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The EU Seveso regime in practice
From uncertainty blindness to uncertainty tolerance

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ABSTRACT

The chemical sector is confronted with risks pertaining to accidents involving dangerous substances. At the European level, a set of regulations – the Seveso regime – aims at controlling such risks. This article explores how this regime is put into practice, by analyzing the local practices of enforcement by Dutch inspectors and compliance by Dutch chemical companies. These empirical insights demonstrate that the classical 'positivistic risk paradigm' – which treats all risks as calculable, controllable and reducible – seems to dominate in the Seveso regime. The analysis in this article shows that this can lead to 'uncertainty blindness'; a regulatory regime where only yesterday's accidents are managed and salient future risks are potentially overlooked. We suggest that both regulators and regulated should start accepting the possibility of uncertain risks, which implies a cultural change in the current regulatory regime to 'uncertainty tolerance'.

1. Introduction

Regulation plays an important role in controlling risks. This also holds for risks associated with chemical industry. Industrial risks are complex because within a chemical plant the processing, storing and transport of dangerous substances involve risks, hereby creating accumulation and interplay of many risk factors. The chemical sector is confronted with the possibility of accidents involving dangerous substances. Past accidents in the chemical industry in, amongst others, Bhopal, Mexico City and Seveso, have led to attempts in the European Union (EU) to control such major accident hazards. A set of two EU directives and three amendments – together defined as the 'Seveso regime' – aims to regulate the chemical industry in order to prevent accidents. In the history of the Seveso regime, it is clear that each time a major accident happened, the rules were redefined and sharpened. It is thus assumed by the regulators that tight(er) regulation is the best way to regulate risks in the chemical industry.

In this paper we explore the local practices of Dutch companies and inspectors in applying the Seveso rules and regulations. How do regulators and regulated perceive the risks at stake? Based on in-depth interviews we will argue that the classical 'positivistic risk paradigm' which treats risks as calculable, controllable and reducible seems to dominate within the Seveso regulatory regime. The Seveso definition of risk suggests a focus on simple, calculable risks at the expense of risks that are uncertain. This impression of 'uncertainty intolerance' is supported by the very detailed and complex character of the regulation, which breathes the pretence of full control and absolute safety. Two rounds of semi-structured interviews ($n = 17$)[1] with Dutch inspectors and chemical companies provide insight into the way in which risks are perceived and regulated. Our analysis shows that the current Seveso regime – to put it somewhat provocatively – could be labeled as 'uncertainty blind'. This paper concludes by stating that we are in need for a more reflexive regime in which regulators stimulate 'uncertainty tolerance'.

2. The Seveso regime

A series of major accidents in the European chemical industry in the 1970s (see Table 1 for an overview) led to long discussions in the European Parliament on the need for regulation. While most member states of the European Union at that time had their national systems to regulate such risks, the quick succession of these acci-

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[1] The first round of interviews took place in 2000 ($n = 11$); the second round took place in 2008 ($n = 6$). The first round resulted in a book on the implementation of the Seveso regime [1]. Handling risks was only a marginal part of this study and the second round of interviews was held to test the assumptions derived from the first round.

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Table 1
Overview of relevant major industrial accidents since the 1970s.

Country/location	Year	Company	Episode	Fatalities and injured
UK/Flixborough	1974	Nypro	Fuel air explosion	28 fatalities, > 50 injured, property damage
Netherlands/Beek	1975	DSM	Vapour cloud explosion (Ethylene)	14 fatalities, 109 injured
Italy/Seveso	1976	ICMESA	Vapour cloud explosion (Dioxin)	No fatalities, injuries and damage to environment, animal life. Long-term adverse health effects
1982 – Seveso I Directive				
India/Bhopal	1984	UCIL	Methyl Isocyanate	Estimated fatalities between 3500 and 18.000, and >500.000 injured, major property damage
Switzerland/Basel	1986	Sandoz AG	Fire at a chemical plant for agricultural chemicals	No fatalities, damage to natural resources and properties
1987 – Amendment I (based on Bhopal)			1989 – Amendment II (based on Basel)	1996 – Seveso II Directive
Netherlands/Enschede	2000	SE Fireworks	Fireworks	23 fatalities, >1000 injured, property damage
Romania/Baia Mare	2000	Aurul SA Company	Cyanide	None, water supply affected, major environmental consequences
France/Toulouse	2001	Grande Paroisse	Ammonium Nitrate	29 fatalities, >2000 injured and property damage
2003 – Amendment III (based on Enschede and Toulouse)				

dents on European territory called for the need for international action due to the 'dread, novelty nature and uncontrollability of the hazard' at stake [2].

After three years of negotiations, the Seveso directive was adopted in 1982. Further accidents led to amendments that broadened the scope of this first directive. As it was recognized that approximately 85% of over 300 accidents reported under Seveso I have shown some deficiencies in the management system' [3], a second (replacing) Seveso directive adopted in 1996 changed the scope from identifying a list of named substances and regulating individual technical installations to focusing on the management systems of entire establishments. The latest amendment (2003) was again introduced after accidents.

Every change in the Seveso regime is a response to a major accident. Each time the rules were redefined and sharpened. It is thus assumed by the regulators that tight(er) regulation is the best way to regulate risks in the chemical industry. It is to be realized, however, that each accident revealed a new risk, i.e. a possible hazard neither considered nor known from previous experience. As a representative of a chemical company stated: "in case something new happens you get new insights". Instead of anticipating a broad range of both known and imaginable new risks, the regulators mainly seem to manage yesterday's accidents rather than tomorrow's risks.

Under this European Seveso regime, chemical companies that house a certain threshold of listed chemical substances (e.g. ammonium nitrate, hydrogen, or chlorine), are 'Seveso establishments' and are firstly required to prevent major accidents from happening and secondly, in case accidents do happen, to control the consequences for humans and the environment. Seveso companies have to draw a 'major accident prevention policy' via a 'safety report' and internal and external 'emergency plans'. Furthermore, they have to control 'domino effects' in areas where Seveso companies are located close together (e.g. industry parks), and they are to alert all people liable to be affected by a major accident. Member state governments are to ensure that Seveso risks are considered in land-use planning legislation, and they have to appoint 'competent authorities' responsible for inspecting the regulated. All in all, the directive asks for a considerable number of required activities from both regulators and regulated. This article analyzes the regulation of risks via the safety report requirements (directive 96/82/EC, article 9).

3. The Seveso regime and the positivistic risk paradigm

In the Seveso directive, risk is defined as the "likelihood of a specific effect occurring within a specified period or in specified circumstances" (directive 96/82/EC, article 3). The definition of risk in the Seveso regime resonates the classic definition of risk as a function of probability (likelihood) and effect inspired by the work of the economist Knight [4]. He argued that it is possible and necessary to distinguish uncertainty sharply from risk. Langlois and Cosgel [5] argue that 'Knight's distinction between risk and uncertainty has been taken to differentiate between the measurability/immeasurability'. In this paradigm – also referred to as the 'positivistic risk paradigm' [6,7] – risk is used to refer to hazards which are known and calculable from previous experience.

This dichotomy is still the dominant way of looking at risk. However, an increasing number of authors [8–10] argue that uncertainty and risk cannot as easily be distinguished as is assumed in the positivistic risk paradigm. Some risks are simple, in the sense of certain enough to be calculated as a function of probability and effect, as for example car accidents or seasonal flooding. In those cases, due to past experience and the associated availability of statistical data, probability can be estimated and a measure of effect can be derived. Simple risks are calculable and relatively easy to manage. Existing risk assessment tools and risk management approaches suffice.

However, many risks are not that simple. Risk refers to potential events with consequences that are evaluated as negative. In many cases such events and/or consequences are highly uncertain, because they involve new hazards or situations with structural changes compared to the past. In the latter case, the available statistics are of limited value to estimate probability and effect as the historical data no longer do justice to current and future situations. Risks may involve complex causalities, non-linear relationships as well as interactions between effects. Uncertainties about the relevant phenomena and the underlying multi-causal relationships may render it difficult, if not impossible, to determine what may happen.

Effects may extend into the long term and measures of effect, if available, cannot easily be added. Such risks are thus not, or at best only partly, calculable, because the probability of occurrence or the damage cannot be estimated, and even the potential hazard and the relevant causalities may not be established, although there are suspicions of danger. van Asselt and Vos [8] used the notion of 'uncertain risks' to refer to such risks. In the positivistic Knightian risk paradigm, uncertain risks are overlooked. The most important reason to differentiate between simple and uncertain risks is that they require fundamentally different assessment, management and communication approaches [8,9,11–13].

The Seveso definition of risk as the "likelihood of a specific [adverse] effect" suggests that accident risks in the chemical sector are simple. However, we would like to argue that uncertain risks require consideration. Risks in the chemical industry do not

concern singular risks, but involve accumulation and interplay of different, but correlated risk factors, as well as multiple, heterogeneous and long-term effects. For example, within a chemical plant, not only the processing installations, but also the storing facilities and transport involve interdependent risks, which need to be addressed both separately and in relation to each other. Uncertainties about the underlying processes and the complex multi-causal relationships between causes and effects may render it difficult, if not impossible, to determine what may happen. Many parties with different perspectives (for example, emphasizing either environmental risks, health risks or economic benefits) have a stake in the regulation of major accident risks in the chemical industry. For example, one of the interviewed companies has a pit below a weighbridge that can accommodate the complete contents of a tank-lorry. Sometimes a bit of rainwater falls into the pit:

> "We have a level meter with a little pump connected to it, that automatically pumps away the water after it has reached a certain level. The environmental inspector argued that the pump should not work automatically because you cannot be certain what kind of liquid is in the pit. But the fire inspector said that it is important that the pump always works automatically as the risk of an overflow of liquids is too high. So these are contradictory advices".

Inspectors argue along similar lines:

> "Overall, you have to deal with several political levels which complicates matters, especially when they have different priorities".

Both spokesmen from the inspection and industry indicated that the different parties involved do not necessarily have contradicting goals, but the reality of the Seveso regime is a complex combination of different policy fields and of different governmental levels. This social reality stimulates ambiguity about the risks. When uncertain risks are not considered, unprecedented accidents happen as surprise.

The Seveso definition of risk suggests a focus on simple, calculable risks at the expense of risks that are uncertain. Close reading of the safety report requirements provides some further support for this impression. Annex II of the Seveso II directive specifies the minimum data to be included in a safety report. Safety reports produced by the chemical industry are on average 400 pages. So this one-page annex is extremely ambiguous in defining the criteria [1]. A safety report should, amongst others, contain a "detailed description of the possible major accident scenarios and their probability or the conditions under which they occur including a summary of the events which may play a role in triggering each of these scenarios" (directive 96/82/EC, annex II). It is not specified, however, what a scenario is, what is meant by a detailed description, or what types of events are referred to. A further problem is more fundamental. In the context of risk management, scenarios are coherent descriptions of alternative hypothetical futures as an effort to capture a wide range of possible future developments and/or circumstances. It is possible to reason about conditions under which they may occur or the events that may trigger a scenario to unfold, however, establishing the probability, i.e. likelihood of occurrence, of a scenario is difficult, if not principally impossible. Generally speaking, there are two ways to arrive at probability estimates: (1) statistics about previous accidents are used to estimate how often such accidents occur, which is used as a basis to forecast the likelihood of such an accident in the future (the frequentist approach), and (2) probability is interpreted as a subjective degree of belief, which implies that expert judgments are used (the Bayesian approach). Especially when scenarios feature conditions or events not experienced before, the frequentist approach is not applicable and the question is how to value experts' degrees of belief, as it is difficult, also for experts, to take unprecedented scenarios seriously [14]. In such cases, probability is solely a reflection of our experience with past accidents, and does not necessarily inform about future risks. The series of accidents (see Table 1) demonstrate that unprecedented scenarios do happen in practice.

In the positivistic risk paradigms, risks only existed when they have manifested themselves. This stimulates reactive risk regulation. The history of the Seveso regime, i.e. changes after an accident that has demonstrated the reality of a risk, suggests that the positivistic risk paradigm frames this regime. The regulators aim to learn lessons from recent accidents, which is to be applauded. However, it can be argued that an important lesson which can be drawn from the series of major accidents, i.e. the need to question the positivistic risk paradigm and to recognize uncertain risks, is not (yet) understood.

4. The Dutch regulatory practice

So far, we have examined the Seveso regime from a risk perspective through close reading of the directives and amendments. The second part of this article discusses the Dutch regulatory practice.

4.1. Conceptualization of risk

As the Seveso directive is the basis for regulation in member states, it should not surprise that we also observed the positivistic risk definition in the interviews with both the regulators and the regulated in the Netherlands:

- "There are two sides to risk: chance and effect. In case of large effects within a scenario, you will work on chance calculations" (regulator).
- "First they [risks] are quantified and then classified" (regulated).

Recently, a further distinction has been introduced in Dutch regulation and in inspection procedures. Risks are classified into controllable or so-called 'leftover risks' (in Dutch: *rest-risico's*). 'Leftover risks' are either difficult to control pro-actively, or pertain to too expensive, exceptional situations. One of the interviewed inspectors described them as follows:

> "Leftover risks are an articulation of the fact that you know upfront that a certain disaster with a very small calculated chance of occurring cannot be prevented. It is a theoretical model, but there is a risk that you tolerate".

What does this category of leftover risks, and the ways in which it is described, tell about the underlying risk assumptions? Different characteristics are ascribed to leftover risks. They are difficult to manage or it is undesirable to manage them, because that is considered too costly or the costs are considered disproportional. So these risks are tolerated, in the sense that no risk management measures are taken to prevent or mitigate these leftover risks. With the notion 'leftover', it is suggested that these risks are unimportant from a risk management point of view. However, the key issue is the recognition of limits to controllability, which is also visible in the following interview quote from a chemical company:

> "We can control the normal risks that derive from operating a chemical factory. But we do not control all risks; when a plane crashes down, there is nothing I can do".

Although it is recognized that there are limits to controllability, neither uncertainty with regard to occurrence and effects nor ambiguity with regard to tolerability, which is a normative notion, are considered. By presenting uncontrollable risks as 'leftover' and/or

exceptional scenarios, this category is marginalised. Notwithstanding the distinction between controllable and leftover risk which is a slight departure from the positivistic risk paradigm, major accident risks are still treated as calculable and controllable.

So we conclude that also in the Dutch practice, uncertainty is not acknowledged in the framing of risk. Risks are presented as a function of probability and effect. Nevertheless, in a single interview with a senior inspector, some uncertainty awareness could be sensed:

> "With some QRA [quantitative risk analysis] methods your calculations will be caught up by the improvements that have been carried out, which makes your value unreliable".

Here it is recognized that past data do not do justice to present and new circumstances, which have structurally changed compared to the past, in this case because of improvements at the Seveso establishment.

4.2. Adding additional requirements

The European Seveso regime works with directives. Directives regulate the aim to be achieved, allowing the member states the freedom how to achieve this. The Seveso directives are so-called 'minimum directives' that only set minimum standards, which allow member states to decide to 'go beyond' these minimum requirements. The Netherlands used this opportunity and added more additional requirements than other member states. Transposition of the Seveso II directive in the Netherlands took place via one act of primary legislation ('wet'), five acts of secondary legislation ('besluit') and one alternative instrument ('circulaire').[2] In comparison to other member states, this resulted in a relatively strict and detailed interpretation of the Seveso rules on paper in the transposition phase [1]. Especially in relation to the safety report, the Netherlands made use of the right to add additional requirements. Dutch companies are required to conduct a Quantitative Risk Analysis, in which the risks of chemical substances reaching humans or the environment should be calculated. The Dutch government set a fixed number as the maximum acceptable risk. If the calculated risks are higher, the company will have to take more preventive measures, or install more 'lines of defense' or 'layers of protection'.[3] So in the Dutch transposition, the calculability of risks gets even more emphasis. Uncertainty is presented as a threat and is, in the same breath, waved aside, as illustrated by the following quote from an inspector:

> "Companies need to depart from the assumption that you can identify and control the risks, otherwise you cannot normally operate a company".

The decision by the Dutch government to require a Quantitative Risk Analysis determines how companies address risks. That said, we witness that many multi-national companies already used some sort of quantitative approach themselves. Not surprisingly taken into account the risk framings inscribed in the Seveso regime and the Dutch transposition. Dutch 'Seveso companies' generally speaking calculate risks by using matrixes that categorize potential hazards in terms of probability (i.e. ranging from 'occurs frequently' to 'hardly occurs') and calculate the possible number of fatalities or injuries (i.e. effects). These risk calculations serve as a foundation for exploring pro-active, preventive and/or mitigating possibilities.

Not all companies favor a quantitative approach. One of the companies used brainstorming with all relevant experts to identify which scenarios are most probable as a way to assess risks. Although they did accept the probability framing, their more qualitative approach was considered too subjective, according to our interviewee. It was one of the reasons that the safety report was rejected four times:

> "They found our approach not sufficiently objective, too much 'natural wit'. Only when we started working with matrixes scoring chance and effects for all scenarios, they found the approach acceptable".

This impossibility to deal with qualitative assessments which in principle provides more room to consider uncertain risks is another observation which adds to the impression of uncertainty intolerance.

4.3. The inspection practice

As the Seveso regime combines a series of aims, there is more than one inspectorate involved in its enforcement. While preventing major accidents is the prime aim, mitigating the consequences of accidents which nevertheless occur, is crucial as well. The subject of the directive – protecting the environment, employees of companies as well as people in the neighborhood – influences the inspectorates involved: the environmental inspectorate, the labor inspectorate and the fire brigade. In the Netherlands, interdisciplinary teams (usually 3–6 people) assess submitted safety reports. In the first years, the assessment of the safety reports was very time-consuming. The main reason for this is the Dutch interpretation of the directive. Whereas the directive states that member states have to organize inspections to check whether operators can demonstrate that they have taken the appropriate measures to prevent major accidents (directive 96/82/EC, article 18), the Dutch transposition added the requirement that the inspectors should also test the 'acceptability' of the measures. In other words, instead of 'just' assessing the safety reports, the inspectors had to approve the safety measures inscribed in the reports. For many inspectors this proved problematic due to potential problems with accountability. As safety reports piled up at desks of inspectorates, it was quickly decided that the Dutch legislation should be changed in this respect. Now inspectors only have to assess the 'completeness' ('are the relevant topics documented?') and 'suitability' ('are the described measures sufficient in line with the current technical and scientific knowledge and suitable for the situation?'). The fact that the inspectors felt uncomfortable with the responsibility for the safety measures, may also be read as a sign that they realized that in the positivistic Seveso regime, uncertain risks are overlooked and that the safety measures inspired by previous accidents do not guarantee that new accidents will not happen or will be mitigated adequately. So they did not agree with the pretence of control which would have been further strengthened by their approval stamp.

5. Conclusions and recommendations

In this article we discussed the Seveso regime and the Dutch Seveso practice from the perspective of uncertainty. Every change in the Seveso regime is a response to accidents. Although it is wise to learn from past accidents, we argue that this is not enough to be prepared for future accidents. In this article, we suggested that a major lesson which can be drawn from the series of accidents is that unprecedented scenarios materialize with severe consequences.

[2] Without taking formatting differences into account, comparison shows that the Dutch transposition used much 'paper'. While the directive itself consists of 21 pages, the Spanish transposition was 14 pages, the German 53, the British 62 and the Dutch 71 [1].

[3] These lines or layers serve to either prevent an initiating event (e.g., loss of cooling) from developing into an incident (typically a release of a dangerous substance).

We argued that uncertain risks are overlooked. Uncertainty is neither acknowledged nor explicitly considered. Close reading of the directives and amendments in general and the safety report requirements in particular, examination of the Seveso definition of risk, conceptualization of risk in Dutch practice, the Dutch transposition of the directive, the resulting additional requirements and the impossibility to deal with qualitative assessments suggest that the Seveso regime is rooted in the positivistic risk paradigm.[4] Risks are treated as simple, calculable and controllable.

In other risk regulatory settings, van Asselt and Vos [8,16] observed an uncertainty paradox: uncertainty about risks is acknowledged, but nevertheless the role of experts in general and of risk assessors in particular is framed in terms of providing certainty. Although some limits to controllability are recognized in the Seveso practice, generally speaking uncertainty with regard to accident risks is not broadly acknowledged in the Seveso regime. To phrase it provocatively: the current Seveso regime is uncertainty blind. The famous German sociologist Ulrich Beck coined the notion "organized irresponsibility" to describe a state of affairs in which society is unprepared for inevitable surprises, notwithstanding all institutions in place and the pretence of certainty and control [17]. It is a too cheap shot to conclude that the Seveso regime is currently in a state of organized irresponsibility, but our analysis suggests that it is important to realize that current institutions and procedures tend to suggest that major accident risks are controlled, while uncertain risks are not attended to. In such a context, a new major accident would not only be a problem in terms of the actual damage, but it would also demonstrate that unprecedented scenarios, hence uncertain risks, are not adequately considered. This may decrease trust in regulators and the chemical industry. Lack of trust renders it even more difficult to organize responsible risk governance [12].

Anyone involved in the Seveso regime should learn to accept uncertain risks, although they cannot be calculated with traditional risk assessment tools. This is not a matter of methodology, but of culture. The current regime is rule-based and tends towards stricter rules and enforcement. We would recommend a shift to what one of the interviewed inspectors referred to as "safety culture". The challenge is to develop a regime which focuses on assessing how companies organize as good as possible for safety [18]. Key questions would be: How is the company dealing with simple risks? What does it learn from previous accidents? Is the company uncertainty tolerant? How does it reason about uncertain risks? What kinds of scenarios are considered? How is this reasoning translated into measures, management systems and culture? The role of inspectors would then shift from evaluating whether the assessment is complete to examining these questions. In that assessment process, they could confront the company with examples of uncertain risks as means to evaluate how the company responds and how they propose to be prepared for the kind of situations pointed at in such scenarios. Inspectors would then have a role in stimulating uncertainty awareness.

We, furthermore, conclude that there are limits to standardization and centralization. The regime should be flexible to be able to incorporate change and to become more uncertainty tolerant. A regime should not be too centralized, strict or hierarchical [19]. In a way, the core idea at the European level to manage accident risks through minimum guidelines is in principle a sound approach: it is in line with the idea of regulation that is not too standardized, centralized, strict and hierarchical. But it can be improved. We would recommend the European Commission to differentiate between simple risks, which can be assessed informed by past experience and classical risk assessment tools, and uncertain risks, and to develop minimum guidelines for the different types of risks. With regard to uncertain risks, the Commission could require that companies and member states have to explain how uncertain risks are considered. Also the shift to safety cultures could be explicitly included in minimal guidelines. Furthermore, although minimal guidelines provide discretionary room for the member states, the Commission could warn for the tendency in transposition to reintroduce counterproductive degrees of standardization, centralization, strictness and hierarchy on the national level. In the later case, instead of providing room to be flexible and to adapt to local circumstances (which also increases the degree of compliance), the flexibility and room of manoeuvre are actually decreased.

In our view, the Seveso regime does not have to remain uncertainty blind. The challenge is to develop incentives for uncertainty tolerant assessment and management of accident risks. We suggested how strategic modifications of the directives and guidelines as well as inspection practice could facilitate increased uncertainty awareness. It is not unfeasible to create incentives for uncertainty tolerance, but it requires a departure from comfortable routines and habits and it request the patience and persistence needed for a culture change.

[4] We did not examine risk calculations in detail. Such type of analysis might reveal the extent to which the positivistic risk paradigm is also ingrained at that level (see Verdonck et al. [15] for an example of an analysis of how uncertainty is dealt with at technical mathematical levels).

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