ANALYSIS OF THE PRACTICES OF GOAL-BASED REGULATIONS TO CONTROL INDUSTRIAL RISKS

Discussion document for the workshop organized on 20 November in Brussels (CEN Premises)

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1. Introduction

Goal-based regulations seem to be an attractive regulatory framework both for the authorities and for industry.
It provides flexibility where the requirements cannot be totally prescribed because of the complexity of the processes or systems dealt with. It gives the industry the opportunity to define the state-of-the-art and its quick evolution in particular when innovation is a driver some industry sectors. The role of the authorities is a role of endorsement of the good/best practices and control of implementation. When a goal-based regulation is accompanied with agreed guidance documents or norms, it helps the industry operators to demonstrate to the authorities the conformity with the regulations.
An effective implementation of goal-based regulations implies therefore that strong standards or reference documents are adopted at a wide level in a given industry sector. It is particularly important in Europe to make sure that there is no distortion related to different regulatory constraints (in application of the same directive) and also no difference of treatment from one company to the other in the same industry sector. However, to reach agreement on the implementation of the regulation and achieve converging practices in a given industry sector is a difficult task, especially when there is a lack of knowledge, lack of data, uncertainty and complexity.

The control of major accident hazards, for the protection of the environment against pollutions, as well as for new risks generated by industrial innovations, is a domain where the implementation of goal-based regulations could be seen as beneficial.
The Seveso II Directive (96/82/EC) on the control of major accident hazards which defines a number of requirements for the operators of industrial sites using a certain amount of dangerous substances could be considered as a goal-based regulation even if it has not all the attributes of such a regulation in all Member States. In some Member States indeed, the transposition of the directive follows the principles of goal-based regulations and in others it is rather descriptive.

To gain knowledge and understand the level of implementation of goal-based regulations in the control of industrial risks INERIS in partnership with EU-VRi decided to launch a project and analyze the current practices in several countries and understand the difficulties faced by the authorities and the industry.
The scope of the analysis relates to the following regulations, relating to the control of industrial risks:

- Seveso Directive
- IPPC Directive
- ATEX Directive & the Parent Directive for the Occupational Health and Safety at Work.

The analysis is based on a process of sharing knowledge and information with an international panel of experts and on the organization of an international workshop.
The panel of experts selected to participate in the project constitutes the Programme Committee for the workshop.
The Programme Committee has decided to develop the present discussion document as a starting point to share information and collect suggestions for improvement to implement goal-based regulations for the control of industrial risks.

Therefore, the present discussion document provides an overview of the implementation of the regulations on the control of industrial risks, with a diagnosis of difficulties and brakes that could be overcome by a development of a goal-based regulation.
Then, the basis of goal-based regulation is presented with reference to the key principles of this approach and recommendations for implementation in some Member States.

Finally, suggestions for improvement of the current regulatory framework with goal-based regulation are proposed as a starting point for the workshop and further activities that may be undertaken after the workshop.

2. Main systems of regulations

From the European legal framework, four systems of regulation can be listed:

1. Prescriptive regulation

Some regulations or old directives are self-supporting regulations: they imposed precise and strict technical provisions to the industry operators.
The Member States must simply transpose them but the reading or interpretation is often different by the Member States and a non-harmonization of the practices is sometimes noted. The evolutions of this type of regulation are difficult and heavy to implement. The technological innovations are blocked and the industrials, who must simply respect the whole of the provisions, do not invest themselves for an evolution of the legal text.

2. "New Approach" Directives

The European Commission implemented in 1985 the principle of "New Approach", (supplemented by the Global Approach) which is a legislative technique used for free movement of goods. The ''New Approach'' is defined in a Council Resolution of May 1985 and represents an innovative way of technical harmonization.
This concept of New Approach makes it possible to harmonize the legislations of the Member States while leaving the choice to the companies of the technical means to apply them in the manufacture of their product.

a) Essential requirements

Indeed, the directives "New Approach" fix in a legal and mandatory way the essential requirements which are objectives to ensure safety and health for the people or the environment and the protection of consumer relating to the products used in the European Union. It is a question of guaranteeing safety and public interest.

The five features of "New Approach" are:

- Harmonization is limited to the essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and to circulate freely in the EU.
- Harmonized standards, worked out by European organization of standardization, are presumed to conform to the corresponding essential requirements. The reference numbers of harmonized standards are published in the Official Journal.
- These technical specifications, laid down in harmonized standards, or others technical solutions remain voluntary and manufacturers choose themselves the technical solution that provides compliance with the essential requirements.
- Manufacturers may choose between different conformity assessments procedures provided for in the applicable directive.

The process "New Approach" thus allows an acceleration of the bringing together of the various European legislations and supports the initiative of the companies by facilitating the imports and exports between the countries around one only same standard.

b) Harmonized standards

These directives "News Approach" fix the essential requirements, for which correspond of the technical specifications stated in the harmonized European standards. Therefore, this distinction makes it possible to separate the responsibilities between the European Competent Authorities and the groups from standardization while facilitating freedom of movement for goods.

These European harmonized standards are developed in all transparency and are built on a consensus between all the interested parts.

Products manufactured according to these harmonized standards profit at the time of their marketing of a presumption of conformity to the corresponding essential requirements, fixed by the regulation.

c) Global Approach: evaluation of conformity

The principle of the New Approach requires a reliable evaluation of conformity: it is the Global Approach.

Indeed, the New Approach covers the relationships to the essential technical requirements of the directives of harmonization on the one hand and the harmonized European standards. Then the Global Approach relates to the evaluation of conformity: procedures are described in the directives which an industrialist must apply to prove the conformity of his products with the requirements of the directives.

The Global Approach introduces a modular approach: the evaluation of conformity is divided into several modules which relate to the various phases of procedures of evaluation. These modules are thus evidence of the respect of conformity. These modules refer to the phase design products, of production or to both. The use of modules makes it possible to evaluate conformity. This evaluation rests on the intervention of the manufacturer or an organization notified during the phase of design and/or production. These modules are defined by industrial activity.

d) Market surveillance

Market surveillance is an essential tool for the enforcement of New Approach directives, by taking measures to check that products meet requirements of the applicable directives. Market surveillance is the responsibility of public Authority. It implies an obligation of Member states to organize and carry out market surveillance

3. IPPC Directive

The IPPC directive might be seen as an example of the implementation of a goal-based regulation.

It has an essential requirement of high level of environment protection. This Directive introduces the definition of the Best Available Techniques (BAT). The BAT seems to be the tools to reach the requirement.

The work to define the BAT into technical specifications is supervised by the JRC in SEVILLE, with many actors like representatives from industry, Member States... The final technical specification has the form the so-called BREF (=BAT reference). The BREFs are not mandatory documents but present the state-of-the-art.

The conformity assessment procedure is included into the permit. From the permit, the competent authority will then decide whether or not to authorize the activity.

The Member States are responsible for inspecting industrial installations and ensuring they comply with the Directive.

4. The Seveso Directive

The Seveso II Directive (96/82/EC) on the control of major accident hazards could be considered as a goal-based regulation to the Member States. Under the terms of the principle of subsidiarity, this policy comes under the responsibility of the Member States primarily.
Into the text of Directive there are some brief explanations of the means to reach these requirements.
These requirements are oriented for the operators of industrial sites using a certain amount of dangerous substances but they have to be transposed by the Member States.

The Members States are indeed in charge of the implementation of the Seveso Directive.
As a matter of fact, in some Member States, the transposition of the directive follows the principles of goal-based regulations and in others it is rather descriptive.
The Member States are responsible for inspecting industrial installations and ensuring they comply with the Directive.

The Annex II of the Seveso II directive defines the content of the safety report, but based on several recent studies, it seems not enough to have a homogeneous implementation in all EU countries. The implementation of the Directive varies in the Member States, as well as the control of the implementation.
Some industry sectors or industrial groups have developed their own guidance documents to try to harmonize the practices in their sector. Often this work is undertaken and coordinated by industry associations or federations.

3. Elaboration of goal-based regulations

A definition of the goal-based regulation could be as follows: "development and implementation of lawful texts which prescribe objectives and which leave the choice of the means to reach them" subject to the demonstration of the relevance of the adopted solution.
The implementation of this regulation can thus be done by various techniques while keeping the possibility of provisions of means. The competent Authority remains the principal actor while giving responsibilities to the other actors.
A directive is an example of goal-based regulation.

1. Definition of directive

A directive is a decision of Community legislation aiming at supporting the harmonization of the national legislations of the Member States of the European Union.
It forces on the Member States an objective to be reached, all in their leaving the choice as for the means of reaching that point (general laws, decrees, principles).
Contrary to the European regulations, which are binding directly to the nationals Union, the directive does not have vocation to apply directly to the companies and the private individuals, and requires a transposition. Each member state has the possibility to use or not the goal based regulation at national level for transposition.

2. Means to reach objective

The flexibility of the goal based regulation allows:

- to simplify and centre the regulation on its objectives,
- to develop jointly and by consensus with the actors themselves technical tools by the actors to check the respect of the lawful requirements. These technical tools are often a sum of knowledge coming from a whole of experts larger than that to which has accessed the competent authority.

To define technical tools for emergent or new technologies, for which it would be impossible to define regulations as requested in the traditional regulation with provisions.
These means/tools can be guidance documents or standards.

3. Definition of guidance documents

Often, the drafting of the guidance documents is carried out on the initiative of a grouping of industrials for a branch of industry. The industrials ask for sometimes the support of experts to collaborate in the drafting of the guide. The goal of these guides is to help the industrials to set up the directive/regulation. They generally do not have a legal authenticity.

Unfortunately, these guidance documents are not sufficient and additional operational documents are produced at national and/or industry level.
One means to give legal authenticity to guidance is to write an international or European standard.

4. Definition of standards

Standardization is a mode of development of technical rules, while respecting the five following principles: transparency, openness, impartiality and consensus, effectiveness and relevance, coherence.

Consensus-based standardization in Europe is the responsibility of the three European Standardization Organizations CEN, CENELEC and ETSI. The standards which result from the activity of standardization are applied on a voluntary basis. Only a regulation can make application obligatory the application of whole or part of a standard.

When the standards are approved, they become reference frames: their technical values can be endorsed and promoted by the authorities.

The standards can for example be used as:

- A reference in a regulation;
- A technical reference framework for conformance testing;
- Guidance material on how to apply standards or regulation.

Formal published standards are made available at national level. European Standards are prefixed "EN", and international standards "ISO" or "IEC" (sometimes both these prefixes apply), also with a national prefix (e.g. NF in France, BS in the UK, etc).

There are a number of different types of standards of which the following are relevant here:

- Fundamental standards: they relate to the terminology, metrology, the statistics, the symbols… (e.g. : ISO 9000)
- Standards of testing methods or of analyses: they make it possible to measure characteristics of the products, processes. They describe the methods of analyses. They make it possible to harmonize the practices between all industrials. (IN ISO 10304-1)
- Standards of specifications: they describe the characteristics of a product, a service, a process, a system and the thresholds of performance to be reached. (EN ISO 14001)
- Standards of methodologies: they are guidance documents or guidelines. (ISO/CEI 73 and ISO/CEI 51: Safety aspects - Guidelines for their inclusion in standards))

5. Links between regulation and standards/guidance

There are three possible links between standards and regulation:
The use of the standards to confer a presumption of conformity with a regulatory document:

- Creation of an articulation between the regulation and standardization,
- Use of standards identified in the regulation as a reference framework to facilitate enforcement.

This is about the principle of the "New Approach": the products manufactured in accordance with the European Standards referred to in the EU official journal, are deemed in conformity with the essential requirements of safety (and the manufacturer/importer can place the CE mark on the product). The use of these standards is however voluntary but in practice most of those placing relevant products on the market do so. The standards are made mandatory in regulatory text. To date, in France, approximately 2% of the French standards are mandatory in this way;

The standards can be guidance for market stakeholders as to how to apply regulation. This approach can prove valuable in cases where regulation is still essentially at national level and companies active across borders.

6. *Evaluation of conformity and control*

This choice of means to fulfill the requirements obliges to define into the regulation text :

- the process of evaluation of conformity and,
- the control so that the Competent Authority can make sure that the requirements were achieved.

To reach requirements needs the implementation of a policy and a complete framework for the evaluation of conformity by the Competent Authority. This evaluation can be carried out by thirds party, recognized by the competent Authority in the regulation.

This evaluation of conformity makes it possible to check the demonstration of reaching of requirements: these elements of demonstration are available for a possible control from the Administration and, in certain cases, could be subject of a approval by a third organization indicated by the Administration.

The intervention of the Administration is done by various processes:

- Designation of third organization which analyzes the demonstration of conformity, and a market surveillance with a sampling to evaluate them compared to the requirements of the regulation,
- Validation of the demonstration by the services instructors of the Competent Authority.

Moreover, unexpected controls can be carried out by the Administration which makes of it the request with its services of inspection.

The process of the New Approach might be relevant and effective for directives which do not cover products but methodology and risk assessment for the control of industrial risks.

The main steps are:

- **For the essential requirements, to define the "technical specifications" for the methodology and have them adopted into a harmonized standard or international guidance document**
- **Then, to develop a policy of evaluation of conformity,**
- **And to define a process and a structure for the "market surveillance" aspects.**

4. Current implementation of regulations related to control of industrial risks

1. Situation in Europe

In Europe, although the regulation for the control of industrial risks appears fragmented, with a lack of consistency as pointed out by international companies, it is judged effective, as proven by the F-Seveso Study.

There are new challenges due to the evolution of the economic, technological and social environments. The complexity of the industrial systems and the innovation expected in industry the urge a regulatory framework which is more flexible but with clear objectives in terms of performance.

It appears from the authority point of view a lack of resources to assure the effective control of the implementation of the regulations for the control of industrial risks.

A lot of guidance documents, norms and standards exist but they are not harmonized and endorsed by ALL authorities.
What already exists and is accepted as "good practices" is not recognized by ALL.
The attempts to develop European Reference document, such as the "Guidance on the preparation of a Safety Report" or "Guidance on Land-Use Planning" (See: http://ec.europa.eu/environment/seveso/implementation.htm) are often seen as the lowest common denominator between the practices among the Member States but do not take the best from each experience.

The analysis and feedback from several recent initiatives and projects presented in Appendix show that there is already a common basis to define the minimum requirements to control industrial risks (Seveso aspects) needed to implement a goal-based approach following the principles of the "New Approach".

Detailed guidance documents available at European level would be more beneficial for a converging implementation than the already existing national guidance documents.

The industry should play a major role in the definition and elaboration of the European guidance documents, and in particular, it might be beneficial to have these guidance documents prepared within a given industry sector by the corresponding European association or federation.

For example, in the chlorine and ammonia industry, respectively Euro Chlor (see http://www.eurochlor.org/) and the European Fertilizer Manufacturers Association (see http://www.efma.org/) have developed safety guidance documents for their members.

The European Industrial Gases Association, EIGA (see http://www.eiga.org), has prepared a guidance document to prepare a safety report for companies from the gas industry.

2. Situation in other countries

In other countries such as Canada, Japan and the USA, it appears that there is a mix of prescriptive and goal-based regulations.

In Canada, the regulation for the control of industrial risks has been developed in 2003 based on the recommendations of the CRAIM (Conseil pour la Réduction des Accidents Industriels Majeurs) and the principles of Responsible Care®.

The first round of implementation has shown that the regulation needs to be accompanied by guidance documents and explanations to the industry as well as training for authorities in charge of the control and inspections. The Canadian authorities have launched a new initiative to improve the regulation itself and prepare new guiding principles for effective implementation. It will be announced in autumn 2009.

In Japan, there is a mix of regulatory requirements and voluntary actions performed by the industry sectors. Especially, the chemical policy was heavily based on a hazard-based methodology, and it has gradually moved to a methodology in which the risk-based decision making is placed in the center. Some of the industry sectors have already proposed the framework and action plan of voluntary risk management measures.
Concerning the situation in the USA, it appears that the US regulation is very complex because there are several levels (Federal and State), it is incremental and the roles of OSHA, EPA and the LEPCs (Local Emergency Planning Committees) can vary from one State to the other.

3. An international initiative

At **international level**, it is important to notice the recent initiative from United Nations Environment Programme, Division of Technology, Industry, and Economics - Sustainable Consumption & Production Branch.
UNEP proposes a "Flexible Framework for Chemical Accident Prevention - Guidance for Governments".
In order to coordinate the development and implementation of the Flexible Framework, a UNEP Expert Working Group was created, involving selected experts and institutions in the fields of chemical safety and prevention of industrial accidents. Relevant UN agencies (UNIDO, ILO, UNECE, UNITAR, WHO etc.), the European Commission DG Environment and the Joint Research Centre, the Organisation for Economic Co-operation and Development, the Asia Disaster preparedness Centre, experts and selected countries are represented in the working group.
See:
Guidance document:
http://www.unep.fr/scp/sp/saferprod/pdf/FlexibleFramework_Guidance_270109.pdf

Brochure:
http://www.unep.fr/scp/sp/saferprod/pdf/FlexibleFramework_Brochure_April09.pdf

The guidance document defines the role and responsibility of the authorities, the industry and the public. It helps analyzing the appropriateness of the legal context and availability of the resources. The process proposed to develop a Chemical Accident Prevention Programme can be applied to all countries and context, and shows that there are activities which are the responsibility of the authorities and others that have to be defined and implemented by the operators.

This information will be completed after the workshop on 20 November 2009.

5. Implementation of goal-based regulation for the control of industrial risks: suggestions for improvement

1. Perspectives

Goal-based regulations seem to be a legal system of interest both for the Member States authorities and the industry.
However, it appear more appropriate for the regulations to come than for the existing one, because for the current legal requirements, the industry has already implemented them and supplemented with additional or specific measures which have been agreed within an industry sector or within an industry group.

On the contrary, for emergent and innovative technologies, the goal-based regulation seems to be the most capable to guarantee an effective risk control. It enables a fast adaptation of the risk controlling measures at the same pace as the evolution of scientific knowledge.

The Directives are often based on general principles but are not systematically accompanied by standards. For example, the Seveso directive is not accompanied by standards, there are some guidance documents prepared by some industry sectors.
From the implementation point of views, industry suggests to complement the Directive with an explanatory note and with examples.
The Directives might be developed with mandatory goals and an appendix describing the base of the rules to reach these goals. Then, standards or guidance documents that are effective, operational document would have to be developed, based on recommendations agreed in an industry sectors or proposed by a large industrial group. These standards or documents will constitute the essential requirements.

The outcomes of the discussion at the workshop and the suggestions for improvement collected will be used to update this document and decide for any follow-up on this issue.

2. Issues to be clarified

The Seveso II Directive is considered as a goal-based regulation but it still needs a harmonized implementation in the various Member States.
In order to help converging in the implementation according to the New Approach, the following issues have to be clarified:

Elaboration of the guidance documents:

- How to prepare them at the European level?
- How to take benefit from all guidance documents existing at national or local level?
- What should be the role of the industry: the industry branches and associations, the large companies?
- Should the technical working groups at EU level be more independent from the regulators?

Responsibility split between the authorities, the industry and the organizations involved in the preparation of the standards:

- Is it a benefit for the implementation of the regulation?
- Is it more dynamic to adapt the regulatory constraints to the technical progress?
- What is the economical impact?

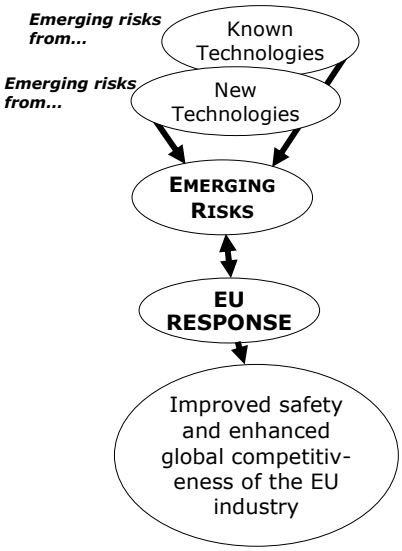
Control of the effective implementation

- How are the reference documents specified in the regulation?
- How is organized the control in practice, with companies such as notified bodies or the authorities themselves?

3. On-going initiatives

The iNTeg-Risk project is a European collaborative project entitled "Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks", see http://www.integrisk.eu-vri.eu/. The project is coordinated by EU-VRi, the European Virtual Institute for Integrated Risk Management EEIG, represented by Prof. A. Jovanovic (CEO) and O. Salvi (General Manager). This section of the paper was prepared by these two persons to explain the importance of standardization when dealing with emerging risks related to new and innovative industrial technologies.

iNTeg-Risk is a large-scale integrating project aimed at improving the management of emerging risks, related to "new technologies" in European industry. This will be achieved by building new management paradigm for emerging risks as a set of principles supported by a common language, agreed tools & methods, and Key Performance Indicators, all integrated into a single framework. The project aim is to reduce time-to-market for the lead market EU technologies and promote safety, security, environmental friendliness and social responsibility as a trademark of the EU technologies. The project will improve early recognition and monitoring of emerging risks, seek to reduce accidents caused by them (estimated 75 B€/year EU27) and decrease reaction times if major accidents involving emerging risks happen.



The "EU response" proposed by the project will be based on 17 individual applications of new technologies like nano, H2 technologies, underground storage of CO2, new materials (ERRAs - Emerging Risk Representative Applications in EU Industry).

The solutions will be generalized and the used for the framework, which will be validated in a second application cycle. Overall solution will be made available to the users in the form of the iNTeg-Risk "one-stop shop" for EU solutions addressing emerging risks. The solution will include issues of early recognition and monitoring of emerging risks, communication, **governance, pre-standardization**, education & training, dissemination, as well as new tools such as Safetypedia, Atlas of Emerging Risks, Reference Library, etc. The project involves leading EU industries and renowned R&D institutions. It is coordinated by the European Virtual Institute for Integrated Risk Management, the dedicated EEIG guaranteeing the sustainability the results after the project.

The project structure is a bottom-up one starting from the problems identified as representative, over the development of the integrated/common approach and methods, towards the "one-stop-shop" containing solutions for different groups of stakeholders: from interested citizen, over students and concerned SMEs, to the scientists at academia or researchers in industry (each of them finding the information matching their respective interests). The solutions will become European references through the procedure of CEN Workshop Agreement (CWA): 5 CWA are foreseen during the project.

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- AFNOR COP n°476: Guide relatif à la bonne utilization des norms (Juin 2009), available in French under www.industrie.gouv.fr, in *normalisation* tab.

7. Acknowledgement

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8. Appendix: Feedback from recent initiatives and projects

This appendix provides an overview of recent initiatives and projects which are food for thoughts regarding the question covered by this discussion document.

1. Shape-Risk

The Shape-Risk[1] project (http://mahb.jrc.ec.europa.eu/shaperisk) concluded that regulations related to IPPC, Seveso and ATEX need to be implemented in a more consistent way and with the support of a one-stop-shop platform to find validated (reference) documents for a converging implementation.

Extract from Shape-Risk conclusions:

Industry health, safety and environment (HSE) assessment and management generally fall in one of the following directives: IPPC, SEVESO or ATEX. However, there are cases when an overlap of directive requirements occurs, causing conflicts in directives application, while there are cases when none of the directives provide risk assessment and management guidelines. In fact, there is a need to define a leading/framework directive, i.e. a framework directive for integrated risk management.

The proposal for one directive covering all safety and environment aspects is the strongest recommendation from SHAPE-RISK consortium, related to regulatory issues. The proposed directive would be a goal-based directive using the New Approach as defined in the Council Resolution of May 1985, asking for a performance-based approach.

The main aims of the framework directive are:

- *to describe the links and interdependencies between the directives dealing with chemicals and industry production (e.g. IPPC, SEVESO, ATEX, REACH[2], GHS[3]) and put them in one common perspectives (similarly to the Water Framework Directive*

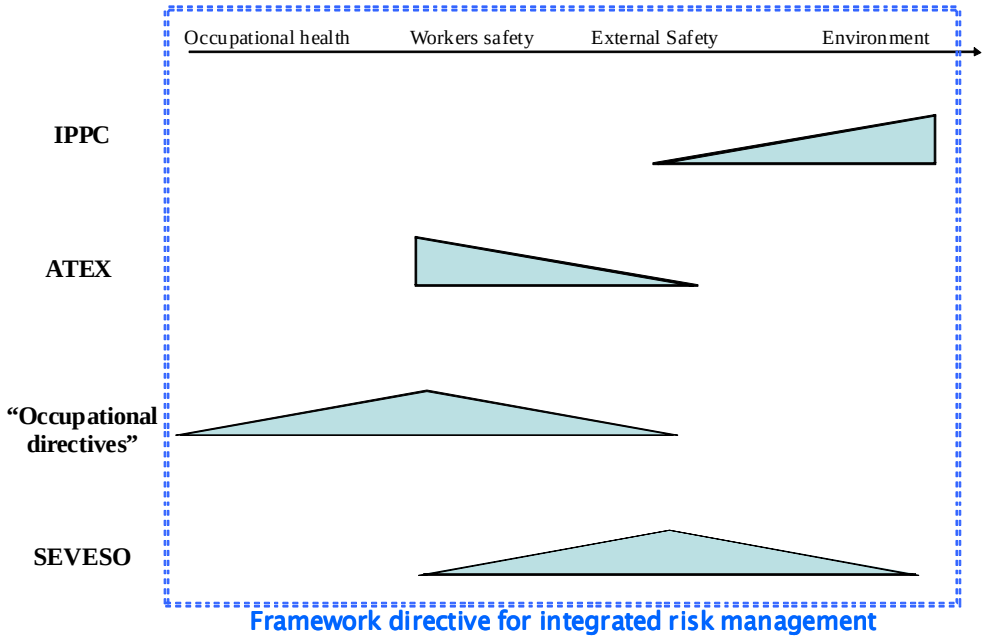
[1] SHAPE-RISK was a European project (2004-2007) structured as a network with 19 organisations providing technical support to competent authorities in charge of Seveso, IPPC and ATEX directives.

[2] Registration Evaluation Authorization of Chemicals

[3] Globally Harmonised System of Classification and Labelling of Chemicals

approach) on the basis of agreed principles and procedures, and on common definitions;

- *to create a framework for prioritization and balanced decision making between aspects covered by various directives;*
- *to extend progressively the scope of the IPPC and SEVESO directives;*
- *to improve the compatibility of the notions of industrial installations in the two directives;*
- *to improve the synergies between the two directives (e.g. include an environmental risk assessment for the abnormal and near-accidental cases);*
- *to reduce the number of legal requirements by good management systems;*
- *to define the borderline between short-time accident and long-time pollution definition, in view of duration of accidental release into environment;*
- *to define the borderline between long-time impact addressed by IPPC and short-time impact deals by SEVESO directive;*
- *to strength co-operation at national level between different authorities involved in the control of industrial sectors under the scope of both directive;*
- *to cover new and emerging risks not dealt with existing regulations/directives.*



In addition, Shape-Risk recommended the creation of a "one-stop shop" to support the converging implementation of these regulations throughout Europe. The "one-stop shop" platform will be the place to find validated information (e.g. accident occurrence, up-to-date and detailed information on "Best available techniques"), tools (e.g. risk management procedures, indicators, and models), guidelines...

Nota Bene:

For the Seveso directive, instead of a triangle, we could have a trapeze with the plateau from "workers safety", through "external safety" to "environment" to better correspond to the reality of the implementation in the EU Member States.

2. F-Seveso study

The F-Seveso study (http://www.f-seveso.eu-vri.eu) consisted in a review of implementation of the Seveso directive, with a search for improvement for the preparation of a new version. The study concluded that

Extract from the Executive Summary of the F-Seveso report:

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.

[…]

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 fulfill 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 Competent Authorities:

- *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 ATEX[4], Occupational Health and Safety[5] Directives, or, as far as implementation is 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.

Nota Bene: In 2008-2009, a second study was launched examining the effectiveness of the main requirements imposed on Public Authorities. The study was run by Environmental Resources Management (ERM) and was based on a web-based questionnaire and follow-up interviews.

Information related to both studies can be found at:
http://ec.europa.eu/environment/seveso/index.htm

3. OECD Report of Survey on the Use of Safety Documents in the Control of Major Accident Hazards

The report Ref. JT03241223 (SERIES ON CHEMICAL ACCIDENTS Number 17), published in February 2008, can be found at the following address:

http://www.oecd.org/document/41/0,3343,en_2649_34369_1889513_1_1_1_1,00.html

[4] Directive 94/9/EC on the equipment and protective systems intended for use in potentially Explosive Atmospheres
[5] 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

It is the result of a survey performed among OECD member states. The survey questionnaire was circulated to member countries in March – July 2006. Responses were received from 22 countries.

The main results of the survey are presented in the section C and D of the report and provide extremely valuable inputs regarding the implementation of a goal-based approach for the control of industrial risks. These main results can be summarized as follows:

- A lot of commonalities for the risk assessment and for the preparation of a safety report

  The information collected by OECD shows that a great majority of the OECD member states implement hazard identification based on risk analysis methods such as HAZOP and use an assessment of the consequences of major accidents. The situation varies regarding the use of probabilities and failure frequencies and the use of risk matrix or risk maps to present the results of the risk assessment.

- Guidance documents are available at national level

  The information collected by OECD shows that all countries (which took part in the survey) have the content of the safety report specified.

  The report explains that all countries (which took part in the survey) have national guidance documents for the preparation of the safety report, but at the same time, most of them do not have "templates" defining in details the content and procedure to prepare the safety report.

  NB: the Annex II of the Seveso II directive defines the content of the safety report, but it seems not enough to have a homogeneous procedure for the implementation in the EU countries.

Here is an excerpt of the overall conclusions of the report:

The overall conclusion is that the majority of OECD members operate very similar systems for the control of major accident hazards. Safety documents are widely used and their purposes are broadly similar. Documents are assessed in detail by regulators and inform subsequent intervention plans. They form the basis of operators' demonstrations that all necessary measures have been taken to prevent major accidents, or to limit the consequences for man and the environment of any accidents that do occur.
This project has provided a useful overview of the systems in operation in different member countries. However, it is difficult to draw detailed conclusions about the differences (or similarities) and a number of questions remain unanswered. To aid in the development of international best practice it may be worthwhile undertaking a further project (or projects) to look at the following issues in more detail:

(i) Content of safety documents
The information elicited by this study was not sufficient to enable detailed comparisons between safety documents from different member countries. Benefit could be gained from examining more closely the variations in style of documents, e.g. in terms of content, presentation and level of detail. Such a study could enable identification of desirable features of a safety document, including essential information and that which could be omitted without detracting from the ability of the document to make adequate demonstrations that all necessary measures have been taken for the prevention or mitigation of major accidents. A key concern of operators is that there is often a need to include information in safety documents that has previously been provided to regulators for other purposes. Approaches for reducing the requirement for such duplication could also be investigated.

(ii) Meaning of "demonstration"
One of the stated aims of this project was to investigate how member countries define the purposes of safety documents and what they consider to be adequate demonstrations that those purposes have been met. As explained above, due to the wording of question 6(c) the second part of this aim was not met. A further study to investigate the demonstration requirements imposed on operators in different member countries, and how different regulators form judgments about the adequacy of those demonstrations, is worthy of consideration. Such a study could assist in forming a view about essential and non-essential information in a safety document, as described in 15.i.

(iii) Time taken to assess safety documents
As stated in the discussion, the time taken to complete assessments of safety documents varies considerably, from under 30 days to in excess of 2 years. The reasons for this variation may be worthy of investigation as part of a further project. Differences could be due, at least in part, to differences in the nature of safety documents (which links to item 15.i), or to differences in assessment methodology and action taken to rectify deficiencies in the document (which links to item 15.ii, demonstration requirements).

(iv) Use of safety documents by operators
A further issue highlighted is that operators often have difficulty making good use of their safety documents, once produced. Bearing in mind that the production of safety documents involves a considerable investment of time and resource by operators, it would clearly be in their interests to put that investment to optimum use. A project to develop best practice in this area would require the involvement of industry representatives (operators, trade associations, etc.), as there would be a need to explore the ways in which safety documents are currently used and to share ideas. Such a project could encompass development of the "living" safety document concept. A living safety document is one that is kept up-to-date such that it continues to reflect actual conditions on site and is fully integrated into operators' safety management systems.

Two further projects will probably be required if members wish to follow up all these issues. The first could deal with some, or all, of items (i), (ii) and (iii), which are linked as described above. However, item (iv), which requires the input of industry representatives, would probably need to be treated as a project in its own right.