for implementation, were charged with deciding how to judge compliance of lower tier sites with this obligation in practice.

#### The European Commission Study of Article 7 Implementation

Despite early efforts to clarify the obligations established in Article 7, it appears that ten years since the Directive's effective entry into force many Member States appear to be still struggling with questions about its interpretation and practical application. To foster further dialogue on this topic, the European Commission proposed to conduct a review of how Member States implemented the Article 7 requirement.

The study of Article 7 implementation consisted of two parts: a survey of Article 7 requirements in EU/EEA/EFTA countries followed by a CCA seminar to discuss the findings with Member States and examine particular cases more closely. The goals of the study was to obtain a general overview of Article 7 implementation across Europe, including strengths and weaknesses of implementation and examples of good practice. It intended to achieve this goal by collecting and analysing the following types of information from each Seveso country:

- 1. The economic character and hazard profile of its lower tier sites
- 2. Formal requirements and implementation practices established in the country to oversee and enforce Article 7
- 3. A perspective on challenges and limitations and strengths and weaknesses associated with Article 7 implementation
- 4. A library of examples of alternative practices, tools and guidance for implementing Article 7
- 5. Recommendations for EU level initiatives that might facilitate greater enforceability, consistency and effectiveness of Seveso implementation in lower tier sites across the EU Member States.

The survey was distributed to CCA Member and Observer (EEA/EFTA) and observer countries in December 2008 and its results were presented in the follow-up seminar in April 2009.

#### **Conclusions from the Survey**

The survey responses produced several important insights in regard to the character of lower tier sites, and requirements and practices associated with implementation of Article 7 in the Member States and EEA countries. Countries were also able to express their opinion about the usefulness of Article 7 requirements and particular challenges as well as benefits linked with this provision and with the way in which it is implemented in their country in

particular. Survey results also provided a perspective on how Switzerland, an EFTA country, adjusted the regulatory burden for lower risk sites.

The following points highlight the most important findings:

- A considerable portion of lower tier sites are a significant challenge for Seveso implementation because of limited resources and risk management capacity.
- Residual risk and location are factors that can make lower tier sites a higher risk than upper tier sites.
- Challenges associated with certain Seveso site profiles are not limited to lower tier sites.
- Many countries have defined a specific legal requirements associated with Article 7 in more detail than the Directive.
- More than half of the countries impose a legal obligation, or equivalent, on lower tier sites to implement an SMS. Moreover, even when there is no specific legal requirement, the enforcement practices of many countries make an SMS a de facto requirement for lower tier sites.
- Countries are more or less split in terms of whether they define the MAPP as a reduced SMS or as a reduced safety report.
- Not all countries systematically require a risk assessment. Countries that
  identified the MAPP with safety report requirements also tended to expect the
  MAPP to include a risk assessment.
- The type of content that constitutes the MAPP proper (without annexes) varies considerably from country to country, causing considerable variation in the length of the document from country to country.
- Most of the countries used the MAPP for enforcement and nearly all felt that the MAPP was also useful for the operators.
- Many countries routinely assess the quality of the MAPP, although an exact proportion of countries applying this practice could not be derived from responses.
- Many countries did not use the same criteria for evaluating MAPPs in lower sites as used to evaluate the safety report in upper tier sites.
- Countries are more inclined to apply a similar approach to evaluating the SMS on lower as for upper tier sites..

## The Seminar on Major Accident Prevention in Lower Tier Seveso Establishments

This one-day seminar was co-hosted by the European Commission and the Czech Ministry of Environment as a follow-up to the survey. It took place on 22 April 2009 in Prague, Czech Republic, coinciding with a meeting of the Committee of Seveso Competent Authorities. Around 80 people attended the seminar, mainly from Seveso competent authorities. Almost all Member States, Candidate Countries, EEA and EFTA countries were represented.

The agenda (see Annex 4) consisted of a presentation on the survey findings and presentations by industry and various countries (both Member States and countries outside the EU) aimed to provide a perspective on regulatory arrangements to establish effective risk management on lower hazard sites (classified as "lower tier sites" within the Seveso regime). These presentations were followed by group discussions intended to identify common points of interest and recommendations for regulatory policy and implementation.

#### **Industry and Country Presentations**

The five presentations were as follows:

- Seveso Impacts Article 7 Lower Tier sites by Douglas Leech, FECC -European Association of Chemical Distributors/CBA Chemical Business Association
- 2. Implementation of Lower Tier Site Requirements in the Czech Republic, by Stanislav Malý,

Occupation

- al Safety Research Institute, Czech Republic
- 3. Implementation of Lower Tier Site Requirements in Italy, Andrea Santucci, Ministry of Environment, Italy
- 4. Addressing Low Thresholds in Switzerland, Bernard Gay, Federal Office for Environment (FOEN), Switzerland
- 5. Korean Experience of Process Safety Management Systems in the Chemical Industry. Hyuckmyun Kwon, Occupational Safety and Health Agency (KOSHA), Korea

Highlights from each presentation are presented in the paragraphs below. The agenda of the seminar is available in Annex 4.

#### **Conclusions from the Seminar**

The findings from the seminar largely reflected the findings of the survey and there was no evidence of any contradiction between the results of these two efforts. In fact, the seminar confirmed many observations on advantages and disadvantages of Article 7 requirements noted by survey respondents. Therefore, in summarizing seminar conclusions, only those findings are mentioned that offer additional insights.

- Lower tier site status can remain a disproportionately heavy burden for small business but it is often difficult for authorities to find effective solutions to make the burden lighter.
- Additional complexity, and therefore, burden may be created for lower tier sites when more than one authority is closely involved in enforcement.
- Several participants noted the importance of having an adequate risk assessment from lower tier sites for emergency and land-use planning. Nonetheless, the demands on resources and expertise associated with risk assessment can make this task challenging for some lower tier sites.

- Both Switzerland and Korea presented alternative practices and useful experience in regard to applying a proportionate approach to lower hazard sites.
- Participants acknowledged that there was a particular lack of coherence between the definition of the MAPP and the SMS. In particular, countries evidenced substantial differences in regard to their interpretation of the MAPP.
- There was a common desire among competent authority representatives to foster greater consistency in applying Article 7 requirements to lower tier sites across the EU.

#### **Recommendations Resulting from the European Commission Study**

Although several countries and workshop participants made recommendations on how implementation of Article 7 could be improved, no consensus emerged on any specific recommendation. The study itself confirmed that exchange of practices among Seveso implementing countries was a first step in providing a common understanding of certain provisions of the Directive. The study also confirmed that flexibility and proportionality were important to achieving the objectives of the Directive in local contexts. However, meeting these objectives is sometimes an impediment to consistency and clarity of the basic Seveso requirements. Given these results, the European Commission undertook to fulfil a more general recommendation to examine the lower tier provisions of the current Directive in the review of the Directive It would also review how the implementation could be improved, for example by facilitating indirect activities, such as mutual exchanges and joint development of technical guidance and tools, that could lead to greater clarity and consistency. The findings and observations from the study and the seminar would be taken into account in this review process.

#### Introduction

The European Union has approximately 8500<sup>3</sup> industrial sites that are considered to present major hazards due to the potential accident risk associated with the presence of dangerous substances as defined by the Seveso II Directive<sup>4</sup>. Approximately, half of these sites are classified as so-called lower tier sites because the quantity of the dangerous substances exceeds the lower threshold quantity stipulated in the Directive. Theoretically, the Seveso II Directive imposes a lower regulatory burden on lower tier sites than upper tier sites, whose quantity of dangerous substances exceeds the higher threshold quantity given in the Directive. This lower burden is manifested particularly in Article 7, designed to apply exclusively to lower tier sites. In 2008-2009, on behalf of the Committee of Seveso Competent Authorities (CCA), the European Commission's Joint Research Centre (JRC) undertook a study of Seveso implementation in lower tier sites, through administration of a survey of competent authorities and subsequently co-organization of a seminar on the topic with DG-Environment and the Czech Republic, which took place in Prague on 22 April 2009. This paper summarises the results of this study.

#### Proportionality and Application of the Seveso Directive to Lower Tier Sites

The proportionality principle forms one of the philosophical pillars of the Seveso II approach.<sup>5</sup> In various parts of the legislative framework there are opportunities to reduce or increase the regulatory burden so that is more or less in proportion to the overall level of risk present on the site. This principle also reinforces

Table 1: Seveso II Obligations Allocated on the Basis of Upper or Lower Tier Status

Seveso II Article Dutyholder Article 7: Major Accident Prevention Policy Lower Tier Sites Only Article 9: Safety Report and Upper Tier Sites Only Safety Management System (including a Major Accident Prevention Policy) Article 11: Internal and External Upper Tier Sites Only **Emergency Plans** Article 13: Information to the Upper Tier Sites Only **Public** Article 18: Inspections Once per year for Upper Tier sites unless a systematic appraisal is applied.

application of the EU subsidiarity principle because it generally

requires that detailed aspects of implementation are left to local actors.

In particular, the proportionality principle is embedded in the definition of the scope of the Directive. Sites are classified as Article 9 (higher) or

lower hazard according to the quantity of a certain substance or category of substance. The Directive refers to these as "Article 9" and "Article 6 and 7" respectively, but they are more commonly referred to as "upper tier" and "lower

<sup>4</sup> Currently defined as substances with specific toxic, flammable, explosive and other reactive properties in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

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<sup>&</sup>lt;sup>3</sup> According to Commission data as at March 2009

<sup>&</sup>lt;sup>5</sup> The principle of proportionality is a political maxim which states that no layer of government should take any action that exceeds that which is necessary to achieve the objective of government.

### Figure 1: Text of Article 7 of the Seveso II Directive

#### **Major-accident prevention policy**

- 1. Member States shall require the operator to draw up a document setting out his major-accident prevention policy and to ensure that it is properly implemented. The major-accident prevention policy established by the operator shall be designed to guarantee a high level of protection for man and the environment by appropriate means, structures and management systems.
- 1a. For establishments which subsequently fall within the scope of this Directive, the document referred to in paragraph 1 shall be drawn up without delay, but at all events within three months after the date on which this Directive applies to the establishment concerned, as laid down in the first subparagraph of Article 2(1).
- 2. The document must take account of the principles contained in Annex III and be made available to the competent authorities for the purposes of, amongst other things, implementation of Articles 5 (2) and 18.
- 3. This Article shall not apply to the establishments referred to in Article 9.

tier". Within the European Union, the lower tier sites generally constitute around 50% of all Seveso sites, and if EEA-EFTA countries are included, the number amounts to more or less 4500 sites in Seveso implementing countries and Switzerland<sup>6</sup>.

The regulatory burden imposed by the Directive on lower tier sites ("LT sites") is intended to be less than that imposed on upper tier sites ("UT sites") on the basis that they generally represent a lower hazard (although not in all cases, a point discussed later in this paper). Most notably, in lieu of a safety report, Article 7 of the Directive requires LT sites to develop a Major Accident Prevention Policy (MAPP). Lower tier sites are exempt from the Article 9 obligation to produce a safety report and demonstrate the existence of a safety management system. Lower tier sites are also exempt from obligations imposed by Article 11 and 13 (see Table 1 on p. 1). Annex III of the Directive also introduces the "proportionality principle" such that "The requirements laid down in the document referred to in Article 7 should be proportionate to the major-accident

hazards presented by the establishment".

#### The MAPP Requirement

The requirement of a MAPP is built on the model established by the international standard community and that had already been applied to management systems for controlling risks to environment health and safety. As shown in Figure 2 (next page) policy is only one part of a management system. For example, the major requirements of an environmental management system under ISO 14001 include a policy statement that describes the company's commitments to prevent pollution, to continually improve the environmental management system, and to comply with all applicable statutory and regulatory requirements.

Despite these early efforts to clarify the obligations established in Article 7, it appears that ten years since the Directive's effective entry into force many Member States appear to be still struggling with questions about its interpretation and practical application

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<sup>&</sup>lt;sup>6</sup> By agreement the European Economic Area countries (Iceland, Lichtenstein and Norway) also enact EU environmental legislation including the Seveso II Directive. Switzerland is a member of the European Free Trade Zone (EFTA) and enacts legislation whose provisions are generally considered equivalent to those imposed by Seveso.

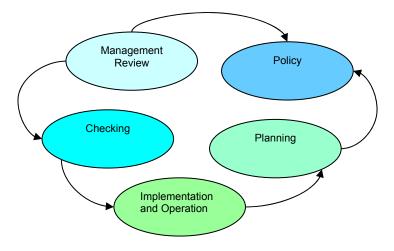


Figure 2: A Typical Management System Structure

According to the Seveso II Directive, lower tier sites are only explicitly responsible for establishing the policy part of the Safety Management System (SMS), which is the MAPP. Annex III indicates that implementation of the remainder of the SMS "should be proportionate to the major-accident hazards presented by the establishment". This approach allowed simplification of SMS requirements on lower tier sites on an individual site basis in relation to the hazard. Member States, being responsible for implementation, were charged with deciding how to judge compliance of lower tier sites with this obligation in practice.

In their paper describing the new Directive in 1999, Porter and Wettig elaborated on the significance of Article 7 requirements:

"[The MAPP requirement] has been derived from an increased recognition that appropriate policies and management systems within a company are necessary to safeguard against major accidents, as seen from the fact that 'management factors' have contributed to many of the accidents which have occurred since the implementation of Seveso I.

The MAPP must be established in writing and should include the Operator's overall aims and principles of action with respect to the prevention and control of major-accident hazards ... "[1]

The EU Guidance on Seveso Safety Management Systems explains the burden imposed on lower tier sites this way:

- "...the requirements for policies and management systems which apply to a lower tier establishment are similar to those for an upper tier establishment except that:
- the Directive states that the requirements should be proportionate to the major-accident hazards presented by the establishment, which is considered to introduce more flexibility;
- it is not necessary to prepare a detailed report for demonstrating how the Safety Management System has been put into effect;
- the document setting out the MAPP must be 'made available' but need not necessarily be sent to the competent authorities." [2]

#### **Recurring Questions about Interpretation of Article 7 Requirements**

Despite these early efforts to clarify the obligations established in Article 7, it appears that ten years since the Directive's effective entry into force many

Member States still appear to be struggling with questions about its interpretation and practical application. EU level efforts to clarify Seveso obligations have largely focused on requirements of upper tier sites, notably the safety report and safety management systems. Similarly, researchers analysing Seveso from an enforcement or implementation perspective have targeted safety reports and safety management systems on upper tier sites, for example, in studies performed by Versluis [3], Brazier and Waite [4], and DiMichaela et al. [5]. There has been little written subsequent to the Directive's entry into force on how Article 7 is implemented in practice and whether it has been effective in both fostering effective risk management on lower hazard sites without imposing an unnecessarily heavy regulatory burden.

Nonetheless, exchanges among Seveso inspectors such as those through the Mutual Joint Visit programme for Seveso Inspections have often included discussions about application of the MAPP requirement. Some recurring questions asked by Seveso inspectors include:

- What does a "major accident prevention policy" look like in other EU countries?
- What did the Seveso II authors intend by a MAPP?
- How do authorities use the MAPP to enforce compliance on lower tier sites?
- Can authorities use the MAPP to drive safety on lower tier sites and if so, how?
- How detailed should MAPPs be in describing components of Annex III, that is, the safety management system?
- What is the difference between a MAPP and a safety management system?
- How is the MAPP different from a safety report?
- What inspection tools and practices have been developed and applied to enforce Article 7 requirements?

The Seveso Inspection Series report on *Necessary Measures for Preventing Major Accidents at Petroleum Storage Depots* [6] is one of the few publications to document the perplexity shared by many competent authorities surrounding the MAPP requirement.

"Several participants considered the [MAPP] requirement important and appropriate for lower-tier establishments. Other participants were less convinced that the MAPP requirement was meaningful in safety terms. In particular, these participants did not feel that the difference between a MAPP and an SMS was very clear, mainly because (in their opinion) the Directive itself does not define the MAPP very well.

Participants differed considerable in their opinions concerning the contents, the size and even the necessity of a MAPP (despite the obligation in the Directive). Moreover, there was not full agreement on what should be the content of a MAPP ...

... In the discussions representatives of some countries reported that they have implemented a stricter interpretation of the MAPP obligation:"

In 2008 the European Commission launched a series of initiatives to solicit stakeholder opinions on effectiveness of the Directive and pinpoint potential improvements.<sup>7</sup> Comments on lower tier site requirements obtained across these channels gave reason to suspect a high level of inconsistency in their application among the Member States. Moreover, the cause of this predicament was by and large assigned to the vagueness of the Directive (and supporting guidance) on lower tier site requirements, particularly the definition of the MAPP and SMS (in general). At the CCA Seminar on Enforceability in 2008 one workgroup identified "poor guidance on MAPP and SMS" as a weakness in current implementation [7]. Another work group recommended clarification between the MAPP, the safety report and safety management systems and also on how the proportionality principle should function. A few participants even questioned the validity of the Seveso division of upper and lower tier as a mechanism for concentrating more resources on higher risk establishments, proposing that perhaps there was really little significant difference in the burden associated with requirements imposed on upper vs. lower tier in many Member States. (This premise was subsequently refuted by the results of the survey on implementation of Article 7 on lower tier sites in Seveso implementing countries and Switzerland.)

In the F-Seveso Study of Effectiveness of the Seveso II Directive some industry respondents expressed doubts about the significance of differentiating obligations imposed on lower vs. upper tier sites.

"For a handful of operators there are still no clear differences between the level of requirements for upper and lower tier Seveso establishments. In their view the proportionality principle needs to be implemented with harmonized criteria to be defined. They recommend developing guidance documents define the principle of proportionality, with concrete examples of implementation." [8]

There was also open speculation about the possibility of formally introducing new obligations for lower tier sites.

"The two tier approach, implementing the proportionality principle, is recognized as appropriate, even if some adjustments could be proposed to require certain effective aspects of the Seveso II Directive [to] be applied not only to upper tier but also to lower tier establishments, like the preparation of the safety report with identification of major accident scenarios, and the implementation of a formal safety management system." [8]

In the light of this collection of comments, the European Commission became interested in gaining more precise knowledge about the application of lower tier site requirements in Seveso implementing countries. Over the course of 2008-2009 it embarked on a two-part initiative to identify and compare different

EU legislation on classification, labelling and packaging of chemicals to the GHS (Globally Harmonised System of Classification and Labelling of Chemicals)). This circumstance was seen as an opportunity to undertake a review of the effectiveness of the Directive more generally to assess whether other modifications to clarify and update requirements of the Directive should be introduced.

<sup>&</sup>lt;sup>7</sup> The European Commission was planning to propose a modification to the Seveso Directive to align the substance criteria with the new CLP-Regulation (EC) No 1272/2008 that adapts previous

practices in the Seveso implementing countries, and identify common challenges and opportunities for improvement.

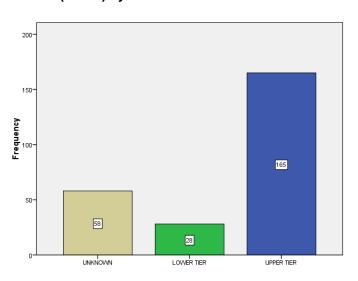
#### **Major Accidents on Lower Tier Sites**

A study of major accidents reported to the European Commission's Major Accident Reporting System (MARS) database by the EU-15<sup>8</sup> from 1999 to 2008 shows 5 times more major accidents on upper tier sites have been reported than on lower tier sites (Figure 3 on this page). (This measure of difference assumes that

the ratio of upper tier to lower tier in the EU

Figure 3: Number of Accidents Reported to MARS (EU-15) by Seveso Tier Status – 1999 - 2008

remained roughly 1:1 across the years as it is currently.) While in earlier years there are many accidents whose Seveso tier status is unknown, the annual summary by tier (Figure 4 on the next page) indicates that in later years, when tier status has been identified more consistently for plants involved in accidents, the difference



between numbers of accidents on lower vs. upper tier sites is even more striking. In 2005 and 2006<sup>9</sup>, for which most of the sites are identified by tier status, and there is at least 15 times the number of accidents on upper tier vs. lower tier sites. (Reporting process for years 2007 – 2008 is still not complete.) In addition, the number of fatal accidents reported for lower tier sites (6) during this period is about one quarter of those reported for upper tier sites (26) as shown in Figure 5 (on the next page). These accident reports recorded 30 deaths for lower tier accidents and 553 injuries vs. 34 deaths and 72 injuries over the same period for upper tier sites (see Figure 6 on the next page). The lower tier figures are largely

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<sup>&</sup>lt;sup>8</sup> The EU-15 consists of the 15 Member States that formed the European Union when the Seveso II Directive became effective in 1999. In 2004 and 2007 12 additional Member States were admitted to the European Union. For most new Member States, the effective implementation of notification and accident reporting process did not start until at least a year following accession into the EU.

<sup>&</sup>lt;sup>9</sup> In 2005 it became mandatory for Member States to identify their Seveso sites to the Commission in the Seveso Plants Retrieval Information System (SPIRS) in accordance with the 2003 amendment to the Directive.

The tendency to over-report environmental consequences in early years makes it difficult to provide a similar comparison of differences between accidents on upper vs. lower tier sites relative to their impact on the environment without analysing each accident report individually. (In fact, until 2006, every accident report indicates some sort of "suspected" environmental damage.) A more in-depth analysis of consequences was not intended as part of the current study.

Figure 4 Annual Frequency of MARS Accidents by Seveso Tier Status 1999 - 2008

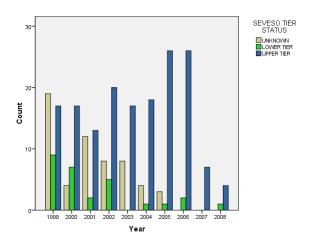


Figure 5: Number of Fatal Accidents Reported to MAHB (1999 – 2008)

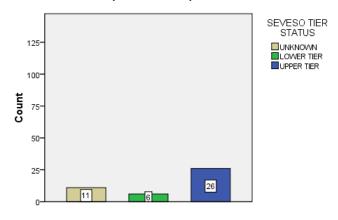
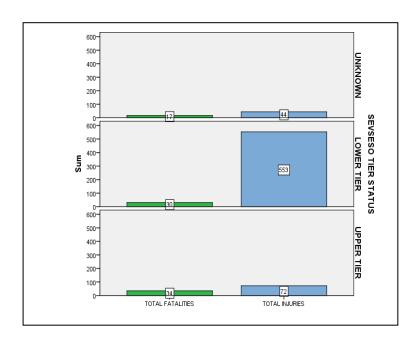


Figure 6: Total Fatalities and Injuries for Major Accidents Reported to MARS (1999 – 2008) by Seveso Tier Status



dominated by the explosion at a fireworks storage facility in the Dutch city of Enschede on 13 May 2000 that claimed 22 lives and injured 540 people.<sup>11</sup>

#### The European Commission Study of Article 7 Implementation

The study of Article 7 implementation consisted of two parts: a survey of Article 7 requirements in EU/EEA/EFTA countries followed by a CCA seminar to discuss the findings with Member States and examine particular cases more closely. The goals of the study was to obtain a general overview of Article 7 implementation across Europe, including strengths and weaknesses of

implementation and examples of good practice. It intended to achieve this goal by collecting and analysing the following types of information from each Seveso country:

The economic character and hazard profile of its lower tier sites

- 1. Formal requirements and implementation practices established in the country to oversee and enforce Article 7
- 2. A perspective on challenges and limitations and strengths and weaknesses associated with Article 7 implementation
- 3. A library of examples of alternative practices, tools and guidance for implementing Article 7
- 4. Recommendations for EU level initiatives that might facilitate greater enforceability, consistency and effectiveness of Seveso implementation in lower tier sites across the EU Member States.

The survey was distributed to CCA Member and Observer (EEA/EFTA) and observer countries in December 2008 and its results were presented in the follow-up seminar in April 2009.

#### Part 1. Survey Description and Findings

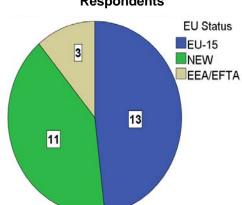
The survey consisted of 11 questions aimed to obtain an overview of country practices and experiences related to implementation and enforcement of the Major Accident Prevention Policy and minimum requirements for Safety Management Systems at these sites. It also sought to gain a rough perspective on the type of industrial sectors represented by lower tier sites and the size of these enterprises and whether these or other characteristics influenced lower tier site compliance.

Annex 1 of this document contains a copy of the survey.

<sup>&</sup>lt;sup>11</sup> The 2003 amendment to the Directive assigned new criteria to the Explosives categories covered by the Directive. It is generally thought that the Enschede site would have been classified as an upper tier site using the criteria effective today.

The response rate to the survey was very high. Out of 30 countries solicited, 27 (90%) responded to the survey. As shown in Figure 7 at left, respondents

Figure 7: EU Status of Country Respondents



included 24 Member States and 3 EEA/EFTA countries.<sup>12</sup>

Moreover, the response quality also appeared to be very high. Most countries completed all the questions and provided a detailed commentary to support their answers. Respondent countries also were quite diligent in representing the diversity of practices in different regions (not just the perspective at national level) which in some cases took considerable effort.

#### **Profile of Lower Tier Sites in Respondent Countries**

The first four questions aimed to solicit data or impressions regarding the number and economic character of lower tier sites in each respondent country. The survey allowed respondents the option of providing best estimates in lieu of precise statistical data. This approach was necessary because economic studies do not analyse lower tier sites as a separate class of enterprise and therefore, a precise assessment of their economic character by country, or indeed as a whole, is not readily available. Moreover, an exact reckoning, even when some data are available, can be a bureaucratic and time-consuming exercise for national governments, and was not necessary to achieve the general perspective sought by the survey.

In the following paragraphs, the responses to each individual question are summarised. Main findings are then highlighted and analysed as a group.

#### 1. Distribution of Lower Tier Sites Among Industry Sectors

Each respondent provided a detailed answer to this question with the majority also including precise figures for each sector. This level of detail made it possible to calculate a reasonable estimate of the number of lower tier sites represented by the 27 countries and also analyze answers with respect to the relative and absolute size of the Seveso influence in their country.

Figure 8 on the next page shows the number of lower tier sites per respondent, with the exception of Denmark and Switzerland for which no data are available. The red line indicates the median. Where respondents provided precise data, these data are reflected in the chart; otherwise, the most recent SPIRS data were used (March 2009). Data for two out of sixteen German Länder were also not available. Although the EU-15 contain the vast majority of lower tier sites in the EU, there is a fairly even mix of EU-15 and new Member States above and below the median. As shown in Figure 9 on the next page, two thirds of reporting countries have more lower tier than upper tier sites (above the dotted line), with

<sup>&</sup>lt;sup>12</sup> Note: For every question, Switzerland is included in the response data presented except when it is specifically indicated that it is not.

one country having a one-to-one ratio (including Germany if it is assumed that the 14 German Länder are representative of the overall German situation).

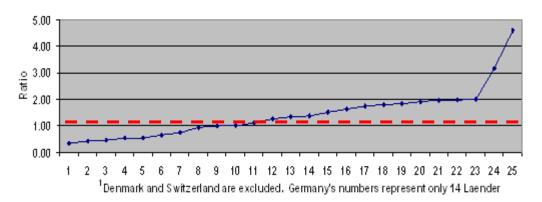
Switzerland+
Denmark+
Waltar
Cyprus
-Ctech Republic
Country
-Cach Republic
-C

Figure 8: Number of Lower Tier Sites Per Respondent Country

Table 2: Statistics on Number of Lower Tier Sites per Country

N	Minimum	Maximum	Mean	Median	Std. Deviation
25	4	979	170.00	71	256.102

Figure 9: Ratio of Lower Tier to Upper Tier Sites in Surveyed Countries (N = 25)



In terms of industry sector, there was no "typical" mix of sectors represented by lower tiers. However, a number of sectors have a significant presence (>5%) in several countries. In particular:

- 1. Distribution centres (LPG, fuels, warehouses) accounted for at least 1/3 of all LT sites in several countries (11 countries).
- 2. The general chemicals sector is significantly represented in most countries with > 100 Seveso sites (15 countries).
- 3. Other industries >5% presence in several countries were fertilizers and pesticides (storage and production), power supply and metal surface treatment.

#### 2. Economic Character of Lower Tier Sites (Respondent Estimates)

As noted in Table 3 below, most respondents estimated that the proportion of lower tier sites representing small or medium-size enterprises (SMEs) was relatively high. More than 75% indicated that at least half their sites might be SMEs. On average about 25% of lower tier sites were thought to have less than 10 employees. Conversely, less than half the sites were estimated to be part of a large multinational corporation. If these estimates are more or less correct, they suggest that the resources available to many lower tier sites to manage risks are limited.

Table 3: Responses to Question 2: What proportion of your sites would you consider ...

	N	Median	Minimum	Maximum	Mean	Std. Deviation		
a are small or medium-sized enterprises?	24	70%	7%	100%	66%	26.242		
19 (76%) indicated >50 %								

b have < 10 employees?	21	18%	6%	80%	24%	15.731		
11 (52%) indicated >20 %								

c belong to multinational corporations?	22	24%	0%	63%	23%	17.692		
4 (18%) indicated >50%								

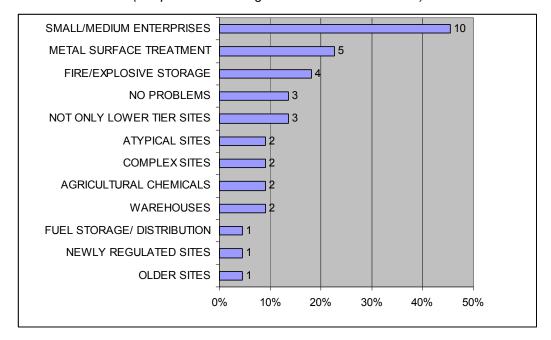
#### 3. Challenges for Oversight and Enforcement

As Question 3 was an open-ended question, the percentage of responses associated with each type of answer can only be considered an indication. For example, as noted in Figure 10 on the next page, a relatively high number of respondents identified small/medium enterprises as typical problem sites. However, these sites were more likely to be mentioned by respondents since the previous question already leads respondents to recall this problem area. Other responses, spontaneously provided by respondents, are more likely to be underestimated with the open-ended approach. Therefore, categories with 5, 4, 3 and even 2 responses may represent more wide-spread challenges than the percentage responses indicate. (The question was open-ended and therefore, individual respondents could have given more than one answer.)

An analysis of the responses to this question reveals the following findings:

Figure 10: Activities or other site characteristics identified by respondents as typical of problem sites (N=21)

(Respondents could give more than one answer.)



- It is quite likely that challenges associated with certain profiles are not limited to lower tier sites, as noted by some respondents. The survey did not examine whether certain sectors or types of sites represent a higher percentage of lower tier sites than of upper tier sites. If a certain profile is more or less equally present in lower tier and upper tier sites, then the potential for compliance challenges associated with this profile are not likely to differ either, regardless of the site's Seveso classification. On the other hand, compliance challenges associated with age, complexity, atypical sites and newly covered sites are probably shared equally with upper tier sites.
- Small and medium enterprises were cited by ten respondents as having more difficulty in complying with the obligations of the Directive. This situation may exist due to a number of factors, such as fewer resources and availability of risk management competence. This finding may also explain why certain sectors are often cited as more problematic for Seveso implementation, in particular, metal surface treatment, fireworks and explosives storage, agricultural chemicals, and fuel storage distribution sites since they may sometimes consist of a large number of SMEs.

One respondent observed that '... In these cases the owner / manager is alone responsible for everything and these enterprises are, above all else, ruled by economic constraints. As an inevitable consequence the operators have only little knowledge of the regulations relating to major accidents which makes communication between authorities and operators even more difficult."

• "Atypical" sites and sites that have never before been covered before by the Seveso Directive were also mentioned by some respondents as more prone to represent a compliance challenge. These sites may require time to become educated on the types of hazards that may be associated with substances on their sites and the concept of systematic risk management strategy. Sectors such as

metal surface treatment and warehouses may experience this handicap in particular.

#### As one respondent noted:

"Companies not belonging to the typical chemical, petrochemical or pharmaceutical sector seem to have less knowledge of codes of good practice applicable and accepted for the (chemical) activity of concern and of process safety. Often the dangerous substances that make the company a Seveso site are only used for an activity that is only a minor part of the companies' activities (for instance Seveso because of storage of one substance used as base product in a metallurgic or surface treatment process). In some companies it is only a back-up fuel storage that brings them under the Seveso scope. In these companies, authorities (in general) spend more time explaining the Seveso obligations. Inspectors are often playing an "advisory" role, giving guidance to the company on how the objectives can be met. However, this does not automatically mean that enforcement is more difficult. Whether a company takes easily (without having to use more stringent coercive instruments) corrective actions to eliminate shortcomings notified by inspection authorities, cannot univocally be linked to a industrial sector, the Seveso status or the size of the company."

• The complexity of risk management challenges may present a challenge for compliance for some sites, such as warehouses. One respondent described complexity as "The complexity of site – two or more technological/ production lines or handling lot of chemicals (about 10-20 and more chemicals which are under the Seveso directive)."

#### 4. Risk Level in Comparison to Upper Tier Sites

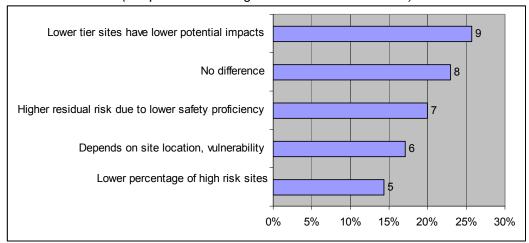
Question 4 was also an open-ended question, but potential responses were more limited and therefore, were in greater agreement than Question 3. Moreover, the explanations provided for relative risk differences given in the responses were more important to the purposes of the survey than quantification of them.

In general few respondents gave an unequivocal answer of "higher", "lower" or "no difference". In any case, answers were not adequately homogenous that they could be quantified in this way. The question was open-ended and therefore, individual respondents could have given more than one answer. However, Figure 11 (on the next page) shows that there were only a few different types of responses provided (and some respondents gave more than one answer). This result suggests that there is particular consensus on the risk comparison between lower and upper tier sites.

Most respondents appeared to acknowledge that the classification of the site as upper or lower tier was a valid, if rough, approximation of relative intrinsic risk because it is based on the quantity of hazardous substance present on the site. Some respondents gave answers that differentiated the intrinsic risk and residual risk and others gave responses reflecting the total risk calculation resulting from these two pieces of the risk equation.

Figure 11: Risk level of lower tier sites compared to upper tier sites (N=25)

(Respondents could give more than one answer.)



For example, one respondent observed that "In relation to hazard in most cases there will be very little difference. There is more inherent risk on the upper-tier establishments but as these will have better risk management in place the actual risk may be greater at lower-tier establishments."

For additional illustration, one respondent provided results of the inspection authority's systematic appraisal of inherent risk levels of upper tier and lower tier sites in the country.

"From [these data] it can be concluded that a major part of lower tier sites is ranked into the lowest danger category, but still one out of five has been estimated as highly (potentially) dangerous. For upper tier sites, the most hazardous category (cat 3) is the biggest group. The difference between upper tier and lower tier can be explained by the activity (no chemical reactions involved) and the amount of dangerous substance (which plays a role in the calculation)"

This respondent also added that lack of data prevented the authority from performing a similar appraisal of residual risk. Furthermore, it should also be recalled that lower tier sites may also have quantities of dangerous substances in amounts very close to the upper tier threshold.

Several respondents noted that location and lack of competency influenced the level of risk. Explained one respondent:

"Whilst a lower-tier site will have a smaller quantity of dangerous substances present, factors such as the type and complexity of the operation, the level of implementation of standards of safety, and the preparedness/professionalism of the workers generally – and particularly in the event of an accident – could lead to a lower tier site presenting higher levels of individual risk than an upper tier site.

Similarly, while higher quantities of substances are likely to create a higher level of societal risk (i.e. more people at more risk) at upper tier sites, it is possible that societal risk could be higher around a lower-tier site. This is because the assessment must consider the off-site situation as well as that on-site. Factors such as the location of the site (e.g. in a residential area), the surrounding population density and type

(e.g. an office building or hospital/school), the type of buildings in the area (e.g. high/low housing density), and the type of accident which could potentially occur at the site, could possibly lead to more people being at more risk around a lower-tier site, despite there being a smaller quantity of dangerous substances present. We estimate that only a very small number lower tier sites (possibly 1-2%) are of societal risk concern."

Another respondent described influences on risks at Seveso sites in this way:

"The risk level (independently on category of an establishment) is connected with the following factors:

#### a) Potential risk:

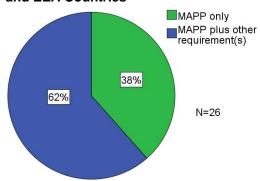
- technological solutions applied, including, for example, storage methods – type of tank, its technical condition and location (underground, on the ground, etc.).
- category, quantity and properties of substances present,
- the establishment's location, e.g., in relation to residential areas or legally protected areas and distance between establishments (domino effect),
- types of technical and organizational safety measures applied,
- educational level of staff.
- b) Residual risk (after safety measures have been taken into account):
  - dangerous substances other than those classifying an establishment into the lower or upper tier group,
  - external factors (beyond the establishment) which can cause a major accident inside the establishment,
  - effectiveness of technical inspections [for compliance with technical standards]
  - a clear, understandable (at each level) safety management system."

#### **Questions on Article 7 Requirements and Enforcement Practicces**

#### 5. Legal Obligations Imposed on Lower Tier Sites

In keeping with the principle of proportionality, Member States may define Article 7 compliance expectations for the MAPP in terms of systematic vs. flexible components. Systematic components are represented by both legal obligations and also by norms and guidance for compliance established by the competent authorities. Flexible components are those documents and demonstrations that are requested on a case by case basis.

Figure 12: Article 7 Requirements in EU and EEA Countries



Questions 6 and 7 aim to distinguish the degree to which countries have established fixed requirements for the MAPP and the type of contents and level of detail that are systematically required. Specifically, Question 7 asked how Member States and EEA countries define legal requirements on lower tier sites associated with Article 7. In transposing EU directives, Member States and EEA countries have discretion to choose the national

forms and methods of implementation which are best suited to ensure the effectiveness of Community law. Therefore, in principle, EU and EEA countries are only bound to require a MAPP document, but Member/EEA states may expand the legal requirements for lower tier sites to achieve the Directive's objectives as they consider appropriate.

As shown in Figure 12 on the following page, over sixty percent of EU and EEA<sup>13</sup> countries impose a specific legal obligation, or obligations, on lower tier sites in addition to the MAPP. Table 4 below lists the types of instruments that are additionally required in these countries by legislation. Eight countries explicitly

require an SMS while three other countries require an "implementation" document in lieu of a full SMS. Although Norway does not specifically require an SMS in legislation implementing the Seveso II Directive, it is counted here because of the pre-existing Internal Control Act of 1992. This legislation requires that every enterprise should undertake systematic actions (at the enterprise level) to ensure and document that the activities of health and safety are performed in accordance with requirements specified in laws and regulations.

Five countries require an emergency plan. France indicated that a safety report is required, commenting that "We have the same approach with the lower tier that we have with the upper tier. There is a land use planning policy and most often an internal emergency plan."

It should be noted, however, that this table summarises what countries have reported as specific requirements on lower tier sites, mainly enforced through Article 7. The survey only asked about requirements imposed in association with Article 7. It is possible that Seveso countries may also impose additional requirements on sites, beyond the requirements of the Seveso II Directive, that were not mentioned in the survey either because they are not specific to lower tier sites (i.e., they are also imposed on upper tier sites), or otherwise, not directly associated with Article 7.

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<sup>&</sup>lt;sup>13</sup> Switzerland is not included in the numbers presented for this section because it does not apply Article 7 of the Directive.

Table 4: Legal Obligation(s) Imposed on Lower Tier Sites in Addition to the MAPP

Country	SMS	Emergency Plan	Risk Assessment	Safety Report	Other
Austria					Implementation must be described
Belgium					Emergency plan . Implementation must be described
Czech Republic					
Estonia					
Finland					
France					
Germany					
Hungary					
Italy					Simplified safety report in some regions
Latvia					
Luxembourg					
Netherlands					
Norway					
Slovakia					
Slovenia					Implementation must be described
Sweden					
Total	8	5	3	1	
		= legal requir	ement exists		

#### 6. Content and Format of a MAPP

Assessing the difference in legal obligations does not in itself provide a sufficient comparison of Article 7 requirements across the Seveso implementing countries. The legal burden imposed by Article 7 is also represented by norms and expectations concerning MAPP content or accompanying documents routinely requested by competent authorities. MAPP guidance for operators and inspection practices create de facto requirements enforced through other competent authority powers not specific to the Seveso II Directive. Question 7 aimed to identify what expectations for documents and demonstration, beyond legal obligations,

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<sup>&</sup>lt;sup>14</sup> This number is likely to underestimate the number of Seveso countries that require a risk assessment of lower tier sites (and also upper tier sites). In many Seveso countries compliance is evaluated with the expectation that a risk assessment has been conducted even though legal requirements may not make specific mention of it.

countries had systematically established as representative of basic compliance with Article 7.

For this reason, the survey also asked respondents to describe the content and format of MAPPs typically considered acceptable by the authorities. The question specifically asked respondents to estimate a typical the length and table of contents of the MAPP. They were also asked to describe any guidance developed addressing the MAPP requirements.

The analysis provided here is at best an approximation of the differences reflecting only a general impression of how the countries may differ in terms of the nature and complexity of MAPP requirements imposed on LT site operators. A more precise analysis is probably not possible via questionnaire since interpretation of what is required and what is not required, and the degree to which requirements are made simple or complex, is very subjective to a country and sometimes to an individual authority.

Several respondents mentioned the subjective nature of the process. One respondent gave the following list of factors affecting MAPP length and structure in the country:

- the individual approach of the person elaborating the MAPP,
- the size and complexity of the management structure and procedures used in the establishment,
- the type of installation,
- the type and quantity of dangerous substances, and
- the probability of a major accident.occurrence.

In fact the survey reveals that a number of both objective and subjective factors may pre-determine the content of what is considered to be the MAPP document proper (i.e., without annexes). According to the survey, the most prevalent factors tend to be:

- The legal requirements imposed on the structure and content of the MAPP. This question did not specifically ask if the content of the MAPP was determined by legislation but according to the survey at least four (4) countries indicated having specific legal requirements.
- Guidelines and enforcement practice that make certain MAPP content more or less standard. An additional eleven countries provided a specific "typical" table of contents that reflected guidance issued by the authorities or (presumably) a specific enforcement preference of authorities.
- <u>The complexity of the site</u>. Sixteen (16) respondents (76%) noted that length varies with complexity.
- The degree to which enforcement is adapted individually to the characteristics of the site. Five countries specifically mentioned that the MAPP varied considerably dependent on the nature of the site.

Moreover, the responses to the question about content of a MAPP generally refer to systematic, that is, uniform practice in the country. On an individual basis, various documentation and demonstration may be requested of lower tier sites based on the judgment of the case officer.

#### Length of the MAPP

Figure 13 below shows the wide range of responses received concerning the length of the document. The minimum length reported was 1 page and the maximum length of over 200 pages. Aggregating the 20 responses that provided specific figures, the average of the minimum and maximum lengths estimated was 13.5 pages and 52 pages, respectively. Five of these respondents gave the typical length as less than 5 pages. In two of the latter cases, the respondent specifically indicated that the MAPP was considered an introduction to other documentation (e.g., emergency response plan) that was also routinely requested (to show implementation of the MAPP).

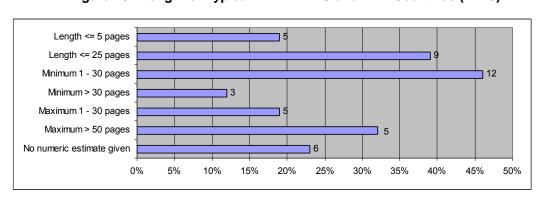
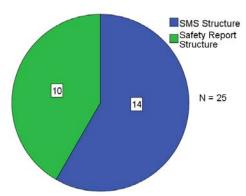


Figure 13: Length of Typical MAPP in EU and EEA Countries (N=26)

#### Table of Contents of the MAPP

According to fourteen (14), that is, sixty percent (60%) of respondents the MAPP table of contents was similar to that of an SMS (see Figure 14 at left). The other 40% described a MAPP that mirrored the structure of a safety report (including

Figure 14: MAPP Table of Contents



the Swiss "reduced safety report"). Another respondent who is not included in this figure indicated that either model could be followed in a given situation. The 14 German Länder responses are also not included in these figures because they were not homogeneous. However, they reflected the same mixed tendency as the other respondents with a similar preponderance of SMS structured MAPPs.

It appeared that most countries did not automatically assume that the MAPP

would include a risk assessment. This expectation was more likely in countries who identified the MAPP with the safety report structure. Indeed, four out of five countries reporting that the MAPP contained a risk assessment, followed the safety report model. (One country that followed the MAPP-as-SMS model also requested a risk assessment.) One country required all three and perhaps not coincidentally, this was the same respondent whose MAPP document was reported to typically exceed 200 pages.

#### Relationship of Length to Content of the MAPP

Responses related to length and content of the MAPP are influenced especially by differences in how countries define the MAPP proper (that is, excluding annexes). Some countries described contents as more of a demonstration or explanatory document, that is, requiring detailed explanation or justification for the elements defined by the MAPP, including in many cases a risk assessment. Of these countries several indicated that typical contents of the MAPP mirrored the contents of a safety report (Annex II of the Directive). Whilst in a number of other countries appeared to take a "summary" approach, in which the MAPP summarises the safety measures and/or elements of the safety management system very briefly. The annex will then (usually) contain the external document that defines the element.

For the survey, most respondents indicated whether their response on length included annexes. Ten respondents said that their estimate of length was all-inclusive (3 with maximum length > 100 pages). In contrast, 5 countries indicated that their estimate was not all-inclusive. It can also be assumed generally that those respondents reporting very short MAPPs ( $\leq$  5) did not include annexed documents.

Although Switzerland does not apply the MAPP requirement, it implements a system in which authorities require a "reduced safety report". On the basis of this reduced safety report, Swiss authorities will determine if a more elaborate report is needed. This respondent noted that "Length varies greatly depending on the size or complexity of the site. As quantity thresholds in the Ordinance on Major Accidents are very low, the minimum may be a few pages. Very long reports are

generally not required (due to the physical proximity of cantonal authorities and enterprises, meetings are held to decide on which elements the reports should concentrate). For more complex sites, reports can be made sequentially for different parts of the site."

The data suggest that the length and complexity of a MAPP is also related to the degree to which the MAPP is viewed as a summary document vs. a demonstration document. A comparison of maximum and minimum length and the prevailing approach (summary vs. demonstration) revealed a significant (99.9%) positive correlation between length and reports aligned more with a demonstration than summary approach. The lack of a significant correlation with minimum length suggests that the demonstration approach does not guarantee a lengthy report. This finding is consistent with observations that site complexity and relative risk are also factors influencing report length. Furthermore, there may also be a relationship between length and the degree to which content is legally mandated.

#### MAPP Guidance Documents

As indicated in Figure 15 below, over half of the respondent countries have created their own guidance for operators on development of the SMS that includes a description of the MAPP. Four countries also cited the EU guidance as a reference; in two of these countries it appeared to be the principal guidance used. Three out of four countries who cited as guidance the MAPP definition in their legislation, said that this definition was the only specific guidance on this topic in their country. Three countries did not provide any specific guidance.

Eleven (46%) respondents noted that MAPPs are assessed by authorities and 3 (13%) specifically said that they were not. (The question was open-ended and therefore, individual respondents could have given more than one answer.)

Nearly a third of respondents have also created guidance for competent authorities on assessing the MAPP/SMS and two countries also use this document as their guidance for operators

Annex 2 contains a list of guidance available for both MAPP and SMS in Member States.

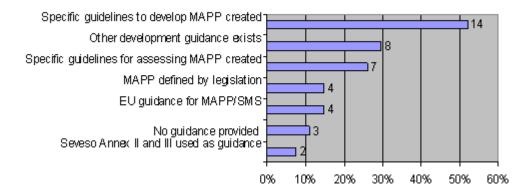


Figure 15: Guidance Used to Develop/Assess the MAPP (N=27)

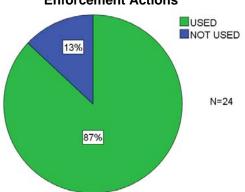
#### 7. Functional Role of the MAPP

Use of the MAPP in Enforcement Actions

A majority of respondents indicated that Article 7 requirements were directly used as a basis for enforcement action (see Figure 16 below). Three respondents that did not routinely use the MAPP in enforcement. Two of these respondents, Belgium and Germany, indicated that stronger enforcement authority lay in other provisions. One German Länder respondent indicated that this practice was largely due to the implementation legislation. "... Enforcement measures are generally not based on Article 8 of the Major Accidents Ordinance/ Article 7 of the Seveso II Directive. Basis for enforcement measures are mainly the specific requirements for safety of installations laid down in licensing notices or other legal provisions, e.g. workplace safety regulations and the corresponding technical provisions. According to the Belgian respondent, "The development of a specific document as required in article 7 has so far not been enforced. See also the answer to question 6a: if the operator of a lower tier site has implemented a safety management system responding to annex III, a separate MAPP document is not necessary."

Figure 17 on the next page shows how the MAPP typically function as part of the competent authority's enforcement programme. (The question was open-ended

Figure 16: Use of the MAPP in Enforcement Actions



and therefore, individual respondents could have given more than one answer.) Notably 16 (60%) of responding countries affirmed that verification of the existence of the MAPP is a routine enforcement action. Thirteen (13 or just under 50%) also cited MAPP as a basis for inspections.

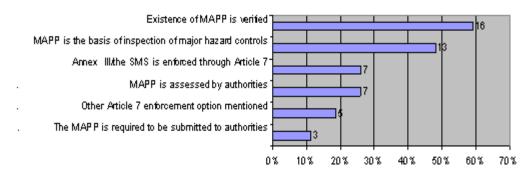
Both Poland and the United Kingdom provided detailed descriptions of how the MAPP was incorporated in enforcement strategy. According to the UK respondent,

"The MAPP informs the intervention strategy and is assessed during inspection and other intervention visits to verify the control measures to prevent/mitigate the effects of potential major accidents. The UK has adopted an integrated approach to implementation of Article 7 in which there are three levels at which safety management systems operate:

- Level 1 management arrangements
- Level 2 risk control systems
- Level 3 workplace precautions.

A balanced intervention approach should incorporate all three levels and inspectors are able to enforce across each level. The inspection activity should be proportionate to the scale and complexity of the hazards at the establishment and the Competent Authority's knowledge of the site ..."

Figure 17: Use of the MAPP in Competent Authority Activities (N=23)



The approach in Poland was described as follows:

"During inspections in the lower tier establishments carried out by the competent authorities the following issues are checked:

- if the MAPP fulfills the law requirements,
- if the information included in the document is reliable and refers to the actual safety level in the establishment,
- if the safety system has been implemented,
- if the MAPP is being revised,
- if the MAPP is up to date, and
- if the MAPP is effective/efficacious/efficient ..."

#### Role in Management of Site Risks

Out of 24 respondents to this question, 23 (96%) considered that the MAPP was helpful to operators in management of site risks, as shown in Figure 18 below. One respondent did not consider that the MAPP had any influence on site risk management. More specifically 14 (58%) considered the MAPP a useful instrument for ensuring that an SMS is implemented on the site. One respondent explained that

"The general approach of lower-tier establishments with regard to major accident hazards is that by managing health and safety at work and by introducing environmental protection regime in accordance with ISO

Figure 18: Benefits of MAPP for Site Risk Management (N=24)

Helping operators with management of site risks. Ensuring that an SMS is implemented on the site. Forces operators to make a site risk assessment Other Sensitizes operators to risks on site For SMEs can be a single (controlled) document Aids communication on risk with the public 10 20 30 40 50 60 70 80 90 14001 all necessary measures have been undertaken also to control risks of major accident hazards."

Another respondent agreed with this perspective but expressed reservations.

"To work with the policy and SMS helps the operator to get a well-structured safety improvement work cycle. A condition for this is however that there are resources for the work and that the work is established and approved by the senior management of the company."

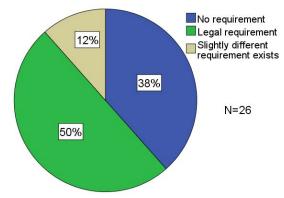
A third respondent highlighted the paradox of Article 7 in that its very flexibility of interpretation for Member States represents both a distinct advantage and a potential pitfall for meeting implementation objectives.

"For small and non complex establishments, Article 7 has the merit that their way of working can be described in a single (controlled) document instead of formal procedures for the different elements of Annex III. On the other hand, Article 7 is in our opinion too ambiguously worded and can be read as aiming only at a one page "declaration" of accident prevention policy."

#### 8. Legal Obligations Regarding Safety Management Systems

Thirteen (50%) respondents said that they specifically required lower tier sites to





implement a safety management system. This result is in conflict with the responses in Section 5 (see Table 4, page 16) concerning legal obligations, in which only eight countries reported an SMS legal requirement. The written comments suggest, however, that these five countries in actuality do not have a legal obligation per se for SMS but standard enforcement practice functions are similar to France, Switzerland and Finland. These

three other countries indicated that they did not literally impose a legal obligation specifically for SMS but that enforcement practice or legal interpretation delivered an equivalent, or nearly equivalent, result. France obliged lower tier sites to establish "procedures of risk management that are less complex [than those of upper tier sites] and that can be [more limited] than a complete SMS." The Swiss respondent explained that "The guidance for the application of [the Swiss legislation] gives SMS the status of a good practice according to [this legislation]. There is therefore an implicit requirement.'

# 9. Availability of Guidance on Implementation of Safety Management Systems

In answer to this question, respondents listed available guidance for lower tier sites on implementation of the SMS. Most publications cited appear to be general

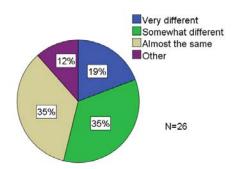
SMS guidance. There does not appear to be any country that has specific guidance on SMS for lower tier sites. Annex 3 provides a list of the information provided by respondents on guidance for implementing the SMS developed in their country.

#### 10. Criteria for Evaluation of Lower Tier Sites

Safety Report vs. MAPP

This part of the question asked respondents to indicate how criteria for evaluating lower tier sites differ from criteria for evaluating upper tier sites for the safety report vs. MAPPs. In general, despite conceptual differences between the safety

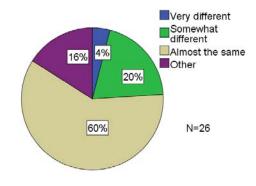
Figure 20: Criteria for Evaluation of MAPP vs. Safety Reports



report and the MAPP in many countries, the majority of respondents (9 or 35%) responded that criteria was almost the same and another 9 (35%) indicated that they were only somewhat different. Several respondents said that they could not make a comparison because competent authorities were not obliged to evaluate the MAPP in their country. As one country noted: "Evaluation criteria for SR of UT-sites (a comprehensive official document on safety relevant issues) can

not be compared at all with the criteria for the MAPP document (a simple summary and declaration of intent together with the concise SMS) of the lower tier sites."

Figure 21: Comparison of Evaluation of SMS on Upper vs. Lower Tier Sites



Evaluation of the Safety Management System

This part of the question asked respondents to indicate how criteria for evaluating lower tier sites differ from criteria for evaluating upper tier sites on implementation of the SMS. Evaluation of SMS appears to be much more uniform between lower and upper tier sites in comparison to evaluation of safety reports/MAPP (see Figure 21 below). It was indicated by one country that "Practically (without explicit requirement) the inspection authorities

follow the more detailed requirements for upper tier sites, with less formality but in essence with the same form of screening." Five respondents (20%) indicated that evaluation of the SMS was somewhat different between upper and lower tier sites. One respondent explained: "All establishments have to have suitable policy and implement of that policy in relation to major hazards. For upper-tier establishments all of this must be set out in writing and demonstrated in the safety report. For lower-tier sites there is [a lower obligation] for documentation and overt demonstration."

#### 11. Recommendations and Comments

For the last question, respondents were invited to provide any recommendations of comments on implementation of Article 7. At least half of respondents listed recommendations, usually several of them. There was not a lot of commonality between the recommendations. The recommendation to make SMS requirements equivalent for lower and upper tier sites was mentioned 4 times, the highest of any recommendation. There were eight MAPP-specific recommendations and seven SMS-related recommendations.

Table 5: Summary of Most Frequently Cited Topics for Recommendations

	Number of respondents
Should have same SMS requirements for both LT & UT	4
MAPP should be required to be submitted	3
Depth of risk analysis should be proportionate to risk	3
Require specification of activities of LT for emergencies	3
Not much difference between UT and LT	2
Safety report should be imposed on LT	2
Clearer guidance on safety measures (for all sites) for LTs	2
MAPP and SMS should not be submitted to competent authority	1
Enhance importance of SMS, clarify and intensify attention	1
Should be deadline for MAPP revisions	1
No safety report requirement should be imposed on LT	1
Employees should be involved in elaboration of the MAPP	1
Location should be considered as part of LT/UT criterion	1
LT should be inspected as frequently as UT	1
Clear instructions are needed on how to document, safe-keep and present the MAPP+SMS	1
LT should be inspected as frequently as UT	1
MAPP does not fit with increasing certification needs (standardisation of practices such as ISO)	1
Operators should have regular change of experience	1

There were also opposing points of view represented in the recommendations with three respondents advocating that the MAPP be submitted to the authorities and one respondent opposed to this measure. Likewise two respondents advocated requiring a safety report of lower tier sites and one respondent was opposed to this measure.

#### **Conclusions from the Survey**

The survey responses produced several important insights in regard to the character of lower tier sites, and requirements and practices associated with implementation of Article 7 in the Member States and EEA countries. Countries were also able to express their opinion about the usefulness of Article 7 requirements and particular challenges as well as benefits linked with this provision and with the way in which it is implemented in their country in particular. Survey results also provided a perspective on how Switzerland, an EFTA country, adjusted the regulatory burden for lower risk sites.

The following points highlight the most important findings:

- A considerable portion of lower tier sites are a significant challenge for Seveso implementation because of limited resources and risk management capacity. In many countries, more than half of lower tier sites are SMEs. SMEs were also cited by many countries as a particular challenge for enforcement and implementation. This finding also may explain why certain sectors, often dominated by SMEs, are often cited as more problematic for Seveso implementation, in particular, metal surface treatment, fireworks and explosives storage, agricultural chemicals and fuel storage distribution sites.
- Residual risk and location are factors that can make lower tier sites a
  higher risk than upper tier sites. Respondents generally agreed that lower
  quantities of dangerous substances present lower intrinsic risk potential.
  However, risk level is not just a function of quantity, but of location and
  competence in risk management. Lower tier sites located near population
  centres or with limited resources may be of higher concern than upper tier
  sites.
- Challenges associated with certain Seveso site profiles are not limited to lower tier sites. For example, compliance challenges associated with age, complexity, atypical sites and newly covered sites are probably shared equally with upper tier sites.
- Many countries have defined a specific legal requirements associated with Article 7 in more detail than the Directive. The Directive only specifies that a Major Accident Prevention Policy (MAPP) is required. However, in over sixty percent of the responding countries, the MAPP definition has included more detail. Most commonly (8 countries or 31%, excluding Switzerland), the MAPP is defined to include elaboration of a safety management system (SMS). In other countries, an emergency planning or risk assessment must be included. One country requires a full safety report.
- Nearly sixty-percent of the countries surveyed impose a legal obligation, or equivalent, on lower tier sites to implement an SMS. Moreover, the enforcement practices of several countries make an SMS a de facto requirement for lower tier sites. In these cases, the MAPP itself as a document, may or may not be considered as a separate entity, from the SMS.
- Countries are more or less split in terms of whether they define the MAPP as a reduced SMS or as a reduced safety report. Thirteen, or nearly half, use Seveso Annex III (elements of an SMS) as the defining structure. Seven (26%) define the MAPP in terms of Annex II (elements of a safety

- report). At least three countries consider that a MAPP should address both elements of safety report and a safety management system.
- Not all countries systematically require a risk assessment. Countries that identified the MAPP with safety report requirements also tended to expect the MAPP to include a risk assessment.
- The type of content that constitutes the MAPP proper (without annexes) varies considerably from country to country. Twenty-one countries (75%) usually had MAPPs under 50 pages, and a little over 20% were under 5 pages. The mean of estimated minimum lengths was 13.5 pages and the mean of estimated maximum lengths was 52 pages. The data also suggest that the length of a MAPP is related to the degree to which the MAPP is viewed as a summary document vs. a demonstration document. However, other influences, such as site complexity and relative risk, almost certainly play a role in determining document size.
- Most of the countries used the MAPP for enforcement and nearly all felt that the MAPP was also useful for the operators. For enforcement the most common activities involving the MAPP were (in order of frequency) verification that the MAPP existed, inspection on the basis of the MAPP, and assessment of the quality of the MAPP.
- Many countries routinely assess the quality of the MAPP. However, the exact proportion was not clear from responses because this question was not specifically asked. A total of eleven countries (42%, excluding Switzerland) volunteered that they regularly assessed the quality of the MAPP. Three (12%) reported that they did not.
- Many countries did not use the same criteria for evaluating MAPPs in lower sites as used to evaluate the safety report in upper tier sites. This is not surprising considering the finding cited above, that many countries consider the MAPP to be a reduced SMS, not a reduced safety report.
- Countries are more inclined to apply a similar approach to evaluating the SMS on lower as for upper tier sites. For SMS evaluation the split was 30/60 (more countries used similar criteria for LT and UT). Sixty percent (14 countries) indicated that it was almost the same.

## Part 2: The Seminar on Major Accident Prevention in Lower Tier Seveso Establishments

This one-day seminar was co-hosted by the European Commission and the Czech Ministry of Environment as a follow-up to the survey. It took place on 22 April 2009 in Prague, Czech Republic, coinciding with a meeting of the Committee of Seveso Competent Authorities. Around 80 people attended the seminar, mainly from Seveso competent authorities. Almost all Member States, Candidate Countries, EEA and EFTA countries were represented.

The agenda (see Annex 4) consisted of a presentation on the survey findings and presentations by industry and various countries (both Member States and countries outside the EU) aimed to provide a perspective on regulatory arrangements to establish effective risk management on lower hazard sites (classified as "lower tier sites" within the Seveso regime). These presentations were followed by group discussions intended to identify common points of interest and recommendations for regulatory policy and implementation.

### **Industry and Country Presentations**

The five presentations were as follows:

- Seveso Impacts Article 7 Lower Tier sites by Douglas Leech, FECC -European Association of Chemical Distributors/CBA Chemical Business Association
- 7. Implementation of Lower Tier Site Requirements in the Czech Republic, by Stanislav Malý, Occupational Safety Research Institute, Czech Republic
- 8. Implementation of Lower Tier Site Requirements in Italy, Andrea Santucci, Ministry of Environment, Italy
- 9. Addressing Low Thresholds in Switzerland, Bernard Gay, Federal Office for Environment (FOEN), Switzerland
- Korean Experience of Process Safety Management Systems in the Chemical Industry. Hyuckmyun Kwon, Occupational Safety and Health Agency (KOSHA), Korea

Highlights from each presentation are presented in the paragraphs below. The agenda of the seminar is available in Annex 4.

Perspective of the FECC - European Association of Chemical Distributors/CBA Chemical Business Association

FECC represents around an industry of around 1,600 companies, the majority of which are SMEs. In total the industry accounts for about 33,000 employees and €30 billion/year in sales revenues across Europe. The direct membership of FECC includes 240 SEVESO sites, of which 72 are upper tier and 168 are lower tier.

The presentation indicated that, due to the large number of chemical distributors that are SMEs, Seveso compliance could be particularly challenging for members of this industry. In particular, it is in the interests of small businesses with limited resources to remain as lower tier sites, but the complexity of Seveso classification criteria complicates such attempts. In particular, for distribution sites, each substance must be evaluated in terms of how it should be counted or

not in accordance with the summation rule<sup>15</sup>. In addition, dangerous substances in transport will be labelled in accordance with norms established for international dangerous goods transport<sup>16</sup> but may not have safety data sheets with the European classification.

The presentation observed, however, that lower tier site status can remain a disproportionately heavy burden for small business. For example, the French requirement of a safety report and the UK practice of charging sites for competent authority services can represent heavy cost burdens for these sites. The complexity, and therefore, cost, of implementation can also increase when more than one authority is involved enforcement, as is the case in many EU countries.

#### Perspective of the Czech Republic

According to the presentation, there are 76 lower tier establishments in the Czech Republic as of March 2009. Czech legislation obliges an operator of such an establishment to prepare a "Safety Programme". Subsequently, the government published a regulation defining the scope and rules for preparing and updating the safety programme. In general, the regulation requires the operator to prepare a draft safety programme based on the results of a major accident risk assessment. The safety programme must describe the overall principles applied for prevention of major accidents, the structure and system of safety management to protect human beings, domestic animals, the environment, and property. If designated a domino site by the regional authority, the operator is obliged to preventative safety measures related to potential domino effects.

In essence the same structure and content of the analysis and assessment of risk is required for both upper and lower tier sites in the Czech Republic. This approach is based on the philosophy that the potential off-site consequences of an accident may be more or less equivalent for lower and upper tier sites in many situations. For this reason, the Czech government determined that there should be only one single document required of Seveso sites, prepared with greater or lesser detail taking into consideration the extent of information, procedures and steps required for each site. The depth of the analysis and assessment of risk depends on the hazard posed by the dangerous substances present on the site, how they are processed and handled, and potential off-site impacts on the surroundings of the site.

The presentation also noted that in principle, it is possible to divide the required elements of the safety programme into different categories of importance as follows:

- items with a fundamental importance,
- items providing supplementary information,
- items for specific types of establishments and irrelevant operational activities

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<sup>&</sup>lt;sup>15</sup> Annex 1, Part 2, Note 4 of the Seveso II Directive provides an algorithm for adding up quantities of dangerous substance categories on-site, in the case of an establishment where no individual substance or preparation is present in a quantity above or equal to the relevant qualifying quantities. This algorithm is called the "summation rule".

The UN Model Regulations for the Transport of Dangerous Goods) <a href="http://www.unece.org/trans/danger/danger.htm">http://www.unece.org/trans/danger/danger.htm</a>) are the basis for classification and labelling requirements of dangerous goods transported within and from Europe and are also generally followed by external EU trading partners.

This division into categories of importance allows some discretion in applying the structure to specific establishments. The value, weight, importance and the expected level of detail of the information of the individual items may differ case by case depending on each individual situation.

The presentation cited lack of appropriate information as a deficiency in many safety programme descriptions. For example, the introduction to the document often does not fully describe the establishment. There may be insufficient information on the amounts and type of hazardous materials. Several elements may not be described with precision and accuracy, such as the technology used, operating parameters, and the character of the external surroundings.

This presentation also included a brief description of the 17 chapters of the Safety Programme document and of the SMS requirements.

### The Perspective from Italy

Currently, Italy has a total of 1,088 Seveso sites, of whom 517 (48%) are upper tier and 571 (52%) are lower tier. Under Italian law, lower tier sites must comply with the following legal requirements:

- Notification and information on safety measures
- Major accident prevention policy
- Safety management system
- External emergency plans
- Hazard control measures
- Documentation of risk analysis

In Italy notification must include certain schematic information on the risk management measures that have been adopted by the operator. Depending on the region, this information may include a description of the nature of the risks, potential of impact on people and the environment, prevention measures taken, main elements of the external emergency plan, the safety data sheet of the involved substances, and the severity and consequences associated with accident scenarios.

The presentation noted that 75% (>400 sites) of lower tier sites in Italy are estimated to be SMEs and nearly 40% (>200 sites) are estimated to have less than 10 employees. Typically, sites in the latter category consist of a family owned activity and have a maximum of 2-3 employees, where a single person may play many roles (e.g., safety manager). It can be culturally difficult for the authorities to achieve proper execution of MAPP and SMS requirements. Sectors well-represented among small sites include surface metal treatment and fireworks manufacturers.

The presentation highlighted that MAPP and notification data may provide insufficient information on lower tier site hazards to authorities. The notification tends to include the results of risk analyses but no detail on the risk elements. This lack of information can pose a particular impediment to effective land-use and emergency planning. Hence, while there is a concern about over-burdening small sites with too many requirements, there is an equal concern that competent

authorities do not have adequate detail about the hazards on site to take appropriate measures to protect the population.

The presentation posed several thought - provoking questions in regard to addressing the challenge associated with Seveso compliance on small sites:

- How can the authorities/regulatory requirements help the operators of small sites to understand and implement an SMS effectively?
- Could it be useful to provide simplified compliance criteria for "non complex" activities?
- Could it be useful to oblige sites to draw up a simple "safety document" (a kind of "light "safety report)?
- Could the Directive include a more simplified criteria or derogation for when hazardous substances or preparations on site do not give rise to a major accident risk?

#### Perspective from Switzerland

The current Swiss Ordinance on Major Accidents (OMA) entered into force in 1991. It contains some important differences in scope from the Seveso II Directive. In particular, since smaller installations were found to be more integrated in urban tissue, ordinance threshold quantities were set particularly low. Hence, OMA also covers installations that, if the Seveso Directive were operative in Switzerland, would not qualify as lower tier sites. OMA also covers major hazards associated with roads, pipelines and transport on the Rhine.

For this reason, there is no summation rule for calculating regulatory coverage. (The latter omission also caused some installations to drop out of coverage.) In addition, OMA establishes a two-step procedure of which the first step is very simple (see Figure 22, below).

OWNER ESTABLISHES SUMMARY REPORT STEP 1 . SERIOUS DAMAGES HARDLY TO BE EXPECTED: PROCEDURE ENDS HERE AUTHORITY EVALUATES SUMMARY REPORT SERIOUS DAMAGES MAY BE EXPECTED: AUTHORITY
REQUIRES A RISK STUDY STEP 2 OWNER ESTABLISHES RISK STUDY RISK ACCEPTABLE: PROCEDURE ENDS AUTHORITY EVALUATES RISK STUDY HERE RISK NOT ACCEPTABLE: AUTHORITY ORDERS THAT SUPPLEMENTARY MEASURES BE TAKEN

Figure 22: Implementation Process of the Swiss Ordinance on Major Accidents (OMA)

In the first step of the procedure, the operator must develop and submit a summary report with the following information:

- a short description of the establishment, incl. a layout plan and details of the surrounding area;
- for substances, products or special wastes which may be present in the establishment in quantities exceeding the threshold quantities: the maximum quantities that may be present;
- details of the safety measures;
- an estimation of the extent of possible damage to the public or the environment that may result from major accidents.

In order to prepare the report, the owner must carry out an assessment of the maximum damage that may be caused to the public or the environment. This assessment can be a rough, conservative estimate. It is often based on a standardized methodology jointly developed by stakeholders. It is considered part of the environmental impact assessment and as such is made available to third parties and the public.

Based on the authority's analysis, a site may or may not have to complete the second procedure. To evaluate the summary report, the authorities must evaluate whether the assumption can be made that serious damage to the public or the environment resulting from major accidents is not to be expected. If they conclude that such an assumption may not be valid, they order the operator to complete the second procedure, which is a risk study.

Currently, 271 sites are required to perform a risk study which includes a description of accident scenarios and a risk analysis. In some types of establishments, standardised criteria have been developed.

The presentation offered the following lessons learned from the Swiss experience:

- OMA has lead a number of small operators to decrease their inventory of hazardous substances so that they are no longer in the scope of OMA.
- Operators of SMEs have trouble generating genuine worst case scenarios.
- Damage to the environment is often more difficult to assess.
- Operators of SMEs have trouble admitting that their activity could cause fatalities among the population. (Often they describe consequences in terms of "casualties" instead of fatalities).
- Local authorities and SMEs still request a lot of guidance in implementation.

Also, with SMEs, authorities are confronted by a much smaller amount of information. Moreover, the "balance of power" between authority and operator changes with the size of the enterprise. Therefore, with SMEs, it is easier for authorities to make the operator adopt certain measures but it can also sometimes tempt the authorities to concentrate on the small sites instead of bigger sites with larger hazards.

The presentation also commented that the overall experience was positive. The broad scope of OMA has particular benefits, allowing a somewhat integrated perspective from authorities. Ensuring that even small operators bear appropriate responsibility is also important.

#### Perspective from Korea

The Process Safety Management (PSM) legislation entered into force in 1996. It covers 21 substances and the following industry sectors:

- Oil refineries
- Petrochemical industries
- Organic composite material & synthetic resin manufacture
- Fertilizer industries
- Pesticide industries
- Industrial explosives industry

Out of 871 covered sites, it is calculated that 367 have less than 50 employees. Interestingly, the data seem to indicate that bigger companies are having more accidents than smaller ones in recent times.

The PSM requirements are similar to the US PSM Rule. It is performance-based legislation that includes assessment of a safety report, implementation of a process safety management programme (including SMS), and on-site inspection of the PSM programme by competent authorities.

The Korean Occupational Safety and Health Administration (KOSHA) administers the programme. It has created an appraisal system for prioritizing inspections and training on individual sites on the basis of performance with the PSM requirements as follows:

- P = progressive over 90%, self-implementation no inspections during the year
- S = stagnant between 80-90% 1 inspection per year
- M = mismanagement < 80% 2 inspections per year and PSM training every 6 months

Korea shares the challenge of Seveso countries in that the PSM (safety) report can be a heavy burden for smaller sites. Future improvements to the legislation may need to include simplification of the requirement for qualifying smaller sites.

#### **Results of the Seminar Group Sessions**

The participants were divided into four groups of approximately 20-30 participants. Groups 1 and 2 focused on whether modifications or additions to current Article 7 requirements would improve the ability of operators and authorities to meet Seveso objectives for lower tier sites. Groups 3 and 4 were to discuss additional tools or guidance that could improve implementation.

#### Group 1

Group 1 identified a number challenges to lower site compliance and discussed the advantages and disadvantages of introducing specific requirements to address them. These challenges included:

- Lack of expertise and resources, especially SMEs
- Difficulty of defining a proportionate approach to the MAPP (SMS) for small sites

- Limited safety expertise available. Often expertise is bought through outside consultants and not embedded into the company
- Information necessary for land-use planning
- Emergency planning for lower tier
- Coherence of SMS vs. the MAPP (how should they be defined and distinguished from each other?)
- Defining MAPPs that are proportionate to the risk or to the size.
- Synergy between management systems, such as the Eco-Management and Audit System (EMAS)<sup>17</sup>

The group also questioned whether it was adequate to define lower risk sites solely based on the presence of quantity of hazardous substances.

In the discussion, some participants noted that consistency throughout the EU could be partly aided by better exchange of information among Member States, noting that the current Mutual Joint Visit Programme for Seveso Inspectors was already a very good tool. It was also commented that the MAPP concept as a stand-alone obligation was not an adequate minimum requirement for lower tier sites. Additional requirements should be required in proportion to the risk and taking into account extrinsic risk factors such as location of the site.

Several participants also thought that the Annex II of the Directive (safety report elements) and Annex III (elements of safety management systems) were not clear in regard to expectations of lower tier sites and the principle of proportionality in general.

#### Group 2

Group 2 participants highlighted several advantages and disadvantages associated with implementation of Article 7. Whether information required of lower tier sites was called a MAPP or SMS or safety report was not particularly important. The central objective was to drive operators to have effective risk management programmes. Competent authorities need to have adequate information from operators to judge the effectiveness of their risk management programme and to fulfil their responsibilities to protect the population and environment.

Two key questions concerned 1) how operators could implement the SMS with limited resources and 2) how authorities could enforce the SMS on lower tier sites with limited resources. One participant noted that the key to effective implementation was to avoid resorting to bureaucratic approaches to obtain information for compliance assurance and enforcement. For this reason, some participants thought that the SMS was a more appropriate instrument than safety reports for lower tier sites because it tends to promote a goal-setting approach. Moreover, some participants commented that every operator should perform a risk assessment. I

In many countries it appeared that there was not a big difference between requirements for upper vs. lower tier sites. A risk-based approach to enforcement makes sense in this context but could also create a high burden for competent

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<sup>&</sup>lt;sup>17</sup> A voluntary European initiative under which companies and other public organisations evaluate, manage and continuously improve their environmental performance. The current version of the programme is defined by Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009.

authorities if too many sites were judged as high risk. A risk-based approach also has to be carefully constructed so as to ensure consistency of treatment.

It was noted that administration in a federal context (i.e. significant authority distributed to the local level) can be a challenge but does not have to provide additional complexity for covered sites. Guidelines and checklists are helpful in harmonizing expectations at national level.

#### Group 3

A number of advantages and disadvantages of MAPP implementation were suggested by Group 3. One advantage often cited was that for some prevention elements it makes sense to take the same approach to lower tier sites as upper tier sites, in particular, the SMS, external emergency plans and land-use planning. However, it can be a challenge to obtain all the information necessary from lower tier sites to execute these measures properly.

Some participants in this group also raised concerns about the definition of a MAPP. It was noted that Article 7 can be read in different ways. It was recommended that a revised Directive be more clearly worded in this regard in order to promote consistency of interpretation and application across the EU. It was specifically noted by some participants that this clarification would be better in the Directive than in guidance because legislative requirements are by and large the easiest to enforce.

This group also noted that the Directive requires lower tier sites to take "appropriate measures" but does not specifically require lower tier sites to perform a risk assessment to determine what the appropriate measures could be. Many countries used the notification requirement to obtain more information on risk factors because they had no authority to require a risk assessment.

It would be helpful to have EU guidance on lower tier site requirements to promote more coherent implementation across Europe. However, such guidance would require a consensus among Member States on how to interpret the most important elements. Currently, reaching such consensus could be difficult since some countries view the MAPP as a mini-safety report and others consider it to be more similar to an SMS. More frequent exchange of good practice could lead to greater convergence among Member States around a common interpretation.

### Group 4

Several participants in this group expressed concern about limitations associated with achieving Seveso objectives on lower tier sites. Limited competency and resources available on lower tier sites mean that many SMEs often contract an external consultant to fulfill their obligations. This solution does not necessarily lead to safer sites since operators may not have proper ownership of a risk management policy and implementation programme designed by parties external to the site.

Many stakeholders representing both competent authorities and industry have raised legitimate concerns about consistency in applying Article 7 requirements across the Member States. This situation was the down side of the flexibility of the Seveso approach. Several participants felt that a minimum flexibility was necessary and appropriate and perhaps the lack of consistency could be reduced by indirect means, such as common training programmes for operators and

inspectors, national or EU level technical working groups, national and multinational exchanges of good practice, such as the MJV programme and initiatives for joint inspections with Seveso inspectors from other countries.

Particular challenges faced by competent authorities in regard to lower tier sites include having competent and sufficient staff to perform inspections, establishing a reliable appraisal system to prioritize inspection of lower tier sites, defining proportional approaches for smaller sites, and making the best use of the MAPP in enforcement. Some participants also wondered if submitting the MAPP to the authorities should be mandatory.

It was suggested that the availability of a simple and effective risk assessment tool, as applied to many cases in Switzerland, could be helpful for small sites and competent autorities alike. It would help both operators and authorities to understand the risk better without performing a full risk assessment.

#### **Conclusions from the Seminar**

The findings from the seminar largely reflected the findings of the survey and there was no evidence of any contradiction between the results of these two efforts. In fact, the seminar confirmed many observations on advantages and disadvantages of Article 7 requirements noted by survey respondents. Therefore, in summarizing seminar conclusions, only those findings are mentioned that offer additional insights.

- Lower tier site status can remain a disproportionately heavy burden for small business but it is often difficult for authorities to find effective solutions to make the burden lighter. To achieve objectives of the Seveso Directive, a minimum awareness and competence of risk management is necessary. A minimum amount of information describing risk management on the site must also be available to authorities. The level of effort must be commensurate with the risk and with the size of the site and may sometimes be disproportionately high in relation to the economic footprint of the site.
- Additional complexity, and therefore, burden may be created for lower tier sites when more than one authority is closely involved in enforcement. This difficulty can be offset in part by continuous efforts to coordinate activities among the authorities and national uniform guidance.
- Several participants noted the importance of having an adequate risk assessment from lower tier sites for emergency and land-use planning. As a result some countries included risk assessment requirements in legislation or guidance. Others, such as Italy, used the notification requirement to obtain more information on risk factors because they had no authority to require a risk assessment. The demands on resources and expertise associated with risk assessment can make this task challenging for some lower tier sites.
- Both Switzerland and Korea presented alternative practices and useful experience in regard to applying a proportionate approach to lower hazard sites. The Swiss approach sought to balance the complexity of certain demands on small enterprises with higher risks in a number of ways, such as simplified risk assessment and uniform approaches for different sectors. The Korean approach also presented an option for using residual risk estimates to prioritize the use of competent authority resources for enforcement on lower risk sites.

- Participants acknowledged that there was a particular lack of coherence between the definition of the MAPP and the SMS. In particular, countries evidenced substantial differences in regard to their interpretation of the MAPP. How sites could implement an SMS proportionate to site risks was not uniformly understood by many competent authorities.
- There was a common desire among competent authority representatives to foster greater consistency in applying Article 7 requirements to lower tier sites across the EU. There was no clear agreement as to whether a direct approach (using legislation) or indirect approach (relying more on exchanges and joint initiatives) would be more practical and effective. It was acknowledged that indirect approaches were more likely to preserve the flexibility of the current requirements.

#### **Recommendations Resulting from the European Commission Study**

Although several countries and workshop participants made recommendations on how implementation of Article 7 could be improved, no consensus emerged on any specific recommendation. The study itself confirmed that exchange of practices among Seveso implementing countries was a first step in providing a common understanding of certain provisions of the Directive. The study also confirmed that flexibility and proportionality were important to achieving the objectives of the Directive in local contexts. However, meeting these objectives is sometimes an impediment to consistency and clarity of the basic Seveso requirements. Given these results, the European Commission undertook to fulfil a more general recommendation to examine the lower tier provisions of the current Directive in the review of the Directive It would also review how the implementation could be improved, for example by facilitating indirect activities, such as mutual exchanges and joint development of technical guidance and tools, that could lead to greater clarity and consistency. The findings and observations from the study and the seminar would be taken into account in this review process.

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# **Annex 1: Questionnaire on Implementation of Article 7 in Seveso Countries for Seveso CCA Country Focal Points**

Implementation and enforcement of Seveso obligations in **lower tier sites** has been signalled by many Seveso countries as a particular challenge for competent authorities. Questions are often raised in relation to implementation and enforcement of the **Major Accident Prevention Policy** (Art. 7) and as a related topic, minimum requirements for **Safety Management Systems** at these sites.

Against this background, the Czech competent authorities in collaboration with the European Commission are hosting a Seminar on Major Accident Prevention in Lower Tier Seveso Establishments on 22 April 2009, one day prior to the twenty-first meeting of the CCA<sup>18</sup> in Prague, Czech Republic. The goals of the seminar are as follows:

- with regard to the existing directive provide recommendations about a set of instruments to optimise compliance;
- with regard to the planned review of the directive provide recommendations for the reviewers to improve the enforceability of the directive.

In addition CCA members and observers are invited to volunteer for the seminar steering group (discussions to be managed by e-mail and teleconference) that will lead development and execution of the seminar programme. All CCA countries are invited to make recommendations regarding potential speakers. Industry and other interest group views are welcome.

As the focal point for your country's participation in the CCA, we are sending you this questionnaire in preparation for the seminar and kindly ask you to manage your country's response to it. We request that no more than one questionnaire be completed by each country.

Responses will be analyzed and the overall findings will be presented at the seminar and also may be used as appropriate for input into future policy or implementation support activities at EU level.

If you could please complete your questionnaires and return them to Maureen Wood (<u>maureen.wood@jrc.it</u>) **by 31 January 2009**, we would be very grateful. Please contact Maureen Wood if you require any clarifications regarding any questions.

To volunteer to assist with the seminar preparation or recommend a speaker presentation, please contact Pavel Forint (<u>Pavel.Forint@mzp.cz</u>), ,Tobias Biermann (<u>tobias.biermann@ec.europa.eu</u>) or Maureen Wood.

<sup>&</sup>lt;sup>18</sup> Committee of Competent Authorities for Implementation of the Seveso II Directive (established by 96/82/EC Art. 22)

#### Questionnaire on Implementation of Article 7

space as necessary to respond to open questions and explain your answers.		
Country Name:		
Contact Name:	Tel:	Email:

Kindly provide your answers to the questions below. Please feel free to use as much

1. Industry profile of lower tier sites in your country. How are lower tier sites distributed among industry sectors (e.g., noting only the most important sectors)? Feel free to use your own words to generally describe the situation or you may provide estimated numbers or percentages, NACE<sup>19</sup> codes, etc. or other more specific information if it is available to you.

#### 2. Size and resource characteristics of your country's lower tier sites.

To the best of your knowledge, please respond to the following questions<sup>20</sup>:

Question: What proportion of your sites would you consider	Your estimate
a are small or medium-sized enterprises?	
b have ≤ 10 employees?	
c belong to multinational corporations?	

- 3. What, if any, industry sectors or establishment sizes pose particular challenges for oversight and enforcement of lower tier obligations? (If these sectors are also present in upper tier sites with similar problems, you may wish to mention this.)
- 4. How would you describe the risk level associated with lower tier sites in comparison to upper tier sites? Potential risk? Residual risk (after safety measures have been taken into account)? Please respond to the best of your ability.

<sup>&</sup>lt;sup>19</sup> European Classification of Economic Activities (Nomenclature européenne des activités économiques – NACE) http://circa.europa.eu/irc/dsis/nacecpacon/info/data/en/index.htm

nttp://circa.europa.eu/irc/dsis/nacecpacon/info/data/en/index.ntm

<sup>&</sup>lt;sup>20</sup> Since there is no other source of objective information on this important aspect of the lower tier site profiles, we have to rely on your expert opinions in this regard. For this reason, we would be grateful for any rough estimates of the situation in your country that you could supply. Answers such as "~25%", "Around 10", and even "a significant majority", though imprecise, would still be helpful. Any subsequent analysis that cites these numbers will qualify them clearly and precisely as rough estimates. (Of course, if you have exact numbers, please cite them and note that they are exact.)

5.	What legal obligations does your country impose on lower-tier sites in association with Article 7 requirements? Please check only one answer.		
	Only the MAPP is required (the minimum obligation of the Directive)		
	A safety report is required (there is no MAPP requirement.)		
	Other (please explain/describe.)		
Ad	ditional comments/explanation:		
6.	In the table below, please describe the content and format of MAPP's that are typically considered <u>acceptable</u> by the authorities? Also, please note any situations that would be considered exceptions to the norm.		
(m. len	ngth. How long is it usually inimum, maximum)? Does the agth vary depending on the size or mplexity of the site?		
he	oical table of contents (or main adders of sections). Other cessary details, annexes?		
the ass	idelines or tools your country ovides for operators to develop e MAPP or for authorities to sess the MAPP. If an electronic cument or html link is available, dly list or attach it.		
7.	Functional role of the MAPP.		
	a. How do you use Article 7 (or the equivalent legal requirement at national level) as a basis for enforcement actions?		
	b. How does Article 7 help operators with establishing good management of site risks?		
8.	Does your country have a specific legal requirement regarding <u>safety</u> <u>management systems</u> on lower tier sites? <u>Check only one answer.</u> If the answer is "yes" or "other", please explain the requirement as necessary for a precise understanding (as well as its advantages and disadvantages) in the additional comments section.		
	No.		
	Yes. Written SMS description and/or documentation is required by authorities		
	Other. (Please explain).		
Additional comments/explanation:			
9.	Please list here any guidelines or tools your country has published for <u>SMS for lower tier sites</u> , if any. If an electronic document or html link is available, kindly list or attach it.		

<ol> <li>Please indicate how criteria for evaluating lower tier sites differ from criteria for evaluating upper tier sites for the safety report/MAPPs and for the SMS.</li> </ol>				
Safety report/MAPP	☐ Very Different	☐ Slightly different	☐ Almost the same	☐ Other
SMS		☐ Slightly different	☐ Almost the same	☐ Other
Please explain your a	answers.			
	mproving the effe	-	ligations for lower-ti	•

### Annex 2: Guidance Available in EU and EEA/EFTA Countries for MAPP and SMS

This list was mainly constructed from responses to questions 6c and 9 of the survey. However, in a few instance, existing sources on the Seveso Inspections are also included for convenience.

Respondent	Guidance		
Austria	No specific guidance exists but transposition into Austrian legislation includes some more details than the Directive text		
Belgium	The inspection instrument "Metatechnical Evaluation System" (M.E.S.) is used for the systematic auditing of the organisational and managerial ability of the Seveso establishments and is applied to lower and upper tier sites. <a href="http://www.employment.belgium.be/seveso.aspx">http://www.employment.belgium.be/seveso.aspx</a> This is based on the fact that both kind of establishments via article 7 and 9 are expected to: • conduct a prevention policy that ensures a high level of protection • guarantee the implementation of all suitable measures, systems, procedures and such like, which are necessary to ensure that the prevention policy is carried out in an effective manner.  The inspection instrument describes in a first part the basic concept of M.E.S., including the view of the inspection authorities with respect to MAPP and SMS. Although the M.E.S. has not been developed specifically for carrying out internal safety audits, companies can use it to do initial surveys to allow them to draw their own appropriate conclusions in order to improve the management system in the domain of major accident		
Czech	prevention.  The following guidelines have been created for implementing MAPP/SMS:		
Republic	• Principles, aims and policy for major accident prevention;		
	Description of a safety management system;     Evaluation form for assessment.		
Denmark	It may be common knowledge to the CCA members but with a fairly low number of establishments falling within the scope of the Seveso II Directive and as the general administrative structure in Denmark is very de-centralised, it is extremely difficult to set up general rules for the implementation of the Seveso Directive.		
Estonia	Guidance for the development of the MAPP and SMS: <a href="http://www.tja.ee/file.php?11397">http://www.tja.ee/file.php?11397</a> This guideline is principally a translation of the EU guidance.		
Finland	For operators we have a guide indicating what the document should contain. We don't have a specific tool for authorities.		
France	No specific tool is provided.		
Hungary	Announcements of the National Authority (National Disaster Management): <a href="http://www.katasztrofavedelem.hu/tartalom.php?id=90">http://www.katasztrofavedelem.hu/tartalom.php?id=90</a> EU Guidelines: <a href="http://www.katasztrofavedelem.hu/tartalom.php?id=432">http://www.katasztrofavedelem.hu/tartalom.php?id=432</a> Publications: <a href="http://www.katasztrofavedelem.hu/tartalom.php?id=387">http://www.katasztrofavedelem.hu/tartalom.php?id=432</a> Publications: <a href="http://www.katasztrofavedelem.hu/tartalom.php?id=387">http://www.katasztrofavedelem.hu/tartalom.php?id=432</a>		
	Guidelines and Assistance publications:  http://www.katasztrofavedelem.hu/tartalom.php?id=388		

	Laws of the Special Authority (Hungarian Trade and Licensing office):
	http://www.mkeh.gov.hu/muszaki/EU/Seveso2/jogszabalyok
	Guidelines by the Special Authority:
	http://www.mkeh.gov.hu/muszaki/EU/Seveso2/utmutato
	Stances by the Special Authority:
	http://www.mkeh.gov.hu/muszaki/EU/Seveso2/allasfoglalasok
	Studies by the Special Authority:
	http://www.mkeh.gov.hu/muszaki/EU/Seveso2/tanulmanyok
Iceland	Guidelines for industry on the website of Iceland's Administration of Occupational Safety and Health (AOSH)
	http://www.vinnueftirlit.is/is/storslysavarnir_efna/_include:
	- General information and guidelines
	- Lower tier sites
	- Upper tier sites
	- Emergency plans
	Checklists for internal AOSH are also used for:
	- MAPP and SMS
	- Safety reports
	- Emergency plans
Ireland	The section of the guidance on assessment of the safety report is used as guidance to operators on the MAPP [create Seveso inspections website link].
Italy	The main criteria for drawing up the MAPP and the SMS are expressed in the Ministerial decree of 09.08.2000. Specific guidelines for the inspectors (issued with a Directorial Decree) are also provided to verify the completeness of the structure of the MAPP, the SMS and their elements. A description of the MAPP/SMS requirements and a copy of the checklist can be found in the Seveso Inspections Library [link] on the Seveso Inspections website.
	Other documents with information pertaining to implementation of SMS requirements on lower tier sites
	■ Ministerial decree of 09.08.2000;
	■ Guide lines for the inspector - Directorial Decree
	http://www.minambiente.it/moduli/output_immagine.php?id=2105
	■ APAT report RT23/2003 http://www.ispra.gov.it/site/it-
	IT/APAT/Pubblicazioni/Manuali e linee guida/Documento/manuali lineeguida 2003 23.html
Latvia	Latvia had guidelines from 2002-2005 years according to the previous Republic of Latvia Cabinet Regulation No. 259 Adopted 19 June 2001
	based on Drective 96/82/EC (before the amendment 2003/105/EC) but these guidelines are no longer used.

Lithuania	Order No. V-131 (issued by the director of Civil Protection Department on 3		
	Requirements of the Convention on the Transboundary Effects of Industrial Accidents and Directive on the Control of Major Accident hazards		
	Involving Dangerous Substances". Indicates the recommendations to operators on preparing documents setting out Major Accident Prevention		
	Policy, safety reports and recommendations on organizing inspections.		
	http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_I?p_id=247519&p_query=	<u>&amp;p_tr2</u> =	
Luxembourg	The descriptions in Seveso Annex II and III are used as guidance.		
Malta	There are no national guidelines but operators normally follow the international guidelines. It is not practical to develop national guidelines given		
	small number of sites. The competent authorities received training in MAPP		
Netherlands	The Dutch Government provides tools for operators as to develop the MAPP and for inspection authorities in order to assess the requirements for		
	a MAPP; Website: www.brzo99.nl under Inspection / Control list / C4		
Norway	A Norwegian guideline is part of the national Seveso legislation. There is no	guideline for assessing the MAPP specifically for Seveso, only for	
_	assessing safety reports. However, there is a guideline for assessing International	al Control Systems, and this includes what is required for assessing	
	the MAPP.		
Poland	•	Methodology for determination safe location of establishments that	
	can cause major accidents,	<i></i>	
	•	Guidelines for carrying out inspections in upper and lower tier	
	establishments,		
	•	Chemical rescue basis,	
	•	"Emergency response guidebook",	
	•	"Major accident prevention" – guidebook for the safety management	
	system inspections,	, , , , , , , , , , , , , , , , , , , ,	
		Guidance on Seveso II Directive implementation – Phare Project PL	
	0105.04.01 Major accident prevention in Poland:	, ,	
	•	Industrial major accident prevention, Central Institute for Labour	
	Protection – National Research Institute (www.pip.gov.pl/html/pl/doc/070400	053.pdf),	
	•	Major accidents prevention service, Central Institute for Labour	
	Protection – National Research Institute ( <u>www.ciop.pl/18382.html</u> ),		
	•	Tools, computer programs for determination of the major accident	
	hazards and its consequences,		
	•	Information on industrial major accidents, part III – Major accidents	
	prevention program, available on: <a href="https://www.mazowsze.straz.pl">www.mazowsze.straz.pl</a> ,	•	
	•	Handbook on safety report evaluation,	
	•	Major accident prevention – handbook,	
İ	•	Guidebook on risk assessment methods connected with dangerous	

	process installations – Institute of Nuclear Energy,		
	• "Safe establishment" – handbook,		
	Guidebook Control of main industrial hazards, International Labor		
	Organization.		
	There are publications available on: <a href="http://www.ichp.pl/pl/Inne/poradnik/5c7121c.htm">http://www.ichp.pl/pl/Inne/poradnik/5c7121c.htm</a> and <a href="http://manhaz.cyf.gov.pl/manhaz/ind_pl.php?f=home">http://manhaz.cyf.gov.pl/manhaz/ind_pl.php?f=home</a> .		
Portugal	The EU "Guidelines on a Major Accident Prevention Policy and Safety Management System" have been translated into Portuguese		
Romania	A guide for preparing the MAPP/SMS was developed in the twinning project RO/2002/IB/EN/02.		
Slovakia	Guidance has been developed in Slovak. In addition, the content and format of the MAPP are defined in legislation.		
Slovenia	<ul> <li>Examples of MAPPs are available on the web page of the Ministry of Environment and Spatial Planning (MESP)</li> </ul>		
	Minimum (obligatory) content of the explanatory part of document* defined in special guideline – available on the web page of MESP.		
	Documents are available in Slovene only. The Ministry of the Environment and Spatial Planning has also adopted a MAPP for its work in the area		
	of major accident hazards' control.		
Spain	In Catalonia a protocol on safety assessment includes checklist questions about the MAPP [create link on Seveso Inspections website]		
Sweden	There is a national guidance for both operators and authorities. This is only available in Swedish. The EU "Safety Management System Guidance of the Company		
	- Seveso II" is also available (in Swedish as well as English). Inspection authorities may also have information meetings for new operators.		
	Checklists are sometimes sent out for the operators to help in their preparation of their programmes.		
Switzerland	■ In French the general guidance is the Manuel I, for MAPP, look for "rapport succinct"):		
	http://www.bafu.admin.ch/stoerfallvorsorge/00231/00754/index.html?lang=fr		
	http://www.bafu.admin.ch/stoerfallvorsorge/00231/06380/index.html?lang=fr		
	■ In German, the general guidance is the Handbuch I (for MAPP, look for "Kurzbericht"):		
	http://www.bafu.admin.ch/stoerfallvorsorge/00231/index.html?lang=de		
	http://www.bafu.admin.ch/stoerfallvorsorge/00231/06380/index.html?lang=de		
	■ In Italian the general guidance is the Manuele L (for MAPP, look for "rapporto breve"):		
	<ul> <li>In Italian the general guidance is the Manuele I (for MAPP, look for "rapporto breve"):</li> <li>http://www.bafu.admin.ch/dokumentation/03393/03526/index.html?lang=it</li> </ul>		
United	Guidance to industry includes:		
Kingdom	<ul> <li>A Guide to the Control of Major Accident Hazards Regulations 1999 (as amended) (L111 - ISBN 071766175X)</li> </ul>		
Killigaoili			
	Major accident prevention policies for lower tier COMAH sites (Chemical sheet 3 )- http://www.hse.gov.uk/pubns/chis3.pdf		
	There is also other guidance which covers specific topics or is aimed at specific sectors. Examples include: Human Factors in the MAPP		
	http://www.hse.gov.uk/humanfactors/comah/12mapp.pdf		

- COMAH application at surface treatment sites <a href="http://www.hse.gov.uk/foi/internalops/fod/oc/600-699/655-7.htm">http://www.hse.gov.uk/foi/internalops/fod/oc/600-699/655-7.htm</a>
- Guidance for the Competent Authority includes:
  - Chemical Industries/Specialised Industries Inspection manual http://www.hse.gov.uk/foi/internalops/hid/manuals/pmenf05.pdf
  - The HID framework for major hazard legislation <a href="http://www.hse.gov.uk/comah/sram/s2-7.pdf">http://www.hse.gov.uk/comah/sram/s2-7.pdf</a>
  - Safety report assessment manual Major Accident Prevention Policy and Safety Management Systems Aspects Chapter 11 (although this relates to top tier sites the principles are equally relevant to lower tier sites) <a href="http://www.hse.gov.uk/comah/sram/s8-15.pdf">http://www.hse.gov.uk/comah/sram/s8-15.pdf</a>
- HSE is also working on Delivery Guide 2N COMAH Lower Tier Major Accident Prevention Policies, but this is not yet available to an external audience.

**Annex 3: Guidance on Implementation of SMS on Lower Tier Sites** 

Respondent	Response	
Belgium	The inspection tool "M.E.S", but is a common tool and guideline for upper and lower tier sites (see answer to question 6a)	
Czech	The Ministry of Environment Guidelines "Principles, Aims and Policy of Major Accident Prevention and Description of Safety Management System"	
Republic	( <u>www.mzp.cz</u> – Czech version only).	
Estonia	http://www.rescue.ee/vvfiles/0/ots.rtf This guideline is based on the guideline in MAHB homepage (http://mahbsrv.jrc.it/downloads-pdf/smsf.pdf.	
	Additionally the guideline takes into consideration national acts and standards of international management systems that Estonia has implemented.	
Finland	For operators there is a guide indicating what the document should contain (only in Finnish).	
Iceland	Guidelines for Seveso companies are available here: <a href="http://www.vinnueftirlit.is/is/storslysavarnir_efna/">http://www.vinnueftirlit.is/is/storslysavarnir_efna/</a>	
Ireland	See Q 6 response	
Italy	<ul> <li>Ministerial decree of 09.08.2000;</li> </ul>	
	Guide lines for the inspector - Directorial Decree	
	<ul><li>http://www.minambiente.it/moduli/output_immagine.php?id=2105</li></ul>	
	APAT report RT23/2003	
	<ul> <li>http://www.apat.gov.it/site/it-IT/APAT/Pubblicazioni/Manuali_e_linee_guida/Documento/manuali_lineeguida_2003_23.html</li> </ul>	
	Se also the answer to question 6, third item of the table	
Lithuania	The director of Civil Protection Department issued the Order No. V-131 on 30/09/2004 "On the Validation of the Documents Corresponding to	
	Requirements of the Convention on the Transboundary Effects of Industrial Accidents and Directive on the Control of Major Accident hazards	
N	Involving Dangerous Substances". It gives only common guidelines for SMS without any difference between lower and upper tier establishments.	
Netherlands	No specific guidelines or tools are published for lower-tier Seveso sites only. There are guidelines and tools which are published and applicable for	
	both lower-tier and upper-tier establishments. See www.brzo99.nl	
Norway	The above-mentioned regulations on internal control.	
Poland	There have not been published any specific guidelines or tools for SMS for lower tier sites in Poland. Nevertheless, the Polish authorities have	
	translated and published several documents (guidelines, recommendations) published by Major Accident Hazards Bureau (MAHB) and OECD. This	
	includes (among others):  "Inspection of main industrial horards", handback corried out within the	
	a. "Inspection of main industrial hazards"- handbook carried out within the PIACT Project,	
	b. "Major accident prevention" - handbook concerned SMS inspection,	
	c. "Guiding Principles for Chemical Accident Prevention, Preparedness	
	and Response" elaborated under the auspices of the Working Group on Chemical Accidents that manages the OECD Programme on Chemical	
	Accidents.	
	Addition.	

	The following studies were carried out within the Phare Project 0105.04.01: Prevention on Major Accident, Seveso II in Poland		
	(Europeaid/114864/D/SV/PL):		
	An introduction and basic information concerning Seveso II Directive,		
	A set of guidelines helpful to implementation of the Seveso II Directive,		
	including "Guidelines on a major accident prevention policy and safety management system, as required by Council Directive 96/82/EC (Seveso II)".		
Romania	The twinning project RO/2002/IB/EN/02 developed guidelines for the SMS.		
Sweden	We recommend the guidelines for SMS for upper tier sites published by the European Commission in 1998. The document has been translated into		
	Swedish. We also give some additional recommendations on our website <a href="https://www.seveso.se">www.seveso.se</a> . This site is entirely in Swedish.		
Switzerland	No guidelines published. Reference is made to OECD Guidance (general and for SMEs).		
United	Specific guidance on SMS for COMAH operators is incorporated in the MAPP guidance referred to in Q6 above. Additionally, HSE has published		
Kingdom	generic guidance for directors, managers, health and safety professionals and employee representatives who want to improve health and safety in		
	their organisations - Successful health and safety management (HSG 165 – ISBN 0717612767) (http://www.hsebooks.com)		

### Annex 4: Agenda and Presentations from the April 2009 CCA Seminar

### Seminar on Major Accident Prevention in Lower Tier Seveso Establishments 22 April 2009, Prague, Czech Republic

The goals of the seminar are as follows:

- To provide an insight in lower tier obligations and to discuss experience with the spectrum of safety requirements applied in Member States
- to provide recommendations on how to optimise compliance;
- with regard to the planned review of the directive provide recommendations for the reviewers to improve the enforceability of the directive.

Morning Session			
	ek, Occupational Safety Research Institute		
09.00 - 09.10	Welcome and Introduction, Pavel Forint, Czech Ministry of Environment		
Part I: Overview of Article	7 and Seveso Implementation in Lower Tier		
	Sites		
09.10 – 09:20	Seminar Background and Objectives, Tobias Biermann, European Commission, DG- Environment		
09:20 - 10.00	Results of the Survey on Implementation of Seveso in Lower Tier Sites, Maureen Heraty Wood,		
10:00 - 10:20	European Commission, JRC-MAHB Industry Perspective SEVESO IMPACTS - Article 7 - Lower Tier sites, Douglas Leech, FECC - European Association of Chemical Distributors/CBA Chemical Business Association		
10.20 - 11:00	Coffee Break		
Part II: Perspectives on Seveso Implementation in Lower Tier Sites			
11:00 – 11.20	Implementation of Lower Tier Site Requirements in the Czech Republic, Stanislav Malý, Occupational Safety Research Institute, Czech Republic		
11.20 – 11:40	Implementation of Lower Tier Site Requirements in Italy, Paolo Ceci, Ministry of Environment, Italy		
Part III: Addressing Lower Threshold Sites in non-Seveso Countries			
11.40 – 12.00	Addressing Low Thresholds in Switzerland, Bernard Gay, Federal Office for		
12.00 – 12.20	Environment (FOEN), Switzerland Korean regulation on process safety management for small chemical companies, Hyuckmyun Kwon, Occupational Safety and Health Agency (KOSHA), Korea		
12:20 - 12:30	Summary of Morning Session (Chairman)		
12.30 - 14.00	Lunch		

# <u>Afternoon Session – Chairperson: Pavel Danihelka, Technical University of Ostrava</u>

## Part IV: Tabletop Discussions

Groups of 10-20 participants each will be established. Each group will discuss questions/reports on key points/recommendations. Subjects will be separated into policy/regulatory issues and implementation discussions.

14:00 - 14:10	Introduction, Group Assignments
14:10 - 15:20	Table discussion and recommendations
15:20 - 15 :50	Coffee Break
15:50 - 16:50	Each Table Rapporteur reports on key points/
16:50 - 17 :20	General Discussion
17:20 - 17:30	Summary, Tobias Biermann, European Commission, DG-Environment
17:30	Adjourn

#### **European Commission**

EUR XXXXX LL – Joint Research Centre – Institute for the Protection and Security of the Citizen Seveso Lower Tier Establishments:
Implementation of Article 7 of the Seveso II Directive in the European Union Maureen Wood
Luxembourg: Publications Office of the European Union
2011 – 66 pp. – 21 x 29.7 cm
EUR – Scientific and Technical Research series – ISSN 1018-5593
ISBN X-XXXX-XXXX-X
doi:XXXXX

#### **Abstract**

The European Union hosts approximately 8500 industrial sites that are considered major hazards due to the potential accident risk associated with the presence of dangerous substances as defined by the Seveso II Directive. Approximately, half of these sites are classified as so-called lower tier sites because the quantity of the dangerous substances exceeds the lower threshold quantity stipulated in the Directive. Theoretically, the Seveso II Directive imposes a lower regulatory burden on lower tier sites than upper tier sites, whose quantity of dangerous substances exceed the higher threshold quantity given in the Directive. This lower burden is manifested particularly in Article 7, designed to apply exclusively to lower tier sites. In 2008-2009, on behalf of the Committee of Seveso Competent Authorities (CCA), the regulatory committee established by the Directive, the European Commission is Joint Research Centre (JRC) undertook a study of Seveso implementation in lower tier sites, through administration of a survey of competent authorities and subsequently co-organization of a workshop on the topic with DG-Environment and the Czech Republic. This paper summarizes the results of this study.

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