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Risk validation by the regulator in Seveso companies: Assessing the unknown.

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ABSTRACT

This longitudinal case study centres around a 'narrative' compiling 13 years of regulatory experience with risk assessment in practice of major hazard control of Dutch Seveso companies. The narrative is written by the first author, retired as an inspector mid-2016. The concept 'narrative' was reviewed, debated and methodically interpreted by the second author.
The narrative story considers risk assessment as the current basis for successful prevention and sound safety management, in line with current thinking. An inventory of risks for society, workers and environment, originating from a company that is eligible to receive a licence to operate, is essential for the regulator's decision-making. It needs to cover all risks since acceptance of incomplete assessments imply implicitly accepted, yet uncontrolled, danger.
Risk inventories in practice tend to be elaborate yet incomplete. Shortcomings identified via assessment by the regulator, are mainly found in the areas of known but ignored danger, lacking evidence for chance and effect, lacking underpinning of the completeness of the inventory and lacking checks whether as yet unknown danger of various types could be threatening safety.
This study has three results: an exploration of current thinking about risk based regulatory approach as described in literature, an experts' narrative on pitfalls in regulatory practice and an analysis leading to new insights about incomplete risk assessments.
Conclusion is that progressing towards validation of company risk assessments by the regulator would require more uniformity of company risk assessments, a standard regulator appraisal method and, as an additional safeguard, a systematically performed completeness check.

Keywords:
Safety, regulator, risk, assessment, validation, appraisal.

1.Introduction

1.1.Flaws in risk assessment

Ale (2008) investigates the history and meaning of the term 'risk' in the negative sense of the word. The word 'risk' was known and used some 2000 years ago. The two main elements of 'risk', probability and consequence, originated in the 17th century. These two rather technical and mathematical constituents were later joined by emotion and perception factors in various ways. Currently the term 'risk' appears to be used by many in many different meanings (Slovic et al., 1984). A clear and unified definition of 'risk' does not exist (Aven, 2012). On the contrary, Goerlandt (2015) lists 9 classes of risk, each using another combination of the parameters *probability*, *severity of consequences*, *expected value*, *uncertainty*, *possible loss* and *effect on objectives*. Most frequently used is the combination of *probability* and *severity of consequences*. This classification implies however that the meaning of the

term ‘risk‘ needs to be questioned each time it is being used. Klinke and Renn (2002) distinguish three main approaches: Risk-Based, Precaution-Based, and Discourse-Based.
‘Risk’, whatever its definition might be, provides a yardstick to assess potential unwanted consequences (also referred to as ‘effects’) of hazards of a wide variety of types. This activity, usually referred to as ‘risk analysis’, ‘risk assessment’ or ‘safety study’, intends to determine countermeasures to prevent or mitigate the unwanted effects.
Not all types of hazard can be studied using quantitative methods since a specific and robust record of incidents from which accurate failure rate data can be derived may simply not exist. Often used qualitative methods or expert judgements to determine the probability of an incident, still leave uncertainty.
A benchmarking exercise to demonstrate this was conducted by Lauridsen et al. (2002). This showed large variation in risk approaches, criteria and calculated risk levels between – equally variating – EU government bodies for the same fictitious installation.
The actual sequence of events and the magnitude of effects in otherwise comparable incidents may also differ considerably due to variability in local or temporal circumstances. Hence, risk assessments themselves contain uncertainty (Rogers, 2003). The current state of the art of ‘risk analysis’ is being criticised from many directions. It is even labelled as an ‘unsettled scientific discipline’ (Goerlandt, 2015).

1.2.The regulator challenge

A government is facing the challenges of unpredictable dangers to society and the obligation to be sufficiently prepared for them. Uncertainties about the likelihood of any of the dangers leading to an incident or disaster, necessitates a way to select and prioritize dangers. Preparing for all conceivable danger is impossible due to restrictions in available resources (Klinke and Renn, 2002). Hence, political decision-making about what to do and – more difficult – what not to do, requires a methodical and agreed approach.
Use of risk as the basis for regulatory intervention makes public decisions and actions easier to take in the presence of uncertainties (Black, 2005).
Regulators increasingly use risk based control in the public sector (Black and Baldwin, 2010).
The world around us and society change continuously. After a while, any assumption in risk analysis may become invalid. As yet unidentified and unknown dangers can make risk assessments outdated and incomplete (Ale, 2008). Completeness as well as the content of the risk assessment can be influenced by subjective opinions or by other than merely safety related interests.
Risk perception by the general public results in individual mortality rates of 0.00005/year in traffic and 0.00000005/year in the chemical industry. Although the likelihood to die in an accident in the chemical industry is a 1000 times smaller, such accident triggers public outrage and safety is placed high on the political agenda (Ale, 2008).
So, not only uncertainties and human values related bias, but also doubt on completeness of the risks inventory, the questionable strength of underlying evidence, too simple causality and poor evaluation, can undermine the credibility of risk assessments (Goerlandt, 2015).
Regulators appraising such risk assessments are human and their rationality may be questioned (Viscusi and Hamilton, 1999).
The underlying assumptions for risk based safety regulation are subject of ethical debate (Aven, 2007).
Current thinking centres around ‘performance based regulation’ (Coglianese et al., 2003).
Generic assurance systems designed to protect the environment are based on demonstrated performance with respect to pre-set and prioritized performance targets, e.g. in Australian rural areas (Andrew et al., 2007).
Performance monitoring logically follows from countermeasures derived from a risk inventory and does not have a bearing on the quality of the underlying risk assessment as such, nor on the targets set.
Regulators – if doing it wrong – can, and will, cause disasters (Black, 2014).
The regulator has no choice but to request risk assessments to be made by the private sector (Rothstein, 2006; Viscusi, 2009) and this applies to Seveso companies.

In spite of 'highly sophisticated risk modelling techniques' in place, recent disasters and crises defied all risk assessments and countermeasures taken. Regulator validation clearly offered no protection against the banking crisis (Terzic et al., 2015) nor against the Fukushima disaster in Japan, for instance.

1.3 Problem definition

This raises many questions. How should a regulator go about appraisal and validation of risk assessments made in the private sector such as in the chemical industry? Can a risk assessment be good enough to appraise it and if appraisal is ok can it then be validated? Goerlandt et al. (2016) have investigated this for known risks, dealt with in a quantitative manner. This is not all there is though.
Risk assessments are getting better and more complete over time, as companies learn from incidents and become aware of the risks involved in their production processes. This suggests that there is a moment in time that risk assessments could reach a perfect quality. Perfect risk assessments would pose no problem to be accepted by a government. Such a perfect risk assessment would be complete and covering all risks, it would be based on sound and uniform methodical principles and on robust empirical evidence. This situation necessitates an accepted standard risk assessment method.
Current less than perfect company risk assessments could be appraised on quality and, if the result is higher than a carefully chosen threshold level, they could perhaps also be accepted, approved and validated by a government regulator.
We have not extended our study towards exploring the boundaries of risk management itself. That would be, among other things, about the inabilities and shortcomings of safety management and its systems, currently prescribed by the EC directives and national legislation which the member states are following. A risk needs to be identified before it can be quantified. Hence, in current imperfect risk assessments, a qualitative unknown risk identification gap precedes any quantitative inaccuracy or uncertainty improvement for known risks. This is why this study aims at finding out whether approval and validation is feasible in current safety practice in the presence of as yet unknown risks. This leads us to the following research question:

To what extent can Seveso company risk assessments currently be validated by the regulator?

2. Method and design of the study

This study uses 3 different methods to explore the problem field to ensure findings have robustness via the scientific approach of triangulation.

2.1.Literature search

An internet search in both scientific and 'grey' sources (Wessels, 1997) was conducted, using key words in various combinations: *"risk validation", "occupational safety", regulator, validation, "risk assessment", industry, "validation method", safety, "Risk assessment appraisal", method.*
Sources were screened on relevance to the subject of this study and then references were searched for further sources.

2.2.Case study

An in-depth investigation of risk assessment practice can best be done using the case study method. The basic principles for this method are described by Yin et al., (2006).
A case study requires several steps. Eisenhardt (1989) presents a generally applicable set of 7 steps.

In this study a simplified set of steps is used: design, execution, analysis and findings. The case study design is described in this chapter. The execution is done in the form of a narrative study with a separate analysis and findings at the end.
Since this study covers a 13 years' time period a longitudinal study is appropriate. Two time cross-sections were compared: 2003 and 2016. A 'time series cross sectional' (TSCS) case study needs safeguards against bias due to a changing perspective of the researcher (Pettigrew, 1990).
For the interpretation of any data gathered, a logic model, often referred to as the *'blue print'*, is required. Such a model describes both the subject being studied and its context (Kohn, 1997).
The comparative analysis over time requires the model to be structured on basis of actors and actions.

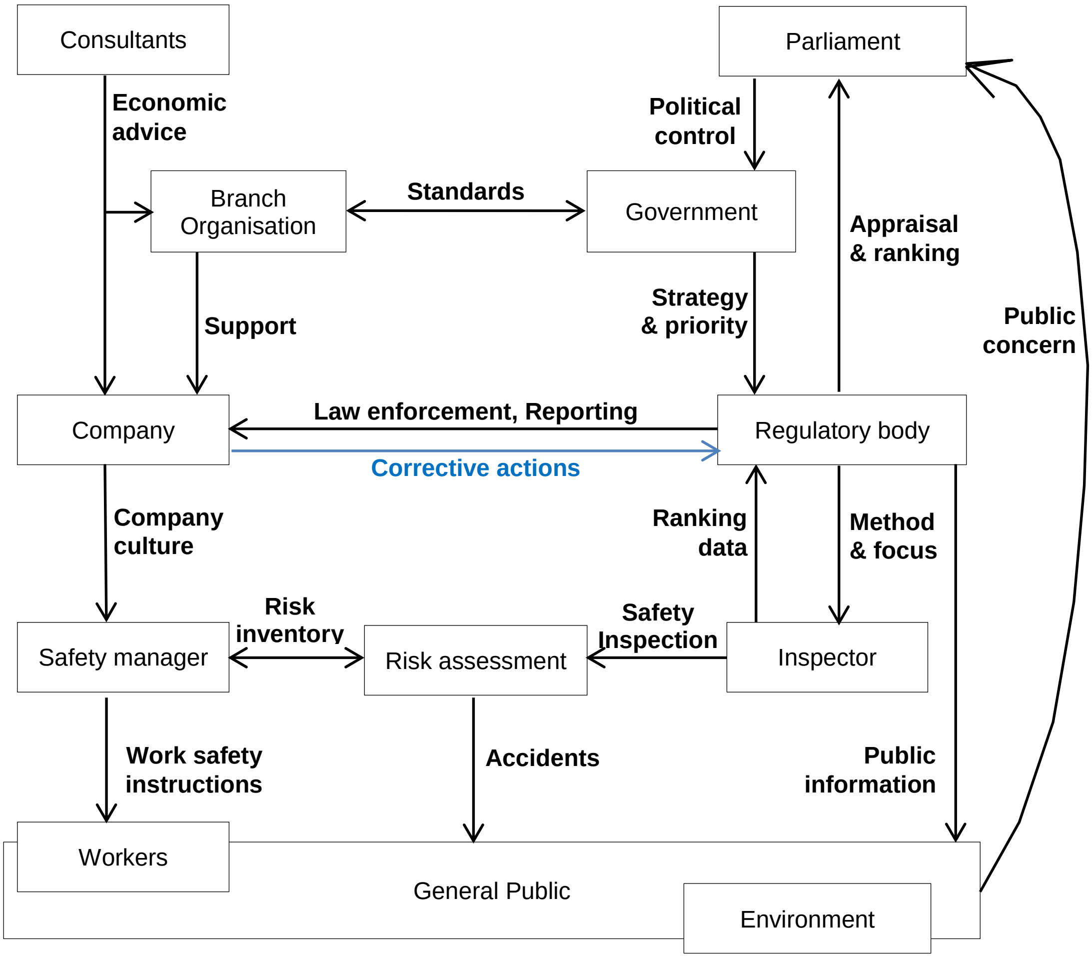

Figure 1 Actors and interactions around risk assessment

In figure 1 the authors depicted several exchange levels involved in a Seveso company risk assessment. These levels are starting from below with the general public, above that, the level of exchange of risk assessment content between inspector and safety manager, above that, company and regulatory body engaged in law enforcement and corrective actions based on reporting, and finally on top, the ongoing negotiations between government and branch organisations. This illustrates that risk assessment content is exchanged between those that write it, the side of the Seveso companies, and those that appraise and approve it, the side of the regulatory bodies. The blue print also provides a template for the observation of changes over time. It uses a number of preconceived 'aspects' (see table 1).

Table 1 Blue print template for time cross-sections after Kohn (1997) and Yin et al. (2006).

Nr	Aspect	Description
1	Safety Inspection	Scope, focus, method, frequency
2	Reporting	Authors, content, uniformity, cooperation
3	Appraisal / ranking	Parameters, method, criteria
4	Public information	Inspection results, ranking results, law enforcement results
5	Law enforcement	Corrective, punitive, activity stops, licence to operate
6	Public debate	Negotiations on standards, inspection frequency, politics
7	Safety information	Dissemination of safety information, safety research
8	Context	General situation, paradigm, economy

2.3.Narrative study

The nature of the risk assessment appraisal problem necessitates gathering in depth experiential knowledge. A 'streetwise' inspector would know that company provided information could be incorrect in ways beneficial to the company, so being critical when it comes to appraising, verifying and validating is necessary (Ale and Mertens, 2012).
An experts' story about current regulators risk approval practice in the Netherlands provides a rare opportunity for scientific study. Similar cases are rare at best, we found only one (In 't Veld, 2015).
The narrative approach in case study is not new. In fact this study is 'auto-ethnographic' (Bochner, 2012; Ellis et al., 2011) and belongs to the field of 'narrative inquiry' (Etherington, 2004) which is part of the 'interpretive social science' area (Ellis and Bochner, 2006).
Andrews et al. (2013) describe a plethora of methods and techniques developed since the late nineteen seventies in this area, ranging from 'essay-style' dialogues to near quantitative 'thematic analysis' based on computerized text screening for e.g. issues content.
We have chosen for a *small true experience centred narrative plus reflexive overlay concept* at the core of this study, to allow for both a pure, original experts' story and a clearly separated interpretation and analysis.
This narrative story reflects the narrators' (the first author) experience over a 13 years period, in his own words. As an additional reflexive layer, we screened the narrative story, focusing on both content and meaning, for observations (Etherington, 2004).
The first author, retired mid 2016 as major hazard safety inspector performing the regulator inspection task according to BRZO (2015), the Dutch implementation of the EU 'Seveso III' directive 2012/18/EC, for 13 years, was asked to tell about his experiences with risk assessment and a reflection on validation. The first author agreed to write an '*honest and in-depth narrative* '(Stake, 2000). A narrative consists of "*episodes*", i.e. text parts with subject- and event information, and analysis identifies "*turning points*", i.e. text parts indicating changes in the interactions between actors in a context, as experienced by the narrator (McAdams, 2001; Taylor, 1983). The first author was asked to indicate both episodes and turning points in the narrative.
Using peer debriefing techniques to ensure adequate quality control (Guba and Lincoln, 1989) the second author concentrated on questioning prejudice, ensuring clarity of the narrative text and interpretation of its content.
The 3 methods framework (literature, case study, narrative) enables research into the realm between regulator practice, politics and safety science in the Netherlands while warranting the quality of the findings, even though it is a single case. The qualitative approach also necessitates an attitude of modesty which we feel is properly taken by calling our findings from the narrative mere "observations". Narrative inquiry has been - and still is - subject of many criticisms. The 'true' part was criticized since a narrative is a subjective story without underpinning, the 'small' part is criticized by those that dislike dominance of narrative text. We contend that this is unavoidable since "*in real life there is always a gap between reality, experience and expression*" (Moen, 2006).

2.4. Analysis

We list observations emerging from the literature search, then screen the experts' narrative to identify observations, and describe differences between situations as identified by the case study time cross sections according to the '*blue print*'.
The narrative was screened in two ways. The first screening was 'meaning' based and looks for turning points. These were included in the narrative by the first author. The second screening was 'content' based and consisted of an elimination process where firstly, any obvious and generally known content, secondly, text not directly relevant to any of the stakeholders identified in figure 1, and thirdly text not relevant for risk assessment were discarded. The text then remaining was condensed and interpreted. The outcome was a set of observations. Both authors took part in this process.
A separate analysis then integrates all the observations from literature, case study and narrative and formulates the findings of this study. It uses the blue print model 'aspects' and time cross-sections to gain insight about the problems associated with risk assessment validation.

3.Literature search

3.1.Applicability of risk assessment

Financial risk (Miu et al., 2010; Terzic et al., 2015), health risk (Vellojin, 2011), toxic substance risk (Aschberger et al., 2010; Tong et al., 2002), natural disaster risk (Apel et al., 2004), underground storage risk (Deel et al., 2007), air transport safety risk (Harkleroad et al., 2013), marine transport safety risk (Goerlandt, 2015), food safety risk (Stirling et al., 2006), emerging technology safety risk (Som et al., 2012), drinking water safety (Roser et al., 2015), buildings safety (Bukowski, 2006) and major industrial accident risk (Ale et al., 2014; Grote, 2012), are among the many subjects, mentioned in scientific literature about risk assessment.
Risk analysis in one area may be useful in other areas since many assessment methods are generally applicable. For instance health and safety risks can be compared to financial risks (Starr et al., 1984), high risk chemical industry has provided inputs to safety management in health care (Hudson, 2003), air transport safety models are applied in the chemical industry (Ale et al., 2013) and toxicological safety assessment methods are being used in food safety and the pharmaceutical industry (Tong et al., 2002).

3.2.Variety of risk assessment approaches

Risk assessments are made in a variety of ways, in different situations and at different moments in time during the design, development and execution of hazardous- or otherwise risky activities. Their scope can vary from a single person doing a single task, to global impact of mankind engaging in a new emerging technology. The variety in methods, techniques and models is accordingly large.
Risk assessment engages three parties: the makers (the assessors, their interests and their data), the recipients (the regulators and their methods) and the potential victims (people in society that might be affected by harm and loss). Hence, in practice, the choice for a particular risk assessment approach depends on the problem at hand and on regulatory requirements which are the result of interactions between these three parties. Practice shows that simply neutralizing hazard via regulation is less problematic than controlling risk via regulation. The former avoids a hazard and a scenario to lead to casualties, the latter allows casualties but only if the chance it happens is very low. The latter is harder to communicate with the general public, since people are for the main part not fully grasping the concept of 'risk' (Bukowski, 2006).
Major industrial hazards and natural disasters with very low probability and big effects are treated on risk basis. Prevention of all possible harm and loss on hazard basis would simply require too much effort and money. The concept of risk is used to reduce disasters and effects rather than avoiding them altogether. This has led to societal risk criteria which can differ between countries. In newly designed situations the maximum allowable likelihood of an individual getting killed, currently used in the

Netherlands, is 1 in a million per year in the Seveso industry. In the UK it is set 10 times higher (Ale, 2005).

3.3.Standards, methods, techniques and models

An international standard describes generic ways to go about risk management and risk assessment: (ISO 31000:2009), and provides techniques (ISO 31010:2009) and guidance (ISO Guide 73:2009). The ISO framework allows organisations "*to identify all the risk for their mission*" (Lalonde and Boiral, 2012). In practice organisations may want to do less than that. Gjerdrum and Peter (2011) coin the term '*risk appetite*' to describe to what extent a company is willing to identify and control risks.
In general, risk assessment, as a process, consists of identification, analysis and comparative assessment (Berezutskyi et al., 2015). Frequently applied methods for risk assessment follow that main line (Lyon and Popov, 2016; Vellojin, 2011).
The identification methods vary between the fully open and unstructured 'brainstorm session' to the systematic, inductive and key-word guided 'hazop study'. In between are a plethora of identification methods using questions, event-trees, failure rates, checklists, Delphi-method, incident history, and so on. (Berezutskyi et al., 2015).
Risk analysis employs statistical data and cause-effect relations. In situations with robust quantitative information available, this can produce more or less accurately calculated effect, likelihood and risk, Bayesian Nets, Markov Analysis and simulations (Newberry, 2014).
When it comes to comparative assessment, risk classification and prioritization methods are being used. These vary between ranking on magnitude of possible harm to a fully-fledged *risk matrix*, plotting scenario's with different kinds of effects and their probability, against qualitative or quantitative scales. In between are methods using exposure factors, number of people affected, qualitative indications of seriousness and other 'severity' indicators (Berezutskyi et al., 2015; Newberry, 2014).
Lyon and Popov (2016) describe risk assessment as an art and add *skill* and *imagination* as requirements on the safety professionals who do the work. They propose to use combinations and sequences of different assessment methods for complex situations.
Duijm (2015) investigates weaknesses in the risk matrix approach and mentions *qualitative* and *subjective* likelihood and effect estimates, influenced by *biases*, *variability* and *uncertainty*. Special attention is given to corporate standards for risk matrices. Such standard may lead to different likelihood parameters ending up in the same matrix: failure rate data get mixed with probability estimates for a single event, thus hampering correct interpretation. Uncertainty cannot be expressed with a risk matrix having discretised axes. A 'continuous probability consequence diagram' with continuous axes and uncertainty boxes around plotted scenario points, is suggested.

3.4.Quality of risk assessments

Lupton (1999) concluded that ". . . *risk management will always involve a significant amount of unpredictability, uncertainty and the unknown* ". The risk assessor might just settle for the notion: "*there seems to be only one guarantee with risk assessment and that is all the risks will never be identified*" (Brady, 2015) and keep the effort down to a minimum, considering that: " . . . *risk management is broken* . . . " (Hubbard, 2009).
In a democratic society the government is responsible and to be held accountable for what goes wrong, in both the public- and private sectors. Hence, disasters may lead to new regulatory approach such as the introduction of a meta-risk management strategy and responsive regulation (Braithwaite et al., 2005). The regulator cannot afford a passive attitude since the consequences outweigh the reduced efforts. Lalonde and Boiral (2012) describe a series of cases where deficiencies in risk management have led to consequences in the form of incidents, accidents and disasters.
So, given all these criticisms on risk analysis in general, can standards and methods be trusted to lead to adequate risk assessments? This requires a closer look to risk assessment quality and its attributes.

The quality of the data and the level of understanding of the safety issues at hand, determine the credibility of a risk assessment. Many factors influence these two aspects. Klinke and Renn (2002) list a range of weaknesses in risk analysis. Issues they mention are: *perception, uncertainty, subjectivity, public concern, variability, indeterminacy, ignorance, lack of knowledge, setting priorities, evidence, gradual precautionary action, moral standard, conflicting values, compromise, disagreement, elapsed time, biases, misinformation, incompetence, divergent views, bargaining, voting, legal verdict, ambiguity* and *decision-making procedures*. They analyse '*uncertainty*' in more depth. They distinguish four components of uncertainties: *variability, measurement errors, indeterminate causal relations* and *lack of knowledge*. Finally they place *complexity*, *uncertainty* and *ambiguity* at the core of risk evaluation and management.
A risk assessment may look ahead but remains based on extrapolated hindsight. Many qualitative, semi-quantitative and quantitative risk assessment methods and techniques exist. Their inputs consists of data from a diverse mixture of sources such as: expert opinion, qualitative likelihood estimates, company estimates, model predictions, incident records, component failure rates, statistical analysis and near-miss registration. *Hindsight* (Vellojin, 2011), *background bias* due to different individuals having different views (Wallace et al., 2006) , *confirmation bias* (Sun, 2008) and *taxonomy limitations* (Lindhout et al., 2011) can limit the validity of conclusions drawn from these methods.
So, are more criteria a guarantee for better quality? Goerlandt (2015) proposes a framework for evaluation of marine risk analysis, using 42 evaluation criteria for appraisal of the credibility.
(Skinner, 2012) explores the nature, location and level of uncertainty in environmental risk and proposes a new typology and system to identify uncertainties. Uncertainties in risk assessment are mainly caused by *lack of knowledge*, *randomness*, *data uncertainty* and *extrapolation uncertainty*. A range of 17 uncertainty management techniques is described.
Klinke and Renn (2002) contend that risk based approach cannot be justified in cases where uncertainties are playing a large role. There the precaution based approach and additional criteria for prioritizing risks are needed, for instance: "*ubiquity*," "*irreversibility*" and "*pervasiveness over time*".

3.5.Quality of Regulator task

Black and Baldwin (2010) identify the regulators' task as: *"detection, response development, enforcement, assessment and modification"*.
Regulator actions affect interests of individuals and groups and is susceptible for communication problems. The way regulatory bodies are organised, cooperate and change may hamper their performance and create trust and accountability issues and misunderstandings with the companies being regulated (Black, 2014; Black and Baldwin, 2010).
The regulatory task on high-risk chemical industry safety in the Netherlands has been subject of evaluation several times in the time period between 2003 and 2016. Three of these cover both the organisational setting and the safety content. Salvi et al. (2008) evaluate the Seveso II directive and use a questionnaire to find issues of concern. Risk analysis is mentioned and respondents state there is a diversity in risk analysis methods and there are problems with imponderable effects of incidents and hence unclear links between scenarios and safety measures to be taken. The contribution of a safety measure to risk reduction is not always possible to estimate.
Ale and Mertens (2012) evaluate regulatory activities in the Seveso industry and address the mix of two approaches: risk based and rule based. They note that the initiative for risk management resides with the companies. This leads to safety systems, to company rules and self-regulation. The regulator's inspector needs adequate expertise to assess safety in this situation.
In 't Veld (2015) reports poor safety performance in the Dutch high risk chemical industry and mentions regulatory softness, conflicting interests, lack of political intent and failing self-regulation by the companies as causal factors. The regulator is to be made stronger, more active and more independent but nothing is specifically mentioned about risk analysis.
These three evaluation reports identify diverse risk assessment methods, uncertainties of risks and of risk reducing effects of measures taken, failing self-regulation and adequacy of expertise of inspectors as the issues of concern when it comes to risk assessments.

3.6. Cause and effect data

Harkleroad et al. (2013) consider validation of risk models and separate qualitative and quantitative models. They identify questions to use for qualitative validation of a (risk)model:
– *Does the model cover all relevant events?*
– *Do modelled event sequences follow reality?*
– *Do influences have appropriate direction and magnitude?*
– *Do resulting outputs have appropriate direction and magnitude?*
For quantitative model validation they identify comparison with *experimental, simulated, or historical data* as the suitable tool and underline the need for independence of consulted experts and data sources in both qualitative and quantitative methods.
Sun (2008) underlines the need for '*structured justification*' and proposes a framework for establishing confidence in safety analysis. Reference is made to Greenwell et al. (2006) which present a '*taxonomy of safety argument fallacies*'. Sun (2008) proceeds along the path of software development to carry out a structured qualitative analysis approach based on 'argument patterns' and 'inconsistency analysis'. An inspiring final goal is set for the future: integration of qualitative-, quantitative- and simulation model analyses.
Mathematical algorithms to assess and model risks are being built on various software platforms. They are constructed with building blocks, representing interactions between model parameters. The blocks could be named '*quantitative structure-activity relationships*' (Tong et al., 2002), '*nodes in Bayesian Nets*' (BN) (Roser et al., 2015), or simply '*cause-effect relationships*', the latter being the generally used term. Normal operations can be analysed with such a model and then be compared to real life testing results to verify the model. Critical for the validity of such models is whether statistical data are available and causality is well understood.
A chemical plant 'Bayesian Belief Net' (BBN) model (Ale et al., 2014) could either be used as a tool to assess risks before a plant is even built, or it could be used with real-time data input to monitor the plant for trends towards danger, once it is in production.
The BN approach depends on credible representation of risk factors in a model. For uncertainties in risks or lacking quantitative information the BN approach needs an 'extension'. The principle of *maximum entropy* is often used when available data is incomplete (Vellojin, 2011). Use of this principle or other 'extension' alternatives in a BN are subject of ongoing research (Aven and Zio, 2011).

3.7. Observations from Literature (OL)

The above literature search leads to the following observations:

OL1-Risk based control is attractive for the regulator since costly measures for highly unlikely events are avoided
OL2-Bayesian nets are preferred by scientists since they accommodate for the complexity of reality and new software starts to provide tools for human error and uncertainty elements.
OL3-Risk assessment is done by private organisations
OL4-Risk assessments are received and approved by regulatory bodies
OL5-Consequences of flawed risk assessments go to public, environment and workers
OL6-Large variety of risk identification, analysis and assessment methods
OL7-Risk is difficult to communicate about
OL8-ISO standard allows identification of all risk
OL9-Private organisations have limited 'risk appetite' and fail on self-regulation
OL10-Risk has several definitions
OL11-Risk identification requires expertise, skills and imagination
OL12-Complex situations need combinations of several risk identification methods
OL13-Unknown risk is seen as unavoidable

OL14-Uncertainty and weaknesses affect the quality of risk assessments
OL15-Expert opinion is a critical factor
OL16-Regulators may show paralysis due to political control and conflict of interests
OL17-Regulator inspectors expertise must be adequate
OL18-Validation needs a structured method, sound data and clear cause-effect relationships
OL19-Mathematical models are no good when uncertainty and lack of knowledge play a role

4. Longitudinal case study

4.1.Context

The situation is investigated per time cross section (see table 2).

Table 2 Time cross sections, description and context after Kohn (1997) and Yin et al. (2006).

Time cross section	**Description** (risk assessment practice)	**Context**
2003	*Brzo 1999 phase* Risk assessments made by companies High risk companies: VR's approval High risk companies use VMS, element #2 Other companies: RIE required by law	Legislation: Seveso II, Brzo 1999, Arbowet Actors: AI, Cities and Provinces acting Coordination: Beterzo project Inspection method/means: [AVRIM-2] Knowledge: AI, BG, BRW trained differently Standards: CPR20
2016	*Brzo 2015 phase* Risk assessments made by companies High risk companies: VR's approval High risk companies use VMS, element #ii Other companies: RIE required by law	Legislation: Seveso III, Brzo 2015, Arbowet Actors: ISZW, Regional OD's, regional SR acting Coordination: LATRB Inspection method/means: NIM, GIR Knowledge: SZW, OD, SR trained similarly Standards: PGS-6, NTA 8620

Key to abbreviations used in Table 2:
AI Arbeidsinspectie (Labour Inspection)
AVRIM Arbeidsveiligheidsrapportage Inspectie Methode (Occupational safety report inspection method)
Arbowet Arbeidsomstandighedenwet (Safe work act)
Beterzo Beter Brzo (Brzo inspection improvement project)
BG Bevoegd Gezag (Environmental regulatory bodies)
BRW Brandweer (Fire brigades)
Brzo Besluit Risico's Zware Ongevallen 1999, 2015 (local Dutch Seveso II, III directive implementations)
CPR Commissie Preventie van Rampen door gevaarlijke stoffen (Haz. chemicals disasters prev. committee)
GIR Gemeenschappelijke Inspectie Ruimte (Common Inspection Workspace)
ISZW Inspectie SZW (Inspectorate at the Ministry of Social Affairs and Employment)
LATRB Landelijk steunpunt risico beheersing (Government agency for Major Hazard Control regulation)
NIM Nieuwe Inspectie Methode (New Inspection Method)
NTA Nederlandse Technische Afspraak (Dutch Technical Agreement)
OD Omgevingsdienst (Environmental regulatory bodies)
PGS Programmareeks Gevaarlijke Stoffen (Program series Dangerous Substances)
RIE Risico Inventarisatie en evaluatie (Risk assessment for occupational safety)
SR Safety Region (Fire brigades)
SZW Sociale Zaken en Werkgelegenheid (Ministry of Social Affairs and Employment)
VMS Veiligheids Management Systeem (Safety Management System for High Risk companies)
VR Veiligheids rapport (Safety Report)

4.2. Cross sections

Over the 13 years' time period both inspection practice and legislation have changed considerably.

2003

In 2003 the Seveso II Directive 96/82/EC and BRZO 1999 required a safety management system with a list of 7 elements. Element 2 was about inventory of dangers, appraisal of risks and adequate countermeasures. There was no agreed inspection method between the three cooperating regulatory disciplines doing Seveso company inspections. Companies received three reports stapled together. There could be conflicting content in these reports. A company that did not comply to legal requirements would end up in court and face small financial fines but rather big image damage. In court there was not enough capacity. The labour inspectorate's strongest tool was to stop the work. The many local environmental regulatory bodies could not harmonize their approach on a national level. Safety reports from high-tier Seveso companies would be subject of a several years long approval process including dedicated inspections. Company inspection results were not published, nor would there be a company ranking order.

Safety was subject of an ongoing debate between regulator and branch organisations. Knowledge was being shared. Many companies saw the introduction of a safety management system as a one-off activity though. A production company would have a close look at the risk inventory, take necessary measures and then go back to business as usual. Safety was first of all a technical matter.

2016

In 2016 the Seveso III Directive 2012/18/EC and BRZO 2015 element ii deals with the risk inventory, not much has changed there. The environmental regulatory bodies now cooperate in 6 regional institutions. Although local 'colours' are still visible, much attention is given to uniformity of inspection activities. Public debate, safety information and safety inspection have not changed significantly, although a new inspection method was developed and introduced in high-risk chemical companies. The three cooperating regulatory disciplines now share a web based registration facility and present one common report. Near the end of the time period the labour inspectorate fines were increased by a factor 100. Fines became an effective tool. The path to court was narrowed down to exceptional cases only. Safety report approval was narrowed down to almost 'table of contents-level'. The contents became subject of regular inspection activities. In 2015 the first inspection summary report was made public. A ranking list of poor performing companies was presented to parliament from 2014 onwards.

Both law and law enforcement changed, leading to dramatically raised fines. Also the companies have changed their ways. Branch organisations still negotiate with the government regulatory bodies. Inspectors still learn from company specialists and vice-versa. Nowadays companies and their consultants produce more automated and therefore more elaborate safety studies. They start to recognize that new technology is emerging and causing new hazards. At the same time ageing chemical plants cause more incidents. Accident causation is changing. Experience is building up. Accident reports increased the knowledge about *what went wrong*[1]. Dropping incident rates make learning from near-miss situations more important. Safety engineers preparing a risk assessment are 'shooting on a moving target'. In the Netherlands, safety is becoming, besides a technical domain, also an area where human behaviour, safety culture and language problems appear in accident causality.

4.3. Observations from Case study (OC)

Comparison between the time cross sections leads to following observed differences :

OC1-Risk assessments (VMS element ii or "RIE") are made by companies
OC2-Risk assessments are assessed by the regulator (over the entire 2003-2016 time period)
OC3-Evaluations did not lead to changes in the way risk assessments are handled

[1] Regrettably the proponent in this field, Trevor Kletz, passed away at age 91 in 2013.

OC4-The way the regulatory bodies are organised and cooperate changed significantly
OC5-High risk inspection reporting became a joint effort between inspection partners
OC6-Company safety performance ranking was introduced
OC7-Inspection report summaries are made public
OC8-Companies are lagging behind on new risks (emerging technologies, ageing plants)

5. Narrative

The narrative story consists of episodes, marked with a chapter number and a caption. The turning point text is marked with "TP". It is written by the 1st author, and hence placed between quotes. It was reviewed by the 2nd author. Minor changes were introduced to clarify the text and to get consistent use of terminology.

5.1.Risk

In Seveso companies 'risk is usually defined as the product of the probability of occurrence of an unwanted event and the magnitude of its effect. For example an unlikely event expected once in a hundred years causing a large destruction could therefore pose the same risk as a frequent, yet small event, causing a little bit of destruction every time.

TP1 - Risk is a somewhat counter-intuitive concept.

Risk is – as in this destruction example – associated with a negative or adverse effect. This effect consists of damage in different forms: harm to people, financial set-backs due to production losses, destroyed installations and buildings, people losing their jobs, just to mention a few.
People try to avoid danger. They spot it and – except for the daredevils, those displaying 'risk-addicted' behaviour in psychology terminology – move away from it. A daredevil likes to cheat the danger and beat the odds. In fact they accept the risk that the danger might hurt them while they are showing off by coming closer to the danger than all others dare to go.
In the chemical industry, many of the Seveso companies work with large quantities of dangerous chemicals. Their situation is quite like the situation of the daredevil when they assess the risks. Where the daredevil takes special measures like speed of his action, special clothing or special moves, the chemical company relies on sturdy containments, a range of safety provisions and dependable workers. Unfortunately every once in a while a daredevil's drag-race might end in a tragic accident and, analogously, a chemical company might go up in flames due to a major accident. This shows that current practice of employing safety provisions does not make a danger completely safe to handle. A chance that things go terribly wrong still remains.
Society accepts only a limited number of mishaps. For major accidents in the chemical industry, as for airplane- and train accidents, this acceptance level is fairly low. For traffic accidents and unnecessary deaths in hospitals, these acceptance levels are considerably higher. Occupational accidents in agricultural-, building- and industrial sectors happen by the thousands. Here, society appears to turn a blind eye since occupational accidents often follow the same patterns. Fortunately, in many places the number of mishaps is a target of reduction efforts. Ideally the goal would be zero in all cases.
Society allows some dangers to cause more damage than others though. While the vast majority of the many casualties in traffic in the Netherlands each year do not reach the news headlines, a chemical plant on fire, even without a single casualty, may dominate the media for months. This exposes large differences in levels of risk acceptance across society. This in turn influences public opinion and induces corrective actions by parliament. The government changes legislation and regulatory bodies follow with a revised approach.

5.2.Risk assessment in theory

Risk assessment is at the basis of preventing such mishaps. Without risk assessment neither companies nor society in its entirety can know which countermeasures to prioritize. It may take a while before a risk is controlled once it is discovered, anyhow. The danger sometimes remains unmitigated while waiting on the action list.

In theory, making an inventory of all possible things that could go wrong, would result in a complete description of known danger in society. Assuming there is also danger we are not aware of, it seems logic at this point to attempt taking that in account as far as possible as well. Evaluating probability and effects of all known danger may then lead to a full view of societal risks. Any dangers we are not aware of, cannot be evaluated but can be assumed to contribute to societal risks.

There are two ways to go about handling a danger. The first is taking counter measures that make it impossible for a danger, e.g. a frequently encountered hazard, to express itself in any way. This is usually called the ‘deterministic’ or ‘precautionary’ approach. E.g. the protective cover on the table saw. In cases where the probability of occurrence of an accident, or the effect that the danger can cause during an incident, or even both, are not known, the deterministic way is also a legally accepted way. If the countermeasure is correctly put in place the danger is neutralized. If not, the danger is unmitigated and the probability of an accident is unknown.

The second way to handle a danger, most likely one with a small likelihood and a large effect, is the probabilistic approach. The product of chance and effect determines the calculated risk associated with such a danger. If the calculated risk is smaller than a chosen acceptance level it remains an unmitigated though unlikely danger. If the calculated risk turns out higher than the acceptance level, measures to reduce chance, the effect, or both, can be used to bring the residual risk down to below the acceptance level. This implies nonetheless that all dangers treated via this approach are either too unlikely to be risk-controlled or left with a residual risk.

Accidents have been subject of investigation by many researchers. Using many different investigation methods, ranging from the UN’s ‘barefoot’ to NASA’s Root Cause Analysis, they found patterns describing the sequence of events in accidents. Records show some of these paths to be more likely than others and provide insight in what damage might occur. Due to the emergence of new technologies and obsolescence of old technologies these event patterns change over time. New, as yet unknown danger, appears. Accident investigation methods, that rely on classification systems, provide trending results efficiently but will start to miss out on changing technology after a while. The ‘open’ methods may be more accurate and up to date but require extensive analysis to find trending information. Knowledge about accidents and safe work is continuously expanding so what was safe in the past may become unsafe in the future.

After decades of successful accident rate reduction activities learning from accidents becomes more difficult, simply because there are less of them. Many Seveso companies have started to look at near-miss incidents to find direction in their safety improvement cycles. Some companies haven’t yet done this and start to lag behind in their knowledge about accident causation. Again unknown danger.

5.3.Risk assessment in practice

A major incident in a chemical plant does not always follow one of the previously described event sequence scenario’s. Occupational accidents on the other hand often follow well known event sequence patterns like falling from height, injury by a falling load and being hit by a vehicle.

Risk assessments often missed the rare accident scenario’s that actually happened and fail to ensure that the correct safety measures are being taken even when the accident patterns are well-known and frequently occurring. In high-risk chemical plants inspectors ask safety managers to utilize several risk assessment methods to ensure completeness. Practice shows that for instance the users of the much favoured and dependable ‘Hazop study’ focus on what happens inside process installations while danger such as a forklift truck damaging a pipe from outside is more likely to be identified with another method.

TP2 - In practice Seveso companies make incomplete risk assessments and have equally incomplete measures in place.

Society continuously corrects unsafety exacerbations via social unrest, political choices and new legislation. Incidents can trigger this chain of events. The UK Buncefield disaster in 2005 is an example. As a consequence independent storage tank overflow prevention devices were made compulsory. Today these devices are still being implemented. This corrective cycle is rather slow and needs enforcement in a minority of cases. Hence, completing such a corrective cycle may take more than a decade. Like the countermeasure waiting on the action list, this leaves opportunity for accidents.
The governments' regulator function verifies compliance with the rules set in legislation. E.g. only specific types of cars are allowed on the road. Captains on board a freighter barge must speak any one of three current languages. Legislation may prescribe the technical means or organisational systems to achieve a safe working environment. Means, like the label on a container with a dangerous substance, are either present or not. The protection gear against falling from a scaffold is either used or it is not. A danger is either identified and properly taken care of, or it is missing from the obligatory risk identification, or it is improperly handled. Verifying compliance with a rule about means is a relatively straight forward task for the regulator. Being compliant with this type of rules is straightforward for companies too. Systems e.g. prescribe instruction of workers about safety provisions before an activity starts. Many companies deal with a mix of rules on means and system induced rules specifying objectives, however. Control of safety risks is such an objective in the EU Seveso III directive.
This implies that legislation merely requires the presence of a company system to effectively manage safety risks. This makes risk assessment by companies a necessity.

TP3 - So, verifying whether a company is compliant with the requirement to implement an effective safety management system is another matter for the regulator. The regulator needs more insight and understanding of what companies do. Establishing a yardstick is not straightforward.

It may e.g. involve finding out about what the state of the art in safe work on international and national level is. It may involve voids in legislation and standards about new emerging technologies. It may involve companies lagging behind with respect to the state of the art, and defending themselves on basis of outdated government permits to operate.
Companies are often producing something with installations and equipment designed and maintained by third parties. Such a plant may be built recently or many years ago, so for either reason their staff cannot be not fully aware of its intricacies. A plant may show children's diseases or deteriorate due to ageing. Or it might, in its operational life, suffer from phenomena such as design flaws, wrong assumptions about up-scaling of the lab pilot plant technology, cost cutting in safety critical areas or problematic interface management and misunderstandings between participating contractor companies during the build. All these may lead to unknown dangers.
Any new or changed production plant goes through a learning curve. Often the company staff present in the development phase and early in the production phase is later being replaced by new personnel. Troubleshooting during start up and running a plant for decades, while continuously optimizing its output, requires a different kind of specialists. At the end of its operational lifetime a plant shows increasing numbers of failures. Companies respond with increased maintenance activities and life extension projects. Dangers, unknown and not identified by the original plant designers within the design lifetime, now get the opportunity to express themselves.
Risk assessments may be bought from the builder, their contractors or from a consultancy company involved in the commissioning phase. Company safety engineers may compose their own safety studies. Companies are especially good in producing and selling their product however. They are less good in making detailed assessments of what could go wrong. Their prime interest is clearly not with indulging in possible incident scenarios and taking preventive measures against all conceivable dangers. On the contrary: some branch organisations even prepare standard risk assessments to be used by all members to avoid consultancy costs. Companies can often easier implement a precautionary countermeasure rather than do research and analysis to find out whether the countermeasure was even necessary in the first place from the risk acceptance level point of view.

Many companies run their factories as a ‘black box’ with a set of historically grown rules. When a problem is encountered they tinker the box and the rules, or patch the box with a new device, and quickly continue production.

> *TP4 - True and full understanding of what goes on in the plant is both not aspired and slowly eroding over time. Hazards and their countermeasures may even be forgotten after several decades. This causes unknown danger, as is sub-contracting safety and thereby losing the overview of the risk inventory.*

Companies seem not very keen to put effort into completion of their risk inventory. For companies a risk assessment is working in two very basic ways. The first is to make production safe enough so a licence to operate is granted by the regulator, the second is to avoid exaggeration in safety measures and associated unnecessary costs. Companies may e.g. adopt a policy limiting how many countermeasures are to be allocated to a risk. Underestimating a risk appears to be financially more attractive than overestimating a risk, at least in the short term. It is a matter of choice for companies. Although seemingly logic at first glance, this short term thinking hides danger. Underreporting of danger, ignoring risk and poor registration of incidents lead to similar safety concerns. They hide unknown danger.

> *TP5 - It would appear that these many types of unknown danger, unmitigated danger, accepted residual risks and flawed safety measures are likely to lead to accidents. These categories of danger might explain the considerable gap between known, identified and controlled risk and incidents caused by scenario’s not mentioned in risk assessments in Seveso companies.*

5.4.Unsafe behaviour

The day inspectors are visiting a spotless and friendly company, it is possible to walk around, look at operations, read documents, talk with personnel and more. Normally all safety goggles are on during an inspection. Inspectors can’t see what goes on the other days when no one is watching. Nor can they see that, shortly after the inspection visit appointment was made, the entire factory had been cleaned and all warning lights were checked, to be ready for the inspector to visit the plant. Like their workers, companies behave in certain ways.
A company likes to present the ideal situation as laid down in their safety documents. E.g. emergency procedures rely on correct alarm response by all workers, even foreign contractor workers which perhaps don’t understand the gate safety instruction leaflet. Safety procedures assume production personnel to respect extra steps to be taken for safety and not skip them for higher production speed. Unsafe behaviour is an important flaw in safety management. The company safety documents sketch a perfect world with dependable workers acting as safety barriers in many situations. The company personnel in reality don’t always follow procedure to perfection. Human behaviour can even spoil the result of a perfect chain of safety measures neatly arranged by a company.

> *TP6 – Besides lack of knowledge and uncertainty in cause effect relationships, corporate- and company cultures might both blur the inspectors’ view and introduce uncertainty in safety system performance.*

Knowingly and willingly endangering people and environment by unsafe behaviour in an attempt to gain time and money has led to several major accidents in recent years in Moerdijk and Nijmegen[2].

> *TP7 - Sometimes companies go into what can only be described as criminal behaviour, looking at the court rulings.*

[2] Sources: Rechtspraak.nl , 2014; Rechtspraak.nl , 2016, see references list

5.5.Regulator

Mother nature can spoil everything too. Companies in the Netherlands have to investigate the dangers and to determine the risks for workers, the general public and the environment. Several types of risk are excluded by the regulator such as volcanic eruption, airplane crashes and acts of war. For other types of risk, previously excluded in the Netherlands, this is no longer so: extreme weather, flooding and earthquake.

Validation of company risk assessments in these conditions is a challenge for the regulator. Inspectors are faced with a balance of forces. On the one hand there are rock-solid and well-defended company risk assessments, on the other hand there is the inspectors' toolbox, laden with government strength.

Currently only Seveso high tier companies must deliver a safety report to the regulator. All other companies must have appropriate safety studies available for inspection in their premises. These vary in appearance from low tier Seveso safety policy documents to risk inventory and appraisal documents in general industry. A range of government guidance documents is available for all business sectors. In some cases there are branch level codes of conduct. Also standards, agreed within industry or between regulator and industry, provide a basis for comparison and appraisal. Last but not least there is the general principle: when executing a safety study, then use a well proven method and follow its guidelines. In practice this has led to a wide variety of safety studies, some are supported by standards on how to conduct them, and for other studies it is left to the company staff and consultants how do go about it. Safety study involves both experts and laymen. Improperly conducted safety studies may fail to discover danger.

This sets the boundaries for what an inspector can do: check the safety studies on whether they comply with legal requirements, respect the agreed industrial safety standards and follow the guidance on safety studies, or merely if they appear sound when looking at it with common sense. If a safety study does not comply with format requirements or guidance, the inspector can enforce this, using the legal instruments in the toolbox. To correct shortcomings such as an incomplete inventory of dangers, just looking at format or guidance is not enough, though.

An inspector can also verify the contents of a safety study and question the completeness and correctness of the study. He can criticize the chances and effects in the study and initiate debate on the company policy on what to do in cases where risks are near to or over the acceptance level. He can dispute the acceptance level itself too. The inspector might also discuss uncertainties in the risk assessment, especially when risks close to the acceptance level are presented. Depending on the depth of the inspectors' knowledge of the plant, the process and the technologies involved, he can require specific improvements on the safety study.

> *TP8 - While drilling down further into the details of a risk assessment, a point is reached at which the inspector is no longer able to assess whether the study is robust and complete. The inspector is e.g. faced with highly specialised chemical knowledge, a mix of old and new technology, a wide variety of degradation mechanisms, an installation design made by third parties and with 'open' web-integrated ict based control systems. He is confronted with sometimes colossal, yet incomplete, quantities of information and is not able to follow in all the footsteps of the many people that prepared this information, and verify, let alone grasp whether it is sound, consistent and complete as a risk assessment. He can only say – frustrating as it is – he cannot see any shortcomings.*

So, in turn, now the eager and suspicious inspector becomes the 'daredevil'. He attempts to find voids and inconsistencies in areas beyond his own competence. In doing so, the inspector enters the realms of unidentified and unmitigated danger, underestimated or ignored risk, flawed countermeasures, slow responding companies, measures still being negotiated on government level, accepted residual risks, forgotten hazards and unknown danger of several types. In other words: the inspector is now in unfamiliar territory where the company he is visiting perhaps doesn't know either. In practice inspectors do indeed find things that are suspect in such situations. The preferable outcome would be that both parties agree there may be a safety issue at hand and that the company will further investigate to establish whether there is a need for additional safety measures.

In a company that is already aware of such issue, coincidently spotted by an inspector, someone at the company may have previously taken a conscious decision not to pursue the matter for a number of reasons. These may be – apart from a 'guestimated' low probability – economic or strategic reasons with no relation to safety. The company can then choose to be open to the inspector about this or not. Although the inspector can require the company to investigate the issue, the outcome in this case will also depend on the willingness of the company to reconsider their previous decision.

5.6. Approval

The regulator provides companies with a licence to operate and allows them to handle dangers under the condition that these hazards are controlled and brought down to an agreed risk acceptance level. Companies deliver proof of this in different documented forms such as safety studies, risk assessments, incident records and safety reports. These documents need appraisal by the regulator. If all the conceivable danger is taken into account and every possible countermeasure is taken, the regulator could, in theory, even approve such documents since risk control would then be perfect.
In practice however, there is no such thing as a perfect risk assessment. This makes approval by the regulator a tricky thing. A government ought better not approve risk assessments including omissions, shortcomings and errors. If it would do so the regulatory body might even become the owner of as yet unknown safety problems and hence compromise their independent role in society.

> *TP9 - As mentioned the regulator is confronted with a wide variety of safety study types. What counts as a safety study? Which methods qualify and what quality level is required? This appears to be subject of ongoing debate not reaching any conclusion.*

How should companies respond when the regulator e.g. accepts the notes taken during a simple '5x why' session[3] in one company but refutes an elaborate set of scenario descriptions in another? How about using 'light' methods for small safety problems and 'heavy' methods for big safety problems? The role of 'expert opinion' in many studies can be questioned but so can the inspectors knowledge. Voids in the expertise at both sides leaves unknown danger unmitigated. The probability an incident occurs changes for the better after implementation of a countermeasure but specific and accurate data on that particular one measure are usually not available. Is a policy statement like "*3 independent barriers must be in place to mitigate a risk*", sufficient or even meaningful, when no statistical information, or in fact no evidence whatsoever, about the individual barrier performances is available? The effect of the 3 barriers could be largely overestimated and result in a risk not as well controlled as is being suggested.
What to say about risk definition discussions? Where risk is usually defined as the product of chance and effect in Seveso companies some of them add an exposure factor. This factor is commonly used in occupational safety to assess long term dangerous substances exposure risks. The debate on whether this factor applies to rare major accidents is already going on for decades.
The regulator ought to be hard to please for many reasons. Companies ought to be in continuous improvement mode at all times. Both parties ought to engage in an ongoing debate about the unknown and uncharted risk territories when it comes to safety. Suspicious inspectors need to keep uncovering safety issues, whether hidden due to other interests or simply hitherto unknown. Companies ought to keep their systems open and transparent to show their safety performance in full depth.
The regulator is – like any government institute – under political control. The regulator uses policy statements approved by parliament to focus on particular elements in legislation. This is by necessity since the government simply has not enough budget and manpower to fully address every article in every law. The angle of inclination of the regulator may change from time to time. Inspectors may be instructed to pay attention to other specific dangers or specific activities. This implies that not prioritized dangers or activities get less attention. Inspectors might waive requirements, accept deviations from standards and allow companies to take their time for transition when new measures are required. This allows danger to put a foot in the safety door.

[3] In a committee, accident causation is discussed using the question "Why ?" five times.

5.7.Rating

In practice the majority of inspections at Seveso companies lead to a compliant result. In all other companies inspections may show either more compliance or non-compliance depending on what induced the inspection: an accident, a complaint or a project. Whereas non-compliance can be treated using the inspectors' toolbox, dealing with compliance is another matter.
The question here is: how can the regulator tell a company that their risk assessment and follow-up actions are satisfactory, while taking proper distance from undiscovered potential problems these may hold at the same time? Is the mere fact of not withdrawing the licence to operate enough? Normally inspectors – reluctantly – tell companies after an inspection that they see no reason for legal enforcement action at the time. Alternatively they might tell the company to proceed with a few minor actions. Possibilities to inform a company about how good or bad their safety risk assessment rating actually is, in the eyes of the regulator, depends on the inspection focus at the time.
Inspectors address the subject 'risk assessment' on a regular basis in all Seveso companies. In the Netherlands a common safety system elements rating level for Seveso companies is being used among inspectors. The element ii indicator deals with the subject risk assessment.

> *TP10 -These very coarse indicators simply rate element performance in 5 levels from 'bad' to 'excellent' and contain the inspectors subjective opinion.*

The rating reflects the regulators' inspectors judgement against the background of the Seveso directive and its local implementation in the Netherlands, and the full suite of legislation and standards about safety at work. This rating therefore contains the subjective, and therefore sometimes criticized, individual inspectors' opinion. Safety assessment ratings are not shared with the general public, although summary inspection reports are being made available to the general public from 2015 onwards. In other than Seveso companies the risk assessment is usually addressed during an inspection but inspection frequencies are significantly lower. No rating system is in place.

5.8.Validation

Ideally a risk assessment consists of an inventory of conceivable dangers, a gathered set of probability and effect data with references to evidence, a calculation of the risks, an established acceptable risk level and assignment of adequate countermeasures and priorities for further improvement. The assessment should also give attention to underpinning of the completeness of the inventory and to a check of the applicability of various types of unknown danger. It should explicitly mention any identified residual risks. Uncertainties in the assessment need to be identified. The risk assessment needs to be made according to agreed standards and methods. Then a rating system, covering both format and contents of the risk assessment could be used to appraise it and to systematically and uniformly report regulator findings. This way company risk assessments would become better comparable and could be combined for assessment of e.g. a complete industrial area. Existing environmental quantitative risk analysis methods based on unified dispersion models already do the same.

> *TP11 - Legislation and standards would need to accommodate for this. Hence, risk validation by the regulator will require a new approach.*

In so doing the regulator obtains clarity on identified risks with their controls, on awareness of extremely unlikely dangers not mitigated and on motivated exclusion of various types of unknown danger. This could both constitute a sound basis for validation of the risks associated with a company and put an end to the ongoing criticism about a hampered level playing field.

5.9.Turning points

Screening for turning points resulted in:

TP1-Becoming aware of risk as a counter-intuitive phenomenon
TP2-Noticing the contrast between theory and practice on both risk inventory and measures
TP3-It is not easy to find a yardstick to measure what companies do
TP4-Realizing that companies have limited ‘risk appetite’ and eroding risk awareness
TP5-Discovering many unknown risk types, which can be present and explain accidents not foreseen
TP6-Awareness of flaws in safety systems due to culture, behaviour, lack of knowledge and uncertainty
TP7-See companies crossing the line and act in a criminal way
TP8-Finding out it is impossible to have enough knowledge to fully understand all risks in a plant
TP9-Uniformity of safety studies is rather poor and blocks appraisal
TP10-The simplicity and subjectivity of company rating with a 5 levels scale by inspectors
TP11-Realising company risk assessment validation by the regulator requires a new approach

5.10.Observations from the Narrative (ON)

The narrative contains besides episodes, several ‘turning points’. In the text of these episodes several observations relevant to risk assessment were made:

ON1-In this narrative the episodes are: *Risk, Theory, Practice, Unsafe behaviour, Regulator, Approval, Rating* and *Validation*, as indicated by the headings within the narrative.
ON2-The interaction surrounding risk assessment interfaces with many actors and authority levels.
ON3-Risk is hard to grasp as a concept for many people
ON4-Acceptance of consequences varies considerably between situations
ON5-Known and unmitigated risks exists and are accepted for a while before their implementation
ON6-Both newly built and ageing plants bring new danger
ON7-In complex situations a combination of risk assessment methods is needed
ON8-Safety is subject of a mix of rules about ‘means’ and ‘objectives’
ON9-Companies display ‘black-box’ behaviour
ON10-Company staff shows ‘loss of understanding’ about a plant over time
ON11-Subcontracting safety causes loss of overview on the risk inventory
ON12-Human error, unsafe behaviour and company culture can frustrate safety systems performance
ON13-Accidents do not always follow identified scenario’s in the risk assessment
ON14-Inspectors cannot see whether a risk assessment is complete due to lack of knowledge
ON15-Inspectors change their priorities from time to time due to political control
ON16-Rating safety assessments is done via a subjective 5 level scale by inspectors
ON17-Lack of uniformity and completeness of risk assessments.
ON18-Validation by the regulators is not possible without ensured completeness and uniform appraisal
ON19-Unknown risk is mentioned many times in many forms and many different situations.

5.11.Assessing the unknown

The narrators mentions various risks encountered in inspection practice that would appear ‘unknown’ at first glance. The narrative story identifies several types of known, yet unmitigated risks and many more types of unknown risks. Usually the latter are perceived as *intangible danger or risk*, and not further dealt with, leaving them unmitigated as well. In fact the narrator associates the vast majority of these unmitigated risks with at least a few identifiable flaws, implying that most of these so-called ‘unknown’ risk types could nonetheless be subject of prevention activities.

Obtaining an inventory listing of unmitigated risk types is possible via screening the content of the narrative text. Some 11 identifiable attributes associated with poor risk control were found to be used repeatedly in most of the narrative episodes. Hence, these terms were lined up (see Table 3) by the authors in an order of increasingly conscious and deliberate decision making, starting from '*unknown*' leading up to '*criminal*'. This set of attributes opens up the possibility to further analyse the narrative content.

Table 3 Identifiable attributes associated with unknown risk

	Attribute	Description
A	*unknown*	Nobody is aware of this
B	*knowledge*	Knowledge about this is not existing
C	*design*	This was not taken up in the design
D	*ageing*	Ageing may affect its performance
E	*analysis*	The risk analysis missed out on this
F	*residual risk*	The remaining residual risk was considered small
G	*failure*	This can happen if something fails
H	*method*	The method used to assess risks is flawed
I	*effort*	More effort on risk assessment would have spotted this risk
J	*choice*	It was chosen not to look at this type of risks
K	*criminal*	This risk is known but kept out of sight

Using the 11 attributes and the words 'risk' and 'danger', screening the text of the narrative resulted in a list of some 44 risk type descriptions identified in table 4. For each of these unmitigated risk types the authors checked the applicability of the 11 attributes. (E.g. "*Known and correctly controlled risk*" gets none of the attributes ticked, while "*Cost cutting on safety critical items*" gets 8 out of the 11 attributes ticked).

Using the number of attributes for each unmitigated risk type as an indicator for seriousness, it is possible to rank these risk types (see Table 4).

This analysis reveals *choice*, *effort*, *method* and *residual risk* as important constituents. It also shows that 1 out of 44 risk types has only *unknown* to work with and none of the other attributes. This indicates there is a lot to know about the many types of unmitigated and unknown risk as identified in the narrative.

Table 4 Ranking seriousness of unknown and unmitigated risk using identifiable attributes

	Risk type	**Attributes**	**Count**
1	Known and correctly controlled risk	-	0
2	Remaining risks of known and probabilistic controlled danger	Residual risk	1
3	Danger too unlikely to occur to be under risk-control	Residual risk	1
4	Unknown danger nobody could possibly know about	unknown	1
5	Danger we are not aware of but could be if we thought about it	Effort, unknown	2
6	Unknown danger due to outdated classification in accident investigation	Method, unknown	2
7	Rare but occurred scenario not identified in company risk inventory	Effort, method	2
8	New compulsory safety measures not yet taken by companies	Choice, effort	2
9	Unknown danger due to loss of expertise with change of personnel	Failure, unknown	2
10	Known danger currently excluded by the regulator	Choice, residual risk	2
11	Unknown danger due to ignorance at both company and regulator sides	Knowledge, unknown	2
12	Unknown danger due to staff unfamiliar with intricacies of old / new plant	Effort, Ageing, unknown	3
13	Unknown danger due to interface problems during building the plant	Method, design, unknown	3
14	Known danger being ignored as a risk	Choice, effort, failure	3
15	Known danger previously excluded by the regulator but currently included	Choice, effort, residual risk	3
16	Unknown danger remaining undiscovered due to low regulator priority	Residual risk, knowledge, unknown	3
17	Unknown danger caused by new technology	Effort, residual risk, knowledge, unknown	4
18	Unknown danger due to design flaws	Failure, design, knowledge, unknown	4
19	Unknown danger due to wrong assumptions for scale-up	Method, design, knowledge, unknown	4
20	Known danger remaining unmitigated due to failing countermeasures	Effort, failure, ageing, design	4
21	Known Risk improperly controlled due to wrong chance or effect data	Method, failure, analysis, knowledge	4
22	Measures not up to the state of the art	Choice, effort, failure, residual risk	4
23	Measures no longer state of the art but still allowed by outdated permits	Choice, effort, failure, residual risk	4
24	Unknown danger due to exceeding the design lifetime of a plant	Choice, failure, ageing, unknown	4
25	Unknown danger due to use of standard- rather than specific inventory	Choice, effort, analysis, unknown	4
26	Unknown danger due to lost overview of risk inventory by subcontracting	Choice, method, analysis, unknown	4
27	Unknown danger due to underestimated risk	Method, analysis, knowledge, unknown	4
28	Unknown danger due to underreporting of danger	Choice, effort, analysis, unknown	4
29	Unknown danger due to improperly conducted safety studies	Method, design, knowledge, unknown	4
30	Risks exceeding acceptance level due to uncertainties in the assessment	Method, residual risk, analysis, knowledge	4
31	Unknown danger obscured by information overload	Method, residual risk, analysis, unknown	4
32	Measures announced but not yet prescribed by legislation or standards	Choice, effort, failure, residual risk	4
33	All other possible things that could go wrong but were not identified	Effort, method, residual risk, knowledge, unknown	5
34	Known danger not fully neutralized the deterministic way	Choice, effort, failure, residual risk, design	5
35	Unknown danger due to poor registration of incidents	Choice, effort, method, analysis, unknown	5
36	Unknown danger caused by unsafe behaviour	Choice, failure, design, knowledge, unknown	5
37	Non-compliant measures allowed / not noticed by the regulator	Choice, effort, failure, residual risk, design	5
38	Unknown danger not considered because of economic or strategic reasons	Choice, effort, residual risk, analysis, unknown	5
39	Risk improperly controlled and in excess of acceptance level	Criminal, choice, effort, method, residual risk, analysis	6
40	Measures not taken for well-known/frequently occurring accident types	Criminal, choice, effort, method, residual risk, analysis, design	7
41	Known danger as yet unmitigated waiting on the action list	Criminal, choice, effort, method, residual risk, analysis, design	7
42	Unknown danger due to overestimated barrier performance	Method, failure, residual risk, analysis, design, knowledge, unknown	7
43	Unknown danger due to improper use of additional risk calculation factors	Method, failure, residual risk, analysis, design, knowledge, unknown	7
44	Unknown danger due to cost cutting on safety critical items	Criminal, choice, effort, method, residual risk, analysis, design, unknown	8
	Total		168

6. Analysis

This study with three research methods produced several types of results: literature observations (OL) in chapter 3.7, longitudinal case study observations (OC) in chapter 4.3 and narrative text based observations of three kinds: Turning Points (TP) in chapter 5.9, other observations from practice (ON) in chapter 5.10. and a ranking of unmitigated risks in chapter 5.11 table 4. The results vary significantly in quality, validity and robustness. However, aggregated together they may provide robust findings and lead to an answer to the research question. The required additional analysis for this purpose consists of : 1) a closer interpretation of the subjective practice oriented results part, the 'turning points' in the narrative, 2) a triangulation of the observations from literature, practice and longitudinal case study leading to common findings and 3) an answer to the research question.

6.1.Turning points

The 'turning points', resulting from the narrative study, provide subjective insights in inspection practice, we call them 'notions'. Without framing these in theoretical concepts they contribute to understanding of the problem field nonetheless.

Notion 1: Risk as a counter-intuitive concept helps keeping down public spending on precautionary measures. This notion is not wholeheartedly embraced by industry though, in spite of potential cost savings, since it is either overruled by specific legal requirements on deterministic measures to be taken, or risk is too complex to assess and precautions are easier to implement.

Notion 2: Theory and practice in risk assessment show a gap of uncovered risk territory. Seveso companies have a limited 'risk appetite', eroding risk awareness, flawed systems due to human error, uncertainties, lack of knowledge and intangible risk components not dealt with. Some companies keep up appearances, others cross the criminal borders.

Notion 3: Inspectors face a near to impossible task when appraising the risk assessments companies produce, regulating without a proper yardstick and detailed plant knowledge. Yet, accidents keep happening, partly following unforeseen scenarios. Systematic appraisal, of the current huge variety of risk assessments, including their shortcomings, requires a new approach and better closure of the gap between identified causality and real accidents.

6.2.Triangulation and aggregation into findings

The observations gathered from three research methods were first screened for commonality.
Six observation clusters emerged. These constitute the findings from three simultaneously applied research methods with different degrees of commonality.

Three clusters emerge from all three research methods:

Finding 1-OL4, OC2, OC3, OC4, OC5, ON2: Risk assessment process at standstill:
The regulatory bodies strengthened their position between the many stakeholders, adapted their organisation and started to make inspection results public. Risk assessments are accepted by regulatory bodies and were handled the same way over the 2003-2016 time period. This approach was left untouched by several regulatory approach evaluations.

Finding 2-OL6, OL18, OC6, ON16, ON17, ON18: Regulator ambition:
In spite of the large variation in risk assessment methods and their quality, the regulator started with company ranking on safety performance, including risk assessments. This simple ranking can be

regarded as an expression of the will to appraise and validate but without uniformity and better ensured completeness that appears to be impossible for the time being.

Finding 3-OL9, OL13, OL15, OL19, OC8, ON5, ON6, ON9, ON10, ON11, ON19: Company attitude and effort:
In spite of recent software developments to model complex situations, uncertainties, lack of knowledge about cause-effect relationships, relying on experts, lagging behind with taking action on measures for known risks, not yet working on the risks from emerging technologies and ageing process plants, a 'black-box' and 'risk subcontracting' approach, ignored erosion of staff understanding of site risks, regarding unknown risk as unavoidable and showing less than adequate 'risk appetite', leave unexplored and unmitigated danger.

Three further clusters are sharing results of two out of the three research methods:

Finding 4-OL2, OL7, OL8, OL10, OL11, OL12, OL14, ON3, ON7, ON8, ON12, ON13: Risk assessment fundamental problems:
Risk is a concept hard to grasp for many people. Although the ISO standard claims all risk can be identified, practice demonstrates otherwise. There are many definitions, a mix of precautionary and risk based approach, uncertainties, poor modelling of human error and various flaws and weaknesses. Inspectors require companies to use multiple methods to be applied in complex situations without theoretical backing. Accidents following not identified scenario's indicate a gap between theory and practice. Scientists are struggling to include all these factors in mathematical models. The regulator faces a lack of consistent, complete, transparent and trustworthy risk assessments.

Finding 5-OL1, OL16, OL17, ON4, ON14, ON15: Regulator attitude:
The regulator uses the risk based approach to avoid excessive costs of precautionary measures. The regulator is controlled by politics. In practice huge differences between risk acceptance levels are present, and changing priorities occur, regarding activities in society. Inspectors must have adequate knowledge but in practice this is near to impossible. Inspectors cannot verify whether a risk assessment is complete and correct.

Finding 6-OL3, OC1: Risk assessor role:
Risk assessments (RIE and VMS element ii) are carried out by private companies, remained unchanged over 13 years while virtually all else did change.

Two remaining observations OL5 and ON1 are not adding new insight and are not further pursued.

6.3.Answering the research question

Answering the research question requires the identification of obstacles jeopardising validation of company risk assessments by the regulator.
Such validation would require a sound theoretical and methodical basis and be applied in a fair, uniform and transparent way by capable regulator inspectors. This approach would expose lack of effort and incompleteness in company risk assessments.

Several of such obstacles were identified:

-debated risk based control:
ongoing scientific debate, political paralysis and unknown territory cause standstill
(Finding 1,4,6) (Notion 1)

-poor uniformity:
many different risk assessment methods make uniform and fair appraisal impossible

(Finding 2,4) (Notion 3)

-lacking appraisal method:
as yet no standard appraisal method for risk assessment has been developed
(Finding 2,4)

-poor effort:
companies fail to provide exhaustive risk assessments and leave risks unmitigated
(Finding 3) (Notion 2,3)

-incompleteness:
unknown and unmitigated risk types make it hard to accept risk assessments
(Finding 3,4,5) (Notion 1,2,3)

-uncertainty:
risks and the contribution of measures to risk reduction are not always accurately known
(Finding 3) (Notion 2,3)

-capability:
inspectors go beyond their level of competence when verifying risk assessments
(Finding 4,5) (Notion 3)

This shows that current risk assessments by companies need to be more uniform and have better quality before any in depth regulator appraisal method can be applied. Such appraisal needs to be developed as a method and acceptance criteria need to be established. Company generated risk inventories need to be made more complete and the currently not dealt with intangible risk territory needs to be investigated and included to better close the gap between identified risks and actual accident causation.

7. Discussion

This study uses three methods to explore the realms of unknown risks in Seveso companies. The findings from literature search, case study and expert narrative largely point in the same direction.
Several critical methodical questions need to be answered though.

-Does this narrative represent current thinking in Seveso health and safety inspection practice ?
The narrative is not intended to be a *counter story* (Polletta, 1998). It does not seek to find differences with the dominant narrative about risk assessment but attempts to explore the path forward. So, probably it reflects current thinking for the most part. At this point it is relevant to mention the variety of safety managers and the variety of inspectors at both ends of the interaction on content level between companies and regulator. Both views on safety are constantly evolving in practice, while learning from experiences.

-Is the objective assumed in the 'safety' paradigm realistic, i.o.w. how safe is safe enough?
This study attempts to proceed towards more complete and uniform risk assessments. Most of the intangible risk types hitherto labelled as 'unknown' were found to be not as unknown as was previously assumed. The fact that really unknown risks still exist, because we do not know anything about them, cannot be denied though. In other words: the unknown is smaller than before but is still there. There is no absolute safety. We contend that acknowledging the existence of 'hard core' unknown risk, after thoroughly assessing all else, means that situation must be deemed safe enough. The regulator cannot do anything else than accepting this theoretically optimum situation and take responsibility.
Practice requires a slightly less ideal risk acceptance level due to economic limitations in what can be achieved (Reniers and Van Erp, 2016). Interestingly enough the identification effort required to only assess the risk types, thus far labelled as 'known but unmitigated' and 'unknown', cannot be as costly

as both assessing the risks and taking measures against them. A government could still accept risks when knowing them from a complete risk inventory and accept that measures are not taken or less than perfect for some of the risks in the inventory due to economic limitations. That would be a significant step forward in risk control.

-Does the current safety performance ranking list do companies justice ?
The regulators' obligation to validate risk assessments from Seveso companies is currently handled with approval of safety reports completeness, with law enforcement and with a simple 5 level scale rating based ranking list supporting political control. The rating scores are provided by inspectors every time they inspect part of the subject of risk assessment element ii, at least once every 5 years.
We contend that this ranking is superficial and has not significantly contributed to making risk inventories more complete nor to making Seveso companies safer over the 2003-2016 time period.

-Can the researchers be biased by changed conditions or context?
The context changes as identified in table 2 show that inspections on risk assessment were carried out by the 1st author, in his capacity as SZW-MHC inspector, in much the same way throughout the case study time period. The changes in regulatory body organisation and in inspection method had no impact on the way the contents of a risk assessment was being scrutinized by an inspection team.
This case study revolves around the Dutch inspection practice over the period 2003-2016. In other European countries inspection practice might have generated different experiential knowledge and different insights. Past and recent research on implementation of the Seveso directive has not identified major differences in context on the subject of risk assessment by Seveso companies in the Netherlands (Ale, 2002; 2008). Incomplete risk inventories and poor company safety performance were found to coincide in both 2002 and 2014 (Versluis, 2002; Kluin, 2014).

-What would be needed to improve company risk assessments?
Comparisons between assessments by a range of institutions in EU countries for the same fictitious chemical plant, demonstrated large differences, of up to a factor 100, in calculated risk levels. Hence, improvement is needed, e.g. by agreement on the precise methods to be used for risk assessment (Lauridsen et al., 2002). Apart from company willingness, an agreed method is currently missing. More complete, detailed and uniform company risk assessments would allow systematic appraisal and more objective rating by the regulator. The currently intangible risks, labelled as 'unknown' need to be included. Development of a more uniform and complete regulatory approach, assessment method, guidance and a standard to support this regulatory appraisal work, would involve the support EU Member state Governments, the Seveso companies, ISO and other stakeholders. Further research as to what part of causation explains the accidents which were not identified in the risk inventory is also expected to help increasing the completeness of company risk assessments.

-What else could we do?
The intriguing question why stakeholders seem to be blind for some of the risks remains unanswered. Risk management can only become active on known i.e. identified risks. Risk managers might decide to take countermeasures or accept such known risk. Even if no countermeasures are taken against it but it is deemed "acceptable" the risk is "controlled". Risk management cannot make such decisions about unknown – i.e. not identified risk. Thereby making the risk uncontrolled by definition. We have not extended our study towards exploring the boundaries of risk management itself however. That could be e.g. addressing the inabilities and shortcomings of safety management and its systems, as they are prescribed by the EC directives and national legislation which the member states are currently following. The existence of such inabilities could be a subject for further research.

8. Conclusions

The research question: "*to what extent can company risk assessments currently be validated by the regulator?*" can only be answered with "*none, or very limited*" for the time being. The main reason for

this is the regulators' intricate balance between taking responsibility and excluding unknown danger. Since not all accidents happen according to scenario's included in the identified risks there is a 'risk inventory gap' between risks the companies present and the true risks the regulator ought to consider.
It would seem that so-called 'unknown' danger cannot be an excuse for the current practice of incomplete and methodically diverse risk analyses and that high risk companies provide. Companies with major hazard installations could do better on this point, as could regulator inspectors intensify their appraisal efforts. Scientific research could explore causality of this category of accidents to spot where risk assessments turn a blind eye towards predictable danger.
We expect that better closure of the 'risk inventory gap', using more uniform assessments, an agreed risk assessment appraisal method, and a systematic completeness check, would bring validation of a company risk inventory by the regulator an important step closer.

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