



F-SEVESO

Study of the effectiveness of the Seveso II Directive

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Final report

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1 Executive summary

1.1 Context and objectives

The Seveso II Directive (96/82/EC) on the control of major accident hazards defines a number of requirements for the operators of industrial sites where a certain amount of dangerous substances is present. In particular, operators of sites where the amount of dangerous substances exceeds the thresholds laid down in annex 1 of the directive have to define a **major accident prevention policy**, and for the upper tiers to establish a **safety report**, implement a **safety management system** and define an **internal emergency plan**. These requirements aim at preventing major accidents and mitigating their consequences, in order to protect human health and the environment.

Since the main requirements of the Seveso II Directive have remained essentially unchanged for many years, the European Commission has begun work on a review of the Directive. As an input to that process, the Commission has launched the present study to assess the level and quality of practical implementation and identify possible improvements.

The study focused on:

- the adequacy of the requirements imposed by the Directive on operators of Seveso II Establishments and the objectives to prevent major accidents and mitigate their consequences;
- the real impact of the requirements and its measurement;
- the effectiveness of implementation, in terms of compliance in the various Member States and industrial sectors, and the assessment of possible market distortion.

1.2 Method for the study

The study was organized according to the following steps:

- Selection of a representative sample of Member States and industrial sectors to analyze the implementation of the requirements imposed on operators of Seveso establishments;
- Promotion of the survey and registration of interested parties, creating therefore a group of contacts for any further dialogue with stakeholders;
- Performance of the survey with a) focused and targeted questionnaires, using web-based tools, b) followed by telephone or face-to-face interviews;
- Analysis of the answers to determine strengths and weaknesses, together with an overall assessment, including possible improvements and recommendations together with an assessment of the advantages and disadvantages of these different options.

The survey was open to all interested stakeholders. However in order to ensure that the responses in terms of geographic spread and industrial sectors covered were representative, it was decided to define the targeted respondents. An analysis of the SEVESO establishment population was therefore performed in terms of

distribution amongst the Member States, contributors to the number of accidents reported and industrial sectors.

The survey therefore focused on 8 Member States covering more than 80% of the total number of Seveso establishments, and of the contributors to the number of accidents reported in MARS¹ during the period (1994-2004), and on 9 industry sectors covering 83% of the Seveso establishments and representing 86% of the number of accidents.

Targeted Member States	Targeted Industry Sectors
<ul style="list-style-type: none"> • Germany • UK • Italy • France • Spain • Sweden • The Netherlands • Poland 	<ul style="list-style-type: none"> • Production and storage of explosives • Metal refining and processing • Wholesale and retail storage • Petrochemical • Pesticides • Pharmaceuticals • General chemicals manufacture • Plastics and rubber manufacture • Power supply and distribution • Food and drink

For the first round of the survey, 3 questionnaires were developed following trial testing with selected potentially interested parties and taking into account the feedback at a study launch workshop on 6 February 2008.

From 13 February to 28 March 2008, 313 persons registered as possible responders and had access to the questionnaires. Access was open until mid-April 2008. By end of April 2008, 156 completed questionnaires were submitted:

- 102 questionnaires from Industry (IND), including operators and associations
- 33 questionnaires from Competent Authorities (CA), at various levels,
- 20 questionnaires from other associations and types of organizations (OTHER), including NGOs, research centers and universities consulting companies, trade unions...

From 21 April to 4 June 2008, 23 interviews were performed with 6 European industry associations, 9 industry operators from 7 Member States, 5 Competent Authorities at central and local level, and 3 persons from the category "OTHER".

The criteria defined to check the validity of the survey results were met concerning the industry, with respondents from 16 countries, of whom 87 % were from the targeted Member States and industrial sectors. Concerning the CA, 16 countries participated, including 5 new Member States.

It is estimated that the number of Seveso establishments covered by the survey is more than 10% of the total population, because a majority of questionnaires were answered by a person in charge of several establishments in a company, or by an association representing many companies. Indeed, 68 % of the operator respondents belong to a multi-national company; and the European associations represent several hundreds of establishments.

¹ MARS data base : Major Accident Reporting System, see <http://mahbsrv.jrc.it/mars/Default.html>

1.3 Results of the survey & suggestions for improvement

The survey enabled an analysis to be made of the situation as regards the 4 following issues:

1. Transposition of the directive requirements and general approach,
2. Practices, weaknesses and problems related to the practical implementation,
3. Effectiveness of the implementation,
4. Impact of Seveso directive on the competitiveness of the EU industry.

and then to conclude with suggestions for improvement.

The survey has shown that all targeted groups think that the implementation of the requirements of the Seveso II Directive has led to a recognizably higher level of safety in comparison with non Seveso establishments. The requirements of the directive contribute to creating awareness of the hazards and developing measures to control risks.

The respondents from all targeted groups agreed that the approach of the Seveso II Directive is well-suited to prevent major accidents and mitigate their consequences and that the requirements are adequate to meet these aims, and valuably complement the other directives dealing with safety-related issues, like "Occupational health and safety" and Integrated Pollution and Prevention Control (IPPC) Directives.

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 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.

From the survey, no respondents concluded that there are unnecessary provisions in the Seveso II Directive.

No clear evidence has been collected on the possible adverse effect of the Directive on the competitiveness of the European industry, because cost estimates are limited. There is also no clear evidence that the non-homogeneous implementation of the Seveso II Directive creates market distortion within the EU. Industry has generally stated that the costs related to the implementation of safety regulations are "on the margin" and that the requirements "have to be implemented by industry anyway". Opinions were divided concerning market distortions generated by the directive as regards Europe versus third countries, in particular emerging economies, as well as about the competitive advantage that the Seveso II Directive could bring. Industry respondents were equally divided about the impact of safety requirements on the delocalisation of production towards third countries. The general trend is that the overall business costs in Europe compared to elsewhere is a more significant factor, with "safety costs" just one part of this wider picture. On the other hand, industry recognises that safety costs are financially beneficial in the long run, because they reduce the chances of facing the huge cost of major accidents.

Some weaknesses and suggestions for improvement have been identified and they can be summarized as follows:

The great majority of the respondents indicate that the implementation of the Seveso II Directive is not uniform within Europe and even in a given country. This represents a problem especially for multi-national companies operating in several Member States because most of them have internal safety standards or approaches, and they have to adapt them to each national context to fulfil the specific requirements. This also impacts on the perception of stakeholders who have the impression that the rules are different in the various Member States, even if it is the same Seveso II Directive. This does not contribute to the effective functioning of the European Single Market.

Therefore, a lot of recommendations were made to support the sharing of best practices and improve the harmonization of implementation of the Seveso II Directive. They are related to the improvement of the coordination of the CAs

- at national level, among the various authorities in charge of the Seveso Directive, and among the various regions,
- at European level, among the various Member States.

In addition, the elaboration of additional guidance documents on the following aspects (in order of priority) is recommended.

Develop guidance document and set of data related to...
1. Risk analysis and risk assessment, including presentation of best practices regarding: a) the general approaches, b) criteria for quantification, and c) methods/tools/data for implementation
2. Assessment of the effectiveness of Safety Management Systems (and, in the long-term, of the safety culture in Seveso II establishments)
3. Good practices for the competent authorities to have a more homogeneous behaviour throughout Europe.
4. Taking into account accidents triggered by natural hazards (e.g. earthquake, flooding...) and provide data and criteria.
5. Investigation techniques for accident analyses
6. Vulnerability criteria
7. Defining the principles of proportionality, with concrete examples of implementation.
8. Domino effects and how to implement in practice Art. 8
9. Assessment of the effectiveness of emergency planning

It was also pointed out by the vast majority of the industry respondents that the Seveso II Directive and the other safety-related directives are complementary, although it was also noted that it sometimes overlaps either at EU level with ATEX², Occupational Health and Safety³ Directives, or, as far as implementation is

² Directive 94/9/EC on the equipment and protective systems intended for use in potentially Explosive Atmospheres

³ Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the health and safety of workers at work, and other specific Directives.

concerned, at national level with fire protection legislation and other safety regulations.

For the overlap due to the EU directives, cross references in the guidelines for the implementation of all these directives should help to lower the administrative burden on the industry. At national level, several Member States are dealing with this problem by coordinating the inspections performed by the various authorities. Such initiatives should be extended to all Member States.

Recommendations were also proposed to improve the relevance of the Seveso II Directive in meeting its goals, by including the following new requirements (in order of priority).

Additional requirements or issues to be considered...
1. Extending the obligation for lower tier establishments to prepare a Safety Report (or at least an identification of major accident scenarios) and the provision of a Safety Management System
2. New requirements to better target the information and communication towards the different end-receivers and reinforce the dialogue with the different stakeholders
3. Addressing environmental aspects in the safety report
4. Better address preparations and mixtures vs. single substances
5. Extend the scope of the directive to other installations such as pipelines, railway stations and harbours
6. Integrate security issue into the Seveso II Directive
7. Clarify the links between the Seveso II Directive and the other safety-related Directives and make the implementation of the Seveso II Directive more synergetic with other occupational health and safety, and environmental, regulations

The majority of the respondents from the category OTHER stressed the need to improve the quality of the dialogue between stakeholders and to reinforce the participation of the public. This recommendation was also supported by several industry respondents. This has to be accompanied by the following activities:

- Increased participation of all stakeholders in the decision making process in particular the public
- Improved risk communication towards the public and its involvement in the risk management process

Finally, the survey led to the conclusion that detailed focused studies might be appropriate to further investigate certain aspects, where the results of this study were inconclusive.

2 Introduction

2.1 Context

The Seveso II Directive (96/82/EC) on the control of major accident hazards defines a number of requirements for the operators of industrial sites where a certain amount of dangerous substances is present. In particular, operators of sites where the amount of dangerous substances exceeds the thresholds laid down in Annex 1 of the Directive have to define a **major accident prevention policy**, and for the upper tiers to establish a **safety report**, implement a **safety management system** and define an **internal emergency plan**. These requirements aim at preventing major accidents and mitigating their consequences, in order to protect human health and the environment.

Since the main requirements of the Seveso II Directive have remained essentially unchanged for many years, the European Commission has launched a review of the Directive. To monitor the implementation of the Seveso II Directive, and its amendments, the Commission Services draw up a report every 3 years, based on the information provided by the Member States. However this information doesn't enable a qualitative analysis of the effectiveness of the directive and of its impact.

Therefore, to complement these regular triennial reports, which are essentially quantitative, the Commission Services have launched the present study to assess the level and quality of practical implementation and identify possible improvements.

2.2 Objectives

The present study focuses on:

- the adequacy of the requirements imposed by the Directive on operators of Seveso II establishments and the objectives to prevent major accidents and mitigate their consequences;
- the real impact of the requirements and the most effective way to measure it;
- the effectiveness of implementation, in terms of compliance in the various Member States and industrial sectors, and the assessment of possible market distortion.

The survey is based on a questionnaire followed by a series of interviews.

2.3 Method for the study

To meet the objectives of the study, EU-VRI has organized the study based on the following steps:

- Selection of a representative sample of Member States and industrial sectors to analyze the implementation of the requirements imposed on operators of Seveso establishments;
- Promotion of the survey and registration of interested parties, creating therefore a group of contacts for any further dialogue with stakeholders;
- Performance of the survey with a) focused and targeted questionnaires, using web-based tools, b) followed by telephone and face-to-face interviews;

- Analysis of the answers to determine strengths and weaknesses, together with an overall assessment, including possible improvements and recommendations together with an assessment of the advantages and disadvantages of these different options.

The study has been organized in 5 work packages, set out hereunder.

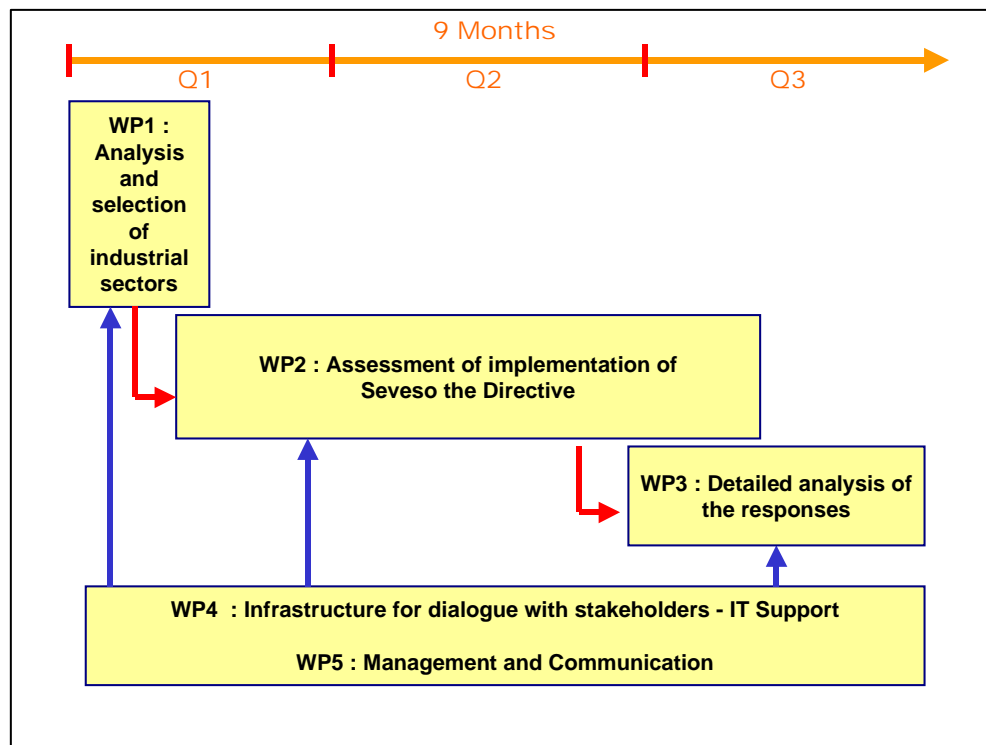


Figure 1: Representation of the method of the survey

To perform the project, EU-VRI, the European Virtual Institute for Integrated Risk Management, used an approach based on:

- **A unique network of contacts** based on the specific statute of EU-VRI as European Grouping of members.
 EU-VRI itself is already a grouping of key organisations working in the field of industrial safety. The network consists of 5 five founding members, over 30 associated members, over 500 contacts within ETPIS⁴ and its national platforms.
- **Direct interaction with experts from consortia performing key recent initiatives** such as S2S, SHAPE-RISK, OECD projects, ARAMIS, ETPIS Focus Groups...
- **A web-based tool** to create a sustainable dialogue with the industry and the other stakeholders responding to the survey.

⁴ ETPIS: European Technology Platform on Industrial Safety, see www.industrialsafety-tp.org

2.4 Organization of the report

The present report summarizes the result of the study. It is organized in 3 main parts:

1. Section 3 contains a description of the method for the study, including the selection of the targeted industry sectors and countries, and the organization of the survey with the on-line questionnaires and the interviews.
2. Section 4 provides the detailed analysis of the survey organized according to the 4 issues identified in the call for tender
 - a. Transposition of the directive requirements and general approach,
 - b. Practices, weaknesses and problems related to practical implementation,
 - c. Effectiveness of implementation,
 - d. Impact of the Seveso II directive on the competitiveness of the EU industry.
3. Section 5 sets out an analysis of the effectiveness of the directive with suggestions for improvement.

Some subjects covered in several issues in the questionnaires and in the interviews might be referred to only in one of the issues of section 4 in order to improve clarity and aid the understanding for the reader. There are also subjects that were addressed only during the interviews that have been included in the relevant issues, as described above.

3 Method for the study

3.1 Criteria to define the targeted respondents for the study

The survey was open to all interested stakeholders. However in order to ensure that the responses in terms of geographic spread and industrial sectors covered are representative, it was decided to define the targeted respondents. An analysis of the Seveso establishment population was therefore performed in terms of distribution amongst the Member States, the number of accidents reported and industrial sectors.

3.1.1 Geographical distribution of establishments

As input to this study, the MAHB⁵ has provided statistical data on the number and type of establishments in the Member States, as they are reported in the Seveso Plants Information Retrieval System (SPIRS), together with statistical analysis on the number of accidents reported in the Major Accident Reporting System (MARS). This analysis led to the conclusion that 8 Member States (Germany, UK, Italy, France, Spain, Sweden, the Netherlands and Poland) have 7091 establishments and thus cover more than 80% of the total number of Seveso establishments, and contribute a similar percentage to the total number of accidents reported in MARS.

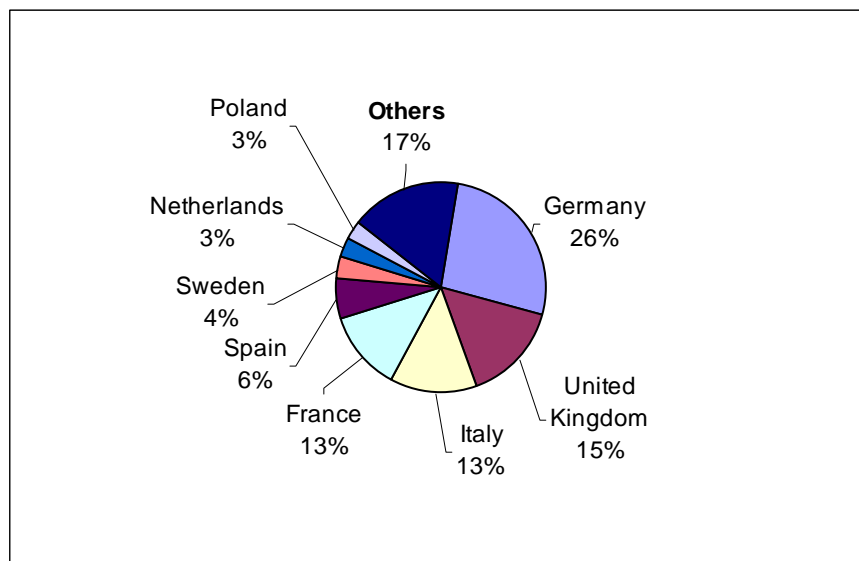


Figure 2: Geographical distribution of SEVESO establishments in Europe (from SPIRS analysis).

Therefore, it was decided to focus on these 8 Member States so that the answers to the survey would be representative. Efforts were also made to ensure that smaller EU 10 Member States were covered.

⁵ MAHB: Major Accident Hazard Bureau of the Joint Research Center (<http://mahbsrv.jrc.it/>), operating SPIRS and MARS

3.1.2 Targeted industrial sectors

It has been estimated that the 9 industry sectors listed in the box cover 83% of the Seveso establishments (based on the available data in SPIRS summarized in Appendix 1: Summary of the data from SPIRS).

In addition, they account for 86% of the number of accidents reported during the period (1994-2004) in the MARS database.

- production and storage of explosives
- metal refining and processing
- wholesale and retail storage
- petrochemical
- pesticides, pharmaceuticals
- general chemicals manufacture
- plastics and rubber manufacture
- power supply and distribution
- food and drink

Figure 3: List of the 9 representative industrial sectors

Therefore, for the same reasons as expressed in the previous paragraph, it was decided to focus on these 9 industrial sectors.

3.2 Organization of the survey

The survey was performed between 6 February and 4 June according to the time line presented in the figure hereunder.

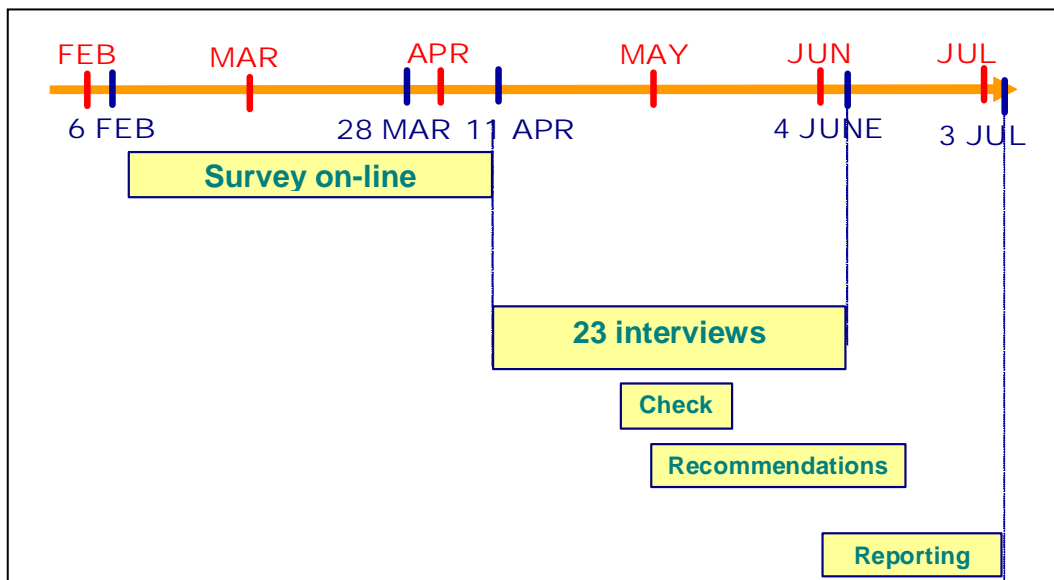


Figure 4: Time line of the survey

3.2.1 Organization of the questionnaires (on-line)

For the performance of the first round of the survey, 3 questionnaires were developed following trial testing with selected potentially interested parties and

taking into account the feedback at a study launch workshop on 6 February, for each category of respondents as follows:

- Industry (IND), including operators and industry associations,
- Competent Authorities (CA), at various levels,
- Other associations and types of organizations (OTHER), including NGOs, research centres and universities consulting companies, trade unions...

From 13 February to 28 March 2008, 313 persons registered as possible responders and had access to the questionnaires. Access was open until mid-April 2008. Registered participants were able to answer the questionnaires in several sessions, if needed, and to download the questionnaires to prepare their answers off-line.

By the end of April 2008, 156 completed questionnaires were submitted:

- 103 questionnaires from IND (102 were useable),
- 33 questionnaires from CA,
- 20 questionnaires from OTHER.

The criteria defined to check the validity of the survey were satisfied concerning the industry:

- 87 % of the industry respondents are located in the 8 targeted Member States,
- 87 % of the industry answers correspond to the 9 industry sectors targeted.

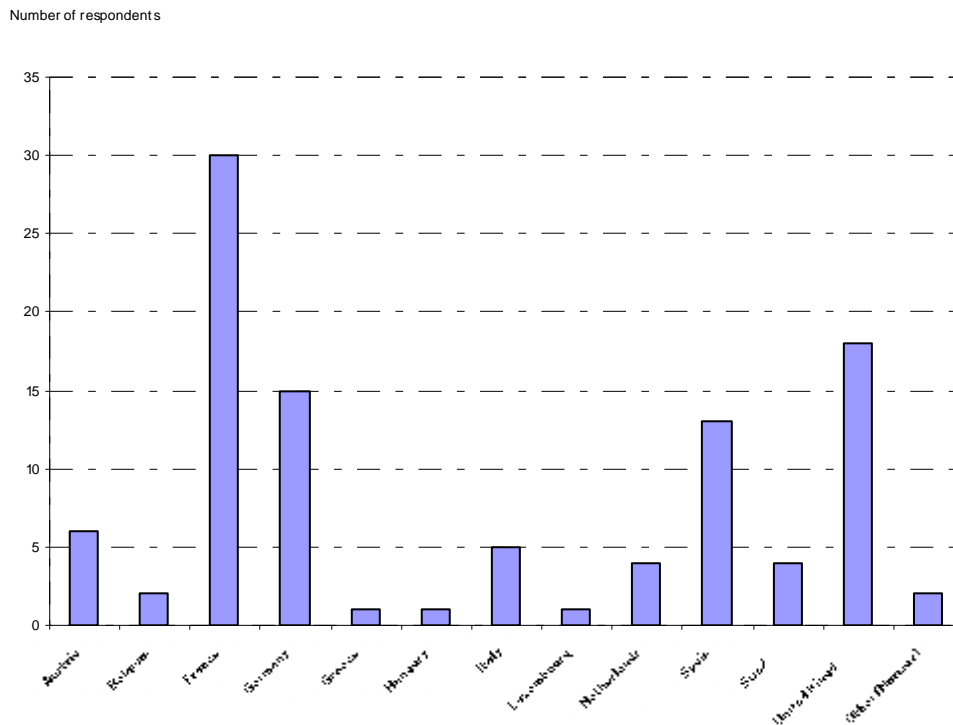


Figure 5: Origin of the respondents from IND

Concerning the CA, the distribution by Member States was quite balanced, as indicated below, with participation of 15 Member States, plus Norway, Turkey and the EU-OSHA.

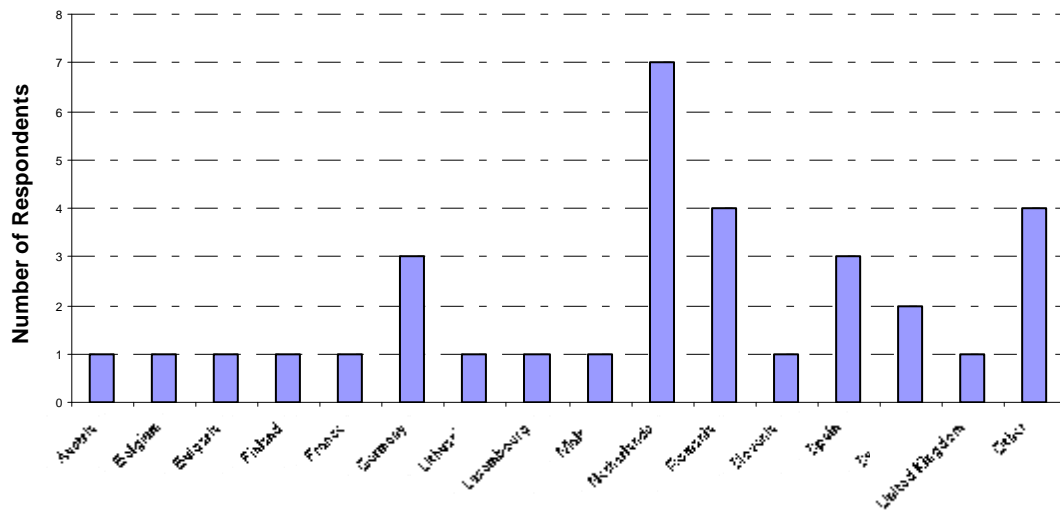


Figure 6: Origin of the respondents from CA

It is important to note that:

- Most of the responses to the survey are from western European countries (99 %), where most of the Seveso establishments (92 %) are located. However 8 of the 33 contributions from the Competent Authorities came from 5 of the new Member States.

- 102 questionnaires answered by industry were usable: some of the questionnaires were answered by a person in charge of several establishments in a company, or by an association representing several companies. Indeed, 68 % of the operator respondents belong to a multi-national company, and often the answer was made by a corporate safety manager sharing his/her experience of several establishments; and the European associations represent several hundreds of establishments. Based on these considerations, the estimation of the number of establishments covered is more than 10%, i.e. ~ 800.

Figure 7 shows the breakdown by size of the companies responding, with the great majority (68 %) belonging to a multi-national company, 16 % being SMEs and 16 % being independent but not an SME (national company).

Figure 7: Distribution of the size of the companies responding under the category "industry"

3.2.2 Organization of the interviews

The interviews took place from 21 April to 4 June 2008. In total, **23 interviews** were performed as follows:

- 6 European Industry Associations from the process industry, and chemical, petro-chemical and gas sectors;
- 9 Industry Operators from Sweden, the Netherlands, Spain, Hungary, UK, France (x3), Italy. (2 of them were SMEs, 2 national companies and 5 multinational companies).
- 5 Competent Authorities at central and local level from Sweden, Spain, France, Germany and Italy.
- 3 from the category "OTHER": an EU trade-union, an EU NGO and a fire protection association from Germany.

The notes presented in the following chapters and annexes are the notes taken by the interviewers, checked by the interviewees.

Confidentiality was requested by several interviewees. Therefore, in such cases, the notes are anonymous and only the category (industry, industry association, competent authorities or "OTHER") and the country are mentioned.

3.2.3 Method for the design of the questionnaires

The questionnaires for the on-line survey were elaborated based on the issues identified in the call for tender, combined with a detailed analysis of the literature (both scientific articles and "grey literature") found by the team performing the study. The list of questions in English can be found in Annex 1A.

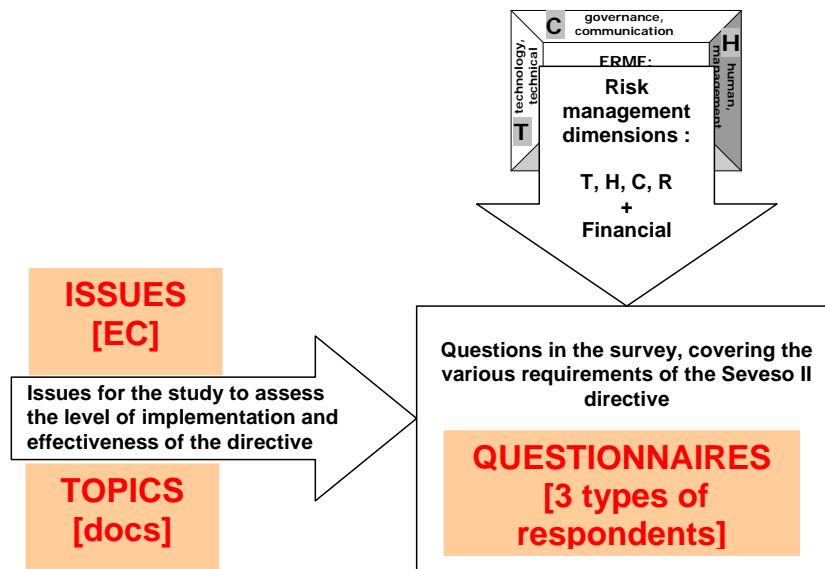


Figure 8: Representation of the method for the elaboration of the questionnaires for the on-line survey

For the interviews, additional questions were elaborated. The list can be found in Annex 1B.

3.3 Remarks on the survey

3.3.1 Registration of the respondents

The registration of the respondents was requested in order to guarantee that the inputs provided by the respondents would meet a certain level of quality and credibility, and at the same time identify the source of the input.

3.3.2 Level of participation in the on-line survey

The registration of 313 respondents on the <http://www.f-seveso.eu-vri.eu> website was very encouraging. From the registered persons, 50 % took the time to answer the questionnaires. This is a satisfactory level of participation compared to other similar studies performed at this level.

The qualitative information collected through the on-line questionnaires and the interviews is full of interesting and useful material. Moreover, a lot of inputs were converging from the various Member States and the various industry sectors.

3.3.3 Interview strategy

The principle implemented for the interviews was to use open questions and let the interviewee talk. The advantage was to collect a lot of thoughts and ideas based on the respondent's own analysis, with some original recommendations.

However this had the disadvantage that sometimes some suggestions were made by only one or two persons. The most interesting and relevant ones are discussed in the Chapter 5, because they converge with other recommendations from the survey, or because the views seem particularly relevant. However, generally, such suggestions would require further investigation before any conclusions could be drawn, which is not possible within the timeframe of this study.

3.3.4 Confidentiality

For the on-line survey as well as the interviews, the individual contributions were made anonymous in the present final report, based on the request of the majority of the respondents.

4 Analysis of the survey

4.1 Introduction

This section includes a detailed analysis of the survey including on-line questionnaires and interviews.

The results are presented under the 4 issues:

- Issue 1: Transposition of the Seveso II Directive requirements and general approach
- Issue 2: Implementation of the main requirements of the Seveso II Directive by the operators: practices, weaknesses and possible problems
- Issue 3: Effectiveness of implementation
- Issue 4: Seveso II Directive and the competitiveness of the European Industry

For each issue, the key findings are presented according to specific aspects of the implementation of the directive. Each paragraph describes the main results and achievements brought by the directive, then the problems and weaknesses pointed out by the participants and, where appropriate, suggested recommendations are discussed.

To help the reader to find the original inputs used for the analysis of the survey, references to the questionnaires and to the interviews reported in Annex 1 are presented in *italic* at the beginning of each paragraph. The reference is constructed as follows:

- Reference to the questions: *XXX – I.Y – QA.B.C.D*

Where *XXX* corresponds to the targeted groups IND [industry], CA [Competent Authorities], OTHER [Others]

Y corresponds to the issues presented here above

Q refers to the number of the questions as reported in Annex 1A.

- Reference to the topics: Topic *ZZ*

Where *ZZ* corresponds to the reference provided in Annex 1B.

Sometimes the information collected was diffused over several answers to different questions, and therefore some statements are based on an aggregation of this information.

No views expressed are specific only to a particular industrial sector or a particular Member State unless otherwise indicated.

4.2 Issue 1: Transposition of the Seveso II Directive requirements and general approach

4.2.1 Adequacy of transposition and implementation

IND – 1.1 - Q1.2

CA – 1.1 – Q2.3.4

OTHER – 1.1 - Q2.3.5.6.7

- Transposition and interpretation

From the on-line questionnaires, more than 3/4 of the respondents from all targeted groups agree that the Seveso II Directive is properly transposed into national regulations in EU countries.

However, a dozen of industry respondents to the questionnaires indicate that national requirements exceed the original requirements of the directive in France, Spain, Italy, Slovakia, and UK.

In general, the requirements of the directive are implemented by several authorities in each Member State.

Therefore, it was recommended by half of the industry operators of the interviews to improve the coordination of the various authorities in charge of the Seveso II directive in some Member States.

“ALARP principle”⁶ and “demonstration that all necessary measures are taken”, which were mentioned by several industry respondents in the questionnaires (see the questions *IND – 1.1 - Q1.2* in Annex 1A) and in the interviews, reveal difficulties of interpretation by the authorities, and some operators clearly stated that there can be situations where the industry is always asked to do more. This type of situation has an economic impact on some companies. It gives the feeling as well that the situation of a company is in the hands of an inspector and not a regulatory system.

On this particular point related to the transposition and interpretation of the directive, two Competent Authorities (from Spain and France, during the interviews) recommended increasing exchanges of experience within the CA to help convergence or greater harmonization of the practices and the criteria used.

Several interviewees from industry and industry associations pointed out that harmonization efforts should be focused first on the Competent Authorities.

- Directive and national requirements

From interviews with a European industry association and an operator, it was made clear that the operators know better the national requirements and have a lack of awareness of the original requirements of the directive. The national system is the one that they have to apply in practice. Additionally, there is a lack of awareness of the practices from one Member State to another.

⁶ “ALARP” is short for “as low as reasonably practicable”, see <http://www.hse.gov.uk/risk/theory/alarpglance.htm>

▪ Environmental issues of SEVESO II

From one Competent Authority's answer to the questionnaire, as well as in one operator interview, it was stated that in establishments with mainly environmental aquatic risks (for substances requiring the use of risk phrase R50-51-53⁷), the analysis is more qualitative than quantitative and often the long term effects of pollution are not well dealt with.

These respondents recommend better addressing the environmental impacts of pollution in the Seveso II Directive, because they are often not covered in the safety reports. Safety reports only rarely deal with the impact of pollution on surface or underground water.

4.2.2 Approach towards translation into national requirements

CA – I.2 - Q1

Respondents from CA noted that methods are used in function of the final objective, and often it is a combination of approaches that is implemented. An operator can use either a deterministic method or a probabilistic one. In most of the countries, no specific approach (deterministic, probabilistic, consequence-based, other...) is recommended.

4.2.3 Issue of multi-operator sites

IND I.2 - Q33.34

Opinions are equally divided about whether or not this issue is sufficiently addressed in the Directive. But the majority (>70 %) of the respondents who consider that the issue is not sufficiently covered consider that the following aspects should be better addressed:

- definition of multi-operator site ,
- impact of the hazardous activities on other operators that should be considered as specific third parties (industrial neighbours),
- opportunities for collaboration (e.g. shared emergency organization).

Recommendations cover the need to better address this issue in land-use planning, and to use the example of the pyrotechnic industry to develop a common approach for multi-operator sites.

⁷ R50: Very toxic to aquatic organisms)

R51: Toxic to aquatic organisms

R53: May cause long-term adverse effects in the aquatic environment

4.3 Issue 2: Implementation of the main requirements of the Seveso II Directive by the operators: practices, weaknesses and possible problems

4.3.1 EU reference and guidance documents

IND – I.1 - Q4, I.2 – Q1.2.3.4.5.6.15

CA – I.2. – Q2.3.4

OTH –I.1 - Q4, I.2 – Q1.2.3

Topics T1, T2 & T3

- National Guidance documents

From the responses to the questionnaires, it is clear that there are a lot of national guidance documents (general and specific) in most of the EU countries, developed by competent authorities, or national/European industry associations. In general, guidance documents are developed for technical aspects like risk analysis, legal requirements and best practices.

Industry national guidance documents have a better impact than EU documents because they accompany the implementation of the national regulation, which is what has to be applied in practice. The European guidance sets out principles and the philosophy of the directive, but it is too generic to be used for the implementation of the Directive in each industry and provides insufficient information to some CAs that demand more than the Directive. In such cases, national guidance documents are generally more helpful and concrete than European guidance.

Existing national guidance documents prepared by Industry are provided by different types of organizations.

For example:

- France: UIC (Chemical Industries Association), FEEM (European federation of Explosive Makers), work groups like "Risk assessment - Safety report", EIGA (European Industrial Gases Association), AFGC, INERIS, GESIP.
- UK: Tank Storage Association (TSA), Energy Institute (EI), CIRIA, Chemical Industries Association (CIA), Chemical Business Association (CBA), CONCAWE, : British Coatings Federation, Responsible Care, LPG guidance on major accident prevention policies, British Aerosol Manufacturers' Association (BAMA)
- Germany: German Chemical Industry Association
- Spain: COASHIQ (Autonomous Commission for Safety and Hygiene at Work in the Chemical and Related Industries), FEIQUÉ (Chemical Industries Association),
- Italy: UNI (Italian national standardisation Institute)

Existing national guidance documents known by Industry cover various types of fields: methodology of safety report, emergency plans, land-use planning aspects, SMS, inspections, etc.

The following is a list of guidance documents prepared by CAs that were quoted by the respondents.

- France: National guidance for writing and reading a safety report (MEDD, December 2006), Guidance for the preparation of a PPRT (INERIS, October 2007)
- Germany: guidance provided by the "Disruptive Incident" Commission (SFK), Technical Committee on Systems Safety and (TAA), The Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety of Germany (BMU)
- Hungary: some books and documents for the implementation of Seveso and preparing Safety Report are in preparation by the National Directorate General for Disaster Management and by Hungarian Trade Licensing Office.
- Italy: attachments I,II and III of the decree DPR 175/88 and further modifications; Document issued by national authority (The Italian Environment Protection and Technical Services Agency, APAT) containing SMS requirements and inspections guidelines
- Netherlands: NL guidance (CPR-20 / PGS-6), BRZO 1999, RRZO 1999
- Spain: decrees (RD 1196/2003, RD 393/2007), guidance documents for the safety report preparation, emergency plan, technical guidelines of the General Direction of Civil Protection,; also there are Guides provided by local authorities (for instance, in Catalonia)
- Swedish: guidance from Swedish Rescue Services Agency.
- UK: HSE and EA guidance on COMAH (Control of Major Accident Hazards) compliance, preparation and review of safety reports, emergency plans, land-use planning aspects.
HSE guidance document L111 Chemical Information sheet nos. 2, 3, 7 Human Factors briefing notes 4, 9, 12 Chemical sheet no. 6 Guidance for operators from the competent authority on review of safety reports, also environmental aspects. DETR guidance on interpretation of major accidents to the environment. INDG leadership for major hazard industries HSG244 LOPA in the COMAH context HSE Research report no 457 Location and design of occupied buildings at major hazard establishments HSL/2006/117 risk control for major hazard incidents HSG 190 HSG 191
Approved Code of Practice of the COMAH Regulations (L111) and associated guidance on Preparing Safety reports & Emergency Plans (HSG 190 & HSG 191)

Table 1: List of guidance documents quoted during the survey

- Situation for SMEs
91% of respondents think that there is no specific guide for SMEs, except in UK (see also paragraph 4.4.6).

- European guidance documents

The participants of the survey have shown a lack of knowledge concerning the existence and use of the European guidance documents for the implementation of Seveso listed in Table 2. 50 % of industry respondents are aware of EU guidance documents, and less than 1/3 of those who are aware use them. On the contrary, 75 % of industry respondents are aware of national guidance documents and they use them.

Table 2: List of EU guidance documents prepared with the support of MAHB

- Safety Management System Guidance - Seveso II
- Safety Report Guidance - Seveso II (1998)
- Guidance on the Preparation of a Safety Report to meet the Requirements of Directive 96/82/EC as amended by Directive 2003/105/EC (Seveso II) - updated
- Land Use Planning Guidance (1999)
- Land-Use Planning Guidelines in the context of Article 12 of the Seveso II Directive, as amended by directive 105/2003/EC, adopted by the Committee of Seveso Competent Authorities - updated
- Guidance on Inspections
- SEVESO II Article 9(6) - Explanations and Guidelines
- Information to the Public Guidance
- Substances dangerous to the aquatic environment in the context of the Council Directive 96/82/EC: Report by Technical Working Group 7
- Carcinogens

NB:

The guidance documents listed in Table 2 are all available at <http://mahbsrv.jrc.it/GuidanceDocs.html>.

They have been developed by Technical Working Groups of experts nominated by the MS Competent Authorities and the Industry.

58 % of industry respondents agree that the Seveso II Directive should be supported by further EU reference and guidance documents.

Interviewees from two European industry associations have mentioned that the guidance documents prepared at EU level are often too generic and of lower value because they correspond to the minimum common denominator of the practices among the Member States. The inputs are more political than technical when the working groups include representatives of industry and representatives of the Member States.

A possible improvement for Industry would be to have guidance documents less generic than the present ones with the goal to standardize European practices related to risk assessment aspects.

Examples of recommendations made by a handful of competent authorities and industry for providing new documents are the development of common EU criteria and tools to assess effectiveness of safety measures on Seveso II establishments.

A Competent Authority recommends the creation of a common EU database to support risk assessment methods and guidance documents. This database should contain agreed (harmonized) values for the end-points thresholds for toxic, flammable and explosive substances to characterize the effects on humans and the environment, agreed values for failure-frequencies of safety equipment, agreed values of the probability of occurrence of some events (Loss of Containment, ignition of flammable mixtures...)

Some "best practices" are suggested by a lot of respondents (Industry and CA) regarding the development of various guidance documents. There is a need to have a clear procedure for the preparation of a guidance document: first involve industry in the drafting, second, send a draft version of the document to different stakeholders to have their feed back; and then test the guidance document. Finally, develop training and workshops for competent authorities.

- Possible topics for new guidance documents

In the survey, a few industry representatives (see Annex 1A, IND - I.1 – Q4 and T1 & T2 from Annex 1B) proposed the development of new guidance documents, in particular on:

- risk acceptability criteria: severity and probability,
- the assessment of Safety Management Systems,
- the assessment of emergency planning,
- the calculation of the consequences of hazardous phenomena, like explosion, fire, releases of toxic substances...,
- best firefighting principles,
- the methodology to do risk assessment that takes into account prevention and protection measures,
- the methodology to assess domino effects.

NB: Useful information to develop specific guidance documents on explosion can be found in the Explosives Directive 93/15/EC together with its associated documents⁸ and in the Pyrotechnic Articles Directive 2007/23/EC together with its associated documents⁹.

In addition, in the on-line survey a few CAs (in CA – I.3 – Q2) recommended guidance documents on:

⁸ see http://ec.europa.eu/enterprise/chemicals/legislation/explosives/index_en.htm

⁹ see http://ec.europa.eu/enterprise/chemicals/legislation/pyrotechnic/index_en.htm

- Assessment of Safety Management Systems and safety culture,
- Investigation of smaller accidents.

A competent authority suggests the creation of a commission independent from the authorities to investigate the causes of accidents (like US Chemical Safety Board),

Another competent authority recommends having more concrete and practical documents. There is a need to develop guidance documents for new topics, and in particular:

- for helping the checking of a safety report: development of reference scenarios (in order to review the exhaustiveness of a safety report).
- for the inspection of establishments: development of a practical document on safety measures and inspection tools.
- For developing new skills in evaluating a safety culture in a plant.

An EU association recommended guidance documents at two levels:

- A high level guidance document for the Seveso II Directive to present an overview, the doctrine of what is needed to be done. This document should explain how to interpret the requirements of the directive.
- Guidance documents for individual industries: Every industry/sector is different. It would be useful to have specific guidance documents for each type of industry. (E.g. there are some good documents developed by HSE, in UK).

For the elaboration of all these guidance documents, there is a strong demand both from industry and competent authorities to involve industry.

Another association recommends developing a guidance document(s) to take into account specific causes of accidents like aircraft impacts or natural hazards (e.g. earthquakes, flooding...).

4.3.2 Major Accident Prevention Policy – MAPP

IND – 1.2 – Q7

From the responses, it appears that more than 4/5 of the industry respondents think that the MAPP is known by internal management and workers through information and training. For industry, the MAPP is often a part of the SMS and of general policies on integrated (risk) management.

Although the MAPP is prepared by the industry, 35 % of industry respondents think that the MAPP does not solve possible conflicts between production and safety.

During interview, an operator from industry recommended that a generic layout and structure for a MAPP should be developed at EU level since there is no prescribed format for this document.

4.3.3 Safety Report – SR

IND – I.2 – Q8.9.10

CA - I.2 - Q7

Topic R2

- Positive impact of the safety report

The survey indicates that safety reports are prepared both by operators and consultants (by operator: 76 % and by consultants: 63 %). 71% of respondents (from industry) consider the Safety Report has a strong and positive impact on process safety in establishments. Two main aspects of a safety report contribute to a continuous improvement in terms of safety: risk assessment and the safety barrier approach, which consists of finding technical or human measures to reduce the impact of major accidents.

During an interview, an operator said that the formalism of the safety report creates more bureaucratic burdens than added-value for safety. Benefits are seen during exchange of information with experts (industry-CA, industry-consultant).

A majority of respondents (74 % from Industry) consider that the preparation of the safety report contributes to a revision of their procedures or to additional safety measures.

- A diversity of tools to carry out a safety report

In general, from the responses to the survey it is clear that there are adequate systems and procedures to ensure the sufficiency of the information. The systems and procedures provided by the competent authorities or by industry associations used are: guidance document, web-site, manuals with criteria, checklist tools and critical assessment by consultants.

There is a diversity of methods/tools for risk assessment within the European Union, because of national constraints, because of the history of the regulatory system... This is, if not the major, one of the major difficulties for the homogeneous and harmonized implementation of the Seveso II Directive in Europe.

An operator recommended during interview that a list of generic accident scenarios is defined at EU level for each type of installation and each type of product/substance.

- The examination of a safety report by competent authority

97 % of respondents think that the necessary updating is assured:

- At any significant change of the site,
- Periodically (e.g. every 5 years),
- After inspections.

90 % of respondents from CA assert that their examination of the safety report influences their decision-making.

51 % of the Industry respondents consider that the length of time taken to get responses and approvals is too long. They pointed out the disparity between the

time that industries get to submit their safety report and the length of time taken to get feedback from the competent authorities.

Some respondents mentioned as well that they have observed different treatment of similar companies from one region to another in the same country. Possible explanations for this offered by respondents were the different level of expertise of the inspectors but also the lack of coordination of the various local inspectorates, or the lack of instructions, guidance documents or training programs.

In some Member States, a second opinion is provided to complement the analysis prepared by the operator. The situation is quite diverse in the various Member States that provided input in the survey.

For example:

In Spain, in some regions, this second opinion is required before presenting the Safety Report to the authorities, and the cost is borne by the operators.

In France, this second opinion is performed only if requested by the authority, and it is paid for by the operator.

In Germany, in some Länder, because of the lack of resources to meet the inspection programs they have developed, some authorities ask third parties (consultants) to perform inspections and control the SEVESO establishments. In this case as well, the cost is charged to the operator.

In Sweden, there is not such a system of second opinion.

During the interviews, an industry association complains about the lack of critical dialogue between CA and industry, and an industry operator complains about the absence of risk acceptance criteria commonly agreed at EU level

In the same vein, during the interviews, 2 industry associations, 2 industry operators and 2 Competent Authorities, and also in several comments collected through the on-line survey, it was recommended to harmonize systems and procedures to improve appraisal of information at EU and national level. This can be achieved with the preparation of EU reference methods, tools, data and corresponding guidance documents.

- The various uses of the safety report

The use made of information in the safety report is different in all EU Member States. An industry association states that, in countries where the rate of accidents is low like in Sweden, stakeholders tend not to be proactive. An interviewee representing an industry association indicates that the safety report is not exploited enough.

2 industry operators point out during the interviews that the use of the safety report is beneficial for workers and internal purposes (training, work on scenarios and corresponding safety measures). However, there may be some difficulties in understanding technical aspects of the document.

Opinions about having several specific reports instead of one vary according to personal perception: one competent authority prefers several reports in order to have more clear results and improve the quality of the information; on the other hand, one industry association recommends keeping only one document.

4.3.4 Risk analysis and assessment methods

IND – I.2 – Q11.12.13.16. to Q24

- A diversity of risk analysis and assessment methods

Respondents reported that several methods are used for the risk analysis.

Example of risk analysis methods cited:

Bow-tie method, fault tree and event tree analysis, risk matrices, HAZOP¹⁰, Preliminary Hazard Analysis, ARAMIS¹¹, and ARPIP (Risk Analysis of Industrial Pyrotechnic procedures)...

For 81 % of Industry respondents these methods are used in a working group composed of employees and consultants.

Even if there is a diversity of approach in Europe for risk assessment, the probabilistic approach is the most used according to the responses.

- The selection of scenarios and the link with safety measures

From the various responses for IND – I.2 – Q18, it can be concluded that identified scenarios in a preliminary analysis are excluded from further analysis according to criteria, which are generally based on risk ranking that takes into account their likelihood and the severity of their consequences.

From the survey (see CA – I.2 – Q5), one can understand that competent Authorities have problems to determine whether this selection is correct.

Only 24 % of Industry respondents have no difficulties in establishing clear links between the consequences of scenarios and the measures of protection. Some difficulties in linking consequences and measures of protection appear because it is difficult to be precise about the nature of the consequences, to estimate the imponderables linked to the specific natural and industrial environment during the accident. The comments collected for question IND I.2 - Q19 reveal that it is not always possible to estimate the contribution of each safety measure to risk reduction.

During interviews, an Industry association recommended to harmonize data / criteria to assess efficiency of safety measures. This could be done in connection with the IEC/ISO 61508 and 615011 standards, which classify the safety elements according to a Safety Integrity Level (SIL). Those standards are widely used in the industry and are fully compatible with the Layer of Protection Analysis (LOPA) approach, which is also a method widely used.

¹⁰ HAZOP: Hazard and operability studies, see <http://en.wikipedia.org/wiki/Hazop>

¹¹ Method developed in the the ARAMIS project: see <http://aramis.jrc.it/index.html>

4.3.5 Interface with natural hazards

IND – I.2 – Q14.15

According to responses to the questionnaire, natural hazards are generally taken into account in the risk analysis. In some countries there are existing guidance documents for natural hazards; in other countries, they are in preparation.

One industry respondent recommends the provision of specific guidance documents on the likelihood and potential consequences of natural disasters in order to better consider natural disasters in risk analysis.

4.3.6 Safety Management System – SMS

IND – I2 – Q25.26.27.28

CA – I2 – Q8, I3 – Q1

Topic H1

91 % of Industry respondents have developed SMS in most of the establishments, for both lower tiers and upper tiers. The only difference is that, lower tier establishments don't need to report on the SMS but just need to have the information available to the authorities. In Sweden for example, there is no specific SMS required for lower tiers, but a very similar system based on action plans.

During interview, a competent authority from France notes that the SMS has a very good impact for establishments of 10 or more workers, but for establishments of less than 10 workers, it is difficult to maintain a good SMS.

71 % of Industry respondents state that SMS are assessed by CA, but during the interview, one competent authority informs that it has no methods or tools.

The efficiency of the SMS is checked by Industry thanks to audits and internal inspections and also by the means of:

- The European Single Assessment Document II (ESADII), implemented in the chemical distribution sector.¹²
- ISRS system (International Safety Rating) developed by DNV for safety, environmental and business performance.

In the survey, 89 % of Industry mentioned that they use other management systems, in particular: OHSAS 18001, ISO 14001, etc.

¹² The European Single Assessment Document (ESAD) was launched in 1999. This assessment tool is based on SQAS (Safety and Quality Assessment System) but is of lesser scope. Representatives from the chemical producers and distributors jointly developed ESAD. The basis of SQAS is a periodical assessment against 8 Guiding Principles of the ICCTA Responsible care / Distribution generic program. see http://www.sgqs.org/downloads/sgqs_leaflet_printing.pdf

A competent authority suggests developing tools/methods to assess safety culture. In the same vein, an industry association (see Topic T4) recommends that safety culture be assessed according to criteria to be developed.

2 interviewees proposed some suggestions. It was pointed out by an EU association that safety culture should be assessed. This could represent an improvement of the Seveso II Directive and some criteria could be developed for doing this assessment. A French operator considers that it is important and necessary to include human factors in the revision of the Directive.

4.3.7 Internal Emergency Plans

IND - I2 - Q29.30.31.32

CA - I.2. - Q14

OTHER - I.2 - Q7

93 % of the industry respondents report that they measure the efficiency of internal emergency plans through periodic emergency exercises and training programmes.

From the survey, it appears that workers are consulted, informed and trained for developing and applying the internal emergency plan procedures. Subcontracted personnel are also involved in the internal emergency plan exercises (72 % of Industry respondents).

During the interviews, an industry operator recommended to improve the performance (regularity and completeness) of practical emergency exercises, which contribute to create a safety culture within the plant, and also within the neighbourhood if the population surrounding the plant is involved.

4.3.8 Exchange of information between the competent authorities and the industry (including behaviour of the competent authority towards the industry)

CA - I.2. - Q5.6.9.12.13, 16

OTHER - I.2 - Q4.5.6

see also remarks in Topic H1, T4 and T2

- Sufficiency of the information provided and time for examination

74 % of respondents from CA think that the information provided by operators is sufficient for their needs and 81% think that adequate systems and procedures for the appraisal of the information exist.

83 % of respondents from CA think that the length of time taken to provide responses/issue approvals is reasonable. It is between 3 and 12 months (3 months are not sufficient). Excessive length is due to:

- The lack of human resources,
- The deficiencies in original submission of documents,

- The large volume of documentation to assess and approve,
- The involvement of many control and supervision authorities.

- Behaviour of the competent authority towards the industry

87% of respondents think that there is an equality of treatment between operators that is ensured by:

- Directive requirements,
- National legislation,
- National uniform procedures and instructions for all CAs,
- Training of CAs,
- Inspection instruments and criteria to support inspectors.

The difference of treatment between operators could come from:

- the differences between each individual inspectors,
- the lack of uniform criteria that all CAs could follow for inspections,
- the existence of authorized organizations for evaluation that are paid by operators; one respondent suggests that this can disturb their independence of judgment.

From the interviews, 2 industry operators indicated that in some countries, the authorities behave like a technical support for the operators, as a "free technical advisor" providing advice to improve the level of safety. In other countries, the role of the authorities is seen like a "policeman" undertaking control and enforcement. Several interviewees explained that the role of the authorities used to be like a technical advisor, but it has changed due to some accidents and the evolution of the public's perception.

To avoid possible differences of treatment, industry interviewees recommended developing a guide of good practices for the competent authorities to promote a more homogeneous behaviour throughout Europe.

4.3.9 Education and training

Topic H1

- Benefits of training

14 interviewees provided inputs on this topic, and explained that significant experience and appropriate skills among both authorities and industry are beneficial for both.

An EU association explains that a lack of understanding and knowledge on the part of the authorities on practical safety issues can lead to requests for inappropriate measures, and then the negotiation can be very long. Safety discussions with experienced inspectors are more efficient. Additionally, an industry operator in the Netherlands points out that inspectors should have spent time on site or in an engineering bureau to learn the processes and how industry works before working

as a CA. In the same direction, a CA in Germany raised the need to combine academic and company (in-house) education.

Another EU association agrees that to all Member States could be advised to train simultaneously the inspectors and the industry, so that they can work on common basis.

An operator in Sweden mentions that competence is improving thanks to new courses at the universities, and explains that in the past, 25 years ago, Germany, Finland or the Netherlands were ahead in term of safety skills, but today there are no longer such differences.

A trade union in Germany states that training is a part of its primary activities: training and certification of experts responsible for safety. However a good and well developed system suffers from not being recognized at the EU-level.

An Italian operator explains that for big companies resources are enough (clear requirements and educative workshops organized by industrial associations); but for SMEs additional training organized by CA would be useful.

- Accreditation of experts and "Health, Safety, Environment" (HSE) managers

There are inputs from 5 interviewees who expressed divergent views. Two of them, an EU industrial association and a French company, support the idea of accreditation of experts, with the following comments:

- Accreditation of experts in a reasonable time frame would improve the quality of the work on safety, and safety in the industry will improve.
- Accreditation of HSE experts will be a good development (it will be useful to implement in France by enlarging the IPRP accreditation (accreditation for occupational risks assessment)).

On the other hand, another French operator and a CA in Italy point out that HSE experts should not follow any accreditation or that accreditation is not important, with the following comments:

- Experts should not follow any accreditation, but they should be proposed by the director of a plant. This will "give value" to the function of HSE manager.
- Accreditation is not so vital, but it is important that inspectors belong to CA, because private consultants may not go so deeply in the analysis.

A German association explains that the accreditation of safety manager, or of consultants providing support to industry, is partly done in Germany.

Regarding the accreditation of HSE managers, there are inputs from 4 interviewees. An industry association is favourable to an accreditation of the HSE manager. Also a German fire protection association states that knowledge and skills to manage risks in Seveso II establishments need certification. On the other hand, a French operator does not think it useful to accredit a person (particularly for a company that is already good at safety) and also a CA from France considers responsibility should remain with the plant manager.

4.3.10 Risk communication towards the public

Topic C1

6 interviewees provided inputs for this topic.

- References and practices

A European industrial association notes the importance of risk communication towards the public, but indicates there are different approaches on risk communication between all EU countries and it is difficult to have a clear vision of the practices. They think that the approach of risk communication has to be elaborated at Member State level to take into account national particularities because the culture and the national context are different in each EU Member State.

This association mentioned the OECD guidance document "OECD Guiding Principles (2002)", which provides the basic requirements for risk communication. It indicated that in Germany, the industry distributes leaflets about the hazards of a plant and explains the behaviour to be followed in case of an incident. Additionally a guidance paper has been elaborated by the German Chemical Industry Association. The communication deals essentially with emergency preparedness, to mitigate the consequences of an incident.

Two French operators explain that the complexities of the Safety Report (very technical) make communications towards the public difficult (problems for the public to understand), making it less easy to involve the public. One of them explains that they have proposed to the neighbouring public that they participate in emergency exercises. However, people are reassured by this proactive approach and so do not actively participate (only as spectators, not as actors).

Another French operator points out the need to reinforce article 13 of the Directive: "Member States shall ensure that information on safety measures and on the requisite behaviour in the event of an accident".

An Italian operator indicates that communication towards the public must be carried out by qualified CA in order to have a clear understanding of the risks. He explains that in Italy the Safety Report is sent to municipalities and they are in charge of risk communication towards the public. Most of the time, the public is comfortable with the information, but sometimes the CA is not so well qualified and the public is not well informed about the risks.

It was also mentioned during 3 interviews (1 with industry and 2 with NGO) on the topic related to the "adequacy of the requirements" that risk communication towards the public should be improved and that participation of all stakeholders in the decision making process, in particular the public, should be increased. One interviewee said that it should not be made mandatory, but implemented through the promotion of these practices on a voluntary basis.

- Frameworks to improve risk communication

An EU environmental association represented by a German NGO considers that there is no clear vision at EU level on this subject, and it provides information about the current practices in the Netherlands, France and Germany:

- NL: They provide information on-line (internet) www.risicokaart.nl,
- FR: They have an easy access on-line (internet),
- DE: They do not have on-line information because there is a fear of terrorist attacks. Access to information is not easily possible. The main information source is the German Major Accident Commission, which is not open to public.

This association explains that it is difficult to have access to the information in the SR, emergency plans, etc. and the quality of the information is poor (too superficial, incomplete or too much paper).

In several countries, legal or voluntary frameworks have been developed to improve risk communication:

- Germany: there are some committees (One in Stade, Dow Chemical close to Hamburg, and another in Frankfurt, in the industrial park). There are groups with a structure to dialogue.
- In France: there is a framework for the dialogue with the CLICs,
- Rotterdam and the website: www.dcmr.nl. (Expertisecentrum Meetinstrumenten voor Revalidatie); although Seveso is often not the main point at issue because other regulations apply to the whole site. There is more interest on REACH and IPPC regulations.

To improve the dialogue the association recommends more transparency in the procedure to deliver the permit, more participation, and efficient access to data. It points out as a reference the work done with EPRTTR (European Pollutants Release and Transfer Register) and the application documents, which aim at improving public access to information on the environment and thus contribute in the long term to the prevention and reduction of pollution.

An industry operator indicates that a permanent dialogue with the public concerned by a Seveso establishment eases the risk management process and reduces conflicts.

4.4 Issue 3: Effectiveness of the implementation

4.4.1 Adequacy of requirements

IND - I.3 - Q1 to Q4, Q13, Q18

CA - I.3 - Q1 to Q5, Q11

OTHER - I.3 - Q1 to Q5, Q8, Q14

- **Appropriateness of the approach of the Seveso II directive**

It is agreed that the approach of the Seveso II Directive is appropriate to prevent major accidents and mitigate their consequences (84 % of IND respondents, 94% from CA and 81 % from OTHER), in particular thanks to the provision of the safety report and the systematic assessment of risks.

However, a few industry respondents point out weaknesses: too bureaucratic, some risks are transferred to transport... and a few CAs mention that variations in the quality of implementation (the understanding of requirements, the quality of documentation, the qualification of inspectors etc.) cause some uncertainty on this matter.

89 % of industry respondents and 75 % of CA think that the implementation of the requirements of the Seveso II Directive has led to a recognizably higher level of safety in comparison with non Seveso establishments. It has been achieved in particular due to the very positive contribution of the safety report (for upper tier establishments) including risk assessment, of SMS, of emergency planning, and the effect of the yearly inspections.

A majority of respondents from industry and OTHER agree that the approach and the requirements are clear, robust and relevant and not excessive.

It was mentioned by a few interviewees that the level of safety is also ensured by other legislation related to environmental, safety at work, occupational risk assessment, etc. In addition, sometimes the national legislation deriving from the Seveso II Directive influences the level of safety in non Seveso establishments as well, because some national authorities apply certain Seveso requirements to non Seveso establishments. For example, in Spain the new legislation for emergency plans "Norma Básica de Autoprotección" led to similar safety levels in non Seveso establishments.

From the interviews, it was pointed out by a handful of industry interviewees that the level of safety in Seveso establishment seems to be the result of both technological progress and regulatory pressure. The majority of the respondents think that "Seveso requirements would have been applied anyway" in most of the chemical and petro-chemical industry, in particular in large companies. The main reason invoked is that the safety culture is high in these industry sectors and companies apply best practices.

On the other hand, several respondents mentioned that the legal requirements are beneficial for SMEs and for industry sectors like coating and surface treatment, where a safety culture is less developed.

From the interviews, a few industry interviewees explain that compliance with Seveso requirements alone is not enough to reach a high level of safety. They acknowledge that compliance with standards and regulations is necessary but not

enough. Safety culture, understanding of critical situations, development of prudent behaviour, safety leadership and commitment at the level of top management are crucial factors to reach a high level of safety performance.

- Need for additional requirements

A majority of all categories, including 71 % of industry respondents, think that there is no need for additional requirements, but those who disagreed suggested to harmonise risk criteria, to include pipeline transport of hazardous substances in the scope of the directive as well as railway stations and harbours, to define an EU acceptability matrix, to develop tools, to establish an independent commission to investigate the causes of accidents (like US Chemical Safety Board).

A handful of respondents from industry suggested including security aspects in the scope of the directive.

A couple of industry interviewees propose that the Directive be reviewed to better address preparations and mixtures vs. single substances and to include vulnerability criteria in the classification of establishments to determine the level of risk.

An industry association proposes that a requirement be introduced to improve learning from experience by investigating accidents (see 4.4.5).

- Possible transfer of risk

Concerning the possible transfer of some risks to transport systems, opinions are equally divided among IND, CA and OTHER as to whether or not this is a problem. However a few respondents mention that many establishments manage their inventories so as to avoid the higher level requirements of SEVESO. This situation often entails the multiplication of small storage facilities and additional transport. This also puts at risk other workers who would not previously have been exposed. To summarise, one CA explains "there are cases where quantities present on site have been reduced in order not to fall under the scope of the Directive, by transporting more often (in lower quantities) the dangerous substances". The conclusion that "risk management approaches are always a compromise; we need to find the optimum" is shared by the great majority of the respondents from all categories.

4.4.2 Level of compliance between lower tier and upper tier establishments

Topics T4, R5 and R6

- Proportionality of the requirements

From the survey it was stated that a 2 tier approach is suited to the purpose of the Seveso II Directive and this was confirmed during the interviews.

There is still a difficulty in determining if legal requirements for upper and lower tiers produce different levels of safety. No clear answer to this question was obtained, neither during the survey nor the interviews.

However, although most competent authorities only require the provision of the description of the SMS for upper tier establishments, in several countries (France, Sweden, Spain...) the industry operators implement a SMS (or similar) also for lower tier Seveso establishments.

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 to define the principle of proportionality, with concrete examples of implementation.

- The most important requirements

During the interviews, 2 industry associations, 2 operators and 2 CA indicated that the most important requirements are the SMS and the preparation of the Safety Report (risk analysis and risk assessment).

In addition, an interviewee from industry and two from CA consider it necessary to extend the obligation of Safety Management System to lower tiers, although an industry association disagrees.

4.4.3 Consistency with other European "safety" Directives and Best Available Techniques Reference Documents (BREFs), and relation with standards

IND – I.3 – Q5.6, Q16.17

CA – I.2 - Q15, I.3 – Q8.10

OTHER – I.2 - Q8, I.3 – Q12.13

Topic R1

- Explicit common framework for Seveso and environment and safety-related directives

The majority of the respondents from industry (87 %) indicate that the Seveso II Directive and the other safety-related directives are complementary. They have different aims, level of details, and level of complexity.

However, 67 % of the industry respondents note that it sometimes overlaps either at EU level with ATEX¹³, Occupational Health and Safety¹⁴ Directives, but also as far as implementation at national level is concerned with fire protection legislation and other safety regulations.

2/3 of the respondents from CA and OTHER indicate that in their countries the Seveso II and IPPC directives are under an explicit common framework, but the link is less clear with safety at work or EIA directives.

60 % of respondents consider that the Seveso II directive should be made more consistent with IPPC and safety at work directives. Furthermore they think that greater consistency of different regulatory regimes could lead to a simpler, clearer set of requirements for operators and would result in greater compliance and higher standards. A few respondents from all targeted groups suggest integrating safety aspects in the Best Available Techniques Reference Documents (BREF) documents describing the Best Available Techniques (BAT). This was also suggested in the interviews by CA from Spain and Italy. The French CA recommended developing a BREF document for refineries.

Industry tries to establish links between all types of risks in their plants (internal and external risks). In fact, the majority of the companies implement an integrated risk management system because it is more efficient. Integrated management systems are used for quality, business, environmental and safety issues. A few respondents from industry, in both the questionnaires and the interviews, mention that they would like to see more integration from the authority side.

In several countries, like in France or in UK, efforts are made to coordinate the inspections from various authorities and to avoid potential conflicts between regulations.

For example,
in UK, the CA works on a 'Memorandum of Understanding' to avoid potential conflicts and ensure consistent decision-making between environmental legislation and COMAH

In the interviews across several topics, a few industry operators recommend improved coordinated approaches among competent authorities to enable them to deal with integrated risk management.

Two CA (one from Spain and one from Italy) indicate that there is no overlap between the Seveso II and IPPC Directives at national level because they are under the same framework.

¹³ Directive 94/9/EC on the equipment and protective systems intended for use in potentially Explosive Atmospheres

¹⁴ Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the health and safety of workers at work, and other specific daughter Directives.

- Relation with standards

Standards that are implemented by industry are: ISO 9001/14001/13485/22000, OHSAS 18001, EMAS, HACCP¹⁵, GMP+¹⁶...

During the interviews one operator from the Netherlands indicated that some standards, like 61511 on "Functional safety - Safety instrumented systems for the process industry sector" currently implemented by the industry are not always recognized by the Competent Authorities.

4.4.4 Involvement of the public and relevant stakeholders in the decision making process

OTHER – I.3 – Q10

Topic C2

The survey has shown that participation of the public is not the same within all EU Member States. In most of them, the involvement of the public ranges from public enquiry during the licensing process to the establishment of a permanent committee gathering industry, authorities and the public together for an effective dialogue.

68 % of the respondents from OTHER agree that "The public has the possibility to get easily information on the risks related to Seveso establishments" and 62 % that "The public or representatives of relevant stakeholders have the opportunity to be properly consulted in the decision making process" The introduction of "local committees for dialogue" in France is mentioned twice as a good example, but it is an exception in Europe.

A few respondents indicated the following weaknesses:

- sometimes, the information is restricted due to security concerns.
- the information is often difficult to understand by the public, which makes the procedure not always transparent.

In the interviews, it was explained that in several countries, the public is informed about new projects during the procedure to deliver the permit to operate. The information process is organised by the competent authorities, like in France, or by the municipalities, like in Spain.

Additionally, there are initiatives, mainly on a voluntary basis, to involve the public in the decision-making process related to major accident hazard control, which goes beyond the requirements of the directive. Again, the local committees for communication and dialogue (CLIC) imposed by Law of 31 July 2003 adopted after the Toulouse catastrophe¹⁷ in France are quoted. Similar voluntary initiatives are mentioned by an interviewee from a NGO, like local neighbourhood councils in Germany or in the Netherlands.

¹⁵ HACCP: Hazard Analysis and Critical Control Point

¹⁶ Good Manufacturing Practice System (GMP+) applies to all suppliers, producers, farmers and transporters of foreign feed material to be used in the livestock farming.

¹⁷ Explosion of the AZF plant on 21 September 2001 in Toulouse.

The industry operators who covered this topic consider it beneficial to involve the public from the beginning of the process. This can improve the acceptance of new projects and develop trust among the stakeholders.

Examples of initiatives to involve the public in the decision-making process:

France: Local committees for communication and dialogue (CLIC) for Seveso upper tier establishments.

Germany: EPRTR (European Pollutants Release and Transfer Register) to improve public access to environmental information.

Netherlands: During a new permit request, public participates voluntarily through a "neighborhood council" and the safety report can be consulted for a period of 8 weeks. See Expertisecentrum Meetinstrumenten voor Revalidatie, www.emcr.nl

Two interviewees from industry have pointed out that the interest of the public is often limited. They indicate some difficulties during interaction with the public: lack of knowledge to understand information on safety, and heavy dialogue due to the non-cooperative attitude of some individuals. They also experienced that the public behave emotionally, and mainly participate when there are some complaints.

A French operator stated that the involvement of the public should not be made a legal requirement because it is then too formal for real exchanges. Moreover based on his experience of the CLICs, after 3 meetings, the public lost interest. A similar point was made by a representative from a NGO, who explained that voluntary initiatives should be promoted, like "open days" or informal committees.

A European industry association explained that efforts to involve the public and relevant stakeholders should be proportionate to the impact of the establishment in the local area.

An industry association recommended also increasing the public involvement in external emergency plans.

4.4.5 Use of specific indicators, accident reporting and real reduction of the major accident rate

IND 1.1 - Q3, 1.3.- Q7 to Q12, Q14

CA 1.1 - Q1, 1.3 - Q6.7

OTHER 1.1 - Q1, 1.3 - Q6.7.9

Topic R3 & R4

- Use of specific indicators

Most of industry respondents (70%) state that they use indicators to measure their performance related to safety. The use of specific indicators is not a common practice for CA (63 %).

The indicators are used mainly internally to monitor safety management system implementation and performance. Most of the indicators used are outcome and

activities' indicators. Another way of distinguishing indicators is that presented by the process industry, which uses lagging indicators and leading indicators:

- lagging indicators are: number of incidents, number of unexpected shutdowns, etc.;
- leading indicators are: measurement of safety critical maintenance activities, number of inspections and safety walk/observations made by managers.

The list of indicators developed by the Center for Chemical Process Safety (CCPS¹⁸) (report 2007) is the list that seems to be the most widely agreed among the industry. Predominantly the oil and gas/petrochemical sectors favour the indicators listed in CCPS Metrics whilst the downstream chemical sector regards the process-driven UK HSE published methodology HSG254 *Developing process safety indicators* as a credible approach.

Although all industry respondents indicate that they have systems in place to report incidents in establishments, they do not have clear criteria related to thresholds for incident reporting.

An industry association suggests that a guidance document on indicators needs to be developed at EU level. On the other hand, an industry operator indicated that developing a set of harmonized safety indicators at EU level is difficult because the national context in EU Member States is different and the conditions of use in each industrial sector are also different.

During the interviews, with both industry and CA representatives, three recommendations were made concerning the use of indicators.

First, establish a set of indicators that would be collected in all industries in a consistent manner, or at least define recommendations to establish indicators specific to an industrial sector.

Second, make an analysis of the MARS reporting system to identify potential additional incidents currently missing from the system and from which lessons can be learned, and reduce the time for reporting.

Third, create a specific independent European agency for investigation of accidents, which could also undertake the periodic analysis of a set of indicators. This is in line with recommendation from 4.3.1 under "Possible topics for new guidance documents" to create an agency similar to the US Chemical Safety Board¹⁹.

- Real reduction of the major accident rate

12 interviewees provided inputs on this under topic R3.

Regarding the impact of the Seveso II Directive on the overall accident rate, there are inputs from 5 interviewees:

¹⁸ See <http://www.aiche.org/ccps/>

CCPS report on Metrics is to be found on <http://www.aiche.org/ccps/index.aspx> .

¹⁹ See <http://www.csb.gov/>

- 3 of them, an EU industrial association, a German association and an Italian operator, indicate that the Directive has a good impact on the prevention of accidents. For instance, the operator explains that Seveso II implementation has led to a reduction in the probability of accidents over the time on his site.
- 2 other operators (from France and Hungary) indicate that there has been no improvement through Seveso II. The Hungarian operator believes that the Seveso II Directive doesn't bring many benefits because safety measures were already implemented before 2004.

During the interviews on this topic, industry explains that even though safety regulations like the Directive manage the level of safety, benefits like reduction on the major accident rate are strongly influenced by internal actions, more than external regulations.

5 industry representatives indicate that an adequate level of safety is achieved mainly because of costs, competitiveness and company image, but of course the Directive's II requirements help. The image and competitiveness of the company are the main drivers for maintaining a good safety performance.

An EU industry association and an operator in Spain explain that the main driver is the commitment of the top management internally, which enables the development of a safety culture, which is a key factor for the safety performance of a plant. The industry association points out that the position is different for SMEs, which often wish to meet only the basic requirements.

Two EU industry associations point out that "experience-feedback" through exchange of best practices and lessons learned from past accidents also has a positive impact on the level of safety.

A French industry association and an industry operator indicate that an aspect needs to be improved: learning from experience. Regarding incidents, the industry operator suggests that it would be of great interest to share knowledge of past incidents among industries in the same sector. This activity would help lessons to be learned from past experiences and to prevent future accidents. The sharing of knowledge regarding incidents could be performed within the framework of Competent Authorities or under Business Associations. Nevertheless, it is emphasized that sharing information regarding incidents must be accompanied by a culture that avoids penalties or damage to industry's image.

4.4.6 Implementation for SMEs

IND 1.2 - Q6, and from comments and remarks collected in the questionnaires and interviews.

From the 102 Industry respondents to the web survey, 15 were SMEs. Also, 3 interviews with SMEs have been performed.

The answers from this group have been analyzed jointly with the rest, due to the absence of significant differences. Nevertheless, in the results of the survey some issues have emerged that are specifically relevant for SMEs.

From the web survey, 91% of the Industry answered that they are not aware of any guidance document addressing specifically SMEs. However, 3 participants mentioned a guide provided by HSE (UK) and 1 mentioned a German guide (UBA-FB 98-101). It is important to note that none of these 4 participants were SMEs.

From the web survey and the interviews, 4 particular comments have been made regarding requirements and costs being excessive for SMEs: *"could be an important issue discouraging them for starting new activities and in this way reducing competition"*, *"the cost benefit balance is unfavourable for SMEs"* or *"costs of the SR acceptable for a multinational, but this situation may not be the same for a SME."*

For an industry respondent, training organized by CA has been also considered more important for SMEs than for a large company.

Several respondents from the survey and the interviews commented that *"the legal requirements are beneficial for SMEs and for industry sectors like coating and surface treatment, where safety culture is less present"*.

From the interviews with industry operators and associations, it seems that SMEs have more difficulties to comply with Seveso requirements than large companies. In particular, costs and resources needed seem to be acceptable for big companies, but the economic burden and the level of requirements for SMEs may be too high (see the answers of IND - I.3 - Q2).

4.4.7 Involvement of workers

IND I.3 - Q15

CA I.3 - Q9

OTHER I.3 - Q11

More than 70 % of industry respondents disagree with the statements "Internal communication within establishments is not sufficient" and "workers have only few opportunities to be consulted on decisions related to major accident prevention development". The views of CAs are divided equally on the first statement, but 67 % of those who have an opinion disagree with the second. Concerning the category OTHER, opinions are equally divided.

During the interviews, a NGO mentions that, although technical and management levels of knowledge have increased, there is still a need to improve communication (externally towards the public and internally to workers).

4.5 Issue 4: Seveso II and the competitiveness of the European Industry

4.5.1 Cost and resources for Seveso compliance

IND 1.2 - Q35 to 43, 1.4 - Q1

CA 1.2. - Q17.18, 1.4 - Q2

OTHER 1.2 - Q9.10, 1.4 - Q2

Topic F1

- **Cost and resources**

From the on-line questionnaires, 58 % of the industry respondents have an estimate of the costs for the operator related to the implementation of **the safety report** and 42 % do not have.

The costs for the safety report are estimated to be "less than 10 Person.Months (PM)" for 62 % of the respondents, "between 10 and 30 PM" for 16 % of the respondents, and "more than 30 PM" for 10 %.

Internal cost reports are based on contact with the competent authority and time spent on the Seveso II Directive related work. Cost depends on the complexity of the site and the type of site (lower or upper tiers). 51% of respondents think that the consequence analysis with the use of sophisticated models is the most costly part of the SR.

Opinions are divided about the significance of the cost of identification of hazards, of system analysis, and of data acquisition.

The financial cost, on average, ranges from 20 to 50 k€ for the elaboration of the safety report.

For the same questions on the costs related to the **implementation of the SMS**, 60 % of industry respondents do not have any estimate, and 40 % do have.

The costs for the operator related to the implementation of the safety management system are estimated to be "less than 10 PM" for 75 % of the respondents. However, several respondents mentioned that the costs are difficult to estimate because they are structural and integrated with other management systems. The parts that are easier to estimate are the audits and the inspections.

As regards cost estimates for **emergency plans**, the situation is similar: 55 % of respondents do not have any estimates and 45 % do have.

The costs for the operator related to the implementation of emergency plans are estimated to be "less than 10 PM" for 81 % of the respondents.

71 % of industry respondents do not have estimates of the costs of prevention / mitigation measures installed as a result of the systematic analysis of risk performed in the Safety Report.

91 % do not have estimates of the benefits related to the implementation of the Seveso II Directive. For many of them, there is no perceived financial benefit.

Those who consider that a financial benefit is possible have no estimation and point out that it is difficult to measure because financial benefits are indirect.

74 % of CA respondents do not have any estimates of the economic benefits related to the implementation of the directive.

The general question of the costs was also put to the **competent authorities**. 77 % of respondents do not have any estimates of the costs for operators meeting the requirements of the directive, and 13 % do have. The references provided are presented in the box below.

References of estimation of the costs of meeting the requirements of the Seveso II directive:

UK:

A Regulatory impact assessments (RIA) carried in 1999, review of this assessment in 2005 included in the consultative document (at <http://www.hse.gov.uk/consult/condocs/cd193.pdf>), survey about costs and benefits of the COMAH Regulations (<http://www.hse.gov.uk/research/rrpdf/rr343.pdf>)

Turkey:

117.413.483 € (Reference: Directive Specific Implementation Plan for Seveso II directive in Turkey)

Sweden:

Report R 2006:03 about Trade and industries' administrative burdens within the framework of labour legislation (Näringslivets administrativa kostnader på arbetsrättsområdet R 2006:03), study by Nutek (http://www.nutek.se/content/1/c4/35/35/R_2006_01_webb.pdf)

8 interviewees provided inputs under topic F1. Industry interviewees indicate that compliance with Seveso requirements has evolved to a bureaucratic process necessitating more and more costs and time. Nevertheless, benefits have been obtained by increasing level of knowledge, promoting a safer culture and creating more public awareness.

Concerning costs of Seveso II Directive implementation, an EU industry association says that the preparation of the Safety Report and the compliance with the Seveso II Directive generates a lot of bureaucracy. The association reports that UK companies spent between 20,000 and 40,000 € on the preparation of the Safety Report, depending on the complexity of the operations. Another EU industry association recalls that an estimation of the cost of a safety report was presented at the meeting of the Committee of Competent Authorities in Dublin (May 2004). In this presentation, it was stated that the cost of a safety report of an upper tier Seveso establishment can vary from 7.5 to 50 Person.Months, which can represent around 10 % of the profit after tax of the company.

There are inputs from 2 interviewees (UK and Germany) regarding the costs of the competent authorities charged to the companies. One EU industry association

explains the fee system in UK, where the costs of the competent authorities spent on the control of a company have to be covered by the company concerned.

Additional examples are provided in Annex 1B.

- Impact on the competitiveness

A majority of respondents from **Industry** disagree that the resources required by the implementation of the Directive has led to a substantial reorganisation to escape the Seveso requirements, and that the implementation of the directive generates market distortions within Europe.

But industry opinions are divided concerning market distortions generated by the directive as regards Europe versus third countries, in particular emerging economies. Industry is also divided about the competitive advantage that the Seveso II Directive could bring.

Industry respondents are equally divided about the impact of safety requirements on the delocalisation of production towards third countries. The general trend is that the overall business costs in Europe compared to elsewhere is a more significant factor. In this context, "safety costs" are just one part of this wider picture. This was confirmed during the interviews. On the other hand, industry is aware of the fact that safety costs are financially beneficial in the long run, because they reduce the chances of facing the huge cost of major accidents.

Several respondents would like a reduction of the bureaucratic burden, and of the inspections. Another suggestion is the reduction of the delay in the delivery of a permit by competent authority. This factor seems to impact the industry performance.

A majority of respondents from **Competent Authorities** think that the implementation of the directive did not have any impact on industry's competitive advantage and did not require a re-organisation.

A majority of respondents do not see any market distortions within Europe or with third countries, in particular, emerging economies, but on the contrary agree that the "level of implementation is seen to be highly effective, providing an added value and enhancing the industry's image at national, European and/or international level leading to a competitive advantage based on investment in service skills and openness".

A majority of respondents **from OTHER** think that the implementation of the directive did not have any impact on industry's competitive advantage, and that operators re-organised to avoid the higher level requirements of the directive.

A majority of respondents does not see any market distortions within Europe due to the Seveso II Directive, but opinions are divided equally concerning market distortions with third countries. Opinions are also equally divided concerning the added value and positive impact of the directive on industry's image at national, European and/or international level.

4.5.2 Analysis of possible market distortion and adaptability of the regulatory framework to the business dynamic

IND 1.4 - Q2.3.4

CA 1.4 - Q1.3

OTHER 1.4 - Q1.3.4.5

Topic F2 & F3

- Analysis of possible market distortions

Industry and CA respondents have indicated that the level of implementation of the Seveso II Directive does not have a strong influence on the competitiveness of the European industry.

Opinions from industry are divided equally on the impact of safety as regards keeping production in Europe. The following remark from an English operator can be noted: *"Our plants in China and India are constructed and operated to western European standards. European plants only stay open where they are able to control their costs to an equivalent level"*.

A majority of CA respondents (83%) answer that the general approach is consistent with the aim to protect people and preserve at the same time the competitiveness of the European Industry. However, opinions from the OTHER category are equally divided. One CA pointed out that *"safer installations are often more productive (less down time) and provide better means for quality control. In addition, economic losses due to accidents are prevented"*.

89% of industry, 95 % of CA and 86 % of OTHER respondents answer that market distortions have not been evaluated.

The lack of tangible analysis of possible market distortions due to the implementation of the Seveso directive leads to some beliefs and perceptions that are contradictory among the respondents. A few respondents recommended performing a study of market distortions generated by the differences in implementation of the safety regulations within Europe and in Europe compared to other third countries.

10 interviewees provide inputs for this topic under F3, but none of them provide any information about studies on market distortions due to the Seveso II Directive.

Regarding possible market distortions within Europe because of different implementation in the Member States, there are the inputs from 8 interviewees: 3 of them explain about market distortions; 2 speak about minor market distortions; and 3 indicate the need for greater harmonization to avoid market distortions.

An EU chemical industry association explains about the different practices of the CA in the different MS and concluded that it "is not the Seveso II Directive that creates the market distortions, but the implementation by the Member States. The same rules in Europe will certainly contribute to have a Single Market." This idea is supported by two other operators in France who indicated the need for harmonisation to avoid market distortions in Europe.

A UK operator indicates that competitiveness in Eastern EU countries has increased in recent years. Their lower costs and not so strict requirements are leading

companies to transfer the activities from some high-cost countries like UK, Switzerland and Italy. A German association from the OTHER category agrees that the different level of implementation in the Member States has led to significant market distortions within Europe.

On the other hand an EU chemical industry association says that there are minor market distortions within Europe, but the companies have learned to compensate for the difference of treatment by the authorities in the different countries. There might be specific impacts due to the actions of individual inspectors, but it is generally not critical at the country level. This EU chemical industry association suggests that a study to analyze possible market distortion should be made by the European authorities.

Regarding distortions with third countries, there are two inputs from 2 interviewees, both of whom consider that there are market distortions in the short term but not in the long term.

An EU gas industry association explains that in countries like China, India, Russia... the state of the art to safely operate a plant is not the same as in Europe, in particular when it is operated by a local operator, and especially a SME. In the short term, Seveso requirements create market distortion. But in the (very) long term perspective of business and globalization, the companies in these third countries will have to comply with the current and further developing safety requirements.

An EU environmental association represented by a German NGO thinks that in the next 10 years, the situation will change and that the level of awareness and the expectations related to environment protection and safety will improve in these countries... Already in China, it is difficult to deal with hazardous wastes. This NGO suggests promoting the transfer of good practices from EU to third countries, for example, using international programs like those supported by UNITAR²⁰.

- Adaptability of the regulatory framework to the business dynamic

7 industry interviewees provided inputs for this topic.

Regarding the impact of the Seveso II Directive on the European industry's competitiveness, 4 interviewees (from the gas and chemical industry) indicate that EU production performance depends on the costs of operating the sites and not on the costs of safety. For example, delocalization of a site is more influenced by proximities to the feed stock or to the market. On the other hand, 2 interviewees (one operator speaking on behalf of an oil association and an operator in the chemical industry from Sweden) make comments in the other direction; an interviewee mentions different levels of implementation of the Seveso II Directive in the EU.

Knowledge and skills within the authorities have a strong impact on the adaptability of the regulatory framework to the business dynamic. Several industry interviewees from the chemical and oil industry indicated that if the level of knowledge and skill of the authority is high, then the quality of the dialogue is improved and the bureaucratic burden is reduced. The demonstration that all necessary measures have been implemented is easier.

²⁰ United Nation Institute for Training and Research, see <http://www.unitar.org/>

In addition, several respondents reported that if the level of knowledge is low, the experience is not there and there is no clear references indicated in a guidance document about what is expected from the industry. Sometimes the competent authority asks for more measures, more demonstration, or the demonstration provided by the industry based on best practices (e.g. LOPA approach) is not recognized by the authority.

From the interviews, it was suggested by several industry associations to reduce the administrative burden at EU level through implementation of good practices already implemented in some Member States and to harmonize inspections procedures at national level to avoid the difference of treatment in various regions of the same country. Other relevant recommendations relate to the improvement of the skills of the authorities, and the elaboration of clear guidance documents that define the level of detail of the information to be provided by the industry, and therefore how to satisfy the expectations of the authorities.

5 Analysis of the effectiveness of the Seveso II Directive

Chapter 4 referred to the detailed analysis of the situation regarding the implementation of the Seveso II Directive based on the on-line survey complemented by the series of interviews.

This section goes on to summarise the overall results obtained and to describe and assess proposals to improve its effectiveness.

5.1 Results obtained and current situation

The survey, with the results presented in chapter 4, has shown that all targeted groups think that the implementation of the requirements of the Seveso II Directive has led to a recognizably higher level of safety in comparison with non Seveso establishments. The requirements of the directive contribute to create awareness of the hazards and develop the appropriate measures to control risks.

From industry respondents (see IND - I.3 - Q1.2.3):

84 % think that the approach of the Seveso II directive is appropriate to prevent major accidents and mitigate their consequences.

80 % think that the requirements are proportionate to the aims of the directive.

89 % think that the requirements lead to a recognisably higher level of safety in comparison with industrial sites not covered by the Directive.

The respondents from all targeted groups agreed that the approach of Seveso Directive is well-suited to prevent major accidents and mitigate their consequences.

The survey confirms that the requirements are adequate to meet the Directive's aims, and valuably complement the other directives dealing with safety-related issues, like "occupational health and safety" and IPPC Directives.

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 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.

From the survey, no respondents concluded that there are no unnecessary provisions in the directive.

Concerning the question of possible adverse effect of the implementation of the Seveso II directive on the competitiveness of the European industry, no clear evidence has been collected because cost estimates for the Safety Report, Emergency Plan, prevention/mitigation measures, economic benefits, etc. are limited.

There is also no clear evidence that the non-homogeneous implementation of the Seveso II directive creates market distortion within the EU. Industry has generally stated that the costs related to the implementation of safety regulations are "on the margin" (i.e. "less than 10 person months" were the most estimates in responses), and the requirements "have to be implemented by industry anyway".

Opinions were divided concerning market distortions generated by the directive as regards Europe versus third countries, in particular emerging economies. Industry is also divided about the competitive advantage that the Seveso II Directive could bring. Industry respondents were equally divided about the impact of safety requirements on the delocalisation of production towards third countries. The general trend is that the overall business costs in Europe compared to elsewhere are a more significant factor. In this context, "safety costs" are just one part of this wider picture.

On the other hand, industry recognises that safety costs are financially beneficial in the long run, because they reduce the chances of facing the huge cost of major accidents.

However, lack of converging practices and various levels of strictness of approach within Europe are disturbing for the industry, and it gives the feeling that there are differences of treatment in Europe. Knowledge and skills within the authorities have a strong impact on the adaptability of the regulatory framework to the business dynamic. It was suggested by several industry associations to reduce the administrative burden at EU level through implementation of good practices already implemented in some Member States and to harmonize inspections procedures at national level to avoid the difference of treatment in various regions of the same country.

Having concluded that, some weaknesses and suggestions for improvement have been identified and they can be summarized as follows:

1. The main weakness identified from the study: the great majority of the respondents indicate the implementation of the Seveso II Directive is not homogeneous within Europe and even in a given country.
This represents a problem especially for multi-national companies operating in several Member States because most of them have internal safety standards or approaches, and they have to adapt them to each national context to fulfill the specific requirements (method for risk assessment, threshold for the quantification of the consequences...).
This also has an impact on the perception by the stakeholders who have the impression that the rules are different in the various Member States, even if it is the same Seveso II Directive.
This does not contribute to the effective functioning of the Single European Market.
To reduce this weakness of implementation, recommendations addressed the improvement of existing guidance documents and sharing of best practices (see point 3).
2. It was also pointed out by the majority (87 %) of the industry respondents that the Seveso II Directive and the other safety-related directives are complementary. 67 % of the industry respondents indicated that it sometimes overlap either at EU level with ATEX, Occupational Health and Safety directives, or, as far as implementation at national level is concerned,

with fire protection legislation and other safety regulations.

For the overlap due to the EU directives, cross references in the guidelines for the implementation of all these directives should help to lower the administrative burden on the industry.

At national level, from the interviews, it emerges that several Member States (including Sweden, France) are dealing with this problem by coordinating the inspections performed by the various authorities²¹.

These initiatives should be extended to all Member States because this contributes to reducing the administrative burden reported by some industry, and it would show a step forward towards closer integration and a more global approach from the authorities' side. It will be appreciated by the industry, which already has adopted integrated risk management systems. The coordination of the authorities is not an expensive measure, and it could be implemented in the short term.

3. A lot of recommendations were made to improve the harmonization of implementation of the Seveso II Directive, and support the convergence of implementation practices in Europe. 68 % of the industry respondents to the questionnaires and also a majority of the industry interviewees recommended the elaboration of a lot of guidance documents on the interpretation of the requirements (including, e.g. Risk Assessment approaches, SMS, Land-Use Planning) as well as for specific industrial sectors (e.g. metal treatment, storage in warehouses, etc...).

In paragraph 5.2.2, this recommendation is analyzed in detail to optimize the allocation of resources to the task, because there is still a contradiction from the contributions collected: on the one hand, many industry respondents appear to be unaware of existing EU guidance documents; on the other hand, guidance documents are requested to help the convergence of practices. Furthermore the industry has now learned to comply with the requirements in the existing situation, and will adopt new guidance documents only if they are used by the authorities and if they bring added value compared to the current situation.

The development and adoption of European guidance documents require a lot of time and effort. Therefore an action plan related to this recommendation would need to be prepared carefully and discussed with the stakeholders.

4. Recommendations were made to improve the relevance of the Seveso II Directive in meeting its goals, by including new requirements on e.g. improved accident investigation and learning from experiences, inclusion of security aspects, and assessment of the safety culture... These recommendations, their relevance and level of priority are discussed in detail in paragraph 5.2.1.
5. The majority of the respondents from the category OTHER stressed both in the questionnaires and during the interviews the need to improve the quality of the dialogue between the stakeholders and reinforce the participation of the public. This recommendation was also supported by the 2 Industry Associations and the 3 industry operators who discussed the topic during the

²¹ see Instruction DRT du 14 avril 2006 relative à la collaboration renforcée entre les inspections chargées du contrôle des établissements classés «Seveso seuil haut», which presents the collaboration of the French inspectorates from Work Ministry and Environment Ministry.

interviews (see 4.4.4). This recommendation is not surprising since it has been observed that in our information and knowledge society, risk management issues are better dealt with if the relevant stakeholders and the public are involved upstream and if the dialogue is not based on emotional reactions.²²

5.2 Assessment of the recommendations

The proposed recommendations are derived from the suggestions collected during the survey, and are set out in 3 groups:

- Additional requirements and issues to be considered in the upcoming review of the Seveso II Directive,
- Guidance and tools to be developed in order to support the implementation of the Seveso II Directive,
- Other actions to be performed, in order to support an update of the Seveso II Directive.

To aid prioritisation of the recommendations, the following 4 criteria were used:

- Weight given by the respondents,
- Impact expected,
- Costs including resources needed for implementation,
- Level of difficulty involved.

The 3 first criteria – “Weight”, “Impact expected” and “Costs” – are the main criteria for prioritisation in terms of the level of importance of the recommendation.

The last criterion is used to help define the time scale for implementation of the recommendations, according to the following rankings:

- short-term (S), corresponds to between 1 to 2 years,
- medium-term (M), corresponds to 3 to 5 years (to be included in the upcoming revision of the directive, if possible),
- long-term (L). corresponds to between 5 to 10 years,

The table hereunder defines more precisely each criterion, at 2 or 3 different levels (positive and less positive).

In subsequent tables the criteria for prioritisation appear in dark. They are purely indicative; in particular it is difficult to judge the weight to be attached to those recommendations deriving from a limited number of respondents.

When appropriate, the stakeholders responsible for following up the recommendations are identified.

²² See: Ortwin Renn & Katherine Walker (Eds), Global Risk Governance. Concept and practice using the IRGC Framework. Series: International Risk Governance Council Book series , Vol. 1. ISBN: 978-1-4020-6798-3

Classification of the criteria	Value
Criteria for prioritisation	
<i>Weight (main criterion)</i>	
Heavy: when several respondents from at least 2 target groups mention the recommendations, and when the recommendations suggested during the on-line survey were confirmed during the interviews	1
Medium: when several respondents from 1 target group mention the recommendation during the questionnaires or the interviews	2
Light: when the recommendations were mentioned only by a few respondents during the questionnaires or the interviews	3
<i>Impact expected (main criterion)</i>	
High impact: it is estimated that the impact in terms of reduction of major accidents or reduction in terms of costs, will be high.	1
Low impact: impact is not clear or difficult to quantify.	2
<i>Costs for implementation</i>	
Low costs: only small re-organisation or different use of existing resources.	1
High costs: important changes in the organisation and procedures, need for education and training of the stakeholders.	2
Criteria for time line	
<i>Level of difficulty involved</i>	
Level 1: if a lot of information is already available in various Member States, if some preliminary work has been done e.g. in a European Project... then the process of adoption should be more straightforward.	1
Level 2: if there is a lack of data and knowledge, and research has to be performed, or because of the political reality	2

Table 3: Criteria for ranking the recommendations

5.2.1 Additional requirements and issues to be considered in the review of the Seveso II Directive

The following recommendations represent **in order of priority** suggestions for improvements for the directive itself, i.e. the Seveso II Directive in relation with other safety-related directives and the content of the directive.

Additional requirements or issues to be considered...	Weight	Im- pact	Cost	Diffi- culty	Time line
1. Extending the obligation for lower tier establishments to prepare a Safety Report (or at least an identification of major accident scenarios) and the provision of a Safety Management System	1	1	1	1	S
2. New requirements to better target the information and communication towards the different end-receivers and reinforce the dialogue with the different stakeholders	1	1	1	1	S
3. Addressing environmental aspects in the safety report	3	1	1	1	S
4. Better address preparations and mixtures vs. single substances	3	1	1	1	S
5. Extend the scope of the directive to other installations such as pipelines, railway stations and harbours	3	1	2	2	L
6. Integrate security issue into the Seveso II Directive	3	1	1	2	M
7. Clarify the links between the Seveso II Directive and the other safety-related Directives and make the implementation of the Seveso II Directive more synergetic with other occupational health and safety, and environmental, regulations	2	2	2	2	L

Table 4: Ranked list of additional requirements to be considered in the review of the Seveso II Directive

For the short-term, it is proposed to:

- consider **extending to lower tier establishments the obligation to prepare a Safety Report (or at least an identification of major accident scenarios) and the provision of a Safety Management System (SMS)**, because those 2 requirements are seen as the most important ones and they are already implemented also for lower tiers in several Member States. This proposal is easily feasible for large companies from industry. This measure should help to reduce the number of major accidents in Europe²³ and as an indirect impact it will reduce the cost of accidents.

The implementation of the recommendation might require more resources from the industry to formalize risk analysis and organizational safety. It will require even more resources for small companies, but it will help in developing a safety culture in the industry sectors where it is less developed and where a lot of SMEs operate.

²³ Based on the SPIRS data (as provided in Appendix 1: Summary of the data from SPIRS), "metal refining and processing (including foundries, electrochemical refining, plating, etc.)" represents ca. 2 % of the Seveso establishments in Europe. They are generally are low tier establishments. But, based on MARS²³, they have generated 20 (6.6 %) of the 301 accidents recorded, and 13 (8.5 %) of the 153 fatalities. Additionally, the analysis of the accidents at work made by Eurostat²³ in 2004 indicates that the sector of "Manufacture of basic metals and fabricated metal products" employing 4.323 Million (3.0 %) of the 142.230 Million workers, but generates 277 (5.3 %) of the 5,237 fatal accidents and 361417 (7.5 %) of the 4,815,629 of the accidents leading to more than 3 days of absence. As a comparison, the "Manufacture of chemicals, chemical products and man-made fibers" employs 2,029,000 workers (1.4 %) and generates 40,320 accidents (0.8 %) leading to more than 3 days of absence, and 44 (0.8 %) of the fatal accidents. This demonstrates clearly that additional measures leading to the improvement of safety culture and probably to the reduction of the number of accidents will benefit sectors like metal treatment.

More resources from the authorities to review the safety reports, and also to inspect or audit the SMS are anticipated. In order to reduce these costs for the CAs, outsourcing of activities under the competencies of the authorities might be analyzed. Indeed, from the survey, it was explained that several authorities in France, Germany and Spain asked accredited third party organizations either to provide a first (Spain) or a second (France) opinion on the safety report, or to perform audits on behalf of the authorities.

- consider including new requirements such as the preparation of risk communication plans, the creation of local committees for risk dialogue... to better **target the information and communication** towards the different end-receivers and **reinforce the dialogue** with the different stakeholders. This recommendation has to be taken in the context of the Aarhus Convention²⁴, which goes beyond the requirements on communication included in the Seveso II Directive. This recommendation at the level of new requirements to be included in the directive should be accompanied by activities that are described in paragraph 5.2.3.2.
- consider **addressing environmental aspects in the safety report**, dealing with the impact of pollution on surface or underground water in the Seveso II Directive. This recommendation stems from suggestions from a limited number of respondents, but it was already pointed out in the outcomes of the SHAPE-RISK project and in particular in the report from P. Danihelka (2006). It refers to the lack of quantification of environmental (ecological) impact of pollution affecting the environment only. Generally, the safety reports do not contain any quantified assessment of the long term impact of pollution, and mainly focus on accidental risks and short term effects on humans. The knowledge is available to improve the situation, and based on this requirement, in a short term period, this gap could be closed.
- better **address preparations and mixtures vs. single substances**. This recommendation, formulated by several industry operators (see 4.4.1) was not developed sufficiently to provide a clear understanding of what is really needed. However, from the experience of the authors, it is understood that even though the Directive requires taking into account hazardous preparations and mixtures, as well as intermediate products, this is rarely done properly and is difficult to control. Improvements on this matter should be considered at the same time as the amendments that will be developed because of the implementation of the Global Harmonised System GHS.

For the medium-term, it is proposed to **integrate security issues into the Seveso II Directive**, (via e.g. adding consideration of impact of malevolence and deliberate acts, sabotages). The inclusion of this issue, mentioned in 4.4.1, will have to take into account the development of the European Programme for Critical Infrastructure Protection (EPCIP) managed by the DG Justice Freedom and Security. This programme was launched in 2007, and research is still on-going.

In the long-term, it is proposed to:

- **extend the scope of the directive to other installations such as pipelines, railway stations, marshalling yards and harbours**, or apply

²⁴ see Art. 6 of the Convention on access to information, public participation in decision-making and access to justice in environmental matters done at Aarhus, Denmark, on 25 June 1998

similar rules to such sectors in order to reach a consistent approach for all similar infrastructures presenting the same degree of hazard. This recommendation (see 4.4.1) refers to the need to perform a similar approach for the potentially hazardous infrastructures that handle the same type of dangerous substances as those covered by the scope of Seveso II directive. The main benefit of having similar requirements will be to avoid risk transfer from Seveso II establishment to such infrastructures. Indeed, recent statistics from CEFIC²⁵ have shown an increase of accidents recorded in chemical transport when at the same time one can observe a reduction for fixed installations.

Having a consistent framework and level of requirements will benefit safety and reduce the number of major accidents.

- clarify the links **between the Seveso II Directive and the other safety-related Directives** and make the implementation of the Seveso II Directive more synergetic with other occupational health and safety, and environmental regulations. To clarify the link, expanding relevant existing guidelines or introducing a notice or communication, to explain the complementarities of the Directives may be useful. Synergy between the Directives might be achieved by greater coordination of Member State resources for implementation, in terms of a common database, methods and tools, etc.

5.2.2 Guidance and tools to be developed in order to support the implementation of the Seveso II directive

The following recommendations concern principally the elaboration of EU guidance documents and databases to support a converging implementation of the Seveso II Directive.

They should be implemented at the European level, but of course with the participation of the industry, the national competent authorities and, when necessary, other stakeholders.

There are a lot of existing guidance documents in some countries or developed by certain industry associations (see list of guidance documents identified during the survey in section 4.3.1). A first step would be to review these existing documents, and, when necessary, after some adjustment, reach a common agreement at European level to support their wider use. It is also important that some of the guides appear as commonly agreed guides among the national authorities in particular, paying attention not to prejudice the subsidiarity principle.

A very relevant recommendation was to create two levels of guidance:

- High level guidance documents for the Seveso II Directive to present an overview, with the general lines that are to be followed. These documents should explain how to correctly interpret the requirements of the directive and provide information on the approach that should be followed by all Member States, for example for risk analysis, the thresholds to be used for the

²⁵ CEFIC, Responsible Care Europe Annual Report 2006/2007 (2007). (see page 26: chemical transport incidents).

quantification of the consequences, the principles for the selection of the scenarios, etc;

- Guidance documents for individual industries or specific categories like SMEs, which will be the practical application of the high level guidance documents to a given industrial sector.

For the elaboration of all these guidance documents, there is a strong demand both from industry and competent authorities to involve experts from industry.

The high level guidance documents should be developed in the short term, and the other practical guidance documents in the medium term.

The process to develop guidance documents is as important as the outcome, because the sharing of information and best practices are crucial for convergence, leading to a more harmonized implementation.

Exchanges of experience within the Competent Authorities (CA) seem to be a key factor to help convergence or harmonization of best practices and criteria. Efforts towards greater harmonization should be focused first on the Competent Authorities. If guidance documents are developed, they should be disseminated accompanied by targeted suitable training programmes.

All guidance documents should be supported by a data-base, a one-stop-shop, to find all relevant and agreed data, models, and implementing tools. This data-base should contain agreed values for the end-points thresholds for toxic, flammable and explosive substances to characterize the effects on humans and the environment, agreed values for failure-frequencies of safety equipment, agreed values of the probability of occurrence of some events (e.g. loss of Containment, ignition of flammable mixtures, etc.). The data-base should be operated by a European organisation that will have strong links with technical experts from all over Europe. Preferably this organisation should be independent from governments (authorities) and from industry. The data-base will be the shop-window of several processes:

- review of existing documents, models, tools, data... and their validation, using scientific and technical independent experts,
- production of knowledge and data when necessary (if there is a gap) by asking the contributions from all Member States experts,
- organization of training on the various reference documents, models, tools, data...

The difference compared to the current working method would be to nominate scientific and technical independent experts from various Member States, and give them the mandate to elaborate the reference documents, models, tools and data. The selection of the participants in the working group should be exclusively made based on the level of expertise in the field. This is to give priority to technical aspects, and less to political considerations. Once a guide is available, it will have to be reviewed and endorsed by the authorities of each Member State.

During the survey, a lot of suggestions for the development of guidance documents were proposed. The ranked list of guidance documents and sets of high level data at is presented in the following table .

Develop guidance document and set of data related to...	Weight	Im- pact	Cost	Diffi- culty	Time line
1. Risk analysis and risk assessment, including presentation of best practices regarding: a) the general approaches, b) criteria for quantification, and c) methods/tools/data for implementation	1	1	1	1	S
2. Assessment of the effectiveness of Safety Management Systems (and in long-term, of the safety culture in Seveso II establishments)	1	1	1	1	S
3. Good practices for the competent authorities to have more homogeneous behaviour throughout Europe.	2	2	1	1	M
4. Taking into account accidents triggered by natural hazards (e.g. earthquake, flooding...) and provide data and criteria.	3	1	1	1	S
5. Investigation techniques for accident analyses	3	1	1	1	S
6. Vulnerability criteria	3	1	1	2	M
7. Defining the principles of proportionality, with concrete examples of implementation.	3	1	1	2	M
8. Domino effects and how to implement in practice Art. 8	3	1	1	2	M
9. Assessment of the effectiveness of emergency planning	3	2	1	1	M

Table 5: Ranked list of guidance documents and set of data to be developed

NB: The sources of the original recommendations can be found in chapter 4 or in Annex 1A or 1B.

For the short-term, it is proposed to develop guidance documents and sets of data related to:

- Risk analysis and risk assessment to present the current best practices in the various Member States. This recommendation was expressed by all categories of respondents, both in the questionnaires and during the interviews. For this topic, 3 specific aspects have to be covered:
 - a) the general approaches: this should describe the current best practices for risk analysis and risk assessment and recognize the complementarities of deterministic and probabilistic, qualitative and quantitative approaches, the advantages and the drawbacks of each approach regarding the objectives of the Seveso II Directive. The guideline should be informative and help the selection of the best approach depending on the context and constraints in a given Member State and given industry sectors. Several EU projects and studies have been performed on this topic, so that the knowledge is available. To implement this recommendation, a synthesis of this work has to be shared and endorsed by all CAs.
 - b) criteria for quantification: it is important that the risk assessment step, as part of the risk management process, is comparable within the European Union. Based on the results of several EU RTD projects (ASSURANCE, ARAMIS, LUPACS, SMMARTEN, ACUTEX...), the inputs and assumptions for risk assessment should be similar for:

- scenarios definition,
- accident severity estimation, in particular with commonly agreed effect thresholds,
- estimation of probability, based on harmonized probability classes in Europe and agreed data sources and a clear method dealing with how to take into account the efficiency of prevention and protection measures in the risk assessment.

This can be achieved by activating a working group made up of technical experts from industry and from competent authorities who were directly involved in the development of the respective national guidance documents on these matters.

- c) methods/tools/data for implementation: risk assessment implies the calculation of the consequences of hazardous phenomena (explosion, fire, releases of toxic substances), as well as the calculation of risk based on the selection of a list of accident scenarios to be studied according to the type of installation and type of products/substances. The identification of the scenarios is performed thanks to methods like HAZOP²⁶, Preliminary Hazard Analysis... The methods and models, with the corresponding tools and data have to be presented, with their advantage and drawbacks, and made available after endorsement by the industry and the authorities.

All the guidance documents and sets of data should be placed in the one-stop-shop mentioned above, which should become the main tool to support the convergence of practices and the harmonization of the implementation of the Seveso II Directive.

The recommendations should address all aspects of risk assessment in the framework of the directive, but in particular the land-use planning part, for which an initiative supervised by the MAHB²⁷ has already been launched.

- Assessment of the effectiveness of Safety Management Systems (and in long-term, of the safety culture in Seveso II establishments). This recommendation, made by competent authorities, can be addressed based on several national guidance documents that were developed in the Netherlands and in Belgium. A step forwards once the authorities have the capacity to assess the performance of SMS will be to assess the safety culture, but this requires additional research to be able to develop a guidance document that will be endorsed by all authorities.
- Taking into account accidents triggered by natural hazards (e.g. earthquake, flooding...) and provide data and criteria. The so-called NaTech issue is not systematically integrated in the safety report. A guidance document with clear examples of natural hazards and their impacts on the installations will help to better analyze the interactions and define the appropriate counter-measures. This is of particular relevance since it seems that the intensity of natural events has increased with global warming.

²⁶ See footnote 10 on page 31

²⁷ See European Working Group on Land-Use Planning at <http://landuseplanning.jrc.it>

- Investigation techniques for accident analyses. Investigation of incidents and accidents and learning from the experience are important drivers for safety improvement. Techniques exist for investigation to improve understanding not only of the technical problems but also the organizational ones.

For the medium-term, it is proposed to develop guidance documents and sets of data related to:

- Good practices for the competent authorities to develop more homogeneous behaviour throughout Europe. This recommendation complements the suggestions proposed in paragraph 5.2.3.1. The guidance document should cover practices such as inspections, review of the safety reports or how to perform land-use planning (see 4.3.1). It should describe programs of activities or organizational measures to help the CA develop more uniform behaviour in a given country. This recommendation could be implemented by constituting a working group with experienced CAs from several Member States.
- Vulnerability criteria relate to the sensitivity of urban areas, sensitivity of the natural environment, presence of critical infrastructures... These criteria can be included to determine the level of risk. This recommendation (mentioned in 4.3.1) refers to land-use planning and the identification of what can be affected by a major accident. Tools for the estimation of the vulnerability have been developed in several recent EU projects (ARIPAR, ARAMIS...) and information is treated using Geographic Information System (GIS) software. They are included in more and more Quantitative Risk Assessment (QRA) software, but the criteria to characterize the vulnerability should be discussed at EU level. Therefore, the information might be available rather easily in a lot of Member States. Knowing this information will enable prioritizing the requirements and focusing on the establishments that are in sensitive areas, improving therefore the relevance of major accident hazard control.
- Defining the principle of proportionality, with concrete examples of implementation. The recommendation came mainly from industry for who the concrete implementation of the principle is important. See paragraph 4.4.2.
- Domino effects and how to implement in practice Art. 8. Even if this topic is primarily one for the CAs, industry that is concerned by this issue supports the idea to develop such a guidance document. Literature and methods already exist, for example the method developed by the Faculté Polytechnique de Mons for the Walloon CA in Belgium or by INERIS for the Competent Authorities in France. Based on this work, a guidance document could be quickly developed and implemented.
- Assessment of the effectiveness of emergency planning, because there is no recent European guidance document on emergency planning in the framework of the Seveso II Directive. An EU guidance document on emergency planning would provide support for the elaboration of the plans but also help to assess the effectiveness of the plans. See paragraph 4.3.1.
- Taking into account the efficiency of prevention and protection measures in the risk assessment. Human factors have a strong influence on the level of safety of Seveso establishments. However human aspects are not being

taken into account in the risk analysis and it is difficult to develop legal requirements on this topic.

In addition to the proposals listed in Table 5, it was suggested to improve the safety content of the BREF documents prepared in the context of the IPPC directive, and to develop specific European guidance documents for SMEs.

Concerning the BREF documents, it is recommended to integrate clearly and more obviously the organizational and technical safety aspects into the existing BREF documents and there during the selection of the Best Available Techniques (BAT) within the cross-media effects. It could be implemented in the short term.

As stated in a report from EU OSHA²⁸, SMEs employ over 65 % of Europe's working population. The report shows that approx. 90 % of the fatal accidents in 9 NACE branches (agriculture, manufacturing, electricity, gas and water supply, construction, wholesale and retail repairs, hotels and restaurants, transport and communications, financial intermediation, real estate business activities) happen in companies with less than 250 employees. It is also obvious that this population of companies have less resources to fulfil the requirements of the directive. Therefore, specific guidance documents should be prepared for SMEs to ease the work to comply with the regulations. The UK HSE guidance document could be used as a starting point for guidance at European level. This could be implemented in the short or mid term.

5.2.3 Activities to support the implementation of the Seveso II Directive

5.2.3.1 *Coordination of the authorities*

Most of the recommendations concern the improvement of coordination

- at national level, among the various authorities in charge of the Seveso Directive, and among the various regions,
- at European level, among the various Member States.

The need for improvement of the coordination of the various authorities in charge of the Seveso II directive in a given Member State was reported in paragraph 5.1. The lack of coordination can create an additional administrative burden and have a negative impact on the industry. As mentioned in paragraph 5.1, several Member States have already started to work on this issue. The generalisation of this "good practice" could be easily implemented in all Member States, by organising a workshop to share experience among the authorities.

It has been observed that the countries with a strong regionalism have specificities that can give rise to the perception that that the authorities are not at the same level of strictness within a country. Coordination among the authorities from various regions in a given Member State is important to avoid difference of treatment, especially for the review of the safety report and for inspections. It is important that the measures requested by the authorities follow certain programmes and that implementation respects the equality principle.

²⁸ Improving occupational safety and health in SMEs: Examples of effective assistance European Agency for Safety and Health at Work (2003). ISBN 92-9191-043-0. see page 10 of the report.

Finally, improving the coordination of the various Member States to reach a harmonised implementation of the directive is a long lasting effort that started with the adoption of the directive. The survey has shown that harmonised implementation is not yet the norm. To accelerate this process of harmonisation of practices, the adoption of common EU guidance documents will help, but activities like seminars and workshops, and working groups have to be intensified.

Activities to support the harmonised implementation of the Seveso II directive	Weight	Im-pact	Cost	Diffi-culty	Time line
1. Improve the coordination of the various authorities in charge of the Seveso directive in a given Member State.	1	1	1	1	S
2. Harmonize inspection and audits practices in the same country	1	1	1	1	S
3. Improve the coordination of the various Member States to reach an harmonised implementation of the directive	1	2	1	1	M

Table 6: Recommended activities to support the harmonized implementation of the Seveso II directive

5.2.3.2 Communication and participation of the stakeholders

Another series of recommendations focused on the need to increase the quality of communication among the various stakeholders and their participation in the decision making process, in particular increase relations with the public. This will help to develop a safety culture and improve risk acceptance.

Several recent EU projects (Trustnet-in-Action²⁹, STARC³⁰) and international initiatives (Framework from the International Risk Governance Council) have stressed the need to improve inter-relations between stakeholders. The publicly available results of these projects, as well as the OECD Guiding Principles (2002) and Guidance Document on Risk Communication for Chemical Risk Management³¹ (2002) offer the baseline to develop efficient risk communication.

Extract from Deliverable D2 of STARC project, *Risk communication practices in EU Member States, selected other countries and industries*:
 "...countries could benefit from a model **risk communication plan** or set of guidelines at national level that could be used and adapted as necessary by different government departments and agencies as well as by different levels of government."

In addition, it is important to stress, as stated in paragraph 4.4.4, that France has made mandatory the creation of Local Committees for Communication and Dialogue

²⁹ See <http://www.trustnetinaction.com/>

³⁰ STAKEholders in Risk Communication, see <http://mahbsrv4.jrc.it/starc/index.html>

³¹ OECD, Environmental Health and Safety Publications – Series on Risk Management, No. 16

(CLIC) for upper tier establishments. Lessons from this experience should be learned and shared at European level, and if positive based on a cost-benefit analysis, a common EU framework to improve public participation should be adopted.

Activities to support the communication and participation of the stakeholders	Weight	Im-pact	Cost	Diffi-culty	Time line
1. Increase participation of all stakeholders in the decision making process, in particular the public	1	1	1	1	S
2. Improve risk communication towards the public and its involvement in the risk management process	1	1	1	2	M

Table 7: Recommended activities to improve governance

Additional recommendations are suggested to improve the efficiency of the proposed requirements:

- Develop methods to obtain a better understanding of information and avoid that individuals and not well-intentioned persons damage the dialogue between industry and the public.
- Develop new strategies to maintain the attention of the public in the risk management process. People get tired of not having new information. Some actions to take into account are: discussions "in situ", voluntary participation through working groups and exercises.

5.3 Recommendations for possible additional studies

Additional detailed focused studies on the following topics might be appropriate to further investigate certain aspects, where the results of this study were inconclusive (not enough material or opinions are deeply divided).

They concern:

- Reduction of time/resources taken to prepare and review the safety report (see paragraph 4.5.1).
- Improvement of the dialogue between industry and competent authorities (see paragraphs 4.3.10 and 4.4.4).
- Establishment of a set of indicators for use by competent authorities that would be collected in all industries in a consistent manner (such as those mention in 4.4.5).
- Analysis of the costs and resources for Seveso compliance, with a clear definition of how the costs have to be calculated, based on the preliminary information reported in paragraph 4.5.1.
- Analysis of how the bureaucratic burden could be reduced through a better coordination between the CA and reduction of the time taken to deliver a permit and the impact on the industry performance and competitiveness, based on the preliminary results of paragraph 5.2.3.1.

- Analysis of market distortions generated by the difference of implementation of the safety regulations within Europe and in Europe compared to other countries, (see paragraph 4.5.2).
- Analysis of the MARS reporting system to identify potential additional incidents currently missing from the system and from which lessons can be learned, and reduce the time for reporting, (see paragraph 4.4.5).
- Creation of a specific independent European agency for investigation of accidents like the US Chemical Safety Board, which could also undertake periodic analysis of a set of indicators, (see paragraph 4.4.5).

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F-SEVESO

Final report

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Date : 29/08/2008

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7 List of annexes

- Annex 1A: Detailed analysis of the results of the surveys (on-line questionnaires)
- Annex 1B: Detailed analysis of the results of the surveys (interviews)
- Annex 2: Summary results of the questionnaires (from F-Seveso website)
- Annex 3: Notes of the interviews (validated by the interviewees)

Annex 2 and 3 are not for publication.

8 Appendix 1: Summary of the data from SPIRS

**Table 8: List of Seveso establishments, based on SPIRS data
 (as at November 2007)**

Member State	TOTAL Establishments	Lower/Upper			Industry Type	
		Lower	Upper	Not Known/not applicable Missing data	Industry Type selected	Not Known/not applicable Missing data
Germany	2286	697	801	788	391	1895
United Kingdom	1288	818	443	27	0	1288
Italy	1108	698	410	0	1108	0
France	1076	556	520	0	0	1076
Spain	508	289	211	8	463	45
Sweden	321	214	107	0	0	321
Netherlands	252	80	172	0	0	252
Poland	252	146	105	1	237	15
Finland	202	120	82	0	202	0
Romania	202	71	131	0	191	11
Belgium	187	48	139	0	93	94
Czech Republic	154	86	68	0	119	35
Austria	108	65	42	1	0	108
Hungary	106	60	46	0	106	0
Greece	83	0	83	0	81	2
Slovakia	78	33	45	0	78	0
Ireland	64	43	20	1	0	64
Norway	61	0	61	0	59	2
Portugal	54	0	54	0	54	0
Latvia	44	28	16	0	44	0
Switzerland	39	0	0	39	39	0
Estonia	28	15	13	0	12	16
Lithuania	24	12	12	0	24	0
Cyprus	11	0	11	0	0	11
Luxembourg	10	7	3	0	10	0
Malta	10	4	6	0	10	0
Bulgaria	2	0	2	0	2	0
Slovenia	NA					
Denmark	NA					
TOTAL	8558	4090	3603	865	3323	5235

In grey, data from Norway and Switzerland (not part of the European Union).

N.A.: not available.

Remarks from the table:

- a) **8 Member States (MS)** - Germany, UK, Italy, France, Spain, Sweden, the Netherlands and Poland - have 7091 (83%0 of the total population of Seveso II establishments. In this sample, a new MS, Poland, is included.
- b) All MS **report upper/lower** establishments (except approx. 1/3 of the establishments in Germany).
- c) Data regarding **Industry Types**
For the 8 Member States which are the most representative:
- we found insufficient data regarding Industry Type for:
 - o Germany,
 - o UK,
 - o Sweden,
 - o Netherlands.

 - data were available on Industry type for:
 - o Italy,
 - o France,
 - o Spain,
 - o Poland.

Table 9: Industry types more relevant considering number of Seveso establishments (based on data from Italy, Spain and Poland).

INDUSTRY TYPES	ITALY		SPAIN		POLAND		TOTAL	
	Nber	%	Nber	%	Nber	%	Nber	%
wholesale and retail storage and distribution (incl. LPG bottling & bulk distrib., ...)	526	47%	165	32%	123	49%	814	44%
general chemicals manufacture	355	32%	133	26%	23	9%	511	27%
pesticides, pharmaceuticals, other fine chemicals	27	2%	45	9%	2	1%	74	4%
metal refining and processing (includes foundries, electrochemical refining, plating, etc.)	26	2%	3	1%	6	2%	35	2%
power supply and distribution (electric, gas, etc.)	19	2%	8	2%	4	2%	31	2%
petrochemical, refining, processing	18	2%	19	4%	10	4%	47	3%
general engineering, manufacturing and assembly			24	5%	4	2%	28	1%
plastics and rubber manufacture			24	5%	5	2%	29	2%
water and sewage (collection, supply, treatment)			13	3%	7	3%	20	1%
food and drink			8	2%	9	4%	17	1%
paper manufacture, printing, publishing			7	1%	3	1%	10	1%
ceramics (bricks, pottery, glass, cement, plaster, etc.)			5	1%	6	2%	11	1%
electronics and electrical engineering			2	0%	1	0%	3	0%
shipbuilding, shipbreaking, ship repair			2	0%		0%	2	0%
handling and transportation centres (ports, etc.)			1	0%	10	4%	11	1%
medical, research, education (includes hospitals, etc.)			1	0%		0%	1	0%
timber and furniture			1	0%	1	0%	2	0%
waste treatment, disposal			1	0%		0%	1	0%
agriculture					1	0%	1	0%
textiles, clothing and footwear					2	1%	2	0%
- other -	137	12%	1	0%	20	8%	158	8%
- not known / not applicable -			45	9%	11	4%	56	3%
Missing data					4	2%	4	0%
TOTAL	1108	100%	508	100%	252	100%	1868	100%

Regarding the distribution of establishments by Industry Types, several remarks can be made:

- From the 23 Industry Types used by MAHB [MARS Technical Guideline, 2001], 10 sectors, in blue in table 2 (not considering other/not known/ not applicable/missing data) represent only 3% of the total establishments.
- Other 10 Industry Types, marked in yellow in Table 2, represent 86% of the total number of establishments.
- From those 10 Industry Types, two types, "wholesale and retail storage and distribution (incl. LPG bottling & bulk" and "general chemicals manufacture", are the ones that include a higher number of establishments.
- For some countries, it seems that the classification of the establishment between "general chemicals manufacture", "plastics and rubber manufacture" and "petrochemical, refining, processing" is not homogeneous.