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Joint Research Centre and the Dutch Ministry of  
Social Affairs and Employment



## **ENFORCEMENT OF SEVESO II: AN ANALYSIS OF COMPLIANCE DRIVERS AND BARRIERS IN FIVE INDUSTRIAL SECTORS**

**KEY POINTS AND CONCLUSIONS**



Ministerie van Sociale Zaken  
en Werkgelegenheid



**Title:** Enforcement of Seveso II: An Analysis of Compliance Drivers and Barriers in Five Industrial Sectors: Key Points and Conclusions. Mutual Joint Visit for Seveso Inspections, 8-10 November 2006, The Hague, The Netherlands.

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## **Abstract**

This report describes the outcome of a workshop (the Mutual Joint Visit for Seveso Inspections) hosted by the Ministry of Social Affairs and Employment of the Netherlands in November 2006 on “enforcement in Seveso II enterprises” in particular, a subject that has never been dealt with at EU level before. The “Table of Eleven” was used as model in order to facilitate and encourage discussion. The Table of Eleven is a model based on behavioural sciences consisting of eleven dimensions, or factors, which are decisive for the level of compliance with legislation. The use of the Table of Eleven requires the definition of and focus on “target groups” and “rules”. Five specific target groups were selected: Mineral oil refineries, the pharmaceutical industry, fertilizer production, chemical batch processing, and LPG storage. Five specific rules were selected: 1) “The requirement of submitting a notification” (ref. Article 6 sub 1); 2) “Major accident scenarios” (ref. Article 9 and Annex II sub IVa); 3) “Assessment of the extent and severity of consequences” (ref. Article 9 and Annex II sub IVb); 4) “The identification of training needs” (ref. Article 7, 9 and Annex III sub c.i); and 5) “Procedures for management of change” (ref. Article 7, 9 and Annex III sub c.iv). The workshops discussions produced several interesting and useful conclusions concerning the enforceability of the Seveso Directive in general, and differences in compliance drivers in different sectors and across the Member States. On the basis of these conclusions, several recommendations were generated for European, national and inspectorate level regarding the improvement of enforcement strategies, tools and the results of the analyses performed in this workshop overall and by industry sector and by rule.

## **Disclaimer**

The main purpose of the document is to provide a collection of knowledge representing the state of practice in the EU in the expectation that it will aid Seveso inspectors and inspections programmes in reviewing and improving their performance as appropriate. It is understood that several approaches to controlling major hazards may be equally effective and the document is not offered as a definitive assessment of all possible options in this regard. Moreover, the editors note that where information is provided on a practice applied in a particular country it has been provided with the view that this might be useful descriptive information. However, the document does not intend to represent a complete description of any one country’s inspection practices since they often differ internally between regions and sometimes between competent authorities who share Seveso inspection responsibilities.

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# Enforcement of Seveso II: An Analysis of Compliance Drivers and Barriers in Five Industrial Sectors

Key Points and Conclusions

Mutual Joint Visit on Seveso Inspections  
The Netherlands, 8-10 November 2006

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## Preface

The inspection function has always been considered one of the most powerful and dynamic tools available to Member State authorities for enforcement of the Seveso II Directive. For this reason, the European Commission along with competent authorities responsible for Seveso II implementation have long held this area as a priority for EU level technical cooperation. There is a strongly shared commitment to continuing to work together to increase the effectiveness of inspection practices and to ensure a consistent approach with respect to interpreting Seveso requirements through inspections across the Member States.

The Seveso Inspections Series is intended to be a set of publications reflecting conclusions and key points from technical exchanges, research and analyses on topics relevant to the effective implementation of the inspection requirements of the Seveso II Directive. These publications are intended to facilitate the sharing of information about Member States' experiences and practices for the purpose of fostering greater effectiveness, consistency and transparency in the implementation of Article 18 of the Directive. The series is managed by the European Commission's Technical Working Group on Seveso II Inspections (TWG 2), consisting of inspectors appointed by members of the Committee of the Competent Authorities for Implementation of the Seveso II Directive (CCA) to represent Seveso inspection programmes throughout the European Union. The Technical Working Group is coordinated by the Major Accident Hazards Bureau of the European Commission's Joint Research Centre with the support of DG Environment.

This publication, "Enforcement of Seveso II: An Analysis of Compliance Drivers and Barriers in Five Industrial Sectors", is one of a series of publications that form part of the Seveso Inspections Publication Series. The publication series is one of a number of initiatives currently in place or in development to support implementation of the Directive and sponsored at EU level. In particular, a prime source of content for publications in this series is the Mutual Joint Visit (MJV) Programme for Seveso II Inspections. Launched in 1999, the European Commission's MJV Programme was intended to serve as a vehicle for promoting technical exchange among Member State Seveso II inspectors. The aim of the programme was to encourage the sharing and adoption of best practices for inspections through a system of regular information exchange. The visits would be hosted by different Member States (hence visits would be "mutual") and targeted for working inspectors of other Member States (and thereby "joint" visits) charged with assessing compliance with the Seveso II Directive in industrial installations. The MJV Programme is managed by the Major Accident Hazards Bureau in consultation with the TWG on Seveso II Inspections.

Since 2005 the MJV programme has encouraged visits focusing on topics of specific interest for Seveso inspections as identified by the Technical Working Group. To the greatest extent possible, the conclusions and observations of inspectors participating in these workshops will be published as part of the Seveso Inspections Series.

The mission of the TWG is to identify and recommend actions to promote exchange of information and collaborative research among the Member States for improving the quality and consistency of implementation of Seveso II obligations within the Seveso inspection authorities. The results of these efforts may also be published separately on the Seveso Inspections website, or combined with MJV summaries in the Seveso Inspections Series.

For more information on Seveso inspections, please visit <http://sevesoinspections.jrc.it>. This site and the MAHB website (<http://mahbsrv.jrc.it>) contain useful references to Seveso legislation, its implementation and related risk management and assessment projects.



## Executive summary

In November 2006 the Ministry of Social Affairs and Employment of the Netherlands organized the 16th Mutual Joint Visit (MJV) for Seveso Inspections. This MJV was the third “Phase 2” MJV, following two previous MJVs focused on inspections in petroleum storage (Brussels) and refinery (UK) industries. This MJV addressed the topic of “enforcement in Seveso II enterprises” in particular, a subject that has never been dealt with at EU level before. In addition to typical enforcement issues, it was expected that organization, cooperation and responsibilities of different regulatory authorities in enforcement could be important issues in EU-level discussions of this topic. The national context and/or regional differences could also enter into the discussion. The goal of the MJV was to answer the following questions:

1. What are the differences and similarities with regard to enforcement in Seveso II companies in the different Member States? The focus in this respect was on preparing information and recommendations to support more consistent compliance within the Member States.
2. What kind of intervention strategies may be applicable in the area of Seveso II enforcement? With regard to this question, the focus was on identifying proactive tools for improving compliance, such as the use of peer pressure or communication.

The MJV was prepared by a team which consisted of two members from the Ministry of Social Affairs and Employment of the Netherlands and a number of representatives from the Technical Working Group on Seveso II Inspections (TWG 2).

Prior to the MJV, a questionnaire was sent to all participants. The goal of the questionnaire was to fine-tune the programme of the MJV and to gain an informative insight into the context of Seveso enforcement within the different EU Member States. It was aimed at identifying organizational similarities and differences between Member States as well as at obtaining personal insight into the work area of colleagues abroad. This information could potentially lead to cross-pollination on particular items or ideas. The results of the questionnaire were used to divide the participants into five working groups.

During the MJV, the “Table of Eleven” was used as model in order to facilitate and encourage discussion. The Table of Eleven is a model based on behavioural sciences consisting of eleven dimensions, or factors, which are decisive for the level of compliance with legislation. The model can help map the strong and weak points of enforcement of and compliance with a specific rule. In this way, it can be used to design new and/or evaluate existing legislation. The use of the Table of Eleven requires the definition of and focus on “target groups” and “rules”.

Five specific target groups were selected:

1. Mineral oil refinery
2. Pharmaceutical industry
3. Fertilizers production
4. Batch processing and chemicals
5. LPG storage

Five specific rules were selected:

1. “The requirement of submitting a notification” (ref. Article 6 sub I);
2. “Major accident scenarios” (ref. Article 9 and Annex II sub IVa);
3. “Assessment of the extent and severity of consequences” (ref. Article 9 and Annex II sub IVb);
4. “The identification of training needs” (ref. Article 7, 9 and Annex III sub c.i);
5. “Procedures for management of change” (ref. Article 7, 9 and Annex III sub c.iv).

## Conclusions and Recommendations

The MJV led to of the following general conclusions and recommendations about Member State approaches to enforcement:

- **Except for implementation of some rules and the direct or indirect use of classical interventions, limited differences are found between Member States.** These differences seem to depend, on the one hand, on the “age” of the Member State as part of the European Union and, on the other, on cultural differences. Enforcement in “new” Member States appears to be based mainly on respect on the part of enterprises towards the authorities. The authority involved plays a relatively leading role with regard to the rules and means to be applied as well as the goals to be achieved. In “experienced” Members States, by contrast, the authority involved tends to focus on enforcement with regard to (management) processes and (common) goals rather than on the means and methods to be used. All Member States, however, deal with multiple interpretations of rules, the carrying out of joint inspections, the design of inspection methods and the required level of training and knowledge on the part of inspectors.
- **All Member States deal with multiple interpretations of rules, perform joint inspections and cope with the associated challenges of coordination and the (continuous) updating and improving of inspection methods.** Most Member States recognize the necessity of training for inspectors, the need to possess and enhance knowledge of particular enterprises or industrial processes, and the desire to exchange information and “best practices” in order to learn from equivalent European authorities.
- **Self-compliance, image and reputation are a major driver for many companies, but this aspect is not yet integrated in authorities’ enforcement strategies.** Comparing the different target groups studied, reputation and public image is an important issue for large, multinational industries with products used by the public. Enterprises having a good Environment, Health and Safety (EHS) staff with a lot of knowledge will also have a better level of compliance. This factor makes a significant contribution to spontaneous compliance and a reduction in the enforcement effort required. On an operational level, the use of sanctions on the “reputation and image” of enterprises is a possibility to stimulate compliance.

- **A challenge lies in improving the clarity and enforceability of rules, for example “hard” versus “soft” rules.** Companies having a good EHS staff with a lot of knowledge will also manifest better compliance levels. Smaller companies tend to have more problems with new, unclear rules and are more dependent on information from the authorities. “Soft” rules, i.e., where performance is usually measured in qualitative terms, for example “the identification of training needs” often have to be elaborated. There is no general, uniform elaboration of soft rules.
- **The level of knowledge and training of inspectors influences the probability of inspection and the probability of violations being detected during inspections.** A profile of industrial expertise and adequate competence is required for inspectors to be recognized as counterparts for industry. In particular it is recommended to have multinational enterprises inspected and their compliance enforced by experienced inspectors.
- **Information exchange between inspectors both at national and European level is a mechanism for keeping inspectors and inspection programmes informed about good inspection and safety practices.** Modern communication tools can be exploited to overcome the challenge of effecting an exchange of experiences and good practices between Member States. Moreover, MJVs have a important added value in terms of their ability to provide an inventory of common problems relating to Seveso regulations and as a forum for discussing potential solutions. The exchange of information between Member States can be stimulated in a number of ways, for example, by development of appropriate websites, elaboration of a high quality Frequently Asked Questions (FAQ) document, the provision of guidance on good practices of other Member States and actively informing all parties involved.
- **On a European level, it was recommended that the enforceability of legislation should be a subject which legislators take into account.** Within this recommendation the following key points were also underlined:
  - Experienced inspectors and industrial representatives can be of great value in the legislative process due to their specialised knowledge and experience and kept informed, they can also help to secure greater public support.
  - A lack of consistency of Member State enforcement standards and practices continues also to undermine enforceability. Inconsistencies could be mitigated

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<sup>1</sup> In this document the terms “hard” and “soft” rules refer to obligations in terms of the ease with which performance of the obligation can be observed and measured. Compliance with hard rules can generally be measured objectively, for example, through quantitative methods or comparison with clear and widely accepted standards. In contrast soft rules are defined by the absence of an objective standard to which performance can be compared. Sometimes the qualitative nature of a rule makes compliance particularly hard to define but performance measures and specialized verification methods can sometimes be developed to overcome this problem.

through agreement on or development of common technical references, for example:

- Guidance documents pertaining to the “soft”, that is qualitative, parts of the applicable legislation could aid in reducing differences.
- Promoting ISO certification of safety management systems could also reduce inconsistencies in the interpretation of this particular requirement.
- Standard inspection methods at international level could be established and adapted for national and local use. .

▪ **Effective enforcement is often hampered by national level challenges, such as resource limitations and lack of clear criteria for enforcing soft rules.**

Enforceability of legislation is critical in terms of preventing enforcement problems at the source. Implementation of European Union Directives is sometimes fragmented and “cluttered” with other rules because of existing legislation on the subject. Moreover, maintaining an inspections programme empowered with an adequate budget and competent staff to enforce the Directive is essential. In line with these concepts, the MJV made the following specific suggestions:

- National authorities should make as much use of European Union guidelines as possible when implementing, explaining and interpreting the new rules.
- Certification – after examination – of inspectors is an option. Some of the inspectorates are already certified according to ISO 9000. Certification (of inspectors or companies) might help in raising the importance of training and qualified inspectors. Some countries (e.g. England) already have certification systems and certificates for inspectors; a new certificate (“within other certificates”) may create chaos.
- The quality of inspection services may also be improved by setting national minimum requirements for inspectors with regard to knowledge and experience.
- The inspectorates should have adequate capacity, methods and knowledge to perform effective physical inspections.

▪ **Understanding the typical compliance profiles of different industrial sectors may also assist inspectorates in developing more effective enforcement strategies, for example:**

- Public perception and company concerns about reputation should be factored into enforcement strategies and sanctioning.
- Multinational companies should be inspected by experienced inspectors. It is important for all inspections that the inspectors carrying them out have a thorough understanding of what it is they are inspecting.



# I. Introduction

In November 2006 the Ministry of Social Affairs and Employment of the Netherlands organized the 16th Mutual Joint Visit (MJV) for Seveso II inspectors. This MJV was the third “Phase 2” MJV following two previous MJVs focused on inspections in petroleum storage (Brussels) and refinery (UK) industries. This Dutch MJV addressed the topic of “enforcement in Seveso II enterprises” in particular, a subject that has never been dealt with at the EU level before. In addition to typical enforcement issues, it was expected that organization, cooperation and responsibilities of different regulatory authorities (e.g. those which issue environmental permits, fire brigades) in enforcement could be potentially important issues in EU-level discussions of this topic. The national context and/or regional differences could also enter into the discussion.

## I.1 Importance of enforcement for Seveso II

In her opening speech at the MJV, the Director-General of the Ministry of Social Affairs and Employment, Ms Hilgersom, formulated the importance of the subject as follows:

“Chances of a major accident are small compared to accident rates in other industrial fields. However, if an accident happens, the consequences are huge and shocking. We have all seen the smoke plume of Buncefield on television or in the newspaper, the crater of Toulouse and the devastation in Enschede in the Netherlands, where a fireworks factory exploded 6 years ago. Often lives are lost or people are seriously injured, not only on the industrial site itself, but also in the surrounding area. The environment may sustain heavy damage, and material costs often run into millions of euros. The impact of these kinds of accidents on society is enormous.

Fortunately, most of the time, the chain of risk control works and accidents are effectively prevented. But we constantly have to be alert. And here also lies a danger: how to keep your attention and the operator’s attention continuously focused, even after a year of no reportable incidents? Or after two years?

It is the belief that the key to the solution is to always keep optimizing all processes that ensures safety. Do not waste resources on strategies that are not effective, but always keep asking questions: do I achieve the desired effect? Can it be done in a more effective way? This is not only valid for the operator, but also for the way authorities perform their part within the framework of Seveso II legislation. Everyone agrees that the operator should take effective measures to ensure safety in his plant and that he should always check whether the measures taken are indeed effective. It is therefore not unreasonable to ask the same kind of effort from the authorities. Are the Seveso inspectors also effective in their enforcement strategy?

When talking about enforcement strategies, the broadest sense of the word is meant. The classical way of enforcement, for instance by financial penalties or prosecution, should of course always be available if the situation requires. But perhaps different, “softer”<sup>2</sup> enforcement strategies, such as using and promoting industries’ own codes and standards or clarification of the legislation’s requirements, could be even more effective.

On the other hand, it is crucial for the authorities to determine the core Articles in the Seveso II regulations, the level of compliance with these Articles which may be deemed acceptable, and what the actual level of compliance is in the industry concerned. These are the tasks that must be faced on the way to effective enforcement.

The MJV is intended to stimulate participants to find new ways for providing better safety in the major hazard industry and to exchange good practices. There will be differences between the EU countries. Some of the participants have been used to similar legislation for several years, others are relatively new to the Seveso II approach. The intention is to combine strengths: using the benefits of both the experienced and the fresh approach. It is also interesting to know the similarities and shared problems of all participants regarding enforcement.

The great challenge will be to find new and creative ways to keep all people involved focused on the continuous danger, even when safety has reached a fairly high level.”

## 1.2 Goal

The goal of the MJV was to answer the following questions:

1. *What are the differences and similarities with regard to enforcement in Seveso II companies in the different Member States?*

The focus was on preparing information and recommendations to support more consistent compliance within the Member States.

2. *What kind of intervention strategies may be applicable in the area of Seveso II enforcement?*

With regard to this question, the focus was on identifying proactive tools for improving compliance, such as the use of peer pressure or communication.

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<sup>2</sup> “Soft” enforcement strategies refer to indirect methods that an authority can use to improve compliance such as the provision of clear criteria and guidance, establishment of merit programs, or the threat of bad publicity. By contrast, “hard” enforcement strategies consist of the usual punitive measures as defined by the law, such as warning letters, fines and injunctions.



### 1.3 Organization and programme

The MJV was prepared by a team which consisted of two members from the Ministry of Social Affairs and Employment of the Netherlands and a number of representatives from the Technical Working Group on Seveso II Inspections (TWG 2). A facilitation team supported this preparation team.

In the preparation process, the goals for the MJV were set and the tools to achieve these goals were chosen. For fine-tuning the MJV programme and to gain an informative insight into the background of participants and differences in organization of Seveso enforcement within the Member States, a questionnaire was sent to all participants prior to the MJV.

To target and promote discussions among the participants during the MJV, the “Table of Eleven” tool was used. This is a behaviour analysis model used to obtain a picture of the motives for compliance or non-compliance with a *specific rule* in a *specific target group*. The Table of Eleven consists of eleven dimensions which together play a decisive role in determining the extent to which compliance with rules is achieved. The dimensions can be used to assess whether it is possible to enforce and comply with existing legislation. More information on the model is given in section 3.2 and Annex 5 of this report. The usability of the Table of Eleven to facilitate discussions was evaluated during the MJV. The results of this evaluation are reported in Annex 6.

The 3-day programme of the MJV is given in Annex 1. The participants, listed in Annex 2, represented 18 Member States, Croatia as candidate country and Norway. The group was divided into 5 working groups, each with a chairperson and a secretary. To support the discussions in working groups, a number of industrial representatives and/or technical advisors were assigned to each group. During the MJV, some adjustments were made in close consultation with the working group chairpersons. Finally, the working groups presented their conclusions and a plenary discussion was held to draw more general conclusions. In addition, the draft version of the report was distributed to the participants.

## **I.4 Contents of this report**

The results and minutes of the MJV are given in this report.

- Description of applied methods and working groups
- Results of the questionnaire
- Results of working group discussions specified per
  - Target group
  - Rule discussed
  - Intervention strategy
- General conclusions
- Recommendations on European, national and inspector level

Several Annexes have been attached.

- 1: the programme
- 2: a list of participants
- 3: a list of the working groups
- 4: the model questionnaire
- 5: details of the Table of Eleven
- 6: evaluation results on the usefulness of the Table of Eleven
- 7-II: the results of the five working groups

## 2. Methods and structure

In this chapter, the methods, tools and structure of the MJV are elaborated upon. In particular these were the questionnaire that was sent to all participants prior to the MJV, the “Table of Eleven” as a discussion tool and basis of methodological analyses, and the “working groups, target groups and rules” organizing principle to provide structure and focus for the discussions conducted.

### 2.1 The questionnaire

Prior to the MJV, a questionnaire was sent to all participants. The goal of the questionnaire was to fine-tune the programme of the MJV and to gain an informative insight into the context of Seveso enforcement within the different EU Member States. It was aimed at identifying organizational similarities and differences between Member States as well as at obtaining personal insight into the work area of colleagues abroad. This information could potentially lead to cross-pollination on particular items or ideas. The results of the questionnaire were used to divide the participants into five working groups.

The questionnaire, given in Annex 4, consists of 6 main questions:

1. Which authority is primarily responsible?
2. Who are the other competent authorities?
3. How are authorities organized and coordinated?
4. What are the prime responsibilities of competent authorities?
5. How is the Seveso II Directive implemented?
6. What is the knowledge and experience of participants?

The results of the questionnaire are reported in section 3.1 of this report.

### 2.2 The Table of Eleven

The government wants to effect changes in society by influencing the behaviour of citizens and businesses. One of the policy tools that the government can use to achieve this aim is legislation. With the aid of rules, the government can create limits as to what citizens and businesses can and cannot do. Legislation, however, also assumes some level of compliance on the part of the target group. Non-compliance decreases the chance of realizing the policy objective. Moreover, legislation is also meant to be complied with: compliance maintains the legal nature of society and non-compliance affects that nature.

In 1994, the Dutch Ministry of Justice studied the possibility of periodically monitoring the level of compliance with legislation. It was during this project that the Table of Eleven came into being.

Within the Dutch government, legislators, policymakers and enforcers now broadly use this method.

The Table of Eleven is a model based on behavioral sciences consisting of eleven dimensions, or factors, which are decisive for the level of compliance with legislation. The model can help map the strong and weak points of enforcement of and compliance with a specific rule. In this way, it can be used to design new and/or evaluate existing legislation.

When analyzing compliance behavior with the aid of the Table of Eleven, it is important to have a clear idea of the target group and the legislation to be tested. The term “target group” refers to the persons or organizations (businesses) that must abide by a given set of rules. The legislation to be tested, however, may be applicable to several target groups. For the practicability of a Table of Eleven analysis, it is recommended that users opt for one target group and one or more “core violations” of the legislation to be tested. Core violations are understood to mean violations which have a bearing on the heart of the legislation concerned and which may undermine the policy objective of the Act if they occur on a large scale.

The Table of Eleven comprises eleven dimensions to assess compliance with legislation. These dimensions are divided into two groups:

1. Spontaneous compliance dimension group:  
Factors contributing to spontaneous compliance without any governmental pressure or activities like inspection. These factors are:
  - Knowledge of the rule(s)
  - Advantages/disadvantages of (non-)compliance
  - Degree of acceptance of the rule
  - Faithfulness of the target group
  - Non-official control
2. Enforcement dimension group:  
Enforcement-activity factors contributing to compliance with the rule. These factors are:
  - Risk of being reported
  - Risk of inspection
  - Risk of detection of non-compliance
  - Selectivity of inspections
  - Risk of a sanction being imposed
  - Severity of the sanction

The choice for this divisionThis structure was selected was made because it is easiest to recognize shows how different drivers can be viewed from the perspective of the groups from the perspectives of compliance and enforcement. Here, “enforcement” means any government activity aimed at encouraging compliance with legislation.

With the Table of Eleven idea, the user applies the broad definition of the enforcement concept, which does not only relate to the government carrying out inspections and imposing sanctions (enforcement in the restricted sense). Other activities, such as providing information and organizing informal control structures are named in the Table of Eleven. They directly anticipate the spontaneous compliance dimensions and are therefore very important for the purpose of preventative enforcement.

In the Dutch version of the Table of Eleven, a list of possible interventions for each of the eleven dimensions is given. Although this list only applies to the Dutch cultural situation, it can also be used for the discussion about intervention strategies.

A full description of the Table of Eleven method is given in Annex 5.

## **2.3 Working groups**

When using the Table of Eleven to discuss and evaluate the enforcement of Seveso II legislation, the discussions should focus on specific target groups and specific rules. The organization of the working groups is explained in this section.

### **2.3.1 Specific target groups**

For the working group discussions based on the Table of Eleven, the specific target groups were defined as groups of businesses with similar characteristics.

In total, five specific target groups were selected with differences in “maturity”, size and culture:

1. Mineral oil refinery
2. Pharmaceutical industry
3. Fertilizers production
4. Batch processing and chemicals
5. LPG storage

The preparation team of the MJV expected clear differences in enforcement between these selected groups of businesses. Each working group of the MJV discussed only one specific target group. To facilitate and enrich the discussion, the working groups were free to further define the target group (e.g. upper/lower-tier site, multinational company, number of employees). The definition of the target groups is given in the report of each working group. The full reports are attached as Annexes 7-11.

Each working group had a chairperson to lead the discussions and a secretary to make notes,

facilitate the discussion and prepare the working group report. If possible, an industrial representative and/or a technical advisor with knowledge of the target group was also assigned to the working group. The composition of the working groups is shown in Annex 3.

### 2.3.2 Specific rules

The Seveso II Directive consists of different kinds of rules at both the organizational (safety management system) and technical (calculation, technical measures) level as well as specific rules on what and how to report to the authorities. The preparation team of the MJV selected five specific, enforcement-related rules on which the discussions within the working groups were to focus.

The rules selected were:

1. “The requirement of submitting a notification” (ref. Article 6 sub I);
2. “Major accident scenarios” (ref. Article 9 and Annex II sub IVa);
3. “Assessment of the extent and severity of consequences” (ref. Article 9 and Annex II sub IVb);
4. “The identification of training needs” (ref. Article 7, 9 and Annex III sub c.i);
5. “Procedures for management of change” (ref. Article 7, 9 and Annex III sub c.iv).

In the working group sessions during the MJV, each working group had to address at least two of the pre-selected rules. Depending on the time remaining, a choice could then be made to discuss one of the other pre-selected rules or, if agreed by the group, another equally relevant rule.

To make sure each pre-selected rule was discussed at least once by one of the groups, the following discussion sequence was imposed:

Working group	Specific rules sequence					
	Compulsory		Voluntary			
1. Mineral oil refinery	1	2	3	4	5	Case
2. Pharmaceutical industry	5	1	2	3	4	Case
3. Fertilizers production	4	5	1	2	3	Case
4. Batch processing	3	4	5	1	2	Case
5. LPG storage	2	3	4	5	1	Case

### 2.3.3 Intervention strategies

One of the goals of this MJV was to gather information and ideas about intervention strategies for the areas in which compliance with the rules is weak. These intervention strategies could vary from classic enforcement strategies to “softer” intervention tools. Discussion was launched with the help of the intervention strategy list of the Table of Eleven. Ideas to improve the weak points as identified in the working group discussions were then gathered. The type and effectiveness of intervention strategies could vary between Member States. A collective review and exchange of the results of the working group discussions, in a plenary session at the end of the meeting, also resulted in some general recommendations for improvement of Seveso enforcement in the EU as a whole.





## 3. Results

The results of the MJV on enforcement of Seveso II are summarized in this chapter. The first part reports the findings of the questionnaire, followed by a description of the working group discussion results.

### 3.1 Questionnaire

Prior to the MJV, participants from 18 Member States, Norway and Croatia, i.e. ,about 90% of the possible total, sent completed questionnaires to the preparation team of the MJV. The results of these questionnaires were analyzed per question.

#### 1. Which authority is primarily responsible?

In eight (40%) of the participating EU Member States, the Ministry of Environment (including Spatial Planning, Environment, Housing and Environmental Protection) is primarily responsible for the enforcement of Seveso II.

In the other twelve participating States (60%), the authority primarily responsible for Seveso II implementation was indicated as being:

- 2x Ministry of Social Affairs/Employment
- 1x Ministry of Interior (Disaster Management, Civil Protection and Emergency Planning)
- 1x State Fire Service
- 2x Ministry of Trade and Industry/Economy
- 3x HSE Executive/HSE Authority/ Industrial Safety Directorate
- 1x Ministry of Local Defence
- 1x Ministry of Justice and Police
- 1x Local Government and Regional Development

#### 2. Who are the other competent authorities?

The primarily responsible authority communicates with, on average, 4 to 5 other competent authorities.

The competent authorities identified as cooperating most in joint enforcement were noted as follows:

- All: Local authorities (counties, municipalities, etc)
- 65% Ministry of Social Affairs/Employment
- 55% Ministry of Interior/Civil Protection/Emergency Planning
- 50% State Fire Service, Fire & Rescue Services Agency

- 45% Ministry of Spatial Planning/Environment/Environmental Protection (Agency)
- 10% Safety /Security organization
- 5% Police
- 5% Port authorities

For particular industries or risks, some Member States also cooperate with dedicated authorities or groups:

- Petroleum Safety Authority (Norway)
- Explosives and Pipelines (Belgium)
- Seveso Experts' Group (Austria)
- Hungarian Trade Licensing Office (Hungary)

### **3. How are authorities organized and coordinated?**

All participating Member States have a coordinating competent authority (supervisory/HSE). 50% of the participating Member States have dedicated authorities for particular industries or risks:

- Petroleum Safety Authority (Norway)
- Explosives and Pipelines (Belgium)
- Seveso Experts' Group (Austria)
- Hungarian Trade Licensing Office (Hungary)
- Regional Technical Committee
- Industrial Safety Group

### **4. What are the prime responsibilities of competent authorities?**

Primary responsibilities at national level (or delegated to local/regional level) are:

- Implementation
- Supervision
- Coordination
- Providing guidance
- Preparation of the inspection plan (at strategic level)

Responsibilities of local authorities or regional offices (of national authorities) are generally:

- Coordination of (joint) inspections
- Issuing permits
- Enforcement (on tactical, operational level)

In some Member States coordination is also managed at national level; for upper-tier establishments, for example.

In most inspection teams, team members are responsible solely for the inspection activities

within their respective scope of authority, such as:

- Occupational Health and Safety
- External Safety
- Environment (including Emissions/Waste/Water)
- Fire, Emergency, Rescue or Disaster authority/teams

Some countries have inspectors with combined tasks (some or all of the above functions and tasks in one person).

At local level, the assessment manager (lead local or regional authority) communicates to the public, internal authorities and with the enterprises. This manager also may coordinate joint inspections and other related tasks, including:

- Identification and examination of enterprises and activities
- Preparation (local or regional) of the inspection plan
- Assignment and assessment by dedicated teams of specialists
- Joint conclusion and summary report

Only in Denmark are the police involved in preparation of external emergency plans for upper-tier establishments and providing information to the public.

## 5. How is the Seveso II Directive implemented?

Implementing European Directives in national legislation can be accomplished in several ways. Member States are free to choose the way they wish to implement them. Their choice often depends to a significant extent on the existing legislation surrounding the topic and the historical distribution of responsibilities between different competent authorities at both national and local level. For this question, respondents indicated that the Seveso Directive had been transposed into national legislation in the following ways:

- |   |     |
|---|-----|
| • As part of broader (environmental) permitting legislation | 6x  |
| • As stand-alone legislation                                | 19x |
| • Other   | 3x  |

The Netherlands and Belgium indicated that all three answers are applicable, for example:<sup>3</sup>

- Belgium: Some topics were implemented in environmental legislation (e.g. Quantitative Risk Assessment (QRA) in a separate safety report, apart from the safety report resulting from Seveso II).

<sup>3</sup> It is possible that other surveyed countries may have used more than one legislative mechanism to transpose certain aspects of Seveso. However, we assume that the majority of responses reflected the *predominant* mode used to transpose requirements at national level.

- Belgium: Particular aspects of emergency planning are implemented in general law and taxation (e.g. “the polluter pays” principle)
- Netherlands: Local planning procedures and applications

## 6. What is the knowledge and experience of participants?

According to the responses, Seveso-related knowledge and the actual tasks of the participants generally belonged to one or more of the following categories:

- (Field) Inspection and Enforcement (19)<sup>4</sup>
- Direct, lead, coordinate, draft, implement, transpose (12)
- Training, guidance, support to local inspectorates, advising (6)
- Evaluation of risks/effects/domino effects/accident investigation (5)
- Preparation of permits (4)

The experience with Seveso within the group varied from “wish to learn” (new Member States) to profound knowledge and very experienced participants.

## 3.2 Results from discussion on target groups

This section sets forth the specific characteristics for the target groups studied. Each working group produced an individual report containing the detailed outcomes of their discussions. The three main discussion approaches (target group, specific rule, intervention strategy) were used to order these results and draw conclusions. The results on the usability of the Table of Eleven are attached as Annex 6. The details of all the discussions can be found in Annexes 7-11, where all working group reports are also included.

### 3.2.1 Mineral oil refineries

The target group of mineral refineries is a fairly clearly specified group of companies. The working group chose not to look at the related petrochemical industry and storage of crude materials. Most, maybe even all, refineries are upper-tier Seveso companies and there are approximately 5-6 sites in each Member State.

#### General compliance

The image with respect to compliance on the part of this target group was described as “very green”, meaning that, in general, refineries do comply with the Seveso II rules. They tend to do so spontaneously. Little governmental enforcement activity is therefore needed to make them comply with the rules.

<sup>4</sup> The figures in parentheses specify the number of responses in this category.

## Reputation

Public perception and reputation are very important issues for the refinery target group. Refineries are large establishments and cannot “hide” from the authorities and the public. In some cases, the refineries are very active in cooperating with the government and communicating with the public. They want to have the image of being the best. In the case of non-conformities, the reputation-related effects of sanctions are greater than the financial ones.

## Member State differences

The international organization of most refineries ensures that there are no big differences between the way refineries operate within the Member States. In addition, the way refineries are approached by the different authorities is quite similar in the different Member States. Moreover, in the Eastern European countries, there tends to be a high respect for governmental regulations. In Western European countries, refineries are active in influencing the national implementation and interpretation of the regulations.

## Knowledge

The refinery industry can afford to retain high-quality staff with a marked proficiency in keeping the regulator at a distance and interpreting the rules in line with business objectives. Existing management systems, company standards and internal auditing have a strong influence on compliance because they already more or less incorporate most Seveso rules anyway.

The refinery industry’s respect for the authorities can be earned by a demonstration of competence and knowledge on the part of the inspector. It is therefore very important that the authority assigns experienced inspectors to this target group in order to maximize cooperation and the detection of non-conformities (In particular, the inspector must be able to resist being intimidated by the experts on the refinery staff and focus on looking for non-conformities.). The technical details of the refinery are very complex and often resemble the proverbial “black box”. In addition, the knowledge and strengths of technical and legal staff at the refinery can also be quite formidable. Hence, inspectors need equally strong enforcement power (and knowledge about how to use it) in order to be effective in confronting the operator with non-conformities. On the other hand, the refinery’s Health, Safety and Environment (HSE) manager may sometimes ask the inspector to issue a non-compliance notice in order to convince his superiors to allocate money for improvement measures.

## 3.2.2 Pharmaceutical industry

Unlike refineries, operations in the pharmaceutical industry vary considerably in terms of size. Pharmaceutical sites can be small, medium or large, consisting of both upper and lower-tier sites. In order to provide good focus for the discussions, the pharmaceutical industry working

group chose to discuss medium-size, international and upper-tier companies. It was also noted that some Member States have a very small pharmaceutical industry (only one operation or company) and others have no pharmaceutical industry at all.

### **General compliance**

In general, the pharmaceutical industry tends to comply rather easily with Seveso requirements. Production is generally conducted in accordance with Good Manufacturing Practice (GMP). GMP is a worldwide standard for the control and management of manufacturing and the quality-control testing of pharmaceutical products. Quality and good hygiene are critical production concerns and practices supporting these core production values are well aligned with good health and safety practices.

### **Reputation**

The pharmaceutical industry guards its reputation as a “good actor” vigilantly. The industry wants the public to buy its products and to be a good “citizen” and employer. This attitude provides strong motivation to ensure good compliance with Seveso rules. The industry is aware of the risks associated with producing very active substances and the health problems these can potentially cause when released in large quantities. In most cases concern for reputation stimulates spontaneous compliance with the rules. In addition, if a company recognizes that implementation of a specific rule benefits other objectives of the organization (e.g. Good Manufacturing Practice), the rule will be more easily implemented. Despite its high motivation, the industry can run into difficulties with “unclear” rules, that is, when it is not clear how the rule applies specifically to pharmaceutical operations. Enforcement activities are therefore more relevant and needed for unclear rules than for others.

### **Other aspects**

The unloading and storage of solvents is the usual reason that the scope of Seveso regulations becomes applicable in the pharmaceutical industry. The quantity of manufactured substances may also “activate” Seveso regulations but companies often find ways of keeping the quantities of these substances under the Seveso thresholds. This target group was also notable for Seveso implementation challenges associated with identifying and classifying hazards associated with intermediate products and “exotic” (i.e. not widely used) substances. Identifying the dangerous characteristics that should be notified according to the notification rule and addressed in the safety report can be a complex task. (Often, the “summation rule” in Annex I, Part 2 of the Directive must be applied, which can involve the painstaking addition of several small quantities of substances.)

### 3.2.3 Fertilizers production

The fertilizer industry is a target group with a long history and rather conventional production techniques. Changes in production methods tend to evolve over long periods of time. Products of this industry can vary from harmless to very dangerous, and as the accident of 21 September 2001 in Toulouse, France, demonstrated, on-site risk management plans should recognize and address the potential presence of quantities of rejected or non-conforming (“off-spec”) products. In addition, the presence of ammonium nitrate in large quantities on some of these sites poses a potential security concern. The working group centred its discussions on a site with international production and storage operations that uses ammonia and methanol and also produces urea, a common profile for Seveso sites in this sector.

#### General compliance

Discussions for this target group focused solely on “soft” rules<sup>5</sup> mainly taken from the safety management system requirement. It was concluded that compliance with soft rules is not particularly spontaneous in this target group. In general, violations of soft rules may be hard to identify and prove. Moreover, in this target group compliance with technical rules is perceived as more important than compliance with safety management system rules.

#### Reputation

Reputation is not the highest priority issue for this sector. The perceived added value of the rule, in addition to the risk of detection and sanctioning by the authorities if violated, are factors that have a strong influence on operator compliance with soft rules. Experience with this sector indicates that, generally, operators do not value legal compliance with soft rules very highly.

### 3.2.4 Batch processing

The batch-processing sector consists of a wide variety of companies. Establishments vary widely in terms of the types and number of products they produce, the substances they handle, process complexity, organizational structure and scale of operation. The processes can vary from simple to highly complex. The dynamics of change are particularly relevant for this group, especially the effect of changes in site ownership. Smaller companies tend to be mostly independent, larger companies are often part of an international organization. The larger international corporations were chosen as the specific target group for the working group discussions on

<sup>5</sup> In this document the terms “hard” and “soft” rules refer to obligations in terms of the ease with which performance of the obligation can be observed and measured. Compliance with hard rules can generally be measured objectively, for example, through quantitative methods or comparison with clear and widely accepted standards. In contrast soft rules are defined by the absence of an objective standard to which performance can be compared. Sometimes the qualitative nature of a rule makes compliance particularly hard to define but performance measures and specialized verification methods can sometimes be developed to overcome this problem.

this MJV. Unfortunately, the working group did not include an industrial representative who could have provided an additional perspective from the side of the operators.

### **General compliance**

In general, the working group agreed that this sector has a positive compliance attitude, which means that the majority of companies spontaneously comply with the rules. The level of compliance can vary somewhat according to the operator's acceptance of the particular objective of a rule, the effort it requires to implement it, and the economic factors and knowledge involved.

### **3.2.5 LPG storage**

LPG storage companies engage in very different types of activities, including the storage and filling of aerosol applications. LPG storage itself is a rather simple process. Some competent Seveso authorities also inspect smaller LPG sites, even below lower-tier thresholds. For example, Ireland and Finland inspect sites that store amounts of liquefied petroleum gasses in excess of 5 tons.

The LPG sector, and specifically the larger companies and multinationals, is very familiar with safety regulations, as safety standards in this sector were established decades ago. Consequently, rules established by this sector itself are often more readily accepted than rules set by the authorities. Nonetheless, compliance levels for technical rules appear to be fairly high. Very small companies may be less knowledgeable about safety but may adopt rules set by the authorities with less resistance than the large organizations.

For purposes of discussion, the target group was defined as consisting of locally or regionally operating companies, with a particular focus on (un)loading operations. The filling of cylinders and a number of other special activities were by and large excluded from the discussion.

### **General compliance**

The LPG sector is not a proactive sector, but slow and resistant to change. The clarity of rules and economic considerations influence the degree to which specific requirements are implemented. Many operators seem to aim at achieving no more than the minimum requested by the authorities, and usually it requires considerable effort to effect a change. On the other hand, multinationals are often more proactive, because they establish and adhere to their own worldwide standards.

### **Reputation**

Image is not a very important driver for the LPG sector. Reputation in relation to safety is perceived in different ways. In particular, safety at the site is not particularly affected by public



opinion. However, when LPG is used as an energy source in the domestic sphere and an accident occurs, the public can be very sceptical about the LPG sector.

## Knowledge

The level of safety-related knowledge in this sector is higher among multinational companies than at smaller, local or regional operations. The latter companies are often forced to outsource expertise to consultants due to limited in-house capacity. Compliance levels have improved considerably since the early days of Seveso II implementation. Today, operators as well as authorities have much more experience and knowledge of the requirements and how to fulfil them. In addition, companies have a better understanding of the enforcement structure and what to expect, which (positively or negatively) influences compliance levels.

## 3.3 Results from discussion on specific rules

The five specific Seveso rules mentioned in section 3.3.2 were discussed in the different working groups with the help of the eleven factors in the Table of Eleven. The actual rules and cases that were discussed are listed in the following table.

Working group	Rules discussed			
	1	2	5	
1. Mineral oil refinery	1	2	5	
2. Pharmaceutical industry	5	1	2	
3. Fertilizers production	4	5		
4. Batch processing	3	4		
5. LPG storage	2	3	X	Y

The LPG storage working group discussed a number of additional rules:

X = Safety management system, operational control element (Seveso Art. 7, 9 and Annex III sub c.iii).

Y = ATEX<sup>6</sup> at LPG storage, including cylinder filling.

### 3.3.1 Submitting a notification (rule I)

#### General

The rule of submitting a notification was discussed for two target groups in working groups 1 and 2. Both target groups have motivation to spontaneously comply with this administrative rule.

<sup>6</sup> Directive 94/9/EEC Equipment and Protective systems intended for use in Potentially Explosive Atmospheres (ATEX)

## Strengths

- Submitting a notification is a low-cost action and is therefore easily accepted by operators within the sectors who are aware that they handle dangerous substances and are conscious of their responsibility. Also, this rule has a high risk of detection, which stimulates compliance even more. Most of these companies are accustomed to complying with similar rules and do not object to submitting the notification. Non or partial compliance can occur when a company views the rule as an annoying administrative burden, unnecessarily duplicating work that has already been done, i.e., the government has already received the information in some shape or form on the basis of other regulatory requirements.
- Some sites, which already dealt with Seveso I requirements, are not fully aware of this new requirement in Seveso II, and may sometimes fail to notify or properly notify the authorities for this reason. New Member States do not have this problem.
- Compliance and non-compliance with this rule is relatively easy to assess as long as sites that fall within the scope of the Seveso II Directive are easily identifiable by the authorities.
- The notification helps some companies to become more aware of the amounts of dangerous substances that may actually be present at the site. This newfound awareness can sometimes lead to actions by the operator to reduce these amounts, for instance, a shutdown of certain parts of the establishment or a reduction in storage capacity and elimination or phasing-out of the most dangerous goods from their operations. It is not unusual in this situation for a site to drop from upper-tier to lower-tier status due to adjustments to its inventory of substances and improved inventory management.

## Weaknesses

- There are some important differences in the way this rule has been transposed into national laws. Reportable amounts may differ between Member States. In addition, some countries use a variety of mechanisms as the basis for measuring reportable quantities, including maximum capacity amounts listed in the environmental permit and average amounts of dangerous substances on-site in a certain time period (usually a year). The amount of intermediate product during reactions is also often hard to determine.
- For some industries, such as the pharmaceutical industry, classification, particularly of intermediates and mixtures, may be rather more challenging than for other industries. The challenging issues include the complex logistics associated with many substances in small quantities for which classification of dangerous properties is imprecise or uncertain. The waste management industry is another sector that shares this challenge.
- Changes in classification of dangerous substances or threshold values can cause more sites to fall under the Seveso scope, but if these changes are not communicated well enough, sites are unaware of their new obligations. This is mostly the case for smaller sites that do not have the staff to keep track of regulatory changes.

- It may be possible for companies, particularly for those with smaller sites, which are seeking to hide from this rule to do so. To detect them, the authorities would have to discover, firstly, that they exist and, secondly, have reason to suspect that dangerous substances were being handled in amounts close to threshold quantities. In addition, non-Seveso inspectors that may visit these companies are not familiar enough with Seveso requirements to judge whether or not the Seveso Directive applies.
- The role of the public in reporting violations of this rule is very limited due to the limited public access to information as to whether companies did or did not provide notification themselves.

### 3.3.2 Major accident scenarios (rule 2)

#### General

Working groups 1, 2 and 5 discussed the rule relating to the inclusion of major accident scenarios in the safety report. Generally, companies understand the added value of scenario development but face challenges in compliance because they do not necessarily understand how to apply the rule to their own operations (lack of clarity). Furthermore, smaller companies generally lack the knowledge and expertise. Spontaneous compliance is therefore not as high as it could be and active enforcement is necessary to achieve higher compliance levels.

#### Strengths

- Once the scenario requirement is clearly explained (e.g., by an inspector), it is often less difficult to enforce because the companies see that it makes practical sense. It may contribute to greater awareness of the risks. Scenarios also have a more general usefulness, since they can sometimes be used for emergency training and internal auditing.
- In most Member States, there are national guidelines and manuals that elaborate this requirement.
- Scenario development is an important building block of the Seveso requirements, so the authorities will always scrutinize it.

#### Weaknesses

- Considerable technical knowledge is needed to draw up appropriate and useful scenarios. Normally, only the big international companies have adequate resources for this task. Smaller companies must generally rely on external experts for this work, who are often expensive.
- The drafting of major accident scenarios is a time-consuming and thus costly requirement. Moreover, a lack of good guidance in this area raises concerns about errors in the analysis, e.g., overlooked or “missing” scenarios. There is an ongoing debate concerning which and how many scenarios can be considered as appropriate and proportionate to the risk.

- Because guidance and criteria for implementing this rule are unclear, it is also hard to convince company superiors that an actual violation has occurred. Imposing a sanction on the basis of a violation of this rule is therefore rather difficult.
- Differences among the Member States in terms of implementation approach (i.e. transposition into national legislation) and actual enforcement of this rule vary widely. For example:
  - Enforcement actions routinely applied can be as simple as a letter (requesting improved performance) in some Member States, or as harsh as prosecution in other Member States on the basis of an “incomplete” safety report (because the scenarios are judged inadequate or missing).
  - In some Member States, inspectors may request the written scenarios from the records and review them on paper and in practice. This may lead to interesting results because the actual situation can be very different from what is written down in the scenario. In other Member States, the inspection only determines that the record of the scenario exists and there is no further possibility to review the scenario itself.
- Verification that scenarios have been selected and assessed properly requires a particular expertise. Not all inspectors may have the rather high level of technical knowledge and experience required to properly evaluate compliance in this regard, or at least do so with respect to certain sectors.
- Social control on this rule is often impossible because of national security considerations that prevent the public from having access to the pertinent information. However, in some Member States scenario-related information is available to the public.

### 3.2.3 Consequence assessment (rule 3)

#### General

The rule for consequence assessment was discussed in working groups 4 and 5. Another working group concluded that this rule has a lot of similarities with the rule concerning major accident scenarios and therefore chose not to discuss this rule separately.

#### Strengths

- A wide variety of calculation models and programs for consequence assessment are available in the marketplace.
- Consequence distances and risk contours are understood to be important because they have a direct influence on the reputation and expansion possibilities of some sites, particular in relation to potential for future land-use planning.

## Weaknesses

- The different calculation models/programs are also a weakness. Particularly, finding the right tool to analyze a particular site can be difficult, since they are all very different from each other and produce different results. Analyzing and having confidence that the results are more or less in the correct range can also be difficult for this reason. Some Member States prescribe the use of one or two specific models in order to avoid confusion and allow comparison of the results of different sites.
- In calculating consequences, it is often possible to make slight adjustments to the inputs to produce an acceptable outcome, regardless of the reality of the situation.
- As is the case with the major accident scenarios rule, inspectors require special expertise to determine if the assessments have been prepared in the right way.

### 3.3.4 Identification of training needs (rule 4)

#### General

Working groups 3 and 4 discussed this rule. The compliance in both target groups is very different. The fertilizer industry will not spontaneously comply, whereas the batch industry has a spontaneous compliance level of approximately 80%. This is mainly caused by the “softness” of this rule and the specific aspect it deals with. Training is often provided, but the identification of non-standard training needs or a specific retraining programme for specific skills are not areas covered very well, if at all.

#### Strengths

- This rule is seen as a clear and logical thing to do when mentioned, but practical implementation is a challenge.
- Identification of training needs is also part of quality and other management systems. Non-official checks by auditors of quality or environmental management systems can promote spontaneous compliance.

#### Weaknesses

- Identification of training needs is a rather “soft” safety management system rule. It is unclear what criteria are used to determine if the company has done enough to comply.
- Detecting violation of this rule is a challenge. Factors that play an important role in this regard are the expertise of the inspector and the thoroughness with which the management system is inspected. Cases in which a training programme is complete but the formal identification of training needs is not covered are often not reported as instances of non-compliance.
- Additional training as a consequence of the identification of training needs is time-consuming and expensive, and the added value is difficult to determine (for example, how many accidents are prevented by rightly identifying training needs?).

- Sanctions for violations of this rule are rather limited because the added value is hard to prove. However, in cases of accidents due to a lack of training, sanctions can be more severe.

### 3.3.5 Procedures for management of change (rule 5)

#### General

The Seveso rule to have procedures for management of change was discussed in working groups 1 and 2. Generally, most companies spontaneously comply with this rule because of the general advantage for production, quality, environmental and safety purposes of having a good management of change process. Details of implementation are, however, challenging, because it is another soft rule, where a lot of differences in interpretation are possible. The details of the procedures are often part of the discussions between companies and authorities.

#### Strengths

- Management of change (MOC) is broadly accepted as a good and effective process and also forms part of other management systems.
- The actual presence of MOC procedures is not the problem, the quality and coverage of the procedures can be.
- Most MOC procedures cover at least projects, rebuilds and technical changes.

#### Weaknesses

- The Seveso Directive does not give any specific definition of a change. The individual Member States each have their own interpretation as to what should be covered by the procedure.
- Discussions on definition vary in terms of focus from the size and sort of changes that should be covered (organizational, technical, procedural) to the administrative records that should be kept.
- Finding gaps in the MOC procedure requires knowledge and experience on the part of inspectors and a good inspection technique. Several inspection techniques for this purpose are available in Member States.

### 3.3.6 Procedures for operational control (rule X)

The rule to have procedures and instructions for operational control, one of the elements of the safety management system, was discussed by the LPG working group. In summary, the results of the group's discussion were as follows:

- Instructions as required by this rule are often oral instead of written. The smaller companies with a limited number of personnel do not always need to put, or see the

advantage of putting, everything they do on paper. Copies of procedures or instructions from multinationals can be found. Sometimes, a quality or environmental ISO system helps in terms of obtaining written instructions.

- During first inspections, a check is carried out to determine the existence of instructions. Later inspections focus on the contents, which require specific skills on the part of the inspector. Instructions copied from other companies often do not represent the reality (not tailored to the situation in question). Physical inspection is therefore needed in addition to an administrative check.
- Especially at smaller companies with very little personnel, written instructions are seen as an administrative burden and staff of these companies tends to feel that oral instructions are enough. It is hard for the inspector to find the right balance between oral and written instructions and determine what does and does not constitute compliance with this rule.
- Compliance with this rule does not lead to a higher level of safety and enforcing it is overly punitive as a first measure. Only increasing the severity of the sanction can lead to compliance with the rule. The industry is aware that it is not severely sanctioned for initial non-compliance with the requirement of instructions.

### **3.3.7 ATEX regulation regarding LPG (rule Y)**

ATEX regulation is more technical and reality-driven than Seveso. ATEX focuses on high-probability risks. The level of acceptance for this sort of rule is higher because it is related to daily operations. The high costs and limited time for implementation of ATEX requirements is, however, a major disadvantage.

In general, violations of ATEX are easier to detect than Seveso violations.

## **3.4 Intervention strategies**

### **3.4.1 Classical intervention**

In most Member States, classic intervention methods like prosecution and imposing penalties are very effective. In Eastern European countries, the culture of respect for official authority is still very strong. The idea and risk of being prosecuted is enough to induce compliance on the part of companies.

Western European Member States often use official or even unofficial warning letters, especially with regard to “soft” requirements like management system procedures, as a first enforcement step. In addition, agreements are made between competent authorities and companies to ensure that specific actions are taken within a certain time frame to achieve a state of compliance. In most cases, no further action is needed. This is an important way of filtering out the “good

actors”, that is, the companies that simply need guidance on how to comply and do so if they are informed of what is expected of them.

### 3.4.2 Interventions for spontaneous compliance

Spontaneous compliance is, according to the Table of Eleven, dependent on five factors. Possible interventions (for all or some rules) were discussed in the working groups for each factor. The intervention actions and possibilities that resulted are:

#### Knowledge of the rules

- Improving subjective “soft” rules to make them as clear as possible.
- Improving the enforceability of rules by involving inspectors in their formulation.
- Authorities should make clear what their requirements and expectations are, and forward this information to the sector organizations and the main consultants involved in the implementation of the regulation.
- Elaborating qualitative rules in EU documentation.
- Making use of trade organizations to distribute information, promote the importance of the rules and disseminate ways to comply.
- Communication with industry about changes in regulation is important.
- The dissemination of existing instruments, books, websites and other sources of information represents an opportunity to reduce the differences in knowledge and experience between Member States and companies.
- Promoting joint problem-solving with a view to creating sector-specific solutions.
- Supporting public training courses for companies and experts.
- Publishing FAQs on a central website.
- Electronic newsletter for all Seveso companies and professionals (consultants and inspectors).

#### Advantages/disadvantages of (non-)compliance

- Having a special help desk for companies to determine if Seveso applies to them.
- Making notification easy by having a standard (electronic) form, with clear instructions.
- Making it easy to find out the Seveso classification for all substances. Advertise the existing website <http://ecb.jrc.it/classification-labelling/search-classlab/>.
- Providing good guidance in the form, for example, of models, cases that have worked in practice, methodologies, and information on what the major accident scenarios should contain. Exchange these elements of guidance through specialist or trade journals.
- Directing industrial representatives to specialized consultants who know about the specific area the representatives are working in.



**Degree of acceptance of the rule**

- Making use of trade unions and industrial associations.
- Involving the industrial sector in creating and evaluating rules.
- Promoting discussion on the benefits and social value of Seveso II compliance.
- Making industry aware of specific problems by initiating a survey on accidents with certain causes (behaviour, training or maintenance, for example) or the issue of a periodical accident analysis report.

**Faithfulness of the target group**

- Joint problem-solving between industry and authorities. The success and possibility of this strategy depends strongly on cultural factors and the availability of resources.
- Stimulating safety culture initiatives by the government.

**Non-official control**

- Investigating the possible role of NGOs like insurance companies and certifying or notified bodies. A covenant or agreement for the reporting of non-conformities is sometimes possible.

**3.4.3 Interventions with respect to enforcement factors****Risk of being reported**

- Setting up confidential reporting systems for employees (clicking lines), taking into account the cultural problems related to this kind of intervention.
- Advertising campaign targeting employees and focusing on a safe workers' environment and the possibility to inform the competent authority.
- Promoting the establishment of safety committees within companies.
- Educating safety representatives of safety committees.

**Risk of inspection**

- Improving training and guidance for inspectors.
- Changing the mindset of inspectors: raising the profile of the training of personnel in the area of major hazards.
- Splitting up inspection plans into technical and management system inspections.
- Advertising and raising awareness about the likelihood of inspection (through trade organizations).
- Making use of both document inspection and physical inspection of subjects. For instance, the carrying out of physical inspections and checking the outcomes of these against written scenarios is done with success (resulting in surprising non-compliances) in some Member States.
- Publicizing the inspection methods the competent authorities use.

**Risk of detection of non-compliance**

- Dissemination of good inspection practices and the sharing of information.
- Thorough training and guidance for inspectors.
- Improving the quality of inspections by making inspectors aware of the process and hazard risks within the specific industry they are inspecting.
- Making sure that, in addition to having a profound technical knowledge, the inspectors are trained and able to perform audits and inspections of management systems.
- Intensification of the quality and depth of inspections on instructions and procedures.
- Increasing awareness and encouraging feedback from non-Seveso inspectors (“eyes and ears”) to find new Seveso companies or detect those ducking Seveso regulations.

**Selectivity of inspections**

- Having and communicating a clear targeting policy.
- Promoting good examples of individual companies within the sector.
- Ireland has some experience with Volunteer Protection Programme (VPP) systems.<sup>7</sup> VPP is a self-auditing system for all kinds of management systems such as H, S or E. If the company achieves 4 or 5 stars, it receives a flag it hangs outside its premises. Tested with 10 American-based companies. This programme has some similarities with the Danish “smiley system”, in which the level of enforcement for a company that has passed an inspection favourably will be reduced, though enforcement will never become absent as such.

**Risk of sanction**

- Improving enforceability of rules: make it easier to prove qualitative factors in court.
- Publicizing results of inspections and enforcement letters.
- Administrative fining system for “soft” requirements.

**Severity of sanction**

- Clear sanctioning policy affecting reputation.
- Active publication of enforcement letters, inspection reports and accident investigation reports.
- Informing the neighbourhood through negative publication.

<sup>7</sup> See [www.vpppa.org](http://www.vpppa.org) for more information.

## 4. Conclusions and Recommendations

The MJV led to of the following general conclusions and recommendations about Member State approaches to enforcement:

- **Except for implementation of some rules and the direct or indirect use of classical interventions, limited differences are found between Member States.** These differences seem to depend, on the one hand, on the “age” of the Member State as part of the European Union and, on the other, on cultural differences. Enforcement in “new” Member States appears to be based mainly on respect on the part of enterprises towards the authorities. The authority involved plays a relatively leading role with regard to the rules and means to be applied as well as the goals to be achieved. In “experienced” Members States, by contrast, the authority involved tends to focus on enforcement with regard to (management) processes and (common) goals rather than on the means and methods to be used. All Member States, however, deal with multiple interpretations of rules, the carrying out of joint inspections, the design of inspection methods and the required level of training and knowledge on the part of inspectors.
- **All Member States deal with multiple interpretations of rules, perform joint inspections and cope with the associated challenges of coordination and the (continuous) updating and improving of inspection methods.** Most Member States recognize the necessity of training for inspectors, the need to possess and enhance knowledge of particular enterprises or industrial processes, and the desire to exchange information and “best practices” in order to learn from equivalent European authorities.
- **Self-compliance, image and reputation are a major driver for many companies, but this aspect is not yet integrated in authorities’ enforcement strategies.** Comparing the different target groups studied, reputation and public image is an important issue for large, multinational industries with products used by the public. Enterprises having a good Environment, Health and Safety (EHS) staff with a lot of knowledge will also have a better level of compliance. This factor makes a significant contribution to spontaneous compliance and a reduction in the enforcement effort required. On an operational level, the use of sanctions on the “reputation and image” of enterprises is a possibility to stimulate compliance.

- **A challenge lies in improving the clarity and enforceability of rules, for example “hard” versus “soft” rules.** Companies having a good EHS staff with a lot of knowledge will also manifest better compliance levels. Smaller companies tend to have more problems with new, unclear rules and are more dependent on information from the authorities. “Soft” rules, i.e., where performance is usually measured in qualitative terms, for example “the identification of training needs” often have to be elaborated. There is no general, uniform elaboration of soft rules.
- **The level of knowledge and training of inspectors influences the probability of inspection and the probability of violations being detected during inspections.** A profile of industrial expertise and adequate competence is required for inspectors to be recognized as counterparts for industry. In particular it is recommended to have multinational enterprises inspected and their compliance enforced by experienced inspectors.
- Information exchange between inspectors both at national and European level is a mechanism for keeping inspectors and inspection programmes informed about good inspection and safety practices. Modern communication tools can be exploited to overcome the challenge of effecting an exchange of experiences and good practices between Member States. Moreover, MJVs have an important added value in terms of their ability to provide an inventory of common problems relating to Seveso regulations and as a forum for discussing potential solutions. The exchange of information between Member States can be stimulated in a number of ways, for example, by development of appropriate websites, elaboration of a high quality Frequently Asked Questions (FAQ) document, the provision of guidance on good practices of other Member States and actively informing all parties involved.
- **On a European level, it was recommended that the enforceability of legislation should be a subject which legislators take into account.** Within this recommendation the following key points were also underlined:
  - Experienced inspectors and industrial representatives can be of great value in the legislative process due to their specialised knowledge and experience and kept informed, they can also help to secure greater public support.
  - A lack of consistency of Member State enforcement standards and practices continues also to undermine enforceability. Inconsistencies could be mitigated through agreement on or development of common technical references, for example:
    - Guidance documents pertaining to the “soft”, that is qualitative, parts of the applicable legislation could aid in reducing differences.

- Promoting ISO certification of safety management systems could also reduce inconsistencies in the interpretation of this particular requirement.
  - Standard inspection methods at international level could be established and adapted for national and local use.
- **Effective enforcement is often hampered by national level challenges, such as resource limitations and lack of clear criteria for enforcing soft rules.** Enforceability of legislation is critical in terms of preventing enforcement problems at the source. Implementation of European Union Directives is sometimes fragmented and “cluttered” with other rules because of existing legislation on the subject. Moreover, maintaining an inspections programme empowered with an adequate budget and competent staff to enforce the Directive is essential. In line with these concepts, the MJV made the following specific suggestions:
- National authorities should make as much use of European Union guidelines as possible when implementing, explaining and interpreting the new rules.
  - Certification – after examination – of inspectors is an option. Some of the inspectorates are already certified according to ISO 9000. Certification (of inspectors or companies) might help in raising the importance of training and qualified inspectors. Some countries (e.g. England) already have certification systems and certificates for inspectors; a new certificate (“within other certificates”) may create chaos.
  - The quality of inspection services may also be improved by setting national minimum requirements for inspectors with regard to knowledge and experience.
  - The inspectorates should have adequate capacity, methods and knowledge to perform effective physical inspections.

**Understanding the typical compliance profiles of different industrial sectors may also assist inspectorates in developing more effective enforcement strategies, for example:**

- Public perception and company concerns about reputation should be factored into enforcement strategies and sanctioning.
- Multinational companies should be inspected by experienced inspectors. It is important for all inspections that the inspectors carrying them out have a thorough understanding of what it is they are inspecting.

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Project Director : Ms. E. van der Stegen (Ministry of Social Affairs and  
Employment, the Netherlands)  
Date of report : 26 July 2007

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# ANNEX I The Netherlands MJV 2006 Programme

## Tuesday 7 November 2006

Afternoon / Evening      Arrival of participants at hotel

## Wednesday 8 November 2006

09.00 – 09.30	Registration, coffee and tea
09.30 – 09.45	Welcome (host Ministry of Social Affairs and Employment – DG Ms J. Hilgersom)
09.45 – 10.15	Introduction and goal of MJV 2006 “Enforcement of Seveso II” (Ministry of Social Affairs and Employment – Mr J. Oh)
10.15 – 11.00	Feedback regarding results of questionnaire (DHV – Mr J. van Middelaar)
11.00 – 11.30	Break
11.30 – 12.15	Program and methodology regarding the Table of Eleven (Ministry of Social Affairs and Employment – Ms E. van der Stegen)
12.15 – 14.00	Lunch
14.00 – 17.30	Working group sessions (part I)
19.30	Dinner

## Thursday 9 November 2006

08.30 – 09.00	Arrival at the Ministry, coffee and tea
09.00 – 10.00	Feedback regarding results of working group sessions part I (plenary, presentations by 5 working groups)
10.00 – 12.30	Working group sessions (part 2)
12.30 – 14.00	Lunch
14.00 – 17.30	Working group sessions (part 3, including preparation of final presentations)
19.30	Dinner

## Friday 10 November 2006

08.30 – 09.00	Arrival at the Ministry, coffee and tea
09.00 – 10.30	Working group presentations (15 minutes per working group)
10.30 – 11.00	Coffee break
11.30 – 12.30	Conclusions, recommendations, and looking forward
12.30 – 14.00	Lunch (buffet)
12.30	Travel to trains / airport

## ANNEX 2 List of participants

	First Name	Surname	Company
Mr	Lee	Allford	EPSC
Mr	Alvaro	Barroqueiro	National Inspectorate for the Environment
Mr	Bent	Bolstad	Norwegian Pollution Control Authority
Ms	Inger	Bye	Norwegian Labour Inspection Authority
Mr	Robin	Cowley	Health and Safety Executive
Mr	Danny	De Baere	Federal Public Service Employment, Labour and Social Dialogue
Ms	Simone	Dekker- Steehouwer	Labour Inspectorate, Ministry of Social Affairs and Employment
Mr	Daniel	Geisbacher	Slovak Inspectorate of the Environment
Ms	Maria Eugenia	Gil	Regional Community of Catalonia
Ms	Zsuzsanna	Gyenes	National Directorate General for Disaster Management
Mr	Klaus	Hougaard	Fyns Amt
Ms	Valburga	Kanazir	Ministry of Environmental Protection, Physical Planning and Construction
Mr	Hans	Kirudd	Swedish Work Environment Authority
Ms	Miljenka	Klicek	Ministry of Environmental Protection, Physical Planning and Construction
Mr	Themistoclis	Kyriacou	Department of Labour
Ms	Anne-Mari	Lahde	Tukes, Safety Technology Authority
Mr	Giorgio	Mari	ISPESL (Italian Institute for Health and Safety at Work)
Ms	Andrea	Menne	AstraZeneca AB
Ms	Cristina	Miclaus	National Environmental Guard - Romania
Ms	Carmen	Miclea	National Environmental Guard - Romania
Ms	Angela	Moriarty	Health and Safety Authority
Mr	Alfred	Moser	Government of Linz
Mr	Joy	Oh	Ministry of Social Affairs and Employment
Mr	Marek	Podgorski	National Headquarters of the State Fire Service



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Ms	Ausra	Sablinskiene	Fire and Rescue Department, Ministry of the Interior
Ms	Gratiela Roxaba	Sandu	Petrom S.A. Bucharest-Petrobrazi
Mr	Ralf	Schröder	RP Darmstadt, Abt. Umwelt Frankfurt
Mr	Jan	Slijpen	Ministry of the Environment
Mr	Christiaan	Soer	DHV
Ms	Maria	Stangl	Styrian Regional Government
Mr	Gert	van de Donk	CKC Seminars
Mr	Wilfried	van den Acker	Flemish Environment Inspection Authority
Ms	Sonja	van der Meer	CKC Seminars
Ms	Eveline	van der Stegen	Ministry of Social Affairs and Employment
Mr	Henk	van der Veen	Ministry of the Environment
Ms	Joke	van Dijk	DHV
Mr	Johan	van Middelaar	DHV
Ms	Astrid	Verlinde	DHV
Mr	Ralph	Vossen	Ministry of Justice
Mr	Roger	Ward-Dutton	Scottish Environment Protection Agency
Ms	Miriam	Weber	DHV
Ms	Maureen	Wood	European Commission
Mr	Pauls	Zirnitis	Ministry of the Environment of Latvia

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## ANNEX 3 Working groups

Number	1	2	3	4	5
<b>Name</b>	<b>Mineral oil refinery</b>	<b>Pharmaceutical industry</b>	<b>Fertilizers production</b>	<b>Batch processing</b>	<b>LPG storage</b>
<b>Chairman</b>	Eveline van der Stegen	Robin Cowley	Maria Stangl	Jan Slijpen	Danny De Baere
<b>Secretary</b>	Christiaan Soer	Astrid Verlinde	Johan van Middelaar	Joke van Dijk	Miriam Weber
<b>Room number</b>	<b>I.07</b>	<b>I.03</b>	<b>I.05</b>	<b>I.06</b>	<b>I.02</b>
<b>Participants</b>	Marek Podgorski Carmen Miclea	Daniel Geisbacher Henk van der Veen	Klaus Hougaard Zsuzsanna Gyenes	Alfred Moser Ralf Schröder	Themistoclis Kyriacou Angela Moriarty
	Hans Kirudd Roger Ward-Dutton	Giorgio Mari Pauls Zirnitis	Inger Bye Alvaro Barroqueiro	Ausra Sablinskiene Maria Eugenia Gil	Anne-Mari Lahde
	Bent Bolstad			Wilfried van den Acker	
<b>Technical Advisory Team</b>				Valburga Kanazir	
<b>Industrial Representatives</b>	Gratiela Roxaba Sandu	Maureen Wood Andrea Menne	Cristina Miclaus Lee Allford	Miljenka Klicek	Simone Dekker- Steehouwer Dirk Roosendans

## ANNEX 4 Model questionnaire

<b>QUESTIONNAIRE</b>	
<b>MJV November 8, 9, 10 2006 in the Netherlands</b>	
Name	:
Position	:
Country	:
<b>1. Which authority is <i>primarily responsible</i> for the enforcement of Seveso II in your country?</b>	
Answer: (name of one regulatory authority, e.g. Ministry of Environment)	
<b>2. Who are the <i>other competent</i> authorities with regard to Seveso II enforcement?</b>	
Answer: (names of other authorities such as local district boards, municipal councils, fire brigades, Labour Inspectorates etc)	
<b>3. How are the authorities (with regard to Seveso II enforcement) organized and coordinated?</b>	
Answer: (brief description of organizational structure)	
<b>4. Please describe the primary responsibility of each authority involved with regard to Seveso II enforcement.</b>	
Answer: (brief description of responsibility of each authority as specified in your answers to questions 1 and 2)	
<b>5. How is Seveso II implemented in legal terms, by (environmental) permitting or by direct legislation?</b>	
Answer: (please tick as appropriate)	
<input type="radio"/>	As part of (environmental) permitting
<input type="radio"/>	Direct legislation
<input type="radio"/>	Other, namely: .....
<b>6. What is your <u>personal</u> role with regard to Seveso II enforcement?</b>	
Answer: (brief description of, for example, your day-to-day work-related activities, job description, etc)	

**7. With regard to Seveso II enforcement, do you have specific knowledge (e.g. training, certificates) and/or practical experience in one of the following types of industry?**

Answer: (Please specify in terms of "grade" 1, 2, 3, 4 or 5 : 1 = least knowledge or experience; 5 = most expert knowledge and/or experience. Please note that each grade may be used only once.)

- .. Mineral oil refinery
- .. Pharmaceutical industry
- .. Fertilizers production and storage
- .. (SME, small-scale) Batch processing and/or multipurpose chemicals mixing and filling
- .. LPG storage in pressurized vessels

**Please return before 6 October 2006 to:**

**E-mail: [Sonja@ckc-seminars.nl](mailto:Sonja@ckc-seminars.nl)**

**Telefax: + 31 (0)40 212 94 07**

# ANNEX 5 Description of the Table of Eleven

## The Table of Eleven

### A versatile tool

### Table of Contents

## 1. INTRODUCTION

- 1.1 What is the Table of Eleven?
- 1.2 Why use the Table?
- 1.3 What is the origin of the Table of Eleven?
- 1.4 By whom can it be used?

## 2. THE DIMENSIONS OF THE TABLE OF ELEVEN

- 2.1 The spontaneous compliance dimensions
- 2.2 The enforcement dimensions

## 3. THE THEORETICAL FRAMEWORK

- 3.1 Compliance with legislation: cause and scope
- 3.2 Coherence between the different dimensions
- 3.3 The Table of Eleven in practical research and management processes

## 4. CHECKLIST FOR POLICY, LEGISLATION AND INSTRUMENTATION

- 4.1 Spontaneous compliance dimensions
- 4.2 Enforcement dimensions
- 4.3 Golden rules of the Table of Eleven

## 5. TABLE OF ELEVEN COMPLIANCE PROFILE

## 6. COMPLIANCE ESTIMATE

Colophon

Should you have any questions or remarks, please contact the Law Enforcement Expertise Centre of the Dutch Ministry of Justice.

Version: November 2004

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## PREFACE

In 1994, the Dutch Ministry of Justice studied the possibility of periodically monitoring the level of compliance with legislation. It was during that project that the “Table of Eleven” originated. The Table of Eleven is a model based on behavioural sciences, consisting of eleven dimensions. Together, these dimensions are decisive for the level of compliance with legislation. The eleven dimensions are formulated with a view to as high a practicability as possible in the fields of policymaking and law enforcement. The dimensions provide criteria with which we can assess whether or not it is possible to enforce draft legislation. These criteria, however, can also be used to evaluate existing legislation.

In the following years, the Table of Eleven was refined and improved. In addition, we gained the necessary experience in using it. These days, the Table of Eleven is a household name among policymakers, jurists drafting legislation, supervisors and enforcers within the Dutch government.

However, this does not mean that the Table of Eleven has reached its final version and cannot be further improved. New knowledge on compliance and insight into the application of the Table of Eleven also result in the model being adjusted all the time.

The Law Enforcement Expertise Centre (LEEC) of the Ministry of Justice coordinates the use and development of the Table of Eleven within the Dutch government. Since its creation, several tools were developed around the model. One of the simplest applications was the so-called Checklist for the Legislator, a questionnaire with yes/no answers, quickly giving the legislator an impression as to whether it is possible to comply with a new rule for the purpose of the obligatory Practicability and Enforceability Test. The Compliance Estimate is a quantitative estimate (based on several steps) of the compliance behaviour of target groups. The “Can a Rule be Complied With?” test is a frequently used tool by enforcing bodies in order to make an estimate of the dominant compliance and non-compliance motives.

Another use is the so-called Compliance Monitor: a sophisticated system for a major study with a survey to be held among the target group with regard to the level of compliance and the way of enforcement. This monitor is often used for the formal evaluation of legislation.



# I. INTRODUCTION

## I.1 What is the Table of Eleven?

The “Table of Eleven” is a list of factors which are important to compliance with rules. The Table of Eleven can help map the strong and weak points of enforcement of and compliance with such rules. The Table of Eleven consists of eleven dimensions, which together decide the extent to which legislation is complied with. The eleven dimensions are formulated with a view to as high a practicability as possible in the fields of policy development and law enforcement.

## I.2 Why use the Table?

The government wants to effect changes in society by influencing the behaviour of citizens and businesses. One of the policy tools which the government can use to achieve this is legislation. With the aid of rules, the government can create limits as to what citizens and businesses can and cannot do.

Legislation, however, also assumes a certain level of compliance on the part of the target group. Non-compliance decreases the chance of realizing the policy objective. Moreover, legislation is also meant to be complied with: compliance maintains the legal nature of society and non-compliance adversely affects that nature.

The Table of Eleven is an aid making it possible to determine and improve compliance with rules, and in particular legislation, in the following ways:

- The Table of Eleven helps to give a more accurate and well-founded estimate of the level of compliance of future legislation than merely an “off the cuff” approach. To that end, we developed estimation techniques that have a strong relation with the Table of Eleven.
- With the help of the Table of Eleven, it is possible to systematically analyse the enforcement efforts<sup>3</sup> of any enforcement body. It is also possible to estimate the potential effects of compliance.
- With a checklist based on the Table of Eleven, it is possible to increase the quality of policy rules and legislation in the development stage.
- The Table of Eleven can be used for setting up and evaluating enforcement.

## I.3 What is the origin of the Table of Eleven?

The Table was developed during a project studying the possibility of a monitoring tool that could provide insight into the level of compliance with legislation. In doing so, the question arose as to whether the questionnaire could also include causes of non-compliance. During

analysis of the various causes, the Table of Eleven was created. The Table of Eleven was not only used during this study to estimate the level of compliance, it also proved a suitable instrument to get a structured image of causes of compliance or non-compliance within a specific legislative area. In this monitor, the Table of Eleven was applied in a number of ways:

- As a basis for the questions in the survey (face-to-face interviews with the target group)
- As a method of arranging information on law enforcement
- As an assessment tool in expert sessions.

Based on the Table of Eleven, we created compliance profiles of the target group, making it possible to compare enforcement and compliance information. Gradually, we found that the Table of Eleven could be used in many different ways.

#### **1.4 By whom can it be used?**

The Table of Eleven can be used by policymakers, jurists drafting legislation, executive staff, enforcers and consultants. It can be an aid in scientific studies, in assessing the effects of a policy or enforcement, in preparing and evaluating policies. Each of these options for use requires its individual method: the study group meeting in the form of an expert session, or methods that are quantity-oriented, such as the survey. Sometimes, quantitative data is available from some dimensions of the Table of Eleven. In that case, the Table of Eleven can be used to organize this data and make it ready for comparison.

## 2. THE DIMENSIONS OF THE TABLE OF ELEVEN

### *General premise*

When analyzing the compliance behaviour with the aid of the Table of Eleven, it is important to have a clear idea of the target group and the legislation to be tested. With target group, we mean the persons or organizations (businesses) that must abide by the rules. The legislation to be tested, however, may be applicable to several target groups. For the practicability of a Table of Eleven analysis, we recommend that you opt for one target group and one or more core violations of the legislation to be tested. We interpret core violations as violations which affect the heart of the legislation and which may undermine the policy objective of the Act if they occur on a large scale.

The Table of Eleven comprises eleven dimensions for compliance with legislation, which are divided into two groups: the spontaneous compliance dimension group and the enforcement dimension group. The choice for this division was made because it is easiest to recognize the groups from the perspectives of compliance and enforcement. Here, “enforcement” means any government activity aimed at encouraging compliance with legislation.

With the Table of Eleven idea, the user applies the broad definition of the enforcement concept, which does not only relate to the government carrying out inspections and imposing sanctions (enforcement in the restricted sense). Other activities, such as providing information and organizing informal control structures are specified in the Table of Eleven. These activities directly anticipate the spontaneous compliance dimensions and are therefore very important for the purpose of preventative enforcement.

### 2.1 The spontaneous compliance dimensions

#### I. Knowledge of rules

##### a. familiarity with rules

##### b. clarity of rules

*Definition:* The familiarity with and clarity of legislation among the target group.

*Explanation:* Unfamiliarity with the rules may result in unintentional violation of them. Compliance mistakes may (unintentionally) be made as a result of a lack of clarity or the complexity of legislation. A number of aspects can be distinguished in this regard:

- Scope of legislation: on account of the fact that a great number of rules apply (or because one amendment to the law follows another in rapid succession), it may be too much to ask from those involved to know them all.
- Vagueness of legislation: definitions and stipulations may be open to more than one interpretation.

- Complexity of legislation: the rules cannot be understood, for example, unless one has technical or legal knowledge.

Knowing a rule well, however, does not automatically lead to good compliance.

Knowing the rules well in some cases also means that one knows better how to commit fraud or duck the law (think for instance of subsidy and tax rules).

Lack of knowledge, on the other hand, does not always lead to violation of the rules. Sometimes people accidentally comply with the rules simply by adapting to their environment, as in the case of traffic rules. Examples in this regard are being unaware of new traffic legislation or city ordinances, or being unable to read a traffic sign. It must be borne in mind that there may be illiterate individuals or foreign nationals who have not yet mastered the language. In other words, it does not go without saying that everybody can understand the language and therefore the law.

Some legislation can be quite complicated. Compliance with environmental laws often requires a high level of knowledge (chemistry) on the part of the target group, which may be an impediment for compliance.

*Improvement opportunities:* Consider more (specific) information in general, more information by word of mouth or even in translation. Disseminate information through general media (newspapers, magazines, radio, television and the Internet) or, if it concerns a clear target group, via more specific media (professional journals, a special website) or by tendering advice, if need be via pressure groups. Consider education too. Keeping a policy/rule as simple as possible (for instance by limiting the number of exemptions) may also contribute to better compliance.

## 2. Costs/Benefits

### a. financial/economic costs and benefits

### b. intangible costs and benefits

*Definition:* The tangible/intangible advantages and disadvantages arising from compliance or non-compliance with the rule(s), expressed in time, money and effort.

*Explanation:* This concerns all financial/economic and intangible advantages and disadvantages of compliance behaviour. These can be expressed in terms of time, money and effort. We can distinguish four different categories:

- Cost of compliance.
- Cost of violation (violation threshold).
- Benefit of compliance.
- Benefit of violation.

Intangible costs and benefits, such as maintaining a sound image, are also included in this dimension. The costs and benefits arising from inspection, investigation and sanctioning, both tangible and intangible, are *not* covered by this dimension. Often, the benefits of a violation correspond to the cost of compliance and a violation threshold often corresponds to a benefit of compliance.

*Example:* Time-consuming and costly procedures to be followed (such as applying for and fulfilling conditions for environmental licences) can be regarded as *costs of compliance*. In many cases, tax legislation causes heavy administrative burdens.

An *advantage of compliance* could be being granted a subsidy or businesses keeping their good reputation. Withholding data is a form of non-compliance, which does not require much effort. It is quite easy to speed over slow ramps, but it probably causes inconvenience to the passengers and damage to the car. Those are clearly *costs of non-compliance*. *Benefits of non-compliance* can often be found in the financial realm, such as receiving subsidy without officially being entitled to it.

Saving effort, time and money by illegally dumping refuse rather than recycling it into an environmentally friendly product can be regarded as an *advantage of violation*.

*Improvement opportunities:* Compliance can be encouraged by making a subsidy available, additional levies or price regulation. Other options are publishing “black lists” (of organizations not abiding by the rules), certification and statements regarding one’s good behaviour.

### 3. Extent of acceptance

#### a. acceptance of the policy objective

#### b. acceptance of the effects of a policy

*Definition:* The extent to which the policy and associated legislation are considered acceptable by the target group.

*Explanation:* Acceptance relates to the reasonableness (as experienced) of the policy intended by the government and the standards arising from it. Acceptance may relate to a target group's judgement of a rule in general, but also to the judgement of the implications of such a rule in one's own specific situation. The manner in which a policy is implemented may also play a role. Sometimes, there is a tier between the government and the citizens (professional group/ implementing body) which is essential for the design of the policy and thus of the acceptance of the rule. The extent to which a target group feels responsible for the realization of the policy, for that matter, is also an indicator of the extent of acceptance.

*Example:* A low level of acceptance of a policy can be found among young people who all must wear a helmet on their moped or scooter under the traffic laws; only a few of them are of the opinion that it is a useful rule. The authorities also came up against a brick wall and resistance when so-called hobby hens (the owner has no commercial purposes for them) were culled during a fowl pest crisis.

Some speeders do not break the law because they are in a hurry but because they disagree in principle with speed limits (specific or general).

The extent of acceptance may also depend on the judgements of the need for a rule or the scope of the damage caused.

The manner in which a policy is fleshed out may, at times, be decisive for the acceptance of the legislation. This is particularly true for so-called *middelvoorschriften* (a rule telling you how to achieve something rather than what to achieve), the purpose of which the target group may endorse, but not the manner set forth in the rule.

*Improvement opportunities:* Involve pressure groups and influential members of the target group as well as implementing and enforcing bodies in the policy to be developed. Make the target group partly responsible for the success of the policy by way of self-regulation.

## **4. The target group's respect for authority**

### **a. official authority**

### **b. competing authority**

*Definition:* The extent to which the target group respects the government's authority.

*Explanation:* Some people just do what the government tells them to do or what the law says. This sub-dimension concerns the target group's respect for authority in general. This respect for authority is sometimes linked to the authority of the implementing or enforcement body. The sub-dimension "Competing authority" does not deal with the target group's attitude towards respect for the official authority, but with respect for their *own* standards and values, which may relate to their religion or habits. These may be in conflict with the government's intentions.

In general, it is true that this dimension has a more basic and continuous character than acceptance of policy. It relates to the more or less stable attitude of the target group towards the government.

*Example:* Respect for authority may be found, for example, in a specific target group that willingly pays taxes to the state, or, more specifically, who are unwilling to do so. Other target groups test new legislation first for compatibility with their own religious provisions, such as Orthodox Christians who refuse to have their children inoculated, women who are not allowed to become a member of a political party or immigrants who believe that they can rely upon grounds for exemption from criminal liability because of their cultural background (e.g. acts of vengeance for reasons of family honour).

*Improvement opportunities:* It is very difficult to influence this dimension. Upbringing plays an important role and education is possibly conducive to compliance.

## 5. Non-official control (social control)

### a. social control

### b. horizontal supervision

*Definition:* The risk, as estimated by the target group, of positive or negative sanctions on their behaviour other than by the authorities

*Explanation:* Non-governmental control may be informal control in respect of the standards set or a formal kind of control by the target group or professional group of their own members. The latter is referred to as horizontal supervision.

Social control is also exercised by the community, inside or outside the target group: relatives, friends, colleagues, internal or external auditors, nearby companies, competitors. The following aspects play a role in social control:

- the perceived risk of a violation being detected;
- the extent to which the community disapproves or approves the violating behaviour;
- the extent to which the community then feels responsible and takes action (social sanction).

Horizontal supervision is a form of formal social control: non-official control aimed at improving the quality of products and services within specific professional groups or industries. Consider for instance professional codes of conduct, certification and quality marks.

*Example:* Horizontal supervision is, for instance, an audit of the books or audit performed by a certifying institution.

*Improvement opportunities:* Giving information to the people around the target group, so that they will be better equipped to detect violations. Promoting self-regulation, certification and quality marks issued by the trade association.



## 2.2 The enforcement dimensions

### 6. Risk of being reported

*Definition:* The risk, as estimated by the target group, of a violation detected by parties other than the authorities being reported to a government body.

*Explanation:* This concerns the perceived risk of a violation being revealed without the intervention of government supervision. Consider for instance tipping off, coincidence or complaints. Here, several aspects mentioned in the non-official control section (T5) also play a role.

*Example:* The risk of housing benefit fraud being revealed through anonymous tips or the “tipline” of the complaints number of the Dutch Inspectorate for Health Protection. Tips (which may be prompted by the attraction of a possible reward from the Ministry of Justice) may result in the discovery of violations.

*Improvement opportunities:* Setting up tiplines and improving the general availability of supervisory bodies, and encouraging people to report offences.

### 7. Risk of inspection

#### a. records inspection

#### b. physical inspection

*Definition:* The risk, as estimated by the target group, of an inspection by the authorities as to whether rules are being broken.

*Explanation:* The risk of inspection is determined by the inspection density, the number of inspections per, say, 100 target group members per year. The objective risk of inspection will in practice differ from the subjective risk of inspection for several reasons, such as knowledge of inspection policy and the visibility of inspections. The subjective risk of inspection is decisive for the extent of compliance. Often, a distinction can be made between different kinds of inspection (e.g. records inspection or physical inspection).

*Example:* The inspection density in taxation, at least those concerning records inspections, is very high; in principle everybody is inspected. Continuous speed checks on the Dutch motorways meant a considerable increase in the inspection density. The perceived risk of inspection was further increased by advertising it nationwide.

*Improvement opportunities:* When the objective risk of inspection is higher than the subjective risk of inspection (the target group believes that the risk of them being inspected is lower than the actual risk of inspection), it is wise to publish information on the risk of inspection. In addition, the risk of inspection can be increased by carrying out more inspections through making more manpower available for inspections. Finally, inspection powers can be widened. In that case, it is advisable to communicate this to the target group.

## **8. Risk of detection**

### **a. detection in a records inspection**

### **b. detection in a physical inspection**

*Definition:* The risk, as estimated by the target group, of a violation being detected in an inspection carried out by the authorities.

*Explanation:* The violation will have to be detected in different forms of inspection. This will depend on the kind of violation perpetrated and the depth of the inspection. In some cases, it is easy to detect a violation, while it is difficult to trace the perpetrator. The objective risk of detection is the ratio between the number of violations detected and the number of violations actually committed (which number usually is unknown). It is therefore an estimate of the effectiveness of the means of inspection.

*Example:* When an inspection is held as to whether the provisions of herbicide/pesticide legislation are complied with, it is worthwhile to note whether illegal chemicals are present in designated storage places, although their use is also illegal, as well as whether they are kept in other places. It is difficult to reveal such actions, as they are not tied to a specific time or place. Cases of oil pollution, for instance, are often quickly detected, but it often requires a great deal of effort to trace the perpetrator.

*Improvement opportunities:* When a new policy leads to an additional burden on the enforcement capacity, additional resources (e.g. for extra staff or additional training courses) must be made available. Consider also allocating extra powers, applying a sophisticated technique, comparing and exchanging data files and using combined investigation methods (records inspections and physical inspections). Supplying information on the “high” risk of detection applies in this case as well.

## 9. Selectivity

*Definition:* The perceived (increased) risk of inspection and detection of a violation resulting from the selection of businesses, persons, actions or areas to be inspected.

*Explanation:* This concerns the extent to which inspectors manage to inspect those violating the rules more often than those abiding by the law. In principle, the quality or effectiveness of this form of selective inspection (possibly based on risk analysis or crime analysis) can be measured by the ratio of the number of perpetrators in selective inspections and random inspections. Selection increases the probability of perpetrators being caught. This dimension is mainly important to analyses of enforcement; the target group will probably offset this effect in T7 and T8.

*Example:* Some characteristics of the target group can be linked to potential violations (offender analyses). Inspecting a (known) group of recidivists, for example, will often lead to a higher number of people being “caught” than a random inspection.

*Improvement opportunities:* Examine which persons in the target group are more likely to commit offences, so that investigation activities can be focused on those people.

## 10. Risk of sanction

*Definition:* The risk, as estimated by the target group, of a sanction being imposed if an inspection reveals that a rule has been broken.

*Explanation:* Once a violation is detected, a sanction may be imposed by a special investigating team, the police, the public administration or the court. However, not every violation will make it to that stage. The policies relating to the dismissal of charges and whether or not an offence can be proved, and the policy of legitimate non-enforcement of the public administration, are important factors in this regard. The matter therefore concerns the target group’s expected chance of some sort of punishment.

*Example:* The perceived risk of a sanction concerns the estimate of the target group that the inspection and detection of a violation will actually be followed by a sanction. Compliance will not be encouraged if the target group knows that it is not easy to handle the relevant violation administratively, that it does not have a high priority at the Public Prosecution Department and/or if the court’s capacity is inadequate.

*Improvement opportunities:* When a new policy leads to an additional burden for the judiciary and the prison system, additional resources must be made available. Make sure that the new policy is a priority of the investigating teams, the Public Prosecution Department and the public administration.

## **II. Severity of the sanction**

*Definition:* the severity and nature of the sanction associated with the violation and additional disadvantages of being sanctioned.

*Explanation:* The severity of the sanctions concern the duration of detention, the amount of the penalty or the effort needed to repair the damage incurred. Legal fees may also play a role. The sanctioning process may also have additional, intangible disadvantages such as the loss of respect/reputation as a consequence of coming into contact with justice system. The severity and seriousness of the different types of sanction will not have the same impact on all offenders/target groups. The speed and certainty of sanctioning may increase that impact (“tit for tat” approach) and is possibly discounted in T10.

*Example:* Legislation regarding the deprivation of illegally obtained gains from criminal activities aims at a more serious disadvantage to the person concerned. Sanctioning a business under the criminal law system may affect the good name and reputation of that business.

*Improvement opportunities:* increasing the sanction, higher penalties or longer prison sentences. Immediate sanctioning (tit-for-tat policy) will have more effect than postponed sanctioning.

## 3. THE THEORETICAL FRAMEWORK

### 3.1 Compliance with legislation: cause and scope

When the government asks questions concerning the scope of compliance and non-compliance, it usually links that question to the wish to realize the highest possible level of compliance. If the compliance level is too low, the result may be an improved provision of information, an adjustment of the government policy in question, more inspections or more enforcement efforts. Apart from information on compliance as such, it is also of interest for the government to gain insight into the factors that explain the level of compliance found, i.e. insight into the causes. Such insight creates the possibility of intervening in those causes of poor compliance, if any, and that is, of course, better than treating the symptoms. Law enforcement through government supervision is one of the reasons why people abide by the law, but there are many more, as you will have read in the preceding chapter. The eleven dimensions of this Table together determine the extent to which an individual Act or series of Acts is complied with. They are the compliance causes or motives. Apart from causes, the government is often (though at other times insufficiently) interested in the number of compliant/non-compliant people. That is very difficult if not impossible to measure with the Table of Eleven. However, the Table of Eleven can be used for quantitative studies to estimate the levels of compliance in a more substantiated manner. The added value of the Table of Eleven is on the one hand the fact that it allows the user to divide a group into different sorts of non-compliant and compliant people (the so-called Compliance Estimate) and, on the other, that a Table of Eleven analysis gives a systematic overview of the compliance and non-compliance motives, so that a slightly more objective estimate can be made. These quantitative methods can be used best in ex ante evaluations of compliance behaviour, which by definition are surrounded by uncertainties. In that situation, the Table of Eleven contributes to reducing the number of uncertainties.

### 3.2 Coherence between the different dimensions

The Table of Eleven is made up of eleven dimensions, and is not based on a single theory or set of theoretical notions. Several theories and theoretical notions have been used as a source. A list geared to practicability was the main objective in developing the tool, and selecting just one theory was incompatible with that objective. Fishbein and Ajzen's theory of reasoned action from social psychology, for example, could have served as the basic theory. We decided against an explicit application of it, although elements of that theory (and those of kindred authors) can definitely be found in the Table of Eleven. The causal links between the different dimensions

emphasized by Fishbein have been abandoned here. We use, for example, the opportunity theory in the dimensions covering spontaneous compliance and several enforcement dimensions, while the notion of the correlation between severity, certainty and speed of sanctioning (in the sanction sections T10 and T11) can be referred to for determining the impact of sanctioning.

As an extension of the question as to what theory the Table of Eleven is based on, there is the question as to what the correlation between the dimensions is. The eleven dimensions of the Table are divided into two groups:

- Spontaneous compliance dimensions consisting of the target group's decisive motivations to comply with a rule, if no government control were to take place;
- Enforcement dimensions, which determine the risk of being caught in a government check and which determine the government's sanctioning policy; the perception of both influences the compliance behaviour.

The dimensions are categorized according to type of contribution towards compliance: voluntary compliance on the one hand and compliance that is more or less compelled on the other. The starting point is that the dimension groups each have their own effect on the inclination towards compliance, as do the independent dimensions. Apart from the fact that the dimensions have a direct effect on the inclination towards compliance, the groups also influence each other. That is particularly true for the enforcement dimensions. The questions regarding sanctioning (T10 and T11) increase or reduce in pertinence according to the questions regarding inspection (T7 and T8), and in most cases cannot exist without these inspection dimensions. After all, people can only be sanctioned if they were found guilty of a violation during an inspection.

The eleven dimensions are then put in order. This means that the assumption is that each of the dimensions directly influences the inclination towards compliance. All the same, there may be a link between the various dimensions. One dimension may influence another one. We have already pointed out that there is a correlation between the different inspection dimensions (T7 and T8). It is difficult to gauge the relationships between the dimensions (the relative importance of each dimension to compliance) and these may differ from one law to the other, or from one target group to the next. Moreover, the relationship may change over time. The advantage realized by violating legislation governing the handling of refuse may be greater in three years' time because by then processing refuse in a legal way may have become more expensive. This means that it is difficult to gauge or estimate the actual influence which each of the dimensions has on compliance. The Table of Eleven is therefore suitable for making a qualitative compliance analysis (strengths and weaknesses), but is less suitable for serving as a calculation model for the quantitative estimate of compliance and non-compliance behaviour.

### 3.3 The Table of Eleven in practical research and management processes

The government wants to effect changes in society by influencing the behaviour of citizens and businesses. With the help of rules, the government can create limits as to what citizens and businesses can and cannot do.

Legislation, however, also assumes some level of compliance on the part of the target group. Non-compliance decreases the chance of realizing the policy objective. Moreover, legislation is also meant to be complied with: compliance maintains the legal nature of society and non-compliance adversely affects that nature. Part of the target group will spontaneously comply with almost every regulation.

If this is not the case, the government will attempt to influence the target group's behaviour. Enforcement – any government activity aimed at encouraging compliance with the rule in question – may contribute to compliance.

The Table of Eleven can be used to illustrate the compliance behaviour, per core rule and per homogenous target group, concerning the regulation in question. Based on an estimate of the eleven dimensions and the step-by-step Compliance Estimate, it is possible to make an estimate of the level of spontaneous compliance, the required enforcement efforts and the effectiveness of enforcement in respect of new and existing legislation.

Weak scores in the Table of Eleven provide policymakers and enforcers with information on the dimensions which are potentially linked to violation of a rule and therefore should be “developed” by the government. Enforcement activities (in the broad sense) have a potential effect on those dimensions.

## 4. CHECKLIST FOR POLICY, LEGISLATION AND INSTRUMENTATION

The Table of Eleven may be used as a supportive checklist in the legislation-making and policymaking processes. This is especially true when the behaviour of people is a contributing factor in the policy objectives to be achieved. The Table of Eleven can be applied to a large part of the policy-tool legislation and also to some parts of criminal law. The checklist (T1 to T11) specifies points of attention (in the form of questions). The answers to those questions give an indication of the extent to which the rule can be complied with. It also lists several points of attention, which could help remedy certain aspects, if any, which are weak/vulnerable in terms of compliance.

### 4.1 Spontaneous compliance dimensions

#### I. Knowledge of the rules

*Familiarity and clarity of legislation among the target group*

##### a. Familiarity

- Does the target group know the rules?
- Does it only need to make limited efforts to find out about the rules?
- Is the legislation not too elaborate?

##### b. Clarity

- Are the rules formulated in such a way that the target group can understand them easily?
- Is the target group actually capable of understanding the rules?
- Is it sufficiently clear to the target group what the rules apply to?
- Is it clear to the target group what rule applies?

#### Points of attention

- Use of additional educational materials.
- Use of general media (radio, TV, newspapers).
- Giving advice through workshops and trade organizations.
- Setting up a help desk for questions.
- Providing information in other languages.
- Increasing technical means to heighten visibility and simplify usage.



## 2. Cost/Benefits

*The tangible/intangible advantages and disadvantages of breaking or complying with the rule, expressed in time, money and effort*

### a. Financial/economic

- According to the target group, does complying with the rules cost relatively little time, money or effort?
- Does it think that breaking the rules will yield little or no advantage in terms of time, money or effort?
- Does it think that breaking the rules could yield any disadvantages?
- Does it think that complying with the rules could yield any advantages?

### b. Intangible

- Does the target group believe that complying with the rules yields emotional or social advantages?
- Does the target group believe that breaking the rules yields emotional or social disadvantages?

## Points of attention

- Inspection pressure from the government (burden) can be diminished if the rules are abided by.
- Competitive advantages and profit can be emphasized, as well as gains in efficiency.
- Financial rewards for compliance.
- Additional effort or costs for non-compliance.
- Physical barriers, such as fences and slow ramps.
- Emphasizing good reputations or making them visible (quality marks).
- Publish bad reputations (black lists).

## 3. Degree of acceptance

*The degree to which the target group regards the policy and the rules as acceptable*

### a. Acceptance of policy objective

- Does the target group regard the policy (and the principles it is based on) as reasonable?
- Does the target group feel it shares responsibility for putting this policy into practice?

### b. Acceptance of effects of policy

- Does the target group regard the way the policy objective is being put into practice as acceptable?
- Does it regard the resulting rules that follow from this policy as acceptable?

## Points of attention

- Correct any inaccurate perception of reality among the target group.
- Provide support among the target group, trade associations and executives.
- Provide explanation on the underlying objectives, the means used to achieve those objectives, the gravity of the problem, the considerations made and the issues which the government should and should not interfere with.
- Reasonableness of the punishment.
- Take possible arguments put forward by members of the target group into account; arguments such as defending their own property, privacy, right to work and income, rights of the environment, judgement of seriousness of offence or damage caused, division of power and money in society, right of the weaker opposed to the stronger, political beliefs, religious conviction.
- The target group's participation/involvement (interactive) in the policymaking process.

## 4. Target group's respect for authority

*The extent to which the target group is willing to respect governmental authority*

### a. Official authority

- Does the target group generally abide by the rules?
- Does the target group generally have respect for authority?
- Does the target group respect the judgement of those responsible for law enforcement?

### b. Competing authority

- Are the target group's own values in line with legislation?

## Points of attention

- Education.
- Attention to standards and values.
- Emphasize respect for official authority.

## 5. Non-governmental control (social control)

*The risk, as estimated by the target group, of positive or negative sanctions being imposed on its behaviour by parties other than the authorities*

#### a. Social control

- Does the target group feel that any violation would soon be noticed by its community?
- Does the target group community generally disapprove of such violations?
- If so, does the community try to correct this behaviour in some way or other?
- And does this social sanction have an impact on the target group?

#### b. Horizontal supervision

- Is there any horizontal supervision, e.g. financial auditing, disciplinary codes, auditing for certification?
- Does this horizontal supervision contribute to better compliance with the standard in question?
- Does the target group see this horizontal supervision as an additional form of control?
- And does this horizontal supervision have an impact on the target group?

### Points of attention

- Inspection possibilities by the target group or professional group.
- Visibility of violations for passers-by, stakeholders, trade associations.
- Possibilities of informal sanctions: status, image, rejection from the group.
- Loyalty of inspectors or inspecting bodies towards those inspected.
- Possibilities of (legal) pressure.
- Possibility of social control in effect encouraging violations.

## 4.2 Enforcement dimensions

### 6 Risk of reporting

*The risk, as estimated by the target group, of a violation detected by parties other than the authorities being reported to the authorities*

- According to the target group, is its community generally inclined to report detected violations to the authorities?
- According to the target group, are those exercising horizontal supervision generally inclined to report detected violations to the authorities?
- Does the target group think that people generally know which government department to report detected violations to?

## Points of attention

- The nature of the violations: not covering one's tracks, detection only possible by catching someone in flagrante delicto, whether the violation be proved (c.f. also dimension 8).
- Interest of those detecting the violation in reporting it to the authorities.
- Fear of those reporting a violation of an (angry) reaction from the perpetrator.
- Encourage reporting by tip money or opening a tipline or complaints service.

## 7. Risk of inspection

*The risk, as estimated by the target group, of being inspected by the authorities for possible violations*

### a. Records inspections

- Is there a major objective risk of records inspections?
- Does the target group think that there is a major risk of records inspections?

### b. Physical inspections

- Is there a major objective risk of a physical inspection?
- Does the target group think that there is a major risk of a physical inspection?

## Points of attention

- Actual objective risk of inspection (number of inspections per year or per person/business, number of inspections per violation or per member of the target group).
- Subjective risk of inspection and difference with the objective risk (depends on visibility of inspections, knowledge of inspection policy, prior experience with inspecting bodies, experiences of others, ideas on government activities and the impact of inspections).
- The accuracy of the inspecting body, response time of inspectors, impact of inspections by using auditing powers, show of strength, such as visibility of inspections, use of uniforms.
- "Reward response" from the authorities: compliance is rewarded with fewer inspections (and vice versa).
- Inspection burdens may invade one's privacy, serious delays, costs to be borne by the person inspected.
- Ensure that inspections are always unpredictable (otherwise people may alter behaviour to suit the scheduled inspection) by differentiating supervision and inspections (in the fullness of time) in terms of (1) frequency, (2) time, (3) depth and (4) place.
- Always hold a number of random inspections. Doing so keeps them unpredictable but also ensures that everybody always runs the risk of being subjected to an inspection. Moreover, random inspections produce objective input on the degree of compliance, in contrast to selective inspections, where usually relatively more violations are detected.

## 8. Risk of detection

*The risk, as estimated by the target group, of a violation being detected if the authorities inspect*

### a. In a records inspections

- Is all the data being checked in a records inspection?
- Is it easy for the inspectors to detect violations?
- Is it difficult to falsify records?
- Is there a major objective risk of detection in a records inspection?
- Does the target group think that there is a major risk of detection in a records inspection?

### b. Physical inspections

- Is everything being checked in a physical inspection?
- Is it easy for the inspectors to detect violations?
- Are violations restricted to a particular place and/or time?
- Is the inspection technology used sophisticated enough?
- Is there a major objective risk of detection in a physical inspection?
- Is the objective risk in a physical inspection large?

## Points of attention

- The nature of violations (not covering one's tracks, detection only possible by catching someone in flagrante delicto).
- Camouflaging violations (by screening off, hiding, changing the composition of indications of a violation, by misleading the inspector).
- Possibilities of tracing who the actual perpetrator/responsible person is (consider legal structures, making the actual perpetrator not the legal addressee, the causal link between the violation and perpetrator is missing).
- The capacity of the investigating body: special expertise of techniques required, sufficient resources available at the investigating body.

## 9. Selectivity

*The perceived increased risk of inspection and detection of a contravention resulting from selecting the businesses, persons, actions or areas to be inspected*

- Do offenders have the impression that they are always inspected more frequently than those who comply with the rules?

- Do selective inspections find more offenders, relatively speaking, than non-selective inspections?
- Does the target group believe that the enforcement agency is capable of “separating the chaff from the wheat”?

### Points of attention

- Targeting.
- Violation ratio in random and selective inspections.
- Cost of the discovery of a violation.
- Possibilities of setting up databases.
- Possibilities of linking files from various enforcement organizations.

## 10. Risk of sanction

*The risk, as estimated by the target group, of a sanction if a violation is detected in an inspection*

- Is there a major objective risk of a sanction being imposed once a violation is detected?
- According to the target group, is it easy to prove a violation?
- Does the target group estimate the risk of a sanction as a result of a detected violation as being high?

### Points of attention

- Lack of capacity.
- Lack of evidence.
- Social relevance of the offence (policy to dismiss charges).
- Legitimate non-enforcement policy of the enforcement body.
- Errors in the implementing or enforcement bodies.

## 11. Severity of the sanction

*The severity and type of sanction associated with the violation and additional disadvantages of being sanctioned*

### a. Severity of sanction

- Does the target group know what sanction they face in the event of a violation?
- Do they regard it as severe?
- Is the sanction imposed quickly (tit for tat)?
- Does the enforcement of the sanction have any additional tangible or intangible disadvantages for the party concerned?

b. Damage to reputation as a result of the sanction

- Does the target group mind that it becomes known that it has been sanctioned?

### Points of attention

- Disadvantages of sanction for the party concerned.
- Types of sanction: penalty, damages, goods seized, deprivation of illegally obtained profits, imprisonment, restore to legal situation, alternative punishments, withdrawing rights and favours, bringing business operations to a halt, etc.
- Additional disadvantages of enforcement.
- Social status, reaction of community, court fees, legal fees, costs of furnishing proof.
- Financial capacity of the perpetrator.
- Psychological effects, such as the manner of presentation and public nature, the speed with which a sanction is imposed, the “appearance” of the sanction system applied: criminal law, disciplinary rules, administrative law, private law.
- Possibilities of alternative sanctions.

### 4.3 Golden rules of the Table of Eleven

1. Compliance behaviour is determined by a few core dimensions rather than by the correlation of all dimensions: 80% of compliance behaviour is determined by 20% of the dimensions (the core dimensions, which may vary from violation to violation). Try to find the core dimensions for the legislative area in question that can influence your organization.
2. Properly filling in the dimensions requires knowledge of the target group: the relevant background characteristics must be mapped.
3. A cause for non-compliance may be found in the discrepancy between the objective values of dimensions (such as the actual risk of being caught) and the subjective judgements in the target group. It is therefore important to make that distinction and know the difference.
4. Influencing one dimension in order to increase the degree of compliance will usually *not* be successful. Effective behavioural changes normally require influencing all core dimensions, therefore opt for an integrated strategy.
5. Dimensions may be “averaged” among the whole target group. On the other hand, there may also be various sub-target groups, with each sub-target group giving the dimensions a different valuation. In that case, you will need to tailor the use of preventative or punitive

instruments.

6. Target groups are dynamic and change in the course of time. Compliant people may slip into the category of (potential) perpetrators due to the blurring of moral standards. Combating that situation requires presenting the compliant people and non-compliant people alike with a form of “confirmation of standards” every now and then. This means that part of the inspections must always be random.
  
7. The manner in which implementation and enforcement issues are introduced in the policymaking process to a large extent determines the practicability and enforceability of legislation. It is therefore important that those issues are discussed as early as possible in the policymaking process.

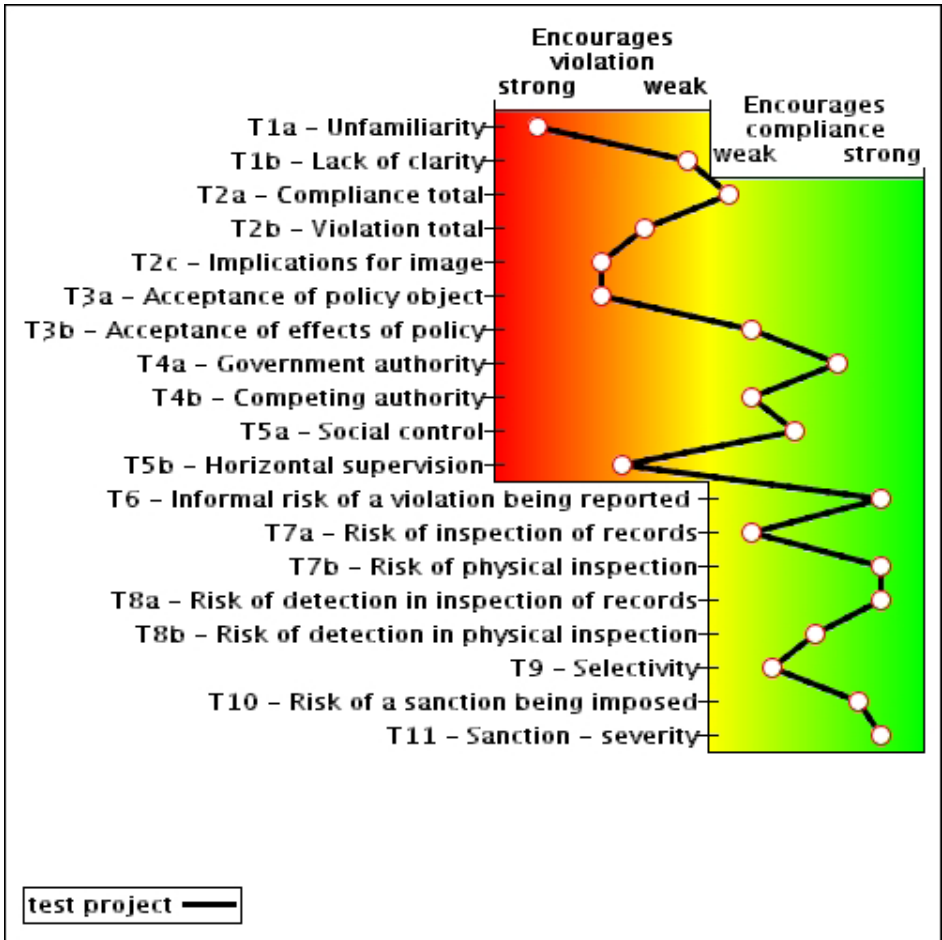


## 5. TABLE OF ELEVEN COMPLIANCE PROFILE

To estimate the weak and strong points of compliance with a rule or policy (whether existent or future) with the help of experts, a Compliance Profile can be drawn up. In that case, the dimensions of the Table of Eleven are divided into dimensions encouraging violation or promoting compliance. Some dimensions may have both an encouraging effect on both violation and compliance. This depends on the target group on which the rules have a bearing. Therefore, it is always necessary to carefully define the “target group” and the “rules” in question before drawing up a Compliance Profile.

The Compliance Profile shows the strong and weak points of the 11 dimensions. Dimensions with a strong score in the compliance profile encourage violations; those with a weak score do not promote compliance. Dimensions which fall in those zones are vulnerable and require extra attention in the policymaking and legislation-making processes. Dimensions which have a low score with regard to encouraging violations and are strong in promoting compliance are (relatively) safe dimensions.

In general, many vulnerable dimensions will be an indication of a high percentage of perpetrators and many safe dimensions will indicate a high level of compliance. This does not, however, always apply. The importance of a single safe dimension may sometimes outbalance many weak ones. In other words, be careful in drawing conclusions regarding the degree of compliance.



## 6. COMPLIANCE ESTIMATE

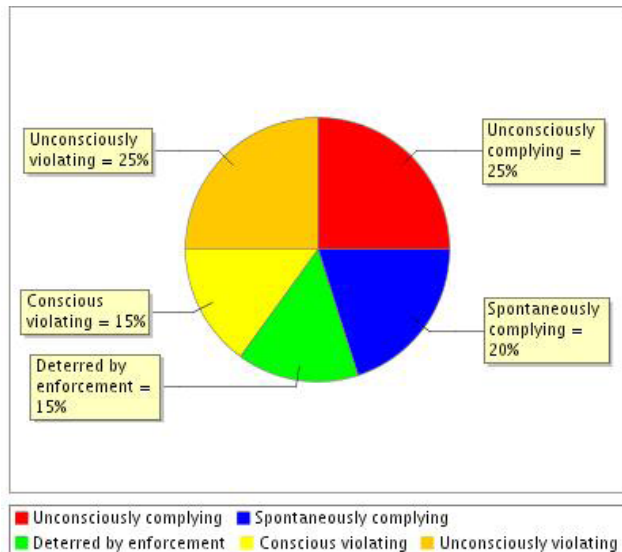
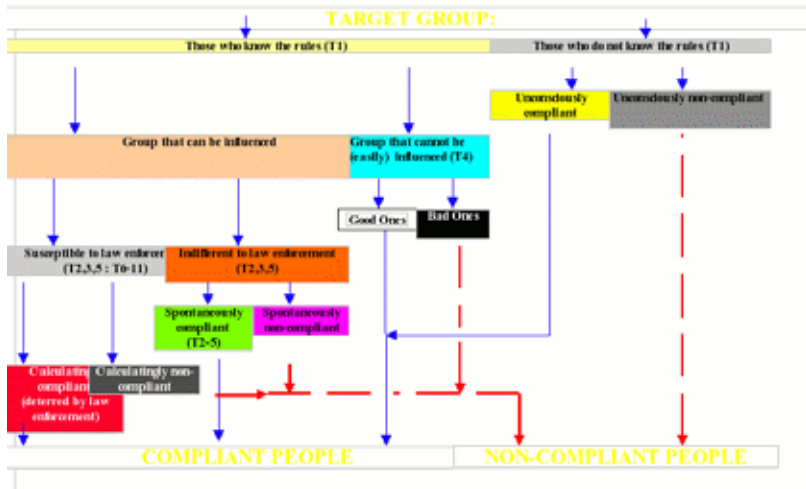
The so-called Compliance Estimate was developed to obtain a more substantiated insight into the potential number and types of people complying or not complying with the rules. With this method, the target group is divided step by step into a number of different kinds of violating and complying people. It is, for instance, possible to place people within different categories:

1. **Unconsciously compliant people:** those who do not know the rules very well and who unknowingly comply with them (for instance because they copy other behaviour, such as people do in traffic).
2. **Unconsciously non-compliant people:** those who break the rules because they do not know the rules well.
3. **Spontaneously compliant people:** those who know the rules and would comply with them of their own accord, even if (in theory) there was no enforcement whatsoever.
4. **Spontaneously non-compliant people:** those who know the rules and would always break them spontaneously, regardless of the risk of inspection, the risk of detection, the risk of punishment or the severity of the potential punishment.
5. **People deterred by enforcement or calculatingly compliant people:** the people who know the rules and who would break them but, rather, decide against doing so due to enforcement activities.
6. **Consciously or calculatingly non-compliant people:** those people who knowingly break the rules and consciously accept the risk of being caught.
7. In addition to the groups described above, there is a group that will not be influenced, or is very hard to influence. This group can be either very respectful to authority (**the good ones**) or very disrespectful to authority (**the bad ones**).

For an overview, consult the organizational chart. The chart, however, is not complete. All motivations from the Table of Eleven that can explain compliance are included, but some disturbing variables can occur between the *intention* to comply with rules and the actual compliant *behaviour*. These variables can also be linked to a specific situation (e.g. physical barriers, chance opportunities) or may have to do with irrational actions (violating a rule by accident, not being accountable for one's actions). It is therefore conceivable that the outcome of the estimate has to be adjusted for these variables. The chart could make this visible by adding arrows, which enables "cross-fertilization" between those who are ultimately violating the rules and those who are complying. A person can, for instance, violate a rule knowingly, but ultimately comply with it, and vice versa. These complicating factors have been left out for reasons of clarity.

The Compliance Estimate is now based on the unravelling of the relationships in the chart by answering a number of specific questions. This technique, however, is complicated and requires a lot from the respondent. The Compliance Estimate technique is processed in a computer system, making it better and easier to use.

The result could, for instance, be as follows:



## ANNEX 6 Results regarding the usefulness of the Table of Eleven

### Usefulness of Table of Eleven

One of the sub goals of the MJV was to test the Table of Eleven as a discussion tool and subsequently ask the users about their experiences with the method. The usefulness of the Table of Eleven was one of the issues to be reported on by the working groups.

The working groups unanimously concluded that the Table of Eleven is a good tool that incorporates a systematic approach and process for starting discussions on particular issues. The results are clearly presented. It should be used in a group: the discussion is as important as the instrument. The presence of a representative of the target group is crucial. The tool can also be used very well for the ex ante evaluation of regulations.

The tool is generally accepted as useful, but some improvements can be made. The strengths, weaknesses and recommendations that emerged from the discussions are listed below:

#### *Strengths*

- Good for starting a discussion and creating a common language.
- Structures the discussion and helps in directing focus on the right things.
- Diagnostic tool for problem-solving.
- Instrument for designing regulations in general.
- Distinction between spontaneous and enforced compliance is clear.
- User-friendly.
- Clear results.
- Graphs are useful and in line with the expectations, providing an indication as to what to focus on in enforcement.

#### *Weaknesses*

- Time-consuming method.
- Not a good tool in terms of proactivity because target group and rule must be very specific. This is essential to having a good discussion.
- The tool is really effective only for particular and/or detailed rules.
- No distinction between short and long-term effects.
- Must be used in a group with appropriate representatives.
- Steps must be taken to ensure that the discussion is as important as the tool itself.
- A limited trial relating to the Seveso Directive in its entirety showed that the tool may not be sufficiently selective for the Directive as a whole.

- The Table of Eleven makes a number of artificial assumptions, such as the assumption that it is possible for neighbors of a company to know that it is violating the rule in question.
- Sometimes understanding the questions or the grounds on which they are based is difficult due to a lack of clarity.
- The checklist and estimate mode have limited or no added value. The checklist can help in understanding the question being answered in the test mode.
- A number of issues must be clarified before the tool is used.

#### *Recommendations*

- Use for EU legislation or Directives.
- To be used for core violations only (maintenance, domino effects, notification).
- Include suggestions on interventions in the elements, giving the possibility to discuss interventions in direct relation with the elements.
- Make use of the tool during the drafting of legislation.

## ANNEX 7 Report of working group I

### “Accidents will happen and all accidents can be prevented.”

#### *Definition of the target group*

The target group of working group I was defined as follows: Oil refineries, including the storage of the finished product, excluding the storage of raw materials. Furthermore, petrochemical industries are not included. There are approximately 5-6 refineries in each Member State represented in the working group (Norway, Sweden, UK, Romania, Poland, Netherlands).

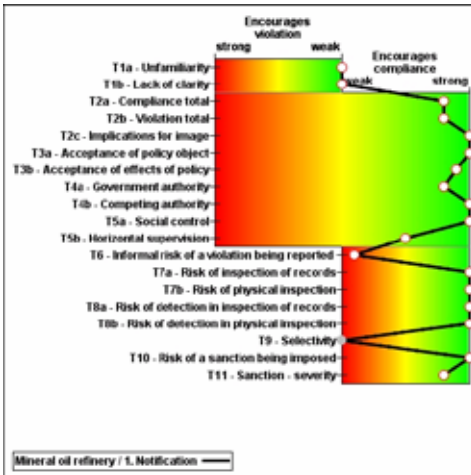
#### *Conclusions regarding the usefulness of the Table of Eleven*

- A good way of structuring a discussion.
- Introduces a good basis for a common language.
- Question whether it should be applied to the Seveso II Directive, as it is mainly goal-oriented.
- Not possible to distinguish between short term and long term.
- Checklist: 2.1-2.4 and 2.5-2.6 are not fully independent.
- Test: Delete “more” in 4.2.

#### *Lessons learned for Europe*

- There are no major differences between the Member States in the working group.
- It is an international industry.
- Approaches in terms of regulation are quite similar.
- Self-compliance factors are very important; enforcement factors are hardly needed.
- International exchange of inspectors would be beneficial.
- Enforcement must be cost-effective.
- The management of change concept cannot be viewed in terms of short-term thinking.

Results for rule 1: Notification



Strengths

I. Spontaneous compliance

- Public perception is very important.
- Refineries are large establishments and cannot hide; authorities and the public know where they are.
- The press is active with respect to refineries, going into authorities' decisions in-depth and exposing violations to the public.
- Sometimes the notification process helps the refinery to clarify the actual amounts of dangerous substances present (Romania). This might lead to the shutting down of certain parts of the establishment, resulting in a situation in which the Seveso Directive is no longer applicable and thus contributing to a greater level of inherent safety. (It was noted by Poland that this does not entirely apply to refineries but is true for storage facilities).
- The question is whether a notification is reassuring for the surroundings or creates a sense of insecurity once people know that there is a potentially dangerous establishment next door.
- It is impossible to inspect absolutely everything; completeness of the notification can be an issue.



## 2. Respect and authority

- There is general respect for government rules (Romania).
- In Sweden and Norway, an agreement between an inspector and a company is drafted when an instance of non-compliance is detected. The agreement concerns actions to be taken by the company in order to ensure compliance. In 95% of the cases, no further action is needed; 5% of the cases lead to an official enforcement decision by the government.
- Large organizations like refineries can afford to retain staff that can keep the regulator at a distance; the staff can also interpret the rules in line with business goals.
- Sometimes, the HSE coordinator asks for a formal notice of non-compliance to be issued in order to secure a budget from management to fund certain measures (Norway).

## 3. Horizontal control

- Internal assessments, ISO 14000 and insurance assessments are not incompatible with Seveso goals, but are no guarantee that those goals will be reached.
- Large companies sometimes feel that they have to comply and be the best in this regard (Norway/Sweden).
- Horizontal supervision can contribute to compliance, but can also contribute to an illusion of safety.
- A saturation point can be reached with all these different audits. In Sweden, an establishment remarked that the inspector found all the non-conformities detected earlier by the insurance company and the certifying company. The inspector, however, was for free!
- Horizontal supervision is crucial because of its integrating effect (Poland).
- In Norway, the frequency with which an establishment was visited was related to having a safety management system (SMS). The quality of the certifying companies was low, because they rushed their work. As a result, this procedure is no longer followed in Norway.
- It is the input for an SMS and the first principles that are most important, not the SMS itself (UK).
- An SMS is no guarantee for safety.

## Weaknesses

### 4. Access for the public

- Members of the public do not know exactly whom to call when they suspect the existence of a non-conformity, partly due to the delegation of competences.
- In Romania, the government, in close cooperation with refineries, communicates actively with the public. Companies are obliged to report non-conformities.

General remarks and questions

### 5. Classification

- Classification of substances is difficult and confusing, partially because of the ADR classification.
- Aggregation of different substances and mixtures is difficult.
- What should be done with regard to intermediate products? In Sweden, there was a discussion about bio fuels: ethanol-gasoline mixtures were fully classified in such a way that every gasoline pump became a Seveso establishment.
- Do actual quantities (Sweden) or capacities (UK, NL) determine whether an establishment fall within the scope of the Seveso Directive?

### 6. Miscellaneous

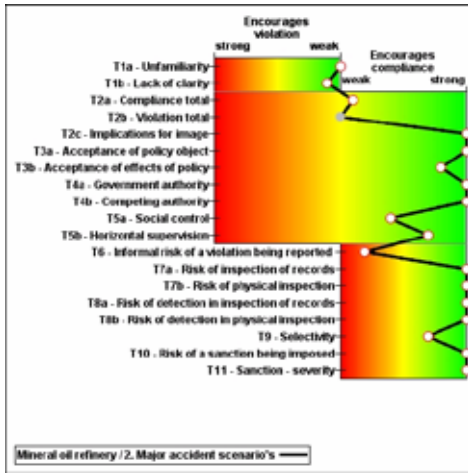
- Can small companies hide?
- Can small companies afford a good staff?
- How to cope with cross-border (in)consistency?
- Respect is earned by the competence and knowledge of the inspector (“Do not send a novice to a refinery, it will eat him alive!”).
- It is, however, necessary to have enforcement powers: you need a (big) stick in the trunk of your car / you need the teeth to bite.
- Active business relations can also contribute to compliance, e.g. Volvo urged an oxygen delivery company to comply within the hour when Volvo was told by the authorities of a non-compliance concerning an oxygen storage tank for testing purposes.
- When a company adopts a “We shall have no non-compliances” policy, the labelling of violations as a non-compliance during an inspection becomes a problem; violations labelled as observations and recommendations meet less resistance (Norway).
- An active community or press contributes to compliance; enforcement powers are needed.

### Interventions relating to rule 1

No interventions needed; there is a high level of spontaneous compliance.

Only the access for the public is poor.

### Results for rule 2: Scenarios



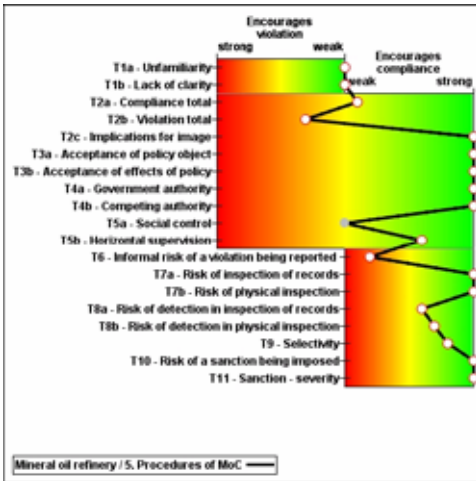
The findings on the “scenarios” subject do not differ much from the findings on the “notification” subject. No interventions needed; there is a high level of spontaneous compliance. Only the access for the public is poor.

### Additional remarks:

- There are national guidelines and manuals that elaborate the abstract Seveso requirements.
- It takes considerable effort to comply with the rule: approximately 1 man-year during a 6-month period.
- It does not pay for refineries to break the rule; in contrast to, perhaps, “1-scenario companies” (e.g., LPG).
- There is a debate on what scenarios are proportionate.
- Social control [i.e., fear of a negative public perception] is impossible in the UK because of national security; in other countries the safety report is still public. There is not much interest in safety reports. However, indications in the media are that a refinery that does not draw up scenarios is very likely to meet with the public’s disapproval.
- Intra-company supervision is very important.

- Flaws in the details in scenarios are very hard to detect.
- Small flaws in the scenarios will result in recommendations by the authority; large omissions will result in immediate, severe enforcement action.
- A near miss reporting system can be used to validate the scenarios.
- There is a difference between US company standards and EU company standards.
- Selectivity (T9) is very difficult when choosing scenarios.

*Results for rule 5: Management of change*



The findings on the “management of change” (MOC) subject do not differ much from the findings on the previous subjects. Not many interventions are needed; there is a high level of spontaneous compliance. Only the access to the public is poor and there is a negative cost-benefit ratio. From a short-term point of view, it might pay to avoid the MOC procedure. In the long term, however, a good MOC procedure is always advisable. Inadequate MOC is the cause of many incidents.

*Additional remarks*

- If MOC has only been introduced recently, there might be some undetected changes from the past.
- There are national guidelines and manuals that elaborate the abstract Seveso requirements. However, it is difficult to identify a change.
- MOC procedures should be pragmatic.
- Rewards for the employee following MOC procedures help to improve compliance.
- In extreme situations, employees might report MOC violations to the authorities.
- It is very hard for an inspector to detect small changes that have not been reported.

*Possible interventions relating to rule 5*

- Disseminate good practices, share information.
- Increase level of concern at corporate management level about safety culture.
- Gather evidence on cultural level.
- Involve line management in improving culture.
- There are only limited enforcement possibilities for “soft” factors, e.g. it is difficult to prove “high risk of violation” in court. Issuing an improvement notice might raise awareness in the press and on the shop floor.
- Do we need human factor specialists to complement the inspection team?
- Do we need specialists on automated process control (black box)?

## ANNEX 8 Report of working group 2

### *Definition of the target group*

The working group had discussions with a target group in mind, namely a large multinational pharmaceutical organization. In practice, this is a company of medium size with a limited number of employees. In the pharmaceutical industry, hygiene and quality are the main focus, but safety is also covered. Reputation is an important issue. Upper-tier companies have to submit a safety report to the government that is inspected. In general the targeted rules are more applicable to upper-tier than lower-tier sites.

Lower-tier sites are different in terms of inspection frequency and record inspection. They do not have to submit a safety report, nor their MAPP or SMS documentation. They will therefore have a lower score on inspection frequency for record inspections. In some countries upper-tier sites are more frequently inspected than lower-tier ones. In other countries it is the other way around.

The most important aspect for the pharmaceutical industry seems to be the reputation issue, which is in most cases responsible for spontaneous compliance with the rules. For unclear rules, enforcement is, however, more relevant and needed than for others. The difference between the three rules analyzed and actual compliance with these rules is made visible in the pie charts.

Quality is one of the main issues in production, in accordance with Good Manufacturing Practice (GMP). Quality is considered consistent with good health and safety management. Other relevant characteristics are good citizenship, being a good employer and attractive to the best employees, flexible production possibilities, a lot of minor and major changes in production every few years and production of often very active substances which can cause health problems if released in large amounts.

### *Conclusions regarding the usefulness of the Table of Eleven*

- Useful aid for structural thinking and focusing on the right things.
- Time-consuming method.
- Good diagnostic tool for problem-solving.
- Not a good tool in terms of proactivity because target group and rule must be very specific.
- Good instrument for designing regulations in general.
- Distinction between spontaneous and enforced compliance is clear.
- Checklist and estimate mode have limited or no added value. The checklist can help

in understanding the question being answered in the test mode.

- From the estimate mode, one will obtain a rough idea about how many of the target group will spontaneously comply; one can acquire insight into where efforts must be directed.
- It was found that some intervention approaches were suggested as solutions more often than others.
- It is a user-friendly instrument.
- The Table of Eleven makes a number of artificial assumptions, for example, that it is possible for neighbors of a company to know that it is violating the rule in question.
- There are a number of mistakes in the Table of II software program (translations, incorrect scoring labels).

### *Conclusions regarding lessons learned for Europe*

Some aspects are very difficult to comply with for industry and also very difficult in terms of enforcement by inspectors. An example in this regard is accident scenarios.

- These rules should be made clearer in Seveso III.
- It would be good to have an EU instrument that defines the rules more clearly.
- The existing instruments, books, websites and other information should be spread more actively within and between Member States. These instruments, however, do not always fit with the national implementation models.
- A number of Member States do not have the space and capacity to help the industry and develop models and information material. This should be done more at European level to ensure the creation of normative instruments; share the new inspection method of the Netherlands or NTA 8620 in Europe, for instance.
- More international exchanges between inspectors on enforcement issues, as a part of central training.
- Better communication on changes in the regulations (classification).
- More emphasis on Seveso inspector competences, promoted at EU level. The working group believes this will be a cost-effective way to improve the quality of inspections.
- Seveso inspectors' website for exchanging experiences.

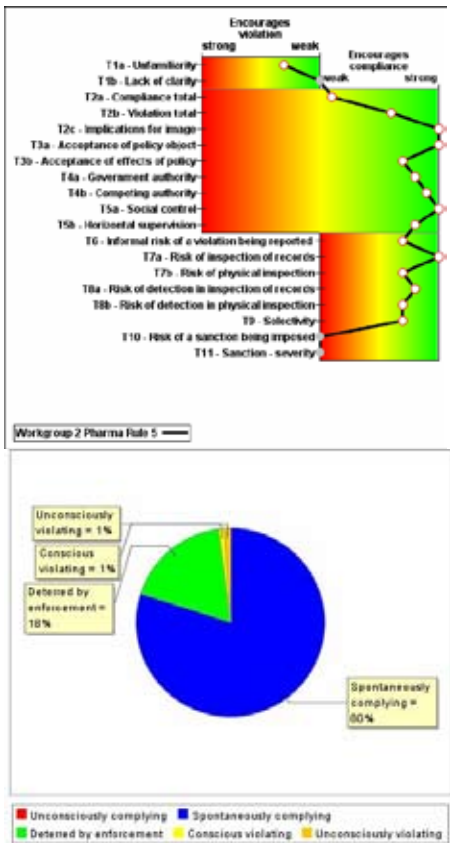
### **Other comments**

Companies should be more open to the public and give members of the public a look into the "black box" of dangerous substances and associated risks (responsible care, corporate social responsibility). MJVs are useful for the exchange of information.

*Results for rule 5: Management of change*

In the discussion, the rule is explained as the obligation to have procedures on management of change (MOC) *and* reporting these procedures in the Safety Report and the MAPP. In some cases, the practical implementation of MOC was discussed.

The results obtained by the working group through filling in the Table of Eleven instrument for this particular rule are given in Figure I. It is very clear that compliance with this rule is not a major problem for the pharmaceutical industry, since it sees the direct profit of having a good MOC procedure. Some elements are scored as “not applicable” due to considerable differences existing between working group members. These subjects are seen as weak points.



**Figure I. Results of Table of Eleven for rule 5: Management of change**



## Strengths

- The pharmaceutical industry target group sees the advantage of having an MOC procedure, not only for major accident prevention. Also for insurance reasons, it is necessary to have a good score (excellence) in safety management. MOC is one of the key issues insurance companies look at.
- Adding specific procedures in an existing quality system should be easier.
- Quality, as well as efficiency and some other factors, can also be positively affected by implementing an MOC procedure.
- Reputation issues like credibility, the risk of more inspections and being caught violating the rule encourage compliance with all the rules.
- The target group clearly accepts the aim of the policy, which is that they should have MOC procedures. Lack of clarity regarding MOC regulations makes the standard arising from the policy less acceptable.
- The pharmaceutical industry cares about what people think of it in terms of its efforts to be a good citizen and a good example, and so automatically follows the rules of the authorities. In some Member States the fear of enforcement alone is enough to ensure compliance.
- Internal standards are very important, and these function in support of this rule.
- All safety reports are inspected. MOC is an important issue targeted routinely by inspectors. The description of MOC does not always provide enough information to firmly demonstrate compliance. In the Netherlands, a checklist is used that specifies every point that must be included in the report.
- Inspectors are likely to check the MOC procedure and implementation when inspecting Seveso companies. The manner and depth of the inspection, however, depend on the level of expertise and inspection resources; considerable effort is required to carry out the inspection properly.
- The system of selectivity (i.e., prioritizing inspection of sites considered low safety performers or higher risks) works in practice but authorities do not inform companies that they are doing well and are therefore being inspected less. Systems are not transparent for companies. The pharmaceutical industry is not the most dangerous in terms of major accident probability, so fewer inspections should be carried out.
- Sanctions differ considerably among Member States. Authorities in some issue warning letters first and the institution of legal proceedings is a comparatively distant remedy, but other Member States have a very strict system which does not allow the issuance of warning letters first on clear violations. Prosecution is then immediate if the company in question does not have an MOC procedure in accordance with the law.

## Weaknesses

- The target group is aware that it has to have an MOC procedure, but this is not something that is easy to comply with. It is comparatively easy to adapt a plant by changing a number of lines or connections, but there is a risk that this is not seen as a major change. Often, the procedure is not used in case of minor changes or organizational changes. Implementation is therefore a problem. In some countries, like Italy, the law explains what is expected much more clearly than in other countries, where only the text of the Seveso Directive is copied and no further explanation is provided.
- Due to differences in transposition of the Directive into national law, a number of items are not applicable as a result of differences between countries regarding how much clarity the law should provide.
- It is rather complex to implement the MOC due to problems relating to varying interpretations of the definition (or lack thereof), and the information and documentation its implementation often requires. It takes a lot of time and effort to implement the MOC procedure.
- Companies within the pharmaceutical industry do not audit each other due to the “trade secret” factor.

## Interventions

- Although companies in the pharmaceutical industry do not seem to need enforcement, it is still important for companies manifesting high levels of compliance to be inspected by competent staff. (In the UK companies even have to pay for inspections, so competent staff is even more of a requirement.) Nonetheless, companies in this sector generally know whether they are doing well in terms of compliance and keep abreast of changes in legislation and the interpretation of authorities in this regard.
- Using trade associations is a good way of disseminating information and promoting spontaneous compliance.
- A spontaneous compliance level of 80% suggests that enforcement efforts should concentrate on the remaining 20%. These efforts may include:
  - Advertising and raising awareness about the likelihood of inspection (especially through trade associations)
  - Applying a clear targeting policy (selectivity)
  - Applying a clear sanctioning policy (affecting reputation)
- The ombudsman has a role in inspections (contacted by the trade union involved).

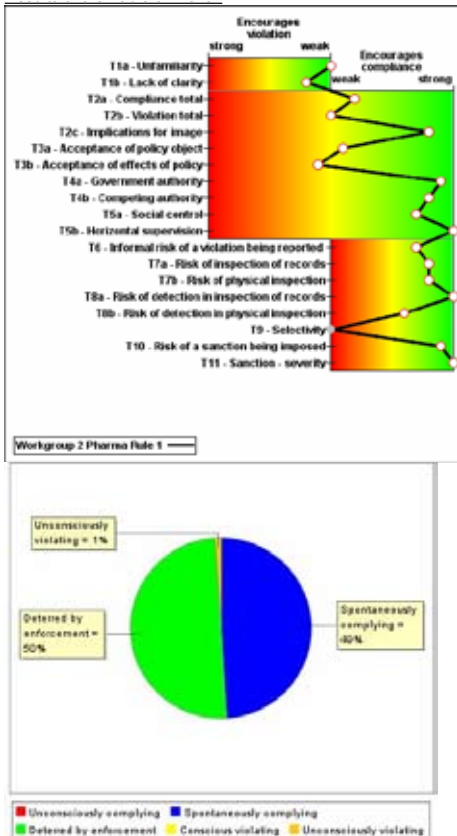
**Other comments**

With respect to Sweden, the obligation of having procedures is clear but the communication aspect of MOC is very complex. Changes have to be reported to four different authorities and none of them have the legal obligation to send this information to each other. If even one organization is overlooked in the distribution of information, it may experience considerable difficulty, even if the other three have received the information.

*Rule 1: Submitting a notification*

This rule concerns the requirement to submit a notification and the information that should be in it. There was some discussion about differences in the way this rule is implemented in national laws. It is hard to get the proper information for the notification because classification of substances (intermediates, mixtures) and calculation of quantities (maximum, allowed, normal, average, capacity) are not always straight-forward. For the pharmaceutical industry, the problem of mixtures and intermediates can be even greater than for other industries.

*Results of the Table of Eleven*



## Strengths

The notification is a rather simple administrative rule about which most companies are indifferent. This attitude is often deliberate and even can represent a strategic decision. . Moreover, some discussions will arise between the operator and the authorities because companies often see the requirement to submit a notification as simply one more administrative obligation; the government has already been given the information in other ways and formats.

However, because of the potentially negative effect on reputation from non-compliance, willingness to comply remains an advantage.

## Weaknesses

There are differences between the rules in the Member States, such that it may be more difficult to collect the proper information for the notification. In some Member States, this information is already in the environmental permitting process. In other Member States, the maximum allowed quantities are not automatically available.

Unanticipated changes in the classification of a particular dangerous substance at European Level (via procedures laid down in Council Directive 67/548/EC) sometimes cause confusion and substantial disruption to operator compliance efforts. Communication in this regard should be improved. Sometimes even the regional competent authorities are not aware that something has changed.

When performing a physical inspection, the inspector has to be well-informed about the possibility that companies with dangerous substances may be Seveso companies. Some companies, whose Seveso status is not immediately clear, can easily hide from the authorities.

## Interventions

- Promote discussion on the benefits and social value of Seveso II compliance.
- Make notification easier by using a standard (possibly electronic) form, with clear instructions.
- Make it easier to find out the Seveso classification for substances. Advertise the existing website <http://ecb.jrc.it/classification-labelling/search-classlab/>.
- Ensure better communication with specific target groups and regional inspectors about changes in Seveso classification, thresholds (class 9) and new substances. .
- Engage in joint problem-solving with industry and authorities, though there can be cultural and time/resource problems in this regard.
- The probability of detection through physical inspection can be improved through increasing awareness and encouraging feedback from non-Seveso inspectors.
- Establish a special help desk for companies to help them find out if they are Seveso companies.

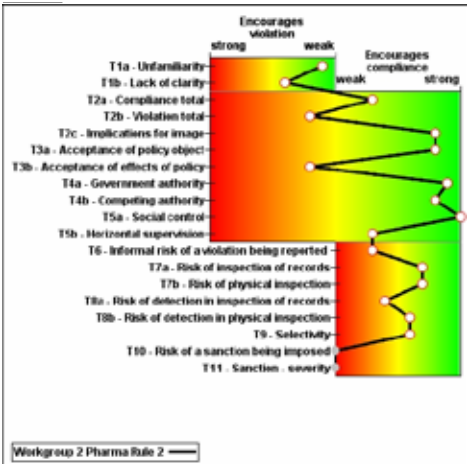
Other comments

The unloading and storage of solvents is the principal reason that the pharmaceutical industry falls under the scope of the Seveso Directive. The amounts of chemicals that companies in this industry produce can be the reason, but for these substances, it is easier to keep under the Seveso threshold.

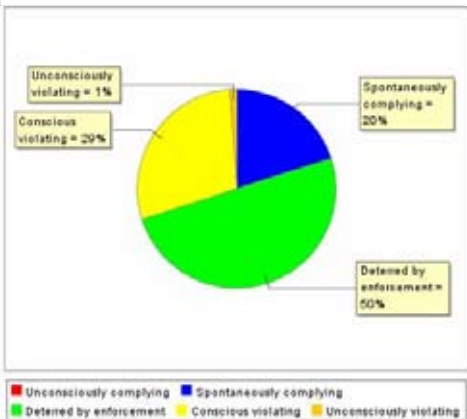
New Member States are not bothered by the differences between the original Seveso I Directive and the Seveso II Directive, so they often have less difficulty in obtaining notifications from this sector. *Rule 2: Major accident scenarios*

This rule is about the selection, description and reporting of major accident scenarios. It requires a major effort to comply with this rule and it costs a lot of money. Generally, if one wishes to do it properly, input from experts inside or outside the company (consultants) is necessary.

Results



Workgroup 2 Pharma Rule 2



## Strengths

The policy itself makes sense, as it helps to generate insight into the risks.

Violation of this rule is not likely to be reported because it is not likely to be detected by a third party.

Scenarios are the most important building block relative to the operator's Seveso obligations, so they will always be targeted for inspection. It is, however, hard for the regulator to see if something is missing in the scenarios since detailed information and understanding of site operators is required for this analysis.

## Weaknesses

These rules are very difficult to comply with because of the lack of clarity as to how compliance should be achieved. There is some literature, but there is no standard method for assessing risk. There are many conflicting methods and consultants all have their own techniques. Interpretation is difficult and dependent on expert advice.

This rule is not well-aligned to the needs of the company. It is never quite clear whether the right scenarios have been selected. On the other hand, this can be an advantage for companies because inspectors cannot easily disapprove and assert that the rule is being violated.

There are a number of differences in approach among the Member States in particular in regard to the physical inspection of major accident scenarios. In some Member States, only a paper inspection is carried out, while in others a physical inspection appears to be the more common approach.

Looking only at the safety report does not usually yield the whole picture. It is a difficult process to produce the scenarios and also to detect missing scenarios. Disagreements about which ones should be highlighted often arise, even between experts.

When physically inspecting scenarios, it is necessary to have a high level of technical knowledge and understanding to detect violations.

There are differences in the approaches taken by Member States with regard to sanctioning. Some steer towards prosecution if scenarios are lacking. Interpretation-related issues such as the number of scenarios required and their quality can make it difficult to prove that there is in fact a violation, however, and direct prosecution is not possible. In this situation, companies receive an enforcement letter intended to motivate them to improve. The penalty imposed in the UK and the Netherlands is the obligation to improve or resubmit the report, if not, prosecution is the next step.

One Member State requires that matters be improved in the next safety report, whereas others use an enforcement notice. One Member State reported that significant sanctions were never imposed.

*Interventions*

- Making the rule more clear and improving enforceability.
- Providing better guidance (models, examples that work or have worked in practice, example methodologies) on what the major accident scenarios should contain. Exchange these through trade journals.
- Referring industrial parties to specialized consultants who know about the specific processes present on site.
- Supporting public training courses.
- Publishing FAQs on a central website.
- Electronic newsletter for all Seveso companies and Seveso professionals (consultants, inspectors etc).
- Talking to trade organizations and/or sites stressing the benefits of scenarios.
- Promote joint problem-solving with a view to creating sector-specific solutions.
- Carrying out physical inspections to cross-check the written scenarios.
- Improving training and guidance for inspectors as to how to inspect this rule.
- Publishing the fact that physical inspections are being carried out to cross-check scenarios.
- Publishing the results of inspections and enforcement letters.

## ANNEX 9 Report of working group 3

### Definition of the target group

#### Fertilizer production and (process) storage

Profile: An international manufacturing (process) and storage fertilizer plant.

The main objective of the (large) production plant is to utilize natural resources for manufacturing ammonia and methanol petrochemical products. The plant manufactures between 100-1000 MT/day of both ammonia and methanol. A granular urea plant is constructed in addition to help widen the business spectrum through downstream development. The on-site facilities include ammonia and methanol storage and urea silos.

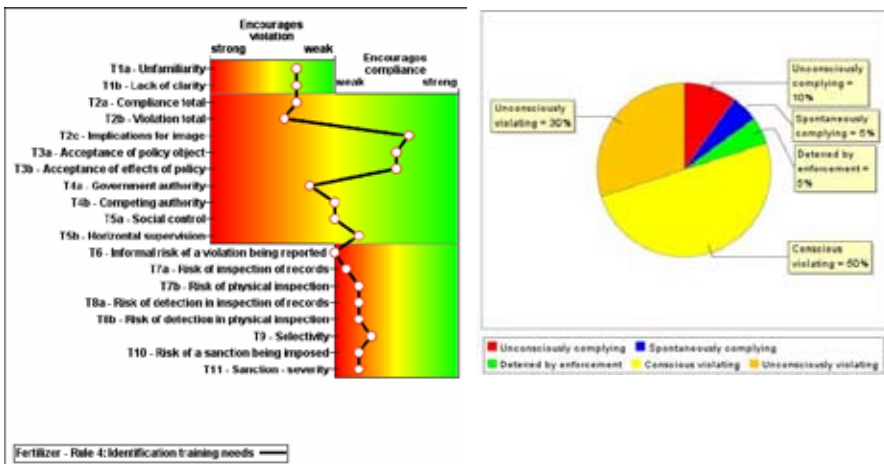
### Conclusions regarding the usefulness of the Table of Eleven

With regard to the usefulness of the tool:

The group generally agreed that the Table of Eleven is a good tool that offers a systematic approach and process to facilitate discussion on particular issues. The following points were highlighted:

- The tool enables results to be presented clearly.
- The tool should be used in a group (rather than by individuals).
- The discussion it generates is as important as the instrument.
- The presence of a representative of the target group (of the rule) is crucial.
- The tool may also be used very well for ex ante evaluation of regulations.

### Results for rule 4





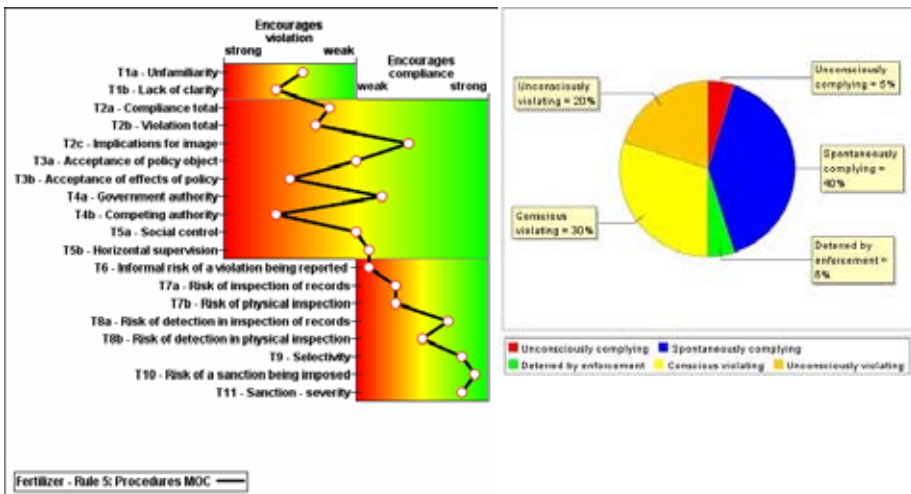
*Conclusions regarding rule 4*

- The charts and discussion indicate a sector that cares more for reputation than for legal compliance. In fact, there are motivating factors for violating the rules. The group cited the following potential reasons:
  - training needs (relating to rule 4) are perceived as having relatively low added value for the industry
  - sanctions for violations are relatively low
  - “soft” requirements (such as training) are not regarded as being as important as “hard” factors (mainly technical measures).
- A gap in knowledge between the authority and the enterprise, with the enterprise considering that it is much more knowledgeable about the production process than the authority. This situation also encourages violation of the rule. In particular, it is difficult for the inspector to identify gaps in the application of rule 4 (assessment of training needs).
- Inspectors must also be attentive to security concerns associated with the presence of ammonium nitrate.

*Conclusion regarding rule 5*

The fertilizer industry is rather conventional with respect to production techniques. Changes in production methods take place over longer periods. These “minor” changes (or apparently minor changes) in particular are an important issue: they may lead to high risks (for example, the Toulouse disaster, one of the causes of which was an off-spec product). Bigger changes, such as the construction of a new plant, are easier to identify and are usually addressed in a more standard way.

*Results for rule 5*



- There is a tendency to overlook (seemingly) small changes in production and handling processes.
- Management of change is usually applied to major, obvious changes but changes in maintenance practices may often be overlooked. There is also a concern in dealing with “I for I” (or “like for like”) substitutions in the process which the operator may not necessarily categorize as a change.
- Small changes are hard to identify using written records. The probability of detection depends on:
  - the presence and quality of the MOC procedure, as prepared by the company
  - the scale of the change
  - the (technical) abilities of the inspector, and the inspection technique applied (asking the right questions of the right people).
- an important part of the MOC procedure is selecting and executing a certain type of risk analysis, e.g., a HAZOP for major changes, an FMEA for minor changes. Assuming the procedure is followed and the risk analyses are completed, the probability of detection is relatively high.

#### *Lessons learned for Europe*

1. The tool could be used by the European Commission. It also could be used by global organizations (for different types of rules), either internally or in cooperation with other stakeholders or other competent authorities.
2. Organize training courses at EU level, e.g., for EU inspectors on particular issues or topics.
3. The identification of waste companies with dangerous substances was identified as a major issue.
4. Seemingly minor rules that are in fact of importance may intentionally be disregarded that is, not considered as relevant for major hazards, but in fact they can be important for particular cases (e.g., MOC in the fertilizer production industry).

*Summary of interventions*

Rule	Checklist Test no.	Interventions
4	7 – II	Change the mindset of inspectors: raise the profile of the training of personnel (inspectors) with respect to major hazards.
	7 – II	Set up confidential reporting systems for employees.
	7 – II	Improve the training of inspectors and enhance understanding of process and hazards risks within the fertilizer industry in order to improve the quality of inspections.
	7 – II	Some Member States have identified a need to increase the training of inspectors for the inspection of SMS.
	7 – II	Split up inspection plans (and inspections) into a technical inspection and a management inspection; dedicated focus on training.
	7 – II	Launch network (or industry survey) to identify and register the number and severity of industrial accidents and near misses (to review the importance of training). “Drivers” to set up this initiative expected from inspections.
5	General	Prepare guidance documents for operators as well as training programmes for operators.
	7	Scrutinize breakdown records to gain insight into the number and severity of breakdowns, in particular as regards the link to safety (data mining).
	3b	Involve the sector in question in the creation and evaluation of the (national) rules.
	3b	Investigate the role and effect of NGOs, not for a single establishment but for the fertilizer sector as a whole (even though the sector is not particularly “sexy”).
	4b	Raise awareness within the inspectorates, in particular with regard to the security risks (explosives), i.e., the vulnerability of the sector. Communicate (example) with the Ministry of Defence or the Ministry of Interior. Discussions about countermeasures will raise safety awareness in the sector in general.

# ANNEX 10 Report of working group 4

## Main conclusions

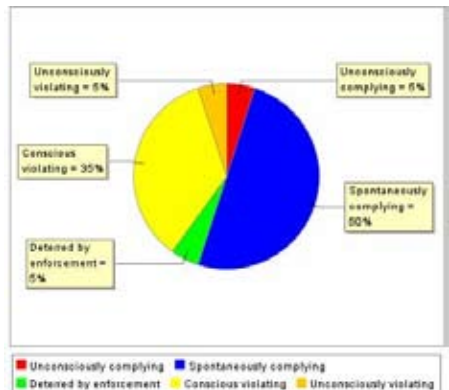
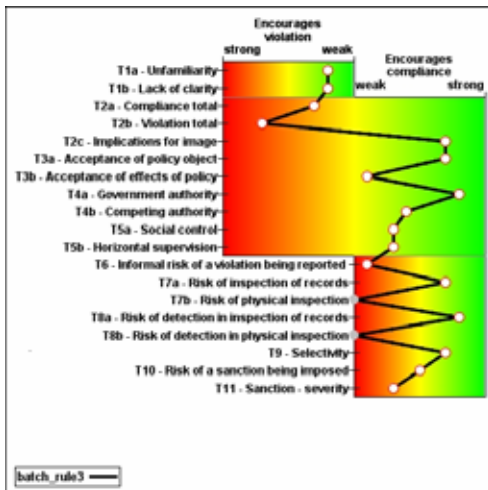
Spontaneous compliance for the batch processing target group is relatively high for the rules considered (3 and 4). The expectation is that this applies for most rules. The level of knowledge of the rules is high. Respect of government authority is relatively high and recommendations are usually followed up. The probability of violations being detected during inspections is high. Quality criteria for the interpretation of compliance with certain rules are lacking and form the subject of discussions with the companies.

## Results for batch processes

### Description of the target group

The batch processing sector consists of a wide variety of companies. There are differences in products, differences in terms of organization and differences in the scale of the companies. The rate of change is high, especially as regards the effect of changes in the ownership of these companies. The processes can have a high degree of complexity. It seems that there are small and big Seveso companies. The smaller companies are usually independent (Belgium, Croatia). The big companies are usually part of a larger (parent) organization and have their own SHE members of staff, with production taking place in various countries. The big companies were defined as the target group.

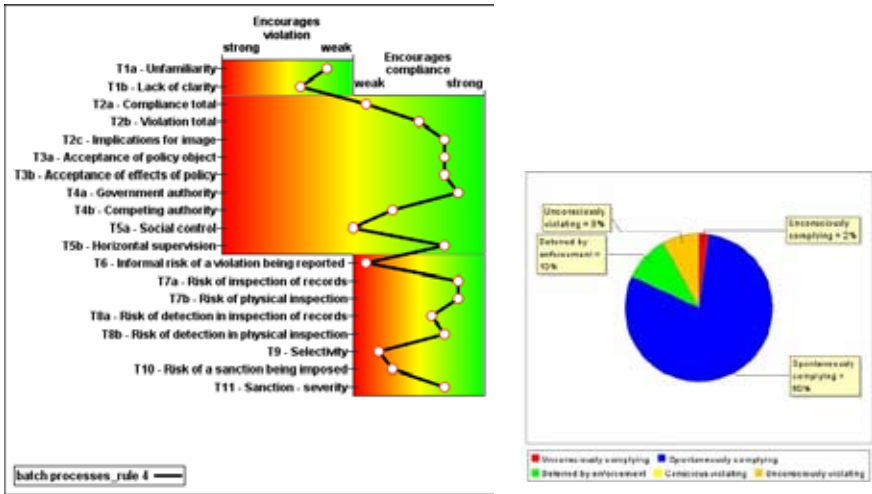
## Results for rule 3



Conclusions regarding rule 3

- Test results are mainly positive (green area).
- The objective of the rule enjoys a high degree of acceptance.
- Enforcement is not the most important reason for compliance: 50 % of the target group comply spontaneously.

Results for rule 4



Conclusions regarding rule 4

- On the whole a positive score.
- Weak points: T6 (risk of reporting), T10 (selectivity: training is a “soft” aspect).
- 80 % spontaneous compliance, the remainder comply after enforcement.

## Results of testing rule 3

**Work title:** batch\_rule3

**Editor:** J. van Dijk

**Last changed on:** 2006.11.09

**Official name of rule** Assessment of the extent and severity of consequences (of identified major accidents)

**Type of rule:** Seveso II

**Target group:** batch processes

## Results of the Table of Eleven test

### T1 - Knowledge of the rules

- 1.1 How much does the target group know about the rules? 8 Austria: 8 - 10 Holland: 8 - 10 Belgium: 7 discussion about scenarios Germany: 8 - 10 Lith: 8 - 10 Spain: 7 Croatia: 6 - 7
- 1.2 In the target group's opinion, are the rules clear? 8 Sp: yes, but different points of view between industry and inspectorate - 8 L: 8 methodology clear? G: 7 - 8 B: target group has a view about how to comply - 9 A: 8 discussion in congress C: 4 - 5 government does not provide much information, score = 8 note: lower in Croatia!

### T2 - Advantages/Disadvantages

- 2.1 In the target group's opinion, what does it take to comply with the rule in terms of time, money and effort? 8 C: 8 A: 6 "they forget the consequences", why? B: 8 "they forget the consequences for the environment!" G: 8 L: +- 8; quality of evaluation of the consequences is a discussion point Sp: 6 - 8, see remark B
- 2.2 In the target group's opinion, what is the advantage of breaking the rule? 8
- 2.3 In the target group's opinion, how much does it cost to break the rule? I difficult question!
- 2.4 According to the target group, how much advantage is there in complying with the rule? 5 High advantage, as it can cost a lot more in the future. A good assessment is the basis for the right measures. This is what we mean. How do people within the industry think? Average score for the target group.
- 2.5 To what extent does the target group find complying or not complying with this rule

important for its reputation? 7 B: 8 A: 8 L: 7 Sp 7 -8 C: 5, more important for the head office, less in C itself G: 8

### **T3 - Degree of acceptance**

3.1 To what extent does the target group regard the policy objective as reasonable? 7 explanation to the target group is necessary! Target groups do not always want to communicate.. Note about rating: it is not correct, very reasonable = 10, indifferent = 0?! A: 8 - 9 S: 6 - 8 G: 7 H: 7 B: 6 L: 6

3.2 To what extent does the target group regard the standard arising from it as acceptable? I Probably low or indifferent. What is the influence of Seveso? Members of the target group are not really aware of the underlying philosophy.

### **T4 - Faithfulness of the target group**

4.1 To what extent is the target group in general inclined to do what the government asks it to do? 8 N, B, G: >8 L: C: 9 be aware of the time required by the target group, depending also on economic factors.

4.2 To what extent does the target group feel that its own cultural or religious standards and values are in competition with those of the government? 4 methodology is an issue, e.g. qualitative or quantitative assessment? A: <4 N: 4 C: 4 S: 4 L: 4

### **T5 - Non-official control**

5.1 Does the target group believe that its community (neighbours, colleagues, competitors, relatives, passers-by etc) - knowing that the target group breaks the rule - is likely to call the group to account for its behaviour? 3 Remark: they look at other Seveso companies. It depends on the sector in question. Look at accidents. Look at economic factors L: not common to do so S: 2 - 3 G: 2 - 3 A: 2 C: 3 N: 4

5.2 To what extent does the target group experience horizontal supervision as an additional form of supervision of the rule? 3 OHSAS certification could help (not many) ISO 14.001 could help (many) A: 2 - 3 B: 3 N: 3 G: 2 - 3 C: 4 S: 3

### **T6 - Risk of being reported**

6.1 In the target group's estimation, how high is the risk of the government learning about a violation other than through government supervision? I quite low A/G/B: 0

## T7 - Risk of inspection

- 7.1 In the target group's estimation, how high is the risk of the government inspecting the records to see whether legislation is or is not being complied with? 7 target group members experience it as high. S: 6 - 8 only administrative L: 7 - 8 G: 8 B: 7 - 8 A: 7 C: 8
- 7.2 In the target group's estimation, how high is the probability of the government carrying out a physical inspection to see whether legislation is or is not being complied with? N.A.

## T8 - Risk of detection

- 8.1 Assuming that someone broke a rule, how high is the risk, in the target group's estimation, of the government - when inspecting the records referred to in 7.1 - detecting the violation? 8 L: 9 C: 6 A: 8 G: 9 B: 8 N: 8 It is very likely to find the violation. We need competences and time to make good detections. The industry can "hide" the violation. The group has different views on this matter!
- 8.2 Assuming that someone broke a rule, how high is the risk, in the target group's estimation, of the government - when carrying out a physical inspection referred to in 7.2 - detecting the violation? N.A.

## T9 - Selectivity

- 9.1 To what extent does the target group feel that the enforcement strategy used is successful (in the sense that offenders are inspected more frequently than those complying with the rules)? 7 general inspection strategy on EU level is available. Most companies know this strategy. Not in Austria. The Netherlands also has its own strategy, as does Belgium. It is not very clear if the target group knows. The target group is aware of the behaviour of the inspector. Inspections are announced. Results are generally reported. C: 6 - 7 A: 7 B: 9 G: 8 L: 7 S: 7 N: 8

## T10 - Risk of sanction

- 10.1 How high is the risk, in the target group's estimation, of a detected violation actually resulting in the imposition of a sanction? 5 In historical terms in the Netherlands: going from negotiating to "police officers". Again back to the first strategy, think before enforcement. L: sanctions are not likely for this rule; more for technical violations G: low C: 6 B: 9 ! A: 1 G: 4 S: 5 L: 4 N: 6



## TII - Sanction - severity

11.1 How does the target group experience the sanction that is usually imposed for breaking this rule? 3 Netherlands: only criminal sanctions are applicable, not administrative ones. Members of the target group are afraid of having to go to court. Belgium: permit is withdrawn because of not having a management system in place: 5 L: administrative: 5 C: 4 A: 1 G: 1 - 2 S: administrative: 4 - 5

## Results of testing rule 4

**Work title:** batch processes

**official name of rule** identification of training needs

## Results of the Table of Eleven test

### T1 - Knowledge of the rules

1.1 How much does the target group know about the rules?

8

Is it clear for the target group what the identification of the training is?

1.2 In the target group's opinion, are the rules clear?

6 Not completely.

Some training programmes are available.

### T2 - Advantages/Disadvantages

2.1 What does it take to comply with the rule, in terms of time, money and effort, in the target group's opinion? 8

2.2 In the target group's opinion, what is the advantage of breaking the rule? 2

2.3 In the target group's opinion, how much does it cost to break the rule? 7

2.4 According to the target group, how much advantage is there to complying with the rule? 9 the motivation for technical training is higher than, for example, for awareness, emergency or safety training.

2.5 To what extent does the target group find complying or not complying with this rule important for its reputation? 7

### **T3 - Degree of acceptance**

- 3.1 To what extent does the target group regard the policy objective as reasonable? 7
- 3.2 To what extent does the target group regard the standard arising from it as acceptable? 7

### **T4 - Faithfulness of the target group**

- 4.1 To what extent is the target group in general inclined to do what the government asks it to do? 8
- 4.2 To what extent does the target group feel that its own cultural or religious standards and values are in competition with those of the government? 3

### **T5 - Non-official control**

- 5.1 Does the target group believe that its community (neighbours, colleagues, competitors, relatives, passers-by etc) - knowing that the target group breaks the rule - is likely to call the group to account for its behaviour? 0
- 5.2 To what extent does the target group experience horizontal supervision as an additional form of supervision of the rule? 7

### **T6 - Risk of being reported**

- 6.1 In the target group's estimation, how high is the risk of the government learning about a violation other than through government supervision? 1

### **T7 - Risk of inspection**

- 7.1 In the target group's estimation, how high is the risk of the government inspecting the records to see whether legislation is or is not being complied with? 8
- 7.2 In the target group's estimation, how high is the risk of the government carrying out a physical inspection to see whether legislation is or is not being complied with? 8 Austria: low score, not many inspections are carried out with respect to this "soft" aspect. Croatia: inspections on behavioural aspects carried out by different competent authorities; training is one of the aspects. Belgium: training as a safety manager, 1 day a week, 2 years. Germany: less training than B/H Netherlands: ISO certified, examples will be sent.

## **T8 - Risk of detection**

- 8.1 Assuming that someone broke a rule, how high is the risk, in the target group's estimation, of the government - when inspecting the records referred to in 7.1 - detecting the violation? 6
- 8.2 Assuming that someone broke a rule, how high is the risk, in the target group's estimation, of the government - when carrying out a physical inspection referred to in 7.2 - detecting the violation? 7

## **T9 - Selectivity**

- 9.1 To what extent does the target group feel that the enforcement strategy used is successful (in the sense that offenders are inspected more frequently than those complying with the rules)? 2

## **T10 - Risk of sanction**

- 10.1 How high is the risk, in the target group's estimation, of a detected violation actually resulting in the imposition of a sanction? 3 the chance for a sanction being imposed is low, but when an emergency situation has occurred it is a different matter. This is not so much a violation: too "soft".

## **T11 - Sanction - severity**

- 11.1 How does the target group experience the sanction that is usually imposed for breaking this rule? 7 They find it hard, as members of the target group/the inspectors do not really see it as a violation.

## ANNEX II Report of working group 5

### *Description of the target group*

LPG storage companies engage in different types of activities, including the storage and filling of aerosol applications. In addition to Seveso companies, the specific inspectorates that supervise Seveso legislation in some Member States also inspect companies with lower threshold values, e.g., Ireland and Finland setting the threshold at 5 tons.

The LPG sector is very familiar with safety regulations, as these were already set decades ago. Compliance levels on technical measures based on that specific legislation seem to be high. LPG storage is a comparatively simple process.

The sector, and specifically the larger companies/multinationals, is very familiar with and knowledgeable about the safety regulations. Therefore, rules set within their own context are often more easily followed than the rules set by the authorities. Very small companies, even within the scope of the Seveso Directive, are less knowledgeable but may adopt rules set by the authorities more easily.

For TII sessions, the LPG storage sector consists specifically of the local/regional operating companies and the (un)loading of LPG. The number of employees of those kinds of companies varies from between 5 up to about 30 persons. Multinationals were separately assessed where feasible or necessary for the assessment of strengths and weaknesses and for selecting intervention mechanisms.

The filling of cylinders, storage and filling of aerosol applications, refineries and ship offloading have been excluded in the definition of the target group.

Image is not a very important driver for the LPG sector, although some aspects, such as promoting the clean aspects of LPG, are image-sensitive. Image in relation to safety is perceived in different ways; i.e., safety at the site is not specifically sensitive to public opinion. However, when LPG is used as an energy source in the domestic sphere and an accident happens, the public can be very skeptical about the LPG sector.

The LPG sector is not a proactive sector, but slow and resistant to change. Clear rules and economic aspects influence the implementation of specific requirements. Companies in the sector only do the minimum that is asked by the authorities and usually a stick is needed to force them to change. Multinationals tend to be more proactive because of their own (worldwide) standards.

*Conclusions regarding the Table of Eleven as a tool*

## Conclusions

- Interesting and complete tool; to be used as a problem-solving/clarifying tool; questions stimulate discussions.
- In its present form, the tool is somewhat tedious to use, specifically when using it for rules being investigated separately.
- Graphs are useful and in line with expectations, giving an indication on where to focus in enforcement.
- Assessing non-compliance with the tool is a useful activity.

## Recommendations

- More effective at higher level (policy/regulation as a whole) and not at the level of specific rules/articles.
- Include suggestions on interventions in the elements, giving the possibility to discuss interventions in direct relation with the elements.
- Reporting option should be improved and comments should be automatically included.
- Interaction between the checklist module and the test module (verifying the scores given).
- Tool will have to be used within an expert group; discussion is required. Not to be applied by a single inspector.
- Make use of tool during the drafting of legislation.

General remark: During the assessment of the TII tool, the group agreed to fix the time period at the moment directly following the entry into force of the Seveso II Directive, which meant that the point in time at which operators would have to face the new requirements. The compliance rate at this moment naturally differs in comparison to compliance levels at the present time, in which operators as well as authorities have gained more experience and knowledge of the specific Seveso requirements and how to fulfil them. In addition, companies at the present time are aware of the authorities' enforcement and sanction structure and will (positively or negatively) anticipate it.

### *Main conclusions regarding intervention strategies*

Agencies operate on a relatively individual basis. A more integrated approach involving combined enforcement could increase the level of compliance (more applicable to ATEX than Seveso).

Intervening in the market is a mechanism that does not work in promoting compliance with ATEX, PED and machine-related rules, as too much efforts is required to build up a technical dossier to have a product taken out of the market. This effort (and associated costs) cannot be borne by the authority.

Interventions should be proposed with specific elements of the obligations in mind, giving the possibility to discuss interventions directly in relation to the elements targeted.

Enforcement in general is still too much defined by (recent) accidents or public pressure, and not always systematically planned. Seveso is one of the few directives that requires a systematic and periodic inspection approach.

There is only a limited understanding of regulations on the part of operators and the guidance provided to them is also limited. This means that operators have to be informed more and also be informed more in advance in order to increase spontaneous compliance. First, general information has to be given during the implementation phase, afterwards to be followed by sector-specific practical information.

Enforcement actions are often served under general (labor or environmental) legislation and not on the basis of the Seveso Directive, as the latter is a very difficult piece of legislation to enforce (too many general descriptions, not specific enough).

#### *Lessons learned for Europe*

- Interesting and informative discussions; MJVs have added value.
- Differences in the approach to and implementation (translation into national legislation) of Seveso still occur.
- Practical application in addition to knowledge of national legislation is essential for exercising supervision with respect to the Seveso Directive and related legislation.
- There is a need for Seveso inspectors to have a strong technical background as well as experience in the field.
- Competences need to be strengthened (persuasive, decisive, strong personality).
- Training on health and safety management systems is necessary.
- EU-wide standards for inspectors on HSE training are needed.

#### *Other considerations*

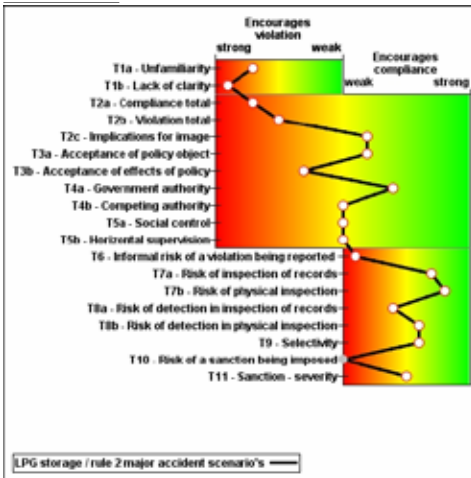
- Do we really make a difference?
- Has safety increased over recent years due to the Seveso Directive?
- Is all the energy expended by authorities in line with the results achieved?
- Seveso has been positive in emergency planning, involving other stakeholders, and in the cooperation with spatial planners etc.

#### *Rule 2: Major accident scenarios (Article 6, paragraph 1)*

Knowledge levels of both industries and authorities is higher among multinational companies than it is in the smaller, local/regional-oriented companies, the latter having to face new

regulations and requirements that they did not have to comply with before the introduction of Seveso II. Due to the limited capacity at these companies, expertise is often outsourced to consultants.

### Results for rule 2



The drafting of major accident scenarios is a time-consuming and thus costly requirement that does not lead to any (perceived) advantage for the company other than compliance with this specific Seveso rule. Not performing a risk assessment is therefore saving costs, as no costs are associated with non-compliance. As this requirement is an administrative task that cannot in all cases be traced through the publication of a report, detection of non-compliance by other groups is unlikely.

There are emotional/social advantages in selectively complying (underestimating consequences) for companies that have to provide (publicly available) safety reports. Pressure groups can also play a role in terms of the way in which emotional (dis)advantages are perceived. Scenarios are also applied in land use planning; e.g., densely populated areas and questions relating to who came first, “industry or inhabitants”, thus influencing the perception of emotional/social advantages.

Member States can develop an enforcement strategy that specifically takes Seveso requirements into account or set up a more integrated system, e.g. including IPPC enforcement as well. According to the Seveso Directive, the inspection mechanism should, however, be independent from (non-)compliance with the safety data reporting requirement.

Rule 3 on the assessment of the extent and severity of the consequences of identified major accidents will probably lead to the same conclusions as reached for rule 2. Rule 3 has therefore not been applied for the target sector.

As the working group wanted to evaluate some of the “soft” requirements of the Seveso Directive as well as some elements of the safety management system, the group decided that the requirements regarding operational control would form very interesting subject matter for investigation on the basis of the Table of Eleven.

*Interventions relating to rule 2 concerning unfamiliarity and lack of clarity (TI)*

Interventions defined for **major accident scenarios** are the following:

- Create and publish guidance material for companies.
- Make information available on websites such as l'Association Européenne des Gaz de Pétrole Liquéfiés (AEGPL, [www.aegpl.com](http://www.aegpl.com)) as umbrella organization for national LPG associations; inventory of industries within this sector.
- Hold meetings with companies (sectors) and informing them about these requirements.
- Encourage use of approved software, improve description of functionalities.
- Training of inspectors on sector-specific issues; building more competence for motivating/imposing compliance (“terrier mentality”).

*Rule X: Operational control (to a lesser extent also we took into consideration rule 5, management of change)*

Written instructions as required by Seveso and other specific national regulations sometimes do not exist (oral instructions instead) or are often copied from multinationals. Sometimes, ISO systems have been implemented, in which case formal written instructions do of course exist. During first inspections, the existence of such instructions is ascertained. Later inspections focus on the content and the issues that have to be addressed in the written instructions such as maintenance, safety measures, personal protective measures, and very specific operations (sampling and water draining). This means specific skills are required on the part of the inspector.

*Results for rule X*

The consequences of copying instructions from other companies are that instructions often do not represent the reality (not tailored to the situation in question) and that operators do not fully understand the contents of the instructions. Physical inspection is therefore needed in addition to an administrative check.



Larger companies have a better insight into the requirements for instructions that generate performance as intended, since they have people dedicated to these tasks. At smaller companies, the requirement of drafting written instructions and procedures means a considerable effort due to time pressures, low margins, less personnel and a lack of experience in drafting as such. Smaller companies regard technical issues as more important than this kind of administrative requirement, which, as technical issues constitute their core competence, they experience as a burden.

In addition, small companies do not consider the drafting of instructions as necessary, as they know their business very well and undergo only limited changes in process and personnel. In some cases they consider oral instructions to be enough. Written instructions are not part of daily practice; they do not have a strong link to a hands-on and practical mindset.

The only horizontal control consists of checks through suppliers or ISO certification.

Administrative inspection consists of checking test certificates and not always specifically the written instructions. Administrative inspection can be part of a physical check. The rule relates to the existence of written instructions, the (quality of the) content of the instructions and their implementation in practice. The inspector needs to be very familiar with the sector and its operations to be able to ask for the relevant instructions. Interpretative ability and knowledge of the sector on the part of the inspector is very important in checking instructions. The detection of violations depends on the knowledge and experience of the inspector.

The probability of a violation being detected is greater at the beginning, as the focus is on its actual existence and not specifically on the content of the written instruction. This initial phase requires less knowledge on the part of the inspector. Persistence is, however, required on the part of the inspector – a “terrier mentality” – for focusing in-depth on all instructions after the requirement has already been in operation for a longer period.

Companies complain that they are inspected by specific Seveso inspectors (with specific skills) because they are Seveso companies, comparing themselves in this regard with non-Seveso LPG companies. The selectivity element of TII, number 9, is therefore not really applicable. Remarks on inspections of other sectors are not specifically relevant or reflective of companies.

Compliance with this rule does not lead to higher levels of safety and enforcing this rule strictly is overly punitive as a first measure. Only increasing the severity of the sanction can lead to compliance with the rule. The industry is aware that it is not severely sanctioned for initial non-compliance with the requirement of instructions. A sanction will be imposed not because of non-compliance with this specific rule, but more for not acting in accordance with the requests of the authority more generally. It can be useful if companies are informed by their sector organization, federation or gas supplier as part of daily operations. For instance, a

Member State could elaborate the ATEX Directive. This elaboration would be backed up by a practical example that would serve as a useful rule to illustrate the TII process.

#### *Interventions relating to rule X*

Interventions relating to non-compliance with the **written instructions** requirement would have to be focused on the cost-benefit ratio (spontaneous compliance) and on the probability and severity of sanctions (enforcement dimension). However, according to the working group, it would be best to focus on sanctioning rather than on preventative measures.

#### *Interventions relating to the cost-benefit ratio (T2)*

- Informing the neighborhood through negative publication facilitates social pressure on the company.
- Pressure of the members of sector organizations or (upstream) suppliers requiring compliance, also in relation to management systems. Explain and substantiate the benefits to these stakeholders.

#### *Interventions relating to probability and severity of sanctions (T10 and T11)*

- Use administrative fines for “soft” requirements of the Seveso Directive such as the written instructions requirement.
- In severe cases, a “blame and shame” instrument after administrative sanctions did not have the expected effect. Intensifying the inspections is a possible option (in some countries these inspections are even charged to the company, leading to a financial driver in addition to the time constraints).
- Build up a dossier on other infringements in which this non-compliance issue can be addressed as well.

#### *Combination of preventative and repressive interventions*

- Seminars with industry groups, clarifying conditions, the quality expected and the (inspection and enforcement) steps that will be taken after a certain period.

#### *Rule Y: ATEX in relation to LPG storage, including cylinder filling*

ATEX is more reality-driven than the Seveso Directive, as it deals with a higher probability of accidents. This regulation is therefore more easily accepted by operators than the Seveso Directive, which deals with risks of a completely different dimension/probability. This specifically accounts for the electrical source requirements, but less for the non-electrical.

#### *Results for rule Y*

The practical consequences of the ATEX requirements regarding non-electrical ignition sources (12) are not clear to the target group. The electrical requirements are clear, however, as they have been applicable for a long time.

Complying with ATEX rules is very expensive, e.g., for the non-electrical sources. Existing equipment may have to be replaced in order to be in compliance with the new regulation or additional equipment may have to be installed, resulting in interruptions to daily operations, the need to look for new suppliers and so on (considerable efforts). Finally, the risk assessment that has to be carried out is a costly requirement. There is no advantage for the operator in complying with the ATEX rule spontaneously.

ATEX as a policy is known and more or less accepted by the LPG sector. Effects of the ATEX policy, meaning the obligation to comply with all its specific requirements, are less accepted due to the burden such compliance entails, especially with regard to the requirements relating to non-electrical ignition sources. Mechanical (non-electrical) sources have seldom led to risks, and complying with these (new) requirements is far less accepted by the sector.

Insurance inspectors inspect compliance with a number of ATEX-related requirements. In addition, operators can receive a reduction of insurance premiums if they periodically produce inspection reports stating satisfaction of requirements. This might act as a positive incentive for compliance.

The sector is aware that inspectors will ask for the explosion-protection documents. The probability of a violation being detected is rather high. The documents that must, by law, be drafted are very specific and are easily checked and verified by the inspector. The documents can be easily checked during a physical inspection. The zoning (with the exception of the EX mark) and mechanical requirements are more difficult to inspect.

ATEX is new legislation for authorities as well as industries. The level of expectation in the target group with regard to enforcement and sanctioning is therefore not very high. The risk of being sanctioned is higher relative to certain Seveso rules because some ATEX elements are easier to inspect and non-compliance easier to prove. The severity of the sanction can be high; premises can be put temporarily out of business, for example.

#### *Interventions relating to rule Y*

In particular, non-compliance of *ATEX rules*; experience with enforcement of ATEX rules as yet limited.

#### **Intervention relating to probability of reporting (T6)**

- Covenants or agreements with insurance companies, certifying bodies, notified bodies to report back non-conformity with some elements of ATEX.
- Require and ask for reports on specific items from other (non-authority) bodies.
- Feeding back information and exchanging information between different inspectors (signalling function).

- Advertising campaign targeting employees which focuses a on safe workers' environment and the possibility to inform the competent authority.
- Promoting the establishment of safety committees within companies.
- Education of safety representatives of safety committees.

### **Intervention relating to acceptance of policy implementation (T3)**

- Provide practical examples on implementation of non-electrical ignition sources.
- Give examples of accidents (warning function).
- Put pressure on equipment suppliers to provide useful, practical information to the end users.
- Agree on an approach with the industrial sector on how to tackle the issue of technical requirements in order to simplify this aspect for each individual operator.
- Authorities have to make clear what their own requirements and expectations are, and forward these to the sector organizations and the main consultants involved in the implementation of the regulation.
- Promote good examples of individual companies within the sector.

### **Intervention relating to clarity of the rules (T1)**

- FAQs on authority website.

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The Dutch Ministry of Social Affairs and Employment has a role in the implementation of the Seveso II Directive 96/82 EG concerning the prevention of major accidents. Its duty is to verify that the most appropriate measures have been taken to prevent major accidents and to limit the consequences of major accidents for personnel in the enterprises.

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