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Why Doesn't the (Watch) Dog Bark?

Logics of Risk Regulation and Management in the Italian Railway Sector

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CONTENTS

INTRODUCTION 5

PART ONE. THEORETICAL FRAMEWORK: FROM RISKS TO ACCIDENTS THROUGH THE INSTITUTIONAL LOGICS PERSPECTIVE 25

1. RISK 28
1.1 The concept of risk 28
1.2 Risk management 55
1.3 Risk regulation 87
2. INSTITUTIONAL LOGICS PERSPECTIVE 103
2.1 The core meta-theory 105
2.2 Logics and the focus of attention 117
2.3 Institutional logics between theory and empirical research 121
3. ORGANISATIONAL ACCIDENTS 136
3.1 Main theories 137
3.2 Organisational accidents' genesis 146

PART TWO. RESEARCH DESIGN: THE CASE OF THE ITALIAN RAILWAY SECTOR 153

1. A CASE STUDY RESEARCH DESIGN 157
1.1 Why a case study? 157
1.2 Case selection 162
2. DATA USED IN THIS DISSERTATION 166
2.1 Data collection 166
2.2 Data analysis 171
3. A MENTAL EXPERIMENT 177

PART THREE. DATA ANALYSIS: LOGICS OF RISK MANAGEMENT AND REGULATION IN THE ITALIAN RAILWAY NETWORK 183

1. LOGICS OF RISK MANAGEMENT AND REGULATION 187
1.1 Politico-economic level: risk-based logic 187
1.2 Inter-organisational level: cost-benefit, standard and possibility logics 201
2. LOGICS INTERPLAY AND DEGREE OF LEGITIMACY 335

PART FOUR. FINDINGS: COULD THIS NETWORK INTERCEPT AN ACCIDENT BEFORE IT HAPPENS? 343

1. FROM INTER-INSTITUTIONAL SYSTEM TO ORGANISATIONAL ACCIDENTS 344
2. LOOKING AT THE EVENTS WEARING THE INSTITUTIONAL LOGICS' GLASSES 352

CONCLUSION 373

LIST OF FIGURES AND TABLES 385

ANNEXES 390

REFERENCES 406

[…] I saw by the Inspector's face that his attention had been keenly aroused.
"You consider that to be important?" he asked.
"Exceedingly so."
"Is there any point to which you would wish to draw my attention?"
"To the curious incident of the dog in the night time."
"The dog did nothing in the night time."
"That was the curious incident," remarked Sherlock Holmes.

[…] Before deciding that question I had grasped the significance of the silence of the dog, for one true inference invariably suggests others. The Simpson incident had shown me that a dog was kept in the stables, and yet, though someone had been in and had fetched out a horse, he had not barked enough to arouse the two lads in the loft. Obviously the midnight visitor was someone whom the dog knew well.

Arthur Conan Doyle, *Silver Blaze*

INTRODUCTION

The object

The starting point of this dissertation is a specific type of event, the organisational accident. Organisational accidents are man-made (Turner, 1978; Turner and Pidgeon, 1997); not in the sense that they are intentionally driven, but are unintended consequences of human activities (Baldissera, 1998) such as, for example, the production of nuclear energy, the transport of goods and people, or oil drilling. These events are by definition extremely low in frequency and extremely high in magnitude. They differ from individual accidents because they happen to organisations, rather than to single individuals, and because of the high magnitude of their consequences (Reason, 1997). Thus, organisational accidents are extremely rare, but have important adverse and harmful consequences on health and the environment.[1] Recent events such as the *Costa Concordia* accident, which occurred near Giglio Island on 13 January 2012; the Fukushima nuclear accident on 3 November 2011; or the Deep Water Horizon oil spill, which happened on 20 April 2010 in the Gulf of Mexico, are clear examples. Moving backward historically, the Chernobyl nuclear accident – 26 April 1986 – and the Bhopal gas leak accident – 2 December 1984 – are the most tragically famous examples with the greatest long-term consequences.[2]

During the last 30 years, the analysis of organisational accidents' genesis has become a well-established and recognised field of study. This field has provided important insights into the genesis of organisational accidents identifying mechanisms/factors leading to the accidents within and from the point of view of the organisations in which the accidents happened (Turner, 1978; Reason, 1990; 1997; 2008; Vaughan, 1996; Turner and Pidgeon, 1997; Perrow, 1999; Snook, 2000; Catino, 2006; Downer, 2011). Thus, their focus has been at the organisational level. Let us take the example of the Deep Water Horizon oil spill mentioned above. The available studies analysing the accident genesis, focus on the mechanisms within British Petroleum – the company responsible for the management of the oil plant –

[1]The term environment is used in a broader sense including all kinds of material damage.

[2]The focus of the study is on technological accidents. Natural disasters as well as financial and, more in general, business-related side-effects are not part of the primary focus though some ideas developed here could, in principle, be applied to these areas as well.

which contributed to the accident's occurrence. Examples of these mechanisms are: the presence of safety indicators referring exclusively to occupational safety, therefore individual rather than organisational accidents; a tendency to reduce costs without taking into account the possible consequences on safety; the existence of an organisational structure in which safety experts were responsible for setting standards but not for monitoring and enforcing them; and the reluctance of the management of the company to consider 'bad news' (Hopkins, 2012). However, organisations such as British Petroleum operate in a complex and vast environment. On the one hand, the possible dangerous and adverse consequences of human activities are the target of different organisations promoting and enforcing different ways of managing and regulating human activities in order to avoid, cope with, and/or handle the possible negative and unwanted outcomes of such activities. These organisations can be considered networks of private companies and public organisations interacting in order to avoid possible adverse and unwanted outcomes – thus at an inter-organisational level. On the other hand, the roles, responsibilities and regulatory approaches of the public and private organisations involved are shaped by the definition of legislative frameworks established at different levels of government such as the national, as well as the supra-national one – thus at a politico-economic level. Nevertheless, the inter-organisational and politico-economic levels rarely become the object of specific inquiries. For example, the available studies on the Deep Water Horizon oil spill do not analyse the network of public organisations in charge of monitoring and/or regulating the possible adverse outcomes of oil drilling, as well as their interactions with companies dealing with oil drilling – the inter-organisational level. Hence, organisations such as the US Environmental Protection Agency (EPA), the Mineral Management Service (MMS) – to which the US Department of Interior delegated its regulatory authority – and the US Coast Guard (USCG) are not objects of investigation. In the same way, available studies do not analyse the broader political and economic approach to regulating the negative outcomes of oil drilling – the politico-economic level. Therefore, the principles and ideas driving the definition of such a network of organisations, and specifying the roles and responsibilities in oil drilling monitoring and regulation, expressed in legislation such as the Outer Continental Shelf Lands Act (OCSLA), are not objects of inquiry.

Considering other fields of study that deal with the ways in which organisations and societies should avoid, cope with, or handle the possible negative outcomes of human activities, such as risk management and risk regulation studies, does not allow us to fill the identified gaps. Risk regulation and management both deal with ways of organising in order to avoid, cope with, and/or handle possible adverse and unwanted outcomes of human activities, but they have different targets. Risk management examines the organisations dealing with a specific activity such as oil drilling, and fosters organisational processes and structures in order to deal with the possible negative outcomes of the on-going activity – the organisational level. In contrast, risk regulation targets the broader legislative frameworks organising human activities and fostering roles, and the responsibilities and regulatory approaches of the different organisations involved, in order to avoid, cope with, and/or handle possible negative outcomes – the politico-economic level. In the case of oil drilling in the United States, risk management would look inside companies such as British Petroleum. Risk regulation would look at the legislative framework such as, for example, the Outer Continental Shelf Lands Act (OCSLA), defining the network of organisations in which companies such as British Petroleum are embedded – the US Environmental Protection Agency (EPA), the Mineral Management Service (MMS), and the Coast Guard (USCG).

Available studies on risk management share a focus on the organisational level with organisational accident studies. In addition, such studies have a theoretical-normative nature. Thus, they highlight the ways in which organisations should organise themselves in order to avoid, cope with, and/or handle negative outcomes, rather than what the organisations actually do in order to avoid, cope with, or handle such outcomes.

Risk regulation studies examine the management of adverse outcomes from a macro point of view taking into account the politico-economic level: governance strategies to keep human activities inside safe boundaries. For example, this field of study considers the variability of risk regulatory frameworks between nation-states (e.g., Jasanoff, 2005a; 2005b), or within nation-states through different regulatory domains (e.g., Hood et al., 2001). Consequently, on the one hand, the inter-organisational level, which examines the interactions and coordination of the different organisations involved in risk regulation activities, is still not addressed. On the other hand, analysis from the politico-economic perspective remains at a high degree of abstraction. Therefore, the available studies do not consider, for example, the practical interpretation of such regulatory frameworks provided by the organisations in charge of specifying, monitoring, and enforcing such frameworks. Continuing with the US oil drilling example, the available studies analyse the regulatory strategy of oil drilling and possible negative outcomes by looking mainly at the national legislative framework. Thus, for example, an examination of the regulatory framework shaped by the Outer Continental Shelf Lands Act (OCSLA), and a description of the organisations involved in its implementation, such as the US Environmental Protection Agency (EPA), the Mineral Management Service (MMS), and the Coast Guard (USCG), and their formal roles and responsibilities (Dagg et al., 2011). However, they do not take into account the processes implemented, promoted and enforced by such public organisations, as well as the interactions between these organisations and the private ones such as British Petroleum; both involved in the regulatory process aiming to avoid, cope with, and/or handle the dangerous outcomes of oil drilling. Thus, risk regulation studies fail to address the way in which these public and private organisations offer a practical translation of such high-level regulation in their everyday activities: they do not analyse the politico-economic level 'in action'. Furthermore, risk regulation studies do not consider the connections, possible contradictions and/or overlapping between different levels of government such as the national and the supra-national ones. An example in the US oil drilling case is the possible overlap, and/or contradictions between national and international agreements, such as the United Nations Convention on the Law of the Sea (UNCLOS) and the Outer Continental Shelf Lands Act (OCSLA).

More in general, the main gap that the risk management and risk regulation studies share is the absence of a clear link between risk management and regulation approaches/strategies and the available insights on the genesis of organisational accidents. Thus, the need 'to understand the limitations of risk management [and regulation] approaches, that is to analyse situations in which they are helpful and when they might be counterproductive' (Hutter, 2006: 220), is still not fulfilled.

The purpose of this study is to fill these gaps creating a bridge between these three fields of study – organisational accidents' genesis, risk management and risk regulation – as well as closing in on the inter-organisational level whose analysis is still lacking. The aim is to focus on higher levels – inter-organisational and politico-economic – in contrast with organisational accidents and risk management studies, while maintaining a link with what is actually going on by observing such high levels 'in action'. This contrasts with risk management – which is normative in nature – and risk regulation studies – which remain at a high level of abstraction. Our focus is on the inter-organisational level, thus on organisations in charge of regulating, monitoring and enforcing specific regulatory frameworks, but without losing the link with the possible negative outcomes of the regulated areas of human activities, as well as with society as a whole. Accordingly, the study aims to keep together two objects of analysis:

- The networks of organisations involved in the management and regulation of human activities in order to avoid, cope with, and/or handle possible negative outcomes. This with a specific focus on the point of view of the organisations in charge of monitoring, and/or regulating the possible adverse outcomes of such areas of human activity at different levels of government – national and supra-national – but that are not involved in the core activity of the regulated domain. Thus, in the example of oil drilling in the US context, the network of organisations involved in management and regulation includes public regulators – the US Environmental Protection Agency (EPA), the Mineral Management Service (MMS), and the Coast Guard (USCG) – and private companies such as British Petroleum. In this network, we would consider the point of view of organisations such as the US Environmental Protection Agency (EPA), the Mineral Management Service (MMS), and the Coast Guard (USCG). Thus, organisations in charge of regulating and monitoring negative outcomes of oil drilling, but not dealing directly with oil-drilling activities and differing in this sense from companies such as British Petroleum;

- The organisational accidents, thus unintended events (Baldissera, 1998) happening to organisations rather than to single individuals, and characterised by extremely low frequency and extremely high consequences for health and environment (Reason, 1997). We can consider such events as a specific type of negative outcome that the network of organisations mentioned above should avoid, cope with, and/or handle.

By taking the point of view of regulators, we mean looking at:

- The politico-economic level 'in action': the way in which regulators interpret and translate the legislative framework, of which they are part, into practise;
- The inter-organisational level: the relationships within the network that go from the regulators to the regulated organisations, to other regulators, and to the phenomena they are in charge of regulating. Thus, the processes dealing with possible negative outcomes that the regulators promote, enforce, and monitor among the regulated organisations. The ways in which regulators coordinate themselves, as well as the ways in which they promote, enforce, and monitor processes among other regulators located at different levels of government. The processes such as information gathering and information analysis that regulators perform in order to gain awareness, and face the possible negative outcomes linked to the regulated area of activities, are also considered.

We focus on processes that fit within the concept of risk regulation, aiming to fill the gaps opened by the lack of inter-organisational-level analysis, as well as by the high degree of abstraction at the politico-economic level of study. Nevertheless, some of these processes can be considered as overlapping between the concepts of risk management and risk regulation. For example, if we look at the relationship between regulators and regulated organisations, the regulating organisations could promote and enforce specific processes of risk management fostering the way in which the regulated organise themselves in order to avoid, cope with, and/or handle the possible negative outcomes of their own activities. Such promotion and enforcement is part of their risk regulation strategies, but *de facto* expresses a specific approach to risk management. In addition, if we look at the relationship between regulators and the outcomes of the regulated activities, regulating organisations could develop their own processes of risk management directly within their own organisations, targeting the possible negative outcomes of the regulated area of human activity. Again, such processes are part of the risk regulation strategies of the regulating organisations, but identify a specific practical implementation of a risk management strategy. Returning to the example of oil drilling in the US, part of the regulatory activities performed by the US Environmental Protection Agency could be the promotion and enforcement of specific ways in which to manage risks in order to affect the way in which the possible adverse outcomes are managed within British Petroleum. In addition, organisations such as the US Environmental Protection Agency could look straight to the outcomes of British Petroleum's activities in order to monitor the effectiveness of the risk management performed by such an organisation. Consequently, the US Environmental Protection Agency could perform risk management by itself, directly targeting the outcomes of the oil drilling activity. Thus, processes that can fit within both the concepts of risk management and risk regulation are taken into account.

The puzzle and the question

The question this study aims to answer arises from a puzzle regarding the relationship between the two objects of analysis mentioned above: networks of organisations dedicated to risk management and risk regulation, and organisational accidents. On the one hand, during the last three decades, the number of organisations and networks of organisations dedicated to risk management and regulation, as well as the resources and public attention dedicated to the regulation of human activities in order to avoid, cope with and/or handle negative outcomes, have increased. On the other hand, the number of organisational accidents has not decreased. More specifically, scholars from different disciplines have underlined an increasing focus by our (Western) societies on the avoidance of possible negative outcomes as a by-product of different areas of human activity (Hood and Jones, 1996; Coles et al., 2000; Hutter and Power, 2005; Taylor-Gooby and Zinn, 2006; Hutter, 2006; 2010; Rebora, 2007; Gephard et al., 2009; Minelli et al., 2009). Risk management and regulation have turned out to be a crucial public and political issue (Hood and Jones, 1996; Aven and Kristensen, 2005; Hutter, 2006; 2010; Taylor-Gooby and Zinn, 2006; Gephard et al., 2009). In addition, despite the variability affecting the definition of what harmful outcomes are, as well as the ways in which human activities should be/are managed and regulated in order to avoid, cope with, and/or handle such possible negative outcomes (Hood and Jones, 1996; Hood et al., 2001; Jasanoff, 2005a; 2005b; Rothstein et al., 2012), the number of public agencies dedicated to risk management and regulation has grown both at the national, as well as the supra-national levels (Braithwaite, 1982; 2003; Ayres and Braithwaite, 1992; Thatcher and Sweet Stone, 2002; Baldwin et al., 2012). Looking at the supra-national level, the creation of worldwide organisations in charge of coordinating the management and regulation of the possible negative outcomes linked to specific areas of human activities, such as the World Health Organisation, or the International Atomic Energy Agency, can be taken as examples (Scheytt et al., 2006). Consequently, a growing number of human activities have fostered complex networks of organisations – regulators and regulated organisations interacting at different levels of government – dedicated to risk management and regulation (Ibid.). In essence, a massive increase in attention, resources, and organisations dedicated to the risk management and regulation of human activities in order to avoid, cope with, and/or handle possible negative outcomes – organisational accidents among them – has emerged. Nevertheless, despite such an increase in attention, resources and the number of organisations, organisational accidents still happen. A look at recent news reports gives a considerable number of examples. The latest ones include: the derailment and explosion of an oil-transport train in Alabama on 8 November 2013; the Santiago de Compostela high-speed train derailment, which occurred 24 July 2013; the derailment and explosion of an oil-transport train in the town of Lac-Mégantic, Quebec on 6 July 2013.

From this puzzle, the question the study aims to answer arises: ‘why doesn’t the (watch) dog bark?’ Thus, why despite the presence of regulators in charge of monitoring and regulating human activities in order to avoid, cope with, and/or handle the possible negative and unwanted outcomes of such activities, do organisational accidents keep happening?

The question does not directly consider organisational accidents' genesis: why do accidents happen? In contrast with organisational accident studies, we do not aim to explain the aetiology of the accident. More specifically, organisational accident studies identify the mechanisms or factors within the organisations in which the accident happened, that acted as contributing factors creating a context prone to the accident's occurrence (Reason, 1997). On the contrary, our aim is to explain why the regulators – organisations in charge of monitoring and/or regulating the possible negative outcomes of areas of human activity at different levels of government, but not involved in the core activity of the regulated domain – do not recognise the presence and the potential gravity of such mechanisms/factors. Thus, we are not linking or fostering the role of regulators as a contributing factor in the accident genesis. Instead, we question the possibility of such regulators becoming aware and acting in order to reduce or eliminate those mechanisms/factors, which can contribute to the accident genesis within the regulated organisations.

The example of the *Costa Concordia* accident cited previously can help to clarify this point. On 13 January 2012 at around 9:45 p.m. the cruise ship *Costa Concordia* approached Giglio Island after a deviation from the programmed route. It partially sank and ran aground near the island. The sinking led to the loss of 32 lives. The collision with rocks followed an unplanned near-shore salute (or inchino, which literally means bow, or curtsy) to the local islanders which brought the ship to a distance of 0.5 miles from the coast instead of the 3 miles programmed during the ship's route planning. From the point of view of the question: why did the accident happen? We would focus on the mechanisms/factors within Costa – company owner of the *Costa Concordia* and operating in the cruise ship business – which contributed to the accident genesis. Let us take the *inchino* practise as an example of an organisational mechanism, which played a role in the accident. The *inchino* performed by Captain Francesco Schettino that night was not a violation, but a regular custom as testified by many cruise ship crewmembers during the trial following the accident. The captains of cruise ships had the habit of navigating near the shore of islands. In addition, the company itself used to promote such practises as a business incentive in order to sell the cruises as an analysis of the company website conducted after the accident testified. Hence, the *inchino* practise was a dangerous practise constituting a constant violation of the safety limits stated in the route plans. Nevertheless, such a violation, performed since 1993 (Palombo, 2008) without leading to an accident until the *Costa Concordia* one, has on the one hand, become a habit over the years and, as a result, the dangerousness of such a custom was no longer perceived by captains or other crew members. On the other hand, the company itself started to encourage rather than discourage this dangerous practise. Basically, the *inchino* ritual was normalised (Vaughan, 1996): the constant violations of common sense safety boundaries were accepted and, given the absence of related accidents, such violations became a routine. Consequently, the dangerousness of the exercise, as well as the possible harmful consequences of such a practise, were underestimated or not perceived. Such a mechanism known by organisational accident scholars as the normalisation of deviance (Ibid.) can be considered an explanation of the organisational accidents' genesis answering the question: why the accident happened?

From the point of view of the question: 'Why doesn't the (watch) dog bark?', we would consider that the possible dangerous outcomes of the cruise ship's activities are the target of a network of organisations. This network includes companies such as Costa, as well as different regulators such as the *Corpo delle Capitanerie di Porto*, dealing with navigation safety at the national level of government in Italy; and the European Maritime Safety Agency, at the European one. Consequently, our focus with regard to the *inchino* practise would be that such a custom was performed for almost thirty years before the *Costa Concordia* accident, without any awareness or intervention on the part of public organisations such as the *Corpo delle Capitanerie di Porto* and the European Maritime Safety Agency. Hence, they are the very (watch) dogs of maritime transport activities in charge of monitoring and regulating such activities in order to avoid possible negative and unwanted outcomes for health or environment. Our question aims to explain why, for example, none of those organisations recognised the dangerousness of the *inchino* practise; whether they were aware of such a practise; if they recognised the possible harmful outcomes linked to the practise; if they established clear safety limits – e.g. maximum mile limits – to shore approaches; monitored such practises; or monitored the consideration of such a ritual among the company's risk evaluation processes.

Research pathway and main results

In order to answer the question – 'Why doesn't the (watch) dog bark?' – we propose a two-step research design.

As a first step, we analyse the case of a regulatory network: the Italian Railway Regulatory Network. An analysis of the Italian railway transport legislative framework allows us to identify the regulating organisations, the points of view of which, this study considers: the European Railway Agency (ERA), at the European level of government; the *Agenzia Nazionale per la Sicurezza delle Ferrovie* –

National Safety Authority (NSA); and the *Direzione Generale per le Investigazioni Ferroviarie* – National Investigation Body (NIB), at the Italian level of government. These three organisations can be considered the (watch) dogs of the Italian railway sector: organisations in charge of managing and regulating rail transport activities in order to avoid, cope with, and/or handle the possible negative outcomes of such activities, but not involved in rail transport operations. In order to understand the way in which the selected regulatory network works, we need a theoretical-analytical framework allowing us:

- On the one hand, to hold together different levels of government – national and supra-national – leaving room for contradictions and/or overlapping;
- On the other hand, to ensure an in-depth understanding of the processes, interactions and coordination strategies shaped by such organisations, as well as of the cultural and cognitive basis of such processes, interactions and coordination strategies.

The institutional logics theoretical-analytical framework (Alford and Friedland, 1985; Jackall, 1988; Friedland and Alford, 1991; Thornton and Ocasio, 2008; Thornton, Ocasio and Lounsbury, 2012) satisfying these requirements, frames the empirical analysis developed here. Institutional logics are 'conceptual lenses' (Allison and Zelikow, 1999) through which the regulating organisations see, interpret, and represent reality. The logic concept binds a set of symbolic components – categories and associated meanings, rationales, legitimate ends – and material ones – processes such as legitimated means to reach legitimated ends and structures – shaping and shaped by the organisation's everyday on-going activities (Friedland and Alford, 1991). Thus, their identification and analysis allows us to understand the way in which the regulatory network functions, as well as the way in which such a network frames the negative outcomes and interacts in order to avoid, cope with, and/or handle them. The logics' identification and description, and an understanding of their interaction are the product of the analysis of: different types of documents produced by the three regulating organisations – around 6,000 pages; 40 interviews conducted mainly with members of the three organisations; and observation of the everyday activities within each organisation – for a total of five months.

As a second step, in order to understand how the identified logics affect the possibility of regulators to intercept an accident before it happens, we develop a 'mental' or 'conceptual' experiment (Weber, 1922). The majority of the studies dealing with institutional logics concentrate on explaining the logics' origins and their alterations. For example, in considering the role of individual actors in triggering changes, the logics' legitimisation process, or the interplay between the symbolic and the material dimensions in triggering a change, is addressed. In contrast, a minority of the available studies go in the other direction, considering the consequences of observing and interpreting reality from a specific logic's point of view. Here the aim is to concentrate on this less examined point of view regarding the institutional logics' role: what are the consequences of the prevalence of specific logics on individual actions and decisions? The basic idea driving such a focus is that logics represent 'conceptual lenses' that are a way to see and a way not to see at the same time: logics focus individuals' attention on certain problems, but not on others, as well as on certain solutions despite the potential multiplicity of available solutions (Simon 1947;1962; March and Simon; 1958; Simon, 1972; March and Olsen, 1976, Ocasio, 1997; Thornton and Ocasio, 1999; Thornton et. al., 2005; Cho and Hambrick, 2006; Lounsbury, 2007). An analysis of the logics' focus of attention mechanism allows us to understand which type of events the logics focus regulators' attention on. Through a mental experiment, between the various informational inputs that inform the regulators' activities, we show where regulators' attention tends to focus by wearing the different logics' conceptual lens. In addition, the presence of three different logics allows us to see how different logics focus regulators' attention on different events: in changing the lens, the kind of events 'in focus' and 'out of focus' changes. Once we have identified which informational input the regulators' attention is focused on, we need a term of comparison, which allows for the possibility of regulators to focus their attention on events that are relevant in organisational accidents' genesis to be understood. Thus, we consider the available insight about organisational accidents' genesis (Turner, 1978; Reason, 1990; 1997; 2008; Vaughan, 1996; Turner and Pidgeon, 1997; Perrow, 1999; Snook, 2000; Catino, 2006; Downer, 2011), and we compare the events on which logics focus regulators' attention with the events that previous studies show as relevant in organisational accidents' genesis. The comparison allows us to understand whether given the available logics and their interaction, regulators' attention is focused on events that are potentially relevant in order to intercept an accident before it happens.

The case selection follows two sets of criteria, according to this two-step research design. Looking at the first step, we develop a case study research design selecting a case from a population of regulatory networks – networks of organisations involved in the management and regulation of human activities in order to avoid, cope with, and/or handle possible negative outcomes of such activities. Looking at the examples mentioned above, the regulatory network for oil drilling in the US, or the regulatory network of maritime transport in Italy, can be considered members of such a population of reference. The case selection follows some fixed attributes of the regulatory networks identified looking at previous risk regulation studies. More specifically, risk regulation studies have identified a general trend affecting the legislative frameworks promoted nowadays by (Western) societies in order to avoid, cope with, and/or handle the possible negative outcomes of human activities (Braithwaite, 1982; 2003; Ayres and Braithwaite, 1992; Osborne and Gaebler, 1992; Majone, 1994; 1997; 2002; Burton, 1997; Hood, 1991; Haufler, 2001; Hutter, 2001; James, 2001; Thatcher and Sweet Stone, 2002; Power, 2005; Estache and Wren-Lewis, 2010; Yeung, 2010; Aven, 2011; Baldwin et al., 2012). Such legislative frameworks shape some general attributes of the regulatory networks such as: the involvement of private organisations in regulatory activities (Haufler, 2001; Power, 2005; Aven, 2011); the presence of regulating organisations with a specific technical-scientific orientation, but out of the political arena and electoral pressures (Burton, 1997; Thatcher and Sweet Stone, 2002; Baldwin et al., 2012); and the existence of organisations located at different levels of government dealing with the same regulatory areas of activity (Estache and Wren-Lewis, 2010; Baldwin et al., 2012). We identify a case as close as possible to those attributes, thus some of the concepts and ideas developed here could in principle be useful to understand a broad and increasing population of cases.

Looking at the second step, we follow an 'extreme case' (Flyvbjerg, 2006) selection strategy. More specifically, available explanations considering the failure of regulators in avoiding, coping with, and/or handling the possible negative and unwanted outcomes, focus on the presence of inappropriate relationships or conflicts of interest between regulators and regulated organisations (Froud et al., 2004; Hirsch, 2003; Citron, 2003), the regulators' adoption of unethical or immoral behaviours (Mintzberg, 2004; Froud et al., 2004; Williams, 2004a; 2004b; Ghoshal, 2005), or the impossibility for regulators to have sufficient or sound information because they are too close to regulated organisations or too far away from them (Vaughan, 1996; 2003; Reason, 1997). Here, we focus on another unexplored 'causal chain' (Weber 1904; 1906; 1913), showing how the failure of regulators in avoiding, coping with, and/or handling the possible negative and unwanted outcomes is not just the result of deviant behaviour or lack of information about regulated organisations' outcomes. The case selection pursues the aim of exploring how the logics' focus of attention mechanism works in preventing regulators from seeing events that are potentially relevant in order to intercept an accident before it happens. The study aims to understand if, and in which way, the mechanism affects the possibility of seeing warning signals that can allow regulators to intercept accidents before they happen.

Thus, following the ‘extreme case’ (Flyvbjerg 2006) strategy: an example of a regulatory network which performs particularly well has been selected. More specifically, the Italian case was chosen because:

- There is genuine commitment to the mission of ensuring a safe functioning of the regulated area of human activity, and various and effective risk regulation and management strategies have been developed pursuing such an end;
- There are a considerable amount of resources and skills dedicated to risk management and regulation within all the three organisations studied;
- There is a specific focus on the need to ensure regulator independence from the regulated organisations as well as from other regulators – the creation of three independent regulating organisations located at different levels of governments goes in this direction – and regulator accountability to society as a whole;
- There are structured processes of information gathered in place.

The extreme case strategy allows the effect of other intervening variables influencing the regulators’ activity to be minimised. Thus, minimising the interaction of other mechanisms that could affect regulators’ possibility to see warning signals, the logics’ focus of attention mechanism can be better identified.

The analysis points out that the regulatory network follows specific institutional logics. Looking at the politico-economic level in action – the way in which regulators interpret and translate the legislative framework of which they are part into practise – we identified a shared logic that we name the risk-based logic. With reference to the inter-organisational level – the relationships within the network that go from the regulators to the regulated organisations, to other regulators and to the phenomena they are in charge of regulating – we identified three different logics characterising the three regulating organisations’ approaches: the cost-benefit logic, prevalent within the European Railway Agency (ERA); the standard logic prevalent within the Italian National Safety Authority (NSA); and the possibility one prevalent within the Italian National Investigation Body (NIB). The three logics present different degrees of legitimacy, thus in their interplay one logic tends to prevail over others. Generally, the more legitimated one is the cost-benefit logic, thus the focus of attention shaped by this logic’s point of view tends to prevail during interactions and discussions.

The ‘mental’ or ‘conceptual experiment’, analysing the focus of attention mechanism, and comparing the events on which regulators’ attention is focused with the events that are potentially relevant in organisational accidents’ genesis, shows how the available logics and their interactions can prevent regulators from focusing on events that are relevant in order to intercept organisational accidents before they happen. More specifically, this study indicates how the same organisational processes, methods of reasoning, assumptions and principles shaping and shaped by regulators' actions and decisions in order to manage the possible side-effects of the regulated area of human activity, tend to divert regulators' attention from informational input that is potentially relevant in order to intercept an accident before it happens. Thus, it is not just a deviance or functional lacuna of the regulatory activity that can lead to an accident happening without any intervention by regulators, but it is the actual 'normal' functioning of the regulators' activities that can prevent regulators from seeing events that are potentially relevant in intercepting an accident before it happens. Consequently, even in a perfect world of full resources, perfect and sound information and morally oriented behaviour, regulators' activities are still affected by a bias of perspective that tends to select information focusing regulators' attention on certain events instead of others. In conclusion, the study shows how despite the presence of regulating organisations, accidents do not happen because regulators are linked to regulated organisations exhibiting inappropriate relationships or conflicts of interest (Froud et al., 2004; Hirsch, 2003; Citron, 2003), adopt unethical or immoral behaviour (Mintzberg, 2004; Froud et al., 2004; Williams, 2004a, 2004b; Ghoshal, 2005), or lack sufficient or sound information (Vaughan, 1996; 2003; Reason, 1997). On the contrary, accidents can happen because standardised processes, accurate categories, precise definitions, scientific rigor and market rationality, can lead regulators to look away from events that are significant in organisational accidents' genesis. In addition, even if other points of view are available, the high degree of legitimacy reinforcing such standardised processes, accurate categories, precise definitions, scientific rigor and market rationality, prevent other points of view from being considered. Thus, the (watch) dog does not bark because when the killer is approaching the victim, it is looking in another direction where it cannot see the killer nor hear him approaching.

Structure of the dissertation

The dissertation is structured in four parts. The first part is dedicated to the description of the theoretical framework. Three main fields of study are considered: risk management and regulation; institutional logics; and organisational accidents. Chapter 1 examines the risk definition and historical origin (Section 1.1), and then, it presents, and discusses the main available theoretical-normative approaches to risk management (Section 1.2). In conclusion, the risk regulation meaning is discussed and the contributions of previous studies that inform the case selection are described (Section 1.3). Chapter 2 presents the institutional logics perspective, as well as previous contributions dealing with the logics' focus of attention mechanism. Chapter 3 is dedicated to organisational accident studies: organisational accidents' main theories, and mechanisms/factors contributing to the accidents' genesis identified by previous studies, are presented.

The second part deals with the research design. First, the case study research design is presented: justification of the choice to conduct a case study research design; explanation of the criteria used for the case selection (Chapter 1); and description of data used in the dissertation, as well as of the techniques used for data collection and analysis (Chapter 2). Then, the structure of the mental experiment, its limits and assumptions are presented (Chapter 3).

The third part is dedicated to data analysis. In order to specify the general background up on which this study is based, we propose a brief reconstruction of the history of the Italian railway sector identifying the main turning point in the legislative evolution of the management and regulation of possible negative and unwanted outcomes of railway transport activity. Then, we present the main evidence collected. First, the logics identified at the politico-economic level, as well as at the inter-organisational level are described (Chapter 1). Subsequently, the logics' interplay and degree of legitimacy are discussed (Chapter 2).

The fourth part relates the identified logics to the macro and micro levels of analysis. First, the identified context-specific logics are located within society as a whole, and the contributing role of the various institutional orders such as the market, professions, and the state in shaping the context-specific logics, are examined (Chapter 1). An examination of the focus of attention effect – micro level effect – of the available logics follows. Then, by comparing the events up on which the logics focus regulators' attention, and the events previous empirical research identifies as relevant in organisational accidents' genesis, we can finally answer the question 'Why doesn't the (watch) dog bark?' (Chapter 2).

In conclusion, we highlight the practical and theoretical implications of the main findings.

PART ONE.

THEORETICAL FRAMEWORK: FROM RISKS TO ACCIDENTS THROUGH THE INSTITUTIONAL LOGICS PERSPECTIVE

This part aims to present the theoretical framework that has guided the development of the study. The structure of the chapters follows the three main fields of reference this dissertation looks at: the ‘risk province’, the institutional logics perspective and the organisational accident field.

With reference to the ‘risk province’ chapter, the aim of each section is to discuss the definition of risk (Chapter 1, Section 1.1), risk management (Chapter 1, Section 1.2), risk regulation (Chapter 1, Section 1.3); and to describe the main contributions of each field of reference. Before looking closely at each field of reference, a few words on the way in which these fields crop together are needed. With reference to the distinction between risk management and risk regulation, as already mentioned, the boundary between the two fields has become more and more blurred over the years. There are two main reasons for the overlapping: on the one hand, a change in regulatory strategies (Braithwaite, 1982; 2003; Ayres and Braithwaite, 1992; Osborne and Gaebler, 1992; Estache and Wren-Lewis, 2010; Yeung, 2010; Aven 2011; Baldwin et al., 2012); on the other, an effort made by scholars for the development of an interdisciplinary field of study (Hutter, 2006). The change in regulatory strategies indicates a move away from the control-command role of the state as well as a strong involvement on the part of the regulated organisations in regulatory activities. (See Part 1, Chapter 1, Section 1.3.) The distinction between the role of the state and the role of the regulated domain becomes less defined. Consequently, the distinction between regulation and management loses relevance as well. With reference to the scholars’ role, Hutter (2006; 2010) describes it as ‘a concerted effort to delineate a new interdisciplinary area of risk regulation studies which would bridge regulation and risk management studies.’ Such a concerted effort has slowly led to the definition of a more hybrid field of study still in development. Despite such blurring boundaries, in this chapter the two fields are dealt with separately. On the one hand, risk management (Section 1.2) and regulation (Section 1.3) remain two historically different fields of study. On the other, these fields’ statements have played a different role in the definition of the research design. More specifically, the risk regulation studies available played a crucial role in the case selection; in contrast, available work on risk does not played a role in the definition of the criteria for case selection. However, during the description it is possible to notice some overlapping.

This study aims to locate itself within such a risk regulation hybrid field, and the choice of the institutional logics perspective (Alford and Friedland, 1985; Jackall, 1988; Friedland and Alford, 1991; Thornton and Ocasio, 2008) as the theoretical analytical framework structuring the empirical analysis (Part 1, Chapter 2) goes in this direction. The institutional logics perspective effectively allows a bringing together of risk management and regulation, in a dialectic way, modelling these two elements in a multilevel analytical framework.

Finally, the examination of the organisational accident field forms the basis for the comparison between the logics' focus of attention and accident genesis to be established. More specifically, the main available theories on organisational accidents' genesis are presented first, then the mechanisms of failure leading to accidents are considered in-depth.

1. RISK

1.1 The concept of risk

This section aims to explore the concept of risk. First, by analysing some fields of human activity in which the concept is used, we identify the different meanings as well as the various phenomena bound under such a concept in society nowadays. Then, we present the main anthropological and sociological theories on risk, highlighting the way in which they differ from one another, as well as from the 'technical-scientific' approach to risk. Such an analysis allows us to understand the main strengths and weaknesses of the available theories and establish the scenario in which this study aims to locate itself. In conclusion, the definition of risk used as a starting point of this dissertation; the kind of phenomena this study aims to focus on using the term risk; as well as the position this study aims to maintain with respect to previous anthropological and sociological theories, are specified.

Risk: the meaning

As Hood and Jones (1996: 2) underline 'there is not a clear and commonly agreed definition of what the term "risk" actually means.' The Oxford English Dictionary[3] defines risk as:

- A situation involving exposure to danger;
- The possibility that something unpleasant or unwelcome will happen;
- A possibility of harm or damage against which something is insured;
- The possibility of financial loss.

The origin of the term remains unknown, but it is first used around the middle 17th century. The etymological root is the French *risqué* – noun – and *risquer* – verb – and the Italian *rischio* – noun – and *rischiare* – verb (Ibid.). Despite the uncertain origin of the term, as well as its overlapping with other neighbouring terms such as hazard, uncertainty, or fate, the idea of risk was already conceived during the Roman Empire. For example, in 215 B.C. Livy (XXIII, 48 and 49) describes a government guarantee, requested and obtained by some goods producers and sellers for transporting goods from Rome to Spain, in order to supply the legions deployed there

[3]Oxford Dictionary, http://www.oxforddictionaries.com/definition/english/risk?q=risk, Website consulted 16 January 2014.

at that time. More specifically, the agreement referred to the uncertainty of maritime transport: in case of loss of the transported goods due, for example, to adverse weather conditions, the value of the lost goods would be reimbursed by the Empire (Trenerry, 2009). Thus, the Empire took the risk – the possibility of losing the transported goods during the trip – covering the cost of the goods even if they were lost or damaged during transportation. Moving forward historically, in the Middle Ages, maritime trade into uncharted waters exhibits a similar conception of risk (Oppenheim, 1954; Ewald, 1991; Luhmann, 1993; Giddens, 1999).

A first formal definition of the term appears at the beginning of the 20th century. The risk panorama has been considerably shaped by such a mainstream definition, which, from its origin, (Knight, 1921) has deeply influenced further development of the identification of risks and their management. Following such a definition risk is the product of two variables:

- Probability of the event: the estimation of the number of times the event could happen given a specified period of time;
- Magnitude of the event: an evaluation of the consequences there would be if the event actually happens (e.g., Knight, 1921; Gobbi, 1938; Williams and Heins, 1964; Wood, 1964; Kaplan and Garrick, 1981; Borghesi, 1985; Bertini, 1987; Urciuoli and Crenca, 1989; Misani, 1994; Adams, 1995).

Nowadays, the term risk is used in different fields of human activities such as insurance, business and finance, technology and work, and national security; as well as when referring to the possible dangerous consequences of natural phenomena such as, for example, landslides, earthquakes or tornados. The meaning of the concept, the phenomena bound under such a concept, as well as the overlap with neighbouring concepts, varies accordingly. Let us look closely at the different fields in which the term risk is employed. (See Table 1.)

Fields	*Meaning*	*Neighbouring concepts*	*Bound phenomena*
Insurance	Risk is an unavoidable danger (irreducible – fate, destiny), but with quantifiable monetary losses if we take into account groups of individuals/organisations as a whole	Risk vs. Fate Risk = Probability of an event and monetary loss linked to the event (estimated only when referring to classes of events affecting groups of people/organisations, not estimable for single individuals or organisations)	Negative events clearly linkable and affecting groups of individuals or organisations (e.g., negative event: car crash affected group of individuals: car drivers)
Business and finance	Risk as intrinsic component of any enterprise with a positive or negative meaning according to the variance affecting the expected outcome	Risk vs. Uncertainty Risk = Probability (measurable uncertainty) per magnitude. Risk bound phenomena that can be linked to phenomena of the same kind that happened in the past	Monetary outcomes of the business or financial activity
Technology, health care, safety at work	Risk has to do with the reliability of human activities: the possibility of negative and unwanted outcomes for health or environment rising from the side-effects of intentionally driven human activities.	Risk vs. Hazard: Hazard becomes risk if it enters into a process aiming to estimate – qualitative or quantitative estimation of probability and magnitude (formal mainstream definition not used in all the mentioned fields) – deal with and control it Risk vs. Fate: Outcomes are not completely out of human control and can in principle be avoided, coped with and/or handled	Side-effects of human activities (e.g. nuclear power plant: accidental release of radiation into the environment; health care: accidental confusion of one drug with another leading to the death of a patient)
Natural hazard and national security	Risk identifies the possible consequences of an external threat (nature or human activity expressively aiming to create damage to society). Risk is conceived as, in principle, manageable, not completely out of human control National security: relational nature of the phenomena	Risk as Hazard/Threat: The focus is on the consequences of the events on health and environment. Risk vs. Fate or Destiny: despite the external nature of the threat, human activity can interact with the dangerous event in order to avoid, cope with and/or handle it.	Consequences of external threats: consequences of natural phenomena such as landslides, earthquakes or tornados; consequences of terrorist attacks.

Table 1: Insurance, business, finance, technology, work, natural phenomena and national security – the various meanings of risk (My elaboration.)

Looking at the insurance field, in which the maritime trade's guarantees and agreements mentioned above can be considered historical precursors, the term risk identifies the monetary losses as consequences of negative events that can affect individuals or organisations. As insurance agents are known to say: insurance cannot change destiny, but can limit the monetary damage associated with it (Pellino at al., 2006).[4] On the one hand, given the unavoidable nature of the events, risk is linked with fate or destiny; but, on the other hand, the global amount of monetary losses carried out by fate or destiny can be estimated and quantified. Thus, the quantification of the monetary losses linked to the negative events is what characterises the definition of risk and distinguishes risk from fate or destiny. For example, we can estimate the number of car crashes happening every year in a specific location, as well as the monetary costs associated with such car crashes, but we cannot estimate exactly when and to whom they will happen. In addition, the insurance risk concept binds phenomena that can be associated with a specific class of individuals – e.g.: car insurance for human beings that drive a car, life insurance and health care insurance for human beings in different health conditions, such as smokers and non-smokers – or organisations – e.g. public liability insurance and environmental damage liability insurance for companies, dealing with different types of activities, such as nuclear energy production, or building carousels. Following the insurance approach, risk can be quantified, but only taking into account the class of individuals or organisations as a whole (Ewald, 1991). Thus, with a fixed class of individuals/organisations of reference, there is a component of certainty that relates to the total amount of adverse events and the costs linked to the consequences of such events in a given period of time, as well as a specific spatial location. A component of uncertainty related to establishing when, during a selected period, and to whom, within the selected class of individuals or organisations, the event will happen. The formalisation of a mathematics of probability – dated generally at 1713, the year of publication of Bernoulli's *Ars conjectandi* (Hacking, 1975) – constituted an important turning point in the estimation of risk (Taylor-Gooby and Zinn, 2006). Thus, the estimation of potential monetary losses as consequences of events affecting specific groups of individuals/organisations has become more and more

[4]To give another example, promoting life insurance Cantu (2011) states: 'You cannot change the destiny, but you can surely take a Term Life Insurance and ease their hardships a bit. Loss of the member of the family doesn't just break the family emotionally, but also monetarily.' (http://www.articletrader.com/finance/insurance/term-life-insurance-and-%23150%3B-choose-the-best-one.html, Website consulted 21 January 2014).

sophisticated. Thereafter, the development of actuarial science since the end of the seventeenth century has led to the implementation of increasingly advanced statistical-mathematical models (Haberman and Sibbett, 1995; Lewin, 2003). Consequently, the quantification of the number of negative events and of the amount of monetary damage carried out by such events, as well as the characteristics defining the various targeted classes of individuals or organisations to which a specific amount of events and monetary damage is associated, has become more and more formalised.

The development of the mathematics of probability, as well as of actuarial science, has also played a crucial role in the fields of business and finance. In these fields, risk is an intrinsic component of any business or financial enterprise and has to do with the possibility of not meeting the expected outcomes of such enterprises. Unlike other fields, when used in business and finance, the concept of risk can have a positive as well as a negative meaning (Taylor-Gooby and Zinn, 2006): risk identifies the variances affecting the expected outcomes; such variances can be positive – monetary gain – or negative – monetary losses. To put it simply, looking at business risk, a company proposing a new product to the market, for example, takes the risk. On the one hand, of not meeting the required outcome of selling 10,000 pieces of the new product per year, in order to ensure the coverage of all the costs linked to the production, merchandising etc. – a negative outcome: less gain than the expected one. Alternatively, on the other hand, of exceeding such coverage limit – a positive outcome: more gain than the expected one. Looking at financial risk as an example, an investor buying the stocks of a company runs the risk that these stocks will not provide the adequate return in order to cover the buying price – a negative outcome – or will provide a return that exceeds the buying price – a positive outcome. Since the 20th century, entrepreneurial philosophy has placed a strong emphasis on risk taking as a challenge for all businesses or financial enterprises (e.g. Knight, 1921; Schumpeter, 1976): without taking risks, there is no gain (O'Malley, 2004; Power, 2007). During the same years, right within the 'economic province' (Knight, 1921: VIII, preface to the first edition) of business enterprise, the mainstream definition of risk mentioned above – probability per magnitude – was formalised. Knight's 1921 foundational essay aiming 'to isolate and define the essential characteristics of free enterprise' (Ibid.) clearly distinguishes the concept of risk from the concept of uncertainty. The risk concept binds phenomena, which are characterised by measurable uncertainty. Thus, phenomena that have a measurable and quantifiable probability based on previous phenomena of the same kind, allow for the grouping of specific phenomena into a pattern of similar ones. In contrast, the uncertainty concept binds phenomena, characterised by non-measurable uncertainty: phenomena that are one-off ones, not linkable to previous phenomena of the same kind. Using Knight's (1921: 233) words:

> The practical difference between the two categories, risk and uncertainty, is that in the former the distribution of the outcome in a group of instances is known (either through calculation *a priori* or from statistics of past experience), while in the case of uncertainty this is not true, the reason being in general that it is impossible to form a group of instances, because the situation dealt with is in a high degree unique.

Since the beginning, Knight's idea of probability has been criticised by scholars sustaining a subjectivist interpretation of probability (e.g. Ramsey, 1931; de Finetti, 1937; Savage, 1954), in which the strong boundary between risk and uncertainty identified by Knight loses relevance. Nowadays, the Bayesian theory of probability offers a formalisation of the subjectivist element affecting the probability estimation (e.g. Aven and Kristensen, 2005; Aven, 2011).[5] Despite such developments, the deterministic and objectivistic assumptions on which Knight's definition relies have been broadly accepted and have spread into other fields of study – for example, engineering technological risk management – currently representing the mainstream approach to risk definition and management.

While the business and financial fields include the variability of intended outcomes of business and financial enterprise under the concept of risk, in other fields such as technology-based activities, health care, or safety at work, the concept of risk identifies the unwanted outcomes of such activities as by-products of the intended ones. In this case, the term risk refers to the possibility of negative and unwanted outcomes for health or the environment arising from the side-effects (Merton, 1936; 1940; 1968) of intentionally driven human activities: consequences of actions that contrast with the intentional ends of such actions. Thus, risk has to do with the reliability of the performed activities rather than, as the business or financial definition of risk indicates, with the efficacy of such activities. For example, looking at technology-based activities, the end of a nuclear power plant is to produce energy, but such an activity runs the risk of leading to unwanted negative side-effects such as

[5] Following the Bayesian view 'risk is a way of expressing uncertainty […] [Thus,] the Bayesians are not relativist in the sense that there is no way of evaluating the "goodness" of risk assessments' (Aven and Kristensen, 2005, 2). But, they recognise the uncertainty linked with the estimated probability and formally integrate a subjective evaluation of such estimation.

the release of radiation into the environment: the possibility of a radiation release – side-effect of the intentional end of a nuclear plant which is the production of energy – is part of the technological risk to which a nuclear power plant is exposed. Looking at health care, the purpose of a nurse's working activity in a hospital is to take care of ill people, for example through the delivery of pharmaceuticals, but as a possible side-effect of the process of care, the nurse could accidentally confuse one pharmaceutical with another one – e.g. potassium chloride instead of sodium chloride – and such an error could lead, in the worst case, to the death of a patient. The possibility of delivering an incorrect pharmaceutical that leads to the death of the patient is an example of the risk associated with health care activity, usually named clinical risk. Looking at work safety, the end of a press-worker is, for example, to shape a piece of steel through the activation of the press. As a side-effect of such activity, the worker runs the risk of accidentally activating the press while he is placing a piece of steel inside the press crushing his hand under the press. The possibility of crushing his hand is an example of the risk associated with the working activity usually named occupational risk. Other examples of risk as side-effects of human activity are: attacks on children from convicted paedophiles released from prison; injuries and death from motor vehicles on local roads; adverse health effects from exposure to pesticide residue both in food as well as in drinking water (Hood et al., 2001).[6] The definition of risk as a side-effect differs from business, financial and insurance risk. On the one hand, even if the economic losses following the negative events are in principle quantifiable, the accent is usually on the negative consequences on health and the environment rather than on the monetary value of such consequences. On the other hand, risk is seen as something not completely out of human control, such as fate or destiny, but there is a possibility to interact with the on-going activities in order to avoid, cope with, and/or handle the possible negative events. Mainstream technological and health care risk management usually distinguishes between hazard and risk, in a way similar to Knight's (1921) distinction between uncertainty and risk: hazard is the possible identified threat, the identified threat becomes a risk once a probability – defined quantitatively or qualitatively – and a magnitude are associated with it (e.g. British Health and Safety Authority).[7]

[6]Hood et al. (2001), in analysing the variability of the risk regulation regime within the UK, place their attention on the phenomena mentioned above enlarging the targets of scholars' analysis, which previously focused mostly on technological, occupational or clinical risks, onto other areas of human activity similarly affected by risk as a side-effect of such activities.

[7]http://www.hsa.ie/eng/Topics/Hazards/, Website consulted 20 January 2014.

Despite the different bound phenomena, many concepts and management strategies developed within the business and finance fields have been borrowed from, and adapted, by technology-based activities and health care fields.

Natural phenomena as well as national security are other fields in which the term risk is employed. Such fields differ from the business, finance, and side-effect ones because of the external nature of the threat. The insurance risk definition is partially bound by these phenomena, however. Nevertheless, despite the external nature of the threat, in this case, unlike the insurance case, risk is conceived as manageable, in principle, in order to avoid, cope with, or handle it; thus, clearly separating it from the contiguous concepts of fate or destiny. Natural phenomena such as landslides, earthquakes or tornados are not in principle dangerous but, within the human environment in which they happen, they can have important negative consequences on health or the environment. Such a focus on the consequences of events, rather than on events in and of themselves, leads to the use of the term hazard instead of, or as a synonym of, risk (Hood and Jones, 1996). National security risk, such as a terrorist attack threat, is the intended outcome of other activities that national intelligence has to face. In this sense, a national security threat shares the external nature of danger with the negative consequences of natural phenomena. However, national security threats differ from natural phenomena for the relational nature of any intervention (e.g. Allison and Zelikow, 1999). For example, if a terrorist attack threat is identified and control measures are implemented in order to avoid it, the terrorists planning the attack can change their strategy as well in order to bypass the adopted control measures. Despite such differences, threat identification and assessment show many contact points with other fields of human activities, as well as with the identification of the possible negative consequences of natural phenomena. In addition, as a side-effect risk, the definition of risk binding possible negative consequences of natural phenomena, as well as of terrorist attacks, focuses on the negative consequences on health and the environment, rather than uniquely on the quantification of the monetary losses linked to the consequences of such events.

An examination of the various fields employing the concept risk mentioned above, shows the different meanings associated with the concept, as well as the different types of phenomena bound under such a concept. In addition, it demonstrates, according to the different associated meanings, that the term risk can be associated or separated from other related concepts such as uncertainty, hazard or fate. In summary, risk is:

- The monetary loss of negative events – linked in some respect to fate or destiny – associated with specific classes of individuals or organisations – insurance risk;
- The positive or negative variance of the outcomes of any business or financial enterprise quantifiable through the product of probability – distinguishing risk from uncertainty – and the magnitude of the outcome – business or financial risk;
- The possibility of side-effects of human activities leading to negative consequences on health or the environment, thus the identification of probability and magnitude of such events distinguishes risk from hazard – technological risk, clinical risk and occupational risk;
- The possible consequences – a focus on the consequences leads to the use of both the terms risk and hazard – of external phenomena such as natural phenomena or a terrorist attack – environmental risk and terroristic risk.

The variability affecting the different examined fields provides an initial idea of the complexity surrounding the risk concept. Since the end of the 1980s, social sciences have started looking closely at the concept of risk, underlining the socially constructed nature of such a concept, and contrasting it with the objectivistic assumptions upon which the mainstream 'technical-scientific' approaches rely. The next section summarises the main social science theories on risk, stressing the differences between the ontological and theoretical views on which such theories are based. Such ontological and theoretical plurality reflects the complexity surrounding the use of the concept in the different fields of human activities mentioned above.

Risk and social science: an analytical map

> Risk is objective and scientifically knowable. Risk is subjective and socially constructed. Risk is a problem, a threat, a source of insecurity. Risk is a pleasure, a thrill, a source of profit and freedom. Risk is the means whereby we colonise and control the future. Risk society is our late modern world spinning out of control (Garland, 2003: 49).

If an examination of the different fields in which the term risk is employed shows a high degree of variability, Garland's (2003: 49) quote gives an initial overview of the variability affecting scholars' approaches to risk as well. Allison and Zelikow's (1999: 2) paramount work on the Cuban Missile Crisis shows how an alternative 'conceptual lens' reflects our interpretation of events, as well as the relevance attributed to different issues. Basic and sometimes unrecognised assumptions influence the way in which scholars deal with the definition of risk, and build on theories. Furthermore, those assumptions ‘lead to different research programs as well as different interpretations of the results’ (Zinn, 2008: 2). This chapter aims, to map the main social scientists’ theoretical works on risk, locating them with reference to their ontological and theoretical starting points. In order to offer an analytical synthesis of the main theoretical approaches. We propose a Cartesian diagram (see Figure 1) based on two main dimensions: the theoretical dimension – x-axis – and the ontological dimension – y-axis. Both the axes are conceived as a continuum along which the various approaches are located. The theoretical dimension – y-axis – draws attention to the different accents placed by scholars on individuals or on society. More specifically, the top-down pole underlines a focus on social structures, institutions or functions and a deterministic role of society in shaping individuals’ perceptions and behaviour. In contrast, the bottom-up pole focuses on individuals’ perceptions and behaviour weakening the role of social structures, institutions or functions. The various approaches to the study of risk can be placed on a continuum, moving from a micro level, focusing on the individual, to a macro level, focusing on society. The ontological dimension – y-axis – refers to the nature of risk and can vary from realism to constructivism.[8] Realism conceptualises risk as a real object, having an objective existence and being objectively knowable. Constructivism emphasises the role of culture and society in risk identification and definition. This conception is well represented by Ewald’s famous statement (1991: 199): ‘nothing is a risk in itself; there is no risk in reality. But on the other hand, anything *can* be a risk.’ (Emphasis in the text.) The various theories can be located along a continuum leading from risk as real to risk as social construction.

Figure 1 shows how the main approaches of social scientists on risk are situated on the Cartesian diagram taking into account both the theoretical as well as the ontological continuum. This analytical synthesis has the advantage of offering an overview of a diversified set of theoretical frameworks. However, ‘every classification is a trade-off between analytical rigor and empirical appropriateness’ (Catino, 2013: 220), and involves a loss of information. Thus, classifications have the advantage of allowing us to clearly locate this dissertation’s approach from the previous contributions – see next section – although they imply a simplification and

[8]This distinction was first assessed by Lupton (1999a; 1999b). Zinn (2009) underlines that a one-dimensional opposition of realism and constructivism, even if effective, is too narrow to fully understand the differences between the various sociological approaches to risk. Thus, he suggests looking back at the epistemological foundation of the main theoretical approaches.

polarisation of the analysed theories. Let us look closely at the main sociological and anthropological contributions contextualising them through the diagram and in relation to the approaches of other disciplines. Anthropological and sociological contributions arise as a critique of ‘technical-scientific’ risk identification and analysis – engineering, medicine, epidemiology – and, looking at social sciences – psychometric, psychology, and economics – are all located in the fourth quadrant of the Cartesian diagram. Those disciplines look at risk as an objective and measurable phenomenon, and their main research interests are ‘identification of risks, mapping their causal factors, building predictive models of risks relations and people’s response to various types of risk and proposing ways of limiting the effects of risks’ (Lupton, 1999b: 2). Social sciences closest to the technical-scientific approach – e.g. psychometric, psychology and economics – are usually focused on individuals seen as acting independently from the social, cultural and historical context in which they live. In contrast, anthropological and sociological analyses of risk bring the social and cultural dimensions on the scene, and highlight the role of cultural and social elements in risk identification and definition. The main anthropological and sociological theories on risk can be grouped into five main categories: cultural symbolism, risk society, systems theory, governmentality and edgework (Lupton, 1999b; Arnoldi, 2009; Zinn, 2009). As a first approximation, the diagram shows a clear distinction between theories giving a dominant role to individuals – third quadrant – and theories focusing on structures, institutions, or functions – second quadrant. With regard to the ontological status of risk, even if all theories refute the definition of risk as an objective and measurable entity – any theory located in the high part of the first and fourth quadrant – we can see the more blurred positions of the different theories. A description of the five identified theoretical approaches focusing on the main scholars’ works within each category follows.

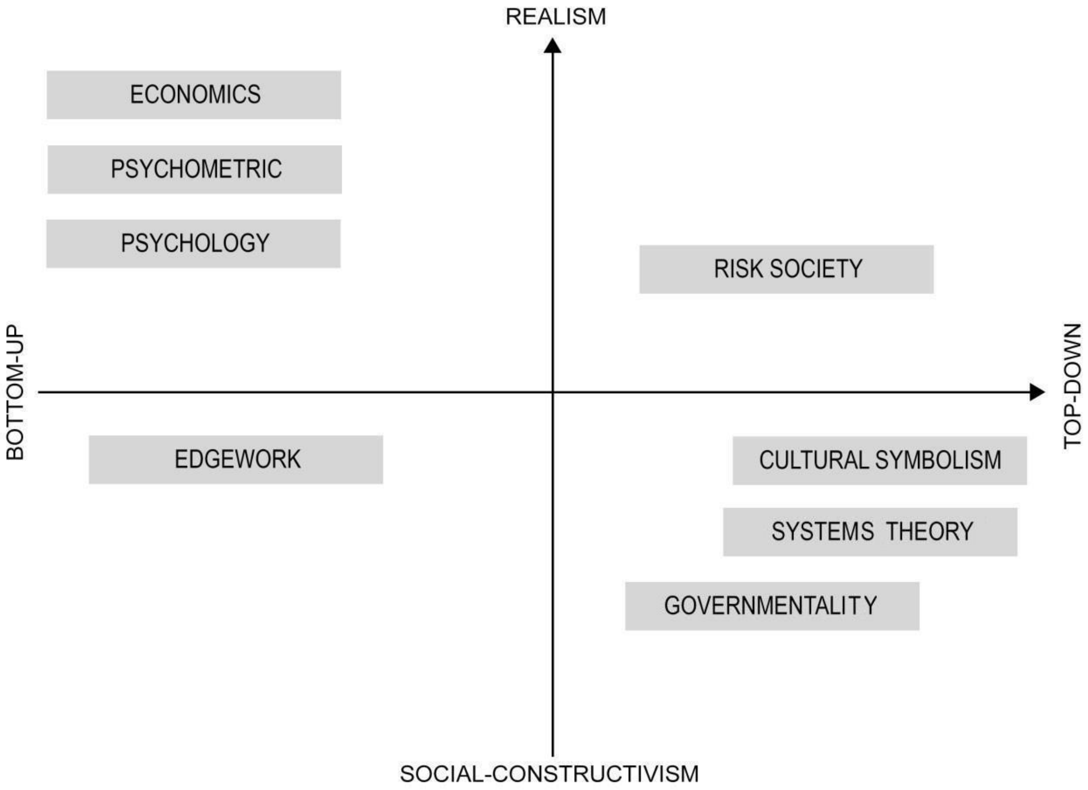

Figure1: Social sciences and risk – an analytical map (My elaboration.)

Cultural symbolism

Cultural symbolism refers mainly to the work of Mary Douglas (1966; 1978; 1985; 1986; 1992). As she highlights, her studies are finalised toward the development of a cultural theory of risk. The title of the conclusive chapter of her book: *Risk is a Collective Construct* (Douglas and Wildavsky, 1982), clearly positions the author near to the social-constructionist pole – the y-axis of the diagram. However, looking more closely at her work, and considering other sociological approaches, Douglas presents an intermediate position. In particular, she states repeatedly that potentially dangerous and threatening elements undoubtedly exist in reality, so risks can have an objective existence. However, the way in which we choose, understand and define them are socially mediated and socially constructed: 'undoubtedly people and the environment face risks from technology. The perils of nuclear wastes and carcinogenic chemicals are not figments of imagination (Douglas and Wildavsky, 1982: 1-2), but 'the perception of risk is a social process' (Ibid.: 6). At the same time, 'people agree to ignore most of the potential dangers that surround them and interact so as to concentrate only on selected aspects' (Ibid.: 9).

With respect to the theoretical dimension – the x-axis – Douglas's approach to risk is clearly situated near the top-down pole. More specifically, functionalism and structuralism are the frames of reference of her analysis: 'for an anthropologist the human factor would mean the general structure of authority in the institution' (Douglas, 1992: 12). Following such an approach, individual perceptions of risk and the future are shaped, or determined, by the characteristics – mode of social organisation and membership – of the community of belonging: groups, organisations, institutions or society as a whole. Cultural beliefs guide the way in which people frame risk and the future, so the perceptions and the definitions of risk are culturally shaped. Culture is just a product of social institutions and, at the same time, those institutions are supported by the culture they form. For example, the grid and group typology (Douglas, 1978; Douglas and Wildawsky, 1982, Thompson and Wildawsky, 1986) well represents Douglas's approach. The group dimension identifies the degree of commitment of the members of a group – community, organisation, or society – and the degree of demarcation of the borders separating the members from broader society. Instead, the grid dimension focuses on the structuring degree of the group – hierarchy, and chain of command. From those two dimensions, Douglas identifies four main types of groups: hierarchy, entrepreneurs, sectarian, and excluded. Each type of group reflects different values outlining a specific conception and expectation about risk, the future, and the environment.

The group dimension allows us to underline another central lynchpin of Douglas's analysis: functionalism. Risk – a system of belief and linked practises – has the function of maintaining order inside the community, and of marking the symbolic and/or physical borders between the community and the surrounding society. The four types of cultures linked to the four grid and group types 'differ in generating different patterns of blame allocation' (Douglas, 1992: 17). Thus, risk becomes a way to manage deviance as well as to blame and to attribute responsibility to individuals who violate social order; consequently, risk is always in some way related to the moral principles shared by a community. Thus, following Douglas's approach, risk has strong moral, ethical and political implications. In addition, Douglas's analysis rejects risk as a social construction, with reference to how society chooses to cope with it as well. She states that 'the choice of methods of risk assessment imply a prior choice of the risks we have already chosen to face' (Douglas and Wildavsky, 1982: 66). Risk assessment is not exempted from cultural frames: 'all modes of assessment are biased by the social assumption they made'

(Douglas and Wildavsky, 1982: 14). The moral and political implications in risk definition are also rejected in terms of the processes of objective scientific inquiry on risk:

> In a context of scientific inquiry, an objective statement is arrived at by standardised techniques; the inquiry can be replicated and under the same conditions will reproduce the same answer. However objective the process, the interpretation is not guaranteed right by objectivity in the research design (Ibid.: 72).

Douglas's historical analysis of risk indicates continuity between modern and pre-modern society. She argues against the distinction between modern and rational ways of coping and managing risks, and pre-modern and irrational ones (Douglas, 1986). She underlines the continuity between traditional and modern responses to risk bringing risk back to structural factors: 'The difference is not in the quality of knowledge but in the kind of community that we want to make […] or […] the community that technology makes possible for us' (Douglas, 1992: 10). Douglas's work is of great value for social sciences since she introduces the cultural dimension into risk analysis, but it is subject to the same criticism traditionally addressed to functionalism and structuralism. In brief, there is no room for individual agency, therefore it is not clear how social changes could be possible and, on a global scale, a static vision of cultural processes emerges.

Risk society

Risk society theory's most famous contributions are the works of Urlich Beck (1986; 2007).[9] Beck aims to develop a general theory of our society, focusing on the turning points – end of 1960s – between industrial society and what he has called risk society. Risk is seen as a distinctive element of society today. With regard to the theoretical component, risk society theories are located close to the top-down pole. These theories focus on macro-structural elements influencing radically modern, specific and elevated concern about risk. The main institutions of modernity – government, industry and science – are indicated as the main producers of contradictions and risks. The scientific statements regarding risk lost their

[9]Antony Giddens's (1990, 1991) work on risk is fairly close to Beck's. In this summary, I chose to focus on Beck's studies. Please see Giddens's work directly or in Arnoldi (2009) for a deeper analysis of Giddens's position.

objectivity, and a lack of trust in science and technology emerged. The intangibility and obscure nature surrounding the definition of risk, and its management, opened the scene for political, values-related and moral considerations. This reasoning is closely related to the reflexivity (Giddens, 1990, 1991) characterising our society. According to risk society scholars, our society is distinguished by constantly questioning itself, and raising doubts about the side-effects of modernisation: modernity focuses on its own contradictions and limits. Thus, risk's identification, acceptability, and management become a matter of political and values-related conflicts:

> […] production of toxins and so on is not only a question of which industries, but of fixing acceptable levels. It is, then, a matter of coproduction across institutional and systemic boundaries, political, bureaucratic and industrial […] Here one is no longer concerned with questions of ethics at all but with how far one of the minimal rules of social life - not to poison each other - may be *violated.* It ultimately comes down to how long poisoning will not be called poisoning and when it will begin to be called poisoning (Beck, 1986: 65, emphasis in the text).

This institutional frame has important consequences on individual lives. With a main reference on biographical risks, Beck highlights individualisation as a new institution of radical modernity, as well as another side-effect of progress and development. Linking individualism to neo-liberal tendencies, individuals are seen as fully responsible for risk production and management. As a conclusion, individuals are obliged to defend themselves from risks, coping with the contrasting and shifting demands of the various social institutions. In addition, Beck underscores that in contrast to industrial society's risks, risk society's risks are democratic, affecting different social classes in the same way. Examples are 'Mad Cow Disease', or the radioactive clouds generated by nuclear power plants' releases.

With references to the ontological dimension of the diagram, risk society theories are located closer to the realism pole than other sociological theories. In this sense, it is possible to see the distance dividing Beck's approach to other macro-constructionist ones. Loon (2002: 63) defines Beck's approach as a 'weak social constructivism'; since the distinction between real and non-real is by-passed because risk is by definition unreal: risk ceases to be risk if it is turned into something more than, or different from, an expectation of becoming. Nevertheless, the reality of the potential consequences of risk as an expectation of becoming are framed as extremely real and they are specifically linked with the distinctive characteristics of a risk society. Beck's theorisation on risk shows a tension between risk as real and risk as a social construct, but he emphasises a constitutive change in the kind of risks modern societies have to face. In Beck's view, the risks our society has to manage are radically and constitutively different from industrial as well as pre-modern ones, framing our society through new political conflicts and contestation – risk *versus* wealth distribution. Consequently, risk's definition arises in contrast with non-industrialised society as well as with the industrialised stage of modernity. More specifically, 'in the course of the exponentially growing productive forces in the modernisation process, hazards and potential threats have been unleashed to an extent previously unknown' (Beck, 1986: 19). Modernity links risks to human activity. The key difference between pre-modern and modern society is a human responsibility in risk's generation as a side-effect of science and technology. In addition, moving from modernity to radical modernity, paradoxically, science and technology shift from a source of improvement for human life to a source of uncertainty and risk:

In contrast to early industrial risks, nuclear, chemical, ecological and genetic engineering risks (a) can be limited in terms of neither time nor place, (b) are not accountable to the established rules of causality, blame and liability, and (c) cannot be compensated for or insured against (Beck, 1996: 2).

Very briefly, in Beck's view new risks are: side-effects of technological development; global or transnational; intangible – only identifiable through scientific testing; and latent – not fully predictable and manageable through science.[10] Consequently, conventional technology for risk assessment and management becomes ill-suited. Moreover, this statement is linked to the macro-structural elements characterising society today. More specifically, the lack of instruments able to identify, assess and manage risks is brought back, in Beck's words, to the institutional contradictions linked to radical modernity:

Societies find themselves confronted with the institutionalised contradiction according to which threats and catastrophes […] increasingly escape all established concepts, causal norms, assignment of burdens of proof and ascription of accountability. As long as this

[10] Beck (2007) mentions three examples of new risks: ecological, financial and terrorist attacks. The characteristics those risks have in common are: involving technologies; being hard to control; and having a global or transnational range.

relation of definition are not uncovered and politically transformed […] the world will continue its fruitless search for its lost security (Beck, 2007: 32).

Risk society's approach to risk has the merit of highlighting important contradictions linking institutions, risk definitions, and reality. In particular, the incongruence between real new risks, and the instruments to cope with them, opens theoretical and empirical reflections on risk management and regulation. Some scholars criticised Beck's choice to assume an intermediate position between realism and social constructivism (e.g. Lupton, 1999a; Elliott, 2000; Mythen 2004), others appreciated his choice of conducting a sociological study of risk from a pragmatic position (Zinn, 2008). Another important aspect underscored by scholars is the lack of a strong empirical dimension, and the choice of moving exclusively at an extremely macro level of theory (Lupton, 1999b). As in Douglas's work, individual agency is absent from the scene and, at the same time, the role of institutions and organisations in risk definition and assessment is not fully developed. In addition, the key distinction between industry and risk societies with regard to the different types of risks affecting industry and risk society, has been demonstrated as without empirical underpinnings by an empirical historical analysis of modern technological development conducted by Fressoz (2012).

Systems theory

Niklas Luhmann's (1993; 1995; 1998) systems theory deals with risk as a crucial aspect of a general theory on the functioning of modern society. Risk is a product of modern structures and functions, and it clearly distinguishes modern from pre-modern society. However, it is, in a way, radically different from Beck's risk society theory. Looking at the theoretical dimension, systems theory is fairly close to the top-down pole. The starting point of Luhmann's analysis is the definition of society as a communicative system. Communication is, in Luhmann's view, the basic social operation. Society is functionally divided into different sub-systems. Each sub-system fulfils a specific societal function, and the form of communication depends upon the specific sub-system's functions. In particular, each sub-system follows specific codes: 'binary distinction orienting the operations of the function system' (Japp and Kushe, 2008: 77). For example, the economic sub-system follows the code property/non-property. System theory makes a distinction between first-order and second-order observations. More specifically, while first-order observations are framed by the specific code in use in a sub-system, second-order observations of an analytical perspective look at the codes themselves. Consequently, second-order observations can revisit facts and perceptions that seem to be obvious statements of reality from a first-order observation and communication perspective. Looking at the emergence of the term 'risk' Luhmann (1993: 24) states:

> it is probably due to the fact that it accommodates a plurality of distinctions within one concept, thus constituting the unity of this plurality. It is not simply a matter of a description of a universe by an observer of the first order who sees something positive or something negative, who establishes the existence or absence of something. It is rather a matter of reconstructing a phenomenon of multiple contingency, which consequently offers different observers differing perspectives.

Multiple contingency is a distinguishing feature of modern society. Modern society is, in Luhmann's view, a functionally differentiated society in which each sub-system can only refer to its own logic and binary codes to communicate observations. In contrast, in previous societies, religion was an external system of reference reinforced by a vertical stratification of society. Functional complexity removes all external references – religion in the case of the transition from pre-modern to modern societies. In a society characterised by functional non-hierarchical sub-systems, all indications of external references are framed by the internal logics of the sub-system. The concept of risk emerges from this functional structure of our society. In particular, processes of communication imply the selection and formation of expectations – sub-systems' codes and logics reduce complexity but, at the same time, leave room for possible risks. This reduction places a consistent number of possible consequences outside of the frame. Thus, all decisions open the door to an almost infinite set of possible negative consequences and, between such sets of consequences, different selections are possible. These selections imply putting some elements out of the frame to focus on others. The term contingency states that different selections are possible, but no single one of them has necessary or certain consequences; so, they are risky. Pressure for decision-making is a consequence of contingency: if no alternatives are possible, there is no room for decisions. Contingency itself is a product of the absence of an external point of reference, as religion was. In conclusion, modern society's functional structure places pressure on decision-making, but the decisions have no certain point of reference. Consequently, individuals and organisations have to manage this 'indeterminateness' generating risk.

With reference to the ontological dimension, Luhmann's work is clearly close to the constructivist pole. More specifically, interpreting risk as an objective entity is appropriate only for first-order observations linked to the different sub-systems. From a second-order observation point of view, risk is only a consequence of the self-reference of the communication of each sub-system. Risk is not something in the real world, but is a side-effect of the functional structure of non-hierarchical sub-systems generating contingency and, consequently, the need for decisions between alternative consequences that do not necessarily negate one another.

Luhmann's risk approach is part of a complex general theory of modernity. In this sense, Crook (1999: 166) defines Luhmann's work as an 'abstrusely system-theoretic account of risk.' Even if Crook's statement finds little support, it cannot be denied that Luhmann's theory leaves room for many of the critiques of structural-functionalism: mainly, the absence of individuals from the scene, the functional approach to society as a series of functional components, and the little attention given to social change. In addition, Zinn (2008: 206) underlines that 'the relative abstract level of [Luhmann's] analysis and the claim for a non-normative theory may conceal implicit normative considerations.' In contrast, the concept of selection and expectations linked to specific frames of reference, as well as the need to observe risk definition and assessment from a second-order observation point of view, are of great interest.

Governmentality

The term governmentality was first introduced by Foucault (1978) in order to highlight a change in government rationality from the *status quo* of the seventeenth century to modern Europe. In particular, a shift from a focus on sovereignty and command to one on new technologies of self-governing is underscored. The two concepts of government and rationality are merged together in order to highlight a focal point on governmentality as the study of the 'conduct of conduct.'[11] More specifically, individuals are seen as self-responsible, and socialised through knowledge and behavioural rules of conduct. The main empirical focus is on knowledge, practises and technologies of control. Instead of a general theory of power, the accent is placed on contingency. Governmentality stresses the multiplicity of power relations: power is seen as fragmented and displaced through different agencies and technologies of control (O'Malley, 2008: 53). In modern societies, state disciplinary power regulates citizens' behaviour not through centralised and

[11] English translation of Foucault's (1994: 237) 'conduire des conduits.'

oppressive apparatuses, but influencing them to adopt certain behaviours and habits. Although Foucault does not specifically analyse risk, some authors (Donzelot, 1977; Defert, 1991; Ewald, 1986; 1991; Castel 1991) deal with risk from a governmentality point of view. In these contributions, risk is framed as a 'technology of government and power': risk is one of the new apparatuses of power by which external control is replaced by the internal control of citizens through self-regulation. A more detailed description of the approach of governmentality to risk through the analysis of Ewald's (1991) work on insurance follows.[12]

With regards to the ontological axes of the Cartesian diagram, the governmentality approach to risk is located very close to the constructivism pole. More specifically, risk does not exist in reality, but is just a way in which reality is defined. Today, risk is the framework to govern social problems: reality becomes objective and thus, governable through a risk lens. Insurance is, in Ewald's (1991: 198) view, one of the possible applications of a technology of risk and presents a 'variability of form […] relates to the economic, moral, political, juridical, in short to the social conditions which provide insurance with its market, the market of security.' Thus, insurance as a technology of risk does not assume a fixed shape, but it varies over time, defining and managing new and different kinds of risk. Insurance structures risks according to three main characteristics: it is calculable, it is collective and it is capital. With reference to calculability, to classify an event as a risk, it must be possible to link the event to a probability. Risk definition is closely related to the statistical techniques that allow setting an individual's characteristics and trends into a distribution. Distributions become, on the one hand, a point of reference to set probabilistic predictions and, on the other hand, a way to establish a benchmark to compare, analyse and, consequently, manage individuals' behaviours, habits and characteristics:

> For an event to be a risk, it must be possible to evaluate its probability. Insurance has a dual basis: the statistical table which establishes the regularity of certain events, and the calculus of probabilities applied to that statistic, which yields an evaluation of the chances of that class of event actually occurring (Ewald, 1991: 202).

Insurance sets out, through statistical distributions, a risk's probability according to specific classes of events or individuals sharing some key characteristics. In this

[12] Another example of the application of Foucault's approach to risk is Castel's (1991) work on psychiatry.

sense, insurance operates by defining mutuality and can be conceived only by referring to a collective. Population is re-composed by selecting and dividing risks among groups of individuals. Thus, risk is partitioned and each individual represents just a fraction of risk. Nevertheless, this kind of mutuality differs from family, union or corporation ones, because it constitutes an abstraction without any qualitative obligation:

> it allows people to enjoy the advantages of association while still leaving them free to exist as individuals. It seems to reconcile those two antagonists, society-socialisation and individual liberty. This, as we will see, is what makes its political success (Ewald, 1991: 204).

In addition, linking risk to specific practises and groups of individuals, insurance converts risk into a monetary value: everything could be converted following this equation, including life. In so doing, a distinction is made between correct, and incorrect ways of living. Consequently, individuals are induced to self-regulate their lifestyle in order to position themselves near the mean values of the distributions of a population identifying 'good citizens.' In this sense, 'insurance is the practise of a type of rationality potentially capable of transorming the life of individuals and that of populations' (Ewald, 1991: 200).

Even if identifying the location of governmentality on the ontological axis of the diagram is fairly easy, its position on the theoretical axis is more contested. More specifically, this aspect is closely related to one of the main critiques of this approach. Governmentality scholars are criticised because they focus attention on formal documents in their research – government plans, legislation, commercial documents sponsoring a specific way of life – without paying attention to what is going on in everyday practises (O'Malley et al., 1997). Consequently, a top-down vision of society emerges: individuals, organisations and population agency have no room, and they are seen as just adapting passively to proposed practises and procedures (Frankel, 1997). However, as O'Malley et al. underline, some authors have stressed the role of individuals in modifying and restructuring proposed governmental practises. In this sense, the studies of Rose (1998) and Novas (Novas and Rose, 2000) regarding psychiatrists' resistance to the adoption of risk technologies in their profession, and about internet as an opportunity to develop a bottom-up governance in health discipline, are crucial. Thus, the choice to locate governmentality in the second quadrant of the diagram, but closer to the bottom-up pole than other top-down approaches to society, is appropriate.

The governmentality approach to risk has the merit of questioning the neutrality of some diffused instruments to collect and analyse information, such as statistics and probability, as well as to underline the link between risk definition, and risk analysis. At the same time, little room is given to change, contestation and individual agency despite a focus on structures and government-proposed practises. Thus, despite the declared intention, a stable and fixed representation of government emerges.

Edgework

Under the category of edgework, we aim to cover a more general individual turn a rising from the central critique of all the theoretical approaches previously described. More specifically, many recent contributions to risk analysis stress the need to focus on everyday practises, as well as on the role of emotions in individual risk assessment. The main purpose is to provide insight into risk, through a thin-description of everyday individual experiences. Consequently, these works are located near the bottom-up pole of the theoretical axis. Looking at the ontological axis, the various analyses vary according to the status attributed to risk; however, all these studies can be located near the constructivist pole. The nature of risk is closely related to the definition proposed by individuals, as well as to which object of analysis is chosen. The edgework perspective, examining risk-taking in extreme sports (Lyng, 1990; 2005), represents one example of this individual turn tendency.[13] As Zinn (2008) highlights, the main limits of such risk's thin descriptions is that they do not allow additional theorisation about risk and often remain just an in-depth description of a specific and not so diffused phenomenon.

Despite such ontological and theoretical variability, the anthropological and sociological contributions on risk share the merit of demonstrating the socially constructed nature of the concept of risk and, in so doing, transforming it into an object of anthropological and sociological inquiry. Consequently, the objectivistic assumptions of the mainstream technico-scientific strategies to define, assess, and manage risk are recognised and questioned. Thus, today 'most risk analysts, regardless of their disciplines, would probably agree that risk assessment is not an

[13] About the individual tendencies of risk studies see, for example, Lupton (1999a); Alaszewski (2006); Tulloch (2006; 2008); and Wilkinson (2006).

objective, scientific process; that facts and values frequently merge when we deal with issues of high uncertainty; [and] that cultural factors affect the way people assess risk' (Jasanoff, 1993: 123). At the same time, the statement that 'developing a definition of risk requires a variety of explicit value judgements [and thus] choosing to express risk in a numerical index may itself make a statement of value' (Fischhoff et al., 1984: 137) is broadly accepted among scholars. Nevertheless, despite such recognition, the consequences and implications of such a statement, for the actual management and regulation of risk, are not yet fully considered and explored.

The main limits that the anthropological and sociological theories about risk share relate to the theoretical macro-micro position of such contributions. The cultural symbolic, risk society, system theory and governmentality approaches are located at a high macro level. Thus, on the one hand, the link between such high-level theories and their empirical foundation is lacking. Consequently, the implication of such cultural and social foundations on the way in which societies today define, frame, and manage risk is still lacking. On the other hand, the majority of such theories bring a structuralist and functionalist view of society, leaving extremely little room for individual action and the variability of risk definition, assessment and management. In contrast, the individual turn of the edgework approach completely loses the link with society as a whole, thus limiting the contribution that anthropological and sociological approaches on risk can actually provide for understanding and improving the ways in which society today defines, assesses and manages risks. More generally, the absence of a meso-level in which structure and individuals interact, extremely limits the practical usefulness of the precious contribution of anthropology and sociology on understanding risk.

Risk: the definition and approach used in this dissertation

The previous sections allow us to understand:

- On the one hand, the variability affecting the meaning and the phenomena bound under the concept of risk within different fields of human activities;
- On the other hand, the variability, as well as the strengths and weakness, of the ontological and theoretical approaches of the previous anthropological and sociological contributions on risk;
- And consequently, the need to better clarify the definition of risk used as a starting point of this dissertation; the kind of phenomena this study aims to focus on using the term risk; as well as the location on the ontological and theoretical axes this study aims to maintain.

Recognition of the socially constructed nature of risk, as well as of the filtering in or out action of phenomena given by a specific risk definition such as the distinction between risk and uncertainty (Knight, 1921),[14] show the need to keep a definition of risk as open as possible to empirical evaluation, as a starting point. This, in order to avoid determining the point of view of the studied individuals/organisations through an *a priori* definition. Looking at the specific question this study aims to answer – 'Why doesn't the (watch) dog bark?' – understanding the way in which regulators define risk, and which kind of phenomena are bound in such a definition is extremely relevant, thus, we start from an open definition of risk that we aim to fill with the available empirical evidence. An examination of the different fields in which the term risk is used, allows us to identify two conditions that have to be fulfilled in order to speak about risk:

- The uncertain nature of an event/phenomenon/outcome;
- The negative nature of the consequences of such events/phenomena/outcomes – in terms of monetary loss or damage to health or the environment – or, looking only at financial and business risk, the positive nature of such events/phenomena/outcomes defined as a monetary gain.

In order to clarify the relevance of these two components – uncertainty and negative/positive events/phenomena/outcomes – it is useful to recall some considerations by Holton (2004) about financial risk that are, in our view, extendable to the concept of risk in general. Let us take two examples. Looking at the uncertain component of risk, if I shoot myself in the mouth with a fully charged and well-functioning gun, I'm sure to die, thus there is no risk of passing away, but certainty of passing away, and we cannot define such an event as a risk. In contrast, if I shoot myself in the mouth playing Russian roulette, with a gun charged with a single round in a spinning cylinder, there is the possibility – one in six if I want to express such uncertainty through numbers – that I will die. However, it is not a certainty, thus in this case we can define such an event as a risk. Looking at the negative/positive component, let us take the classic example of an urn with some black and red balls. In this case, if I extract a ball from the urn, there is the uncertainty that I will extract a red ball. If I know how many red and black balls the urn contains, I can also quantify this uncertainty. However, the extraction of a ball cannot be defined as a risk if I do not bet on the red or the black ball being extracted. Thus, if the negativity

[14]For example, Knight's (1921) definition filters out all phenomena that cannot be linked to previous phenomena of the same kind, which are bound under the concept of uncertainty, from the risk concept.

or positivity of the event is missing, we cannot speak of risk. The uncertainty and negativity/positivity of the event/phenomenon/outcome are two intrinsic components of the concept of risk, but at the same time, the recognition of such components does not restrict the possibility to leave open the definition of risk through empirical analysis. The definition of what can be defined as uncertain and positive/negative; to which degree an event/phenomenon/outcome can be defined as uncertain, positive or negative; and in which way we can express such a degree of certainty, positivity, or negativity remains open to empirical definition. In our case, it remains open to the regulators' definition, thus, the organisations in charge of monitoring and/or regulating the possible adverse outcomes of such areas of human activity at different levels of government, but not involved in the core activity of the regulated domain.

Using the term risk, we bind a specific type of event characterised by uncertainty and negative consequences: the side-effects of human activities. Thus, our focus is on the possible negative consequences on health and the environment as unwanted side-effects of human activities: events that are not the intended end of the activities, but that arise from such activities as an unwanted and unplanned by-product. Examples of such events are: the release of radiation in the atmosphere as a side-effect of the energy production of a nuclear power plant; the derailment and explosion of a train carrying LGP as a by-product of the rail transport of such gas; or the collision of two aircrafts as a by-product of the air transport of people. Thus, we consider a specific type of side-effect usually named technological risk. In contrast, we do not consider clinical and occupational risk. We mainly focus on the dangerous events in which negative consequences affect more than just a single individual, but society – locally or globally – as a whole. Using Reason's (1997) terminology, we focus on the possibility of events that have to do with the concept of organisational accidents. Such accidents differ from individual ones because they happen to organisations rather than to single individuals, and for the broad relevance of their consequences. Historically, the Seveso Directive agreed upon at the EU level in 1982, six year after the Seveso disaster occurred in Italy as a consequence of the release of toxic dioxin-laden gas from a chemical plant, represents a turning point in public and governmental consideration and awareness of the specificity of organisational accidents. This Directive officially and purposely binds organisational accidents within the risks that organisations and governments have to avoid, cope with, or handle at the EU level. In so doing, this Directive directly targets the side-effects of human activities that can be considered by-products of a working activity, but that are not already bound under the concepts of occupational risk, as objects of risk management and regulation: dangerous outcomes for workers' health.

Once we've specified the definition of risk, as well as the phenomena that we specifically bind under the risk concept, let us discuss the location this study aims to maintain on the ontological and theoretical axes with respect to the previously described anthropological and sociological theories on risk.

Looking at the ontological dimension, this study frames the issue risk as real risk *versus* risk as a social construction in a similar way to Mary Douglas's (1966; 1978; 1985; 1986; 1992) idea that 'undoubtedly people and the environment face risks from technology. The perils of nuclear waste and carcinogenic chemicals are not figments of imagination' (Douglas and Wildavsky, 1982: 1-2). While we recognise the socially constructed nature of the concept of risk, we still highlight it as a concept binding a set of phenomena that can potentially become real, if they by-pass the uncertainty component of the concept. Even if risk identifies phenomena that are not yet actually dangerous, but that could become dangerous, the possibility of harmful and negative consequences for health and the environment linked to such events is extremely real. As demonstrated by many recent tragedies already mentioned such as, for example, the Santiago de Compostela high-speed train derailment, which occurred 24 July 2013, or the derailment and explosion of an oil-transport train in the town of Lac-Mégantic, Quebec on 6 July 2013. The socially constructed nature of risk does not relate to the events themselves, which may actually exist with the potential for negative and harmful consequences; we do not 'invent' them, but we socially place attention on them. The social construction factor relates to what importance we assign to a given reality. The socially-constructed nature of risk considers, for example, whether such real events are or are not bound under the definition of risk shared by societies, organisations or individuals, and are thus taken into account by societies, organisations, or individuals. In addition, whether and in which way these real events are assessed and managed by such societies, organisations, or individuals. Or if and in which way the activity by which these real events may result in side-effects are managed or regulated in order to avoid, cope with and/or handle such events, should be taken into account. Considering the research question this study aims to answer – 'Why doesn't the (watch) dog bark?' – the socially constructed nature of risk considers, for example, which definition of risk is shared among the regulators. Which strategies of risk management, if any, they promote and reinforce among the regulated organisations and/or carry out by themselves. Or more in general, which strategies they adopt in order to avoid, cope with, and/or handle the possible negative outcomes for health and/or the environment arising as a by-product of the activity they are in charge of regulating.

Looking at the theoretical axes, this study aims to address some of the weaknesses of the previous anthropological and sociological contributions identified above. More specifically:

- Unlike the individual turn of the edgework approach, we aim to understand the cultural, cognitive and organisational foundation of the concept of risk, without losing the link with society as a whole. But unlike previous macro perspectives, our purpose is to leave room for change and individual agency, and not to fall into a functionalistic or deterministic view of society;
- Within the micro-macro polarisation, we aim to locate this research at the level in which structure and individuals intersect each other: at the meso level, where study is still lacking. The meso-level analysis is, in our view, crucial in our society in order to understand the ways in which risk definitions and management allow us to face the truly dangerous events to which we are exposed. In today's society, the place in which risk is defined, regulated and managed is in the organisations and the network of organisations in charge of managing and regulating the areas of human activity whose dangerous events are side-effects. Thus, looking within these networks and organisations is essential to understand and explore the socially constructed nature of the concept of risk, as well as the consequences of such socially constructed decisions and processes regarding the possible negative outcomes for health and the environment affecting our society;
- Allowing room for change and individual agency means giving room to the variability of risk definitions, management and regulation. Not employing an *a priori* definition of risk means recognising that different risk definitions could exist even in the same networks of regulated-regulating organisations. Starting from a high-level general theory, the main problem is to focus on the mainstream approaches to risk, without understanding the contradictions and dialogical interactions between different approaches that could lead to changes and conflicts. This could have important consequences on the possibility of avoiding, coping with, and/or handling the negative outcomes of human activities. In starting from high-level general theory, as Friedland and Alford (1991: 280) underline, 'social scientists run the risk of only elaborating the rationality of the institutions they study, and as a result become actors in their re production.'

The institutional logic theoretical-analytical perspective (Alford and Friedland, 1985; Jackall, 1988; Friedland and Alford, 1991; Thornton and Ocasio, 2008; Thornton, Ocasio and Lounsbury, 2012) chosen to frame the empirical analysis proposed here, permits facing the identified purposes: not losing the references to society as a whole without falling into a functionalistic or deterministic approach; keeping together different levels of analysis specifically focusing on the meso-level – organisations and networks; leaving room for change and individual agency and, in so doing, opening the door to variability and contradiction. A detailed description of the institutional logics perspective is given later on in this study (Part 1, Chapter 2). The next two chapters are dedicated to the other two key concepts used in this dissertation: risk management and risk regulation.

1.2 Risk management

As Mary Douglas underlines, if risk definition is culturally and socially grounded, risk assessment and management are not exempt from cultural and social frames: 'all modes of assessment are biased by the social assumption they made' (Douglas, Wildavsky, 1982: 14). The purpose of this chapter is to better understand such cultural and social foundations of risk management definition and processes, discussing its historical, ontological and epistemological foundations. First, the historical origin of risk management, as well as the different areas of human activities in which processes of risk management have been developed, are examined. Subsequently, today's mainstream definition and process of risk management, formalised in international standards such as the COSO (2004) and the ISO 31000 (2009) ones, is described. Then, we aim to go beyond the differences between the fields, the variability between areas of human activity, and the mainstream approach to risk management, looking transversally at the various theoretical normative studies on risk management, in order to highlight the presence of worldviews that cross the various identified fields. Four main worldviews are identified and described: anticipation, resilience, imagination and auditability-accountability. In conclusion, a mapping of the available worldviews on risk management constitutes a background upon which the definition of risk management used in this dissertation, as well as the processes we are interested in, in accordance with our focus on the regulators' points of view, are discussed.

Risk management: the meaning

The risk management concept presents multiple developing lines. An examination of the available management literature allows us to identify nine main developing lines: strategic and supply-chain risk management dealing with business risks; financial risk management dealing with financial risk; project risk management dealing with the risks associated with the development of a specific business project; insurance risk management dealing with insurance risk; engineering risk management dealing with technological risks; clinical risk management dealing with clinical risk; disaster risk management dealing with the risks associated with natural phenomena; security risk management dealing with national security risk such as terroristic risk; and enterprise risk management, which is a recent development attempting to bring together the different kinds of risks an organisation has to face. Looking transversally at the different areas, risk management represents a way of organising aimed to avoid, cope with, or deal with risk. Nevertheless, a high degree of variability affects the terminology used, as well as the types of risk targeted by the management activity within the different identified fields. The formal development of risk management as a corporate function began between the 1940s and the 1950s. Scholars’ analysis and the formalisation of such practises have grown since the 1960s (Williams and Heins, 1964; Crockford, 1982; Dickinson, 2001; Harrington and Niehaus, 2003). As for the concept of risk, despite the formalisation of the concept, the idea of managing risks was not conceived between the 1940s and the 1960s, but dates back historically. For example, the risks affecting the maritime trade mentioned above gave rise to different strategies aiming to avoid, cope with, and/or handle such risks until the Middle Ages. In this context, risk linked to trade in uncharted waters was faced through agreements between traders, as well as between traders and commissioners in order to share and cover the potential economic losses linked to the destruction or the deterioration of goods and ships due to bad weather conditions or to piracy (Oppenheim, 1954; Ewald, 1991; Luhmann, 1993; Giddens, 1999). The first documented formal organisation of such practises dates back to 1687. That year, the insurance company Lloyds of London was established in a coffee shop in which ship captains used to meet and share information about future trips, safe routes, weather conditions and risks linked to upcoming trips. In this coffee shop, a first risk management practise – risk sharing – was formalised: the ones willing to share a risk wrote their name on a board available in the shop and these signatures represented the agreement under a written contract available to anyone signing the board (Vesper, 2006).

The first broadly recognised academic book on risk management – *Risk Management in the Business Enterprise* – was published in 1963 by Robert I. Mehr and Bob Hedges (D'Arcy, 2001; Dionne, 2013). The authors state the novelty of the concept and thus the difficulty in reaching a common definition. More specifically, top managers tended to bind all of corporate management under the concept of risk management. In contrast, others only bound the activities of corporate insurance buying under such a concept. The authors aim to take an intermediate position classifying 'risk management as a corporate function [that is] something more than corporate insurance management and something less than all management' (Mehr and Hedged, 1963: VII). In addition, they bind the kind of risks that are the target of risk management as all 'those risks for which the organisation, principles, and techniques appropriate to insurance management are useful' (Ibid.: VIII). Thus, they do not fix a pre-defined limit on the kinds of risks a process of risk management has to take into account, but they define the principles and techniques managers have to shape, in practical terms, in order to guarantee effective risk management. Such principles, practises and techniques are gathered from the available knowledge developed within different fields: business finance, probability and actuarial sciences. The objective of risk management is defined as the effort 'to maximise the productive efficiency of the enterprise' (Mehr and Hedge, 1963 in D'Arcy, 2001: 3). The assumption guiding the book's development is that the knowledge developed within the insurance field can, in principle, lead to the development of other strategies to avoid, cope with, and/or handle risk that are different from simply insuring them. To reach this objective the authors define a structured process that has to be translated into practise by managers who must select the fitting techniques and strategies among the available ones to create a practical process of risk management that reflects the formalised process. Risk management is defined as a process composed of the following steps: 1) identifying loss exposures; 2) measuring loss exposures; 3) evaluating the different methods for handling risk – risk assumption, risk transfer, and risk reduction; 4) selecting a method for handling risk; and 5) monitoring the results obtained through the selected method (D'Arcy, 2001: 5).

The challenges addressed from the 1940s to the 1960s, which transformed the previous forms of risk management, are on the one hand, the formalisation of a generalised organisational process that managers have to follow in order to avoid, cope with, and/or handle risk; and on the other hand, the definition of risk management as a corporate function. Thus, from the 1940s to the 1960s, risk management started to define the organisation as its target of reference and the risk management process started being shaped from the organisations' – mainly companies – point of view. Consequently, risks are defined from the perspective of the possible economic losses the company could face. In addition, scholars transformed risk management from a practical management process implemented by companies into a normative process companies should follow in order to stay in business, despite the possible sources of economic losses they are exposed to. Thus, scholars did not study how companies managed their risk, but they established the bones upon which every company should tailor its own risk management process, from available actuarial, finance, and probabilistic knowledge. Despite the inclusive aim of the first scholars' contributions to risk management (Mehr and Hedges, 1963; Williams and Heims, 1964), risk management in different risk areas has historically developed mainly independently. Since the 1990s, an additional effort to bring together the management of different areas of risk led to the development of Enterprise Risk Management (ERM) that has established itself in today's mainstream formal process to manage risk. ERM aims to bring together different risk management lines of development within a unique general frame of reference, thus developing a common approach to the management of different areas of risk (Dickinson, 2001; Dionne, 2013). Examining ERM and the different fields it aims to bring together allows us to briefly reconstruct the historical development of risk management as it is conceived today, and the progressive enlargement of the concept covering various areas of risk. Looking at the precursors of EMR, which this approach aims to bring together, we can identify four principle lines of development:

- Insurance risk management: it is historically the first developed form of organisation in order to face the possible events that can affect the business outcomes of companies. This kind of risk management focuses on the identification of risks and the integrated transfer of such risk to insurance companies. Basically, in the case of negative events the economic losses affecting the company are at least partially covered through an insurance programme. The insurance programme ensures economic support to the company in order to cover the monetary damage caused by the phenomena against which the company is insured such as, for example, atmospheric agents, theft, or fire (Dickinson, 2001; Harrington and Neihaus, 2003; Dionne, 2013);
- Financial risk management: the need to manage finance-related kinds of risks has arisen since the 1970s in order to avoid, cope with, and/or handle the possible negative consequences for the business outcomes of the variability affecting phenomena such as exchange rates, prices and interest or credit rates. Such areas of variability were a new phenomenon in the

1970s inasmuch as exchange rates, prices, interest and credit rates were maintained constant previously by state intervention – thus they were certain and, in principle, not definable as risks. A crucial aspect of financial risk management is the evaluation of risk in order to establish which kind of risk to accept, to transfer outside the company through an insurance program, to offset through external arrangements, or to manage inside the company through the development of special coverage funds in case of important variability affecting negatively on business outcomes (Dickinson, 2001; Dionne, 2013);

- Contingency planning and business continuation risk management: due to the rise of financial risk, especially between the 1960s and the 1980s (D'Arcy, 2001; Dickinson, 2001; Dionne, 2013), as well as the increasing prices of the insurance market and the impossibility of insuring certain kinds of risks, many companies started to develop forms of internal risk management, including preventive activities of various risks, self-protection, and self-insurance. In this sense, the development of contingency plans and management strategies to ensure business continuation, as well as specific coverage, funds and preventive interventions for work related illness and accidents, became crucial (Dickinson, 2001);
- Engineering risk management: the engineering risk management line of development targeting the risks of technical system failures has developed in parallel, and mainly autonomously, from the other three identified lines of development since the post-World War II period (Kossiakoff et al., 2011; Dionne, 2013). System engineering guides the development and operation of complex and engineered systems: 'a multiplicity of interacting parts that collectively perform a significant function [– system –] […] in which the elements are diverse and have intricate relationship with one another [– complex –][…] exclud[ing] such complex systems as living organisms and ecosystems [– engineered –]' (Kossiakoff et al., 2011: 4). The management of risks affecting a complex and engineered system should consider four main sources of failure: hardware failure; software failure; organisational failure; and human failure (Haimes, 2009). The estimation of risks – probability per magnitude – affecting each component should be considered under both the design, development and operational life-cycle of the system. The identified and measured risk has to be assessed in order to understand if it is economically sustainable in

order to implement control measures to reduce the risk of a specific component failure. Reducing the risk means reducing the probability or the magnitude of a risk (Haimes, 2009; Kossiakoff et al., 2011). Looking at hardware failure, an example of a control measure to reduce the probability of a risk is the second engine of the aircraft. In case of failure of the first engine, the second one allows the aircraft to fly anyway, thus, it creates a redundancy that reduces the probability of an aircraft crash due to engine failure.

ERM looks at the similarities between the processes of risk management distinctly formalised within these lines of development, trying to create a unique and integrated process addressing all these areas of risks. Thus, on the one hand, ERM is an answer to the perceived need for homogeneity in risk management practises between different areas of human activities. On the other hand, it recognises the presence of common available standards within different fields such as for example insurance, finance and technological risk management. The AS/NSZ 4360 Standards Australia and New Zealand published in 1995 constitute a first attempt to fix common standards for ERM, which have international validity. The UK ERM Enterprise Risk Management – Integrated Framework (COSO - Committee of Sponsoring Organisations, 2004) and the ISO 31000 (2009) standards are the latest developments in such a direction (Woods, 2011). The definition and process of risk management proposed by these three documents is quite similar and is, in principle, applicable to private as well as to public organisations. We focus on the latest ones: the COSO (2004) and ISO 31000 (2009) standards. We present the COSO risk management definition and process and then we show the affinity with the ISO 31000 ones through the reproduction of the table of the ISO standard, summarising the risk management process. Before beginning the description, we need to highlight, once again, that the ERM definition and process represents today's mainstream approach in the field of risk management, but it is not the only available solution. We will provide an in-depth analysis of the other available approaches later on in this chapter. In addition, ERM is a normative approach: it does not tell us anything about what the organisations actually do in order to avoid, cope with, and/or handle risk, but it tells us what the organisations should do in order to avoid, cope with and/or handle risk in order to remain in business.

The COSO (2004) defines ERM as:

a process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and managed risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.

Such a definition stresses the concept of risk appetite as the willingness of an entity to take risks, thus the reference frame through which risk is evaluated is not directly linked to the magnitude or the probability of such a risk, but the willingness of the entity to run or not run the risk. Following the COSO (2004) standards, the process of risk management should be composed of eight steps:

1. Internal environment definition: the definition of the internal environment aims at explicitly identifying the general approach of an entity to risk. Elements of the internal environment are, for example, the philosophy of the entity on risk taking – definition of risk appetite – as well as the ethical values from which the risk issue is framed;
2. Objectives setting: the objectives setting is crucial in order to develop a process of risk management that is expressly driven to the identification of the possible threats that can obstacle the achievement of such objectives. The objectives should be coherent with the risk appetite and the ethical values expressed in the internal environment definition;
3. Events identification: the events that can affect the objectives achievement are identified. Among such events, threats and opportunities are distinguished and the opportunities are used as input to the previous steps of objectives setting and internal environment definition;
4. Risk assessment: the likelihood and magnitude of the identified threats are defined and they are evaluated in order to decide how to manage them. Risk evaluation follows as a frame of reference for the internal environment definition established in the first step;
5. Risk response: through risk assessment and using the risk appetite of the entity as a frame of reference, management identifies the fitting risk response; mainly to avoid, to accept, to reduce, or to share the risk under assessment. The chosen risk response strategy depends on the risk appetite and thus, the risk acceptability the entity is willing to tolerate;
6. Control activities: procedures are established in order to ensure that the chosen response to risk are correctly put in place;
7. Information and communication: the risk management process is based on sound and rapid information, identification and communication;

8. Monitoring: the whole process is monitored in order to identify changes in the risk appetite or entity's objectives, the emergence of new threats, or the efficacy of the chosen control measures.

Enterprise risk management is an interactive process: the process should be continuously monitored and each step is constantly revised on the basis of the other ones.

Figure 2 shows the enterprise management process formalised by ISO 31000 standards. Even if in some cases different labels are used, the identified steps are quite similar (Woods, 2011). To facilitate the comparison, the eight steps of the COSO (2004) standards described above are added to the figure. The missing step is the second one – objectives setting – but it is in part taken for granted and in part comprised in the establishment of the context and the risk assessment steps.

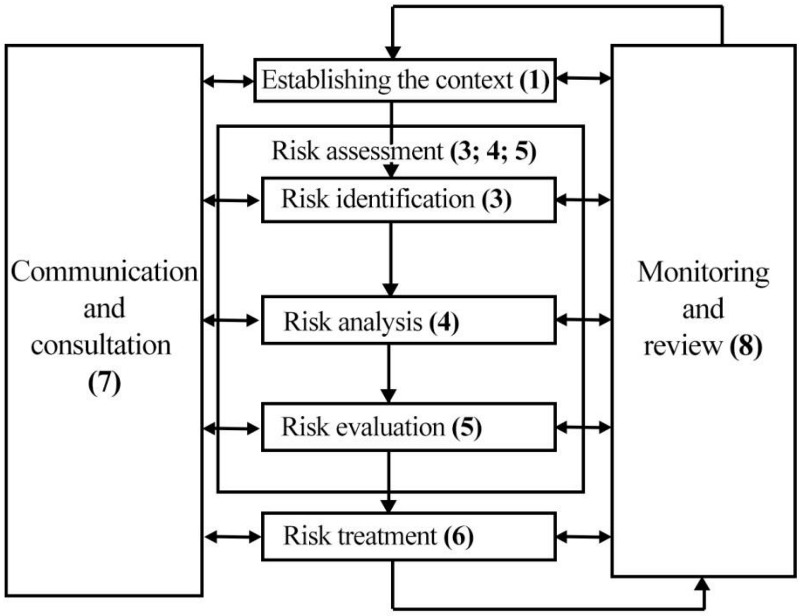

Figure 2: Risk Management Process in ISO 31000 (IS/ISO 31000, 2009: 14) – the numbers show the overlapping with the COSO (2004) standards

The affinity with Mehr and Hedge's (1963) foundational book is impressive as well (D'Arcy, 2001). The concepts and risk management steps formalised in the COSO (2004) and ISO 31000 (2009) standards are broadly accepted nowadays as normative references in different fields such as health care or project management, for example.

As already mentioned, the formalisation of risk management started during the 1940s to the 1960s and was reinforced by the COSO (2004) and ISO 31000 (2009) standards, which embody the natural focus of risk management within organisations, allowing them to develop their own objectives and processes. Risk management is defined as a process organisations put in place in order to avoid, cope with, and/or handle the threats that could affect reaching their own objectives evaluated in the face of their own risk appetites. Thus, risk management is a process shaped within the organisation and from the point of view of the organisation in order to achieve its own goals. However, the concept of risk management has recently been extended, covering processes and objectives located out of the original organisational boundaries. This extension relates, on the one hand, to the use of the concept of risk management with reference to the possible negative consequences of natural phenomena and terrorist attacks; and on the other hand, to the development and promotion of risk management processes within the organisations in charge of regulating human activities in order to avoid, cope with, and/or handle the possible side-effects of such activities. Both these recent extensions in the use of risk management strategies are developed by organisations – mainly governmental and non-governmental agencies such as: the US Environmental Protection Agency, the World Agency of Planetary Monitoring and Earthquake Risk Reduction, the Central Intelligence Agency and the European Railway Agency – targeting external processes and external outcomes instead of their own objectives/outcomes. These phenomena shift the focus of risk management from the organisation's own outcomes to the outcomes linked to other organisations' activities or natural phenomena.

Looking at the use of risk management strategies in order to deal with the possible negative outcomes of natural phenomena or terrorist activities, risk management processes are developed by organisations such as the World Agency of Planetary Monitoring and Earthquake Risk Reduction (WAPMERR) – natural phenomena – or the Central Intelligence Agency – terrorist attacks – in order to avoid, cope with, and/or handle the possible negative effects of external threats. Thus, the organisations developing such processes do not directly target their own outcomes, but the outcomes of external phenomena that represent a possible health or environmental risk. The management of possible negative consequences of natural phenomena cannot act directly on phenomena trying to avoid them, but can adopt measures in order to reduce their magnitude. For example, the WAPMERR cannot avoid the occurrence of an earthquake, but it can estimate the typical expected tsunami arrival time at the nearest coastal zone in the Pacific, in order to formulate a possible warning and rescue plan reducing the loss of human lives.[15] Furthermore, it can develop early warning systems in the case of earthquakes allowing the population to evacuate the area – for example, the EU SAFER project's objective, to which WAPMERR is a partner, is the development of an early warning system across Europe.[16] Thus, natural disaster risk management is a way of organising in order to manage the risk, but such risk is not directly linked with the outcomes of the organisations that develop or put into practise such risk management processes. If we look at the management of terrorist attack risks, in this case national intelligence identifies and evaluates the possibility of a planned attack and suggests measures to the governments that can impede the attack, or reduce its impact on the target population and the environment. For example, the restriction on substances passengers can carry on an aircraft as hand baggage, can be considered a measure to try to avoid the possibility of a terrorist attack.

Looking at regulatory activities, since the 1990s a change affecting the approach to regulation – the shift from a command-control to risk-based regulation, which we will address in-depth in the next section dedicated to risk regulation – has led to the use of risk management strategies by regulators as well. On the one hand, regulators have targeted the outcomes of the regulated areas of human activities applying processes of risk management in order to evaluate the performance of the regulated sectors. In addition, they have identified the need for a formal regulatory intervention, such as prohibiting certain activities or fixing specific ways of carrying out an activity. Thus, government agencies and policy-makers have started to perform risk management processes in their regulatory activities (Rimington, 1992; Hutter, 2001). On the other hand, regulators have promoted and enforced the development of specific risk management processes among regulated organisations, which are considered more effective in managing the possible side-effects arising from the regulated activity. For example, governmental agencies such as the European Aviation Safety Agency (EASA), have developed guidelines that the air companies can follow in order to develop their own risk management processes (e.g., the EASA Management Standard, 2013).[17] In addition, the EASA performs a process of risk management by itself gathering and analysing information about the

[15] http://www.wapmerr.org/activities-internallyfunded.asp, Website consulted 18 March 2014.
[16] http://www.saferproject.net/, Website consulted 18 March 2014.
[17] http://easa.europa.eu/docs/quality/LI.MRIMS.00006%20EASA%20Management%20Standards.pdf, Website consulted 2 February 2014.

performance of the sector. This information informs the Agency's development of new guidelines or regulations.[18]

In summary, in speaking of risk management we refer to a process – a way of organising – finalised to avoid, cope with, or handle possible negative outcomes. From the 1940s to the 1960s risk management was formally defined as a corporate function. The different fields using the concept and formalising normative strategies of risk management have their own history and have been developed mostly autonomously. Nowadays, the mainstream approach to risk management, ERM, has tried to put together the management of different kinds of risks: insurance, finance, business continuation and technological risks. The ERM definition and process has been defined by different international standards such as the COSO (2004) or the ISO 31000 (2009) standards. Considering other sources of risk such as terroristic and natural phenomena, as well as a change in the regulatory strategies – from control-command to risk-based regulation – allows for the identification of a new development with respect to the original organisational target of risk management. Thus, risk management processes include the management of events that can affect the outcome of the organisations implementing a risk management process. They also take into account the negative outcomes of external threats: natural phenomena, terrorist attacks, or the side-effects of the regulated areas of human activity. Now we aim to go beyond the differences between the fields as well as the mainstream approach to risk management, looking transversally at the various theoretical normative studies on risk management in order to highlight the presence of worldviews that differ from the mainstream one and cross the various identified fields. This is the aim of the next section.

Risk Management: four main worldviews

A bird's eye view of the different fields dealing with risk management allows us to see that, despite the strength of the mainstream approach formalised in international standards such as the COSO (2004) and ISO 31000 (2009), the current accounts of the way in which risk can be managed are still controversial and contentious (e.g., Hood and Jones, 1996). Moreover, the management of risk is not necessarily a process as simple and linear as is represented through the

[18] http://easa.europa.eu/safety-and-research/safety-analysis-and-research.php, Website consulted 2 February 2014.

standards. These controversial and contentious accounts have brought together academics and practitioners from different fields of reference; the 'current debates about risk management reflect competing worldviews' (Hood and Jones, 1996: 8) that cross such diverse fields. As a result, a broad amount of theoretical-normative accounts on the way in which possible adverse events should be avoided, coped with, and/or handled has been developed. In considering these theoretical-normative accounts, we are not looking at the way in which risk is actually managed by organisations, but at assumptions and ideas reflecting the main available worldviews on the way in which risk should be managed by organisations. In order to answer the question guiding this study – 'Why doesn't the (watch) dog bark?' – the actual practises of risk management developed by regulators is a crucial element of the empirical analysis aiming to understand the ways in which regulators translate management strategies in their everyday activities into practise. In contrast, the purpose of this section is to offer a background to the empirical analysis, summarising the available theoretical normative accounts and '[identifying] elements that keep cropping up in these debates' (Ibid.), delineating different worldviews on risk management. With this in mind, we identify four main worldviews, namely: anticipation, resilience, imagination, and accountability-auditability.

As in the case of all classifications, the proposed one represents a simplification of the world: the world of risk management is a more blurred and overlapping one. For example, some authors (e.g., Ansoff, 1975; 1980; Weick and Sutcliffe, 2007) suggest a mixture of anticipation, resilience and imagination as the proper way to manage risk guaranteeing a balance between different needs. Thus, the four identified worldviews can be seen as ideal types (Weber, 1922): the emphasis is placed on the crucial aspects contrasting between the four views allowing us to distinguish the different risk management strategies they promote. A brief description of these four main worldviews follows.[19] Each description starts with the Oxford English Dictionary definition of the terms used

[19]An in-depth description of these worldview would require an entire book. As already mentioned, in this chapter, our aim is simply to give an idea of the variability and the competing available approaches to risk management in order to offer a context for our empirical analysis, as well as to explain the empirical orientation we chose in the definition of the concept of risk management. For further details see Hood and Jones (1996), Hutter and Power (2005), or Hutter (2011) about anticipation and resilience; Weick (2005) about imagination; or Power (2007) about auditability-accountability, for example.

– anticipation, resilience, imagination and auditability-accountability. Then the ontological and epistemological basis of each worldview is presented, and the ways of organising each approach proposes in order to avoid, cope with, and/or handle risks, are discussed. Table 2 summarises the main characteristics of each worldview. After the description, the links between the different worldviews, their critical aspects and relative legitimacy, are discussed.

	Definition	*Fields of Reference*	*Ontology*	*Epistemology*	*Risk Management Strategies*
Anticipation	The action of anticipating something; expectation or prediction	Enterprise Risk Management; Financial and Business Risk Management; Engineering Risk Management	A world of certainty and clear causal relationships (control measures that reduce probability and/or magnitude presumes the presence of clear causal relationships)	A world of fully knowledgeable phenomena and causal relationships	Four-step process: Risk analysis/assessment; identification of control measures; cost-benefit analysis; implementation and monitoring of control measures
Resilience	The ability of a substance or object to spring back into shape; elasticity; the capacity to recover quickly from difficulties; toughness	Organisational studies on risk management Risk Management of Natural Phenomena	Hazards are characterised by multiple and interconnected genesis, thus, it is really difficult to identify or even to imagine the possible risky scenarios before the fact	The world looks predictable just because of the benefit of hindsight	Technological flexibility; reluctance to simplify interpretations; sound communication; a shared vision and set of values; not hierarchical and constraining organisational structure; and effort to maintain situation awareness
Imagination	The faculty or action of forming new ideas, or images or concepts not present to the senses; the ability of the mind to be creative or resourceful	Terroristic risk management; organisational studies on risk management	Complexity and interactivity of the genesis of possible negative events, complex interaction and unclear causality	Knowing adverse outcomes before they happen is possible, but the state of mind and methodologies fitting for the characteristic of the event are needed	Framing through clues looking at the future rather than at the past previous experiences; just culture; perceptual-based knowing rather than category- based knowing; abductive reasoning rather than a deductive one; mindfulness (five HRO characteristics)
Auditability-Accountability	From audit: an official inspection of an organisation’s accounts typically by an independent body; a systemic review or assessment of something – The fact or condition of being accountable; responsibility	Accounting and organisational studies	The ontology of the genesis and nature of possible negative events is not relevant, because the management of risk is not the very end of the development of risk management process	The “knowability” of the genesis of possible negative events is not relevant, because the management of risk is not the very end of the development of risk management process	Rationality and science; standards and strictly defined procedures that ensure auditability and accountability: risk management processes and documents ensuring legitimacy to risk producers as well as to reassure the public

Table 2: Four worldviews on risk management (My elaboration.)

Anticipation

The Oxford English Dictionary[20] defines anticipation as 'the action of anticipating something; expectation or prediction.'

The definition holds together two different terms: expectation and prediction. The anticipation worldview on risk management is closest to the prediction meaning rather than to the expectation one. In fact, the anticipation worldview assumes a closed world in which interactions are limited, future events are in principle predictable, and there are not unexpected interactions. Ontologically, we are in a world of certainty: identifiable negative events linked by clear causal relationships. Epistemologically, we are in a world of fully knowledgeable phenomena and causal relationships. The anticipation worldview shapes the mainstream approach to risk management formalised into international standards such as the COSO (2004) or the ISO 31000 (2009) ones, summarised above. The fields in which an anticipation worldview is prevalent are the ones presenting a 'technical-scientific' approach to risk management: financial and business risk; the engineering approach to technological risk; management in general and, in part, the management of risk associated with natural phenomena. Let us look closely at the main steps an organisational process aiming to manage risk should follow, from an anticipation worldview perspective: risk analysis/assessment, identification of control measures, cost-benefit analysis, risk control measures development and monitoring.[21]

Saying that possible negative events are predictable means that possible negative events are identifiable and risks are estimable: probability/frequency as well as expected magnitude/consequences are clearly associable with each possible negative

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[20]http://www.oxforddictionaries.com/definition/english/anticipation?q=anticipation), Website consulted 3 February 2014.

[21]Usually, practitioners distinguish risk analysis/assessment from risk management (e.g., National Research Council, 1993; United States Environment Protection Agency (EPA), http://www.epa.gov/oswer/riskassessment/pdf/s1-ra.pdf, Website consulted 3 February 2014). Risk analysis is the hard scientific and technical step. In contrast, risk management steps relate to policy makers and more generally to decision-makers. While risk assessment is seen as scientifically based and value free, risk management steps recognise the value-related dimension of risk decisions on resource allocation between different risk areas, different kinds of remedial measures and risk acceptability criteria. Scholars question such distinctions highlighting the difficulty of tracing a clear line between the two steps as well as the value-free nature of the risk analysis steps (Jasanoff, 1993; Cohen, 2001).

event. This process of possible negative events identification and risks estimation – probability and magnitude of the identified possible negative events – is commonly named risk analysis or risk assessment. Risk analysis/assessment is the first step a risk management process should develop. Through entry into a risk management process, uncertainty is transformed into risk, thus uncertainty is translated into certainty establishing clear likelihoods and the expected magnitude of all the possible events (Power, 1997).[22] Risk analysis/assessment relies on expert judgment and/or on historical data on previous events (e.g., National Research Council, 1993; United States Environment Protection Agency)[23] and, therefore, on previous experiences. The identification of possible negative events and the estimation of risk are followed by an evaluation of the acceptability of the identified risks. In particular, a risk can be defined as acceptable, tolerable, or not acceptable, according to the associated degree of probability and magnitude, as well as to the attitude of the organisations performing the process on risk taking.

If a risk is defined as acceptable, the process ends; if it is defined as tolerable, it is just monitored in order to avoid an increase of the probability or magnitude. If a risk is defined as unacceptable, an examination of the possible control measures that can reduce the probability or the magnitude of the identified risks begins. The identification of control measures also relies on the existence of predictable causal relationships, which lead to the expected negative outcomes, as well as on the 'knowability' of such relationships. An example of a control measure would be the second engine of the aircraft mentioned above, aiming to reduce the likelihood of a crash. Another example could be the European Rail Traffic Management System (ERTMS) that automatically stops high-speed trains in cases when speed limits are exceeded or a signal, which requires trains to stop, is passed, in order to avoid collisions or derailments. An additional example, would be buying insurance coverage that addresses the economic losses linked with possible negative events. If we frame the risk management practise from a government regulation point of view, a control measure would also be the introduction of new laws and/or standards.

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[22] Scholars highlight the danger of such certainty assumptions leading to a phenomenon known as 'illusion of control': having a clear process of identification and estimation/quantification of possible dangerous events leads to the illusion of full controllability of negative events, identification of all the possible negative events, as well as absence of emerging phenomena not directly linkable to previous classes of events (Power, 1997; Celati, 2004).

[23] http://www.epa.gov/oswer/riskassessment/pdf/s1-ra.pdf, Website consulted 3 February 2014.

Once the control measures are identified, another step begins: the cost-benefit analysis. Cost and benefit estimation relies on the quantification of the cost of the consequences of the dangerous events, as well as on the quantification of the cost to reduce/remove the magnitude and/or the probability of the dangerous events (e.g., Aven and Kristensen, 2005) – in other words, the cost of the identified control measures. Thus, cost/benefit analysis relies on predictable and knowledgeable assumptions as well: in order to estimate costs and benefits we need to know exactly what the outcomes of the event will be and how many events of the same kind we will face in a given period. In addition, the starting point is that the identified control measures will actually act in order to reduce the magnitude or the likelihood of the negative events, thus it relies once again on the assumption of clearly identifiable causal relationships.

More specifically, two main ratios are developed to calculate the economic assessment of risk: the cost/benefit ratio and the disproportional ratio (Bowles, 2003). The cost/benefit ratio compares costs and benefits while the disproportional ratio weights the costs and benefits comparison with the willingness to pay for statistical lives saved. The willingness to pay notion was first introduced by Starr (1969), former president of the Atomic Division of Rockwell International. This notion considers the amount of money that society would pay for having one statistical life reduction. Thus, the disproportional ratio tries to formally integrate the way in which the public perceives risks (e.g., Pidgeon, 1998; 1999;) in the process of risk management (Bowles, 2007). Even if this evaluation usually includes other considerations about the role of unquantifiable factors,[24] as a general rule of thumb, a cost/benefit ratio equal to zero means that there are no losses and no benefits in implementing the control measure; a ratio greater than zero means that there are economic advantages in implementing the measure.

In contrast, a ratio less than zero means that there are no economic advantages in implementing the control measure. In the first two cases, the control measures are in principle implemented. In the third scenario, the control measures are not implemented. The cost/benefit ratio is also used in order to evaluate which measures to implement between a set of possible alternatives. In this case, the implemented measures will be the ones that assure a better positive ratio.

[24]For example, if we consider a risk management process promoted by regulators in order to understand if a new regulation is required, a positive economic benefit ratio could lead to the decision not to regulate the examined matter through formal laws because the regulated organisations would already be motivated to adopt the control measures having a positive cost/benefit ratio.

If the cost/benefit analysis reveals that the control measures are economically feasible, such control measures are in principle put into practise. The anticipation approach includes a monitoring step, where the chosen reduction/removal measures are monitored in order to check their efficiency (Hood and Jones, 1996). The implementation of the monitoring step shows a high degree of variability going from quality management to risk-based priority methods (e.g., US Department of Health and Human Services Food and Drug Administration, 2013). This step assumes the certainty and 'knowability' of the causal relationships, as well as the causal relationship between the measure and the reduction of the probability/magnitude of the negative event. In particular, it must be determined whether the measures in the end will reduce the probability or the magnitude of the event.

Recently, the strong objectivistic assumption has been relaxed among scholars following the development of the Bayesian theory of probability that recognises the uncertainty linked to estimated probability, and formally integrates a subjective evaluation of such an estimation (e.g., Aven and Kristensen, 2005; Aven, 2011). Nevertheless, it is uncommon for practitioners to consider the Bayesian theory of probability in their risk estimation. They usually are, however, open to a qualitative estimation of likelihood, such as categorisations of extremely high, high, medium, low, or extremely low likelihoods of occurrence. At the EU regulatory level, another step toward the easing of the objectivistic assumption is the introduction of 'precautionary principles', which, in case of uncertainty of the estimated likelihood and magnitude, requires taking a conservative position to develop corrective measures or to ban potentially dangerous activities or products. This, even if the cost-benefit analysis produces a negative outcome (Tait and Levidow, 1992; O'Riordan and Cameron, 1994; Tait, 2001).

Resilience

The Oxford English Dictionary[25] definition of resilience is:

- The ability of a substance or object to spring back into shape; elasticity;
- The capacity to recover quickly from difficulties; toughness.

The etymological origin of the term is the Latin *resilio* that means jump back (Kleina et al., 2003). Since the 1960s, scholars from different disciplines have started

[25]http://www.oxforddictionaries.com/definition/english/resilience?q=resilience, Website consulted 30 January 2014.

to use the term ‘in a more metaphorical sense to describe systems that undergo stress and have the ability to recover and return to their original state’ (Ibid.: 35). Holling (1973) first introduced the term as a characteristic of ecological systems. More specifically, the term resilience was used to underline the presence of non-linear dynamics affecting ecological systems discovered through the study of interacting populations as predators and preys (Holling, 1973; 1986; 2001). Subsequently, the use of the term spread across disciplines and has been used to study natural hazards (Carpenter and Gunderson, 2001; Berkes et al., 2003; Peterson et al., 2003; Kinzig et al., 2003; Folke, 2006; Park et al., 2011), high reliability organisation (Rochin, LaPorte and Roberts, 1987; Weick, 1987; 1993; Roberts, 1990; 1993; LaPorte and Consolini, 1994; Weick and Sutcliffe, 2007; Roe and Schulman, 2008) and criminal organisation (Ayling, 2009). In the context of organisational studies, resilience specifically identifies the capacity of organisations ‘to cope with unanticipated dangers after they have become manifest, learning to bounce back’ (Wildavsky, 1988: 77).

The resilience worldview calls into question the key assumptions of the anticipation one:

- Ontologically, scholars underline the complexity, interconnectedness and instability of today’s world. Consequently, possible negative events are characterised by multiple and interconnected geneses (Wildawsky, 1988; Rinaldi et al., 2001; Vespignani, 2010; Aven, 2011; Park et al., 2011). In addition, unexpected as well as unplanned outcomes are always possible: all the actions, thus even those performed to avoid dangerous outcomes, may have adverse and unintended consequences (Wildawsky, 1988). Therefore, the world of possible negative events is characterised by uncertainty and complexity;
- Epistemologically, Wildawsky (1988) underlines that usually the world looks predictable because of the benefit of hindsight. More specifically, *ex post*, events look predictable, but *ex ante*, they are not: uncertainty is so substantial that it is impossible to distinguish which one will actually occur in the entire set of hypothetical dangerous events. Thus, it is extremely difficult to identify or even to imagine possible risky scenarios before the fact (Wildawsky, 1985; 1988; Rinaldi et al., 2001; Vespignani, 2010; Aven, 2011; Park et al., 2011).

Consequently, organisations should focus on the ability to cope with and manage dangerous events if they are happening, rather than to anticipate and manage them before they happen. Negative events are not predictable and all we can do is to recover when they manifest themselves: ‘try as we may, we are not likely to be successful anticipators, [but] we can always resort to resilience' (Wildavsky, 1988: 83).

The resilience worldview being popular among both scholars and practitioners nowadays, represents the most supported alternative to the anticipation worldview, but does not achieve the same degree of legitimacy. The resilience worldview is generally recognised as a challenge in the structuration of risk management practises (Klinke and Renn, 2002). However, 'clear guidance as to how resilience can be promoted is lacking' (Kleina et al., 2003: 35-36). Nevertheless, scholars have identified some key characteristics that organisations should fulfil in order to be resilient – to be able to jump back. For example: technological flexibility (Collingridge, 1980; 1983; 1992); a reluctance to simplify interpretations, encouraging multiple and complex interpretations and strategic/scenario planning (Dervitsiotis, 2003; Seville, 2006; Weick and Sutcliffe, 2007); sound communication within (Horne, 1997; Horne and Orr, 1998; Oldfield, 2008; Seville, 2006) and outside the organisation (Seville, 2006); a shared vision as well as a clearly communicated and reinforced set of values (Coutu, 2002; Horne, 1997; Seville, 2006); a non-hierarchical and constraining organisational structure – decisions based on expertise rather than on hierarchy (Cunha and Cunha, 2006; Weick and Sutcliffe, 2007); and aptitude to improvise and an effort to maintain situation awareness (Coutu, 2002; Cunha and Cunha, 2006; Weick and Sutcliffe, 2007).

Imagination

The Oxford English Dictionary definition[26] of imagination is:

- The faculty or action of forming new ideas, or images or concepts of external objects not present to the senses;
- The ability of the mind to be creative or resourceful;
- The part of the mind that imagines things.

The term imagination refers to the creative mental activity which, by recombining available information, fosters new hypothetical scenarios that have not yet become reality, but that could become so. The concept of imagination first appeared with reference to terroristic risk and, in particular, the lack of imagination identified as a contributing factor to preventing the US National Intelligence's understanding of the

[26] http://www.oxforddictionaries.com/definition/english/imagination?q=imagination, Website consulted 3 February 2014.

forthcoming 9/11 terrorist attacks (Commission Report, 2004; Weick, 2005). Weick (2005) stressed that a lack of imagination prevented US National Intelligence from developing and going beyond the available information to discover the danger waiting to happen through a terrorist attack: even though all the needed information had been collected, what was lacking was the frame of reference through which to read this information; thus, the property of recombining the available information in a creative and new way.

For example, the Federal Aviation Administration imagined the suicide hijacking scenario before 9/11. Nevertheless, this scenario was considered implausible because it would prevent the terrorists from developing a dialogue in order to free the terrorists imprisoned in the US, for example. Thus, they didn't consider that terrorists could be uninterested in any dialogue. Such a conjecture would be the result of an imaginative process: the product of recombining the available information in a new way despite the characteristics of previous experiences, such as terrorists seeking dialogue in order to free prisoners (9/11 Commission Report, 2004 in Weick, 2005).

In addition, Weick (Ibid.) extended the imagination concept in order to understand the genesis of a technological accident: the Columbia shuttle disaster. After the Columbia launch, different groups at NASA asked for further images in order to evaluate the damage caused by some fragments, detached from the left wing of the shuttle during the launch, which the shuttle collided with. Despite the availability of 17 days of mission in which NASA experts could develop a recovery plan to ensure a safe landing for the shuttle, the Mission Management Team denied NASA staff these extra images. Consequently, the shuttle exploded during its landing on 1 February 2003. NASA's failure of imagination is linked with the categories in use at NASA to classify problems.

Categories simplify the world, but at the same time bridle imagination preventing the recombination of available information in new ways, as well as the understanding of new phenomena which, through the use of categories, are reconnected to previous experiences. NASA distinguishes problems between 'in-family' and 'out-of-family.' The debris detachment was classified as an 'in-family' problem, thus a problem already faced without any negative outcomes. Such assumptions led to the Mission Management Team's lack of imagination: that is, to consider such a fragment detachment as not dangerous, and the staff's request was perceived as a question of scientific curiosity rather than a real possibility of danger (Columbia Accident Investigation Board, 2003 in Weick, 2005).

Weick (Ibid.: 427) defines imagination as 'a shaping and modifying power': 'imagination is the power to present in concrete, particular forms and expression what before has been only general and abstract knowledge, hazy feeling, or impression' (Engell, 1991: 101 in Weick, 2005: 427). Imagination is then distinguished from fancy. If imagination allows us to create alternative scenarios fostering new concepts and frameworks, fancy looks at the available information aggregating and associating it in a different scenario. Thus, it is stuck in the past through the definitions of categories and classes of phenomena, creating the assumptions through which organisations interpret and frame reality by taking apart relevant details. Organisations are more likely to exercise fancy rather than imagination. As the 9/11 Commission Report states (2004: 344):

> imagination is not a gift usually associated with bureaucracies. […] It is therefore crucial to find a way of routinising, even bureaucratising, the exercise of imagination. Doing so requires more than finding an expert who can imagine that aircraft could be used as weapons.

The concept of imagination has been developed within specific fields – terrorist attacks and space shuttle missions – with specific characteristics, nevertheless such concepts can be linked to a more general worldview on risk management. The imagination worldview can be considered as a frontier of risk management, however, some organisational study scholars' work, in addition to Weick's, fit within this worldview. By putting these studies together, it is possible to develop and extend the concept of imagination into a worldview on risk management. Let's examine the imagination worldview within the chosen framework of reference: ontology, epistemology – assumptions – and management strategies.

The imagination worldview shares the ontological objection made by the supporters of the resilience one – the complexity and interactivity of the genesis of possible negative events. Negative events are the outcomes of different contributing factors and it is extremely difficult to re-conduct such complex interactions into clear causal patterns or categories. In contrast, epistemologically the imagination worldview shares the assumption that anticipating adverse outcomes is in principle possible with the anticipation approach. In this sense, the imagination worldview is close to the conception of anticipation as expectation rather than as prediction. Imagination leads to the development of expectations on the future that are based on the available information but, unlike predictions, goes beyond it.

Past events offer stimuli for reflection, but in order to anticipate future negative outcomes such stimuli should be used creatively. Imagination is a way of knowing what could happen in the future, but the possibility of such negative events can be addressed and managed in order to leave such events in the world of the unrealised. Thus, as in the case of the anticipation worldview, anticipating and managing – knowing – possible adverse outcomes is possible, but the imagination worldview presents a different position on the methodologies that can fit with this purpose. Methodologies need to be adapted to the nature of the phenomena they are trying to face. Organisational processes and structures should be adapted in order to encourage imagination rather than fancy and thus, create the expectations needed to understand the forthcoming possible dangerous events. Such a revision relates to two key steps of risk management: information gathering and information analysis.

Information gathering should be open and not constrained by rigorous and predefined framing categories and classifications (Vaughan, 1996; Weick, 2005). In addition, the population of hazard indicators should be considerably enlarged to include strong and weak signals (Ansoff, 1975; 1980) as well as slips, lapses, mistakes and violations (Reason, 1990; 1997; 2008): without details, imagination is not possible.

Information analysis should not be driven by strong statistical tools, but by an open- minded, intuitive, and in-depth analysis of the available information. Imagination means the ability to recognise and conceive of an alternative future: 'imagination represents things that are absent; imagination unifies the empirical and the ideal; and imagination fills out and extends incomplete experience' (Weick, 2005: 427). Imagining an alternative future is not possible if the analysis of the available information is strongly framed by past experiences. In addition, the development of an imaginative ability requires tools to understand how to distinguish between signs and noise (Silver, 2012). Thus, one must select relevant information between a normally confused and massive amount of information that is not significant, in order to figure out the actual potentially negative scenario.

Scholars underline some organisations' characteristics, which could be useful to encourage such modifications in both information gathering, as well as information analysis, allowing for an imaginative point of view on future possible negative events.

With reference to information gathering, a crucial element is the development of a sound reporting procedure. Scholars from the organisational accident fields emphasise sound reporting based on the presence of a 'just culture' as crucial (Reason, 1997; Vaughan, 1999; Catino, 2008; Dekker, 2009; 2012). A 'just culture' recognises that human beings make mistakes, but moves away from blame attribution in order to create a learning environment. Such a culture tolerates mistakes, but punishes omissions in reporting such mistakes, creating a climate of trust that rewards sharing relevant safety information.

At the same time, a 'just culture' clearly discerns what is tolerable behaviour and what is not, distinguishing the cognitive limits of every human activity from intentionally irresponsible behaviour such as being inebriated in the work place. A 'just culture' is needed in order to recognise signs that differ from data obtainable through following rigid categories and preventing the strong and constant involvement of front line operators. More in general, the need to collect information without omitting even feelings or impressions, is a crucial element that can foster imaginative reasoning.

In order to encourage imaginative analysis, the available literature pinpoints some characteristic of organisations that can threaten imagination. Both the 9/11 Commission Report as well as Weick's (2005) analysis of imagination stress that organising in itself represents a threat to imagination (Weick, 2005; 9/11 Commission Report, 2004). Weick (2005) identifies three main constraints to imagination that are linked to organising: shareability, inference and mindfulness constraint.

The shareability constraint is linked to a key need of organisations: coordination. Coordination between people requires us to 'shift from perception-based knowledge to category-based knowing' (Ibid.: 432). Such a shift toward a category that allows people to communicate and coordinate their activities implies a movement away from details:

> people preoccupied with coordination tend to remember the name of the things seen rather than the qualities that were observed and felt. If significant details lay out the connotations of these remembered names, then coordinated people will be the last to see them (Ibid.).

Thus, formalised abstractions and generalisations – categories, formally identified roles and responsibilities, and structured and rational organisational processes – lead to a misperception of details. But such details are an essential fuel for imagination. Consequently, the coordination that requires the shareability of schema, concepts and categories can be considered a constraint to imagination. In contrast, weak coordination leaves room for imagination. However, weak coordination can be reached only in structures that are 'tight coupling around a small number of core values and loose coupling around everything else' (Ibid.: 433), and such characteristics do not fit with the standardised procedures, roles, and responsibilities of bureaucracies. Thus, imagination and coordination are perceived as a trade-off.

With reference to the inference constraint, another characteristic of organising is the development of norms of rationality, rules that guide interpretations and deductive methods of reasoning useful to reduce uncertainty through ordering and predicting. Such a deductive approach leads to the imbalance of interpretations toward available schemas and frames developed through past experiences, rather than toward the development of new schemas and frames shaped in order to understand the future. Thus, new clues are re-conducted into available interpretation schemas.

In contrast, imagination requires abductive reasoning. Through abductive reasoning 'when people imagine reality, they start with some tangible clue and then discover or invent a world in which that clue is meaningful that link new clues framing new schemas' (Ibid.: 433). When people imagine such worlds they are invented and new, when they fancy such worlds they are linked to previous ones. Consequently, organising and imagination are again the poles of a trade-off between deduction and previous past worlds *versus* abductive reasoning and future new worlds. In order to understand possible dangerous outcomes, the creation of new worlds through which we can make sense of available clues is essential. Thus, the inferential process shaped by organising that re-conducts available clues to old worlds represents a threat to danger identification. Finding a balance between deduction and abduction is a key issue that organisations have to face in order to develop imagination.

The mindfulness constraint to imagination in Weick's (Ibid.) analysis is linked to specific types of organisations: high reliability organisations (HROs) (Rochin, LaPorte and Roberts, 1987; Weick, 1987; 1993; Roberts, 1990; 1993; LaPorte and Consolini, 1994; Weick and Sutcliffe, 2007; Roe and Schulman, 2008). HROs are organisations that are potentially high risk, but perform a low rate of errors or accidents through the development of 'specific successful cognitive processes' (Weick, Sutcliffe and Obstfeld, 1999). Scholars identify five processes by which HROs reach high performance in safety management ensuring mindfulness:

- Preoccupation with failure rather than success: HROs perceive errors, close calls and near-misses as failures revealing the possibility of dangerous events rather than as proof of the health of the systems or its ability to avoid dangers. Small failures are framed as crucial information and chances for learning, as well as warning signals of future possible dangerous events. The implementation of such an attitude becomes reality through daily failure detection and reporting. Learning from failure is the end of a complex process for which a just, safety-oriented culture is a prerequisite – tolerance for mistakes of commission, but intolerance for omission, as well as belief that possible dangerous and adverse events can be carried out;

- Reluctance to simplify interpretations: HROs reject simplifying analyses of events and encourage multiple and complex interpretations: 'with closer attention to context, more differentiation of worldviews and mind-sets. And with more differentiation comes a richer and more varied picture of potential consequences, which in turn suggests a richer and more varied set of precautions and early warning signs' (Weick and Sutcliffe 2007: 53);
- Sensitive to operations: HROs are sensitive to the activities performed by front-line operators. Front-line operators endeavour to uphold situational awareness: being fully aware of what is going on, what may be the implication of actions actually going-on to future functioning, and then eventually making continuous adjustments in order to prevent errors and their dangerous consequences. Managers also have to be sensitive to the operations performed by front-line operators by being informed of what is going on in the front line, taking into account suggestions and opinions from front-line operators in order to be conscious and adapt decisions and plans;
- Commitment to resilience: HROs commitment to resilience 'is a combination of keeping errors small and of improvising workarounds that allow the system to keep functioning' (Weick and Sutcliffe, 2007: 14). HROs are able to reorganise dangerous situations and cope with errors and malfunctioning – they keep going even in the face of de-structuring external or internal changes;
- Deference to expertise: HRO scholars separate the concept of expert from that of expertise. Expertise is a relational concept shaped and rendered significant by the interaction between different people bringing together different qualities and experiences. Through deference to expertise, HROs go beyond hierarchy and power relationships formalised in organisational charts. They decentralise the decision-making process and decisions on the front-line are made regardless of a person's rank.

These five processes 'of mindfulness favour imagination because they preserve details, refine distinctions, create new categories and mis-understanding' (Weick, 2005: 435). In contrast:

when organising is more mindless and takes the form of attention to success, simplicity, strategy, anticipation, and hierarchy, fancy is more likely because people tend to focus on formal abstractions, remembered experience, and institutionalised pathways of associating discrete elements. Under these conditions, an act of imagination is often interpreted as an act of insubordination (Ibid.).

Thus, mindfulness is a crucial element ensuring imagination, in order to ensure mindfulness five characteristics should be developed within an organisation: preoccupation with failure rather than success, avoiding simplification, being sensitive to operations, organising for resilience rather than anticipation, and deferring to expertise. Such characteristics can be considered management strategies that can encourage imagination. This statement shows an overlapping between the resilience worldview and the imagination one. More specifically, the attention to resilience can encourage imagination rather than anticipation. Resilience and imagination are not mutually exclusive, but present different contact points. Finally, both these worldviews on risk management represent a critique of the mainstream anticipation worldview.

Auditability-Accountability

The Oxford English Dictionary defines auditability as being auditable. The definition of audit[27] is:

- An official inspection of an organisation's accounts, typically by an independent body;
- A systematic review or assessment of something.

It defines accountability[28] as:

- The fact or condition of being accountable; responsibility.

Scholars from accounting and organisational studies have developed what we call the auditability-accountability worldview on risk management which underlines a shift affecting today's strategies on risk management. In particular, through the development of standards such as the COSO (2004) and the ISO 31000 (2009) ones, the risk management process tends to be shaped in order to ensure a clear definition

[27]http://www.oxforddictionaries.com/definition/english/audit?q=auditability#audit__14, Website consulted 3 February 2014.
[28]http://www.oxforddictionaries.com/definition/english/accountability?q=accountability, Website consulted 3 February 2014.

of the responsibilities of the involved actors – accountability, on the one hand; and the development of processes that fit with standards rather than with the very identification and management of possible negative outcomes – auditability, on the other. The point of developing a risk management process is no longer to manage risk, but to ensure compliance with auditing practises and rules; thus, risk management's end is being auditable/accountable and not ensuring the protection from possible negative events for health and the environment.

The auditability-accountability approach calls into question the meaning and purpose of risk management practises in society today. Such an approach highlights the diffusion of specific types of management tools – or standards – but questions the root assumption that risk management tools actually work for reducing/eliminating adverse outcomes. Consequently, the ontology and epistemology of the characteristics and genesis of possible negative events is not relevant, because the management of risk is not the real end of the development of risk management processes. The auditability and accountability worldview underlines that the driving 'role of accounting style of knowing and of logic of auditability' (Power, 2005: 852), leads to producing an easy-to-audit scenario and a comfort level, but does not serve the purpose of managing risk (Clarke, 1999; O'Brian, 2000; Power, 1997; 2005; 2007; Power et al., 2009).

The easy-to-audit nature of risk management practises is linked to the rise of internal audit strategies, as well as of external assessment bodies checking formal processes rather than the content of such processes. Such easy-to-audit risk management practises are based on a modification in risk management's dominant discourse: 'the dominant discourse of risk management has shifted from the logic of calculation to that of organisation and accountability' (Power, 2007: 3). This shift leads to a loss of primacy for the anticipation approach in favour of the development of 'management control system[s]' (Ibid.). Thus, the anticipation approach is incorporated into a complex control system based on processes of internal control and formal external assessments. Consequently, the sense of risk management is 'lost in the procedural detail of organisation-specific internal control, compliance and accounting systems' (Power, 2005: 852). The rise of auditing has led to the development of formalised check box lists rather than informed risk management strategies. In addition, the focus of auditing bodies has become whether a risk assessment has been conducted according to the recognised principles, standards and rules, rather than whether it promotes aware risk decisions (O'Brian, 2000).

As Douglas and Wildawsky (1982: 1) famously put it: 'Can we know the risks we face, now or in the future? No, we cannot: but yes, we must act as if we do.' Central to this response is the production of visionary documents and the design of processes of risk management in the form of standards and guidelines. These recipes and recommendations constitute a new normativity for risk management at a time when it is becoming a central part of the definition of organisational governance. Consequently, there are extensive efforts to design risk management processes which allocate responsibility and which appeal to the value of science and rationality translated into standards (Power, 2007), in order to ensure an impression/illusion of control on human activities. The comfort-producing nature of science and rationality, as well as of strictly defined risk management processes, addresses the question of what the meanings and purposes of such risk management processes are. Scholars state that the role of such risk management processes is not to avoid or reduce adverse events, but to ensure legitimacy to risk producers as well as to reassure the public.

On the one hand, risk management as 'the right way to do it' pushes organisations to be formally compliant with it in order to gain legitimacy (Power, 1997; 2007; Power et al., 2009). On the other hand, it is a way to give the public the illusion of control by identifying who is responsible for what, and hiding dangerous activities under objectivity and rationality (Clarke, 1999; O'Brian, 2000): the management control system responds to a 'functional and political need to maintain perception of control and manageability' (Power, 2007: 5). In addition, such management processes function as attributors of responsibility about risk and risk decisions, increasing the illusion of accountability to the public, as well as the power of specific categories of risk experts (Power, 2007). Consequently, the outcomes of risk management are not an increase of safety, but a set of 'fantasy documents' (Clarke, 1999: 16):

> they are fantasies either because the promises they make can never be fulfilled or because we can never know whether they will be fulfilled until major catastrophe befalls us.

Such fantasy documents reassure the public and legitimise risk taking and the production of dangerous outcomes, rather than contributing to reduce the frequency or magnitude of such outcomes. Consequently, in following the auditability-accountability worldview, risk management is a way of coping with risk, rather than a way to avoid or handle it, which renders it possible to live with risk.

The different worldviews presented here do not have the same weight and historical foundations. The anticipation worldview on risk management, which is today's mainstream approach, is still the most formalised, and has the most long-standing historical origins. Anticipation represents the worldview shaping the 'technical scientific' approach to risk which the main anthropological and sociological theories on risk described in the previous section have questioned since the end of the 1980s. The resilience, imagination, and auditability-accountability worldviews can be considered as relatively recent developments within the risk management debate. The starting point of such competing worldviews – resilience, imagination, and auditability-accountability – is a critique to the objectivistic and realist assumptions on which the mainstream anticipation worldview is based. The anthropological and sociological theories on risk have had a flywheel effect on such debate laying the foundation for those competing worldviews.

Consequently, the strong objectivistic assumptions of the anticipation worldview have been, on the one hand, relaxed and corrected with the introduction of corrective elements such as the Bayesian theory of probability, or the use of a precautionary principle in cases of uncertainty of the estimated probability and magnitude. On the other hand, new approaches to risk management have been formalised and sustained as better ways of avoiding, coping with, and/or handling possible negative events – resilience and imagination. The main limit of such relatively new worldviews, in particular, the resilience and imagination ones, is to result in over reactions – being ready or intervening in events that will never become reality –, and consequently do not fit within a cost-benefit ratio that, in contrast, represents a crucial idea of the anticipation worldview.

Risk management in this dissertation

The previous sections have indicated that:

- The management of risk presents different historical lines of development within diverse areas of human activity – for example, health care organisations, project management, or transport systems – and various phenomena bound under the management process – for example, business and financial, clinical, or technological risks;
- Despite the presence of various worldviews on risk management, representing the correct ways in which risk should be managed – anticipation, resilience, imagination and auditability-accountability – a strong emphasis on the mainstream anticipatory approach is still prevalent and formalised in specific standards such as the COSO (2004) and the ISO 31000 (2009) ones.

In this study, we aim to go beyond theoretical-normative definitions and the mainstream approach in order to understand the way in which regulators frame risk management. Thus, we are looking to understand the point of view of the organisations in charge of monitoring and/or regulating the possible adverse outcomes of the regulated areas of human activity on the management of risk. As for the concept of risk, we need an open definition – not one pre-defined by a specific worldview on risk management – that can be filled in with empirical evidence. With these factors in mind, we define risk management as a process that:

- Aims to avoid, cope with and/or handle possible negative events;
- Is informed by informational input – e.g., data, sensations, impressions, perceptions and clues – about the on-going activities/phenomena that could be related to possible negative events;
- Results in tangible outputs – e.g., decisions, control measures, actions, laws and documents;
- Is evaluated as fitting in order to ensure the (perceived/fixed as) right degree of avoiding, coping with, and/or handling;
- Is hindered or favoured by the characteristics of the organisation in which the process is developed.

If we consider the different worldviews on risk management described above, all of them can fit within such a definition. For example, resilience – the capacity to bounce back – requires information input on ongoing activities and has actions and fitting decisions as outcomes in order to ensure the right degree of avoiding, coping with, and/or handling which, in this case, is to bounce back from danger. This process is favoured if the organisation developing the process is differentiated by some characteristics such as: technological flexibility (Collingridge, 1980; 1983; 1992); reluctance to simplify interpretations and encouragement of multiple and complex interpretations and strategic/scenario planning (Dervitsiotis, 2003; Seville, 2006; Weick and Sutcliffe, 2007); sound communication within (Horne, 1997; Horne and Orr, 1998; Oldfield, 2008; Seville, 2006) and outside the organisation (Seville, 2006).

In looking at the auditability-accountability worldview, the process is an adaptation between the available standards and on-going activities (informational input). The tangible output are the resulting fantasy documents appropriate for the purpose of coping with risk and reassuring public opinion on potentially risky activities. Such a process is favoured by some characteristics of the organisations in which the process is carried out such as the presence of internal or external auditing processes. If such different worldviews fit within the definition, we can be confident that the definition is broad enough to collect the empirical evidence, without pre-orienting the process by adopting a specific point of view on risk management.

Looking at the identified worldviews, their description constitutes a background for our analysis, but none of them was used as a starting point to define the research design or the development of the questionnaire submitted to the interviewed regulators. On the contrary, their identification and the discussion of their ontological and epistemological basis permitted understanding the need for being ‘open minded’, and trying not to fall prey to mainstream assumptions without leaving room for the presence of other interpretations and conceptions among regulators.

Using the term risk management in accordance with the risk definition given above, we refer to the management of the possible side-effects of human activities. In accordance with this study’s aim – maintaining the regulator’s point of view – we refer to:

- The direct risk management process developed within the regulating organisation, which targets as informational input the activities of the regulated organisations and as dealings outcomes, laws, bans on activities or products, guidelines, warnings, etc.;
- The indirect risk management process regulators promote and enforce as the right way of managing risk that regulated organisations should follow.

Risk management is in our case not an organisational process as the classic definition of risk management frames, but an inter-organisational process. Risk management as an organisational process is a procedure developed by an organisation in order to manage its own outcomes, thus the informational input originates within the organisation developing the risk management process. Risk management as an inter-organisational process is:

- Developed within an organisation whose informational input originates in other organisations – direct risk management;
- Defined in an organisation but developed in other organisations – indirect risk management.

Due to the transformation occurring in regulatory strategies from control-command to risk-based regulation – the next section is dedicated to an in-depth analysis of risk regulation. Risk management can become a crucial aspect of regulatory activities. Thus, direct and indirect risk management strategies developed by regulating organisations are a crucial element in the definition of the institutional logics shaping and shaped by these organisations. They are, therefore, a crucial element in order to understand ‘why the (watch) dog doesn’t bark’.

1.3 Risk regulation

We can define risk regulation as a way to avoid, cope with, and/or handle risk, which, unlike risk management, focuses on a higher politico-economic level. Thus, it goes beyond the possible negative outcomes of a specific organisation, dealing with the broad legislative frameworks organising human activities and fostering the roles and responsibilities of the different organisations involved in order to avoid, cope with, and/or handle possible negative outcomes. As stated in the previous chapter, direct and indirect risk management processes can be developed by regulators as part of their regulatory activities. Nevertheless, such management activities are part of a broader risk regulatory frame in which regulating and regulated organisations operate.

The regulation of the side-effects of human activities – the focus of this dissertation – addresses a more general trend affecting the regulatory strategies of today's (Western) societies. More specifically, scholars underscore the way in which regulation itself has generally become a way of managing risk leading to the involvement of private and public organisations in the definition of the regulatory framework in which they operate, on the one hand. On the other hand, they examine the spread of risk management and regulation strategies to areas of human activities not directly related to the traditional risk areas identified in the previous chapters (see Sections 1 and 2) such as financial and business, or technological risks. Power (1997; 2004a; 2004b; 2007) has called this trend the 'risk management of everything.' Thus, the regulation of the side-effects of human activities has been affected by a more general trend regarding the spread of risk and risk management frames among the regulatory strategies in different areas of human activities (Power, 1997; 2004a; 2004b; 2007; Clark, 2000; Moran, 2003; Hutter, 1997; 2001; 2006; 2010). The purpose of this section is to describe such general trends locating the regulation of the side-effects of human activities within such a trend.[29] First, the meaning of the concept regulation and the way in which it has changed over time is examined. Then the key differences between previous regulatory strategies – the control-command approach to regulation – and the risk-based regulatory strategy, which emerged in the mid-1990s, are discussed. The section that follows is dedicated to a summary of the

[29]Risk regulation literature has become extremely broad during the last few years. The purpose here is to offer a selective summary of such literature focusing on the aspects that are more relevant with reference to the focuses of this dissertation: the regulation of side-effects and the regulators' point of view.

general trends associated with the spread of a risk-based approach to regulation considering the identification of new actors, roles and responsibilities. Subsequently, we focus on the contributions that look inside broader concepts such as risk-based regulations exploring other levels of analysis and recognising the variability still affecting the regulation of the side-effects of human activities between nation-states, and between different regulatory domains within the same nation-state. In conclusion, we specify how such elements – general trends and variability – fostered the definition of the research design as well and the case selection in this dissertation.

Risk regulation: the meaning

An overall vision of the available literature on regulation allows us to gain a better understanding of the development of the regulation concept and its relatively recent association with the concepts of risk and risk management. More specifically, the development of the concept of risk regulation mirrors a not new and more general issue in social sciences: the relationship between the object of study and the way in which such an object is studied. The concept of risk regulation reflects a change in the actual regulatory strategies and practises, as well as a change in the way in which scholars look at these regulatory strategies and practises. This process leads to the definition of new concepts as well as to the attribution of new meanings to existing one. Such a conceptual turn allows scholars, on the one hand, to see new trends, and on the other, to acknowledge certain aspects that are not fully understood of existing phenomena.

With reference to the attribution of new meaning to existing concepts, the social science definition of regulation has experienced important changes during the last 50 years. Hutter (2006: 202-205), in particular, identifies four main broad definitions of regulation that over the years have been associated with such a concept (see Table 3):

- Regulation as the promulgation of authoritative rules – from 1900 to the 1940s;
- Regulation as the efforts of state agencies to steer the economy – from the 1950s to the 1970s;
- Regulation as organised social control – from the 1980s to the 1990s;
- Regulation as the control of risk – from the mid-1990s until now.

Moving from the first definition to the last one, the meaning of regulation becomes more inclusive and the sources of regulation become increasingly complex and articulated. For example, the first two definitions narrow the sources of regulation to direct state intervention. In contrast, the second two definitions open the field to other sources of regulation including both state as well as non-state actors.

Years[30]	*Definitions*	*Fields*
1900-1940s	Regulation as the promulgation of authoritative rules	Law Sociological legal studies
1950s-1970s	Regulation as the efforts of state agencies to steer the economy	Economics Political Science
1980s-1990s	Regulation as organised social control	Sociology Socio/legal studies
mid-1990s	Regulation as the control of risk	Political Science Socio-legal studies Sociology Social Psychology

Table 3: Definitions of regulation over time (Adapted from Hutter, 2006: 203.)

The definition of regulation as 'attempts to control risk' (Hood et al., 2001: 3) allows scholars to identify a different approach to regulation characterising today's society, which can be defined as a risk-based approach. The characteristics of such an approach to regulation can be identified in opposition with the control-command approach characterising the regulatory definitions/practises before the mid-1990s (Power, 1997; 2004a; 2004b; 2007; Clark, 2000; Moran, 2003, Hutter, 1997; 2001; 2006; 2010).

The control-command approach defines regulation as an activity performed exclusively by the state mainly through the emanation of laws. This approach is a balance between two complementary instruments: 'command' through the law's emanation, and 'control' through the actions of the legal authority of the state (Kagan, 1978; Hutter, 2001). This approach is based on a strong separation between state and market: the target of regulation is the market and the regulatory authority of the economic activities is the state. The market actors are expected to follow the rules defined by the state, and not to develop their own rules – this in contrast with the risk-based approach. The responsibility of market actors is to conform to the rules

[30] The indicated years refer to the period of time in which the definition was introduced. But different definitions still coexist.

without a consideration for evaluating the actual efficacy of such rules, thus without any direct responsibility on the outcomes of their own activities. Focusing on the regulation of the side-effects of human activities, the control-command approach, on the one hand, bans the specifically dangerous products or activities and, on the other hand, defines rigid parameters regarding the way in which such activities must be carried out. For example, in order to transport dangerous good by road they have to be transported in containers designed following specific measurements and constructed with specific materials, etc. The transporters have to be sure to be compliant with such design definitions; they mustn't question the efficacy-effectiveness of such design details in order to ensure the safe transport of the dangerous goods. The main purpose of the regulatory activity is avoiding side-effects and the responsibility of such avoidance relies on the state by means of the emanation of rules. The side-effect producers are not responsible for the avoidance of such side-effects, but they are responsible for conforming to such legally state-defined rules. State enforcement of such rules, when infringed upon by side-effect producers, is legally upheld through fines or detentions, for example: thus, through punishment for non-compliance.

Following the risk-based approach, regulation is a way of controlling risk, and thus of evaluating and managing it. The instruments are not laws, rules and punishment, but the definition of processes to follow. It is, therefore, not designed to fix a specific way of doing things, but to define processes allowing regulated organisations to develop and enforce the rules they have created, as well as to delineate auditing and accounting strategies to verify conformity with such processes (Power, 2007). For example, following the risk-based approach, the transport of dangerous goods is regulated through the definition of a process the transporters have to follow in order to guarantee that the transport activity does not lead to side-effects. State enforcement strategies, usually put into practise by public agencies relate to compliance with the identified process of management and not to the efficacy/effectiveness of the process. The COSO (2004) and the ISO 31000 (2009) standards described above (see Section 2) are expressions of such regulatory strategies: these standards define a process to follow in order to evaluate risks, but do not define the content through which the regulated organisations have to fulfil these processes.

Thus, risk-producers are responsible for their own risks and the state has a role in the definition of the management process they should follow, but has no direct responsibility on the avoidance of side-effects; this responsibility is placed on the regulated organisations. The strong separation between state and market is less defined and the market actors are involved in the regulation as well. For example, through the analysis of the regulation of railway occupational risk, Hutter (2001) underlines that the regulation of different areas of human activities have progressively become closer to risk management moving away from a control-command approach to regulation. Risk regulation as a process of risk management tries to manage the regulated areas of human activities in order to stay inside defined/acceptable boundaries rather than to eliminate risk or describe the way in which to carry out these activities in detail. Moreover, responsibility to define these boundaries relies on the regulated organisations that are fully involved in the regulatory activity. In this sense, the analysis of the regulation of railway occupational risk in the UK highlights the major involvement of the regulated organisations – railway companies – in the regulation of occupational risk as the factor that has led to a transformation in the purpose of risk regulation strategies, locating the regulation of risk within the company, and placing occupational risk within the risk management strategies of such companies; thus within the trade-off between production and protection. Therefore, through the development of a risk-based approach, the aim of regulation has become the control of risks through establishing management processes involving regulators and regulated organisations, rather than implementing bans and punishing rules about what can and cannot be done: 'the purpose of regulation is to manage rather than to eliminate risks' (2001: 314) [and] 'the management of risk is what regulation is all about' (2001: VII).

The risk-based approach to regulation is not linked to the phenomena traditionally bound under the concept of risk such as financial, business, or technological risks. In contrast, such a regulatory approach has progressively spread around to 'new' areas of risk, and to other phenomena not directly linked to the original meaning of risk, but that have started being seen from the risk-based frame. Scholars highlight how the risk and risk management regulatory frame has progressively colonised the regulatory approach of today's society (Power, 1997; 2004a; 2004b; 2007). For example, Power (2004a: 2) in distinguishing between first-level and second-level risk within the context of financial risk, underlines as 'the primary risk – financial risk – that the financial statements are materially misstated, has come to be thought of also in terms of a secondary risk, the risk of financial and reputational losses to auditors.'[31] It should thus be regulated accordingly as stated, for example, in

[31] Another example can be the definition of actuarial risk which, in considering the second-level risk of insurance risk defines 'the risk that the assumptions that actuaries implement into a model to price a

international standards on banking regulation such as Basel 2 (2004) released by the Basel Committee on Banking Supervision. Table 3 sums up the differences between the risk-based and the control-command approach, looking specifically at the focus of this dissertation: the regulation of side-effects of human activities.

	Control-command	*Risk-based*
Regulatory focus	Rules/Law	Processes
Responsibility on side-effects regulation	State	Side-effect producers
Side-effects approach	Avoidance	Evaluation/Management

Table 4: Control-command vs. risk-based approach to the regulation of side-effects (My elaboration.)

The scheme that goes from a control-command to a risk-based approach to regulation has resulted in important changes affecting the regulation of areas of human activity in order to avoid, cope with, and/or handle the possible negative outcomes – side-effects – of such activities. Looking selectively at risk regulation literature, we can identify elements specifically relevant to the focus of our analysis – regulation of human activities in order to avoid, cope with, and/or handle the possible negative outcomes of such activities while maintaining the point of view of regulators. The next sections are dedicated to an examination of the elements within risk regulation literature, which have played a crucial role in defining the research design and the selection of the case of the Italian Railway Sector from the population of the regulatory networks.[32] More specifically, they deal with:

- The general trends associated with the spread of a risk-based approach to regulation regarding the identification of new actors, roles and responsibilities, usually grouped under the concept of 'regulatory state' (Majone, 1994);

specific insurance policy may turn out wrong or somewhat inaccurate' (http://www.investopedia.com/terms/a/actuarialrisk.asp, Website consulted 11 February 2013).

[32] The identified elements are of course not the only significant ones within the risk regulation field of study. Other important developments refer to, for example, the democratisation and the trans-nationalisation of risks. For further information see, for example, Hutter (2006; 2011).

- The identification of other levels of analysis and the recognition of the variability of existing risk regulatory approaches, as well as of a more blurred situation with respect to the contraposition between the risk-based vs. control-command approach to regulation.

A general trend toward risk-based regulation

Scholars highlight that the transition from a control-command to a risk-based approach to regulation has fostered the definition of new actors, as well as a different distribution of roles and responsibilities between these actors. This re-configuration has led to the formation of the actors, which this study aims to focus on. In particular, non-majoritarian organisations – differing from the Ministry and located outside the classical state bureaucracy – in charge of regulating the possible adverse outcomes of areas of human activity at different levels of government – national and supra-national – but not involved in the core activity of the regulated domain have emerged. In addition, it has fostered the network of private and public organisations located at different levels of government that this study aims to focus on, which render the analysis of the inter-organisational level relevant: within a network, the relationships between regulators, as well as between regulators and regulated organisations become specifically relevant. Let us look closely at the highlights of previous work conducted on this issue.

As already mentioned, the recognition of the role of risk as an 'organising concept for regulation within and beyond the state' (Hutter, 2006: 210), allows scholars to identify new trends affecting regulatory processes. Furthermore, the inclusive nature of the definition of regulation as a way to control risk allows us to overcome some traditional dividing lines of regulation studies; namely, the distinctive role of the state compared to that of private organisations, as well as the boundaries between the state and the market. The starting point of this general shift of perspective on regulatory processes is the introduction of the concept of the 'regulatory state' (Majone, 1994). The concept of 'regulatory state' was first proposed by Majone (1994) in the context of the European Union, and then extended to embrace other areas and levels of government, such as national and global ones. This concept is an analytical construct that aims to keep together some general changes in the nature and function of the state, as well as in the style of governance (Yeung, 2010). Even if scholars disagree on the reasons for such a general transformation (See, e.g. Baldwin et al., 2012), as well as on the extent to which such a concept can be generalised – for example, Yeung (2010) suggests referring to 'regulatory states' instead of 'regulatory state' – the core shift identified by such a concept is broadly accepted and recognised.[33] In particular, the 'regulatory state' encapsulates five main shifts:

- The regulatory state represents a shift from equity to efficiency (Baldwin et al., 2012). After the Second World War through the Cold War period, states focused on reconstruction, economic stabilisation (e.g., Majone, 1997), as well as on the control of strategic resources such as infrastructure and energy. Thus, many states exerted direct ownership of key industries and public utilities. From the 1980s, a growing programme of privatisation and, more generally, of efficiency followed. In Britain, such trends are grouped under the label of 'New Public Management.' In this context, the search for efficiency led to the application of business and management tools, historically linked to private organisations, to public agencies and state bureaucracies (Hood, 1991; James, 2001; Yeung, 2010). This privatisation and the efficiency programmes led to important changes in state behaviour. More specifically, the states progressively transferred the ownership of many public utilities to the private sector, or undertook measures to keep such public suppliers of services and goods more reactive to competitive market logics. The role of the state changed accordingly: '[the] state's function had shifted from that of rowing to steering' (Osborne and Gaebler, 1992: 25);
- The regulatory state relies on a proactive role of private companies in the regulation of their own activities, shaping the so-called, public role for the private sector (Haufler, 2001). In following such self-regulatory trends, 'the firms have the full responsibility for their activities' (Aven, 2011: 513). However, such regulated organisations are also fully involved in the regulatory decisions as well as in the definition of standards and processes. Consequently, the regulated organisations function 'as insiders in knowledge production rather than as lobbying outsiders' (Power, 2005: 582).
- The regulatory state regulates through non-majoritarian regulatory institutions (e.g., Thatcher and Sweet Stone, 2002): bodies detached from a direct ministerial direction (Burton, 1997). These bodies are supposedly out of the

[33]The available literature on the 'regulatory state' as well as on its implications on governance, management, accountability and democracy is almost endless. The purpose here is to acknowledge and summarise the agreed upon and broadly accepted statements by scholars as general trends of today's regulatory activities. A full reconstruction of the broader scholars' debate on the regulatory state is beyond the scope of this dissertation. For further highlights see, for example, Majone (1994), Moran (2003), Yeung (2010), and Baldwin et al. (2012).

political arena and not under electoral pressure. In contrast, such technical-focused and freestanding bodies are shaped by expertise, specific knowledge, and specialisation, overcoming the strength of previous ministerial bureaucracies. Non-majoritarian agencies have spread quickly at different levels; national and supra-national as well. For example, the EU counted thirty-one different agencies in 2012 (Baldwin et al., 2012).[34]

- The regulatory state governs at a distance (e.g., Yeung, 2010), changing the role of the state from direct supplier to overseer. The instruments used to fulfil states' regulatory and management activities can no longer be the hierarchical, discretional, unilateral, and direct surveillance linked to ownership – control-command (Power, 2005). Thus, state 'reliance on more arm's length forms of oversight' (Yeung, 2010: 67), establishing general principles, and leaving the judgement on the practical translation and monitoring of those general principles to other organisations – public agencies and private companies, mainly through risk management tools (Hutter, 2001).
- The regulatory state shows a fragmentation of regulatory activity through networks of public and private actors (e.g., Estache and Wren-Lewis, 2010). Such a broad process leads to placing regulatory activities at different levels of government; thus, shifting management and regulation upward – to supra-national and international organisations – and sideways – to specialised agencies detached from ministerial departments, as well as the regulated organisations themselves. As a consequence, 'most domestic regulatory regimes rely on different levels of government for standard-setting, behaviour-modification, and information-gathering' (Baldwin et al., 2012). In addition, the roles of public non-majoritarian agencies become complex and articulated. More specifically, public agencies become responsible for fixing standards and rules to control the dangerous and unintended consequences of the regulated organisations' activities; enforcing self-regulation processes among the regulated organisations (Braithwaite, 1982; Ayres and Braithwaite, 1992) and coordinating the activities of the regulated and regulators operating at different levels (Braithwaite, 2003).

[34] For example, the European Chemical Agency, European Marine Safety Agency, European Medicine Agency, European Food Safety Authority, Agency for the Cooperation of Energy Regulators, and the European Centre for Disease Prevention and Control.

In conclusion, scholars highlight important changes affecting regulatory activities. These changes shape new actors – non-majoritarian regulatory institutions – as well as new roles for already existing ones – states and private companies. Consequently, regulation becomes a collective activity carried out by networks of public and private organisations located at different levels of government – national and supra-national. In this context, in order to understand how regulation works becomes extremely relevant to understand the way in which regulators – non-majoritarian agencies – frame and put into practise the broad regulatory framework that they are part of. In addition, it is crucial for understanding the focus on the relationships between the different organisations involved and the coordination between them – inter-organisational level – which are the focus of this study. For example, if we look at the EU, different areas of human activities are regulated through 'decentralised agencies', that is, non-majoritarian state agencies. Such agencies 'carry out technical, scientific or managerial tasks that help the EU institutions make and implement policies. They also support cooperation between the EU and national governments by pooling technical and specialist expertise from both the EU institutions and national authorities.'[35] Today, the 'decentralised agencies' are thirty-six. Among them, the agencies dealing formally with the regulation of human activities in order to avoid, cope with, and/or handle the possible side-effects of such activities are six: European Aviation Safety Agency (EASA), European Chemicals Agency (ECHA), European Food Safety Authority (EFSA), European Maritime Safety Agency (EMSA), European Railway Agency (ERA), European Agency for Safety and Health at Work (EU-OSHA).

Looking at the regulatory network of such areas of human activities, three of them fit within the identified trends: European Aviation Safety Agency (EASA), European Maritime Safety Agency (EMSA), and European Railway Agency (ERA). The regulation of the chemical sector does not present regulatory agencies at the national level; this level is still exclusively within the competence of the ministries of the various EU Member States. The food sector as well as the occupational risk sector present a variable situation between Member States, some adhere to the dedicated agencies while others leave regulation to national ministries. Even if different examples that fit within the general trends highlighted above are identifiable, scholars looking closely at the difference between nation-states, or between regulatory domains within the same nation-state, underscore how the regulatory

[35] http://europa.eu/about-eu/agencies/index_en.htm, Website consulted 10 February 2014.

approaches can be affected by variability. In addition, they show an overlapping between the control-command and the risk-based approaches to regulation instead of a clear orientation toward one approach or the other. This space of variability/overlapping is examined in-depth in the next section.

Variability within and between nation-states

A crucial factor for broadening the understanding of risk regulation promoted by some scholars within the risk regulation fields relates to remembering that 'overarching theories of risk and its management need to be modified or supplemented to account for […] variations' (Hood et al., 2001: 3). More specifically, risk regulation studies stress the importance of looking within the macro concepts of 'risk society' (Beck, 1992), 'audit society' – risk management of everything – (Power, 1997; 2004a; 2004b; 2007), and 'regulatory state' (Majone, 1994), as well as the need to understand the contents and context-specific nature of risk regulation and management empirically (Hood et al., 2001). Consequently, the debate on risk regulation and management has moved down from the high-level overarching theories focusing on the differences, rather than on the similarities between regulatory approaches. Thus, states (Jasanoff, 2005a; 2005b; Rothstein, 2012), as well as risk regulation domains within the state (Hood et al., 2001) have become key objects of empirical research.

Since the beginning of 1990s, the contribution given by qualitative social sciences research in increasing the understanding of risk, and of the limits of risk analysis and regulation,[36] has been extremely relevant. Jasanoff (1993) has introduced the concept of 'contingency' or 'context-dependency' as a key dimension of risk management and regulation.[37] An understanding of the contingent nature of risk knowledge is linked to the recognition that scientific knowledge in itself is neither as objective nor homogeneous as broadly believed. (See also Jasanoff, 2000; 2005a.) A major

[36]For a definition of risk analysis see the anticipation approach to risk management described in Chapter 2.

[37]The author also identifies two other dimensions: 'scale' and 'interactivity'. The 'scale' dimension refers to the spatial, temporal and distributive parameters that are subjected to a size choice in risk analysis affirming that if the chosen scale is too small or too large, it can prevent an accurate estimation of risk. 'Interactivity' refers to the interactions between nature and society. Such interactions are often underestimated, not fully considered, or not visible during a process of risk evaluation.

consequence of the contingent nature of risk knowledge 'is that what people claim to know about risk is in fact constructed in different ways in different political and cultural settings' (Jasanoff, 1993: 128-129). Thus, to increase the understanding of risk regulation and management, scholars underline the need to look closely at cross-national as well as within-national differences (Jasanoff, 1993; 1998; 2005a; 2005b; Hood et al., 2001; Rothstein et al., 2012).

With reference to cross-national differences, comparing three states – the US, the UK and Germany – Jasanoff (2005a) shows how the relationships between state, science, and society shape the cultural specificities of the politics of biotechnology in different nation-states. The author defines such culturally-specific and historically-grounded public-knowledge-ways as civic epistemologies. This concept stresses that 'there are shared understandings about what credible claims should look like and how they ought to be articulated, represented, and defended. These understandings vary across well-defined cultural domains such as nation-states' (Jasanoff, 2005a: 249). Therefore, the way in which risk is framed, presented and accepted in a specific public and political arena changes according to the specific public-knowledge-way shared by that arena.[38] Consequently, risk regulatory strategies vary according to the cultural and political context in which it is developed.[39]

With reference to the within-state differences, Hood et al. (2001: 6) highlight that 'even more striking than these differences between states in handling a given hazard are variations in the ways risks and hazards are handled across policy domains within the same country.' In order to describe, compare and explain such variations within a state and between domains, the authors introduce the idea of the risk regulation regime. The term regime denotes 'the complex of institutional geography, rules, practises, and animating ideas that are associated with the regulation of a particular risk or hazard' (Ibid.: 9). In order to better qualify the concept of regime, as well as to guarantee a systematic empirical translation of the concept, the authors describe the 'anatomy of regulatory regimes' (Ibid.: 21). More specifically, they identify two dimensions through which different regimes can be classified and distinguished. On the one hand, the three main dimensions of a control system: standard-setting, information-gathering, and behaviour-modification are delineated. On the other, the

[38]Jasanof (2005b) uses the same analytical framework to analyse the post-event reaction in India – Bhopal – the UK – BTE disease – and the US – 9/11 terroristic attack.

[39]The research of Rothstein et al. (2012) goes in the same direction stressing that the definition of risk and the application of risk-based governance vary substantially across Europe: the UK, France and Germany are examined.

distinction between context – the setting or state of the world in which the regulatory activity is in place – and content – the policy choices and the configuration of the state and of other organisations involved in the regulatory process – of a regulatory regime are stressed. Table 5 links and summarises this analytical definition of risk regulation regime.

	Information gathering	*Standard setting*	*Behaviour modification*
Context: e.g., type and level of risk being tackled, nature of public and media attitudes, configuration of lobbies and organised interests	Example: risks individuals can assess at low cost vs. risks assessable only by professionals or at high cost	Example: risk involving high stakes for organised groups vs. risks with no lobby groups	Example: risks where mass public opinion resists state control vs. regulation 'with the grain' institution-based
Content: e.g., regulatory stance, organisational structure, operating conventions and regulator attitudes	Example: active vs. passive information-seeking by regulators	Example: cost-benefit vs. technical feasibility approaches to goal setting	Example: price signals vs. command approaches to control

Table 5: Control components and regulatory regime content and context (Hood et al., 2001: 22)

The analytical definition is then used to examine nine different domains: for example, an attack by dangerous dogs outside the home, an attack on children by convicted paedophiles released from prison, injuries and death from motor vehicles on local roads and adverse health effects from exposure to pesticide residue both in food as well as in drinking water. A key result of such an analysis indicates the contraposition between a control-command and a risk-based approach to regulation. The analysis shows that the control-command and risk-based approaches described above are both present as regulatory strategies. Some regulatory domains currently show a tendency to a control-command regulation, rather than a risk-based one. In addition, the analysis highlights how the control-command and risk-based approaches can be seen as located on the extreme of a continuum on which the regulation of specific risk domains can be located, showing a hybrid, rather than mutually exclusively approach to regulation.

In brief, Hood et al. (2001) and Jasanoff's (2005a; 2005b) work show the variation affecting the risk regulation regimes within and across nation-states. This statement means recognising the variations affecting the risk regulatory strategies, as well as their cultural and political foundations. In addition, it provides a more blurred view on the general trends associated with the mid-1990s risk-based shift regarding regulation.

Risk regulation in this dissertation

The previous sections shows how available studies about risk regulation highlight:

- General trends affecting different areas of human activities moving to a risk-based approach to regulation;
- Some structural/organisational characteristics – roles, responsibilities, new actors – linked to such trends, leading to the configuration of multi-level – national and supra-national – networks, with regulators and regulated organisations interacting between them, dedicated to risk regulation;
- The variability affecting risk regulation strategies between nation-states, as well as within nation-states between different regulatory risk domains, showing the relevance of cultural and political factors in the definition of risk regulation regimes.

Now let us focus on the role played by such statements in the definition of the research design:

- The emergence and diffusion of a risk-based approach to regulation guided our choice to focus on a case that 'on paper' is as close as possible to this trend. We focus on the risk-based approach to the regulation of human activities in order to avoid, cope with, and/or handle the possible side-effects of such activities. The case selection was based on the structural/organisational characteristics related to a risk-based approach to regulation identified above, mainly: the involvement of private organisations in regulatory activities (Haufler, 2001; Power, 2005; Aven, 2011); the presence of regulating organisations with a specific technical-scientific orientation, but out of the political arena and electoral pressures (Burton, 1997; Thatcher and Sweet Stone, 2002; Baldwin et al., 2012); and the existence of organisations located at different levels of government dealing with the same regulatory areas of activity (Estache and Wren-Lewis, 2010;

Baldwin et al., 2012). We identify a case as close as possible to those characteristics, thus some of the concepts and ideas developed here could in principle, be useful to understand a broader and increasing population of cases. Following these criteria, the case of the Italian railway sector was selected.[40]

- The identification of such trends shows how from an organisational point of view, the risk-based approach to regulation of the possible side-effects of human activities fosters a specific organisational configuration: a multi-level – national and supra-national – network of organisations – regulators and regulated – interacting in order to avoid, cope with, and/or handle the possible negative outcomes of the regulated domain: in our case, railway transportation. Within this network, we aim to maintain the point of view of regulators – in our case the European Railway Agency, at the supra-national level of government, the Italian National Safety Authority and the Italian National Investigation Body, at the national level of government. Consequently, in order to understand the regulation of risk within such a network, the coordination between organisational actors becomes extremely relevant. Thus, we look closely at the ways in which regulators coordinate their interactions as well as the interactions between regulators and regulated organisations – in our case: for example, infrastructure managers, railway undertakings, suppliers and entities in charge of maintenance;
- Considering the two statements about the growth of a multi-level network configuration dealing with risk regulation, and the variability of risk regulatory approaches according to cultural-political factors affecting, for example, nation-states, it is important to look at the variation within the network. For example, between the supra-national and national level, the within-network variation could be extremely relevant for understanding the way in which regulatory activities work;
- We define risk regulation as a possible way of avoiding, coping with, and/or handling the possible side-effects of human activities, thus we focus on all the processes, decisions and actions the regulators put into place in order to avoid, cope with and/or handle risk. Previous studies underscore an overlapping between risk management and risk regulation (e.g., Hutter, 2001; Power, 2007). Here such overlapping relates to two specific phenomena

[40]The case selection is described in-depth in Part 2 of this dissertation.

identified above. (See Section 2.) On the one hand, the direct risk management process developed within the regulating organisations which target the outcomes of the regulated organisations as informational input, process these informational input, and elaborate tangible output in order to avoid, cope or handle such side-effects – for example, organisational processes, laws, bans of activities or products, guidelines, warnings, etc. – is considered. On the other hand, the indirect risk management process that regulators promote and enforce – the expected outcomes and process definitions as the right way of managing risk that the regulated organisations should follow in managing their risk – is taken into account. Direct and indirect risk management can be considered as part of the regulatory strategies developed by regulators. An examination of the high-level approach to regulation, developed by the studied network, is considered looking at the politico-economic level. The direct and indirect risk management processes are addressed looking at the inter-organisational level of analysis.

Consequently, we need a theoretical-analytical framework allowing us:

- To keep together different levels of government – national and supra-national – while leaving room for variability – contradictions and/or overlapping;
- To ensure an in-depth understanding of the processes, interactions and coordination strategies shaped by such organisations, as well as of the cultural and cognitive basis of such processes, interactions and coordination strategies.

The institutional logics perspective (Alford and Friedland, 1985; Jackall, 1988; Friedland and Alford, 1991; Thornton and Ocasio, 2008; Thornton, Ocasio and Lounsbury, 2012) satisfies these requisites and is the theoretical-analytical framework guiding the empirical analysis. The next chapter is dedicated to a description of this perspective.

2. INSTITUTIONAL LOGICS PERSPECTIVE

The emergence of the institutional logics perspective is linked to dissatisfaction with the available institutional theories which instead of resolving, highlight the dichotomy between individuals and society, and action and structure that historically has affected the social sciences. Institutional theories define institutions as ‘rules, norms, and beliefs that describe reality for the organisation, explaining what is and is not, what can be acted upon and what cannot’ (Hoffman, 1999: 351). Institutions are taken-for-granted facts that constrain individual action through ‘stable designs for chronically repeated activity sequences’ (Jepperson, 1991: 145). Following such a definition, institutions constrain and determine individual perceptions and behaviour without any possibility for individuals to retroact on institutions and modify or interpret them. Consequently, a static and deterministic view of society prevails. In contrast, the institutional logic concept allows individual agency to be introduced within institutional theories, as well as the deterministic features of institutions to be blurred.

More specifically, the institutional logic perspective aims to find a way of keeping together action and structure through the definition of an analytical mechanism linking individuals and institutions: a mechanism explaining how institutions constrain individual agency but, at the same time, how individuals retroact on institutions legitimising or modifying them. This analytical bridge between institutions and actions is the institutional logic concept. The institutional logic analytical bridge allows for the change of institutions’ content, as well as individual agency to be conceived and explained. However, embedding this agency within historically available institutional orders, allows the constraining role of institutions to be recognised as well. Institutional logic is the mediating concept that ‘position[s] individuals and organisations in society’ (Friedland and Alford, 1991: 242).

As a first approximation, institutional logics can be defined as worldviews (Flighstein, 1990), frames of reference (Thornton et. al., 2012), and conceptual lenses (Allison and Zelikow, 1999) through which reality is seen, defined and interpreted (Ocasio, 1995; 1997; Thornton and Ocasio, 1999; Thornton, 2002; 2004; Glynn and Lounsbury, 2005; Lounsbury, 2007). Institutional logics are linked with the institutional orders they are promoted by, but differ from the institutions being adapted and combined by actors, given the specific context in which they act. Institutional logics keep together a symbolic, as well as a material nature. More specifically, the logics are composed by symbolic elements such as, for example, values, beliefs, assumptions, as well as material ones, such as, for example, structures, practises, and organisational processes. The logics constrain and limit individual actions, for example, through defining legitimate ends to pursue and linking those ends with specific means to reach them formalised in structures and processes. They also identify the values to refer to in order to make decisions, as well as the categories and associated meanings through which reality is defined and interpreted (Friedland and Alford, 1991). All at once, logics are promoted and created by individuals' actions and interactions that can stabilise and legitimise, or modify and change them. This retroaction is possible because the available institutional logics are multiple, in contrast amongst themselves, and individuals can recombine such available scripts and adapt them to the context in which they are acting. Over time, such a recombination can acquire legitimacy through individual action and promotion, and even stabilise other institutional orders, or modify the available ones. Thus, individuals can simply apply the available logics as taken-for-granted facts, and in doing so confirm and stabilise institutions. Alternatively, they can combine different elements promoted by the available logics, or adapt the available logics to the specific context in which they are acting. In this way, they define new frames of reference over time, retroacting on institutions and, in some cases, changing them (Jackall, 1988; Friedland and Alford, 1991; Thornton and Ocasio, 1999; Thornton et al., 2012).

As Thornton, Ocasio and Lounsbury (2012: 1) underline, 'the concept of institutional logic is intuitively attractive, but arguably difficult to define and even harder to apply in an analytically useful manner.' More specifically, such intermediate features as a bridge between institutions and actions, as well as the analytical nature of the concept *de facto* lacking a clear empirical reference, renders a definition of the concept difficult without considering the theoretical-analytical framework in which it has been introduced. Thus, we prefer to examine some of the theoretical-analytical cornerstones of the perspective, before turning back to the institutional logic definition driving the empirical analysis presented here. First, we describe the core meta-theory on which the concept of institutional logic is embedded. The description of this core meta-theory layering under and sustaining the institutional logic concept allows the theoretical viewpoint of this dissertation to be clarified as well. Thus, it allows us to specify the conceptual lens (Allison and Zelikow, 1999) we wear in order to analyse the logics of risk regulation and management available within the railway regulatory network. Later on, we describe a characteristic of institutional logics specifically relevant to the question this study aims to answer, 'Why doesn't the (watch) dog bark?': the focus of attention. In conclusion, we turn back to the definition of institutional logic, specifying the different analytical components of the institutional logic concept we aim to fill with content empirically, through the analysis of the regulatory railway network's logics of risk regulation and management.

2.1 The core meta-theory

The institutional logics perspective arises within a context of general dissatisfaction with reference to the limits affecting the available institutional theories (Meyer and Rowan, 1977; 1983; Zucker, 1977; Di Maggio and Powel, 1983; Mayer and Scott, 1983; Tolbert and Zucker, 1983). More specifically, two key limits of the available theories on institutions are perceived as in need of being addressed by institutional scholars themselves. On the one hand, the imbalance in favour of the deterministic role of institutions that does not leave room to theorise agency and change (Di Maggio, 1988). On the other hand, the focus on the structural dimension of institutions that does not explain and integrate the role of culture and cognition in the legitimising and spreading processes of common institutional patterns (Powell, 1991). However, the role of institutions is still recognised as a key element in order not to reduce the social dimension uniquely to the individual. An acknowledgment of the limits affecting institutional theories, as well as dissatisfaction for available alternatives – imbalance toward individuals to the detriment of society – constitute the fertile ground on which the institutional logics perspective begins to take shape. Between the various contributions that followed such statements, Flighstein's (1990) analysis of the conceptions of control guiding the governance of large industrial corporations, and Di Maggio's (1991) study of the organisational field of art museums constitute two key empirical precursors of the institutional logic perspective.

Both Flighstein (1985; 1987; 1990) and Di Maggio's (1991) empirical works are in close continuity with Di Maggio and Powell's (1983) institutional approach. However, they go a step further in the study of organisational fields' structuration, showing the path toward the institutional logic perspective. Di Maggio and Powell's (1983) work itself represents a development of the isomorphism theory (Meyer and Rowan, 1977). The isomorphism theory's starting point is the statement that formal organisational structures (goals, policies, formal roles and responsibilities settled within organisational charts etc.), spreading within the institutional environment in which organisations operate, do not respond to the technical needs of organisations of pursuing efficiency in order to be competitive in the market. Thus, the main question the theory aims to answer arises: if the homogeneity of organisational structures does not respond to the need of efficiency in absolving the organisations' technical mission, what is the actual reason for such an isomorphic approach on organising?

Meyer and Rowan's (1977) answer is that the sources of the stated isomorphism are the cultural myths and symbols that are identified as the legitimate way of doing things, within the institutional environment in which those organisations operate. Consequently, in order to survive the organisations should show compliance with those institutional myths and symbols promoting the diffusion of specific organisational forms: 'organisations are driven to incorporate the practises and procedures defined by prevailing rationalised concepts of organisational work and institutionalised in society. Organisations that do so increase their legitimacy and their survival prospects, independent of the immediate efficacy of the acquired practises and procedures' (Meyer and Rowan, 1977: 340). The institutional sources of legitimisation of the organisational forms are mainly two: state and profession, which are the two main sources of rationality affecting modern society as well. The level of analysis includes the entire society defined as the institutional environment in which organisations operate.

Di Maggio and Powell (1983) propose a variant of Meyer and Rowan's theory looking at a differing level of analysis, the organisational field instead of the institutional environment; and focusing on the structure and structuration process within the field rather than on culturally taken-for-granted social myths and symbols.

The organisational field is composed of 'those organisations that, in aggregate constitute a recognised area of institutional life: key suppliers, resources, product consumers, regulatory agencies, and other organisations that produce similar services or products' (Di Maggio and Powell, 1983: 148). Differing from isomorphism theory, even if they recognise that the pursuing of efficiency for market competition is not the only source of isomorphism, they still identify the market as one of the possible sources of legitimacy, promoting the structuration of an organisational field toward a specific organisational structure: this kind of isomorphism is called mimetic isomorphism. Mimetic isomorphism considers the imitation of organisational forms that have been successful within the market. Nevertheless, the market is not the only available source of legitimacy and rationality. In contrast, the state and the profession are considered as playing a crucial role in the structuration process as well. The isomorphism promoted by the state is a coercive one: it is linked with political power and cultural expectations (e.g. regulations or laws) that lead to the structuration of an organisational field in order to be compliant with the social requirements prevalent within the field. The isomorphism promoted by the profession is linked with professional values and socialisation: the professionalisation of the field is identified as the main source of normative isomorphism. The three institutional orders – market, state, and profession – represent different sources of legitimacy pushing toward the adoption of specific organisational forms within a given organisational field and leading to the isomorphism of such an organisational field.

Flighsteins's (1985; 1987; 1990) study of the large industrial corporation shows the key role of the corporation's institutional order in structuring the organisation of large industries. In so doing, the role of institutional orders differing from market, state, and profession in structuring modern society, is stated for the first time. The importance of various institutional orders in the structuring of context-specific logics is one of the key elements stressed by the institutional logics perspective as well. In addition, looking within the corporation's institutional order, the author identifies three competing conceptions of control driving the governance of large industrial corporations: the manufacturing, sales, and finance conception of control. Thus, it shows that an institutional order can promote different definitions and conceptions of power linked with different practises. Flighstein (1990: 295) defines the conceptions of control as 'worldviews that define one firm's relationship with others, what appropriate behaviours is for firms of that type, and how those kinds of organisations ought to work.' The definition shows us that even if the term institutional logic is not yet used, the definition of conception is quite close to the one of institutional logic. The statement that three different conceptions are available and such conceptions conflict between them in order to foster the structuration of the large industrial corporations' field, leaves room for plurality, conflicts and interactions. Thus, it opens the institutional field to variability, and overtakes the static and deterministic picture given by Meyer and Rowan (1977) and Di Maggio and Powell's (1983) theories. In so doing, Flighstein's study opens the door to different form of rationality leading to the recognition of different possible and contending ways, instead of one best way of organising: 'it does not assume the rationality of action or some absolute standard of efficiency. There is not one most efficient mode of organisation, nor is there only one way in which organisational goals can be pursued […]. It allows for the rules by which worlds are constructed to be negotiated and changed' (1990: 303-304). The ideas of different available possible ways, various forms of rationality, as well as multiple and negotiable options detach Flighstein's work from the available institutional theories (Meyer and Rowan, 1977; Di Maggio and Powell, 1983), and constitute crucial ingredients in the further development of the institutional logic perspective.

Di Maggio (1991), one of the theorists of institutionalism and neo-institutionalism, carries out another relevant empirical study that we can consider a precursor to the institutional logic perspective. The author examines the organisational field of art museums and identifies two competing models: the Gilman and Data models. The author links the concept of model to the Weberian concept of ideal type. Again, like Flighstein's (1985; 1987; 1990) use of the term conception, the term institutional logic is not yet introduced, but the way in which the two models are described remind us of the description of two context-specific institutional logics, conflicting within a field. The study highlights two contrasting cultural models, which condition the rise of a strong power struggle in order to redefine the functioning of the art museum field. The relevant element from an institutional logics perspective's point of view is the recognition of the contending and conflicting nature of alternative models which, instead of leading to the peaceful history of diffusion and isomorphism of a legitimate model; promotes a heated conflict between alternative existing views in the structuration of the art museum field. Thus, once again variability enters into the institutional theorisation, as well as the role of different institutional orders, which can be conceived in order to explain the development and coexistence of alternative models.

Recognition of the limits of the institutional theories, as well as the empirical findings of Flighstein (1990) and Di Maggio's (1991) studies, show how the theoretical context is prone to the emergence of the institutional logic theoretical analytical perspective. In effect, more or less simultaneously, different scholars present the concept of institutional logic independently. In 1988, Jackall presents the concept in his book *Moral Mazes*. In 1991, Friedland and Alford define the concept and the main cornerstones of the institutional logic perspective in the article that is considered the foundational essay of the perspective, *Bring the society back in*. The foundational essay remained unheeded for almost ten years. Thornton and Ocasio's work dated 1999, brings the institutional logic perspective and theoretical framework back to scholars' attention. From here on, scholars adopt the institutional logics theoretical-analytical framework to explore a heterogeneous set of empirical objects. Healthcare organisations (Scott et al., 2000), universities (Gumport, 2000), consumers (Moorman, 2002), mutual funds (Lounsbury, 2002), French cuisine (Rao et al., 2003), financial markets (Zajac and Westphal, 2004), accounting firms (Thornton et al., 2005), and drug courts (McPherson and Sauder, 2013), can be taken as examples. Following Thornton and Ocasio (2008) and Thorton, Ocasio, and Lounsbury's (2012) analyses, despite the variety of empirical objects, five general and shared assumptions constitute a common meta-theory underlying the empirical research referring to the institutional logic perspective: embedded agency; material and symbolic nature of institutional logics; multiple level of analysis; historical contingency and context specificity; and society as an inter-institutional system. Let us examine those assumptions in detail.

Embedded agency

The term embedded agency (Seo and Creed, 2002; Battilana, 2006; Greenwood and Suddaby, 2006) refers to the dual nature of institutional logics that represent constraints, as well as opportunities for action at the same time. Institutional logics are at once shaped by individuals and organisations in their actions and decisions, and shaping individual and organisation actions and decisions (Giddens, 1984; Jackall, 1988; Friedland and Alford, 1991; Sewell, 1992; 1996; Thornton and Ocasio, 1999). Rethinking Scott's (1995) definition of agency within the institutional logic framework, we can define agency as the possibility for actors to engage in strategic behaviour retroacting on logics and, consequently on institutions, and modifying them. The possibility of exerting such agency is related to the capacity of individuals and organisations of strategic actions in adapting the available institutional logics to the context they are facing, combining them, innovating them, and using them according to their interests. If plurality and contradictions are prerequisites for agency, agency is at the same time a prerequisite for plurality and contradiction. Without conceiving agency, we would witness the reproduction of the same logic(s) in different contexts, levels of analysis and historical periods: there would be no change or plurality. In contrast, agency opens the possibility of looking inside organisational fields and institutional environments, and finding a plurality of views, and different interpretations or practical translations of the same logic, rather than isomorphism.

Still in need of further studies is the question of how changes are activated at the micro level, and how a change activated by individuals can reach institutional orders and be institutionalised. More specifically, what are the mechanisms explaining this micro-macro link between individuals and institutions? How can an individual embedded within a given institutional system conceive and promote a different view with respect to the available logics? In this context, the main research branch trying to address such questions is institutional entrepreneurship. The institutional entrepreneur is an actor that violates the assumptions, principles and practises fostered by the available institutional logics in a given context, and is able to institutionalise new and alternative assumptions, principles and practises (Garud and

Karnøe, 2001; Battilana, 2006; Battilana et al., 2009). In order to reach such changes in institutional logics, the institutional entrepreneurs, on the one hand, should imagine alternatives to the existing and prevalent assumptions, principles and practises (Emirbayer and Mische 1998: 963). Such conception of alternatives is linked with the possibility of borrowing elements from other institutional orders and institutional logics available, for example, in other contexts (Battilana, 2006). And, on the other hand, on being a strategic (Lawrence, 1999) and skilled (Perkmann and Spicer, 2007) actor, this in order to provide motives to other affected actors to recognise the new assumptions, principles, and practises as necessary, binding, effective, and suitable (Rao, 1998). Despite the characteristics institutional entrepreneurs should fulfil, it is recognised that the changing of institutional logics is always a contested and difficult political process that can often fail (Seo and Creed, 2002; Garud et al, 2002).

The theorisation of embedded agency differentiates the institutional logic theoretical analytical framework from institutional theories (Meyer and Rowan, 1983; Di Maggio and Power, 1983). Following the institutional theory, the structure tends to prevail on the individual determining or pre-orienting individual's actions and decisions. In contrast, institutional logic's position on the duality structure and action is more balanced. If, on the one hand, the available and prevailing institutional logics orient and limit individuals and organisation's actions, on the other hand, the contradictions and plurality of available logics, as well as the entrepreneurship of actors, leave room for individual agency and change.

Material and symbolic foundation of institutional logics

As already mentioned, institutional logics have a material and a symbolic nature: the term material refers to structures, practises and processes; the term symbolic refers to ideas, values, beliefs, principles and assumptions (Friedland and Alford, 1991; Thornton et. al., 2012). Both the material and symbolic aspects are crucial in the definition, modification and foundation of institutions. The symbolic and ideational aspects of institutions, and the material and structural ones, 'are intertwined, constituting each other. Meanings are encoded in structures and practises, while structure and practises express and affect those meanings' (Zilber, 2008: 152). Nevertheless, the interaction between those two aspects is crucial in order to understand how logics interplay with each other, and the mechanisms through which they are stabilised and institutionalised. Thus, looking at those dimensions as two distinctive analytical components in the definition of institutional logics is crucial (Thornton et al., 2012). More in general, it is broadly recognised by institutional logics' scholars that 'by integrating the symbolic with the material, the institutional logics perspective integrates research with culture and cognition to provide an orienting strategy for theory on how culture [and cognition] shape action' (Thornton et al., 2012: 11).

The relationship between the material and symbolic can differ from the context under examination: on the one hand, the symbolic can favour the creation of specific structures; on the other hand, structure can sustain and shape the definition of the symbolic aspect of the logics. For example, examining the interactions between cultural views, habits and networks structuring, Lizardo shows how cultural tastes form and sustain the relational networks (2006) and, more in general, how 'worldviews are strong predictors of changes in network composition among US youth' (Vaisey and Lizardo, 2010: 1595). Less studied within the field of institutional logics is the interaction between cognition and structures. An important exception is Weick's study of the way in which organising for coordination within organisations affects the cognitive processing (Weick, 2005). Weick's contributions do not refer to the institutional logic perspective, but give important insight into the possible interaction between cognition and structure. For example, as already mentioned presenting the imagination worldview on risk management (see Part 1, Chapter 1, Section 1.2), studying the failure of imagination in organisations such as the US National Intelligence and NASA (Weick, 2005), the author shows how coordination strategies affect the possibility of engaging in imaginative reasoning. Imaginative reasoning, essential for predicting possible unwanted outcomes, such as, for example, the 9/11 terrorist attack, or the Challenger disaster, is absent within the studied organisations because of the loss of crucial information the bureaucratic management of organisations produces. More specifically, embedding available information in pre-defined categories and formalised processes of analysis, and structuring interaction in hierarchy-based relationships, the details as well as the development of various points of view on the details, needed in order to develop an imaginative reasoning, are lost within the constraints of a bureaucratic structure. We return to the need to consider the symbolic and structural aspects of institutions later on in this chapter, in defining the analytical component of the concept of institutional logics that we focus on in the empirical analysis.

Multiple levels of analysis

In their foundational essay Friedland and Alford (1991: 240) state, ‘an adequate social theory must work at three levels of analysis – individuals competing and negotiating, organisations in conflict and coordination, and institutions in contradiction and interdependency.’ The importance of developing research considering different levels of analysis is vital from the point of view of the institutional logic perspectives. On the one hand, looking across levels allows the contradiction of institutional logics to be seen. On the other, considering the cross-level effects allows the relationship between structure and action – micro-macro link – to be seen and better understood. Thus, the need to look at different levels of analysis is linked to the need to understand the notion of institutional contradiction. Referring both to the contradiction between different institutional orders, as well as to the contradiction between different levels of analysis, the notion of institutional contradiction is identified by Friedland and Alford (1991: 241) as the only way of ‘[restoring] meaning into social analysis in a way which is neither subjectivist, functionalist, nor teleological.’ More specifically, the authors stress the important gap of available theories, which use one of the identified levels as the unique domain of analysis. Subjectivist approaches look uniquely to the individual and in so doing ‘tend […] to become open-ended, solipsistic, and voluntaristic approaches in which the entire world is renegotiated in every social interaction’ (1991: 241). Managerialist theories focusing uniquely on the organisational level tend to conceive organisations as completely detached from both the society in which they operate, as well as the individuals that compose them. For example, ‘[assuming] abstract individuals, else it would not be possible to separate the person from office’ (1991: 261). Macro-level theories that consider the entire society uniquely ‘tend toward a structural functionalism in which society has deterministic relationship to individuals and organisations’ (1991: 242). In contrast, to look at the interactions between different levels of analysis allows researchers to perceive the differences between those levels, and to understand the way in which they interplay by offering different context-specific combinations of different institutional logics. In so doing, they do not overestimate the role of one level over the other ones, preventing the development of subjectivist, managerialist, or structuralistic interpretations. The three levels of analysis are nested in one another: the institutions and organisations ‘specify progressively higher levels of constraint and opportunity for individual action’ (Ibid.). The distinction between levels of analysis is an analytical one: each level is an ‘abstraction and reification’ (Ibid.), an analytical trick in order to better understand how society works. Further empirical work shows the utility of looking at other levels of analysis, demonstrating how the choice of the levels of analysis is extremely relevant and should be carefully defined according to the specific questions and the research aims being answered. Other examples of analytical levels considered by previous empirical studies are inter-organisational networks, geographical communities or organisational fields (Thornton and Ocasio, 2008).

The need to consider different levels of analysis together crucially differentiates the institutional logic perspective from institutional theories. More specifically, institutional theories focus their attention on a unique level of analysis, the societal level (Meyer and Rowan, 1977) or the field level for the neo-institutional theory (Di Maggio and Powell, 1983; Powell and Di Maggio, 1991).[41]

Historical contingency and context specificity

Even if a certain degree of stability of the institutional orders is stated,[42] scholars underline that the prevalence of one logic over another one varies over time. The aim of the perspective is to take into account such historical variability in order to understand the specific contexts in which specific logics are institutionalised. Recognition of the historical contingency is stated by the institutional theories as well. However, the focus is more on modernisation as ‘an evolutionary or linear progression driven by ‘scientisation’ (Meyer et al. 1997), or market rationalisation (Di Maggio and Powell, 1983)’; (Thornton et al., 2012). In contrast, by not theorising modernisation as a progressive and linear process, the institutional logics perspective does not exclude changes in the prevalence of certain logics over others over time, reversing the process of progressive prevalence of the market, state, and profession characterising society today.

The historical contingency of institutions is closely related to another critical element characterising the institutional logics perspective: the context-specific

[41]Even if the need to consider individual agency in order to develop the institutional approach (Di Maggio, 1988) is recognised; further studies inspired by the neo-institutional shift (Powell and Di Maggio, 1991) fails to do so. The main focus remains the macro level, and the actor theorisation remains peripheral compared with societal and field levels.

[42]For example, the prevalence of market, state, profession and corporation institutional orders in society today is recognised. In addition, many studies highlight that, during the last three decades, the market institutional order is gaining prominence over other orders (e.g.,Thornton and Ocasio, 1999; Scott et al., 2000; Meyer and Hammerschmidt, 2006).

formation of institutional logics. The consideration of the interplay between institution and action leads to the definition of a ‘particular social world’ (Jackall, 1988: 112) in which specific logics shape and are shaped by individuals and organisations. The context-specific nature of the process of translation, analogies, combinations, and adaptation of institutional logics is closely related to one of the more important criticisms the institutional logic perspective has for the institutional theory: to not situate the actor within the organisational and social context in which he acts. In addition, to state the context-specific nature of the logics allows the bottom-up process through which context-specific environmental stimuli allow actors to activate alternative views, to be conceived. In this sense, the institutional logics perspective differs from institutional theories. From the institutional theories’ point of view, the role of the context is conceived, but not as a stimulus for agency and change, but rather as pressure for isomorphism (Di Maggio and Powell, 1983).

Society as an inter-institutional system

The theorisation of society as an inter-institutional system composed of different institutional orders is a crucial element of the institutional logics perspective. Such theorisation allows us to conceive of society as an external element with respect to individuals and organisations, without falling into a determinist or functionalist view (Friedland and Alford, 1991). Friedland and Alford (Ibid.), in referring to Western society today, identify five main institutional orders each of which promote a specific institutional logic: capitalistic market, bureaucratic state, democracy, nuclear family, and Christian religion. Thornton (2004) develops the classification proposed by Friedland and Alford (1991) through an examination of various empirical studies. The author identifies six institutional orders: market, corporation, profession, state, family and religion. Further studies (Thornton, Ocasio and Lounsbury, 2012) add the community to the six institutional orders identified by Thornton (2004). Table 6 presents the inter-institutional system: on the x-axis, the institutional orders are located; on the y-axis, the elemental categories, or building blocks, that define the institutional orders (Thornton et al., 2012).

	Family	*Community*	*Religion*	*State*	*Market*	*Profession*	*Corporation*
Root Metaphor	Family as firm	Common boundary	Temple as bank	State as redistribution mechanism	Transaction	Profession as relational network	Corporation as hierarchy
Source of legitimacy	Unconditional loyalty	Unity of will, believe in trust and reciprocity	Importance of faith and sacredness in economy and society	Democratic participation	Share price	Personal expertise	Market position of firm
Source of authority	Patriarchal domination	Commitment to community values and ideology	Priesthood charisma	Bureaucratic domination	Shareholder activism	Professional association	Board of directors, top managers
Source of identity	Family reputation	Emotional connection, ego-satisfaction, reputation	Association with deities	Social and economic class	Faceless	Association with quality of craft, personal reputation	Bureaucratic roles
Basis of norms	Membership in household	Group membership	Membership in congregation	Citizenship in nation	Self-interest	Membership in guild and association	Employment in firm
Basis of attention	Status in household	Personal investment in group	Relation to supernatural	Status of interest group	Status in market	Status in profession	Status in hierarchy
Basis of strategy	Increase in family honour	Increase status and honour of members and practises	Increase religious symbolism of natural event	Increase community good	Increase efficiency profit	Increase personal reputation	Increase size and diversification of firm
Informational control mechanisms	Family policy	Visibility of actions	Worship of calling	Backroom politics	Industry analysis	Celebrity professionals	Organisational culture
Economic system	Family capitalism	Cooperative capitalism	Occidental capitalism	Welfare capitalism	Market capitalism	Personal capitalism	Managerial capitalism

Table 6: The inter-institutional system (Thornton et al., 2012: 73)

Institutional orders are linked to institutional logics; those logics are the ingredients through which context-specific logics shape and are shaped by individual action. The theorisation of society as an inter-institutional system composed of different institutional orders linked to various organisational logics, constitutes an important answer to the perceived limits of other available theories. More specifically, the theorisation of various logics differing and contrasting amongst themselves allows the availability of multiple rationalities to be underlined. Thus, it allows us to highlights that the rationality of action, besides being bounded (Simon, 1972), is also multiple[43] and varies according to the institutional orders that sustain it. With reference to rational choice theory, the presence of various rationalities specifically linked to self-interest and market institutional orders, together with the acknowledgement that a decision can also be based upon other rationalities linked with other institutional orders, is evident. Thus, if we refer to market logic, the rationality of the decisions we make is based on self-interest, but if we refer, for example, to the profession logic our decision is not based, or is only partially based on self-interest, and is instead based, or also based, on personal reputation and professional association (Friedland and Alford, 1991; Thornton et al., 2012).

Recognition of the relevance of different institutional orders differentiates the institutional logic perspective from the institutional theories. Institutional theories only recognise the state, market, and professional institutional orders as relevant in today's society (Thornton et al., 2012: 45), and do not consider the corporation, family, religion, and community institutional orders.

Table 7 summarises the main elements of the institutional logic's core meta-theory, and the ways in which institutional theories differ from the institutional logics perspectives on those elements.

[43] An extremely relevant precursor of the theorisation of various rationalities is the theory of action proposed by Weber (1922). Weber's theory of action typifies two possible types of rational action: rational action informed by interests, and rational action informed by values. Interest rationality is the one linked with the market logic. In contrast, the value rationality represents the opening to alternative forms of rationality that are not driven by self-interest, thus actions that are not considered irrational, but inspired by other logics, such as, for example, family, profession or community.

	Institutional logics	*(Neo)Institutionalism*
Individual vs. structure	Embedded agency	Primacy of structure on agency
Material and symbolic	Importance of the material and symbolic nature of institution and the relationship between the two	Major focus on the material dimension
Levels of analysis	Multiple levels of analysis	Societal and organisational field levels
Historical contingency and context specificity	Historical contingency of institutional orders prevalence Context-specific nature of institutional logics	Historical contingency is recognised, but not explained The context-specific dimension is not explored, unless from a field level point of view: pressure toward isomorphism
Institutional orders	State, Market, Corporation, Profession, Religion, Family, Community	State, Market, Profession

Table 7: Institutional logics' core meta-theory – differences between institutional logics perspective and institutional theories (My elaboration.)

2.2 Logics and the focus of attention

The majority of the studies dealing with institutional logics focus on explaining the logics' origins and their alterations. For example, in considering the role of individual actors in triggering changes, the logics' legitimisation process, the interplay between the symbolic and the material dimensions in triggering a change, the role of the different institutional orders in shaping a logic, and the struggle between conflicting logics in shaping an organisational field, is considered. A minority of the available studies go in the other direction, by considering the consequences of observing and interpreting reality from a specific logic point of view.

Here the aim is to focus on this less examined point of view on the institutional logics' role: what are the consequences of the prevalence of a specific logic on individual actions and decisions? This point of view is specifically relevant in order to address the question this dissertation aims to answer: 'Why doesn't the (watch) dog bark?' Thus, in looking at the available information and environmental stimuli wearing logics' conceptual lens, we consider which phenomena regulators focus attention on, and in which way such information or environmental stimuli is selected or filtered out through the logics' lenses. The focus of attention on a phenomenon is extremely relevant, in order to understand how and why regulators select, interpret and classify the available information, and in doing so sort in or out potentially relevant information in organisational accident prevention. The basic idea driving such a focus is that logics represent 'conceptual lenses' that are at the same time a way to see and a way not to see: logics focus individuals' attention on certain problems, but not on others, as well as on certain solutions, despite the potential multiplicity of available solutions.

Within the institutional theories, the first author recognising the importance of this micro-impact on institutions is Zucker (1977). The author stresses the importance of looking at the perception that individuals have of institutions as taken-for-granted facts: 'social knowledge once institutionalised exists as a fact, as part of objective reality, and can be transmitted directly on that basis' (1977: 726). The individual perception of institutions is a key element in fostering specific interpretations of reality that focus individual attention on taken-for-granted problems and solutions, preventing the consideration of alternative problems or strategies in order to face such problems.

Further developments in the study of the focus of attention come from organisational and decision-making studies. Simons (1957) shows how decision-making in organisations is limited, on the one hand, by the cognitive limit affecting human capacity to consider all the available information – bounded rationality – and on the other hand, by the organisational structure in which such decisions take place. The authors highlight that the organisations and institutions in which individuals operate, focusing the attention of individuals on specific problems and solutions, direct behaviour in certain directions instead of others. More specifically, 'organisations and institutions provide the general stimuli and attention-directors that channel the behaviour of members of a group, and that provide those members with the intermediate objectives that stimulate action' (Simon, 1957, ed. 1997: 110). The author identifies different mechanisms through which organisations can influence individuals' attention:

- The division of work, limiting individual attention to the specific task they are assigned to;
- The definition of standard practises, establishing that one particular task should be done in a particular way;
- The transmission downwards of decisions, defining, for example, the hierarchy of formal authority in decision-making;

- The definition of channels of communication;
- The training and indoctrination of organisation members (internalisation).

Such mechanisms embed decision-making within organisational processes, structures, assumptions and values, that shape individuals' attention. More in general, the recognition of the cognitive limits affecting individual rationality, leads organisational scholars to consider the ways in which organisations foster structures and processes in order to direct and limit individuals' attention. Structures and processes link individuals' responsiveness on a limited set of phenomena, problems, events, issues, and possible solutions that are considered as more relevant, appropriate, or fitting for a purpose. Individuals in organisations face a great number of ambiguous attentive stimuli from different arenas. Such stimuli tend to exceed their cognitive capacity, consequently, through the organising process, they accept routinely oriented focus of attention strategies, rather than constantly processing all the available stimuli (March and Simon, 1958; Simon, 1972; March and Olsen, 1976; Ocasio, 1997).

Within the institutional logics field, the available studies go in the same direction examining the institutional logics' focus of attention empirically (Thornton and Ocasio, 1999; Thornton et. al., 2005; Cho and Hambrick, 2006; Lounsbury, 2007). For example, Thornton and Ocasio's (1999) study on logics in high-education publishing shows the editorial area and the market as two contrasting logics in the field, focusing attention on the different fields' dynamics. Editorial logic focuses attention on the prestige of the publishing house; in contrast, market logic focuses attention on market competition. Consequently, market logic is more likely to consider corporate acquisitions as an organisational solution compared to the editorial one.

The contributions examined so far, tend to interpret focus of attention as a top-down process that goes from institutions, organisations, institutional logics to individuals, constraining their interpretation and definition of reality and, in doing so, their conception of problems and solutions. More recent developments within the institutional logic field show how, in order to understand the role of logics, attention should be paid to the situated attention process considering not only the role of logics, but also the interaction between logics and environmental stimuli (Ocasio, 2011). More specifically, situated attention is the product of the available logics, as well as of the specific stimuli coming from the environment. Organisations and individuals can face situations in which the existing schemas are not appropriate in order to understand the available environmental stimuli.

Consequently, a stimulus can activate the available logics in ways that vary from the expected schemas or structure-oriented behaviours, even leading to a change in the available logics. Scholars highlight how, in order to trigger this bottom-up process that goes from environmental stimuli to alternative logics activation, organisations and individuals should perceive such stimulus or situation as salient (Hoffman and Ocasio, 2001; Fiske and Taylor, 2008; Nigam and Ocasio, 2010). The definition of a stimulus as salient 'can result from multiple factors: from unusual or unexpected actions and outcomes, from novelty, or from explicit attention control by other social actors' (Thornton et. al., 2012: 92).

In summary, the relationship between logics and environmental stimuli is, on the one hand, a top-down process in which logics predefine which stimuli among the various available ones are objects of the attention of organisations and individuals. On the other hand, under certain conditions – such as the salience of the stimulus or situation – this relationship can assume the form of a bottom-up process in which environmental stimuli focus the individual's or organisation's attention, and retroact on the context-specific logics, activating them in an unexpected way. This bottom-up process activated by environmental stimuli, according to the salience of the stimulus or situation, can lead to a modification of context-specific logics or, if the change persists over time, of institutions as well. Figure 3 offers a graphic representation of such top-down/bottom-up interactions between environmental stimuli, focus of attention, context-specific logics and institutional logics. We return to the relationship between environmental stimuli, focus of attention, context-specific, and institutional logics later on at the end of this chapter in describing the levels of analysis we decided to consider in this dissertation. Let us now return to the definition of the institutional logic concept.

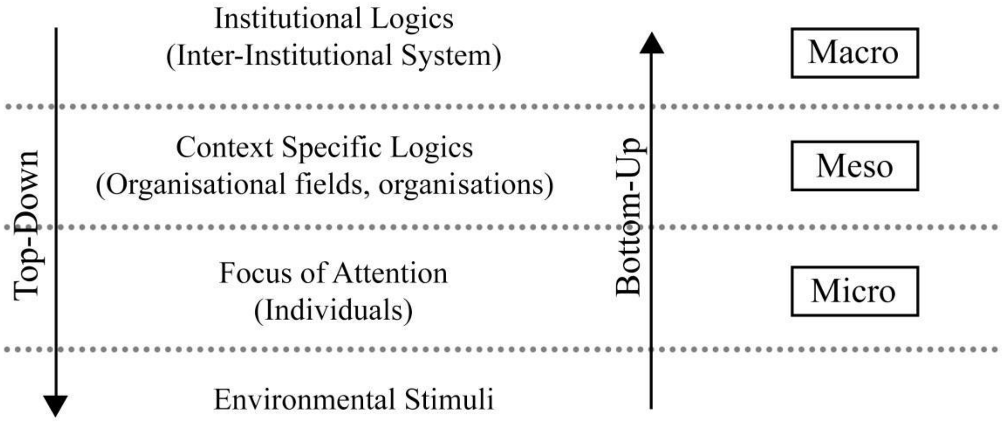

Figure 3: Institutional logics and the focus of attention: a graphical representation (My elaboration.)

2.3 Institutional logics between theory and empirical research

As already mentioned, the intermediate nature of the institutional logics concept – bridge between institution and action – as well as the absence of a clear empirical reference of the concept, renders the concept's definition fleeting and its use in a valuable analytical manner difficult (Thornton et. al., 2012). In addition, as the previous core meta-theory description illustrates, institutional logics is not only a concept, but also a theoretical-analytical framework that can be plastically adapted to the empirical object and objectives of research. Thus, the operativisation of the concept, as well as the definition of the levels of analysis, are two crucial steps in proceeding from the theoretical to the empirical footing. This section aims to build this needed step by focusing firstly, on the institutional logics concept definition and operativisation, and then, on the analytical framework specifying the chosen levels of analysis.

The empirical definition of the institutional logic concept

Over time, three main definitions of institutional logics have been proposed; Table 8 shows these three definitions, the scholars that propose it, and the year in which it was proposed.

Year	*Authors*	*Definition*
1987-91	Alford and Friedland	Set of material and symbolic constructions which represent the institutional orders organising principles (1991: 243)
1988	Jackall	Institutional logic is the way a particular social world works; of course, although individuals are participants in shaping the logic of institutions, they often experience that logic as an objective set of norms (1988: 112)
1999	Thornton and Ocasio	The socially constructed, historical patterns of material practises, assumptions, values, beliefs, and rules by which individuals produce and reproduce their material subsistence, organise time and space, and provide meaning to their social reality (1999: 804)

Table 8: *Institutional logic – main proposed definitions*

Friedland and Alford's (1991) definition focuses on the symbolic and material nature of logics. Jackall's (1988) one stresses the constraining role of logics that once institutionalised acts as taken-for-granted norms. Thornton and Ocasio's (1999) aim is to keep together the focuses of Friedland and Alford (1991) and Jackall's (1988) definitions: the symbolic – assumptions, values, beliefs – material – material practises – and the constraining role of logics – rules. The developed definition is highly complex bringing together a broad spectrum of concepts and research fields. Such complexity makes the concept closer to the theoretical side than to the empirical one. Accordingly, given its capacity to include the different components of logics – symbolic, material, and normative – and to recall the cornerstones composing the core meta-theory sustaining the concepts, we decided to refer to this definition. However, we recognise that the definition leaves room for further work on the empirical operativisation of the concept.

More specifically, given the aim to keep together different levels of analysis – micro, meso, and macro – holding together different levels of governments – national and supra-national – in which the three different organisations operate, the empirical operativisation of the concepts becomes extremely relevant. To put it simply, we need to make the logics observed in the three studied organisations at the politico-economic and inter-organisational levels, comparable. Thus, to look at the same elements in all the studied organisations and in all the chosen levels. Otherwise, it would not be possible to compare the identified logics jeopardising the analysis results, as well as the understanding of the focus of attention mechanism.[44]

An examination of previous empirical studies shows that the empirical operativisation of the concept varies considerably between authors, and few authors have suggested a systematic definition and/or operativisation of the concept. Consequently, we decide to go back to Friedland and Alford (1991) and Jackall's (1988) foundational work, aiming to identify empirical indicators of the symbolic, material, and normative components of the logic concept. More specifically, we identify four main analytical components: cultural, cognitive – symbolic – organisational – material – and coercive-normative – normative. For each analytical dimension, we identify a set of empirical indicators distinguishing the content of the logics – cultural, cognitive, and organisational components – from their legitimacy and interplay – coercive-normative component.

With reference to the content of the logic – cultural, cognitive and organisational components – the main reference is Friedland and Alford's (1991) foundational essay. For each component, we identify indicators allowing for an empirical account of the logics of risk management and regulation available within the risk regulatory railway network. Let us look closely at the indicators of each component that are summarised in Table 9.

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[44]The concept 'operativisation' allows the definition of the concept to be detailed. This section constitute a middle ground for the theoretical framework – Part 1 of this dissertation – and the methodological specification – Part 2 of this dissertation. Nevertheless, we prefer to locate this section here privileging the clarity and continuity of exposition, rather than the rigor in separation of the theoretical and methodological arguments.

Cultural component	
Categories and associated meanings	Risk definition and reference objects of the concept Regulating and regulated organisations' role in this definition
Ends	Mission and objectives (way in which the organisations studied define their mission; targets they aim to reach in terms of level of safety) Regulating and regulated organisations' role in this definition
Cognitive component	
Method of reasoning	Deductive, inductive, and abductive reasoning Balance between the three methods of reasoning
Organisational component	
Means	Processes and strategies to reach the identified ends Direct/Indirect risk management process Soft or heavy regulation
Structure	Coordination by standardisation, by plan, by mutual adjustment

Table 9: The logic content – empirical indicators (My elaboration.)

The cultural component

With reference to the cultural component, the chosen indicators are:

- *Categories and associated meanings* – in their foundational essay, Friedland and Alford (1991) repeatedly remind us of the need to understand the relevant and available categories, as well as the meaning that individuals and organisational actors attribute to those categories. More specifically, they warn social scientists not to fall within the logics in use by distinguishing the meaning of the categories they use, from the meaning associated to those categories by the actors they are studying:

  without understanding the historical and institutional specificity of the primary categories of analysis, social scientists run the risk of only elaborating the rationality of the institutions they study, and as a result become actors of their reproduction (1991: 260).

  Given our specific focus on risk management and regulation strategies regulating organisations put into practise, we decided to pay particular attention to the category of risk. This with the aim of understanding which meaning the three studied organisations associate with this concept, as well as whether this meaning is in continuity between them and with the one promoted at the politico-economic level. In looking at the risk meaning, we pay attention to the object of reference of the concept, the studied organisations associate with such a category. For example, we look at which kind of events can be considered an empirical reference of the concept of risk and in which way risk can be measured and evaluated. In this sense, we pay attention to the role attributed by regulating organisations to the regulated one in such a definition, and in the identification of what kind of phenomena can be considered risk. More specifically, which is responsible for the definition of the category of risk: the regulating or the regulated organisations?;

- *Ends* – institutional logics focuses the attention of individuals and organisations on specific ends that are considered as legitimate and pursuable by the individuals and organisations (Ibid.). We decided to focus on the way in which the organisations studied define their mission, as well as at the targets they aim to reach in terms of levels of safety. As for the categories and associated meanings, we intend to understand if the organisations share the same idea of the mission that should be pursued, as well as whether the mission fostered at the politico-economic level coincides with, or differs from, the one fostered and effectively pursued at the inter-organisational level. In addition, the role attributed by the regulating organisations to the regulated ones in the definition of the targets, in term of safety levels that should be reached, is considered.

The cognitive component

Friedland and Alford (1991) state that logics are ways in which individuals and organisations organise reality, and sort and prearrange the various environmental stimuli they face. Different logics present different ways of organising, sorting and prearranging, which reflect different types of inferential reasoning (Pierce,1958; Brent, 1998). Pierce (1958) classified the inferential reasoning in deductive, inductive and abductive reasoning. We decided to refer to this classification in order to investigate which kinds of inferential reasoning are promoted and sustained by the available logics of risk management and the regulation, shaping and shaped by regulators activities. Pierce's classification has already been used in the study of organisations facing unwanted and unexpected events such as terrorist attacks, technological accidents (Weick, 2005), or medical emergencies (Catino et al, 2012).

Such studies underline the importance of considering those inferential processes in order to understand the way in which individuals and organisations interpret reality and, by filtering and analysing information they have about reality, make decisions. Let us examine the three methods of reasoning classified by Pierce in detail (Pierce, 1958; Fann, 1970; Brent, 1998; Paavola, 2005).

Method of reasoning	*Definition*
Deductive reasoning	From general to particular To infer conclusion from premises of general validity
Inductive reasoning	From particular to general To infer knowledge from the analysis of empirical evidence
Adbuctive reasoning	From the present to the future To infer hypotheses or guesses on the way in which phenomena are linked, starting from pieces of information and details in order to foster alternative scenarios that go beyond the information actually available

Table 10: Methods of reasoning

- Following *deductive reasoning*, individuals and organisations infer conclusions from general theories on reality, those theories constitute the taken-for-granted assumptions in which the inferred conclusions are already implicitly stated. Thus, the conclusion automatically follows the assumptions and principles on which it is based. The foundation of the concept of deduction dates back to Aristotele. The origin of the term is the Latin *de* and *ducere*, which means to infer – *ducere* – from – *de* (Catino et al., 2012). Deduction is a logical method, through which, using general assumptions on reality, conclusions about reality are gleaned. It goes from the general to the particular: starting from general assumptions and principles – theories – about the way in which things go, and sets up conclusions on specific and tangible events, cases or relationships. Those conclusions disregard the specificities of the event, case or relationship under examination, but are already settled in the theory from which this event, case or relationship is seen and interpreted. The correctness of the conclusion is already settled in the assumptions and principles driving such conclusions. Nevertheless, in order to work, deductive reasoning should be based on a correct inference on the link between the specific phenomenon and the general theory. Thus, if the premises are true, the consequences are true, given the appropriateness of the inference linking the specific phenomenon under study and the theory stating those premises;

- Following *inductive reasoning*, individuals and organisations try to state general and universal rules starting from specific and tangible events, cases, or relationships. The etymological origin of the term is the Latin *induction*, which literally means carried in (Catino et al., 2012). Induction infers the opposite way of deduction, proceeding from the particular to the general: general theories are discovered through the recognition of regularities linking tangible and empirically observable events, cases, or relationships. Thus, assuming that the recognised regularity will persist in future phenomena of the same type, inductive reasoning infers rules and theories from empirical evidence. As soon as the empirical instance of the phenomenon increases in number, the theory or rule becomes more and more certain. Nevertheless, further empirical evidence – such as for example the black swan (Taleb, 2007) – could always falsify the theories or rules stated through an inductive inference;
- Following *abductive reasoning*, individuals and organisations elaborate guesswork about hypothetical scenarios from the available pieces of information. The etymological origin of the term is the Latin *ducere*, which means to drive or to pull. Abductive reasoning is the most innovative one, but at the same time the less certain. The conclusions derived by the available fragmented pieces of information are considered simply plausible. Nevertheless, this reasoning allows alternative scenarios to be fostered representing the appropriate ground for discoveries and prediction: it provides something new and plausible, but no certainty about what happened, is happening or will happen. (See Table 10 for a summary.)

The aim is to understand if the available logics promote a specific method of reasoning through which the regulating organisations tend to interpret reality. In addition, if more than one method of reasoning is promoted, the purpose is to understand the balance between them.

As already mentioned (see Part 1, Chapter 1, Section 1.2; and Section 2.2 of this Chapter), the methods of reasoning are linked by Weick (2005) to the characteristics of the organisations in which such inference processes are embedded. More specifically, the author links the method of reasoning to the 'shareability' constraints that organisations have to face. The 'shareability' constraint refers to the need for coordination that encourages standardisation and the use of pre-defined and not easily modifiable categories, leading bureaucracies to stick with deduction. Following Weick's intuitions, we consider the processes and the structures the different logics promote, examining the way in which the different types of reasoning are embedded and oriented by those processes and structures. Nevertheless, in order to look at the interaction between the symbolic and material nature of institutional logics, we consider the organisational structures and processes separately as main indicators of another analytical component of the institutional logics: the organisational component. Let us examine this component in detail.

The organisational component

With reference to the organisational component the chosen indicators are:

- *Means* – institutional logics identify the ends to which individual and organisation orient their actions and decisions and, at the same time, link those ends to the means through which they pursue them:

  > the retreat from society has been associated with an analytic strategy that builds upon a supposed universalism of means, as opposed to the historical particularism of ends, which increasingly fall outside the purview of social sciences. But this science of means lacks meaning. […] Institutions constrain not only the ends to which their [individuals and organisations] behaviour should be directed, but the means by which these ends are achieved (Friedland and Alford, 1991: 251).

  Thus, we pay attention to identifying the strategies and the processes developed within the organisations studied in order to pursue the stated mission and objectives. More specifically, with reference to risk regulation strategies, we pay attention to the kind of regulatory approaches the available logics foster, looking specifically at the balance they offer between light and process-oriented regulation – risk-based approach to regulation – and heavy, prescriptive rule-oriented regulation – control-command approach to regulation. With reference to risk management processes, we look at the balance between the direct and indirect risk management processes promoted by the available logics. In addition, in examining the direct risk management processes characterised by targeting the outcomes of the regulated area of human activity by regulators themselves, we focus on the way in which specific methods of reasoning are embedded in those processes fostering the filtering and interpretation of the available information;

- *Structure* – following Weick's insight, we consider the coordination strategies developed between and within the studied organisations. This in order to understand the ways in which the symbolic and material dimensions of institutions interact sustaining, or hindering the development of specific logics. In analysing the coordination strategies, we follow the classification of three types of coordination proposed by Thompson (1967). Thompson highlights how organisations develop coordination strategies in order to diminish uncertainty. Different types of coordination strategies are identified according to the kind of interdependence existing between the different parts of the organisation. Different degrees of interdependence characterise organisations. The author distinguishes between:
  - Pooled interdependence – when the branches of an organisation do not directly interact, if one branch does not perform adequately it can, nonetheless, affect the organisations as a whole. Thus, 'we can describe this situation as one in which each part renders a discrete contribution to the whole and each is supported by the whole' (Ibid.: 55). The different branches of a bank can be taken as an example of pooled interdependence;
  - Sequential interdependence – when the interdependence between a branch, unit, or division is sequential, thus, for example, one branch produces technical parts that another branch should assemble. In this case, the branch 'Keokuk must act properly before Tucumcari can act; and unless Tucumcari acts, Keokuk cannot solve its output problem' (Ibid.);
  - Reciprocal interdependence – refers to the situation in which 'the outputs of each become the input for the others' (Ibid.: 56). The author gives the example of the operation and maintenance units of an airline in which the maintenance of the aircraft component is essential in order to operate flights, but at the same time the flights' operations are essential in order to be in need of maintenance.

  The three types of interdependence are located in a Guttmann-type scale; thus if an organisation is characterised by reciprocal interdependence, it means that the interdependence is also sequential and pooled. If it is sequential it is also pooled. In contrast the pooled type is the simplest one and does not coexist with other types of interdependence.

  After identifying the three types of interdependence, Thompson highlights the coordination strategies that are most efficient for each of the interdependence types. Progressing along the Guttmann scale, coordination becomes more and increasingly difficult because the degrees of contingency between the parts increase. More specifically, because coordination has a cost, certain coordination strategies are justified only if the degree of interdependence characterising such organisation is high:

- With pooled interdependence coordination can be achieved *by standardisations*: 'establishment of routines or rules which constrain action of each unit or position into oaths consistent with those taken by others in the interdependent relationship' (Ibid.: 56);
- With sequential interdependence, coordination can be achieved *by plans* that require 'the establishment of schedules for the interdependent units by which their actions may be then governed' (Ibid.: 57);
- With reciprocal interdependence, coordination can be achieved *by mutual adjustments* which 'involv[e] the transmission of new information during the process of action' (Ibid.).

The three kinds of coordination can be located in a scale that goes from certainty to uncertainty, the more unpredictable is the situation, the more useful is the coordination for mutual adjustment strategies. Standardisation strategies tend to be linked to strong hierarchical decisions. In contrast, mutual adjustment strategies may imply constant communication, which reduces the hierarchical dimension of decision-making processes.

In our analysis, we consider which one of these coordination strategies characterises the available logic at both the politico-economic, as well as the inter-organisational level. We focus, on the one hand, on the coordination strategies within the organisation studied and, on the other hand, on the coordination strategies within the network both between regulators, and between regulators and regulated organisations. In addition, we consider the role of hierarchy in decision-making processes, in order to understand if decisions are positioned uniquely at the top-management level, or are more distributed within the organisations through constant communication between different levels of hierarchy. This as an indicator of standardisation *versus* mutual adjustment of the relationship within the organisation.

The *coercive-normative component* refers to both the material and symbolic nature of logics, but is located on another analytical level, differing from the cultural, cognitive, and organisational one. This component is related to the others, but instead of looking at the content of the logic, it looks at the ways in which individual and organisational actors perceive and use them, as well as at the interplay of the available logics showing their relative relevance and prevalence. In order to observe the coercive-normative component of the logics, we decided to look at two main indicators (see Table 11):

	Coercive-normative component
Situated interaction	Logics conflicting with each other in a situated interaction reveal the force of a logic that prevails on the other ones
Network decision-making process	Which organisation is in charge of made decisions and can decide to consider or not issues raised by one or the other logic, and consequently what are the logics which prevail

Table 11: Logics' legitimacy and interplay – the coercive-normative component (My elaboration.)

- The *situated interactions* between individuals and organisations; the definition of logics proposed by Jackall (1988: 112) stresses the legitimacy the logics can achieve through the experience individuals and organisations have with them. More specifically, despite their role in logics implementation and creation, individuals and organisations can experience logics 'as an objective set of norms.' Thus, logic has a coercive-normative component that can be summarised by the use of the term legitimacy defined as 'a generalised perception or assumption that the actions of an entity are desirable, proper or appropriate within some socially constructed system of norms, values, beliefs, and definitions' (Suchman, 1995: 574). Friedland and Alford's (1991) contribution stresses another key property of logics: logics are multiple and conflicting; thus, different logics can coexist and conflict in the same social context. The link between the legitimacy and the multiple and conflicting properties of logics shows how the legitimacy of logics is a question of degree. Thus, it becomes extremely relevant to look at the interplay of the available logics in order to understand which logic is more legitimised, stronger, or resilient, in shaping actions and behaviour among the organisations or individuals under examination. Consequently, it becomes extremely clear that the coercive-normative component of the logics can only be examined by looking at the relationships between individuals and organisations. It is when two different logics conflict with each other, in a situated interaction which, depending on the prevailing interpretations, actions or decisions, the force of a logic on another one can be seen. Thus, we pay attention to the context-specific interactions within and between the organisations under study, in order to understand which weight the available logics have in fostering regulation of the railway sector;

- The regulatory network decision-making process; another element we chose to look at, in order to understand the degree of legitimacy of the available logics, deals with how coordination between the organisations studied is structured. More specifically, which organisations can take actions in order to modify legislation, or request specific behaviour or adjustments to regulated organisation, and which cannot do so, but should report to other regulators, is considered. This structural element is relevant in order to understand which organisations are in charge of making decisions and can decide to consider issues or not, and consequently which are the logics that prevail. Thus, we aim to understand if coordination among the network shows a hierarchical configuration that allows certain interpretations to pass through and reach the regulated organisations, or stops them by showing the prevalence of other interpretations sustained by other logics.

To sum up, the empirical analysis of the railway regulatory network aims to identify and describe the main available logics by analysing their cultural, cognitive and organisational components. After having described the available logics, an analysis of the context-specific interactions, as well as of the decision-making process within the regulatory network, will allow the degree of legitimacy of the available logic to be understood – the coercive-normative component.

Levels of analysis

The analysis proposed here takes into account three levels of analysis: micro, meso, and macro. Nevertheless, the empirical research focuses only on the meso level. The macro and micro levels are considered only *ex post*, on the one hand, by locating the context-specific logics identified at the meso level within the inter-institutional system – macro – and on the other hand, by analysing the way in which the meso level identified logics focus individuals and organisations' attention on the available environmental stimuli (informational inputs) – micro. Figure 4 offers a graphical representation of the levels of analysis considered showing the object of reference corresponding with each level of analysis. Let us examine the considered levels of analysis in detail.

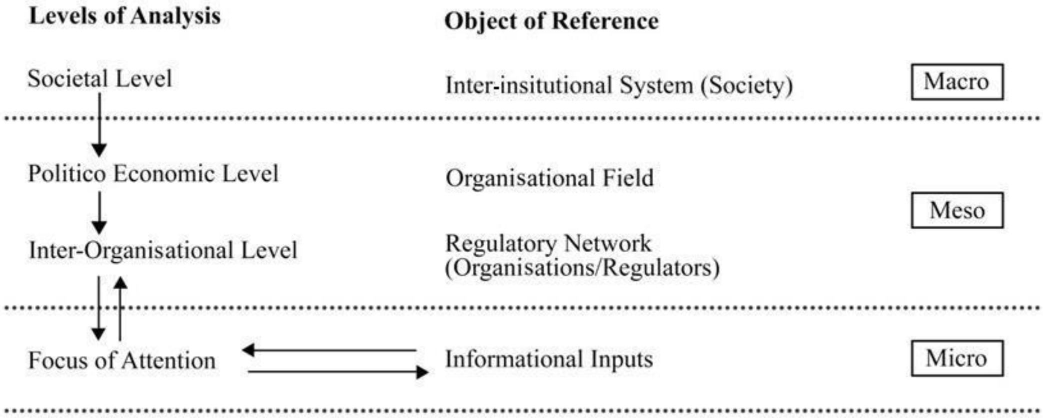

Figure 4: Levels of analysis considered in this dissertation (My elaboration.)

Meso level

We decided to examine the logics of risk management and regulation available within the railway regulatory network empirically by considering two levels of analysis:

- The politico-economic level – the politico-economic level corresponds with the regulatory model fostered by the legislative framework shaping the roles, responsibilities and regulatory approaches of the public and private organisations involved. We decided to focus on the risk-based regulatory approach, and the case selection is based on the attributions of such a model of regulation highlighted by previous studies. (See Part 1, Chapter 1, Section 1.3.) Our aim is to keep the point of view of regulators. Thus, the politico-economic level analysis is based on the way in which regulators understood and presented the regulatory model orienting their activities. By looking at the politico-economic level, our focus is on the commonality between the studied organisations instead of their differences. The aim is to understand if there is a common view within the network about the regulatory strategies fostering the organisational field structuration;
- The inter-organisational level – the inter-organisational level refers to the network regulatory strategies seen from within. Thus, the focus is on the differences between the studied organisations in the practical translation

of the politico-economic level regulatory logic, as well as on interaction and coordination among the regulating organisations, and between the regulating organisations and the regulated ones. The inter-organisational level of analysis, takes into account interaction between different levels of government – national and supra-national – as well.

The object of reference of the politico-economic level is the organisational field, in which the railway regulatory network operates, with the inter-organisational level coinciding with the regulatory network. Thus, we consider the regulating organisations as interacting among themselves and with the regulated organisations.

In our interpretation, those two levels can be seen as Argyris and Schon (1974) distinction between 'theories in use' and 'espoused theories.' The politico-economic level logics correspond with the 'espoused theories', thus on the way in which regulators present the regulatory logics they are embedded in. The inter-organisational level corresponds with the 'theory in use', thus the way in which regulators translate the assumptions and principles fostered by the politico-economic level – in practise fostering context-specific logics. This does not mean that the politico-economic level logics are necessarily in contrast with the inter-organisational ones. However, the practical translation of high-level regulative framework into every-day activities, requires a process of definition, adaptation and interaction between different actors that could lead to the connection and overlapping with other institutional logics. In addition, a focus on the inter-organisational level allows the variability within the regulatory network to be seen and understood.

Macro level

The macro level corresponds with the societal level and the reference object is the inter-institutional system. We do not aim to examine this level directly through the empirical analysis, but once the politico-economic and inter-organisational level logics are identified, we aim to locate those logics within society as a whole. Thus, from the description of the meso level logics, on the one hand, to understand which institutional orders have a role in the logics definition. On the other hand, if significant differences between the identified meso level logics emerge, what is the role of the different institutional orders in shaping those differences? This investigation is conducted with a specific focus on supra-national and national interactions: if there is a difference between levels of government what is the role of the different institutional orders in shaping such a difference?

Micro level

The micro level refers to the logics' focus of attention effect. Our focus is the top-down effect through which the meso level logics affect regulators, focusing their attention on specific problems. Looking at the informational input informing the process of risk management and regulation developed by regulators, an examination of the logics' focus of attention mechanism allows us to understand the way in which available logics filter such information, defining certain phenomena as relevant information and others as irrelevant. In order to explore the bottom-up effect as well, we consider the interaction between environmental stimuli and focus of attention. More specifically, we take into account if among informational inputs there are certain phenomena that do not respond to available schemas or theory, and retroact on logics activating alternative management or regulation processes, or questioning the available assumptions and principles.

The analysis of the micro level effects of institutional logics, as well as of the interaction with informational inputs and logics, is the needed step in order to structure the 'mental' or 'conceptual' experiment through which we aim to answer the question: 'Why doesn't the (watch) dog bark?' On the one hand, the micro level analysis shows where regulators' attention is focused. On the other, the comparison between the logics' focus and the phenomena that previous studies have identified as relevant in the organisational accidents' genesis, shows the gaps opened by the presence of specific regulatory logics in preventing a specific kind of event: organisational accidents. The 'mental' or 'conceptual' experiment allows us to understand if the informational input that the logics classify as relevant are actually relevant in the organisational accidents' genesis. We return to the mental experiment definition, limits, and assumptions in Part 2, Chapter 3. The next chapter is dedicated to a description of organisational accident main theories, aiming to highlight the insight that previous empirical studies have provided on organisational accidents' genesis.

3. ORGANISATIONAL ACCIDENTS

During the last thirty years, the organisational accident has become a relevant object of study within the field of social sciences. In sociology, organisational accident geneses are among the most addressed issues within the field regarding the side-effect of human actions (Hayek, 1952; Merton, 1936; 1940; 1968; Boudon, 1977; 1992). Within the organisational field, specific interest in such a research topic refers to the organisationally constructed nature of such an event (Vaughan, 1996; Turner and Pidgeon, 1997; Perrow, 1999; Hutter and Power, 2005). More specifically, organisational accident studies focus theoretical attention on the organisation in which accidents happen, identifying the contributing factors which lead the situation to being prone to human errors or technological failures that act as triggers in the accident genesis. Our focus on organisational accident studies is specifically oriented by the objective of creating a link between this field of study and the risk regulation and management ones. More specifically, we aim to capitalise on the findings of the organisational accidents field with reference to the elements that play a crucial role in the genesis of such an event. The organisational accidents field's findings are reconnected here with logics' focus of attention mechanism. The aim is to evaluate if the logics available within the railway regulatory network, by focusing the regulators' attention on certain phenomena and hiding other phenomena, allows regulators to see the elements that previous studies on organisational accidents highlight as significant in the genesis of organisational accidents.

It is important to emphasise that our aim is not to evaluate the functioning of the regulatory activity, but whether the logics orienting the regulators activity allows it to pay attention to elements that are significant in a specific and extremely rare type of event. Organisational accidents are not phenomena organisations face daily, and they are just one type of event among a broad set of possible side-effects that regulators and regulated organisation could face. Consequently, defining which kind of phenomena we refer to using the term organisational accident is particularly important. In defining organisational accidents, we trace the boundaries of our focus of attention, and consequently, the validity of our results as well.

Using the term accident, we refer to an unexpected and unwanted event with dangerous consequences for people, damage to the environment, and/or economic losses (Baldissera, 1998). Organisational accidents are man-made (Turner, 1978; Turner and Pidgeon, 1997); not in the sense that they are intentionally driven, but are unintended consequences of human activities (Baldissera, 1998) such as, for example, the cases of the production of nuclear energy, the transport of goods and people, or oil drilling. These events are by definition extremely low in frequency and extremely high in magnitude. They differ from individual accidents because they happen to organisations rather than to single individuals, and because of the high magnitude of their consequences (Reason, 1997). Thus, organisational accidents are extremely rare, but have important adverse and harmful consequences on health and the environment. As mentioned previously, recent events such as the Costa Concordia accident, which occurred near Giglio Island on 13 January 2012; the Fukushima nuclear accident on 3 November 2011; or the Deep Water Horizon oil spill, which happened on 20 April 2010 in the Gulf of Mexico, are clear examples. Moving backward historically, the Chernobyl nuclear accident – 26 April 1986 – and the Bhopal gas leak accident – 2 December 1984 – are the most tragically famous examples, with the greatest long-term consequences.

Analysis of organisational accidents' genesis has become a well-established and recognised field of study. This field has provided important insights into the genesis of organisational accidents, identifying the mechanisms/factors leading to them (Turner, 1978; Reason, 1990; 1997; 2008; Vaughan, 1996; Turner and Pidgeon, 1997; Perrow, 1999; Snook, 2000; Catino, 2006; Downer, 2011). The following section aims to summarise some of the most important insights the organisational accidents field has given for understanding the genesis of such events. Three main theories have been developed in order to explain organisational accidents' genesis: Normal Accident Theory; Epistemic Accident Theory; and Organisational Accident Theory. The first section of this chapter is dedicated to a description of these theories. We conclude the section by highlighting how the three theories can be represented as a taxonomy of different types of accidents. Subsequently, we focus on one of the types of accident included in the taxonomy: the organisational accident type. More specifically, we examine the most recognised empirical studies of this type of accident, with the purpose of specifying the crucial elements in the genesis of the organisational accidents those empirical studies identify.

3.1 Main theories

Normal accident theory

The normal accident theory (Perrow, 1984; 1999) focuses on the structural properties of complex organisations as a crucial feature explaining organisational accidents' genesis. Highly complex systems, as in any human activity, are constantly exposed to possible breakdowns: each single part of such systems can potentially work in a wrong or unplanned way. However, normal accident genesis is not linked to a single part's malfunctioning, but to the possible and unpreventable interaction between distinct and multiple failures. Indeed, even if small, single parts fail slightly, they may interact together in a way that is neither foreseeable nor imaginable – therefore training, formal procedures, or project specifications are not shaped to face this kind of event – leading to the collapse of the whole system. This unexpected interaction leads to catastrophic 'one-off' events, linked to the structural characteristics of highly complex systems. Thus, accidents are as normal, or systemic, even though extremely rare, as unavoidable properties of highly complex systems: 'the odd term normal accident is meant to signal that, given the system characteristics, multiple and unexpected interactions of failures are inevitable. This is an expression of an integral characteristic of the system, not a statement of frequency' (Perrow, 1999: 5). Two main structural dimensions distinguish several types of organisational systems: the type of interaction and the degree of connection.

- *Interactions* can be linear or complex. On the one hand, through linear interactions (e.g. a production line), the production sequences are simply connected and easily monitored and understandable by front-line operators. Thus, failures are easily recognised and stopped before the occurrence of dangerous interactions. On the other hand, when interactions are complex, failures lead to unfamiliar, unforeseeable and unplanned sequences of events. These sequences are not immediately visible or understandable by a front-line operator (e.g. nuclear reaction), thus the interruption of the chain of events leading to an accident becomes extremely difficult;
- *Connection* can be a tight coupling or loose coupling. Loosely coupled systems have loose links between the different parts of the system and these parts can vary in a relatively autonomous way. On the contrary, tightly coupled systems have high connections and each variation in one part of the system, leads to an immediate variation in the others, thus an uncontrolled and rapid propagation occurs.

Locating the two dimensions – interaction and connection – in a table, Perrow identifies four types of organisations (Figure 5). Organisations with complex interactions and tight coupled connections (second quadrant) are most likely to originate normal accidents.

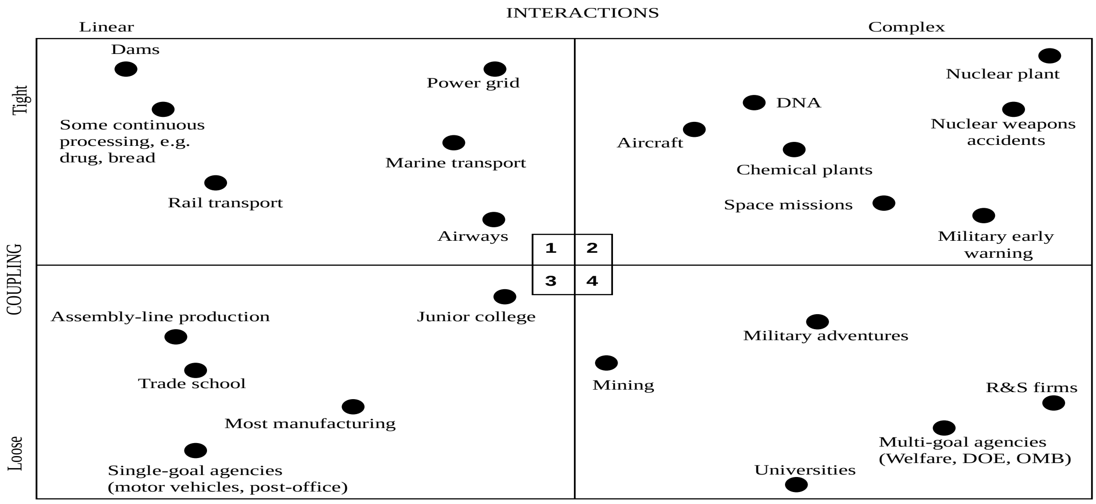

Figure 5: Interaction/Connection – systems more vulnerable to normal accidents (Perrow, 1999)

As a result, Perrow moves toward a political theory of organisations. Specifically, he underlines the need to quit the complex systems most exposed to normal accidents (tight-coupled and complex-connected), such as nuclear power plants or chemical plants. Recently, Perrow (1999; 2004) specified the limit of the applicability of the concept of normal accidents. On the one hand, he recognises the role played by organisational factors in the accident aetiology, regardless of the structural properties of such systems; on the other hand, he points out the inappropriateness of the use of the theoretical framework of normal accidents, with respect to certain empirical objects such as the Challenger and Columbia disasters, or the recent financial crisis (2010).

Epistemic accident theory

The epistemic accident theory (Downer, 2011) is a recent development in the explanation of accident genesis. The theory's starting point is the 'canonical rational-philosophical model' (Collins, 1992: 185) shaping engineering and technical approaches to knowledge. Following such a model, engineering knowledge is structured as a process governed by formal rules, incontrovertible premises, and objectively knowable facts that are deterministically connected. Consequently, accident occurrence, as a consequence of a technological failure, can be easily classified as an error. Such errors are by definition potentially avoidable, and the consequence of faults in the design, projection or implementation processes.

Grounding his findings on core insights from the sociological constructivist perspective of scientific knowledge, Downer identifies the intrinsic limits of the engineering way of knowledge, which remains unnoticed from a rational positivistic approach, as well as the consequences of such limits on preventing and foreseeing organisational accident occurrence. Specifically, at the onset of the engineering and technical approaches to knowledge it emerges that:

- There is 'an irreducibly social component to every "fact"' (Downer, 2010: 739): technical engineering knowledge is strongly based on logical premises, tests, and strict experimental methodologies, however, even in the most rigorous statements, a fundamental ambiguity persists, so statements imply judgements;
- The complexity of the real world cannot be reproduced in a closed laboratory – laboratory experiments are not able to take into account all the variables potentially affecting a technological component in the real world. In addition, the selection by researchers of relevant variables is based on assumptions and theories potentially weakened, compared to the real empirical world.

Showing it would be impossible, in the real world, to know completely and objectively the way in which technological components work, the constructivist approach highlights that:

> the idea of 'failing' technologies as recognisably deviant or distinct from 'functioning' technologies is an illusion of hindsight. By this view, there need be no inherent pathology to failure because there can be no perfect method of separating 'flave' from 'functional' technologies (or 'true' from 'false' engineering beliefs) (Downer, 2011: 741)

Accidents, thus, could not be the consequence of errors and/or of latent organisational factors, but could be originated by the shared knowledge and statements on which technology implementation is based. Essentially, the epistemic accident is a consequence of the structure of technical engineering knowledge. Thus, through the epistemic accident theory we can differentiate '*those accidents that occur because a scientific or technological assumption proves to be erroneous, even though there were reasonable and logical reasons to hold that assumption before (although not after) the event*' (Downer, 2011: 752, emphasis in the text). These accidents present some properties and implications distinguishing them from the normal as well as the organisational ones:

- Epistemic accidents are not predictable or avoidable *ex ante* – they are unforeseeable because by definition they elude any form of control and cannot be identified before their occurrence. They question the assumptions and theories guiding a technological component's ideation, projection, and implementation. Thus, as the accident highlights new elements in contrast with such assumptions and theories, it cannot be intercepted before it occurs. They are unavoidable because their genesis is embedded in the structure of the technical engineering knowledge (ambiguities leading to judgements formulation as well as distance between the real word and the laboratory);

- Probability epistemic accident occurrence increases as a consequence of the introduction of new technologies – such a statement does not exclude the occurrence of an epistemic accident with technologies used over enough time. However, given that long used technology implies a lot of experiments, observations, research and tests during operation, the probability that new events breaching shared assumptions and theories will happen decreases;
- Learning may follow epistemic accident occurrence – epistemic accidents may retroact on the assumptions and theories leading to a reformulation of the existing paradigms. Thus, such accidents may generate knowledge improvement and learning through a reconfiguration of the previous assumptions and theories on which the implementation of the technological components triggering the accidents was based. As a consequence, the occurrence of new accidents of the same kind may be interrupted, given the new knowledge developed by the accident itself, 'by portraying all new technologies as "real-life experiments" with uncertain, but ultimately instructive outcomes, a constructivist understanding of failure highlights the instructive nature of accidents, as well as their inevitability' (Downer, 2011: 756).

To sum up, the Epistemic Accident Theory shifts the focus from organisational factors to the structure of engineering knowledge in itself, and offers a new and innovative approach to the explanation of organisational accidents' aetiology.

Organisational Accident Theory

The importance of looking at accident genesis from a large organisational perspective was first emphasised by Barry Turner (1978; Turner and Pidgeon, 1997). Turner frames accidents as the outcome of the everyday organisational decision-making process. Accidents are man-made, following from the interaction of social, organisational and technological processes. They are not unforeseeable events, but the results of a long 'incubation period', in which errors and dangerous events keep happening even though they are not noticed or fully understood by the management of the organisation. Through the *Disaster Incubation Model*, Turner identifies six sequential stages of disasters' aetiology, basing his theory on a large number of empirical cases (Turner, 1978: 85):

- Notionally normal starting point – 1) initial culturally accepted beliefs about the world and its hazards; 2) associated precautionary norms set out in law, codes of practise, mores and folklore;
- Incubation period – accumulation of an unnoticed set of events which are at odds with the cognitive framework and with the shared image of the world;
- Precipitating event – forces itself to the attention of the general perception of the incubation period;
- Onset – the immediate consequences of the collapse of cultural precaution become evident;
- Rescue and salvage – first stage adjustment;
- Full cultural readjustment – an inquiry is carried out and new norms and legal safety guidelines are developed to link to the new framework.

According to Turner's analysis, accidents are generated by the organisations and their bounded rationality. However, the incubation period, during which chains of discrepant events are generally unresolved or unnoticed (either the events are not known or they are known but not really understood), reveals that accidents could be prevented, if these signals were previously identified.

Turner's legacy remained undeveloped for a long time. However, several years after, Reason (1990; 1997; 2008) returned to it and developed Turner's work. Reason's first analysis is on human contribution, but from the outset, the focus rested on the role of the organisational factors, making errors and violations by front line operators possible. Specifically, a key idea drives Reason's approach: even though an accident's trigger may be the action performed by a front-line operator (errors or violations), this action is induced or even produced by latent organisational factors. Latent factors result in a situation prone to such errors or violation occurrence (Figure 6). Examples of latent factors are: communication problems, a training deficit, inadequate or ambiguous procedures, fallacious control systems, erroneous management decisions, etc. They are conditions or actions whose harmful consequences persist silently over time and become evident only when, combined with local factors (errors or violations) and having passed through the defences of the system, an accident has occurred. Latent factors in organisations are comparable to a pathogen organism in the human body: the more there are, the more the possibility to contracting a disease increases. Similarly, the number of latent factors affecting an organisation increases the probability of occurrence of an error or a violation leading to an accident.

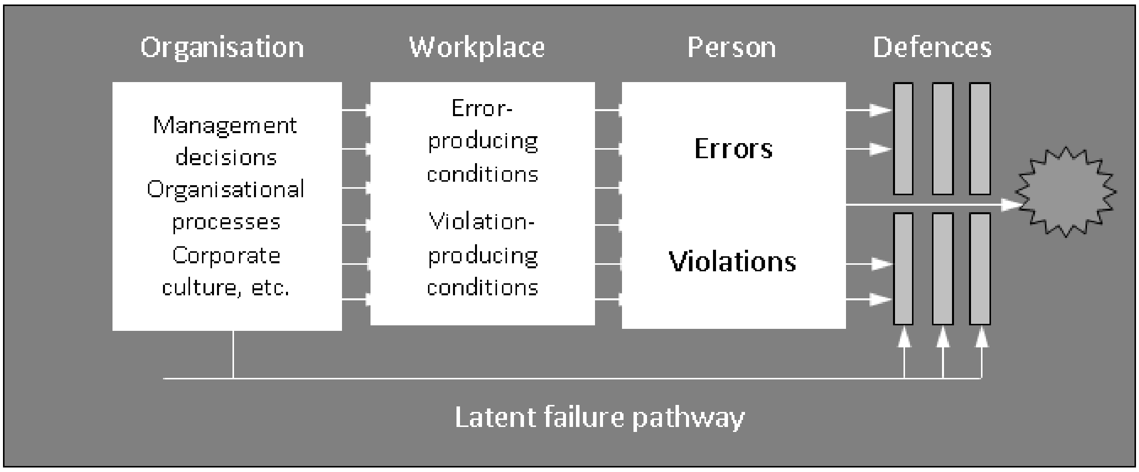

Figure 6: The latent factors model (Reason, 1997)

The Swiss Cheese Model (1997) symbolises the presence in an organisation of a series of defences (layers of cheese) protecting the system from dangers and threats (Figure 7). However, each layer has holes – the latent factors. Reason (2008: 101) states that:

only when a series of holes 'line up' can an accident trajectory pass through the defences to cause harm to people, assets and the environment. The holes arise from unsafe acts (usually short-lived 'windows of opportunity') and latent conditions. The latter occur because the designers, builders, managers and operators cannot foresee all possible accident scenarios. They are much more long-lasting than the gaps due to active failures and are present before an adverse event occurs.

The latent factors made the scene prone to accidents. Nevertheless, latent factors are not 'causes' of the accident, but conditions increasing the probability of an accident's occurrence. Therefore, the identification and correction of the latent factors can strengthen organisational defences and decrease the probability of dangerous events.

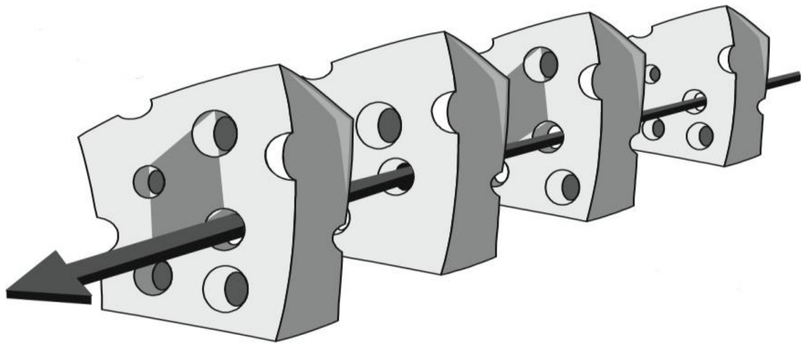

Figure 7: Swiss Cheese Model (Reason, 2008)

To sum up, the Latent Factors Theory underlines the importance of latent conditions for developing disasters. Most significantly, human errors can cause an accident, but these errors are closely linked to the organisational condition which ‘may be present for many years before they combine with local circumstances and activate failures to penetrate the system’s many layers of defence’ (Reason, 1997: 10). Following the Swiss Cheese model, even if a large number of dangerous acts may be perpetrated, fortunately such actions usually don’t result in an accident because they don’t find subsequent cracks in the defence system. Organisations have several defence levels. The holes are not fixed, but they can move over time, in relation to the complex internal and external system of safety regulation.

Organisational accidents from theories to ideal types

By comparing the three available theories on accident genesis, a cross-sectional distinction emerges between them: on the one hand, organisational accident theory looks at accidents as potentially avoidable phenomena and thus, in principle, they consider prevention and prediction as potentially possible. On the other hand, the normal and epistemic accident theories stress the radical uncertainty surrounding those events and frame accidents as unavoidable phenomena, given some specific condition – e.g. tight coupling and complex interactions. The variability of the available theories shows how a single theory cannot explain the accidents phenomenon in its complexity, but it explains different possible genesis scenarios leading to accidents. More specifically, the theories are not ‘general’ and all-comprehensive, but ‘particular’ (Catino and Bianco Dolino, 2013), and strongly linked to their empirical foundation. Such a conclusion suggests a possible reinterpretation of their outcomes as accident ideal types (Weber, 1922), rather than theories. With this in mind, we advance a taxonomy of three types of organisational accidents, grounded on the three theories described above, looking at two dummy variables – predictability and learning:

- Predictability looking at the past, focuses on the incubation period (Turner, 1978; Turner and Pidgeon, 1997) preceding an accident's occurrence. More specifically, the distinction between potentially predictable events and unpredictable ones refers to the presence or the absence of signals (weak or strong) of the possible incoming dangerous events. The presence of signals does not mean that these signals are seen by the organisations involved. As Turner specifies, signals – chains of discrepant events – could be unnoticed or not fully understood by the organisations before the accident happens. Thus, this dimension refers to the presence or the absence of signals regardless of whether they are actually seen or understood. On the contrary, unpredictable events are in principle without signals and, consequently, totally outside the possible organisational awareness of them. For example, being one-off interactions of different components, or based on wrong assumptions on the system's functioning, they cannot become evident until after the accident;
- Learning looking at the future, concentrates on Turner's post-tragedy cultural readjustment (the sixth phase of the Disaster Incubation Model). In particular, this dimension aims to distinguish events through which an organisation may potentially learn something useful to avoid other accidents of the same kind; from events through which any learning process cannot follow. For example, because no other events of the same kind may happen again in the future (one-off events); or the available new information may not be translated into improvements of systems' resilience (change is complex, expensive or unfeasible). As for the predictability dimension, to state learning as possible does not mean that it actually occurs. Learning from accidents is a complex process that is extremely difficult, even if in principle practicable (e.g. Vaughan, 2005). To sum up, something useful and feasible may or may not potentially be learned from the accident occurrence to avoid other accidents in the future.

Crossing the two dimensions in a table (Table 12), we can distinguish three types of accident: organisational accidents (first quadrant: yes-yes); epistemic accidents (third quadrant: yes-no); and normal accidents (fourth quadrant: no-no).

		Learning	
		Yes	*No*
Predictability	*Yes*	Organisational accident	
	No	Epistemic accident	Normal accident

Table 12: Taxonomy of accidents (My elaboration.)

Normal accidents are not preventable as one-off interactions between multiple failures. In addition, any new knowledge is available after an accident of this type occurred. Epistemic accidents are not preventable, because they originate in the limits of knowledge, but it is possible to learn from these events and improve the available knowledge and, consequently, the system functioning in order to avoid other events of the same kind. Organisational accidents are potentially predictable, given the signals preceding them, and the learning after the accident is in principle possible (e.g. discovery of latent organisational factors rendering the scene prone to errors and violations). Consequently, normal and epistemic accidents are not in principle preventable. The next section is dedicated to the examination of organisational accidents. More specifically, we look at those studies that examine empirical cases of organisational accidents which highlight what are the relevant elements in organisational accidents' genesis that, potentially, allow the accidents to be prevented.

3.2 Organisational accidents' genesis

In looking at previous empirical studies dealing with organisational accidents' genesis, we focus on two elements: organisational accidents' precursors which, if seen, could allow for the interception of an accident before it happened (Turner, 1979; Heinrich, 1931; Turner and Pidgeon, 1997; Reason, 1997); and the mechanism through which warning signals tend to remain unnoticed – the normalisation of deviance mechanisms (Vaughan, 1996).

Precursors

Since the 1980s, scholars have started to look at organisational accidents not as random events linked to fate or misfortune, but as potentially preventable phenomena preceeded by a set of warning signals that can be defined as accident precursors or near-misses (Heinrich, 1931; Turner, 1979; Turner and Pidgeon, 1997; Reason, 1997). As already mentioned, Turner (1979; Turner and Pidgeon 1997), in studying several accident cases, noted the presence of an 'incubation period' that precedes accident occurrence. During that 'incubation period', 'unnoticed sets of events which are at odds with the cognitive framework and with the shared image of the world' (Turner and Pidgeon, 1997: 85), keep happening. Accidents are not bolts from the blue, but the final outcomes of chains of discrete events generally unresolved or unnoticed (either the events are not known, or they are known but not really understood or considered). Thus, if these warning signals were previously identified accidents could, in principle, be prevented. Studying insurance data concerning the frequency of potential-injury accidents, Heinrich (1931, ed. 1980: 60) offers a quantification of the link between warning events and accidents. More specifically, he estimates that 'in a unit group of 330 accidents of the same kind and involving the same person, 300 result in no injuries, 29 in minor injuries, and 1 in major lost-time injury'. (See Figure 8.) Thus, warning events have a frequency that is about three hundred and thirty times higher than the accident they are warning about.

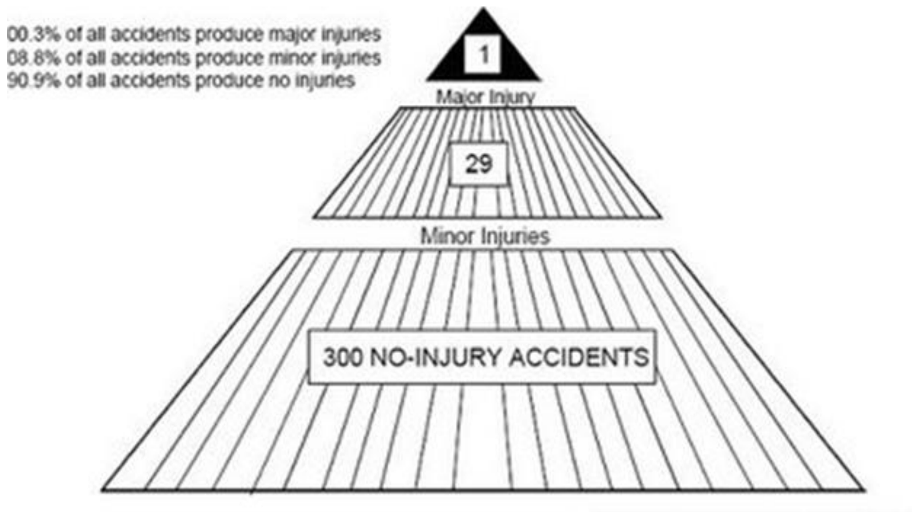

Figure 8: Heinrich's pyramid (Heinrich, 1980: 61)

By looking within the 'incubation period', further case studies on organisational accidents' genesis highlight the presence of warning precursors, weak or strong signals, and near-misses preceding the accidents (Vaughan 1996; Snook 2000; Catino 2006; 2010). Those warning events are activities that have not led to any consequences or damage but, under certain conditions, or by interacting with other events, could trigger an organisational accident. Let us examine some organisational accidents focusing on the events' trigger and the warning events of the same type of trigger, that preceded the accident:

- The Challenger and Columbia disasters.
  Vaughan's (1996) analysis of the Challenger disaster shows how the O-ring malfunction that acted as a trigger for the accident was a known phenomenon that happened several other times before the Challenger disaster, but had not led to consequences of the same magnitude. A similar scenario preceded the Columbia disaster as well: a foam detachment, a known event that had happened many times before the Columbia tragedy without serious consequences, led to damage of the left wing's panel which caused the destruction of the space shuttle when it re-entered the Earth's atmosphere (Vaughan, 2003);
- The *Linate* accident.
  Another example is Catino's (2010) analysis of the Linate disaster which occurred in Milan on 8 October 2001. The accident transpired because of the collision of two aircrafts at the Linate airport. While one aircraft was taking-off, another aircraft took the wrong exit entering the taxiway. The two aircrafts collided leading to the loss of 118 lives. The same accident scenario had happened the day before. An aircraft had taken the wrong exit and entered the taxiway. However, better visibility conditions allowed the aircraft taking off to stop, thus avoiding the collision;
- The *Costa Concordia* accident.
  The '*inchino*' practise that acted as a trigger for the *Costa Concordia* accident is another example of not fully understood warning signals. As already mentioned, on 13 January 2012 at around 9:45 p.m. the cruise ship *Costa Concordia* approached Giglio Island after a deviation from the programmed route. It partially sank and ran aground near the island. The sinking led to the loss of 32 lives. The collision with rocks followed an unplanned near-shore salute to the local islanders – or *inchino*, which literally means bow or curtsy – that brought the ship to a distance of 0.5 miles from the coast instead of the 3 miles programmed during the ship's route planning. The *inchino* performed by Captain Francesco Schettino that night, was not a one-off event, but a regular custom. The captains of cruise ships had the habit of navigating near

the shore of islands. As in the Challenger and the Columbia cases, the *inchino* trigger, performed since 1993 (Palombo, 2008), has happened many times without leading to an accident until the *Costa Concordia*.

In conclusion, organisational accidents are preceded by warning events. Those warning events are potentially dangerous ones without any dangerous consequences, but which, under other conditions or by interacting with other events, can lead to an accident. Such warning events have a frequency that is usually higher that the accident they are warning about. Nevertheless, organisations tend not to see or not to understand such warning signals. In studying the Challenger disaster, Vaughan (1996) identified the mechanism that tends to prevent organisations from understanding and giving importance to those warning signals: the normalisation of deviance. The next section examines the normalisation of deviance mechanisms in depth.

Normalisation of deviance

Vaughan (1996) introduced the concept of normalisation of deviance by analysing the activity of one organisation: NASA. More specifically, Vaugha developed the concept by studying the Challenger disaster, focusing on the organisational factors within NASA that made the setting accident-prone. Thus, we start from a short description of the event before examining the concept of deviance normalisation in depth.

On 28 January 1989 at 11:38 EST, NASA launched the Challenger space shuttle from the Cape Kennedy launch site. A few seconds after take-off, the space shuttle exploded leading to the loss of the lives of seven crew members. The Challenger disaster had important consequences not only in terms of loss of lives and massive economic resources, but also because it represented the symbol of the deterioration of a longstanding space industry technological myth. The trigger of the event has been identified as the breaking of the O-rings, the circular rubber seals that sealed the air space between the components of the shuttle's rocket boosters, to stop the escape of fuel. More specifically, the O-rings' breakage led to a fuel leak that set a sequence of events in motion which led to the space shuttle explosion 72 seconds after the launch. The shuttle was designed in order to resist O-ring breakdown through the back-up supply of this component. Nevertheless, the cold weather of the night before the launch, had frozen the rubber of both the back-up rings, creating cracks and leading to the ineffectiveness of the redundant design. NASA staff was aware of the link between cold and possible O-ring breakage. In fact, the day before the launch a teleconference between the directors of NASA's Marshall Centre and the technical engineers of Thiokol, the company that had manufactured the O-rings, was held in order to address this matter. The technical engineers suggested postponing the launch until improved weather conditions. Nevertheless, NASA directors expressed perplexity about the postponement. On the one hand, they stressed the numerous delays that had already occurred making another postponement an improbable option. On the other hand, they stressed the uncertainty surrounding the correlation between low temperature and possible O-ring breakage. At least, Thiokol's vice-president, who stated that in addressing the ring issue they needed to think like managers and not like engineers, agreed to stay with the scheduled launch. Finally, an agreement was reached and the launch was approved for the day after. The enquiry that followed established the responsibility of NASA in pursuing a launch without the needed safe conditions. The decision to still carry out the launch despite the unsafe conditions was motivated by an evaluation of the economic and 'reputational' consequences that an additional launch delay could lead to from the point of view of NASA's managers. The enquiry commission verified that the O-ring problem was not a new one, but a well-known problem. Evidence of the correlation between the rings failure and weather conditions dated back to 1977. Despite the evident problem, NASA decided to go on with the launches and, in the meantime, search for a solution to the problem. Nevertheless, the opinion of Thiokol's engineers regarding the need to postpone the launch was not taken into account leading to the prevalence of economic and reputational rationales over safety ones. The commission concluded that the causes of the disaster were not only the technical one, but also economic difficulties and management pressures resulting in a violation of safety standards. Vaughan's (1996) analysis illustrates a different interpretation of the disaster's causes. More specifically, she demonstrates that the disaster's main cause was not the violation of available safety rules, but the respect of those rules. More specifically, in studying the accident and the organisation in which the accident occurred for nine years, Vaughan (1996) demonstrates a disparity with the commission's conclusions, the accident was in compliance with the available regulations, and not the result of a violation of the existing safety standards. Paradoxically, it was not a violation that led to the disaster, but respect for the rules available at that time in NASA in order to ensure the safety of the mission's operations. Thus, the accident was the product of rational actions, and not the result of errors, violations, or of the irrational, impulsive, self-interested or amoral behaviour of NASA's managers. The decision to launch the Challenger was made in conformity with the decision-making model established progressively over time within the organisation. Vaughan shows how risk and safety were not objective scientific categories, but the product of the organisational culture that decision after decision and action after action had structured the approach to risk regulation shared at NASA. Through ad hoc processes of risk analysis, evaluation and estimation, the perceptions of the dangerousness of the ongoing events were progressively reduced. Thus, the available procedure acted as a process of re-definition and minimisation of the risk instead of focusing NASA's attention on the possible side-effects of space operations. Vaughan reveals how 'disastrous consequences can emerge from the banality of organisational life' (1996: 410). She follows three main explanatory lines: the normalisation of deviance; the culture of production conditioning NASA's operations; and the structural secrecy affecting the circulation of information deriving from the vast and complex organisational structure of NASA. Here, we focus on the normalisation of deviance explanatory line.

If we look at the Challenger disaster genesis, we see the same type of trigger as a series of precursors that led to the accident, and those precursors were not fully understood or considered by the organisation in which the disaster happened (Turner and Pidgeon, 1997). The normalisation of deviance mechanism explains how it is possible for an organisation, despite the presence of warning signals, not to notice, consider or understand those signals before an accident happens. More specifically, 'the explanation of the Challenger launch is the story of how people who work together develop models that make them blind to the consequences of their actions' (Vaughan 1996: 409). The normalisation of deviance concept refers to the process through which organisations gradually normalise – consider normal – small changes or deviations from the normal course of events. Such a process minimises the dangerousness of those deviations providing the basis for accepting additional changes or deviations. This to a point in which the deviation from the norm, instead of being a warning signal, becomes the normal course of events. The normalisation process is structured through the organisational processes that regulate the way in which organisations identify, define and evaluate risks. For example, at NASA a codified procedure allowed a situation of acceptable risk to be reached:

1. To warn of potential risk;
2. To draft a formal document for the identification of risk;
3. To describe and prove the possibility that an accident can happen;
4. To draft a second document of risk evaluation, and finally, of the acceptability of the risk;
5. If needed, to decide to react.

Going through such a codified procedure every anomaly was normalised. Thus, risk was progressively classified from 'uneliminateable' or 'residual' – all the procedures to avoid it had been identified – to 'acceptable'. Through those processes, organisations progressively transform deviation from the norm into the norm, and the uncertainty surrounding risk evaluation and estimation into certainty. This mechanism was particularly relevant at NASA given its unique technical conditions, as well as the high-risk profile of its activities. Consequently, on the one hand, risk was a constant the organisation should face in all of its activities, on the other hand, there were no other concurrent experiences the organisation could look for in order to interpret its own results. As a result, the organisational processes produced the belief that deviation from the norm does not constitute a threat to safe operation, and the repetition of deviant event without dangerous consequences tended to be interpreted as a sign of safe operation, rather than warning signals of the potentially dangerous consequences of those deviant events. Thus, launching with defects became normal and acceptable, rather than deviant.

To sum up, the normalisation of deviance mechanism explains why, despite the presence of warning signals, organisations tend not to consider or fully understand those signals as possible accident precursors. More specifically, (1) the formalised organisational processes that tend to reduce the dangerousness of deviant events by classifying them as not further reducible and thus, acceptable; (2) the fact that those deviant events do not lead to dangerous consequences encourages framing those events as non-threatening; and (3) the lack of concurrent interpretations, leads organisations to normalise deviant events and progressively classify the deviant operation as a safe one.

PART TWO.

RESEARCH DESIGN: THE CASE OF THE ITALIAN RAILWAY SECTOR

In order to answer the question – 'Why doesn't the (watch) dog bark?' – we propose a case study research design. The case selected is the case of the Italian railway regulatory network. An analysis of the Italian rail transport legislative framework allows us to identify the points of view of the regulating organisations which this study considers: the European Railway Agency (ERA), at the European level of government; and the *Agenzia Nazionale per la Sicurezza delle Ferrovie* – National Safety Authority (NSA); and the *Direzione Generale per le Investigazioni Ferroviarie* – National Investigation Body (NIB), at the Italian level of government. These three organisations can be considered the (watch) dogs of the Italian railway sector: organisations in charge of managing and regulating rail transport activities in order to avoid, cope with, and/or handle the possible negative outcomes of such activities, but not involved in rail transport operations.

The institutional logics theoretical analytical framework (see Part 1, Chapter 2) constitutes the theoretical point of view from which the case of the Italian railway regulatory network is analysed. The research design is structured in two steps according to the chosen levels of analysis (see Part 1, Chapter 2, Section 2.3, for further details, and Figure 4, for a graphical representation of the levels of analysis chosen):

1) Meso level analysis;

   The aim of this step is to identify and describe the logics shaped by and shaping the three regulating organisations' actions and decisions. In addition, it is to examine the logics interplay and degree of legitimacy. (See Part 1, Chapter 2, Section 2.3.) The analysis of the logics of risk management and regulation available within the railway regulatory network considers two levels of analysis:

   - The politico-economic level – the politico-economic level corresponds to the regulatory model fostered by the legislative framework shaping the roles, responsibilities, and regulatory approaches of the public and private organisations involved. We decided to focus on the risk-based regulatory approach, and the case selection is based 'on paper' on the attributions of such a model of regulation highlighted by previous studies. (See Chapter 1, Section 1.3.) Our aim is to keep the point of view of regulators. Thus, the politico-economic level analysis is based on the way in which regulators understood and presented the regulatory model orienting their activities. By looking at the politico-economic level, our main focus is on the commonality between the studied organisations instead of their differences. The purpose is to understand whether there is a common view within the network about the regulatory strategies fostering the definition of the organisational regulatory network;

- The inter-organisational level – the inter-organisational level refers to the network regulatory strategies from within. Thus, the focus is on the differences between the studied organisations in the practical translation of the politico-economic level regulatory logic, as well as on interaction and coordination among the regulating organisations and between the regulating organisations and the regulated ones. The inter-organisational level of analysis takes into account interaction between different levels of government – national and supra-national – as well.

2) Macro and micro level analysis;

   The aims of this step are:

   - With reference to the macro level, to locate the context-specific logics identified at the meso level within the inter-institutional system, and to analyse the role of the various institutional orders – state, market, profession, corporation, religion, family, and community – in fostering the identified context-specific meso level's logics;
   - With reference to the micro level, to focus on what are the consequences of the prevalence of specific logics on individuals and organisations' actions and decisions. The basic idea driving such a focus is that logics represent 'conceptual lenses' that are a way to see and a way not to see at the same time: logics focus individuals and organisiations' attention on certain problems, but not others, as well as on certain solutions despite the potential multiplicity of available solutions (Simon 1947; 1962; March and Simon, 1958; Simon, 1962; March and Olsen, 1976; Ocasio, 1997; Thornton and Ocasio, 1999; Thornton et. al., 2005; Cho and Hambrick, 2006; Lounsbury, 2007). The analysis of the logics' focus of attention mechanism allows us to understand which type of events logics focus regulators' attention on. Through a 'mental' or 'conceptual experiment' (Weber, 1922), we show which informational inputs regulators' attention tends to focus on, between the various informational inputs that inform regulators' activities, by wearing a different logic's conceptual lens. The organisational accidents field's main findings (see Part 1, Chapter 3) constitute a comparative element in order to understand if logics' focus of attention allows us to see events that are important to intercept an

accident before it happens. More specifically, once we have identified which informational inputs regulators' attention is focused on, we need a term of comparison, which allows the possibility for regulators to focus their attention on events that are relevant in organisational accidents' genesis, to be understood. Thus, we consider the available insight about organisational accidents' genesis, and we compare the events on which logics focus regulators' attention with the events that previous studies show as relevant in organisational accidents' genesis.

This chapter deals with and renders some methodological choices explicit regarding the definition of the research steps mentioned above and, more in general, the decision of developing a case-study research design. Chapter 1 deals with the reason why case study research design is particularly fitting with our research question and aims, as well as the criteria that have driven the selection of the case of the Italian regulatory network. Chapter 2, focusing on the data used in this dissertation, describes the technique used for collecting the data and the criteria followed for analysing them. In conclusion, Chapter 3 more closely addresses the structure, assumptions, and limits of the 'mental' or 'conceptual' experiment driving the exploration of the meso-micro link, as well as the comparison with the main organisational accident findings.

1. A CASE STUDY RESEARCH DESIGN

1.1 Why a case study?

In comparison with other research strategies, case studies occupy the ‘in-depth’ pole of the trade-off between ‘in-depth’ and ‘general’. This trade-off fosters specific strengths and weaknesses linked to the choice between different research strategies. The main weakness that case studies (small or one *N*) present in comparison with cross-cases (large *N*) research strategies refers to the weight of the identified relevant variables with respect to other contributing ones and, more in general, the specification of to what extent the obtained research results can be generalised to other classes of phenomena. Despite such weaknesses, case studies present some distinctive strengths that make this research strategy particularly fitting for our research questions and purposes (Bennett, 2004; Gerring, 2004; George and Bennett, 2005; Flyvbjerg, 2006; Yin, 2014). A description of the strengths of the case study research design, which has oriented our choice towards this research strategy, follows:

- Case study research strategies are recognised as particularly fitting in order to answer explanatory questions such as ‘why’ and ‘how’ questions (Yin, 2014). ‘This is because such questions deal with operational links needing to be traced over time, rather than mere frequency or incidence (Ibid.: 10)**.’**[45] In examining the differences between the obtainable results through a case study research strategy in comparison with other research strategies, which consider larger *N*, Gerring (2004) distinguishes between causal effects and causal mechanisms. The identification of a causal effect requires the examination of cross-unit variations, thus large *N*. In contrast, the identification of causal mechanisms is more linked to examining a phenomenon in-depth, thus small or one *N*. He concludes that explanatory questions seeking to identify causal mechanisms instead of causal effects, are particularly fitting to be answered through a case study. More specifically, the purpose of an explanatory question – ‘how’ or ‘why’ questions – is not identifying a causal effect, but

[45]Yin identifies two other possible fitting research strategies for the purpose of answering ‘how’ and ‘why’ questions: historical analysis and experiments. The case study strategy is preferable when, unlike with historical analysis, the purpose is to examine contemporary events and direct observation of the events is not possible. And, unlike in experiments, it is not possible to manipulate relevant behaviour artificially, directly and systematically (Yin, 2014).

exploring the mechanism linking the independent to the dependent variables. The kind of explanation that a case study can pursue is not just stating that A affects B, but it is about understanding in which way A and B are related, and in which way A affects B (Bennett 2004; Gerring, 2004; George and Bennett, 2005; Poteete et al, 2010). Thus, it is not just about stating that there is a link between A and B, but explaining the underlying mechanisms in action within this link. Given the why question this study aims to answer – 'Why the (watch) dog doesn't bark?' – the purpose is to understand the way in which logics affect regulators' possibility to intercept an accident before it happens, and not just to state that a link between logics and accidents exist;

- Case studies allow for high levels of conceptual and internal validity to be achieved (Bennett 2004; Gerring, 2004; Kacowicz, 2004; George and Bennett, 2005). George and Bennett (2005) highlight how different concepts and phenomena can assume extremely different meanings in different contexts. For example, they state that 'a procedure that is "democratic" in one cultural context might be profoundly undemocratic in another' (Ibid.: 19). One of the main strengths of case studies is that this research strategy allows researchers to provide a 'contextualised comparison'. Internal and conceptual validity requires 'a detailed consideration of contextual factors, which is extremely difficult to do in statistical studies but is common in case study' (Locke and Thelen, 1998: 11 in George and Bennett, 2005: 19). Considering previous studies' insights about the variability of meaning associated with the concepts this research refers to, such as risk and risk management, as well as the variability affecting the kind of phenomena bound under such concepts. We consider the need of ensuring a high degree of conceptual and internal validity as essential in order to understand how regulators define these concepts, as well as how regulators differ amongst themselves, for example, in classifying phenomena as risky, or procedures as fitting for the purpose of avoiding, coping with, and/or handling the side-effects of the regulated area of human activity, or not. Given the recognition of such a need for conceptual and internal validity, the case study research strategy has been selected.

During the research design definition, other possible research strategies were considered. The case study research design was preferred to alternative research strategies for various reasons, mainly: the specific aims of the research, the present state of knowledge on the phenomena that is the object of study and, more generally, problems linked to feasibility. A brief description of the alternatives considered and of the reasons why they have been rejected follows. This with the aim of providing a better understanding of the reason why a case study research design was preferred:

- Large *N* of accidents and incidents, or of regulators as units of analysis:
    - The exploration of the existing data set on accidents and incidents shows how the available data about accident genesis considers just the technical or human triggers of accidents, and in rare cases, the organisational factors within the organisation in which the accident happened that render the situation prone to the accident. But no data is available about the regulatory context in which accidents and incidents happened;
    - The available knowledge on risk, risk management and regulation shows the variability affecting the meaning as well as the phenomena bound by such concepts. Consequently, the definition of a questionnaire suitable for a quantitative analysis to submit to regulators, given the actual state of knowledge, would be extremely difficult, and the probability of having answers that are *de facto* incomparable, given the different meanings associated by the respondents to the questions, would be high. For example, the European Railway Agency promoted a survey on risk acceptability criteria in order to understand the actual practises and criteria used in real situation within the railway sector. The questionnaire was submitted to both the sector and the National Safety Authorities. The results obtained were extremely difficult to interpret and the objective of mapping the practises of risk evaluation and acceptability were not reached. Those interviewed found the questions difficult to understand, some of them were not able to answer some questions, and a different interpretation of the same questions emerged[46];
    - Using a large N research design, it would not be possible to observe the interplay of the logics and their degree of legitimacy. The legitimacy of a logic is not necessary related to the number of people that sustain it, but it is also related to the power and the legitimacy that the person that supports a logic has in a specific organisational context. Thus, to identify the number of people supporting a logic is not enough in order to consider such logics as prevalent in a given context. Consequently, even if it could be possible to identify and describe the available logics through a

[46]The final report of the study is published on the ERA website (http://www.era.europa.eu/Document-Register/Pages/Human-RAC-study.aspx, Website consulted 12 July 2014).

questionnaire, it would not be possible to understand which one among the available ones tends to prevail in a given organisation or network of organisations;
  - The explanatory aims of the study could not be pursued through a quantitative data analysis. It would be possible to identify what Gerring (2004) calls 'causal effect', but not the mechanism underlying the identified effect;
- Case study of two or more cases of a regulatory network, considering different regulatory domains: two or more cases instead of one case. As Gerring (Gerring 2007: 20, my emphasis) states 'case study research may incorporate several cases, that is, multiple case studies. *However, at a certain point it will no longer be possible to investigate those cases intensively*.' Given the aim of exploring the logics available within a risk regulatory network in-depth, as well as the way in which such logics affect the view of regulators on the potentially dangerous environmental stimuli they face, we consider the point in which it would no longer be possible to guarantee the adequate degree of in-depth study with the extension of the research design to more than one regulatory domain. On the one hand, research on risk management and regulation requires a high degree of knowledge about the technologies employed within the selected domain, in our case railway transport technology. This knowledge is the basis in order to understand the regulatory activities. In addition, we focus on regulators at different levels of government using two different languages, thus the knowledge of the used terminology should be developed in both the languages. At the same time, regulators adopt specific terminology related to the various legislative tools they use, as well as a specific language that has to do with public administration, again at two different levels of government. In conclusion, the analysis of another domains such as airway transport, nuclear energy production, or maritime transport would make the study too superficial. Consequently, in considering the possibility of extending the research to additional domains, we faced a trade-off between studying a case in-depth, or studying two cases with a lesser degree of intensity. We preferred an in-depth analysis. This also considering the fact that adding one case would not add much to the possibility of generalised results, but it would limit and prejudice the possibility of analysing the logics in depth and the mechanisms through which logics focus regulators' attention on certain phenomena instead of others;

- Case study of a case of organisational accident analysing the regulatory network in which it took place. At the beginning, these were the chosen research strategies, but since the onset, it proved to be not entirely useful, or fitting for our purpose. More specifically:
  - It was not actually necessary to add another organisational accidents case study in order to answer our question. More specifically, a considerable amount of study on organisational accidents and their genesis already exists. Thus, we preferred to capitalise on the knowledge on organisational accidents already available, dedicating the available research time exclusively on studying regulators' approach to risk and its management and regulation, a less examined and known object of analysis;
  - In order to define the research design, we examined various cases of organisational accidents. In one case we performed an in-depth analysis to try to understand the main logics affecting the regulatory activities with the idea of relating such logics to the accident and showing where the regulatory logics presented a gap in their point of view from which the signals preceding the accidents could pass unnoticed. This preliminary analysis immediately showed the need to increase the number of observations, thus a single accident was not enough in order to understand the regulatory approach shared within the regulatory network. More specifically, in order to understand the risk management and regulatory logics shaped and shaping regulators' view, we needed to consider how regulators framed various kinds of events, and considering just one or few accidents would not be enough in order to understand the regulators' point of view. A key distinction in case studies refers to case and observations: '*although case-study research rarely uses more than a handful of cases, the total number of observations is generally immense.* [e.g. Making democracy work, Middletown, Yankee City] *It is therefore essential to distinguish between the number of cases and the number of observations*' (King, Keohane and Verba 1994: 52, my emphasis). According to this distinction, we decided to revise the research design and to consider accidents, incidents and near-misses, and more in general, the way in which regulators manage, cope with, and/or handle the possible side-effects of the regulated area of human activity as observations. This instead of considering a single or few accidents as a case or a few cases. At the same time, we reframed the definition of the case focusing our attention on the case of the regulatory network;

- Case study of more than one regulatory network considering more than one country within the same regulatory domain: two or more cases instead of one. The analysis of more than one case within the same regulatory domain is an interesting and possible future development of this research. However, at the time in which the research started, the available knowledge did not allow us to choose the cases in a constructive manner. We considered the possibility of studying other national regulatory networks as a possible further development of this study. In addition, the knowledge produced by this study could allow us to structure other research strategies allowing a larger population of cases to be selected.

1.2 Case selection

The case selection follows two sets of criteria, according to the two steps of the research design described above.

Looking at the first step of the research, we selected a case as close as possible to what recent studies about regulation identified as a risk-based regulatory network. More specifically, one of the most recognised definition of a case study among scholars is the one proposed by Gerring (2004: 342): 'an intensive study of a single unit for the purpose of understanding a larger class of (similar) units.' In our case the unit of analysis is the Italian railway regulatory network, the 'large class of (similar) units' we targeted in the definition of the research design, is the population of regulatory networks. Namely, networks of organisations involved in the management and regulation of human activities in order to avoid, cope with, and/or handle possible negative outcomes of such activities. For example, the regulatory network for oil drilling in the US, or the regulatory network of maritime transport in Italy, can be considered members of such a population of reference. The case selection follows some fixed attributes of the regulatory networks identified looking at previous risk regulation studies. Specifically, risk regulation studies have identified a general trend affecting the legislative frameworks promoted nowadays by (Western) societies in order to avoid, cope with, and/or handle the possible negative outcomes of human activities. (See Part 1, Chapter 1, Section 1.2.) Such a legislative framework shapes some general attributes of the regulatory networks such as: the involvement of private organisations in regulatory activities (Haufler, 2001; Power, 2005; Aven, 2011); the presence of regulating organisations with a specific technical-scientific orientation, but out of the political arena and electoral pressures (Burton, 1997; Thatcher and Sweet Stone, 2002; Baldwin et al., 2012); and the existence of organisations located at different levels of government dealing with the same regulatory areas of activity (Estache and Wren-Lewis, 2010; Baldwin et al., 2012). We identify a case 'on paper' as close as possible to those attributes, thus some of the concepts and ideas developed here could in principle be useful to understand a broad and increasing population of cases.

Looking at the second step of the research, we follow an 'extreme case' (Flyvbjerg, 2006) selection strategy. More specifically, available explanations considering the failure of regulators in avoiding, coping with, and/or handling the possible negative and unwanted outcomes, focuses on the presence of inappropriate relationships or conflicts of interest between regulators and regulated organisations (Froud et al., 2004; Hirsch, 2003; Citron, 2003), the regulators' adoption of unethical or immoral behaviours (Mintzberg, 2004; Froud et al., 2004; Williams, 2004a; 2004b; Ghoshal, 2005), or the impossibility for regulators to have sufficient or sound information because they are too close to regulated organisations or too far away from them (Vaughan, 1996; 2003; Reason, 1997). Here, we focus on another unexplored 'causal chain' (Weber 1904; 1906; 1913), showing how the failure of regulators in avoiding, coping with, and/or handling the possible negative and unwanted outcomes is not just the result of deviant behaviour or lack of information about regulated organisations' outcomes. The case selection follows the aim of exploring how the logics' focus of attention mechanism works in preventing regulators from seeing events that are potentially relevant in order to intercept an accident before it happens. The study aims to understand if and in which way the logics focus of attention mechanism affects the possibility of seeing warning signals that can allow regulators to intercept accidents before they happen. Thus, following the 'extreme case' (Flyvbjerg, 2006) strategy: an example of a regulatory network which performs particularly well has been selected. The extreme case strategy allows the effect of other intervening variables influencing the regulators' activity to be minimised. Thus, minimising the interaction of other mechanisms that could affect regulators' possibility to see warning signals, the logics' focus of attention mechanism can be better seen.

The combination of those two sets of criteria – a regulatory network and an extreme case – led to the selection of the Italian railway regulatory network. More specifically, the railway regulatory domain was chosen because it is a sector that, 'on paper', is extremely close to the risk-based regulatory approach described by previous studies about risk regulation. More specifically, the criteria leading to the selection of the railway sector and entailing the population of reference the case aims to provide insight on the presence of:

- 'Non-majoritarian agency' characterised by knowledge-based expertise, pursuing safety related goals in some cases exclusively;
- Hybrid forms of regulation as self-regulation – private firms handling the core activity of the regulated domain involved in safety regulation – and meta-regulation – promotion and overseeing of self-regulation performed by public agencies;
- Multi-level interactions and relationships between supra-national and national agencies as well as firms now involved in the regulation processes.

From such criteria, a formal inter-organisational and multi-level structure of actors involved in processes of risk management and regulation emerges. Figure 9 shows a graphical representation of this risk regulatory network that represents the organisational structure of the broader population of reference to which this study aims to refer.

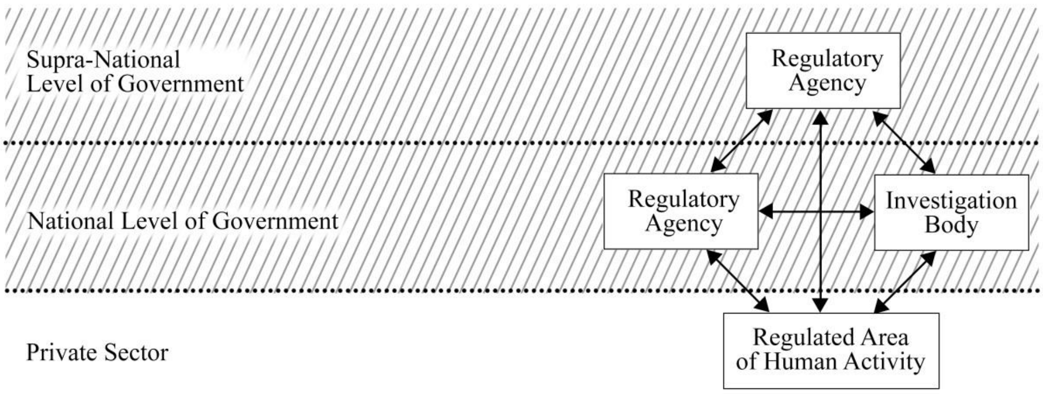

Figure 9: Risk-based regulatory network (The diagonal bars highlight the organisations, the point of view of which, this study aims to maintain)(My elaboration.)

Among the different countries, the Italian case was selected following some specific criteria. In particular because:

- It is not ontologically different from the model promoted 'on paper' at the EU level. Thus, a case advanced in the process of application of the three railway packages promoted at the EU level, as well as advanced in the implementation of the content of the Safety Directive promoted at the EU level and fostering the development of the railway regulatory network mentioned above. Thus, a country that, for example, has already separated the infrastructure manager and railway undertaking of the previous public railway management, and instituted the NSA and NIB at the national level. A case not as advanced in such a process would not be a case of a risk regulatory network. For example, there are countries such as Ireland that have not yet divided operation from infrastructure within the previous public railway management, or that present specificities in the implementation of the EU directive creating variations with respect to the network structure represented in Figure 9, such as Germany, where the NIB is a division of the NSA instead of being an independent organisation;

- It can be considered an 'extreme case' performing specifically well, thus a case in which:
    - There is genuine commitment to the mission of ensuring a safe functioning of the regulated area of human activity, and various and effective risk regulation and management strategies are developed pursuing such an end;
    - There are considerable amounts of resources and skills dedicated to risk management and regulation within all the three organisations studied. In substance, both the NSA and the NIB have been created and are *de facto* operating. Thus, both the organisations have been equipped with resources and skilled staff. This in contrast with other countries such as Greece, for example, where the NIB *de facto* exists, but it employs just one person with an extremely limited amount of resources;
    - There is a specific focus on the need for ensuring regulator independence from the regulated organisations as well as from other regulators – the creation of three independent regulating organisations located at different levels of governments goes in this direction – and regulator accountability to society as a whole;
    - There are structured processes of information gathered in place;
- The available studies on the risk-based approach to regulation, apart from some relevant exceptions (e.g., Jasanoff, 2005a; 2005b; Rothstein et al., 2012), are about the United States and the United Kingdom. Thus, the need also to explore other nation-states arises.

2. DATA USED IN THIS DISSERTATION

The opportunity of using different sources of data is described by Yin (2013: 117) as ‘a major strength of case study’. More specifically, the triangulation of different sources of data is highlighted as specifically relevant in order to increase conceptual validity. In accordance with the main aims driving this research, data triangulation based on three main sources of data has been developed. More specifically, documents, mainly produced by the three organisations studied, interviews, conducted with members of the three organisations, and observation of the interactions and everyday activities of the three organisations, have been considered. A description of the techniques used in order to collect and analyse that data follows.

2.1 Data collection

A description of the process of data collection used according to the three research techniques chosen follows.

Document collection

Document collection started at the very beginning of the research process. On the one hand, the documents published on the websites of the three organisations studied, as well as the information about their activities given by the organisations directly on their sites were the main sources of this first step. On the other hand, the documents, which make up the current legislative framework of the European and Italian railway sector were gathered. The period covered began from the adoption of the first railway package (2001) at the European level, that is, the starting point of the process leading to the configuration of the railway regulatory network as we know it today, to present day. In addition, previous legislation still in force at the Italian level has also been identified and considered.

A second phase of document collection followed the face-to-face encounter with the three organisations and took place during the interview and the observation process. Often during the interview process, depending upon the topic being discussed, interviewees suggested specific documents to read. For example, in describing an activity such as the inspection process, the interviewees provided documents used to conduct this activity, such as check-lists or inspection reports. Quite often, someone would bring documents or work-in-process drafts and say: “I think you may read that, then we can speak about it together." During interviews, documents were the starting point to introduce specific topics addressed in-depth with the interviewee. In addition, in planning the meetings for the interviews, the interviewee was usually asked if he/she could suggest any document that in his/her opinion would be useful in order to prepare for the interview, and to provide an initial idea of his/her tasks.

Full and autonomous access to the internal archives of two of the organisations studied was permitted: the ERA and the Italian NIB. At the Italian NSA, full direct access to their internal archives was not allowed, but interviewees always mediated the document collection. With reference to the ERA and the Italian NIB, during the observation period and the interviewing process, if something relevant emerged, the archives were examined in order to collect relevant documents on the topic. The ERA and NIB's archives were also studied in a more systematic way, in order to verify if there was something that had not yet emerged during the interviews or the observations that was potentially relevant for the study. The examination of existing archives permitted access to the 'documental history' of the organisations studied. For example, documents such as minutes of previous meeting, workshops and task forces, could be examined, as well as the systematic process through which legislative modifications or guidelines took form, or the training programmes held in the past by the organisations studied, were examined.

During the research, documents totalling approximately 6,000 pages were collected and examined.

Interviews

40 members of the three organisations being studied were interviewed. The interview outline was structured in three main areas:

- 'Biographical' background of the interviewee centred around his/her education, previous work experience, and his/her history within the studied organisations and, more in general, within the railway sector;
- Mission of the organisation, and of his/her specific unit/work team within the organisation;
- Tasks and responsibilities of the interviewee within the organisation. Attention was paid to the description of the processes through which the tasks were managed and structured, as well as on the collection of real examples of the activities and tasks performed by the interviewee within the organisation. This with the aim of maintaining, a focus on the 'theory in use' (Argyris and

Schon, 1974) also during the interviews. In order to stimulate discussion on a specific topic, documents' contents, or situations and dialogues registered during the observation process were presented to the interviewee with additional explanations requested.

The criteria through which the interviewees were selected varied according to the organisation. More specifically, with reference to the ERA, and the Italian NIB, there was freedom of movement among the offices and direct contact with the person to be interviewed. Scheduling of interviews was done autonomously. This allowed for the freedom of selecting interviewees following some pertinent criteria. The NIB had an operational staff of six people including the Director, thus all the staff was interviewed. In addition, it was decided to focus on external collaborators as well, thus, two of the investigators, who occasionally collaborated with the NIB on specific investigations, were interviewed. The two external investigators who collaborated more frequently and continuously with the NIB, were also selected. With reference to the ERA, the aim was to cover all the activities (e.g., NSA cross-audit programme, risk acceptability criteria, NSAs and NIBs networks' management, accidents data-base, Member States assessment, etc.) performed mainly within the Safety Unit, thus at least one person for each activity was interviewed. People from other units collaborating more closely with the Safety Unit (Economic Evaluation, Interoperability, Cross Acceptance and Executive Director's Office) were interviewed as well.

In contrast, within the NSA it was not possible to directly contact the interviewed people. A person dedicated to following the research activities within the organisation mediated the interviewee selection and schedule. A topic or a process to be addressed in-depth would be indicated, and the 'supervisor' would identify a person dealing with those topic or processes and scheduled an interview. The selection of the interviewees was in some way oriented by the idea that the people that have the information and the authority to speak about the organisation's activities are the ones that occupy the higher position within the formal hierarchy of the organisation. Thus, the selection of the interviewees was *de facto* unbalanced in favour of the higher hierarchical positions of the organisation.

In all three organisations, a high level of availability and willingness to collaborate in the project was exhibited. Many interviewees were interviewed more than once, and interviews often lasted more than three hours in total.

Observation

A total of 150 days of observation were carried out. The main observed activities were meetings within the organisations studied, between them, and between them and other organisations of the railway sector; NSAs, NIBs and sector plenary meetings; focus groups; workshops; conferences (e.g., Control Command and Railway Communication Conference, Lille, 6-7 November 2012; or Kick-off meeting of the project *Logistica e Sicurezza del Trasporto Merci*, Viareggio (e.g., Logistic and Safety of the Freight Transport, 19 February 2013); and more in general, everyday working activities. It was not possible to participate in some of the activities such as audits of the NSA, assessments of the NIB, audits of the sector, and investigations on accident and incident scenes. The observation of everyday activities within the three organisations was almost completely conducted within the ERA and the NIB. In both those organisations, an office was provided within the organisations and there were no restrictions to freely interact with everyone and to participate in almost all the meetings within the organisations, and between the studied organisations and other organisations. Observation was more mediated within the NSA. It was problematic to find a way of formalising researcher presence within the organisation, thus, there was no fixed location to work within the organisation, and the observations of the everyday activities within the organisation were quite limited. Nevertheless, this process permitted the collection of relevant information on the way in which the organisation works as well. In addition, because the three organisations were *de facto* located within a network, there were many occasions in which to observe the interaction between one organisation and the others, and to talk informally with members of the organisation as well. Being formal organisations, the choices on the research strategies and techniques were limited by the praxis, the habits and the formal internal regulation the organisations followed. Nevertheless, even if, in some respects, the praxis, habits, and regulation could limit the freedom of the researcher in defining the research strategy, they constituted important insights on the way in which an organisation works, which became empirical evidence as well.

The observations were specifically finalised to understand the interaction between the different logics and to explore the coercive-normative components of the logics linked with the context-specific interaction within and between the studied organisations. Thus, attention was paid to the context in which the interaction took place; the organisations involved; the people interacting and their characteristics; the positions expressed and their links with the available logics; and the interpretation of the topic under discussion, which prevailed as a result of the context-specific interaction.

The observation technique selected during the research design definition and mainly practised during the fieldwork, was shadowing. Shadowing is an observation technique in which observers follow the everyday activities within the research context without interacting with the people involved, but simply following them like a ‘shadow’ trying to interact as little as possible with the observed context (e.g., Czarniawska, 2007; Quinland, 2008). The shadowing observation technique is ‘particularly suitable to answering research questions where the unit of analysis is not the individual but the social relation; positions are explored within a complex of interrelated processes’ (Quinland 2008: 1483). Given our specific aim of understanding the interplay and degree of legitimacy of the available logics, this technique was considered particularly fitting with this aim. Nevertheless, during the fieldwork, there were situations in which observation moved from shadowed to participative. More specifically, the observed subject would ask the researcher to participate more directly in the ongoing discussion, or to effectively interact in the on-going activity. For example, in one case the minutes of a working group meeting were written by the researcher. Another time a revision and suggested adjustments to the planning, definition and analysis of a questionnaire was requested. These requests were always accepted. Given the amount of time and the assistance provided during the entire research process, it was considered inappropriate and inopportune to refuse. In addition, those situations were important occasions to better understand the practises in use, as well as to collect additional evidence. For example, the minute of the meeting were sent back to all the participants who could then add comments and request integrations. Being involved in this process proved an interesting opportunity to better understand the degree of importance the representativeness of the various organisations gave to the different topics under discussion, for example.

More in general, the shadowing technique was followed strictly during formal meetings, especially between the studied organisations, other regulators and the sector. Nevertheless, during internal meetings, sometimes questions were asked or examples of issues and topics were suggested. Those internal meetings were extremely relevant in order to comprehend the within-organisation interactions. On the one hand, those situations created the condition for conducting ‘informal’ focus groups around specific issues or topics. On the other hand, they furnished precious information about the weight of the positions expressed by different people within the organisation, as well as about who among the participants was more entitled to answer the questions posed by the researcher, or on dealing with the topic or issue under discussion.

2.2 Data analysis

The technique used for the data analysis was data triangulation. More specifically, data was collected 'from multiple sources but aimed at corroborating the same findings' (Yin, 2014: 119). As already mentioned, logics are different ways in which individuals and organisations frame reality and are characterised by different degrees of legitimacy and institutionalisation. Thus, the use of data triangulation combining three different sources of evidence was particularly relevant in order to describe the content of the logics, as well as to weigh the relevance of the available logics in the three organisational contexts studied, and within the regulatory network as a whole. Consequently, a continuing conversation between the three sources of data was pursued. For example, without informing interviews and data analysis with observational evidence, it might be possible to describe the logics, but no relevant information about the context-specific interactions, as well as about the relevance attributed within the organisation studied to a specific document or point of view, would be available. At the same time, without interviews or document-related evidence, it would probably be extremely difficult to collect data about the observed interactions, seeing as the language utilised is a technical one, as well as the interactions between the studied organisation embedded within the networks' 'rules', without the additional explanations provided by the interviews and documents. Moreover, it would be more difficult to understand the relevance and the positions sustained during a context-specific interaction.

The theoretical analytical framework driving the data analysis is the one defined by the operativisation of the concept of logics, as well as by the chosen levels of analysis. (See Part 1, Chapter 2, Section 2.3.) More specifically, with the purpose of identifying, describing, and analysing the risk regulation and management logics available within the regulatory network and their interplay – meso level as a first step of the two step research design mentioned above – the theoretical-analytical framework considers, on the one hand, the content of the logics, by examining the cultural, cognitive, and organisational components of such logics. On the other hand, it focuses on the interplay of the identified logics: the logics' contents are related to the logics' interplay affecting their degree of legitimacy and prevalence within the three organisations studied, and within the regulatory network as a whole – coercive-normative component. The data analysis follows the choice to look at the meso level by distinguishing the politico-economic from the inter-organisational levels. Consequently, the data collected in all three organisations were examined both separately, looking within each organisation, as well as transversally, looking at the regulatory network as a whole. More specifically, the transversal analysis aims to understand the interpretation that the three organisations offer of the broader legislative framework fostering the current structuration of the regulatory network. Thus, it looks at the high-level frame of reference shared by the organisations studied by identifying what the three organisations have in common regarding their understanding of the legislative framework in which they operate. The separate analysis looks at the inter-organisational level, focusing on the differences between the practical translations the three organisations offer of such high-level legislative framework in their everyday activities. Once the available logics were identified, the analysis moved to the coercive-normative component of the logics by looking at the logic that prevails both within the three organisations studied, as well as within the regulatory network, considering the two chosen levels of analysis – the politico-economic and inter-organisational levels. Some additional details about the data analysis strategies focusing on the three available sources of data follows.

Document analysis

During the first phase of exploratory document analysis, which preceded the fieldwork, no specific criteria of document classification was followed. The driving thought was to get close to the railway and to the railway regulatory network, and to have an initial idea and understanding of what activities and tasks the three organisations under study carried out.

The formal and structured document analysis was started after a first phase of fieldwork (interviews and observations) during which new documents were collected and the ones already read acquired new meaning and/or an in-depth understanding. Documents were classified into three main categories:

- Public documents – documents published on the website of the three organisations or on related official websites, such as the European Commission site. Examples of documents located in this category are: public declarations delivered by the members of the organisations studied, legislative documents, guidelines for the implementation of the legislative framework, annual reports, investigation reports, and annual working programmes;

- Internal documents, not public, but publishable – they are documents acquired or inspected during the fieldwork, but not available on the organisations' website. Those documents are not directly available to the public; they are not published on the organisations' website, but are not affected by specific secrecy or privacy issues. Even if they are not directly available to the public, they are of a 'public nature'. Given the legislation in force at the EU level about the accountability of public institutions, they are in any case available upon request by any citizen who requests them. Nonetheless, the documents were scrupulously analysed in order to eliminate any reference that could compromise anonymity or cause a privacy violation. Examples of documents classified in this category are: slides, reports, procedures, check lists, intermediate reports (e.g., intermediate accident investigation reports), examples of hazard logs or other documents provided by railway undertakings or infrastructure managers;
- Reserved or confidential documents – this category collects all the documents that were acquired or examined during the field work that have a confidential or reserved nature. They are either documents that were shown during the research, but indicated as confidential by the person who showed them, or documents that were acquired without specific restrictions about their use. However, given the comparability of their contents to documents protected by a confidential restriction, they were classified in this category as well. Examples of documents classified in this category are mainly formal and informal written correspondence (e-mails and letters) between the three organisations, and between the three organisations and the sector. All the documents classified as confidential or reserved were used as evidence supporting the analysis, but are not displayed as empirical evidence in the following chapters.

The document analysis followed a pre-defined template that guided the cataloguing. More specifically, for each document the following information was registered:

- Document's category – public, internal, or reserved/confidential;
- Type of document – e.g., legislation, guideline, annual report, investigation report, annual working programme, slide, report, procedure, check list, intermediate report, hazard log, e-mail, or letter;
- Document title – e.g. Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of the Railway Safety Directive;

- Date of document emission;
- Number of pages;
- Institutional author – e.g., ERA, Italian NIB, Italian NSA, European Commission, Italian Ministry of Infrastructure and Transport;
- Factual author(s) (who within the organisations actually wrote the document – when available) and his/her characteristics (information acquired through other data sources, such as observation or interviews);
- Who is the institutionally targeted recipient – e.g. sector, other regulators, European Commission, Italian Ministry of Infrastructure and Transport;
- What are the main aims/ends of the document, declared and not (information acquired through other data sources, such as observation or interviews);
- Main contents;
- Contents of specific relevance for the analysis;
- Relevance of the document within the organisation who wrote it, as well as other regulators (information acquired through other data sources, such as observation or interviews).

As already mentioned, documents were extremely useful as a starting point upon which to stimulate reflection during interviews, observations and informal talks. Nevertheless, the re-examination of the documents conducted after the fieldwork began was essential. More specifically, interviews and observations permitted a better understanding of elements of the documents that had not previously been fully understood, or the ability to identify new relevant elements previously not recognised. In addition, on the one hand, those other sources provided new information about the ‘history’ of the documents, as well as additional information about the aims/ends of the documents. On the other hand, interviews and observations allowed the weight and the relevance of the documents within the regulatory network to be understood. That information was critical to ascertain the weight given to the documents in presenting the logics, as well as to enrich the analysis of the logics interplay and degree of legitimacy within and between the organisations studied.

Documents are presented as evidence supporting the analysis by indicating the institutional author, the document title, the date of emission, and the page number of the document in which the reported contents are located.

Interviews analysis

Being that the three organisations studied were clearly identified, and that at least one of them was extremely small, it was decided, to present the evidence supporting the analysis by indicating only the name of the organisation from which the interviewee came. This in order to ensure the anonymity of the subjects interviewed.

The interview analysis was particularly relevant in order to identify the logics' content (cultural, cognitive and organisational components). With reference to the coercive-normative component, the interview analysis was closely combined with observation data. More specifically, in order to understand which weight the point of view of an interviewee had within the organisation from which he/she came, the analysis of the observational data was especially significant. To understand the importance to assign to the collected interviews, a solid knowledge of the organisations and of the interactions between actors within an organisation was essential. To put it simply, there were opinions and interpretations that counted more than others, and to understand which opinions or interpretations were more legitimate within an organisation is not just about the number of people that sustain it, but it is also about who the person is that sustain it, and the degree of legitimacy that other organisation members attribute to this person and his/her opinions/interpretations. Thus, in order to understand the degree of legitimacy of the available logics, it is not completely relevant or sufficient to count the number of people that sustain it. In contrast, what is more important is to understand *who* the people are that sustain this logic and, given their formal and informal positions within the organisation, if the logic that they sustain tends to prevail over the other available ones. Consequently, engaging in a continuous conversation between interviews and observation sources of evidence was essential.

Observation analysis

With reference to the logics content (cultural, cognitive, organisational components), direct observation of the interaction between different logics allowed the differences in the content of the different logics to be better identified. More specifically, context-specific interactions highlighted the existing difference between the available logics, as well as the way in which statements were sustained through references to different sets of assumptions and principles.

With reference to the coercive-normative component, the analysis of the evidence collected through observation was critical for understanding the prevalence and degree of legitimacy of different logics both within the organisations studied, as well as within the regulatory network as a whole. In analysing those interactions, attention was paid to the context in which interactions took place, the individuals involved and their characteristics, as well as the characteristics of the phenomenon or event under discussion. As mentioned previously, observation data regarding the logics' prevalence and degree of legitimacy closely sustained the analysis of other data sources as well.

3. A MENTAL EXPERIMENT

Once the context-specific logics had been identified, as part of the second step of the research design, we focused on the relationship between the macro and the meso levels, as well as the meso and the micro levels.

With reference to the macro-meso link, by contextualising the context-specific identified logics within the inter-institutional system, we aimed to contextualise the context-specific logics characterising the railway regulatory network within society as a whole. The aim was to understand which institutional orders – market, state, profession, corporation, religion, family, and community – play a role in the definition of the identified context-specific logics. In so doing, we took for granted the description of the inter-institutional system's institutional orders provided by previous studies (see Part 1, Chapter 2, Section 1.1 for further details), and we compared the contents of the institutional orders with the content of the context-specific logics, tracing back to the content of the institutional order of the context-specific content of the available logics.

With reference to the meso-micro link, we structured a 'mental' or 'conceptual' experiment. The expression 'conceptual experiment' was first introduced by Weber. As a crucial part of his methodological and epistemological reflection, Weber highlights that:

> verification of subjective interpretation by comparison with the concrete course of events is, as in the case of all hypotheses, imposable. Unfortunately this type of verification is feasible with relative accuracy only in the few very special cases susceptible to psychological experimentation. In very different degrees of approximation, such verification is also feasible in the limited number of cases of mass phenomena, which can be statistically described and unambiguously interpreted. For the rest there remains only the possibility of comparing the largest possible number of historical or contemporary processes, which, while otherwise similar, differ in the one decisive point of their relation to the particular motive or factor the role of which is being investigated. This is a fundamental task of comparative sociology. Often, unfortunately, there is available only the uncertain procedure of the 'imaginary experiment' which consists in thinking away certain elements of a chain of motivation and working out the course of action which it would then probably ensure, thus arriving at a causal judgement (Weber, 1922: 10).

More specifically, Weber suggests that even if the conditions do not allow for other research strategies to be pursued, social scientists may utilise of another instrument in order to demonstrate the relevance of the proposed explanation: the ‘conceptual experiment’. Such an experiment is based on a mental projection that through counterfactual reasoning – comparing processes that are similar for many aspects, but not for the independent variable chosen for the analysis – allows us to demonstrate the significance of one element in producing a specific result (Weber, 1904; 1906; 1913). Here we face a problematic situation in which the analysis aims to explore the role of logics in affecting the possibility for regulators to intercept an accident before it happens. Accidents are complex and multi-causal phenomena and extremely rare. In addition, the regulatory context to which we aim to link those complex phenomena is neither a direct cause of the accident nor a context in which researchers can intervene by manipulating it. Consequently, following Weber’s advice, we decided to develop a ‘mental’ or ‘conceptual experiment’. The ‘mental experiment’ proposed here combines empirical and analytical elements, and requires an effort by the researcher, and by the reader, to immerse him or herself, and try to see reality as regulators see it, from the different available context-specific logics’ points of view. A description of the structure, assumptions and limits of the mental experiment we aim to conduct follows.

The ‘mental experiment’ is structured in three steps:

1) This step aims to demonstrate that logics change individuals and organisations’ focus of attention on environmental stimuli. In order to show which phenomena logics focus regulators’ attention on, we need a synthetic representation of the informational inputs that inform regulators’ risk management activities. Thus, we consider the accidents, incidents, and near-misses reported within the railway network, in order to define an analytical representation of those informational inputs. Once the informational inputs informing regulators direct risk management have been analytically defined, the idea driving the ‘mental experiment’ is to look at those informational inputs through the available logics’ lenses. To simplify, the process is similar to an eye examination. We try different lenses and according to the lens we wear, certain phenomena are clearly seen and other are blurred and not clearly distinguishable. The scheme is quite the same, we wear different logics’ lenses, and by looking at the informational input we identify the phenomena which, among them, are ‘on sight’, and the ones that are ‘out of sight’. This process allows us to understand if and in which way changing the logic’s lens, the phenomena which attention is focused on change as well;
2) Nevertheless, in order to answer the question – ‘Why doesn’t the (watch) dog doen’t bark?’ – to demonstrate that the logics focus regulators’

attention on certain phenomena instead of others, among the available ones, is not enough. More specifically, in order to answer the question, it is not enough to know where logics focus regulators' attention, but we also need to demonstrate that the focus is not on organisational accidents, mechanisms, or accidents precursors. Here the organisational accidents' field findings are essential in order to ensure a basis for comparing logics and accidents. The question that drives such comparisons is: Do logics focus regulators' attention on organisational accidents or on phenomena relevant in organisational accidents' genesis?;

3) As a third step, we insert logics' degree of legitimacy in the 'experiment'. More specifically, we consider which are the logics that tend to prevail within the network. According to the prevalence of one logic over another within the network, the focus of attention promoted by the prevalent logics tends to affect the focus of attention of the network as a whole. This step allows us to understand whether the regulatory network focuses organisations' and individuals' attention on organisational accidents, and mechanisms and precursors relevant in organisational accidents' genesis.

Assumptions and limits

The 'experiment' we aim to develop is based on some specific assumptions and limits. A description of such assumptions and limits follows.

The main assumptions on which the 'experiment' relies are:

- The reasoning proposed here is entirely based on the assumption that the risk management processes developed by the regulated organisations is not working or is working partially. More specifically, if regulated organisations' risk management processes worked perfectly in identifying and facing potential threats, regulators' direct risk management processes functioning would not be relevant at all in intercepting an accident before it happened. This is related to the question we aim to answer. We are not answering the question 'why do accidents happen?', but we are answering the question 'can regulators' intercept an accident before it happens?'. We are not assuming or sustaining a role of regulators in accidents' genesis. We are just focusing on the possibility that regulators would see such events approaching if they were about to happen (see the Costa Concordia example described in the Introduction);

- The 'experiment' takes for granted previous findings about accidents' genesis. Nevertheless, the available knowledge about accidents' genesis is *de facto* affected by some biases. On the one hand, those studies are by definition *ex post facto*, and thus, biased by a 'hindsight bias' (Fischoff, 1981). On the other hand, being a study of single and rare events (one or small *N*), it is sometimes difficult to establish the extent to which the acquired knowledge refers to accidents studied in and of itself, or the broader population of accidents (e.g., Hopkins, 2006).

The main limits affecting the 'experiment' are:

- Previous studies highlight how the same control measures adopted in order to avoid an accident from happening, can reveal side-effects that instead of avoiding the accident or reducing its magnitude, increase the damage, or create other threats even worse than the accident the control measures are meant to avoid (e.g. Sagan, 1993). This problem is known in social sciences as the unintended consequences of action (Merton, 1936; 1940; 1968). Thus, the 'experiment' allow us to understand if regulators' see accidents, but do not provide any insight on the control measures eventually undertaken by regulators in order to face the identified threat. Thus, the analysis does not say anything about accidents' reduction or avoidance. Paradoxically, the fact that regulators identify the threats can be counterproductive, leading to a worse scenario than the one that would happen if they had not seen the threat;
- The 'experiment' allow us to demonstrate the relevance of the logics and of the focus of attention mechanism in affecting regulators' possibilities of intercepting an accident before it happens. But, it cannot determine the relevance of this contributing factor with respect to others. Additional contributing factors such as conflicts of interest or immoral behaviour are minimised in the chosen cases by the case selection strategy. Thus, we can say that the role of the logics and of the mechanism with respect to other intervening factors, is high in our case. Nevertheless, we cannot say anything about the weight that the logics and the mechanism have, in comparison to other factors having an effect on the same dependent variable, in affecting regulators' possibility to intercept an accident before it happens in the broader population of regulatory networks;
- The 'experiment' is based on a synthetic and analytical representation of the informational input informing regulators' direct risk management processes. Such representation is based on the data collected during the short period spent within the organisations studied. The different sources of information

informing regulators activities, as well as the available statistic on railway accidents, incidents and precursors, have been analysed in order to inform such representation. Nevertheless, the plurality of the information sources, as well as the lack in records of the events that have not being analysed by regulators, can affect the correspondence between the analytical representation and 'reality'. In summary, it is a realistic representation of the informational input, but it is not based on a systematic quantification of the events that actually inform regulators' risk management processes. However, the relevance of this limit on the 'experiment''s results are limited. More specifically, the 'experiment' aims to show how a focus of attention mechanism filters certain information'out of focus', even if the information is available. Thus, even if we consider the hypothesis that some of the information that is available is not included in the analytical representation, or some of the information included is not available, this does not reduce or put into question the role of the mechanism in focusing regulators' attention. It would be just an intervening variable referring to another 'causal chain' (Weber, 1904; 1906; 1913).

PART THREE.

DATA ANALYSIS: LOGICS OF RISK MANAGEMENT AND REGULATION IN THE ITALIAN RAILWAY NETWORK

The Italian railway sector has experienced an important process of change, which began in the early 90s of the last century. More specifically, it is possible to pinpoint a progressive transformation that started with national public service management, moved to the privatisation of national public companies and market liberalisation, and ended with the creation of a unique European market. Given these premises, the need to make adjustments and formulate common standards and methods for safety and interoperability valid across the European railway market arose. At the same time, it became necessary to separate service management from infrastructure, as well as from the supervision of railway operations, which, until then, were exercised by the national public railway giants, the exclusive managers of service, infrastructure, as well as being the regulators, within nation-states boundaries, of their own activity.

At the Italian level, the 'formal'[47] privatisation of *Ferrovie dello Stato* happened in 1992, in close connection with the general attempt to rationalise public expenditures and resources on the one hand, and the progressive enactment of three railway packages (2001, 2004, and 2007) at the European level, on the other.

The theme of risk management and regulation and, more in general, of transport safety is dealt with – at the European level – in the second railway package approved 24 April 2004 and, more specifically, in EU Regulation no. 881/2004/CE and in EU Directive no. 49/2004. These regulatory interventions pinpoint and define the organisational actors involved in the management and regulation of risk and their respective responsibilities, leading to the creation of the regulatory network operating today.

EU Regulation 881/2004/CE institutes the European Railway Agency (ERA), which became effectively operational in 2006 (Baccelli and Cattaneo, 2011). The ERA was given the task of providing for the interoperability and safety of the railway system and of supplying technical support to the Commission. Furthermore, the ERA is indicated as the subject responsible for procuring technical support for EU Directive no. 49/2004/CE, regarding Community railway safety implementation. The ERA does not have decision-making power, yet it is responsible for the definition of the Technical Interoperability Specifications (STI), effective in the entire European Union. Moreover, the ERA does not have direct assessment

[47]The use of the term 'formal' is due to the fact that, as of now, both *Trenitalia S.p.a.* (the railway company established following *Ferrovie dello Stato*'s privatisation) and *Rete Ferroviaria Italiana* (the exclusive manager of the national infrastructure also established as an autonomous company after *Ferrovie dello Stato*'s privatisation) are still 100% state property.

functions, but is designated to interact with all subjects involved in railway transportation, with the aim of promoting and disseminating necessary information in order to advance the application of EU Directive 49/2004/CE's contents.

EU Directive 49/2004/CE was adopted in Italy with Order in Council (*Decreto legge*) 162/2007. That Order radically redefined railway management and safety responsibilities. More specifically, assessment and regulation responsibilities were moved from *Rete Ferroviaria Italiana* (RFI) – exclusive overseer of the railroad network and part of the *Ferrovie dello Stato* holding, instituted in 1992 following the Italian railway sector privatisation, together with *Trenitalia S.p.a.* – to the National Safety Authority (NSA). In doing so, service management was detached from safety assessment and regulation. The NSA is an autonomous and independent authority, but is subject to Ministry of Infrastructure and Transport supervision. The NSA has various tasks: technical regulation of the sector; components, products, applications or subsystem homologation; surveillance over regulation compliance; and more in general, promotion of research and information dissemination throughout the sector. The NSA has been operative since June 2008 (Document: NSA, February 2013, p. 19). The NSA's establishment occurred through successive agreements between the Ministry of Infrastructure and Transport, the Agency itself and *Ferrovie dello Stato S.p.a.* (FS) (Document: Ministry of Infrastructures and Transport, NSA and FS, May 2008). In substance, the passage of expertise was pursued by the movement of staff from the FS group to the NSA; today, the majority of NSA staff comes from the FS group, while a smaller portion comes from the Ministry of Infrastructure and Transport.[48]

Order in Council 162/2007 also sets out the creation of an autonomous authority with the task of investigating relevant accidents: the National Investigation Body (NIB), which operates within and under the surveillance of the Ministry of Infrastructure and Transport. The NIB became operative in 2009. NIB staff comes entirely from the Ministry of Infrastructure and Transport.

In addition, the 162/2007 states that risk management is the exclusive responsibility of railway undertakings and infrastructure managers – they are responsible for the activities carried out by their suppliers, as well. Thus, railway undertakings and infrastructure managers[49] are responsible for locating and monitoring the risks connected with railway operations and, if necessary, for defining

[48]The formal passage of staff from one authority to the other concluded recently.

[49]Railroad network managers must take into account risks related to the presence of more railway companies on the same railroad network.

control measures for their reduction. In contrast, the NSA and NIB, as well as the ERA, at a European level, have tasks (e.g., to promote, regulate, develop and control the processes of risk management carried out by the sector), but do not have duties: they do not have any direct responsibility for what concerns the management of risk.

The legislative framework enacted at the European and Italian levels since 1991 constitutes the network of public agencies located at different levels of government (the ERA, at the European level, the Italian NSA and Italian NIB, at the Italian level). This study aims to focus on the risk management and regulation logics that shape and are shaped by such organisations. The following chapter (Chapter 1) aims to present the logics' contents characterising the two chosen levels of analysis: the politico-economic level (Section 1.1) and the inter-organisational level (Section 1.2), by describing the cultural, cognitive and organisational analytical components characterising the identified logics. The degree of legitimacy of the available logics – the coercive-normative component – is examined in the next chapter (Chapter 2).

1. LOGICS OF RISK MANAGEMENT AND REGULATION

1.1 Politico-economic level: risk-based logic

In looking at the politico-economic level, the aim is to ascertain whether there is a common understanding of a shared railway's risk regulation regime (Hood, 2001), from the regulators' point of view, that is sustained and promoted by a common logic – categories, ends, methods of reasoning, means and organisational structure. (See Part 1, Chapter 2.) Thus, exploring the politico-economic level in action, we can determine whether the three organisations examined – the Italian NSA, the Italian NIB, and the ERA – hold a common view of the railway risk regulation legislative framework, of roles and of responsibilities. Or another way to look at it: here the focus is on the similarities rather than on the differences between the three organisations studied. In contrast, the description of the logics identified at the inter-organisational level of analysis, focuses on the differences rather than on the similarities, and is considered in-depth in the next section.

The analysis highlights the presence of a prevalent and shared logic that underlies and structures the railway regulatory network. Elements supporting such shared logic sustaining a specific risk regulation regime (Hood, 2001) can be found in all the organisations under study. On the one hand, the empirical analysis confirms that the railway sector can be considered a case of a risk regulatory network responding to the general trends affecting the risk regulation described above (see Part 1, Chapter 1, Section 1.3) and guiding the case selection 'on paper'. (See Part 2, Chapter 1.) On the other hand, it allows such an approach to regulation, and the way in which the actors involved define and interpret it, to be considered in an in-depth manner. In particular, an analysis of the cultural, cognitive and organisational dimensions of such shared logic, allows the key elements defining the risk-based approach to risk regulation to be confirmed and better understood through an examination of the point of view of the actors involved. Given such continuity with the previous description of the risk-based approach to regulation, it was decided to name such logic risk-based logic. Let us look closely at the analytical components of risk-based logic summarised in Table 13.

Risk-based logic	
Cultural component	
Risk	Technological risk management as railway undertakings and infrastructure managers business risk
Ends (objectives)	To create a common EU market open to competition and ensuring free access to the market To promote the development of the railway sector by making it business-oriented and competitive To not deteriorate the safety level of railway transport To avoid that the safety argument could be used in order to obstruct free access to the market
Cognitive component	
Method of reasoning	Deductive: theory on the way in which the market should function fosters regulatory strategy
Organisational component	
Means (processes and strategies to reach the ends)	Separation of the former railway companies previously owned and managed directly by nation-states Co-partnership of public agencies and private sectors in the regulation of the possible side-effects of railway activity Light and non-prescriptive regulation: indirect risk management (not rules, but processes and outcomes) External regulators should fix boundaries to the sector, but preserve free market decisions within such boundaries
Organisational structure	Multilevel regulatory network

Table 13: Risk-based logic (My elaboration.)

The cultural component

Category and associated meaning: Risk

Risk-based logic attributes the responsibility of the safe functioning of the railway system to the private sector and specifically to infrastructure managers and railway undertakings:

the responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings. […] each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation, including supply of material and contracting of services, vis-à-vis users, customers, the workers concerned and third parties (Directive 2004/49/CE Article 4, p. L 220/21).

The railway sector's freedom of enterprise should be respected. Railway undertakings and infrastructure managers should ensure the safety performance of their own business as they are responsible for the decisions they made regarding risk acceptability, and for managing the risks linked to their own activities:

because accepting risk is precisely accepting responsibility and so we can say, it's the true exercise of responsibility for the railway operator. I could decide to be more cautious than my colleague, maybe he is compliant with the law, but I want to do something more and I can do it because it's part of exercising my responsibility for the part of the system I'm responsible for (NSA, interview);

the organisation promoted within all the international documents and the 162 (the 162/2007 is the Italian transposition of Directive, 2004/49) is adult organisation that employs self-control, recognises the principles, and places them within its own reality while maintaining safety […] I control myself and find the corrective actions to modify [situations] on my own. Because I control my processes I know, for example, that the use of my wagons during the last six months has increased disproportionately, and so, I have to put corrective action into place in the maintenance cycle […] If I determine that this is not a disruptive modification, I would take responsibility for it […] but it lies within his evaluation and his responsibility […] [everyone is] the holder of an array of competencies to exercise an array of functions (NSA, interview).

External regulators should not make decisions, which they are not charged with, being part of free entrepreneurial businesses. Moreover, external regulators should not share the responsibility of decisions, referring to risk and its acceptability, with the regulated organisations:

we are in the western world, it is a world that we wanted, a world that can serve us well or not, but the vision of the western world in 2013 is one of a monitored free enterprise […] In my opinion this boundary is truly sacred because the relationship of hyper-dependence of the operator with regards to the Agency [NSA] would firstly create a sharing of risk, which is unthinkable because then we would also be an operator and no longer a regulatory agency, [and it would] signify that the system is not balanced (NSA, interview);

the authority has to monitor, it doesn't have to write the rules, the authority tells you: "Alessia, tomorrow write what you want and work as you like. The important thing is that you don't kill somebody." And you say: "I did it." And you start and tomorrow I'm there to check on you, and the next day, and again the day after that. This is fine for two reasons. The first because I am responsible for supervision I'm not responsible for assessment. Secondly, because if I don't monitor you, you have the perception that you can do what you want, which isn't true. It's not deregulation, it's self-regulation. Everyone talks about deregulation, but it's not deregulation. The rule exists and it tells you that it's your problem. [You are responsible for it and it is your problem to ensure safe operation] (ERA, interview).

Consequently, technological risk management is placed within the railway undertakings and infrastructure managers' business risk. The acceptability of risk is the risk you accept for your own business:

paradoxically, we could have two companies which […] have interpreted that they fit into the table [the table with a double entry frequency per magnitude for the classification of risks] corresponding with frequency x which is a value that goes from 10^{-5} to 10^{-6}. If that falls within the scope of the range for that interval there [the interval established by legislation], I don't say anything [to him]. But maybe another person who wants to be more conservative, for him risk is acceptable between 10^{-6} and 10^{-7}, and if they always stay within the scope of that range there, you can do what you like […] You can use a scale of your very own, because the acceptability of risk is what you accept. It's the risk you accept as a business, it's your responsibility […] and you must exercise it, in fact I expect you to exercise it (NSA, interview).

Risk-based logic locates the decisions about the possible side-effects of the railway activity within the 'economic province' (Knight, 1921: VIII, preface to the first edition) of the business enterprise. By shifting the decision about the acceptability of risk onto the sector, the distinction between risk as a side-effect of human activities and risk as a negative business outcome of such activities loses relevance. (See Part 1, Chapter 1, Section 1.1.) Consequently, the reliability of human activities and the efficiency of such activities become closely related. Thus, the stress is not on the negative outcomes of the side-effects for health and the environment in and of themselves, but on the economic impact that the side-effects can have on the achievements of the business objectives of the enterprise.

Ends

Risk-based logic fosters some key ends that railway regulation should meet:

- The creation of a common EU market open to competition ensuring free access to the market;
- The promotion of the development of the railway sector by making it business-oriented and competitive;
- And, in pursuing such an objective, on the one hand, it must not deteriorate the safety level of railway transport and, on the other hand, it must prevent the safety argument from being used in order to impede free access to the market, especially for newcomers. (See Figure 10.)

Figure 10: The ends of risk-based logic (Document ERA, Slide: Dissemination of Commission Regulation on CSM on Risk Assessment, 2009, p. 16)

Looking closely at the safety objective, the purpose is to stick to a broad vision of safety taking into account the balance between safety and other interrelated needs. For example:

- The economic sustainability of the railway business:

> often, there is a narrow view on safety, you don't say the big scope of the risk assessment, even they don't need a Ferrari, they want to buy a Ferrari, but they need a Punto. People always ask more and more, you always have to be safer […], but if the Risk Acceptability Criteria are too high, the system becomes safe, but unusable, we stop the train and that is it (ERA, informal talk);

> whenever we define a certain measure this is related to a cost at least for someone, this is why the balance of it is very important and it is a very good approach to say as soon as you are responsible. So they are made responsible and you are clear about this responsibility and you are managing in a systematic way that is already good (ERA, interview).

- The broader societal risk level taking into account the different safety levels ensured by different transport modes:

  global safety objectives are generally linked to the broadly accepted level of risks taking into account the necessary balance between the safety level and the competitiveness of the transport mode, while local safety levels are considering the exposure of individuals to the risks and the objectives related to the land use planning […] without considering transport as a whole system. Due to […] the economic competition between modes of transport the effect of too high safety requirements on the safest modes may result in shifting a certain volume of transported goods from a safe mode to a less safe one. This situation has clearly been experienced after the Viareggio accident, which resulted in nearly stopping the single wagon dangerous goods transport, in shifting railway transport to road globally resulting in an increase of risks for citizens (ERA, Workshop on Risk Evaluation and Assessment in the context of Inland Transport of Dangerous Goods, 8-9 October 2013, Background discussion document, p. 6-8).

- The interoperability of the EU railway network (the possibility to move from the railway infrastructure of one country to another without technical or operational barriers):

  the EU approach is saying now you are safe and this level of safety is acceptable. What we are trying to achieve is to have a railway as a competitive mode of safety and for this we need to be interoperable and safe at the same time […] The idea is that you are safe nowadays and you are even better compared with before the safety directive because you are now managing risk in a systematic way, so the safety directive is asking that all risks shall be managed, so you need to have processes and procedures for managing risks and the Safety Directive doesn't tell you your safety level is five or three and this is what is acceptable. We don't say this, we say we trust you are safe nowadays and we trust you are even better because now you are managing risk systematically (ERA, interview).

Safety is not an objective in itself, the objective is to substantially modify the railway sector liberalising it and opening it to competition. The concern about safety refers more to the maintenance of the current level of safety than to the improvement of the safety level:

safety levels in the Community rail system are generally high, in particular compared to road transport. It is important that safety is at the very least maintained during the current restructuring phase […]. In line with technical and scientific progress, safety should be further improved, when reasonably practicable and taking into account the competitiveness of the rail transport mode (Directive 2004/49/CE, Whereas (4), p. L 220/17).

Reference to the improvement of safety levels, when reasonably practicable, specifically means: do not compromise reaching the other key objectives such as economic sustainability, the opening of the market and interoperability.

The cognitive component

The method of reasoning guiding regulatory actions is deductive. There are clear statements about the way in which the railway sector should be modified and the processes and strategies that should be developed in order to obtain such a modification. Thus, there is a theory of reference linking ends and means: given the objective of opening the EU railway market to competition, the condition for such an opening should be created. One key condition is the creation of a regulatory strategy that does not interfere with market functioning, thus it does not represent a barrier for entering the market and for competition within the market. Such regulatory strategies, processes, and structures are described in the next section.

The organisational component

Means: processes and strategies in order to reach the ends

Figure 11 shows the main means – processes and strategies – risk-regulation logic identifies and pursues in order to reach the ends mentioned previously (creation of a common EU market open to competition; promotion of the development of the railway sector; non-deterioration of the safety level of railway transport and avoidance of using the safety argument as a barrier).

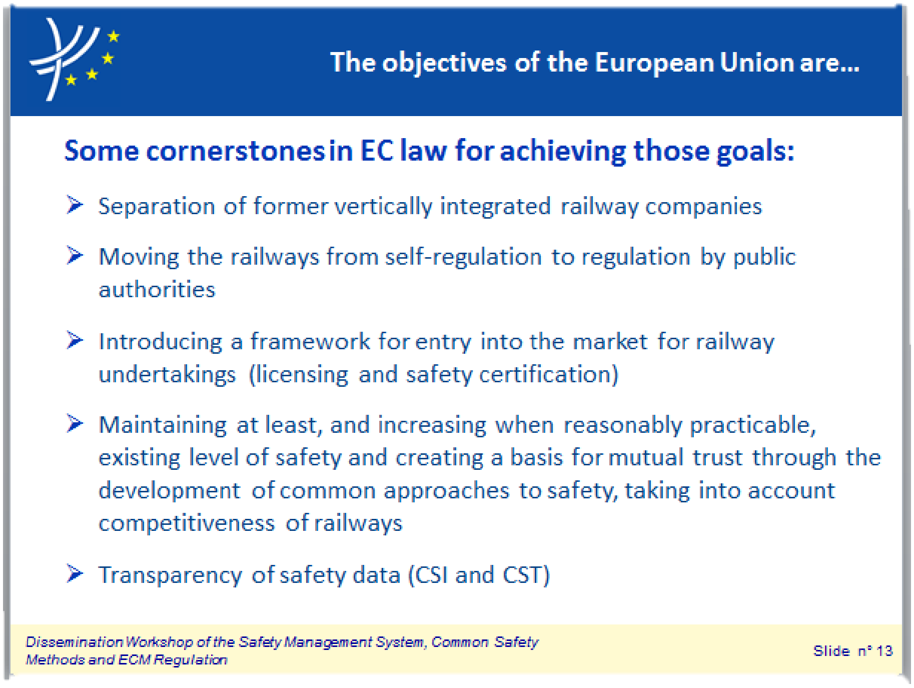

Figure 11: Risk-based logic processes and strategies (Document, ERA, Slides: Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 2013, p. 13)

The first step in the processes developed jointly at the EU and national level in order to ensure liberalisation and free access to the railway market is the detachment of the vertically integrated railway companies, previously owned and managed directly by nation-states. National railways are spin offs according to the two key functions of railway transportation: the transport and management of infrastructure. In so doing, the previously existing companies are separated into two autonomous entities: the railway undertaking and the infrastructure manager. As railway infrastructure is still managed by the historic railway companies, in order to ensure the possibility of entry into the railway market by newcomers through access to infrastructure, the separation of the two functions is seen as a prerequisite:

fair and non-discriminatory access to the infrastructure needs to be guaranteed also through the separation of safety-related functions and/or the creation of a rail regulator fulfilling the control and implementation functions. In any case, railway undertakings may be involved in a non-discriminatory way in enforcement and monitoring of safety standards. Extension of access rights should, as with other modes of transport, proceed in conjunction with the parallel implementation of the necessary accompanying harmonisation measures. (Directive 2001/12/EC amending Council Directive 91/440/EEC on the development of the Community's railways, Whereas (3) (4), p. L 75/1).

The guarantee of free access to the nation-states' railway markets is pursued at the national level through the creation of various public entities – mainly the NSA and the NIB – which are independent and impartial and in charge of regulating the railway sector, but not involved in railway operations:

> the underlying ideas of the 2004/49 were two, which are well expressed in the Directive. One is that this third-party body must be absolutely third with respect to the railway undertaking, […] the Community legislator […] wanted it in black and white so don't think that when you create the NSA you can reproduce your own mechanism [the reference is to the exclusive public railway system], it must be third-party, independent […] Another element for greater guarantees is the distinction between the NSA and the NIB […] [They] wanted these elements of guarantee to be very explicit […] because the Community legislator was afraid that the system would reproduce its own clone. Before the Community Directive who took care of safety? The infrastructure manager. Who investigated accidents? The infrastructure manager. Who did the annual report for the minister who presented it in parliament? The infrastructure manager. Listen, no one is doubting the expertise […] but it is objective […] if I have to monitor myself, it's clear that I take for granted that, from my point of view, my processes are valid (NSA, interview);

> a safety investigation should be kept separate from the judicial inquiry into the same incident and be granted access to evidence and witnesses. It should be carried out by a permanent body that is independent of the actors of the rail sector. The body should function in a way, which avoids any conflict of interest and any possible involvement in the causes of the occurrences that are investigated; in particular, its functional independence should not be affected if it is closely linked to the national safety authority or regulator of railways for organisational and legal structure purposes. Its investigations should be carried out under as much openness as possible (Directive 2004/49/CE, Whereas (24), p. L 220/19).

The creation of the ERA at the EU level goes in the same direction. Such a supranational independent and impartial entity is related to the need, on the one hand, to ensure coordination at the EU level, and on the other hand, to create a harmonised approach between the different nation-states on risk management and regulation. Thus, increasing the interoperability and trust between railway actors within and between the EU nation-states. (See Figure 12.)

Figure 12: European Railway Agency's foundational purposes (ERA, Slide: Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 2013, p. 14)

Looking closely at the regulation of the possible side-effects of railway activity, such changes led to the co-partnership of the private and public sector. On the one hand, the introduction of public agencies clearly separates the operation from the regulation of the sector. On the other hand, the private sector maintains a key role given its full responsibility on risk decisions. In addition, the regulators' activity is shaped by the need to preserve the freedom of enterprise of the sector through:

- The definition of clear boundaries between the responsibilities of the public agencies and the sector – the role of the public and private actors being different, the sector making decisions about risk acceptability and management, and the public agencies not entering into those decisions. The role of regulators is not making decisions, but being sure that the sector understands the extent of their responsibility on the safe functioning of the railway, and overseeing it:

> All those operating the railway system, infrastructure managers and railway undertakings, should bear the full responsibility for the safety of the system, each for their own part. Whenever it is appropriate, they should cooperate in implementing risk control measures. Member States should make a clear distinction between this

immediate responsibility for safety and the safety authorities' task of providing a national regulatory framework (Directive 2004/49/CE, Whereas (5), p. L 220/16);

- The development of light and non-prescriptive regulation – public agencies should not impose detailed rules, but indicate processes and expected outcomes and leave the freedom to choose the ways to carry out those processes and meet such expected outcomes to the sector. The need to avoid a prescriptive regulation is closely related to the need for not restricting and discouraging market competition. If there is just one prescribed way of doing things one cannot promote their competitiveness or singular way of doing things compared with the ways of other companies. Consequently, regulators' activities are focused more on indirect rather than on direct forms of risk management. (See Part One, Chapter 1, Section 1.2.) Thus, it is the promotion and enforcement of a process of risk management that the regulated organisation should put in place, rather than conducting their own risk management process and identifying specific technical devices and organisational or operational changes in order to face the identified risks:

  a western system like ours can't think of putting a police officer on every street corner, it absolutely has to count on the involvement [of the people being regulated] which means expressing authoritativeness [on the part of the regulator], sharing all things that [promote this process] […] One of our fundamental values, not Italian but of western society, is respect for free enterprise which, how can I say, is a principle, is a value more than a principle. The state respects free enterprise when it puts [a business] in the position to exercise its mission of profit in an autonomous way while respecting the limits imposed by the norms. Let me express this more clearly. I have to tell you that the pen must write. I, the state, don't have to tell you the colour of the ink, if the pen is a fountain pen or a ball-point pen. I don't have to tell you anything else, I just have to tell you that the pen must write in the freedom of your business. With respect to how you want to structure it, with respect to your capacity, you will go and place yourself in healthy competition with your competitors also because you are more or less good at making the pen write under certain conditions. If, instead, the state were to say, the pen must write, the colour must be blue, it must be a ball-point pen with a transparent ink tube and a cap on top […] the business could say, bear with me, but what is the value added that the pen has to write? Yes, but write what? And [to] draw a diagramme, but I have a computer. Does it bother you if I do it with a computer? I also have a printer, so it [the diagramme] comes even more defined. I don't know if you get the idea […] The state must be 'light'. It mustn't be invasive, the state must set limits and count on the maturity of the representative, citizen or business – whichever [it relates to]. The state must protect but not be a caregiver, because the state is a caregiver only in dictatorial systems. There the state replaces everything, it replaces values, everything and that is a burdensome state, it is a dictatorship and that is a burdensome state. Fortunately we are in a 'light' western state and so it's absolutely not autocratic. I see it as an absolutely logical sequential route in which railway safety, or work safety or road safety is inserted. Nothing changes for the one who […] takes the pen in hand and writes the legislation, it's always the same underlying model (NSA, interview);

- The responsibility of the sector, as well as the presence of non-prescriptive rules, leads to a detachment from the automatism prescription-conforming action, typically related to the control-command approach to regulation. (See Part One, Chapter 1, Section 1.3.) More specifically, the control-command approach is based on the development of detailed rules that the regulated organisations have to follow. Once they are compliant with those detailed rules their responsibility on the reliability – safe functioning – of their enterprise is fulfilled. In contrast, following the approach promoted by the risk-based logic the regulators should focus on processes rather than on detailed prescriptions. Consequently, the regulated organisations should adapt the non-prescriptive frames of reference to their own business. Being compliant with the rules is not enough; regulators should adapt the available rules creating their own. Thus, they are responsible not only for complying with a rule, but also for the definition of the rule itself. For example, following a control-command approach we fix a speed limit of 50 km/h on a street. Following the approach promoted by risk-based logic, we ask drivers not to have more than one accident per year on a particular street, and/or to evaluate the risk linked with high speeds following a specific risk management process. As an outcome of the risk management process, they decide if it is appropriate to fix a specific speed limit on that street: it is up to them to decide to adopt other measures in order to monitor and, if needed, to reduce such risk. Consequently, in the first case, once the drivers are in compliance with the fixed limits they have fulfilled their responsibility; in the second case, the drivers are responsible for their decision about the acceptability of the high speed, and the control measures they eventually adopt. In addition, even if they are in compliance with the process regulators enforce in order to evaluate this risk, if they do not meet the target, their responsibility is not fulfilled:

I make the comparison with the rules of the road. The rules of the road are a framework law for road transport […] With the rules of the road I have the complete package, that is, the norms to observe and what happens to me if I don't follow them … that is how I envisage obligation. That is to say, I enforce that thing and if you don't do it, something bad will happen to you. In the 162, instead, there aren't obligations there are tasks. There isn't the restriction, there isn't the traditional sanctioning structure, it is not a special penal law. This to tell you how the 162 has introduced a huge novelty in the area of the railway sector (NSA, interview);

I don't do the practise. What do I, railway agency, know, while respecting free enterprise that you have a park of rented train cars that is so numerous […] From the moment you make a strategic choice to decide to rent foreign wagons and resolve all of your risk analysis and maintenance with the signing of a contract between private companies, you evidently analysed, or didn't analyse, that risk. Certainly I can't come, me third-party body, into your house to either stop you from renting foreign train cars because they would start infraction procedures at the AIA for freedom of movement […] Nor can I enter into the private relationships you have with other subjects. None of this takes away from you having to be in charge (NSA, interview);

before this revolution, you as an operator, from the moment in which your business responded to a legislative framework [you] had done things by the rules, you were within those boundaries and your job was to stay within those boundaries. Today, as of today […] each operator must stay inside this fence which is the legislative framework. [But this], in any case, is not sufficient, that is, when faced with an accident […], an operator who can show you he moved within this legislative framework can be reprimanded in any case, or asked if he did all the supplementary risk analysis to calculate the danger that the legislative framework didn't account for; that is, he not only must respect the rules but the operator must also be able to evaluate risks that have not yet been considered (NSA, interview);

- External regulators should fix boundaries to the sector through the promotion of risk management processes or by targeting objectives, but regulatory intervention should pay attention to not alter the market's functioning by preserving the free market decision within the defined boundaries. For example, regulators are careful not to recommend or impose the adoption of specific technological devices. If such technological devices are produced by just one company, the requirement of such a component would represent an alteration of the market favouring one company over another one:

> it would be a discriminating action to make the derailment detection mandatory at the EU level, while other technical measures currently existing on the market are assessed as being more efficient for reducing the risk related to the transport of dangerous goods (Document: ERA, 2012, p. 8).

To sum up, the regulation of the railway sector is structured as a mix of private and public co-operation, the regulatory strategy aims to be non-prescriptive, identifying processes and outcomes rather than rules, and leaving the responsibility of risk decisions, as well as the way in which to fulfil such processes and meet such outcomes, to the sector.

Organisational structure

The separation between infrastructure managers and railway undertakings; the creation of public agencies at different levels of government – national and European; and the co-operation of public and private entities in the definition and implementation of regulatory strategies and processes; shapes a specific organisational structure: the multilevel regulatory network. Figure 13 offers a graphic representation of such a network identifying the main actors involved in the regulatory activity of the Italian railway sector. The diagonal lines in the background identify the organisations involved in external regulation, dedicated to risk management and regulation, but not involved in the core activities of the regulated domain. The specific regulatory logics shaping and shaped by such organisations are discussed in detail in the next section.

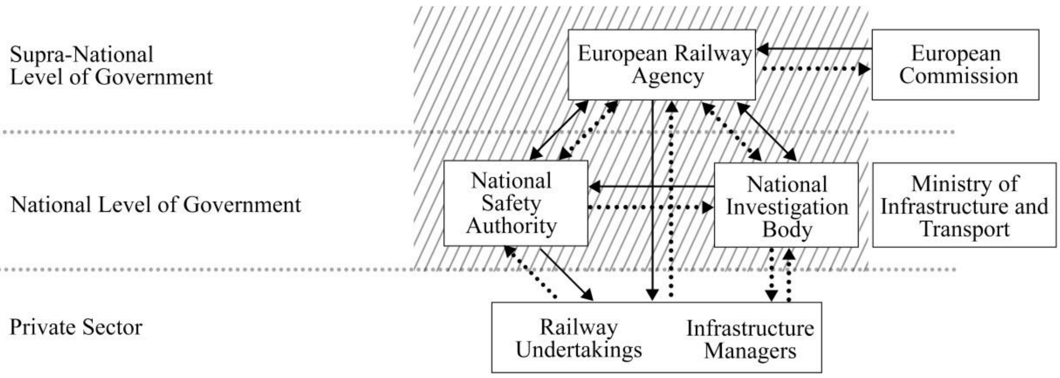

Figure 13: The Italian Railway Regulatory Network[50]

1.2 Inter-organisational level: cost-benefit, standard and possibility logics

The following section is dedicated to examining the inter-organisational level of analysis. In looking at this level, the aim is to understand if, given the general frame of reference depicted by risk-based logic, the three studied organisations present different ways in which such a general frame of reference is put into practise. If the focus of the previous section was on commonalities, the emphasis here is on the elements that differentiate the three organisations considered. Thus, this section examines the specific features of the three organisations studied with reference to their approaches and relationships to the possible side-effects of the regulated domain, on the one hand, and the regulated organisations, on the other. The empirical analysis illustrates how the logics shaping and shaped the three organisations studied present three different practical ways of implementing risk-based logic. In particular, the three organisations examined shape and are shaped by three different prevailing logics: the cost-benefit logic prevalent within the European Railway Agency (ERA); the standard logic, which prevails within the Italian National Safety Authority (NSA); and the possibility logic prevalent within the Italian National Investigation Body (NIB). The logics developed by the three organisations can in some respects be in contrast with the assumptions and principles fostered by the risk-based logic, re-adapting such assumption and principles in their everyday activities. An analysis of

[50]The arrows represent the presence of a relationship between organisational actors, the black solid ones are structured, formal relationships, the dotted ones non-structured informal relationships. The nature of the relationship within the network is in-depth in the inter-organisational level examination.

the differences between risk-based logic and the practical translation of such logic in the three logics developed at the inter-organisational level is discussed later on. (See Part 4, Chapter 1.) Here the aim is to offer a description of the three logics considering the cultural, cognitive, and organisational analytical components characterising them, and highlighting the elements that differentiate the three logics from each other. Table 14 summarises the characteristics of the three logics.

Cultural component			
	Cost-benefit logic *ERA*	*Standard logic* *NSA*	*Possibility logic* *NIB*
Risk	Probability*Magnitude No acceptability limit	Probability*Magnitude Limit: deaths and injuries unacceptable	Possibility*Magnitude Limit: deaths and injuries unacceptable
Ends (mission)	To provide technical support at the politico-economic level To develop and implement the legislative framework To ensure a correct balance between the different ends driven by the politico-economic level	To improve safety To preserve the collective interest by guaranteeing the safety of citizens and preserving transportation service as a crucial public good To show independence and impartiality	To improve safety Safety mission is seen as a moral one and perceived as a personal mission more than an institutional one Regulators should flush out problems even within the legislative framework in which they operate The regulators' mission of ensuring safety levels is seen as an on-going and open mission that should be constantly re-defined
Cognitive component			
	Cost-benefit logic *ERA*	*Standard logic* *NSA*	*Possibility logic* *NIB*
Method of reasoning	Deductive Inductive (but only evidence-based, not one-off events)	Deductive Inductive (also one-off events)	Abductive
Organisational component			
	Cost-benefit logic *ERA*	*Standard logic* *NSA*	*Possibility logic* *NIB*
Means (process and strategies)	Un-balance toward indirect risk management processes	Mix of direct and indirect risk management processes	Direct risk management processes
Structure (coordination strategies)	By standardisation and by mutual adjustment	By standardisation and by plan	By mutual adjustment

Table 14: The inter-organisational level – cost-benefit, standard and possibility logics

The cultural component

Category and associated meaning: Risk

Looking at the categories and the associated meaning, the three identified logics prevalent among the three organisations under study present different definitions of the concept of risk. Let us look closely at the definition of risk proposed by the three logics: cost-benefit (ERA), standard (NSA) and possibility (NIB) logics.

Cost-benefit logic (ERA)

The definition of risk sustained by the cost-benefit logic prevalent within the ERA follows the classic definition of risk proposed by Knight (see Part 1, Chapter 1, Section 1.1): the risk associated with an event is defined as the product of the frequency and the severity of such an event. The concept of risk is distinguished from the concept of hazard. The concept of hazard reflects uncertainty in Knight's definition. Thus, a hazard is a potentially dangerous event. If a frequency and a magnitude are associated with this event, it becomes a risk. (See Figure 14.)

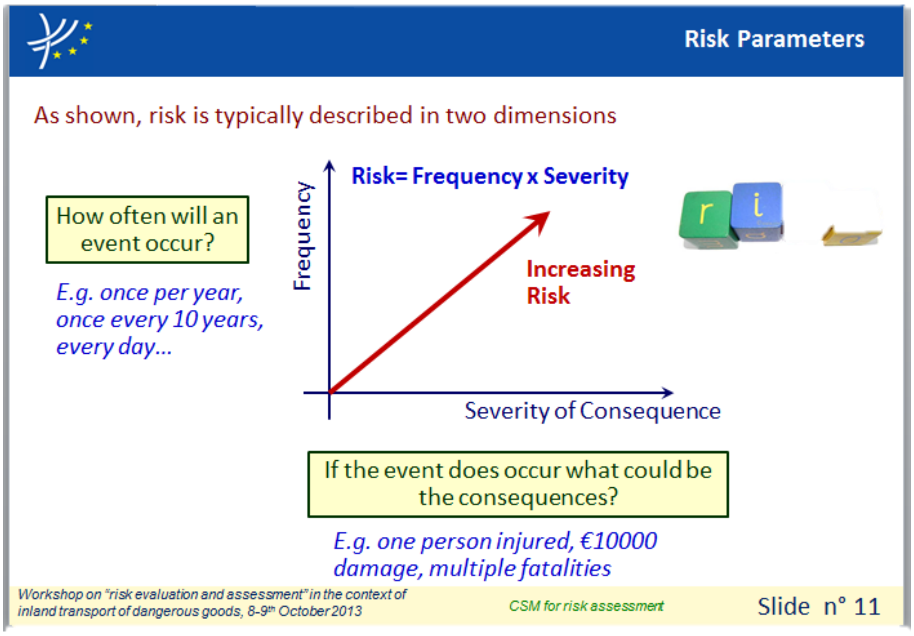

Figure 14: Cost-benefit logic – risk definition (ERA, slides: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 11)

Cost-benefit logic follows risk-based logic closely leaving hazard identification, risk estimation (definition of frequency – number of times an event happens given a defined period of time – and magnitude – quantification of the negative consequences that follow the event), definition of risk acceptability criteria, as well as, if necessary, implementation of control measures in order to reduce the severity or frequency of an event, to the sector:

we believe that the idea is that it's really the railway undertaking and infrastructure managers who take responsibility. They are closest to the risk, so they should prevent it, they should take measures, they are the best place to decide what it is appropriate to do, so we leave it to them (ERA, interview);

those how control the risks are those how create the risks, so railway companies (ERA, interview).

Thus, cost-benefit logic does not, a priori, fix a limit on what can be acceptable or not, but leaves such decisions to the actors directly involved in the core activity of the regulated domains:

you (company) will decide if you can or not neglect some risks, you have identified them and you say for me it is acceptable and you just log it (ERA, interview);

so it is clearly you [who] are responsible for the safety of the operation, it is not the agency it is not the European Union, we are not responsible for you instead of you. But with your responsibility we expect you to be managing risks systematically and as soon as we are clear about responsibility and a systematic approach for us this means you are doing things in an acceptable way that is safe enough […] so this is the approach we are having, we don't need to say your risk is five or three (ERA, interview);

we are not able to decide what is acceptable for someone else you are not supposed to take his responsibility, his context will always be different from whatever you can imagine, it is a stupid idea (ERA, interview).

Following cost-benefit logic, regulators should pay attention not to steer the sectors' decisions about risk. Regulators should not fix limits or indicate types of risks that should be accepted or not. For example, regulators try not to give detailed examples, models for risk estimation such as a fixed frequency per magnitude matrix[51], or lists of hazards to consider. This in order to avoid that the sector simply 'copies' the tools provided without pondering and adapting them to their own activities, evaluating risk in an informed way:

In our guidance we are very cautious when we give these types of examples because I mean it is human when you are trying to learn something and you don't have access to information and you see [for] many Member States it is difficult to get information about risk management in their own language, of course you will take the guidance and our guidance this one about risk assessment […] They take it and when they see something they try to re-use it, I mean it is normal it is the way in which we learn things to take what is familiar to you and make a link […] but normally they would probably not go within the content, but they would take the steps only […] This is why we are so careful, even in the guidelines where we explain things not to give this type of details […] we had a lot of discussion about what is appropriate and what is not […] We are trying to avoid to define risk acceptance criteria for the companies because they have their own responsibility. If you define this it means that you take the responsibility from them and responsibility is what allows you to grow in maturity too and what allow you to improve (ERA, interview);

this [matrix frequency per magnitude see, for example, Figure 8] is just an example. In your company you have to put what is in what column you put negligible and so, what is for you acceptable tolerable and so, this colour that you have in the standard from company to company can change. So the risk acceptance matrix in standard is not specific, it just gives you the principles and then based on your statistics you build your own matrix and you put the colour of what is acceptable, what is not and then when you have a risk you locate it on the matrix and then you can say, for me it is acceptable, for me it is not acceptable it is not tolerable I have to take action. In the red area you must take [action], in the orange you decide depending on also the influence and strength of the NSA in your country and in the green you are allowed, you allow yourself. I don't do anything, this is just the principle this matrix I know that people from the industry take the matrix from CENELEC [European Committee for Electro-technical Standardisation – EN50126 Standard] and they say they are compliant, but you are compliant against what it is not a fixed matrix (ERA, interview);

this is the problem when you give an example people use it as a requirement, CENELEC [European Committee for Electro-technical Standardisation – EN50126 Standard] gives an example and people use it as a requirement, so when you have someone else asking you another requirement you say you are not allowed why are you more restrictive than what is

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[51]For an example of a frequency per magnitude matrix see Figure 15.

in the standard? But the standards are just an example, the best is to give the matrix with nothing inside and then you don't know what is inside and you have to build your own matrix […] But the people would complain I don't know what to do there is no example […] When you give a check list to people they use it blindly as a check list, they do only what is on the check list and nothing more and this is why we have tried to not put the check list of hazards in the guideline and unfortunately we were forced to put it in the end of the second document a list of hazards […] So this is the risk also of giving examples of matrixes (ERA, interview).

Even when additional explanations regarding the principles stated in the legislation are given, the regulators highlight the non-mandatory nature of all the suggestions contained in official documents such as guidelines:

the guidelines are possible ways to implement the legal text, but not the only way (ERA, informal talk).

In so doing, they reaffirm the faculty of the sector to choose other instruments and ways in order to fulfil legislative requirements:

this guide does not contain any legally binding advice. It contains explanatory information of potential use to all actors whose activities may have an impact on the safety of railway systems and who directly or indirectly need to apply the CSM Regulation. It may serve as a clarification tool without however dictating in any manner compulsory procedures to be followed and without establishing any legally binding practise. The guide provides explanations on the provisions contained in the CSM Regulation and should be helpful for the understanding of the approaches and rules described therein. Actors may continue to use their own existing methods for the compliance with the CSM Regulation (ERA, Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3) (a) of the Railway Safety Directive, 06.01.2009, p. 6).

Similarly, like risk-based logic, cost-benefit logic clearly links technological risk with the business one, stressing the impact a negative event could have for the railway undertakings and infrastructure managers in terms of negative financial outcomes, quality of the service provided and time lost:

risk could impacts basically three areas which are financial, time or quality. Safety risks could appear, in shapes of hazardous events in all three areas, which could be connected to technical systems, human or organisational factors (SMS Wheel, Risk Assessment, Introduction).[52]

Despite such statements on the private nature of risk decisions, cost-benefit logic presents some features that can allow the assumptions steering and steered by this logic with reference to risk and risk acceptability, to be identified. The examination that follows of the concept of broadly acceptable risk, the reference to the EN50126 standard, and risk acceptance criteria, allows us to identify and describe such assumptions.

A broadly acceptable risk is a risk that 'is so small that it is not reasonable to implement any additional safety measure' (Commission Regulation (EC) 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council, Annex I, 2.2.3, p. L 108/13). In effect, a broadly acceptable risk is a risk with an extremely low frequency or an extremely low magnitude:

in practise an expert judgement can enable to decide whether the considered hazard could be associated with a broadly acceptable risk in the following cases:

(a) either if the hazard frequency of occurrence is judged to be sufficiently low due to e.g. physical phenomena (such as fall of meteorites on the track) regardless of the potential severity;

(b) or/and if the potential severity of the hazard consequence is judged to be sufficiently low, regardless of the hazard frequency of occurrence (ERA, Guide for the application of the CSM Regulation, 2009, p. 36).

The reference to the concept of being broadly acceptable represents a criterion of prioritisation as well: if there are a certain number of risks to face, the ones closest to the broadly acceptable levels give priority to other risks considered more likely to happen, or of a more severe magnitude. Note that the frequency and the magnitude can also be seen as two separate criteria. As the example of the meteorite on the track shows; a meteorite on the track can have extremely high magnitude, but the

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[52] http://www.era.europa.eu/tools/sms/design-improve/risk-assessment/Pages/default.aspx, Website consulted 26 March 2014.

extremely low frequency that characterises such an event makes it a broadly acceptable risk:

A broadly acceptable risk is something that is minor compared to the other risks related to the project, when you have big problems for managing the safety […] for you it is not the first priority to control the risks related to unauthorised people intrusion in some location […] I don't say that you don't need to control those risks, but that they are not the first one that you will control…This is an example of what at the beginning can be up to you to be acceptable and you will have control of the more important risks then you can come to those less important. The idea of this concept of broadly acceptable is based on the judgement of the team who is making the risk assessment to be able to focus the effort and the money where the risks are the biggest and not to tiny things (ERA, interview).

The concept of being broadly acceptable is closely linked to the statement that 'zero risk doesn't exist.' The possibility of dangerous outcomes is not reducible to zero or close to zero and the economic sustainability that the railway imposes requires choosing which phenomena to concentrate the preventative effort on:

there are phenomena that are external, yes, but it's like that everywhere: earthquakes, for airplanes it's the same thing, for road traffic it's the same … for illnesses health insurance, that's the way it is, but if you work in a world, if you live in a world in which you can't do a blood exam every day – even if in 20 years this would allow you to avoid a tumour – it will never happen that someone does a blood test every day to avoid that because the cost of such a procedure is much higher than the benefits that you can obtain. And in the railway [sector] it doesn't work differently than other sectors. Then this is unpopular, I understand, from a moral point of view, also difficult to accept, but it is reality (ERA, interview).

The cost-benefit logic's assumption that a certain degree of risk should be accepted, and that it is not possible to act in order to avoid all possible dangerous events, is reflected in the definition of the concept of safety as well. More specifically, safety 'means freedom from unacceptable risk of harm' (Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council, Art. 3, p. L 108/6). Thus, it is not the freedom from risk of harm, but the freedom from the risks that are not categorised as broadly acceptable.

Another key reference of the cost-benefit logic also goes in the same direction: the EN50126 standard. In particular, because the criteria of risk acceptability have not been developed yet as common EU criteria, the sector is encouraged to refer to such standards:

> the explicit risk acceptance criteria that are needed to support the mutual recognition will be harmonised between the Member States by the on-going Agency work on the risk acceptance criteria. When available, additional information will be included in this document. In the meantime risks can be evaluated using for example the risk matrix that can be found in section § 4.6 of the EN 50 126-1 standard {Ref. 8}. Other types of suitable criteria can also be used, given that these criteria are deemed to deliver an acceptable level of safety in the concerned case. (ERA, Collection of examples of risk assessments and of some possible tools supporting the CSM Regulation, 2009, p. 46).

The EN50126 standard arose with reference to the railways' electro-technical components. Such a standard represents a benchmark that new projects have to follow in order to demonstrate the reliability, availability, maintainability and safety of the component being implemented.[53] Nevertheless, the standard is now seen, more generally, as a point of reference for risk estimation and evaluation within the railway sector, and it has lost its original explicit reference to electro-technical components. Let us look closely at an example of the risk evaluation tools proposed in the EN50126 standard. Figure 15 represents the frequency per magnitude table proposed by the standard as an example of a tool to use in order to evaluate an identified risk.

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[53]See http://www.cenelec.eu/aboutcenelec/whatwedo/technologysectors/railways.html, Website consulted 10 April 2014.

4.6.3.4 **Table 6** shows an example of risk evaluation and risk reduction/controls for risk acceptance.

Table 6: Typical Example of Risk Evaluation and Acceptance

* Frequency of occurrence of a hazardous event	Risk Levels			
Frequent	Undesirable	Intolerable	Intolerable	Intolerable
Probable	Tolerable	Undesirable	Intolerable	Intolerable
Occasional	Tolerable	Undesirable	Undesirable	Intolerable
Remote	Negligible	Tolerable	Undesirable	Undesirable
Improbable	Negligible	Negligible	Tolerable	Tolerable
Incredible	Negligible	Negligible	Negligible	Negligible
	Insignificant	**Marginal**	**Critical**	**Catastrophic**
	Severity Levels of Hazard Consequence			

* Scaling for the frequency of occurrence of hazardous events will depend on the application under consideration (4.6.2.2)

Risk Evaluation	**Risk reduction/control**
Intolerable	Shall be eliminated
Undesirable	Shall only be accepted when risk reduction is impracticable and with the agreement of the Railway Authority.
Tolerable	Acceptable with adequate control and the agreement of the Railway Authority
Negligible	Acceptable without any agreement

Figure 15: Example of Risk evaluation matrix given in the EN50126 standard (from EN 50126-1, p. 21)

The category of ‘negligible’ (see Figure 15) suggests that the risk should be monitored in order to verify that the magnitude and the frequency does not increase, but that no control measures should be implemented in order to reduce the frequency or the magnitude of the risk under examination. Thus, following the table, there are certain types of risk that can be accepted. The table only represents an example, it is not mandatory. Nevertheless, it shows that the cost-benefit logic assumes, as in principle, that it is not possible or necessary to implement control measures for all the identified risks. On the contrary, it assumes that certain risks can be accepted without implementing measures to reduce their frequency or magnitude. We will return to this table later on comparing it to the one promoted by the standard logic.

Another important element characterising the approach of cost-benefit logic to risk and safety, is the attempt to define a common set of risk acceptance criteria at the EU level. Risk acceptance criteria means:

the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further (Commission Regulation (EC) 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council, Art. 3, p. L 108/7).

The development of unified risk acceptance criteria began a few years ago. The Commission has given a formal mandate to the European Railway Agency in order to develop such criteria. The idea is to develop common and fixed limits shared within the EU railway sector in order to decide at which frequency a risk with a certain degree of magnitude is acceptable. The process of developing risk acceptance criteria is still ongoing and has proven to be arduous given the difficulty to reach an agreement between the different stakeholders involved. Nowadays the only established risk acceptance criteria refers exclusively to the failure of technical systems and is applicable only in the case of introducing a new technical component that is considered a significant modification from a safety point of view. In addition, such criterion refers exclusively to the explicit risk estimation. It is applicable only if there are no codes of practise already in place to refer to, or reference system to which the technical system or sub-system under consideration can be equated. Thus, the area of applicability of the criterion is limited. In addition, it only covers cases in which the random failure of a technical system leads directly to catastrophic consequences (many deaths or injuries). Such criterion has been fixed at a frequency of 10^{-9}. The difficulty of reaching an agreement has resulted in the impossibility of fixing additional criteria:

As an agreement on additional risk acceptance criteria (RAC) could not be reached among the majority of representative experts in the CSM working group, Regulation 402/2013 does not modify the existing requirements on RAC (ERA, Website).[54]

Nevertheless, the need to fix pre-defined criteria of risk acceptability is seen as contrasting with the assumption of the cost-benefit logic. The cost-benefit logic's aim to leave the decisions about risk acceptability and the determination of fixed criteria to the sector seems to contrast with such a statement. However, the need to fix a criterion is recognised as a way to avoid the use of the safety argument as a

[54] http://www.era.europa.eu/Document-Register/Pages/dld-rev-csm-for-ra.aspx, Website consulted 26 March 2014.

barrier to market entry, rather than a need to limit the sector's decisions about risk acceptability. Thus, it gives preference to the liberalisation objective rather than the safety one:

objectively, this we should not put it in here, this [10^{-9} criterion for the failure of technical system] is a risk acceptance criteria that shall not be defined in the CSM for risk assessment that should not be put in the European legislation. The European approach is you are responsible, you are managing in a systematic way and we trust that you are safe enough and this is already good, now why do we have this? It is because in the present practise we are seeing that if you use the CSM on risk assessment mutual recognition is done automatically, but in practise nowadays, even with the standards even with whatever you have, NSAs that have their national companies as their very favourite companies because they are not independent and so on […] and you have a company coming to the different Member States and if the company has a technical system which has proved 10 to the minus nine which is according to the standard, but the NSAs say no I want 10^{-25} and nothing stops them, this is the only reason that we need to put in the legislation for the upper limit of what can be asked from NSAs for mutual recognition. Because 10^{-9} is just the maximum that you can get and if we all agree on that no one should ever ask again about 10^{-25}, and you can ask 10^{-25} to one company and not to another. It is just this closing of the market that we are trying to avoid, however if the system was working correctly we wouldn't be talking about this at all (ERA, interview).

To sum up, the cost-benefit logic defines risk as the product of magnitude and frequency; considers the technological risk decision as part of the free business decision of the sector; tries not to suggest specific methods or prescribe limits on risk acceptability; underlines the impossibility of reaching the 'zero risks' target, and the need to consider the economic impact of risks control measure, and admits the possibility of accepting risks without implementing control measures in order to reduce such risks (frequency or magnitude).

Standard logic (NSA)

Like cost-benefit logic, standard logic defines risk as the product of the magnitude and the frequency associated with an identified hazard. Nevertheless, in contrast to cost-benefit logic, standard logic fixes mandatory limits to the sector with reference to the risk acceptability criteria that should be followed. Within those limits, the free enterprise principle is reaffirmed. Thus, once the limits are given, as long as the regulated organisations stay within those limits they are free to exert their business decisions regarding risk acceptability. A key principle distinguishes the cost-benefit from the standard logic: “there is a regulatory Italian structure – [standard logic] – which follows 0 risk and a European regulatory structure – [cost-benefit logic] – which pursues acceptable risk” (NSA, informal talk). The ‘zero risks’ target is related to an Italian law dated 1980 that is still in force: ‘in running railways we must adopt the measures and precautions suggested by techniques and practises enacted to avoid accidents’ (D.p.r. 753/1980 Article 8). Following the ‘zero risk’ concept, the aim of railway transport is ‘to stretch the number of accidents and the magnitude of their consequences to zero’ (see Figure 16):

the principle is sanctioned […] that all subjects with safety responsibilities in the Italian railway circulation system must follow the objective of maintaining and, where reasonably practicable, constantly improving the safety of the Italian railway system with *the aim of being inclined to obtain a null value of accidents*, taking into account the legislative evolution, technical and scientific progress and giving priority to preventing serious accidents (NSA, Annual Report, 2012, p. 38, my emphasis).

Figure 16: Standard logic – the zero-risk objective (NSA, Slides: Analyses and evaluation of risks in the railway sector. The application of EN 50126, 2012, p. 18)

In addition, standard logic stresses the need for prescribing a maximum level of acceptability that the sector cannot surpass. More specifically, the maximum limit indicated by standard logic refers to the need to ensure that the railway system should not accept any death or injury. In so doing, standard logic detaches the concept of risk as a side-effect of business risk, focusing attention on the consequences on health and the environment rather than on the monetary losses linked to such consequences:

we have national legislation that tells us to tend toward zero accidents; and on this, I agree because essentially it's true that you must essentially improve. But where you have caused a death you can't say that you did well because last year you had two, you haven't [done well]. If that death is your fault you go to jail and that's the way it should be. We're not in a specific case but, in general, where we speak of zero effects on people and we talk about ulterior safety, we can all agree. Where there are people who are hurt then it becomes a different issue […] Our opinion, which is supported by our legislation, is that if someone travels from a to b he/she must arrive there whole, or if he/she gets close to a train that is going from a to b he/she must remain whole […] In general I agree with the optic of the perspective of finding solutions that progressively are economically viable. We can't ask for the collapse of the railway system to guarantee safety – a stopped train is the safest train in the world because it doesn't create train circulation problems [and] it's not what we want – but essentially we can't put people at risk either because maybe spending less you can [hurt people] […] You have to do everything you can based on technique and practise to bring this factor to zero […] Where there is a critical situation that hurts people, in my opinion, you have to intervene (NSA, interview).

Such a maximum limit is mandatory and the acceptance of such a limit is a formal requirement that can influence the release of safety Certificate/Authorisation Part B. The safety Certificate/Authorisation authorises railway undertakings/infrastructure managers to operate on the railway network and is released by the NSA. The Certificate/Authorisation states that the railway undertaking/infrastructure manager fulfils the legislative requirements, has developed the needed processes in order to operate safely on the network and manages the risks their activity poses in a systematic way. The safety Certificate/Authorisation is composed of two parts: Part A and Part B. Part A refer to the entire European network. Part B pertains to the specific factors at the nation-state level required in order to operate within the national infrastructure. The idea is to reach a unique certificate without nation-specific factors for the entire EU, but the certification/authorisation process is currently still divided into two different parts. The risk acceptance criteria, stating that no deaths and/or injuries are accepted, is expressly required in order to obtain a Part B certificate in Italy and reflects a historically consolidated national requirement:

in this game the Agency rules because there are security standards and there has to be a minimum level that is the same for everyone […] Furthermore this addendum makes sense for all regulations […] within the optic of European certification, bit by bit national legislation on all levels, in all areas should tend to disappear. Clearly when they created the European railway market with common rules, each country had its own and so it's not that you could [change] from today to tomorrow because it meant in some countries actually changing their infrastructure […] So all the states communicated their regulations to the ERA and those are the only regulations for Part B that the state can validate. In addition a whole series of things that are still delegated to the State to be able to establish norms […] because each country had its own delta [degree of curvature] and on the basis of that delta it provides communication with Europe […] Like every country each brought its own story. On these things we had said some things and we kept them (NSA, interview);

that is the area of acceptability of risk, Italian regulations say risks that you in your analysis fit into the green – I'll tell you what is the green zone – are acceptable and those outside are unacceptable […] Therefore … in Italy if they, for example, tell me "my seriousness…is a death…every six months", I say : "No, no, you can't set this as a criteria because Italian regulations […] don't consider any deaths … as a level of acceptability." So we don't get into the merits of how … provided that this 'how' doesn't go against the legislative elements … if you stay within the legislative elements and have the possibility to choose, choose as you like, but if your choice is to accept deaths, it goes against the regulations [so] I must stop you. … […] The seriousness means not to accepts deaths … because the 'critical' [title of one of the categories of magnitude qualification within the frequency per magnitude matrix] doesn't have deaths in its acceptability range, it has injuries … therefore you have to put actions in place with the end of eliminating the possibility of causing deaths … This is the philosophy of Italian legislation at this moment. There are other states that have different regulations on risk acceptability criteria. In France there is …in … the UK others that also have … levels of acceptability that are higher than in Italy. At this time because of the famous Italian regulation 753 … it imposes certain conditions thus you cannot accept certain levels of seriousness, they aren't acceptable (NSA, interview).

Such differences between the standard and cost-benefit logics is underscored by the explicit specification of the differences between the frequency-magnitude matrix proposed by the EN50126 standard – reference matrix following the cost-benefit logic – and the matrix mandatory at the Italian level – reference matrix following the standard logic. (See Figure 17.)

Figure 17: Differences between the standard and the cost-benefit logics with respect to the reference to the EN50126 international standard (NSA, Slides: Analyses and evaluation of risks in the railway sector. The application of EN 50126, 2012, p. 23)

Let us compare the two matrices more closely. Once again, the Italian matrix (Figure 18) is mandatory, while the EN50126 matrix (Figure 16) is just an example. Such an example, however, allows an alternative idea about the acceptability of death or injury differentiating the standard and cost-benefit logics to be understood.

PROBABILITA' O FREQUENZA'	*LIVELLI DI RISCHIO*			
Frequente	x	x	x	x
Probabile	x	x	x	x
Occasionale	x	x	x	x
Remoto	Tollerabile	x	x	x
Improbabile	Trascurabile	Tollerabile	Tollerabile	x
Inverosimile	Trascurabile	Trascurabile	Trascurabile	Tollerabile
	Insignificante	Marginale	Critico	Catastrofico
	GRAVITÀ			

Figure 18: Standard logic – risk matrix for risk acceptability evaluation (NSA, Document: R.F.I Provision 51/ 2007)

If we cross the categories of incredible (*inverosimile*) and catastrophic (*catastrofico*), following the cost-benefit logic, the risks located within such a cell are classified as negligible (*trascurabile*). In contrast, following the standard logic, such risks are classified as tolerable (*tollerabile*). Negligible means that the risk should be monitored, but it is not necessary to implement control measures in order to reduce the magnitude or the frequency of such a risk. Thus, the risk is classified as acceptable. Tolerable means that it is necessary to implement control measures in order to reduce the magnitude or the frequency of the event. Thus, the risk is not acceptable. A comparison of the two tables shows that, in following a cost-benefit logic, risks with an extremely low frequency and catastrophic consequences can be within the acceptability limit. In contrast, following the standard logic such risks should not be considered acceptable.

Next, we consider the meaning of the categories through which the different degrees of magnitude and frequencies are identified. The category of catastrophic has two different meanings. The EN50126 table defines catastrophic as 'fatalities and/or multiple severe injuries and/or major damage to the environment' (EN50126, 1999: 21). But, the '[s]ingle fatality and/or severe injury and/or significant damage to the environment' (Ibid.) is classified as critical. In contrast, in the Italian matrix the death or injury of a single person is also classified as catastrophic. Looking at the frequency, the two tables present partially different definitions of the category of incredible (*inverosimile*) as well. The Italian matrix states that a hazard can be classified as incredible only if it never happened in the context under consideration.

On the contrary, following the EN50126 matrix, it is classifiable as incredible even if a hazard has already happened.

Thus, standard logic does not accept death or injury with any degree of distinctions such as the number of injuries or deaths. Cost-benefit logic considers death or injuries acceptable in principle and proposes a different degree of acceptability with reference to the number of deaths or injuries. In addition, following standard logic only accidents that have never happened can be classified as incredible. In contrast, cost-benefit logic also considers events that have already happened to be classified as incredible. Therefore, the two logics present different principles about the value of life as well as the definition of the frequency of the considered hazard. More specifically, standard logic explicitly prescribes the need also to consider events that have never happened.

The ‘zero risk’ target corresponds with a specific assumption that standard logic promotes about the nature of an accident/incident. Following the cost-benefit logic the accident/incident’s nature is closest to the category of random or inevitable (‘zero risk doesn’t exist’). On the contrary, following standard logic, an accident/incident is always linkable to technical, organisational, or operational factors within the organisations in which they happen that are, in principle, avoidable. Accidents/incidents are never an unforeseeable ‘act of God’ (see Figure 19):

> where does an accident come from, the accident never comes from an act of God aside from in exceptional cases. It is always in any case reducible to the organisation’s activity and therefore the system, the process, the product at a different level and so it can always be brought down to an activity (NSA, interview).

Figure 19: Standard logic – accidents are not acts of God (NSA, Slide: Training session POLFER CAPS – Cesena Workshop – Module 2A, 2012, p. 5)

In conclusion, standard logic defines risk as frequency per magnitude, fixes a key mandatory criterion in order to decide to accept risk or not – injuries and deaths are not acceptable – does not consider accidents as ‘acts of God’, but as events clearly linked with the organisation within which they happen.

Possibility logic (NIB)

Possibility logic, prevalent within the Italian NIB, promotes a definition of risk differing from both the cost-benefit and the standard logic. In this case, risk is not the product of the magnitude and the frequency of a hazard, but of the possibility that negative outcomes could occur. The decision to open an investigation is explicitly related to the possibility of negative outcomes, despite whether such outcomes have actually occurred. The investigation of an event is related to the potentially negative consequences this event could lead to; thus, it is related to the definition/imagination of alternative negative scenarios that have not actually happened, despite the frequency related to such an event:

investigations [are conducted]:
following serious railway accidents;

following accidents or problems which, under different conditions, could have led to serious accidents (NIB, Annual Report, 2012, p. 3);

[with reference to an incident in which a locomotive invaded a platform in a station because of the detachment of the wheels of the freight wagon] [It] could have been an extremely disastrous accident and how only through luck the locomotive went onto the platform which in that moment didn't have the elementary and middle school students, who would have arrived shortly … the dramatic significance of what happened is like if you took your car to an authorised garage and in the authorised garage they forgot to tighten the four bolts that hold your tire to the axle (NIB, conference presentation).

Risk is something potential, something that could happen, but does not. It is a possibility, but not necessarily a frequent occurrence or a probability of occurrence. It may have never happened before but, being a potential outcome, it is the object of attention. The investigation activity focuses on this possibility:

episodes that represent motives for reflection to propose improvement procedures for safe circulation are those that, because of the gravity of the event (possibly simply risky, that is, a lucky combination of causes meant it remained in the sphere of risk and didn't become an actual event that can be called an accident) or for an excessive frequency of its occurrence, merits scrutiny to recognise the causes and the critical [factors] that determined them (NIB, Annual Report, 2012, p. 6).

Possibility logic promotes the same approach also with reference to events that lead to accidents/incidents. Once the trigger of an event is identified, the question becomes: in principle could other technical failures, behavioural, or organisational factors favour a recurrence of the same trigger?

Even if there is an awareness that the remaining possibility of adverse events still exists, the run-up to safety is seen as 'philosophically without end'. Possibility logic ideally pursues the 'zero risks' target, notwithstanding the awareness that 'the only safe train is the stopped one'. Such a 'zero risks' target is defined as not having an adverse outcome for health or the environment. The logic defines safety as a never-ending process that is continuously evolving:

the objectives, if we have to consider them, we can get philosophical for a second and then we'll quickly leave philosophy. The objective is to make things improve, let's say improve safety in the railway sector. How do we measure this? We measure it in terms of reducing accidents, we measure it in terms of reducing the consequences on people, on things, on the network and we measure it, however that may be, also in terms of efficient service. The more efficient and the more effective service is, the least impact it will have on [people's safety] …the less impact safety problems will have. And so it means, bit by bit safety will always have less space to be, how can I say… unobtainable. But anyway… there would always be less space for investigation if we always had to dig into the quality of safety. The problem is that, in any case, a maximum limit exists and it is insuperable and is also dictated by technological innovation, and by modifications, which, in any case, occur in the railway sector. Technological innovation brings new goals, but also brings new safety standards, so it is a constant process but an inevitable one, which takes us on an infinite philosophical path. I always make a comparison, even with my collaborators, I make a comparison with technologies which are put into place to safeguard citizens from catastrophic events such as seismic events for example: no matter how much technology can be refined, however much it's possible to introduce new methods of structural calculation, new methods of preventative analyses, new safety measures even after the event has occurred [...] there is a general imponderability in nature's response and the structural incapacity of man to cover safety 100 per cent. So here too, we accept philosophically that inevitably damage to people or things beyond a certain limit are unavoidable and we accept that the instruments available today for planning, for building, are instruments that tend towards maximum safety, but which will not, however, ever achieve this (NIB, interview);

I repeat, modifications especially to the system itself and, therefore, new technologies, augment the average speed of travel time. Infrastructure that changes materials, changes technological control systems, changes control systems that are honed; these are all steps towards safety but, at the same time, all steps towards a territory, which is in any case new and unknown. We take a series of steps but the entire voyage isn't one that has an end. It is a voyage that is philosophically infinite (NIB, interview).

In summary, possibility logic defines risk as the possibility of adverse events. The focus is not only on what actually happened, but also on what could happen. 'Zero risk' is a target, but it is considered unattainable, thus safety is a never-ending and continuously evolving process.

Looking at the differences between the three logics, cost-benefit logic and standard logic define risk as a product of the magnitude and frequency of the identified hazard. Cost-benefit logic does not fix a maximum risk acceptability level; in contrast, standard logic prescribes a clear limit to sector decisions: death and injuries are not acceptable. Possibility logic shares the death and injuries limit as a non-negotiable one with standard logic. The risk definition proposed by possibility logic does not follow the classic definition, but focuses on the possibility that an adverse event could happen. In so doing, it differs from both the standard and the cost-benefit logic.

Ends

The three logics focus their attention on different ends fostering distinctive expectations and ideas on what regulators should pursue and in which way they should behave. Let us look closely at the ends identified by the three logics.

Cost-benefit logic (ERA)

For cost-benefit logic, the main purpose of regulators is to offer technical support to political decisions. Regulators should identify technical solutions and provide recommendations for political decisions in order to ensure the actual implementation of the objectives promoted at the politico-economic level. Consequently, cost-benefit logic identifies and translates the ends shaping and shaped by risk-based logic into technically feasible solutions as a main objective. (See Figure 20.) Adherence to the ends determined at the politico-economic level is related to the close continuity between the European Railway Agency and the Commission. The Agency is depicted more as the technical division of the Commission rather than as an autonomous organisation:

> what is for me personally the role of ERA in the European context is the role of a technical support body to the Commission and to the European Railway and not really more. If you follow the history […] the agency was created because in the work of the European Union at one point […] at a certain point they said well the railways a bit more difficult a bit more challenging quite technical we don’t have enough time here, we don’t have enough technical expertise so for the technical part they create the agency (ERA, interview).

Figure 20: Objectives steered by the cost-benefit logic (ERA, slide Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 12)

The technical mission of regulators is stated as a core value to follow. More specifically, the regulators' recommendations should be 'based on facts' stressing their role as technical analysts that study the phenomena and analyse them through data examinations and not clues or sensations:

Our core values are:
We are drivers of improvement through innovation.
We respect others and believe in progress through diversity.
We build an independent and transparent position based on facts.
(ERA, http://www.era.europa.eu/The-Agency/About-ERA/Pages/Values-and-Mission.aspx, my emphasis).

Such technical value is reflected in the two foci the regulator activities should maintain. On the one hand, the regulator should not drive the ends of the regulated domain of human activity, but should offer the practical implementation of the ends fostered at the politico-economic level. Thus, a core objective is the concrete development of the legislative framework driven by risk-based logic. On the other hand, regulators should find a balance between the different ends the politico-economic level identifies taking into account the economic impact of any political decision:

> the main task is to prepare new and updated legislative acts for adoption by the Commission, after a positive opinion from the Committee of Member States, and to give other technical support to the Commission. The activities carried out by the Agency aim at:
>
> - Developing a common approach to safety, safety regulation and accident investigation, in particular by harmonisation of safety assessment methods, safety targets and safety certification conditions
> - Improving the interoperability of the European rail system by developing the conditions for the free and uninterrupted movement of trains through technical and operational harmonisation, including conditions for mutual acceptance of railway vehicles
> - Facilitating the exchange of information within the railway sector by networking with national bodies, providing registers and databases and giving guidance on the implementation of the regulatory framework (ERA, Website).[55]

In maintaining such a technical approach, the main purpose of the regulators is to write and revise the legislative framework, to monitor its implementation, as well as to help the national authorities and the sector to understand and implement it in a homogeneous way:

> for me we should be the technical support to the Commission to develop the new regulation and revise the railway regulation, but also to support the implementation. And to do that we need to know and monitor what is happening in the real world not only at the level of the industry, but also at the level of the NSAs and NIBs. For me we have three missions: proposing new text or revision of text and supporting the system authorities and the sector […] and measuring if objectives are reached or not (ERA, interview);

> until three, four years ago it was about producing the legislation […] now it is largely complete we are more focused on monitoring the legislation, explaining to our stakeholders, helping them and reviewing it (ERA, interview).

The development and implementation of the legislative framework should always take into account the economic impact of any legislative decision. The economic impact is closely related to the plurality of ends the regulators should consider and

[55] http://www.era.europa.eu/The-Agency/About-ERA/Pages/Values-and-Mission.aspx, Website consulted 13 April 2014.

balance. Thus, the safety objective should be developed parallel to other objectives resolving the conflict between contrasting ends. The economic impact is seen as a 'based on fact' tool in order to solve such conflicts. The main safety objective is that safety should not deteriorate given the important modifications affecting the railway sector during the last two decades. The safety objective is seen as interrelated with the interoperability and liberalisation ones. More specifically, the main safety objective is the harmonisation of safety approaches across Europe in order, on the one hand, to eliminate the safety argument as a barrier to enter the national railway networks. On the other hand, it is to guarantee the necessary homogeneity of the safety approach around Europe, in order to offer an adequate context for an interoperable European network (Figure 21):

so the mission is to provide technical support to the Commission to open up the market…Opening up the market starts with a technical and normative approach problem. Then at a certain point the Member States say 'but safety is important, we have to maintain safety' and so that problem emerges and it is done. You try to harmonise all the processes related to managing safety in a way that doesn't allow Member States to use safety as an access barrier (ERA, interview).

Figure 21: Safety Harmonisation (ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 18)

More specifically, the European level regulators' role is to address problems that cannot be addressed at the national level, given the purpose of developing a unique and interoperable European market:

> my personal interpretation of what we are trying to achieve is there are things that can be best achieved at the European level […] because the traffic is international it needs a European solution, so for me one of the key area we can add some value to the sector is address things that must be addressed at the supra-national level, they can't just be addressed nationally (ERA, interview).

In summary, cost-benefit logic identifies technical support to the politico-economic level as a main aim. Such support is articulated in two secondary level objectives: developing and implementing the legislative framework and ensuring a correct balance between the different ends driven by the politico-economic level.

Standard logic (NSA)

Following standard logic, the main goal regulators should pursue is safety. (See Figure 22.) Unlike cost-benefit logic, the accent is not on a balance between multiple ends or on the need to offer technical support, but on safety in and of itself:

> we are the only ones that are obliged to supervise railway safety in Italy. We are the only entity that has the job of realising this supervision on railway safety and so we are the ones who are deputised to enter into the problems of safety […] From the perspective of railway safety, we are the only ones overseeing and promoting railway safety (NSA, interview);

> then concretely the one who deals with verifying whether functioning is safe in the railway system is the Agency. And, by the way, it does so in a way that has always made me a bit anxious. The 162 says it's like the Agency looms over the railway operators in a way that they can guarantee safe functioning, so it is not a passive role, it is a role that is a studs-up tackle […] In my opinion, the principle task of the Agency is exactly to guarantee that the system works in a safe manner obviously trying to make operators understand their responsibilities. Because compared to the past [railway system] the first world was closed into itself. And now it is open and there are many subjects who know nothing about the railway and look at a market that is fittingly open. But then what must be safeguarded isn't just putting together the train, but moving the people that are on board safely and securely to their destination and this happens through the fact that there are always high levels of attention paid to railway safety (NSA, interview).

Figure 22: Objectives driven by the standard logic (NSA, Slide presentation: Agency training course for railway police, 2011, p. 5)

This difference between cost-benefit and standard logic reflects the institutional mission attributed to the two organisations in which such logics are prevalent – the ERA and Italian NSA – on a political level. For example, at the European level, both the objectives of safety and interoperability are stressed. The objective is not safety in and of itself, but pursuing the interoperability and liberalisation of the European railway network, while maintaining the same level of safety. In contrast, at the national level, the interoperability goal is not recognised as significant as the safety one, and the safety objective does not predominantly consider maintaining the same level of safety, but the improvement of that level:

Noted that the Agency, in effect as of 16 June 2008, has taken on, in line with Article 4, comma 8 of the legislative decree, the tasks regarding railway circulation safety, with particular reference to:

- *Emanation of Safety Norms and Standards* for railway circulation;
- Homologation of rolling stock, or parts thereof, *for aspects connected to the safety* of circulation;
- Issuing, renewal, modification and revocation of *safety certification* to railway companies, including activities related to *system management safety*;
  - Inspection and auditing activities as well as monitoring railway company activities (Ministry of Infrastructure and Transport, Guiding Act concerning the

> identification of priorities and objectives to be realised in 2008 by the National Safety Agency, p. 2, my emphasis).

In improving the level of safety, one should not consider the economic impact of such an improvement. The safety of citizens is seen as the main function of the state. Such a function is not negotiable and regulators should not consider the economic impact on the business aspects of the sector, when the safety of citizens can be improved:

so it's not, let's say, the quality of the measure that is placed in discussion, its impact is on the line, its impact. Now, now, thank goodness us no, I underline in bold, we don't have to worry about the economic, industrial and financial impact of our measures. If we start to consider those aspects, we will dilute our role. We can't ask ourselves how much safety costs, […] it shouldn't be my concern…I have to have the criteria, I have to look towards the efficiency of the measure or at least of my administrative acts. If there is a higher or lower impact on businesses, […] this is an issue that is equal to work safety […] to the extent that work safety has the fact that it derives from Community legislation in common with railway safety, the principles are the same. Great! Do those who worry about work safety have to consider whether it costs a bit more or a bit less? No, that's trouble, then it is clear that one observes reality and is aware that in certain cases, certain measures are accepted and other cases are questioned but that's ok, that's ok. I mean a professor at school has to give a 10 when the boy deserves 10 and must fail him when the boy deserves to fail (NSA, interview).

The physical integrity of citizens cannot be traded-off with other interests such as economic ones. It is a value in and of itself and, from the regulators' point of view, the recognition of such a value is what distinguishes a State from a tribe:

but for my agency which considers safety…if a person trips and falls because a train door had a malfunction [and opened by itself], [the person] trips and falls and twists an ankle…I don't worry about whether my planning for improving the mechanism of the door is sustainable. I worry about the problem that if she twisted her ankle she could have banged her head…and if she banged her head she could have died…and even if she twisted her ankle, and even if the lady is an elderly lady who contributed to the improper opening of the doors, I say that the state must defend citizens from themselves … This is the higher function of the state […] the state must defend its citizens from themselves. It's the first higher function of the state otherwise we are not a state we are a tribe, where the hunters leave in the morning and go hunting and those who hunted more eat and those who hunted less hang on, but this is a state not a tribe… right? In a tribe, you reason like a group: you only do the things that are sustainable so if that guy hunted very little, then his children will also be unwell. It's unsustainable for the tribe to feed them … agreed? (NSA, interview).

The improvement of safety levels is balanced with another key objective that is not driven by cost-benefit logic: the need to guarantee a service of public utility. Railway transport is seen as a key public service, thus guaranteeing a service of public utility is the only element that should be taken into account when a safety improvement is required:

considering that the opportunity to ensure that the move toward higher safety standards occurs rapidly but without negatively affecting the level of the railway service offered to users (Document: Ministry of Infrastructure and Transport, Guiding Act concerning the identification of priorities and objectives to be realised in 2011 by the National Safety Agency, p. 4);

not having defined a system of sanctions, in cases in which nonconformities to Agency requests are verified, the possibility to impose requirements or limitations exists which may, however, inevitably have an effect on the level of service and which, therefore, can be justified only in cases in which the aim is to avoid the repetition of potentially serious incidents (NSA, Annual Report, 2012, p. 62);

as an Agency we were instituted by a decree and that decree is not only the establishment of the Agency but introduces many concepts that represent epic change compared to where we were before and what there should be after […] We are in the same boat, what counts is the Italian system […] keep doing it. I may be taking on more responsibilities to control you, but continue to do it because the Italian system shouldn't be penalised because maybe you haven't prepared yourself or understood the change or something else […], you don't stop the trains. In the end, consider this, [...] let's take the example of dangerous freight. One thing is to have a train of dangerous freight, the safety measures and controls, the evaluations you make are many [more] compared to a truck with chlorine travelling in a city. That is, the checks that are done on the road are a minimal part of those made on rail […] They are a series of checks that, on the one hand, increase the costs of making the train run, so you are safer, but you are penalised in the sense that moving a kilo of gas on the railway costs more than moving a kilo of gas on the road. But you have more security measures in this area so you have to try not to interrupt the service because it's not good for the Italian system. And if you stop the trains that move dangerous freight it's not that, you no longer move dangerous freight, you move them with trucks and if you go and look at the safety, you are damaging the Italian system so you find a way to make them go safely. That is, if you have doubts that what you are doing is safe you must absolutely stop it; but you have margins of evaluation within which you can move, managing it with more checks, with tests, with greater monitoring activities […] With reference to passengers, the motivation is that in any case you are providing a public service to people […] [you see] how full the trains are in the morning, how many people are moving, I mean, if you decide: "Look tomorrow trains aren't running anymore." Are you doing the right thing? Are you doing something good for safety? Are you doing something good for Italy? You have to make sure that XY understands he has to do something in a certain way […] before you say "don't run another train" and leave people abandoned to themselves, you have to evaluate it. You can do it and you have to do it if you really think there is a risk, a danger for the collective, but not if you think this risk isn't imminent and that things can be done, followed and modified by successive steps (NSA, interview).

The role of the regulators is to act in order to defend the interests of citizens. The focus is not market development, but the collective interest. The role of regulators is seen as being in continuity with a view of the state as the protector of its citizens, as well as granting crucial services such as transportation. The regulators' activity is related more to limiting market interests in order to protect all of society, rather than facilitating market activities:

the Agency is an institution […] that can help the system grow, not just from the exclusive perspective of the operators target, but also for the collective good […] Its only interest is that a citizen can safely use the railway service, therefore, [it is] totally removed from the business world. I'm going to quote […] from our Director […] who is a man of the state, a man who therefore has been an executive in public administration with clear origins. One of the first speeches he made, this quote struck me […] "We are not a company for stocks, but we are a structure that works for the collective good." So this mission is the one I see as the future of the Agency […] The Agency has been asked to behave organisationally in a very different way from the way we did before [within RFI] (NSA, interview).

In their function as public servants, regulators should preserve an independent and impartial attitude testifying to their role as guarantor of the collective interest (see Figure 23):

expressing the quality of public administration: independence and transparency in the safeguarding of the collective interests of railway safety. Independence and transparency are the issues of Macchiavelli, the prince must appear honest: these colleagues who are doing the certification of the vehicles today … when they did the same thing before within RFI and the certification request was made by a competitor of Trenitalia, they were just as good. They did their job just as well but someone could say … there was a conflict of interest; they could say it, it wasn't true because people worked in a conscientious manner, but it didn't seem so. Right? The prince must not only be honest but must also appear honest (NSA, interview).

Figure 23: Role of the regulators – Independency and transparency (NSA, Slide presentation: Agency training course for railway police, 2011, p. 7)

In conclusion, the objectives shaping and shaped by standard logic are to ensure and improve safety, to preserve the collective interest while at the same time guaranteeing the physical integrity of citizens and maintaining transportation service as a crucial public good. In doing so, regulators should exhibit independence and impartiality.

Possibility logic (NIB)

Like standard logic, the key objective of possibility logic is driven by improving safety levels:

the fundamental objective of National Investigation Body activities is improving railway safety (Document, NIB, Annual Report, 2012, p. 2).

The safety improvement mission is depicted as a moral one rather that a technical one. Pursuing safety improvements is a moral duty, therefore, regulators should stay on the just side defending the public good, rather than the specific business interests of the sector:

we haven't forgotten to remind the subjects involved in continuing investigations in various moments and occasions of their duty, especially morally even more than institutionally [referring to the Viareggio railway accident]. I am convinced that I can say that this Investigation Body, along with its personnel and its collaborators and external experts, feels privileged by the fact that it can contribute to start and consolidate virtuous processes, operating at all times with the necessary spirit of service towards the State and its Citizens (NIB, Annual Report, 2011, p. 5).

From this perspective, pursuing the safety of citizens is a characteristic of a civilised country:

this moment, this difficult economic situation for the country must […] in some way end and since an act of growth for a country is also measured by the growth in its ability to protect its own citizens and in my opinion [this is] a profile that is not direct, not immediately understandable – like the construction of a new road artery could be – but has a direct effectiveness on the quality of life. And I trust that in some way, besides myself, at the end of my working life, this Investigative Body, which started almost from zero, will gradually become self-aware and assume a role and [obtain] clear recognition also within institutions, and so will be granted more instruments to express itself more effectively (NIB, interview).

Independence from specific interests and the moral integrity of the regulators' activities is seen as a crucial element of a public servant's role:

among other things, we have taken an oath as public servants and we consider it binding. It is evident and tautological, but the things I am saying are factual things. […] In this office, the obligation is recognised to behave in a certain way as public servants and we try to uphold, as much as possible, to the third-party request and independence expressed by Directive 49 in the most ideal manner possible. We operate duly and on the basis of what I told you. Then in the labyrinth of behaviour, there can be things that weaken. For example, we look the other way, we don't raise a fuss for this thing, [because] we already came down heavy on another issue. This in some ways is possible, but [not for] serious things. Work behaviour can't stop at the legislation, but we must go and look at the single risks innate to discretionary behaviour. With our evaluation body, we are looking at the issue of integrity. It is a complex problem because how can you know that an employee is not subject to 'corruption', in a lateral sense, subject to pressure even though not explicitly, etc. Here we say that we monitor every action in order and nothing leaves here without the Director being absolutely sure that there has been independent judgment. It's not a question of wanting to be independent, it's that we must be (NIB, interview).

In this case, personal commitment overlaps with the institutional mission. Defending the public good represents a strong motivation for working hard and doing one's job properly every day. Hence, the safety mission is perceived as a personal moral mission more than an institutional one:

we like our job, I feel like I'm working for a noble cause. I also worked in the private sector. There I worked in the interest of someone, here it's not like that, you're working for safety which is very important (NIB, interview);

I like my job, at least I'm working for something that has a value. It's not like in the private sector that you're only working in someone's interest (NIB, informal talk);

I also do it because I feel protected, I'm sure that nothing will happen to me, I cannot be fired. I can't in any case lose my job, I can afford to do battle for the flag (NIB, informal talk);

our objective is to remain unblemished, to try and do our job. We are a small group that is working in a coherent manner (NIB, informal talk).

Pursuing the mission goes beyond the legislative framework driven at the politico-economic level. The purpose of the regulators' activities is to flush out problems and try to solve them even if the problems are within the legislative framework in which the regulators operate. The regulators should have a content-heavy perspective that goes beyond the principles identified by risk-based logic. For example, a critical element is the focus on the non-prescriptive and 'light' regulation promoted by the risk-based approach. In particular, in following possibility logic, regulators should maintain a significant focus on content, despite the indirect risk management focus promoted by the risk-based approach:

Certification, when something is certified it's not enough for us. Certification occurs through formal processes. ERA, individuals that certify quality like the whole world of quality (ISO 9000 – 9001), quality control**:** for us it matters little, we are sceptical in that sense. We have an external vision with regards to certification. For example, certification in the NOBO environment, you pull your hair out. We are aware that at a certain point the fact that a subject is certified tells me very little. For example, [according to] Law 445 on ECM (Entity in Charge of Maintenance) the subjects that do maintenance are chosen by the Keepers (wagon owners), so I can choose a subject because it costs me x. Moreover, it ensures a revision, puts a stamp on and I'm okay. Consequently, I tend to take some distance from what I'm doing. If an element of the chain of responsibility [between the network of organisations involved in operating and certifying the railway sector] comes less because he's delinquent, am I ensuring safety for people? Obviously there will be roles, profiles of responsibility, etc. But I am also risking that there are professional signers. Certifying can become a profession without anyone really knowing what is happening (NIB, interview);

ECM (Entity in Charge of Maintenance) certification, the risk is that it becomes a bit like a quality brand for the company in the beginning. A consultant arrives that says: "You're missing a quality manual, here is your quality manual." You understand it's unlikely that the manual will be shared, it's not a product of the company, etc. (NIB, informal talk).

More in general, the mission is seen as an open one. Being that safety is a never-ending process, regulators should move in the same direction trying to guarantee the constant improvement of their own activities. The institutional mandate is not seen as a binding one, in order to pursue constant improvement. If necessary, regulators should go beyond their institutional mandate:

for us the main attention is placed on the accidents. The near-misses are opportunities that we seize sometimes to investigate but it is at our discretion. By mandate, we must only investigate accidents. Our mandate is dual in this sense because we have to investigate accidents but also work so that accidents no longer happen (NIB, interview);

it's a procedure that we are still doing, a sort of self-teaching of the range of our mission […] because in the same founding regulation […] there are broad spaces for interpretation on the range of activities that we can do […] We consider the mission of implementing railway safety as a full-fledged mission [and] we think we can express ourselves and thus allow the responsible institutions to express themselves. Those that materially emanate the rules, that materially emanate the modifications to national or international regulations […] not just on macroscopic accidents but also the chain of lack of safety that we can in some way flush out with studies and detailed analyses. We had started doing them in past years as well, but we don't always have sufficient resources in economic terms to address them and, therefore, in some cases we limit our investigative activities […] (NIB, interview);

as an investigative organisation, we don't limit ourselves to the narrow limit of the same founding legislation that is we don't think that we have to investigate, investigations have an air and a reach that still needs to be explored. It isn't [...] possible for us to squeeze ourselves into a boundary or behind a fence, this is fundamentally the plan we gave ourselves. How far we are able to push ourselves we don't know obviously, but we have given ourselves a plan that is without borders. Probably sometimes certain natural limitations will be imposed on us. What do I know, politics or [special] interests, they cut our funding. I don't even want to probe that at this moment (NIB, interview).

In conclusion, possibility logic identifies the improvement of railway safety as its main goal. The safety mission is seen as a moral one and is perceived as a personal duty more than an institutional one. The institutional mission as well as the legislative framework defined at the politico-economic level is not seen as binding. On the contrary, regulators should flush out problems even within the legislative framework in which they operate. More in general, because safety is a never-ending process, the regulators' mission of ensuring a high safety level is seen as an on-going and open mission that should be constantly re-defined.

Looking at the differences between the three logics, cost-benefit logic differs from the standard and the possibility ones because of the plurality of the ends that should be balanced. In contrast, the standard and possibility logics focus their attention on the safety objective. The standard and possibility logics perceive their mission as a moral one, in contrast with the cost-benefit logic, which views its mission as a technical one. The standard and cost-benefit logics perceive the role of regulators as promoting and incorporating the institutional mandate determined at the political level. Instead, possibility logic interprets the role of regulators as an open one in which a moral commitment to safety prevails over the formal institutional mandate.

The cognitive component

The three logics represent three different methods of reasoning. The cost-benefit and standard logics characterise a mix of the deductive and inductive methods of reasoning, but present a different interpretation of the inductive one. Possibility logic is the only logic representing an abductive method of reasoning. Let us look closely at the three logics.

Cost-benefit logic (ERA)

Cost-benefit logic upholds two ways of reasoning which, following Pierce's (1958) classification, can be categorised as deductive and inductive. Nevertheless, in adopting inductive reasoning some important features that characterise cost-benefit logic are present. In effect, the balance between the two methods of reasoning tips in favour of the deductive one. The inductive perspective is basically framed through the assumptions sustaining the deductive one. Let us look closely at the way in which the two methods of reasoning shape and are shaped by cost-benefit logic.

Deductive reasoning

The deductive method of reasoning – I have a theory in mind on the way in which things go and are related to each other and, looking at reality through such a theory, I make decisions – is sustained by three key assumptions the cost-benefit logic represents:

- The railway system is framed as a closed system in which interactions between technical and human sub-systems are finite, certain and knowable and thus, predictable;
- Nowadays, the functioning of the railway system, thus the interactions between sub-systems are known and categorised in theories of reference. Given the experience acquired over a considerable number of years during which railway transport has operated, such theories of reference can be considered, in principle, as consolidated and exhaustive;
- The system nowadays is safe, thus those theories have proved to be right and sufficient to ensure a high level of safety.

Let us examine some processes in which the assumptions shaping a deductive approach to the processes of risk management emerge and are promoted by cost-benefit logic in detail. The risk management processes promoted by cost-benefit logic will be addressed in-depth later on in this chapter. At this juncture, the aim is to introduce some selected elements of these processes in order to offer some actual examples of the way in which deductive reasoning shapes such processes.

Looking at direct risk management, we consider the processes developed within the regulating organisations, which target the outcomes of the regulated ones as informational input, process this informational input, and elaborate tangible outputs in order to avoid, cope with, and/or handle such side-effects. The direct risk management process is based on information that comes from the regulated organisation. Cost-benefit logic considers Common Safety Indicators as the informational input of the direct risk management process. Such Common Safety Indicators include accidents, incidents and near-misses collected from all the railway undertaking and infrastructure managers across Europe. Such indicators are established through Directive 2004/49. The list of the accidents, incidents and near-misses composing the Common Safety Indicators follows:

1. *Indicators relating to accidents*

1. Total and relative (to train kilometres) number of accidents and a break-down on the following types of accidents:

— collisions of trains, including collisions with obstacles within the clearance gauge,
— derailments of trains,
— level-crossing accidents, including accidents involving pedestrians at level-crossings,
— accidents to persons caused by rolling stock in motion, with the exception of suicides,
— suicides,
— fires in rolling stock,
— others.

Each accident shall be reported under the type of the primary accident, even if the consequences of the secondary accident are more severe, e.g., a fire following a derailment.

2. Total and relative (to train kilometres) number of persons seriously injured and killed by type of accident divided into the following categories:

— passengers (also in relation to total number of passenger-kilometres),
— employees including the staff of contractors,
— level-crossing users,
— unauthorised persons on railway premises,
— others.

2. Indicators relating to incidents and near-misses

1. Total and relative (to train kilometres) number of broken rails, track buckles and wrong-side signalling failures.

2. Total and relative (to train kilometres) number of signals passed at danger.

3. Total and relative (to train kilometres) number of broken wheels and axles on rolling stock in service.

(Directive 2004/49/CE, Annex I: Common Safety Indicators, p. L 220/32-33).

If we look closely at those indicators, we can see that:

- There is a focus on the consequences rather than on the contributing factors leading to the accidents/incidents. On the one hand, the number of considered precursors is extremely low. On the other, even when they are considered, there is no attempt to collect information about the contributing factors that lead to the event. For example, the number of signals passed at danger does not give any information about the reasons why a signal indicating the driver to stop was passed;
- The proposed classification does not consider any details about what actually happened, grouping together types of events even if they are very different

from each other. For example, extremely different kinds of events can be grouped under the categories of derailment or fire on rolling stock;

- No place is given in order to report events that do not fit within the pre-defined categories.

The predefined categories, the absence of a special section in which reporting events that do not fit within the available categories, as well as the focus on the events in themselves rather than on the elements that lead to the accidents/incidents, suggests that the reasoning behind such a reporting procedure is deductive. In particular, there is a precise theory on what the relevant accidents and incidents are, as well as on what the factors that lead to those accidents are. By oversimplifying, we already know what is relevant and can decide, *a priori*, what information is needed in order to monitor such relevant elements. Thus, we have a clear idea of what the dangerous events can be and what to look for in order to monitor such dangerous events. We know the problem we have to face, thus we can chose to look selectively at the information that is significant in order to face such problems.

Looking at the indirect risk management process, we focus on the processes that regulators promote and enforce as the correct way of managing the risks that regulated organisations should follow. Indirect risk management is a key strategy of cost-benefit logic. As the responsibility of risk decisions is placed entirely on the sector, indirect risk management processes become the main strategy to ensure that risks are managed in a systematic way. A crucial risk management process that cost-benefit logic promotes and enforces is the Safety Management System. This system is composed of different processes and operational activities the railway undertaking and infrastructure managers have to develop in order to ensure that the risks associated with their activities are managed in a systematic way.

Two crucial elements of the Safety Management System are the Risk Assessment and Monitoring processes. Risk Assessment processes determine hazard identification, risk estimation, evaluation through acceptability criteria, and development of control measures in order to reduce the magnitude or frequency of such risks. The monitoring process refers to the collection and analysis of data, the analysis of accidents, incidents and near-misses and the development of internal audit programs. More in general, the monitoring process relates to the entire development of the Safety Management System and constitutes a safeguard that the system is operating in the right way.

Both the processes of Risk Assessment and Monitoring are the object of specific regulations and guidelines. If we look globally at those guidelines, a precise focus on what aspects the cost-benefit logic promotes emerges. The focus this logic encourages is on planned and intentionally driven changes to the system, rather than on the analysis of accidents, incidents and near-misses. Thus, priority is given to modifications intentionally made by the sector rather than on possible emerging and unplanned phenomena. This focus is related, on the one hand, to the definition of the railway system as a closed system in which interactions are limited and knowable and changes are, by definition, intentionally driven. Consequently, the main sources of danger become intentionally-driven changes to the system's functioning. On the other hand, such a specific focus is related to another assumption sustaining the deductive method of reasoning: the system is known, the possible interactions are in principle known, and such knowledge has proved to be right given the high safety performance of the railway system nowadays. The process the sector has to follow in order to evaluate the risks related to planned changes to the system stresses the importance of such assumptions. More specifically, in order to evaluate the risk associated with a change, the change proposer can chose between three different criteria: application of a code of practise, comparison with a reference system or explicit risk estimation. (See Figure 24.)

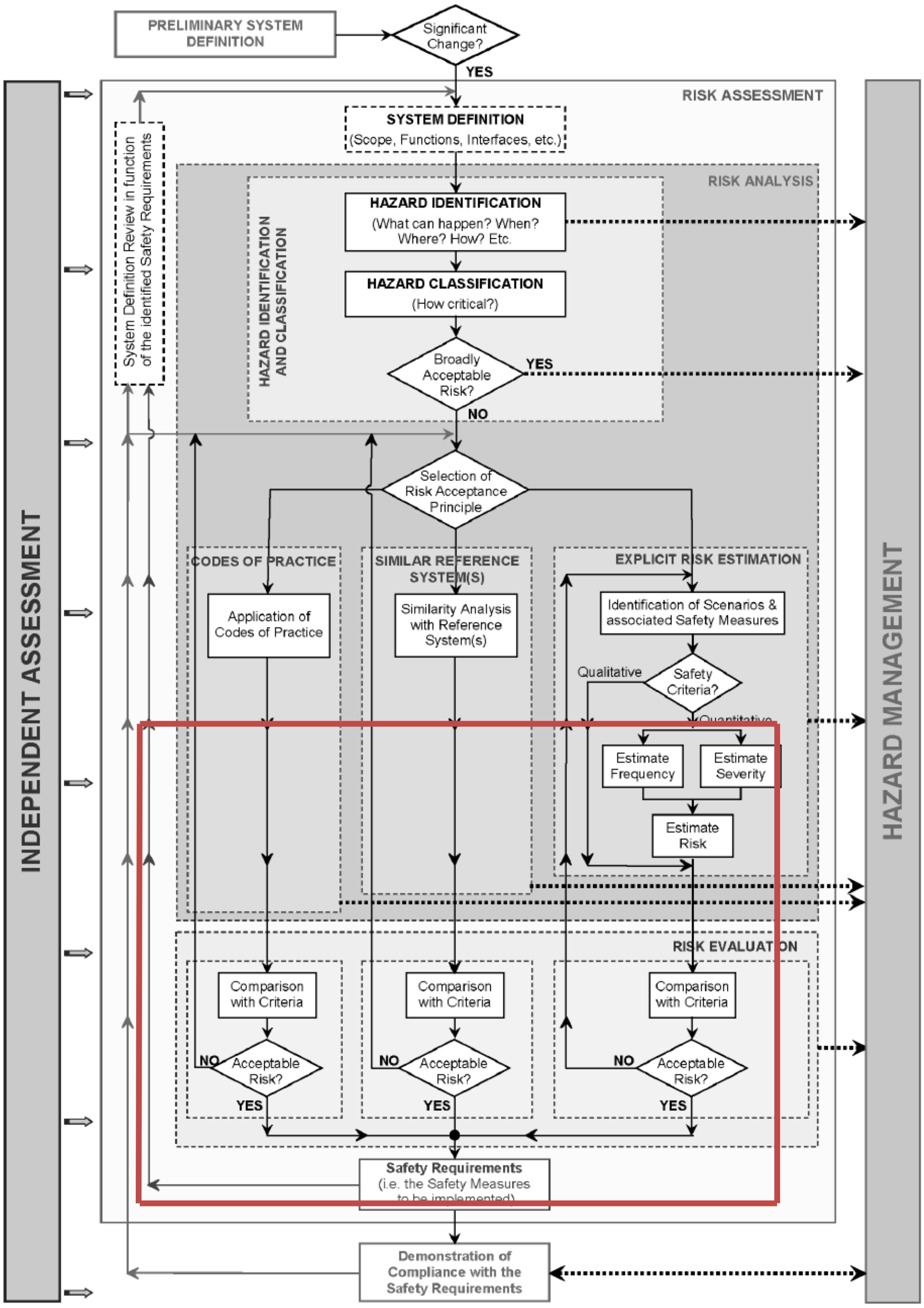

Figure 24: Common Safety Methods on Risk Evaluation and Assessment: Risk Management process diagram (Regulation, 352/2009, Appendix, p. L 108/18)

The use of codes of practise or the comparison with reference systems are expressly related to 'the grandfather right.' Thus, if in the past things were done in a certain way, since the system is safe, there is no need to re-do things or do them in another way:

a reference system is a system that has been built, put in service and it is used for many years and the experience shows that it deliver a sufficient level of safety, sufficient safety performance. So if you build a new system with similar needs you can re-use the same principles as this system that you know and we speak about similar reference systems […] another way to say the same [thing] is grandfather right if it was acceptable at that time it should be acceptable now (ERA, informal talk);

you know why only the changes? Because this is important. In Directive 49 it is written that the system is safe, and this is a fundamental point, that is, at a certain moment in 2004 they made the Directive and they said: "So the levels of European railways are normally very high levels and we must improve them where it is reasonably possible." So we presuppose that all the premises for the safe functioning of standard activities exist in the system. Then what happens is that at a certain moment it was said that we had to clean up national norms, let's do harmonisation, so they put their hands into a system that had been defined as a safe system per se. So the responsibility was given to the businesses to manage these transitions and you have to do it within that guideline […] but the problem is that you take the old rule, the old official personnel guide to locomotive conduct which normally was a book […] where how the engine driver should behave in the case of the disrepair of a series of things is [found]. You can say: "I'll adopt it completely" but you have to verify that the norm is adaptable. If it isn't adaptable you have to adapt it and so the issue changes because you are no longer protected by the railway tradition, you have to invent something new and so you have to apply the common safety methods (ERA, interview).

Inductive reasoning

While deductive reasoning starts from a theory, which aims to interpret reality, inductive reasoning departs from reality in order to derive a theory. Cost-benefit logic encourages inductive reasoning, but with important limitations. Induction is accepted, but only if a certain number of cases sustaining it exist. Thus, the evidence collected has to be significant in number, in order to consider an event as dangerous. In contrast, induction is not encouraged if there are only a few or there is a single case under examination that can sustain an in-depth study or intervention. Cost-benefit logic summarises such an approach through the statement: "We want be evidence based, we want [to be] working on facts not on feelings (ERA, interview)." In order to consider a problem, the demonstration that such a problem is relevant is closely related to the possibility of collecting a considerable number of events in which the same problem has occurred:

the one who can have a higher view […] is the NSA. The NSA can know that in is country all the railway undertakings face the same problem that means that it is not the company itself because if it is everybody it is not probable that everybody is incompetent. That means that there is a problem somewhere with the standard, with the regulation, with the rules […] there is a problem, we have to solve it. We can know that problems are located in the specifications and not in how to apply the specifications. On the contrary, in a country if you have ten operators and only one or two have that problem it means that the problem is not the framework or the rule, the problem is the company. They don't know how to apply or they don't have the right people, they have a problem, but the rule is not the problem (ERA, interview).

The evidence-based approach is closely linked to the need to demonstrate that something is dangerous through facts and not feelings. A single event cannot be taken as a starting point in order to question the system's functioning. The 'could be dangerous' expression is considered irrelevant; the real point is 'is it dangerous or not?':

I want to show some key words to share with you […] I want to be sure we are ready because we have new tasks coming forward in 2014, but also new changes are coming, so talking about processes we have in place, talking about focusing our work and looking ahead […] I want to share some of the principles that are very important for me from where I come from […] I want to be evidence based, safety is the worst subject in the world being evidence based, actually every time […] somebody just says "it could be dangerous" yes it could be, it could be safer you know and there is no science in it. And suddenly the magic words "it could be dangerous" and everything stops and we can't move forward. So I think we have to build evidence around the work we do, we test ourselves […] We have to be sure that there is evidence behind (ERA, Safety Unit Meeting, 2013);

today what we have done, we develop text based on the experience of the staff of the Agency and the experience of the sector. Now we are in the phase in which we have to improve and in that case there are two aspects: one we want to have justification for any changes and the discussion we have with the NSA is that they often generalise with one case […] They say there is a problem in maintenance instructions because they saw one case […], but we have two hundred and thirty-six entities in charge of maintenance, so they generalise directly from the one to the two hundred and thirty-six. So we say no, we cannot work like that because if we continue like that each time there is an incident and there are incidents every day we have to regulate and had a regulation. So we have done if we want to do something at the European level we need to have sufficient facts and evidence that justifies that there are problems and it is not with one accident that we can justify a change in the legislation (ERA, interview);[56]

we need facts not chitchat […] we have to demonstrate that something is wrong […] we speak of justified reason, it's not doubts, not doubts (ERA, interview).

This restriction to inductive reasoning is linked to another assumption guiding the reasoning from a cost-benefit logic point of view. Cost-benefit logic promotes a proactive and not a reactive approach to accidents and incidents. Having a proactive approach means:

that you should not wait till the derailment to see why the control command failed. You should have other alarm that tell you the possible problem with your control command so you can react before your control command cause a derailment (ERA, interview).

The proactive approach is presented as a crucial element, which differentiates the old integrated railway system from the new liberalised one. (See Figures 25 and 26.)

[56]The evidence-based approach also shows the detachment of the component of risk from its constituent – the uncertainty dimension. More specifically, if the 'could be dangerous' is not considered a pertinent statement, it means that the risk is closer to the certain pole rather than to the uncertain one.

Figure 25: Old Scenario vs. New Scenario – reactive vs proactive approach (ERA, Slide: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 3)

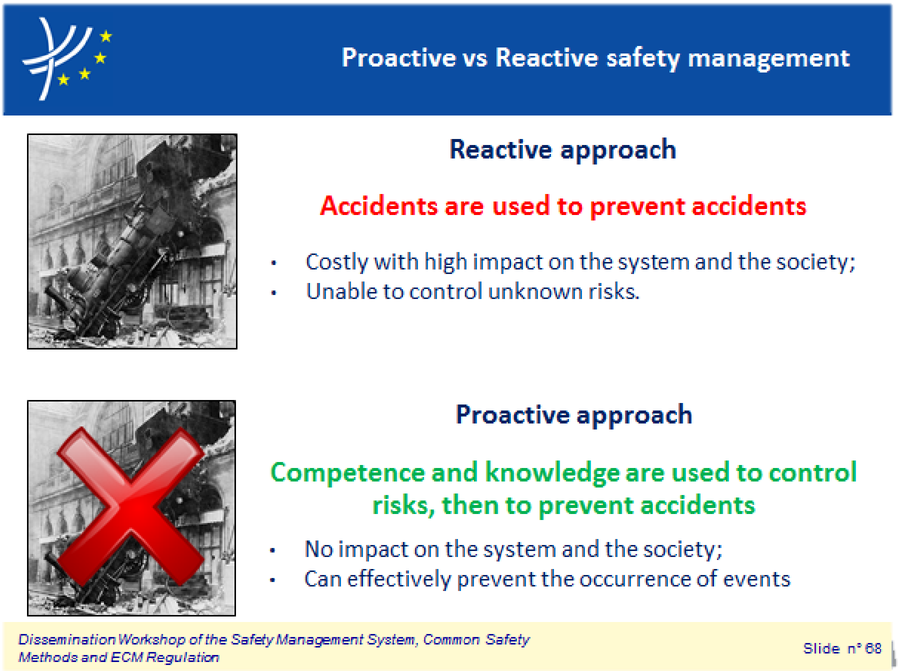

Figure 26: Reactive vs. Proactive approach (ERA, slide: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 68)

Following the previous reactive approach, the railway system waited for accidents to happen and then addressed the problems the accidents raised revising or creating new rules. In contrast, the proactive approach manages risk in a systematic way and is based on the assumption that events are in principle predictable. (See Figure 26.) The key turning point is the change from a ‘react and fix’ to a ‘predict and prevent’ approach. (See Figure 27.)

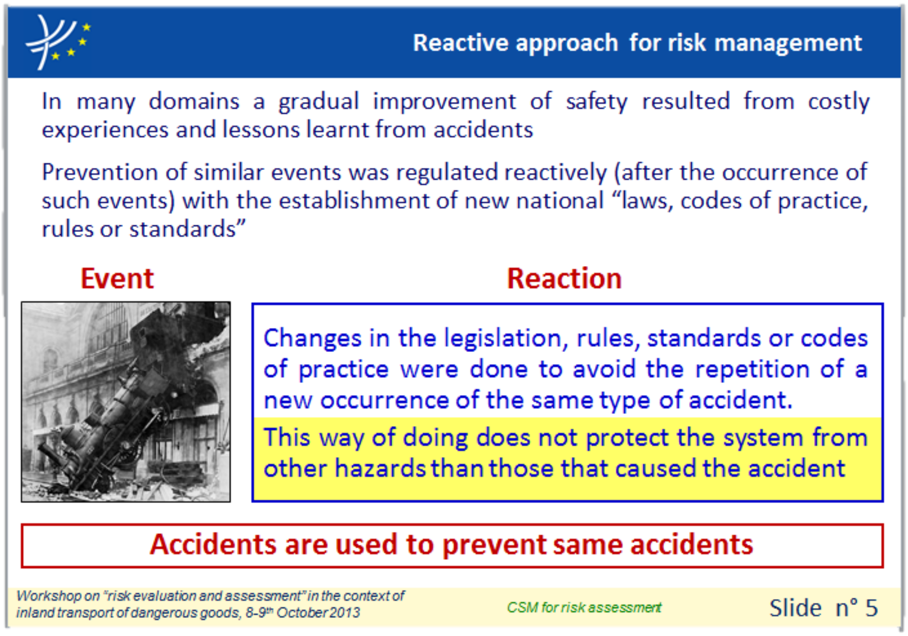

Figure 27: Reactive approach – accident used to prevent accident (ERA, slide: Workshop on ‘risk evaluation and assessment’ in the context of inland transport of dangerous goods - 8-9 October 2013, p. 69)

Cost-benefit logic focuses on the development of processes of risk management allowing one to manage risk in a systematic way that is considered effective and efficient for pursuing railway system safety. In contrast, accidents, incidents and near-misses analysis moves to the background. In parallel, the post-accident reaction is discouraged as feeling-oriented rather than based on evidence and scientific tools that allow the factors affecting the single event to be detached from recurrent events:

the point is to try and prevent accidents starting from the evaluation of risk. That is, once it worked in a way that I applied a rule that in reality was the result of a risk evaluation even if it wasn’t the result of a structured risk evaluation, but they were placed on the table: “Do you see? We have to create a norm that regulates this point too.” Then an accident would happen so they’d recover the rule and correct it or add something, because maybe the rule was wrong or because maybe it didn't cover all the risks. Thus, the system has evolved with a return of experience which, however, considered the possibility of an accident. That is it considered a moment in which it was blatant that the rule wasn't okay or sufficient, so you corrected the norm. The new approach is: "I have to do the risk evaluation in a structured manner and I have to concentrate on the fact that I have to see all the risks", even if it's impossible from a certain point of view … But we have to find a way to prevent accidents, not to have them. So on our part there is less expertise on monitoring inquiries, we don't have a rule on inquiries, analyses of events, we have a CSM on monitoring, which also includes analyses of that stuff. But the piece of the guide that I wrote, the idea is that you must do the inquiry, you have to use it and you have to do it but you must avoid the accident […] You start from the premise that you must avoid accidents (ERA, interview);

one key objective is that the decisions taken after accidents must really target the causes of this accident, therefore in practise it is not possible to take any immediate decision as the causes are generally still unknown. When 'safety-related' decisions are immediately taken, then this could be a purely political decision in reaction to public and media pressures. Such decisions, not focused on the reduction of accident causes could let then think the public that the risk of similar accident has been avoided, while in an extreme situation the decisions will have no effect on the reduction of the risks. (ERA, Workshop on Risk Evaluation and Assessment in the context of Inland Transport of Dangerous Goods 8-9 October 2013, Background discussion document, p. 4).

Let us look at the relationship between the deductive and inductive methods of reasoning. Inductive reasoning is framed by a deductive point of view: inductive reasoning is allowed only if sustained by a certain number of facts and amount of evidence; thus, only if a general theory/rule to refer to is derivable from an inductive analysis. The reaction is not linked to a dangerous event, but when there is a sufficient degree of certainty that the problem is a general one. Cost-benefit logic shares ontological and epistemological assumptions with the anticipation approach to risk management identified through the analysis of previous theoretical contributions (see Part One, Chapter 2): ontologically, regulators face a world of certainty and clear causal relationships, epistemologically such a world is depicted as composed by fully knowledgeable, thus, predictable phenomena and causal relations. Consequently, deductive reasoning is the more effective one.

Standard logic (NSA)

Like cost-benefit logic, standard logic upholds two different methods of reasoning: the deductive and inductive ones. But, unlike the case of cost-benefit logic, inductive reasoning is not linked to the presence of a certain amount of evidence. On the contrary, an induction sustained by a single one-off event is encouraged. In contrast to cost-benefit logic, standard logic still focuses closely on direct risk management processes. More specifically, direct risk management is based on information about accidents, incidents and near-misses collected by other organisations and given to the NSA, as well as on information collected directly by the NSA through the inspections carried out on railway undertakings and infrastructure managers. As mentioned previously, at this juncture we focus on the aspects of such processes that are useful to understand how the deductive and inductive methods of reasoning sustain them. Both such processes will be addressed in detail later on in this chapter, in the section dedicated to the organisational analytical component. Let us look closely at the way in which the deductive and inductive methods of reasoning sustain direct risk management processes developed by the NSA.

Deductive reasoning

Like cost-benefit logic, standard logic adopts a deductive approach to the informative input that accidents, incidents and near-misses provided. In looking at the inspection process, as in the case of cost-benefit logic, the assumptions guiding the development of check lists and categories of non-compliance to collect, are within a closed system in which the interactions are finite and known, and can change when an intentionally driven intervention is made:

> we have identified the macro indicators, that is […] passenger vehicles, freight vehicles, traction means, personnel; these are the macro indicators and then we expanded every macro indicator with its inventory of typical, recurring non-conformities. [...] Therefore, from our experience, when a system is closed into itself, the elements that collide with each other are the same, so the repetitiveness of the non-conformities is something that is fairly certain at least if the elements don't change. So there is a certain repetitiveness of problems that populate our inventory of non-conformities. This doesn't take away from the fact that the inventory of non-conformities tomorrow, when we introduce a new technical element, won't be updated with other non-conformities referring to the new element that have entered the system. So the spirit is exactly this: to fence in the system and take out of the system, both at the legislative level and the typical non-conformity level, which is our inventory (NSA, interview).

The decision about which element to focus on is based on experience, thus there is a clear theory on what to consider, and information is collected looking at the aspects which, in following such a theory, are significant:

> these [check lists] are from experience, from experience […] from our experience because we come from [it]; from experience we have deduced these indicators as macro indicators […] the check lists don't come from nowhere but from our experience (NSA, interview).

The same assumption guides the definition of the indicators that should be monitored through the analysis of accidents, incidents and near-misses:

> so we have standard categories upon which we intervene, regardless, like a train derailment, [or] the improper passing of a signal set on 'stop'; and there we have no [doubt], we don't need to reflect, we intervene directly because they [these categories] have historically placed us in front of major risks. […] We know that all that hasn't worked, and that brought us to the event, should be overseen to be sure that it isn't repeated. [...] So we try to acquire all the necessary information to see how the system is self-regulating to protect itself. [...] These are the situations in which we will certainly intervene. So we have the collision of a train. [These] are principally […] the events we ask for a report for. We are already working mainly on those situations, in which we need to go and see on site. Then depending on the information that we already have, we finish gathering all the information that we need. We don't ask for anything else and we decide if it's necessary to make a recommendation (NSA, interview).

Like cost-benefit logic, the deductive approach coexists with the inductive one.

Inductive reasoning

Adopting an inductive method of reasoning, standard logic illustrates an important difference affecting the key assumptions of cost-benefit logic. The system is seen as closed and composed of finite and known interactions, but standard logic does not assume that the system is completely known and *a priori* knowable. Standard logic opens the door to the presence of new and unknown phenomena. Looking specifically at the analysis of accidents, incidents and near-misses, the examination does not start from pre-defined categories, but from events. Dangerous events are analysed one by one and then, if the events have a theory of reference explaining them, they are classified under the available categories. If the analysed event is completely new and, therefore, does not have a theory of reference within which it fits, a specific analysis is carried out. The parameters guiding the analysis are the frequency of the event, the novelty of the event and the magnitude:

the main criteria, let's say, is the recurrence of the reported event, that is: a thing that maybe last year I hadn't paid attention to, I realise that from last year to this year its phenomenology augmented, or the thing is completely new. Because we don't arrive from Mars, we work in the world of the railway – there are people who have thirty years of railway experience – when something happens that until yesterday had never happened, the doubt about understanding why something is happening may push you to conduct an in-depth analysis, which may lead to nothing, but may also allow you to understand that the new railway context has generated something that didn't exist yesterday […] Maybe nothing will ever happen, but now you have the emergence and frequency of this phenomenon and so you are concentrating on it (NSA, interview);

a 'significant event' can be significant because 32 people died, because it happens often, or because, oh my, the simple fact that you cannot provide an immediate explanation for the genesis of that event can render it significant to me. So [it's] a 'significant event', so we take out 'accident' and 'recurrent' (NSA, interview).

Unlike cost-benefit logic, the magnitude justifies an intervention despite the frequency, even if it is a one-off event:

not just the frequency is relevant, it's also the potential gravity…I was talking to you about situations that are already open, then I told you [about] that one because it also happened often. Then if you have an evident problem, even if it is verified from time to time, but if it is a problem correlated to the bad management of a particular aspect, you intervene on the possible consequences of that event. So, [for example] where you have a sensible rim consumption in a year, it's not that we don't intervene, we intervene immediately on this thing and we advise everyone about it. So it's the potential gravity of that event and its repetitiveness, but obviously the repetitiveness of an event that doesn't result in particular consequences, isn't exactly of interest to us currently. […] That is, if an event is repeated, but doesn't have a possibility of becoming something more serious, then it could also not be a problem for us…We intervene on those aspects that could compromise safety, the moment in which there is something that is susceptible of provoking consequences of a certain type, we intervene […] independently of the frequency (NSA, interview).

If the new event is deemed significant but not urgent, in terms of severity, a new category in which events are classified and supported by a new theory, is created:

> if in the analyses we received, the problems that emerge aren't relevant enough to require our immediate intervention; or if we see that there is a non-conformity, and don't consider it necessary to intervene because it's a non-conformity that isn't significantly relevant for potential causes or for what it might cause, we don't intervene; otherwise we intervene immediately. […] Or if we see that something is relevant, but not that type of relevance, but does, however, require further analysis, we activate other sectors of the Agency to hone the instrument of control because maybe from one single event we are not able to understand what has happened. If we go there and check the entire branch of an activity, maybe we'll understand better. But the filter is: 'could the event cause important consequences?' Yes: we need to intervene immediately. Yes, so we intervene, that is, this is the decision. The other thing: 'could this event be analysed using one of the other instruments?' Yes: this is also an element that gives us another option (NSA, interview).

Standard logic shares ontological assumptions with cost-benefit logic, but differs from the logic regarding epistemological assumptions. On the one hand, the railway system is seen as a world of certainty and clear causal relationships. On the other hand, not all the phenomena characterising that world are, *a priori*, knowable and predictable. Thus, attention to new phenomena is needed. Consequently, standard logic represents a specific version of the anticipation approach to risk management, in which the door is open to emerging and unplanned phenomena.

Possibility logic (NIB)

Possibility logic encourages a specific method of reasoning that differs from the cost-benefit and the standard logics: abductive reasoning. The abductive method of reasoning is closely related to the definition of risk that possibility logic presents. Risk is a possibility that something could happen whether or not it actually happens. The analysis of accidents, incidents and near-misses advances reasoning that goes beyond what happened and values figuring out alternative contributing factors or alternative causal chains leading to the accident, incident or near-miss. Such reasoning is sustained by questions such as what would happen if? Could this error or technical failure happen even if? Could this error or technical failure trigger other chains of dangerous events? Could the same event within a different context lead to consequences that are more dangerous? Abductive reasoning promotes a specific point of view on reality encouraging actors to focus on interstices and emerging phenomena. Abductive reasoning shifts the focus from the main elements to the details putting the background in the foreground, looking at the content of the phenomena rather than at the formal aspects, such as compliance with existing rules and identifying gaps:

the point is to really intercept the sources of risk. If we take EU legislation on paper, most or almost all of it is already there. If we limit ourselves to that, it's all okay, it's all perfect, but a more factual vision of the problem allows us to understand that it's not working yet, in the logic some things don't work yet (NIB, interview);

The devil is in the particulars not the norm (NIB, interview);

I believe that all the analysis activity that is not related to serious accidents is substantial because sometimes it even predicts. Knowing the condition in which accidents that haven't had grave consequences have evolved, but shared a common genesis with ones which had such consequences, can lead to a condition of a forecasting evaluation of gaps in regulations, behavioural gaps, gaps … in management that in some way must be filled and so, by filling those gaps, we can … indirectly prevent more serious accidents (NIB, interview).

Such an approach leads to identification of patterns where they are commonly not seen, linking events that are also extremely different between them if we look at the main causal chain leading to the events. However, through examining the details, even extremely different events can present some continuity, giving clues to important patterns of potential danger:

then there are a series of other setbacks that can be systematically formalised. That is, even if among themselves they seem distinct, they may have a common thread which characterises an analogical form, one to the other, and if we are able to understand what the common thread that joins them is, we can also find a way to affect these event that seem distant from each other (NIB, interview).

The approach also leads to the identification of alternative plot lines and continuity that are usually not recognised. For example, two extremely different events such as a derailment and the detachment of a door from a train in motion were put together because in both the events, the suspicion that the alarm procedure was defective or inadequate arose, and a specific in-depth analysis was conducted on that element. The alarm malfunction is not linked to the main events, but represents a background detail. The association between those different events is possible only by maintaining attention to details advanced by abductive reasoning:

the train conductor declares that when he had information from the TNB personnel (food services personnel), which had heard a strange noise, he was worried and got back on the train and noticed there was no door. The train conductor tries to launch a general warning but there is no coverage. He then tries to speak to the engine driver who after a hundred metres stops [the train]. And that's already quite a distance without a door. We have to request a study on the coverage. It's something that emerges in several accidents. A similar thing emerges regarding the case of Roma Termini: there too there were some elements that suggested problems with the issue of coverage, which is necessary to launch a general warning […] So we put all safety matters on the PDA (personal digital assistant) and then it doesn't work (NIB, internal meeting).

As already mentioned, abductive reasoning promotes different interpretations of the same event, identifying alternative contributing factors or triggering scenarios. Let us take two examples: the Viareggio and the Lavino accidents.

The Viareggio accident happened in Italy in the Viareggio station on 29 July 2013. The axle breakage – the central part of the wheels set of a wagon linking the two wheels (see Figure 28) – of a freight wagon carrying LGP led to the train derailment. The derailment led to the breach of one of the LGP tanks. The breach led to an explosion in which thirty-two people died. The axle breakage was caused by a maintenance procedure that was not carried out or was ineffective. Maintenance did not reveal the fatigue crack affecting the axle that led to its breakage.

Figure 28: Viareggio accident – detached wheels-set (the white arrow indicate the axle.)[57]

Abductive reasoning encourages us not to focus on the possible human error linked to the undetected fatigue crack, but to look at the scenario in which such an error happened in order to reduce the possibility of future errors. Thus, to look at the factors that made the scene prone to the error rather than the error itself:

it seems that the main problem at Viareggio is that the operator didn't perform the technical procedure correctly. It is sustained, with reference to our recommendation, that at base in reality it was a worker's error. But if the worker made a mistake, it is probably because there were elements within the situation which maybe facilitated the error. The operator's error should be avoided by trying to change the conditions so that it can't happen again. It's not that you can say: "Yes but in the end it was a worker's error" […] if we look at things [that way] everything can be brought down to human error, but what does that have to do with anything? (NIB, interview).

The Lavino accident happened on 15 July 2012 near Bologna. To put it simply, a train that was supposed to pass through a railroad switch positioned to grant straight

[57]Font: http://pisanotizie.it/news/news_20111015_indagini_strage_viareggio.html. Website consulted on 15 April 2014.

passage, actually passed through a railroad switch positioned to grant a track change. (See Figure 29: railroad leading to the straight movement or the change of track.)

Figure 29: Example of a railroad switch[58]

The speed limit to pass through a railroad switch positioned to grant straight passage is higher than the limit for passing through a railroad switch positioned to grant a track change. Consequently, because of the speed planned for passing a straight passage railroad switch, when the train encountered a railroad switch positioned to grant a track change, it derailed. The accident did not lead to deaths or grave injuries. The cause of the railroad switch was identified as an error, which occurred during a maintenance procedure. The maintenance workers did not follow

[58]Font: http://www.clamfer.it/13_Dizionario/Immagini_K-L-M/Principale_M.htm, Website consulted the 15 April 2013.

the correct procedures determined by the infrastructure manager for the kind of maintenance procedure they conducted the day of the accident. Applying abductive reasoning during the accident analysis, a different view of the event fostering alternative scenarios emerged. More specifically, even if the crucial role of the maintenance procedure infraction was recognised, the main question became could this kind of error – incorrect positioning of the switch – happen even if the workers correctly followed the maintenance procedures provided? Thus, alternative triggering scenarios were hypothesised and investigated. This example shows one of the main characteristics of abductive reasoning: going beyond what really happened to imagine alternative scenarios that have not actually happened, but could happen.

In summary, possibility logic differs from both the cost-benefit and standard logics by promoting an alternative method of reasoning – the abductive one. Looking at the different risk management approaches identified through the study of previous theoretical contributions (see Part One, Chapter 1, Session 1.2), possibility logic demonstrates a continuity with the imaginative approach and differs from the cost-benefit and standard logics' continuity with the anticipation approach. Ontologically, the idea of facing a complex world made of complex interactions and not clear causal relationships prevails. Epistemologically, much like the anticipation approach, the idea that preventing adverse outcomes before they happen remains, but the need to adopt alternative methods constantly evolving in order to reach such ends, clearly removes the possibility logic from the anticipation approach.

The organisational component

The foci of this section are, on the one hand, the processes – means to reach the fostered ends – that the three organisations studied develop and evaluate as fitting, in order to ensure the right degree of avoiding, coping with and/or handling the possible negative outcomes related to the regulated organisations' activities. On the other hand, the organisational structure within which each organisation sustains these processes and strategies.

The examination of the processes of risk management shaping, and which shaped the three identified logics, follows the definition of risk management presented above (Part 1, Chapter 1, Section 1.2). More specifically, risk management is defined here as a process that:

- Aims to avoid, cope with and/or handle possible negative events;

- Is informed by informational input – e.g., data, sensations, impressions, perceptions and clues – about the on-going activities/phenomena that could be related to possible negative events;
- Results in tangible outputs – e.g., decisions, control measures, actions, laws, documents;
- Is evaluated as fitting in order to ensure the (perceived/fixed as) right degree of avoiding, coping with and/or handling possible negative events;
- Is hindered or favoured by the characteristics of the organisation in which the process is developed.

As already mentioned, in our case risk management processes are inter-organisational processes that can be direct – developed within the regulating organisation, which targets the activities of the regulated organisations as informational input, and provides them with tangibles outcomes – or indirect – promoted by regulators as the right way of managing risk, that regulated organisations should implement. The balance the three logics present between indirect and direct risk management, as well as the content of such processes, are crucial elements in order to understand the actual practical translation given by the three logics of the risk-based approach to regulation. The analysis of such balance, as well as of the contents of risk management processes allows for a better understanding of the balance that the three logics foster between the risk-based and the control-command approach to regulation. (See Part 1, Chapter 1, Section 1.3.)

More specifically, a balance in favour of indirect risk management can be seen as a close practical translation of the risk-based approach promoted at the politico-economic level. In contrast, a balance in favour of direct risk management can be seen as a detachment from risk-based logic. Looking at the content of direct risk management, a focus on the tangible outcomes provided by the three organisations allows for a better understanding of the actual extent of the regulatory intervention within risk decisions. For example, defining detailed rules can be seen as a separation from the risk-based approach in favour of the control-command one, showing an overlapping of the two approaches in the practical translation of risk-based logic given by the three organisations in their everyday activities. In addition, in describing the risk management process, attention is paid to the steps in which the methods of reasoning fostering and fostered by the three logics filter in or out the informational input, selecting the issues on which to concentrate the regulatory activities.

An analysis of the organisational structure allows us to put together ends and processes in looking at whether the organisational structures sustain the processes and strategies developed, and the ends identified by the organisations studied. An examination of the organisational structures shaping and shaped by the three logics allows the last point of the given definition of risk management to be in-depth. Thus, we can understand whether the developed risk management processes are hindered or favoured by the characteristics of the organisations in which these processes are developed. Let us look closely at the risk management processes and the organisational structure shaping and shaped by the three identified logics: cost-benefit, standard and possibility logics.

Means: Process and strategies in order to reach the ends

This section is structured as follows: for each logic, we present the direct and indirect risk management processes considering the balance offered by the logic under scrutiny between the two strategies.

Cost-benefit logic (ERA)

Cost-benefit logic presents a mixture of direct and indirect risk management with a prevalence of the indirect one over the direct one. Let us closely examine the direct and indirect risk management processes developed by the ERA, and fostering and fostered by the cost-benefit logic.

Direct risk management

Cost-benefit logic promotes two main processes of direct risk management: assessment of the safety performance of EU nation-states; and the definition and development of the European railway legislative framework. A description of the informational inputs, the main steps and the tangible outcomes forming the two processes follows.

Assessment of the Member States' safety performance

- Informational input

The informational input of the Member States assessment process are the CSIs (Common Safety Indicators) and the accident statistics collected by Eurostat (Statistical Office of the European Union). As already mentioned, the Common Safety Indicators include accidents, incidents and near-misses collected from all the railway undertaking and infrastructure managers across Europe. The Common Safety

Indicators are established through Directive 2004/49[59] and are collected by the NSA from the regulated organisations. The NSA reports such data to the ERA annually – by September of the following year with respect to the years of data collection – through the introduction of the collected information into a shared database. The other source constituting the informational input of the assessment process is the data collected by Eurostat in each Member State. Regulation 93/2001 specifies the indicators that should be collected by Eurostat. Annex H of Regulation 93/2001, which specifies the data that should be collected annually by Eurostat is illustrated in Figure 30. The two sources of information allow a double check of the accuracy of the data used for assessment to be guaranteed.

[59]See the section dedicated to the cognitive component for further details on the collected indicators.

ANNEX H

STATISTICS ON ACCIDENTS

List of variables and units of measurement	— Number of accidents (Tables H1, H2) — Number of persons killed (Table H3) — Number of persons seriously injured (Table H4)
Reference period	Year
Frequency	Every year
List of tables with the breakdown for each table	Table H1: number of accidents, by type of accident Table H2: number of accidents involving the transport of dangerous goods Table H3: number of persons killed, by type of accident and by category of person Table H4: number of persons seriously injured, by type of accident and by category of person
Deadline for transmission of data	Five months after end of reference period
First reference period	2004
Note	1. Type of accident is broken down as follows: — collisions (excluding level-crossing accidents) — derailments — accidents involving level-crossings — accidents to persons caused by rolling stock in motion — fires in rolling stock — others — total. The type of accident refers to the primary accident. 2. Table H2 has the following breakdown: — total number of accidents involving at least one railway vehicle transporting dangerous goods, as defined by the list of goods covered by Annex K — number of such accidents in which dangerous goods are released. 3. Category of person is broken down as follows: — passengers — employees (including contractors) — others — total. 4. The data in Tables H1-H4 shall be provided for all railways covered by this Regulation. 5. During the first five years of application of this Regulation, Member States may report these statistics according to national definitions, if data conforming to harmonized definitions (adopted according to the procedure of Article 11 paragraph 2) are not available.

Figure 30: Safety indicators collected by Eurostat in each Member State (Regulation 93/2001, Annex H, p. 12)

- Process

The assessment of the annual performances of the Member States consists of a comparison between the performance of the year under assessment and the National Reference Value (NRV). Let us look closely at the way in which these two compared values are calculated.

The value of the year under assessment is calculated computing 1 for each death and 0,1 for each injury. The value is calculated for different categories of people potentially involved in incidents or accidents: passengers, employees, level crossing users, others, unauthorised persons on railway premises and society as a whole. The value is weighted by train-km or passengers per train-km according to the kind of transport: freight or passenger.

The National Reference Value is calculated for each Member State considering the average of the six years before the year under examination. Thus, if we are looking at the year 2011, the years considered for the calculation would be from 2004 to 2010. The calculation of the value of each year considered for determining the NRV follows the one of the year under assessment specified previously. Figure 31 details the NRV calculation process. The process is defined as moving weighted averaging. Moving refers to the consideration of the six years before the year under assessment (point A in Figure 31). Weighted refers to the weight of the observed values of each considered year with the average of all the considered years (points B and C in Figure 31). Averaging refers to the calculation of the average of the weighted six years considered (points D and E in Figure 31). A list of the NRVs of each Member State is compiled by the ERA and formalised by a Commission Decision.

2.3. *Weighted averaging process for the calculation of NRVs*

2.3.1. For each Member State and for each of the risk categories to which the weighted averaging can be applied according to point 2.1.1(c), the following steps shall be applied for calculating, during year Y (where Y = 2009 and 2011), the NRV_Y:

(a) calculation of the annual observations OBS_i (where i is the considered year of observation) returned by the corresponding measurement units listed in Appendix 1, after providing as input the data for the most recent reported n years as referred to in point 2.1.1(a) [initially $n = 4$; from 2011 onwards $n = 6$];

(b) calculation of the arithmetic n-year average (AV) of annual observations OBS_i;

(c) calculation of the absolute value of the difference $ABSDIFF_i$ between each annual observation OBS_i and the AV. If $ABSDIFF_i < 0{,}01 * AV$, to $ABSDIFF_i$ is attributed a constant value equal to $0{,}01 * AV$;

(d) calculation of the weight (W_i) for each single year i, by taking the inverse of $ABSDIFF_i$;

(e) calculation of the NRV_Y in the form of weighted average, as follows:

$$NRV_Y = \frac{\sum_{i=x}^{N} W_i \times OBS_i}{\sum_{i=x}^{N} W_i};$$

where i is a natural number and $\begin{cases} \text{if } Y = 2009\text{: } x = Y - 5;\ N = Y - 2 \\ \text{if } Y = 2011\text{: } x = Y - 7;\ N = Y - 2 \end{cases}$

Figure 31: Method for calculating the NRV (Commission Decision of 5 June 2009 on the adoption of a common safety method for assessment of achievement of safety targets, as referred to in Article 6 of Directive 2004/49/EC of the European Parliament and of the Council, p. L 150/15)

The NRVs represent the level of safety that each Member State and the EU railway network as a whole should achieve each year and is part of the Common Safety Targets determined at the EU level as a common objective to reach by the European railway network as a whole:

Common Safety Targets are presented in the Safety Directive as the safety levels that must at least be achieved by different parts of the railway system in relation to different groups of individuals that are using the railways or being exposed to risks arising from railway traffic indirectly. The Common Safety Targets must ensure that safety performance does not decrease in any of the Member States, which is why the Agency has set up a scheme to target and evaluate both the national performances, through the use of National Reference Values (NRV), as well as that of the EU as a whole through the CST (ERA, Website).[60]

The Common Safety Target is the average of the NRVs calculated at the national level, and represents the NRV valid for all of Europe. The way in which such national and European targets are calculated is in line with the end fostered by the cost-benefit logic of maintaining at least the same level of safety, given the important changes affecting the railway network – liberalisation, common EU market and development of the railway sector. The targets do not fix an improvement of the safety level, but aim to check the maintenance of the same safety level reached during the six years before the year under assessment. The purpose of the assessment process is to ensure that the safety level is not deteriorating across Europe, and not to promote an improvement of that level:

the purpose of the 1st set of CSTs is to ensure that the safety performance of the railway system is not reduced in any Member State. This purpose shall be pursued by harmonising the way in which safety levels for the whole national railway system are expressed in terms of risk acceptance criteria and how compliance with them is monitored in the different Member States (ERA, Recommendation on the Common Safety Methods for calculation, assessment and enforcement to be used in the framework of the 1st set of Common Safety Targets, 29 April 2008, p. 3);

'national reference value' (NRV) means a reference measure indicating, for the concerned Member State, the maximum tolerable level for a railway risk category (ERA, Recommendation on the Common Safety Methods for calculation, assessment and

[60] http://www.era.europa.eu/Core-Activities/Safety/Safety-Performance/Pages/Common-Safety-Targets.aspx, Website consulted 24 March 2014.

enforcement to be used in the framework of the 1st set of Common Safety Targets, 29 April 2008, p. 4).

Thus, the targets fix levels of tolerability/acceptability of the negative consequences of accidents and incidents. Such tolerability/acceptability levels defined as ‘the maximum tolerable level’ are actually a weighted picture of the current safety performance. The tolerability/acceptability is fixed in the performance actually reached during the six years preceding the year under assessment.

Once the NRV and the observed performance of the year under assessment are calculated, the assessment follows the process summarised in Figure 32.

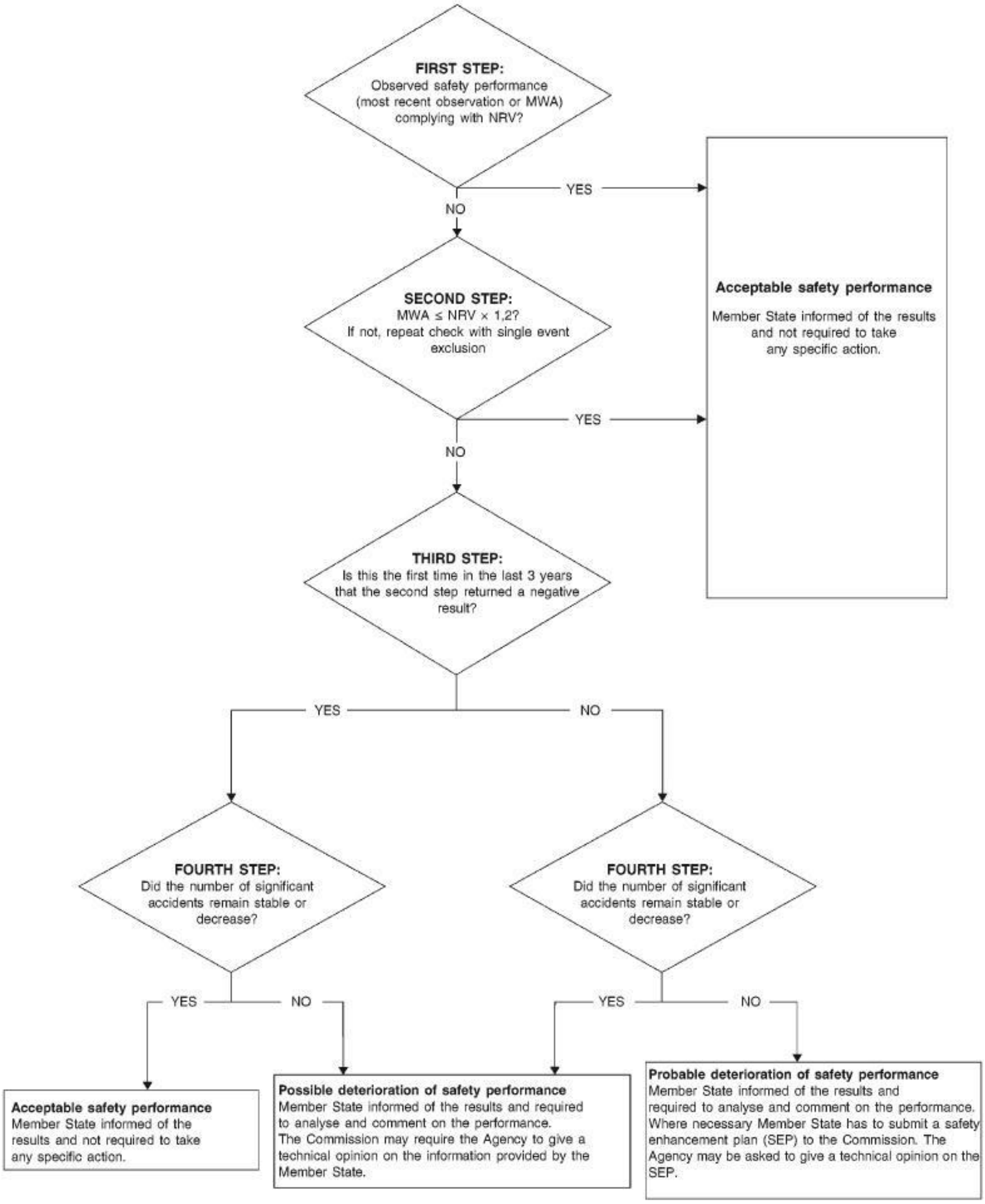

Figure 32: National Safety Performance Assessment Process (ERA, 2013, Assessment of Achievement of Common Safety Targets, Figure 1: Decision flowchart for the assessment procedure of CSTs, p.8)

The first step of the process is the comparison between the observed value and the NRVs. If the observed value is higher than the NRV, instead of using the observed value the comparison is made using the Moving Weighed Average that is calculated as the NRV, but considering the year under assessment in the computation. The following assessment steps redefine the acceptable safety performances introducing other elements of tolerability. Consequently, a performance that is worse than the one fixed by the NRV is actually accepted. Let us look closely to the next steps of the assessment process:

- Step 2: if the observed value of the year under assessment or the Moving Weighted Average are not equal to or less than the NRV, the target to meet can be reduced by 20% and the check repeated. Consequently, a 20% deterioration of the safety level is considered acceptable. This step is in contrast with the objective of maintaining at least the current level of safety. Such a mismatch between the fixed objective and the assessment process is recognised and underlined:

  > In practise it allows you to deteriorate over years, but will not be detected because it allows 20% every year so you can increase every year. This is a weakness (ERA, interview).

  Currently, a working party organised by the ERA and composed of experts from the sector and from the NSAs is working on a revision of the assessment process. The possibility of progressive safety deterioration in contrast with the objective of maintaining at least the same level of safety is underlined as an issue that should be solved in the redefinition of the regulation describing the assessment process. (See Figure 33.)

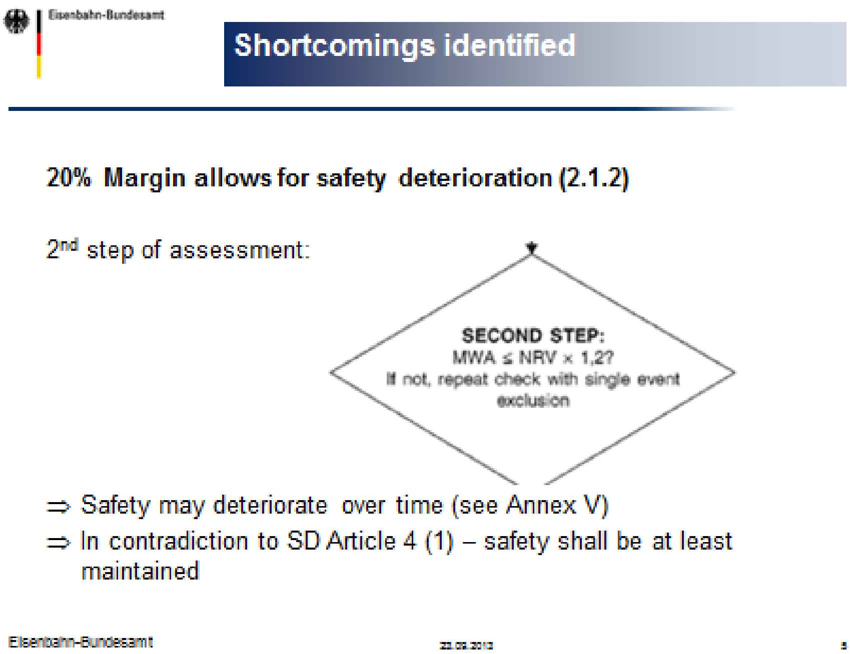

Figure 33: Second step of the national safety performance allowing a safety deterioration of the 20% (ERA slide, Results of TF on CSM for CST, Working Parties Meeting, Lille, 1 October 2013)

If after the 20% increase in tolerability, the Member State does not pass the assessment, the check is repeated 'with single event exclusion.' The 'single event exclusion' means that if during the year under assessment a single accident with more severe consequences than the most severe single accident included in the data used for setting the NRV happened, this accident is excluded from the statistics and the assessment process is repeated. If, after such an exclusion, the observed value of the year under assessment or the moving weighted average is equal to or less than the NRV, given a tolerability of 20%, the country passes the assessment. The exclusion of the most severe accident is in line with the cost-benefit logic assumptions, as we already mentioned describing the methods of reasoning shaping and shaped by cost-benefit logic, a focus on single events is discouraged. The target is not zero accidents, and the one-off event is seen more as an unavoidable effect of every human activity, rather than as a specific negative outcome linked to the characteristics of the system in which it happened. The single accident is framed as closest to the concept of fate or chance rather than of risk: the accident at least for its consequences is a random event.

Consequently, the severity of the accident is not considered as an essential element in order to monitor and calculate the safety level reached by a Member State, but it is classified as a random average fluctuation:

> this is the philosophy used until now, we use this top down approach. You want to ensure that safety from the public opinion point of view is being maintained and the end is that you want be able to say to the public listen even with this huge crash now in Santiago we still have the safety system [that] is safe and it is not deteriorating and this is enough for politicians because the focus is not on safety, but on interoperability (ERA, interview);

> because we assume that an accident can be somehow random it can occur it can happened today the next one can occur tomorrow, but it can also be in twenty years or maybe never, so this is why [we] say ok, we disregard with this high consequence accidents […] it is by chance that it happened this year, so statistically it is right to recognise that it is random that it happened this year it is subject to variation, so in the method we acknowledge that […] we don't want to make big conclusion on a single event […] (ERA, interview).

The process filters out the informational input that, following the cost-benefit logic's assumptions, is not relevant for the assessment process.

- Steps 3 and 4: if it is the first year in the last three years that the Member State does not pass the second step, two options are possible: if the number of accidents remains stable or decreases the assessment passes; if not, the assessment ends with the statement of a possible deterioration of the safety level. If it is not the first time in the last three years that the Member State does not pass the second step of the assessment two options are possible. On the one hand, if the number of accidents remains stable or decreases, the assessment ends with the statement of a possible deterioration of the safety level. On the other hand, if the number of accidents increases, the assessment ends with the statement of a probable deterioration of the safety level. Consideration of the number of accidents is related to the focus cost-benefit logic poses on the event rather than on the consequences of this event. The consequences of an event in and of themselves are seen as closer to a random result rather than as an indicator of a deterioration of the safety level:

> I prefer to do this assessment on the number of accidents instead of the number of victims because this could be really variable, you can even get one or few, but it can happen one time that you have one hundred […] For example, if we look at the

number of accidents the number of fatalities can increase, but safety is actually improved because the number of accident is decreasing (ERA, interview).

- Tangible outcomes

The tangible outcome of the assessment process in the case of negative results is the opening of a confrontation between the Commission and the Member State in order to agree, if needed, upon measures aiming to improve the safety level of the nation-state. As part of the process, the Member State should send explanations of the possible reasons for such a deterioration of the safety level to the Commission. In addition, if the assessment ends with the statement of a 'probable deterioration of the safety level' the different parties should agree on a recovery plan in order to improve the safety level. The Commission can ask the opinion of the ERA on the explanation, as well as on the recovery plans presented by the Member State. The current regulations do not give specific time limits to the process, do not precisely identify the content the explanatory document should have, and there is no formal sanction system to put in place in case the Member State does not participate in the discussion process, or does not implement the agreed measures:

Member States that do not comply with NRV and CSTs should not immediately be subjected to an infringement procedure, but this should be preceded by a dialogue with the Commission, aiming at agreeing on means to improve safety performance (ERA, Recommendation on the Common Safety Methods for calculation, assessment and enforcement to be used in the framework of the 1st set of Common Safety Targets, 29 April 2008, p. 2);

According to the different final results of the assessment of achievement procedure, referred to in Article 10, paragraph 4, the Commission may take enforcement actions as detailed below:

(a) "Possible deterioration of safety performance": require the concerned Member State/s to provide a written statement explaining the likely causes of the results obtained.

(b) "Probable deterioration of safety performance": require the concerned Member State/s to provide a written statement explaining the likely causes of the results obtained and to submit, where needed, a safety enhancement plan.

The Commission may ask the Agency to provide technical opinions for evaluating any information and evidence provided by the Member States according to (a) and (b) (ERA, Recommendation on the Common Safety Methods for calculation, assessment and enforcement to be used in the framework of the 1st set of Common Safety Targets, 29 April 2008, p. 8).

Looking at the different steps of the process, as well as at the informational input on which the process is based, allows the different phases in which the methods of reasoning promoted by the cost-benefit logic are formalised to be identified. More specifically, through the assessment process, the deductive and inductive methods of reasoning filter in/out events. In so doing, the process focuses the attention on certain types of events, sending other types of events to the background. Looking at the informational input, the deductive method of reasoning shapes the indicators chosen as informational input of the process. The CTIs as well as the accident statistics collected by Eurostat define specific types of events, *a priori*, that are considered relevant. The collected indicators refer to predefined categories of incidents and accidents that, given the available theory functioning on the railway network, are defined as relevant in order to monitor the safety performance of the network. Looking at the steps' process, inductive reasoning filters the events considered relevant in order to assess the safety performance. More specifically, the second, third and fourth steps of the assessment process are filters through which the informational inputs are selected. Those steps filter out the informational input that is classified as less relevant following the inductive method of reasoning promoted by the cost-benefit logic. The second step – single event exclusion – and the third and fourth steps – evaluation of the number of accidents – shows how the one-off events are not considered as particularly relevant. This is in line with the focus of attention promoted by the cost-benefit logic on phenomena that have a certain frequency; being that one-off accidents and the consequences of those accidents are classified as random and in some respects unavoidable events.

Given the progressive process reduction of the number of relevant events considered for the assessment, it is *de facto* highly improbable that a country fails the assessment. The entire process is framed more as a way of showing the maintenance of the safety level to public opinion rather than a way to check, monitor and solve possible safety level deterioration:

> they introduce so many securing steps that no one can fail, no one is failing […] it is a kind of protection also with public opinion […] For example after what happened in Spain […] we can say giving the assessment we cannot say that the level of safety is deteriorating (ERA, interview).

Consequently, the assessment process is structured as a direct risk management process, but in some respects detaches itself from a direct risk management strategy. More specifically, unlike the proposed definition of risk management, the aim of the process is not, or not only to avoid, cope with and/or handle possible negative events. The assessment process mainly aims to demonstrate the maintenance of a high safety level to public opinion. In so doing, the accountability of railway sector regulation to public opinion results as the main objective of the process, rather than the safety of the railway network. This element shows the proximity of the risk management approach promoting and promoted by the cost-benefit logic to the auditability-accountability approach to risk management. (See Part 1, Chapter 1, Section 1.2.)

Definition and development of the legislative framework

- Informational input

The process of definition and development of the legislative framework starts with a formal mandate on a specific issue given to the ERA by the Commission. Formally, the starting point of the process can be exclusively a formal Commission input. The ERA can intervene only in the presence of such a formal mandate. Nevertheless, it is *de facto* a two-way relationship in which the ERA can informally suggest the need to work on a specific issue to the Commission:

> I think there are two ways of seeing it, for sure the Agency's work is control, we work on mandates and work programmes or on request from the Commission for opinions or advice […] There is also, I think, the possibility for us to identify particular concerns or issues we think need to be addressed and approaching the Commission to say we think this is an issue. That is less, that has been less common and probably not so well described in the legislation or the process that we use […] but it is possible informally to say I mean we have good contacts we can always say to somebody I think this is a concern […] There are occasions in which we can raise issues and they can agree or disagree. This is at least the beginning of a process […] informally, informally in the sense that I can approach a Member of the Commission and say we are concerned about that subject, but to legally look at it we have to be asked for an opinion, then they can ask us formally and we can do the work (ERA, interview).

The need for opening a working party is identified by the ERA through its own analysis of the trends affecting the railway network, as well as from the requests coming from the sector, the NSAs, and the NIBs. It is important to underline that this is an informal process; the ERA doesn't have a formal mandate representing the sector's, NSAs', or NIBs' points of view to the Commission. The different parties are encouraged by the ERA to follow the formal process of informing the representatives of the nation-states at the Commission in order to highlight issues that should be addressed at the EU level. Nevertheless, the two-way relationship informally exists. The issues suggested by the ERA to the Commission are the product of an informal filtering process in which the relevance of the different issues is established. The criteria through which the issues are filtered by their relevance follow the methods of reasoning promoted by the cost-benefit logic. On the one hand, an issue in order to be classified as relevant should be sustained by evidence, have a certain frequency, and not to be a one-off phenomenon. On the other hand, it should prove to be relevant for the entire railway network; thus, not be linked to the specificities of the nation-state suggesting it, or to a problem related to a specific actor of the railway network.

- Process

Once the Commission formally gives a mandate to the ERA on a specific issue, additional data on the matter under examination is usually collected by:

- Commissioning studies to an external provider and;
- Collecting *ad hoc* information directly, distributing questionnaires to the NSAs, NIBs, and/or the sector depending on the matter under examination.

This is in line with the aim of being evidence based and giving technical opinions based on facts, frequencies and numbers. In parallel, or once the needed data is collected, a working group that has to deal with the matter under examination is set up. The working parties are coordinated by the ERA and experts on the phenomena under examination come from the sector and the NSAs are selected. The NIBs have a specific working group, but usually do not participate in the working group with the sector and the NSAs. This is related to the independent position NIBs aim to maintain: they have to investigate on the appropriateness of the legislative framework as well, thus to participate in working groups dealing with legislative framework definition and development is seen as a threat to their independence. The involvement of the railway sector in the definition and development of legislation is one of the key roles of the ERA. (See Figure 34.)

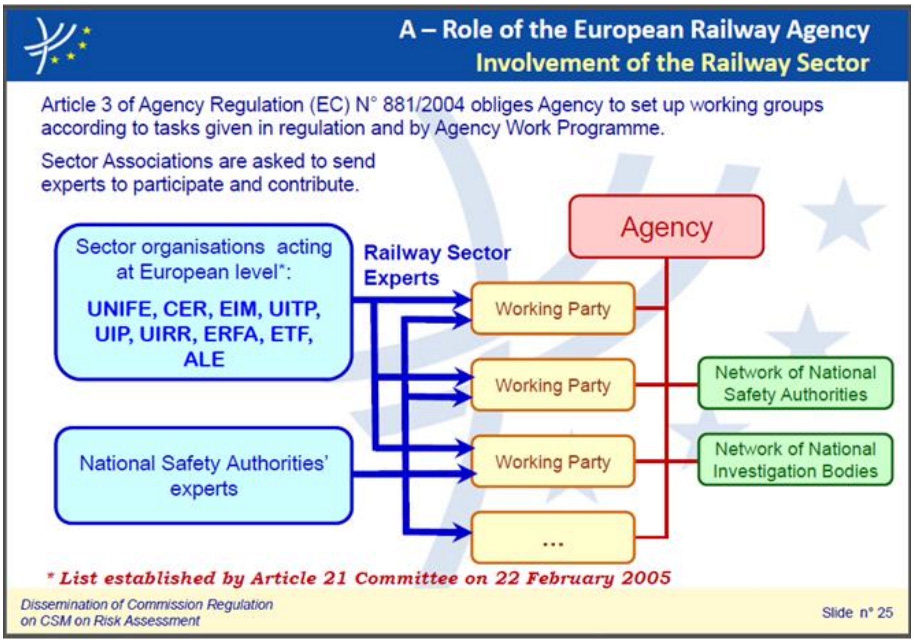

Figure 34: Networking activity as a key role of the ERA (ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 25)

Discussing and sharing any decisions with all the parties involved in railway transport is considered extremely relevant. The co-partnership of the sector in the definition and development of the legislative framework is a key strategy promoted by the risk-based as well as the cost-benefit logic. The risk-based and cost-benefit logics do not frame the regulation as state intervention that limits the free business decisions in order to avoid, cope with, and/or handle the possible side-effects of the business activity. On the contrary, regulation is framed as a co-partnership between state and business representatives in order to reach the development of the railway sector, while maintaining at least the same level of safety.

Once the working group is set up, the formal role of the ERA is simply to coordinate and organise the working group activities. For example, organising the working group meetings; managing the number of meetings according to the deadlines given by the Commission, as well as the available resources; collecting opinions from the involved parties; and providing and sharing information about the items discussed during the meeting. Informally, the role of the ERA is more complex. The ERA role is more about trying to bind together the various views expressed by the different parties involved, on a common-position sector and national public agencies, rather than simply organise and coordinate the working activities. Such a common position should not conflict with the assumptions and principles fostering and fostered by the risk-based logic expressed at the politico-economic level. Mainly, it should not: alter the market functioning; use the safety argument as a barrier for market access; or limit the interoperability of the European railway network. The items discussed during the meetings, as well as the final position expressed by the ERA to the Commission, are informally filtered as well. More specifically, the main principles shaping such a filtering process fostering and fostered by the cost-benefit logic are: ‘be evidence based’ and ‘be systematic.’ Thus, a working group is encouraged to work on a phenomena/issue if the phenomena/issue is seen as relevant: if it has a certain frequency, and if it is proved to affect the railway sector as a whole (more than one company, as well as more than one country). Consequently, the cost-benefit logic prevalent among the ERA discourages the opening of a closer examination in the case of a one-off event, or the discussion of issues that are not supported by strong, available and provable evidence.

Once the different positions are discussed and examined through the activity of a working group, a crucial step in the process leading to the formal opinion, given by the ERA to the Commission, is the cost-benefit analysis. The recommendation the ERA gives to the Commission is supported by that analysis. It considers the cost linked to the adoption of new legislation or a modification of the available one. For example, the cost-benefit analysis examines the cost linked to the adoption of an additional control measure meant to reduce the magnitude or the frequency of a dangerous event. This happens in order to decide if this measure should be settled through formal legislation and become mandatory or not. The cost-benefit analysis compares the cost for the adoption of the control measures with the quantification of deaths, injuries and economic damage linked to the event that the measure is meant to prevent.

Another example refers to the comparison between different types of control measures in order to identify the one that has less economic impact. The reference of such an analysis is mainly the cost that a modification of the available legislation has for the sector, and the cost linked with additional work performed by public agencies. The possible willingness to pay, thus, to cover additional cost collectively by citizens, and thereby obtaining a reduction of the possible dangerous consequences of the on-going private activity, is not considered. This step of the process is seen as a crucial aspect of the recommendation. On the one hand, it helps the Commission to decide whether or not to develop new legislation, or to modify the existing one. On the other hand, it is an instrument allowing a correct balance between the safety objective and the liberalisation, interoperability, business development and free market access ones:

we give that to help them decide […] it is to help them arrive at the decision. May be the cost when you introduce a new safety insurance change in any way or whenever you change something in any company the initial feeling of that is that you have another cost and it may be not just a feeling it is a reality. When you get used to that systematic way of managing your activity quality, safety regardless of what it is then you have this increase, this initial increase of cost, but after that we have such method and principles. This is what we get from the economic impact assessment, cost-benefit analysis is that the benefits are going to be higher than the cost of that (ERA, interview);

if I am regulating a sector and I have to write a rule for the sector, I have to worry that the rule is economically sustainable and applicable because if I destroy competition and only leave the ex-state companies alive I have failed […] We can go back to the old system in which I didn't exist (ERA, interview);

the cost-benefit analysis can be used to find the right balance between saving lives and preserving the competitiveness of an economical sector (ERA, Workshop on Risk Evaluation and Assessment in the context of Inland Transport of Dangerous Goods 8-9 October 2013, Background discussion document, p. 2).

More in general, the cost-benefit logic encourages regulators to consider the economic impact of any decisions they made on the sector. The available resources are by definition limited and finite; thus, the regulators, as well as the regulated organisations, should choose where to intervene prioritising their interventions according to available resources and the frequency and magnitude of the risks. Regulators should keep in mind that the sector has finite resources in order to stay in business, thus they should not ask to adopt additional control measures within the sector if they are not economically sustainable. The relevance of the cost-benefit analysis is expressly linked with the statement that 'zero risk' is a non-pursuable objective. The limited resources impose a prioritisation among the possible dangerous events, choosing the ones to face and the ones to accept without adopting specific control measures. Following the cost-benefit logic, the cost-benefit analysis is the recognised instrument in order to address this choice:

Another parameter affecting the manner decisions are taken is the explicit or implicit integration of the economical parameter. It is also linked to philosophical and cultural beliefs. For example, the "zero risk" target is generally linked with the consideration that the human life is sacred and that it must be preserved at any costs. However this strategy finds

its implementation limits because in reality the implementation of new or improved safety measures has a cost, which needs to be compatible with a finite budget.
Therefore, far from philosophical and cultural beliefs, a pragmatic reasoning would suggest that the use of a finite (by definition) budget should be allocated to the implementation of safety improvements, which will have the maximum achievable effect on the limitation of human impacts. This pragmatic approach corresponds in principle to the objectives pursued by cost-benefit analyses to support decisions, including in the field of human risks management, as the objective is to target the safety investments where they will maximise the reduction of human risks. It is also the role of the impact assessments in the context of the better regulation policy to support regulatory developments, which are cost-effective, based on facts and provides a globally positive impact on the society development. Nevertheless it should be noted that "risk-based decision-making", even assorted with a cost-benefit analysis is not equivalent to "decision-making", and many parameters can influence decisions related to risks, including social and political influences which can potentially be in contradiction with the continuous and global objective of saving lives (ERA, Workshop on Risk Evaluation and Assessment in the context of Inland Transport of Dangerous Goods 8-9 October 2013 Background discussion document, p. 4-5).

As for the Member State assessment process, the legislative framework definition and modification process presents some filtering steps in which the assumption and principles of the cost-benefit and risk-based logics filter the issues and phenomena on which to focus attention in or out. More specifically, three main filtering steps are identifiable:

- Informal relations with the Commission in which issues and phenomena on which open working groups are highlighted;
- Working group management in order to create a common opinion fitting with the principles and assumptions fostering and fostered by the risk-based and cost-benefit logic;
- Cost-benefit analysis constituting the recognised way of making decisions in case of conflicting ends.

- Tangible outcomes

The tangible outcomes of the legislative framework definition and modification process can be new legislation, but also the choice not to modify or add new pieces of legislation, or the development of non-mandatory guidelines or explanatory documents. The tangible outcomes sustained by the cost-benefit logic are based on formal legislation as little as possible. When a modification of the available legislative framework, or the definition of new pieces of legislation are made, the aim is to focus the attention on ‘what to do’, instead of specifying ‘how to do it.’ As the sector is responsible for the safe functioning of the railway system, the regulators should not provide detailed standards or rules, but limit their intervention defining processes the sector should follow in order to manage their risk, or setting expected outcomes the sector should guarantee. The way in which to develop such processes or to meet such outcomes is a decision the sector should make. Regulators should not impose a specific solution to railway undertaking and infrastructure managers, but leave them the possibility to choose the solution that fits better with their own business objectives and organisation:

> here the sector is normally waiting for things that we can’t give it. They would like to see something already ready. We can’t do that for two reasons. The first is that we are not capable […] because you can’t plan something that is good for everyone. So the problem that we have is that when we try to provide concrete examples people copy them […] When you start to propose something that is standardised, they apply it and they do it blindly […] so we try to avoid that (ERA, interview).

In general, the identification of a specific technical solution is avoided, even if the economic impact of such a solution is positive. Let us look at the example of the results of the cost-benefit analysis carried out in order to evaluate the economic sustainability of the Derailment Detection Device. The Derailment Detection Device is a technological device that detects a derailment – a train that loses contact with the tracks. When it is happening, it stops the train limiting the consequences of the derailment. A cost-benefit analysis shows that the adoption of the technological device can have a positive economic impact for the sector as the estimated benefit of adopting the device is mainly related to the economic losses the derailment would cause to the sector. The recommendation following the cost-benefit analysis was to leave the decision to the sector and not make the device mandatory. Another example showing the aim to avoid the constraints of specific legislative requirements is the tangible outcome of the process dedicated to the visual inspection of axles (see Figure 28) in order to intercept whether an axle is in bad condition before fatigue breaks it.

The output of the working group was a guideline on the way in which the visual inspection should be done, in order to guarantee the interception of a possible deterioration of the axle surface that could lead to its possible breakage. Nevertheless, the choice was not to translate such guidelines into formal legislation, thus not to impose adoption of such procedures of visual inspection on the sector, but leave the freedom to decide whether or not to follow the guidelines to the sector. The main principle is to avoid binding and detailed regulation, and to leave the possibility to choose their own solutions to the sector.

Indirect risk management process

Looking at the indirect risk management process, we focus on the processes that regulators promote and enforce as the correct way of managing the risks that regulated organisations should put into practise. Cost-benefit logic identifies the indirect risk management processes as the main strategy in order to reach the end of maintaining a stable level of safety. Indirect risk management is clearly distinguished from direct risk management by the cost-benefit logic through the already mentioned distinction between regulating the 'what' and regulating the 'how'. (See Figure 35.)

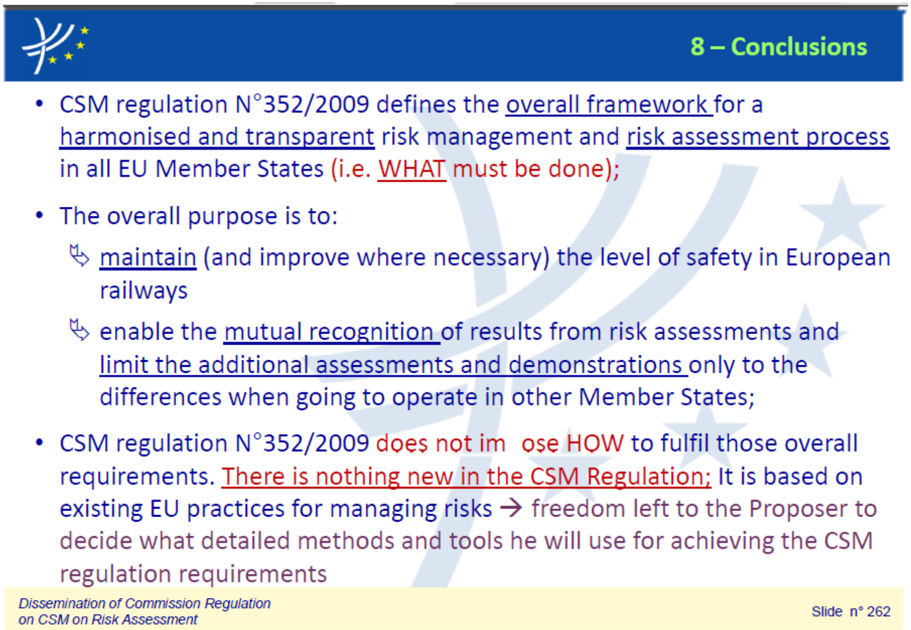

Figure 35: Cost-benefit logic – what, but not how indirect risk management strategy:(ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 262)

The role of regulators is to define the 'what': what the sector should do in order to ensure that the right degree of safety is guaranteed. Thus regulators should define and enforce the processes and the principles the regulated organisation should follow in order to manage the possible side-effects of their activities. Even though regulators should not define the 'how': how to put into practise such processes and principles are the responsibility of the regulated organisations and part of their free business decisions. Thus, the cost-benefit logic stresses a focus on defining the processes – 'what' – rather than on fixing binding and detailed rules – 'how'. Once a risk management process to follow is established, regulated organisations should develop their own way of putting such processes in practise, establishing their own risk acceptability criteria and, in so doing, taking responsibility of their decision as part of their own business risk: "they are managing their cost, they are managing their safety" (ERA, interview). As the responsibility of risk decisions is placed entirely on the sector, indirect risk management processes become the main strategy regulators pursue, in order to ensure that the side-effects of the regulated area of human activity are avoided, coped with, and/or handled. The role of regulators is to define and enforce a common framework of reference that the regulated organisations have to fill with content:

The Agency gives a definition of framework, we don't say how, we write a legislation about what [they] should do, but we don't say how to do it (ERA, informal talk);

Systematic means you have procedures, you have a process and they are well described and you are applying them. This is it, I don't need the European legislation to tell them what should be the template for hazard identification, one template can be good for a company and another one for another […]we never prescribe an approach […] What we are doing is to define what has to be done and we refrain from saying how to do this because if we go into the how this means cost for everybody […] This is the approach we are having we are trying not to go into the how, in the CSM (Common Safety Methods) for risk assessment you have particular steps […] but we don't tell them you must use a matrix or FMEA[61] or whatever. We don't say this and we don't say this on purpose, so we refrain from doing such things and the idea is that the company should be able to do such things and when the company is mature enough […] they are able not only to use the matrix coming from the standard, to take a matrix blindly from the standard and then apply it […] This is then what is expected to happen in the next years […]they are supposed to know the tools and decide which one is better in which situation and to adapt the tools […] The problem when you have pre-defined the how is that people take this (risk matrix) use this [and] it is not adapted to their needs. They don't understand this they are not trying to understand this they are not trying to have competences to adapt and so on and so on […] If you have things pre-defined if it is for a newcomers, one that has never used this before it is very dangerous. And if it is not a newcomer and you pre-define and it does not fit with what they are doing, it is just stupid for them to adopt it (ERA, interview).

[61] Failure Mode and Effects Analysis, is a methodology for failure analysis.

The risk management process the cost-benefit logic promotes and enforces toward the regulated organisations is part of a more general frame of reference: the Safety Management System (SMS). The SMS collects and records through *ad hoc* written documents, all the processes and organisational structures that railway undertaking and infrastructure managers should develop in order to obtain Part A of the Safety Certificate/Authorisation. The Safety Certificate/Authorisation allows railway undertakings and infrastructure managers to operate on the European railway network. The SMS is the cornerstone of the risk-based approach to risk regulation: the development of such a system is considered a guarantee that regulated organisations are operating safely on the European railway network. Safety Directive 2004/49 defines the SMS as: 'the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations' (Directive 2004/49, Article 3). Annex 3 of Safety Directive 2004/49 gives some specifications on the basic elements the SMS developed by railway undertaking and infrastructure managers should contain:

The basic elements of the safety management system are:

(a) a safety policy approved by the organisation's chief executive and communicated to all staff;

(b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;

(c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions […];

(d) procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations;

(e) provision of programmes for training of staff and systems to ensure that the staff's competence is maintained and tasks carried out accordingly;

(f) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;

(g) procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;

(h) procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;

(i) provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;

(j) provisions for recurrent internal auditing of the safety management system (Document, Safety Directive 2004/49, Annex 3).

In brief, the SMS constitutes the collection of:

- All the processes developed by the regulated organisations in order to safely perform their activities;
- The organisational structures in which such processes are developed;
- The roles, responsibilities and skills needed in developing such processes;
- And, more in general, a safety policy stating the general principles and commitments the company intends to follow in order to reach the desired level of safety:

The safety management system must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured (Directive 2004/49, Annex 3).

Figure 36 shows a graphic representation of all the elements an SMS should contain – the SMS wheel. The SMS wheel's aim is to offer support to railway undertaking and infrastructure managers in developing their own SMS. The black triangle highlights the sections of the wheel, in which the process of risk management promoted and enforced by the cost-benefit logic that the regulated organisation should translate into practise, is described in detail.

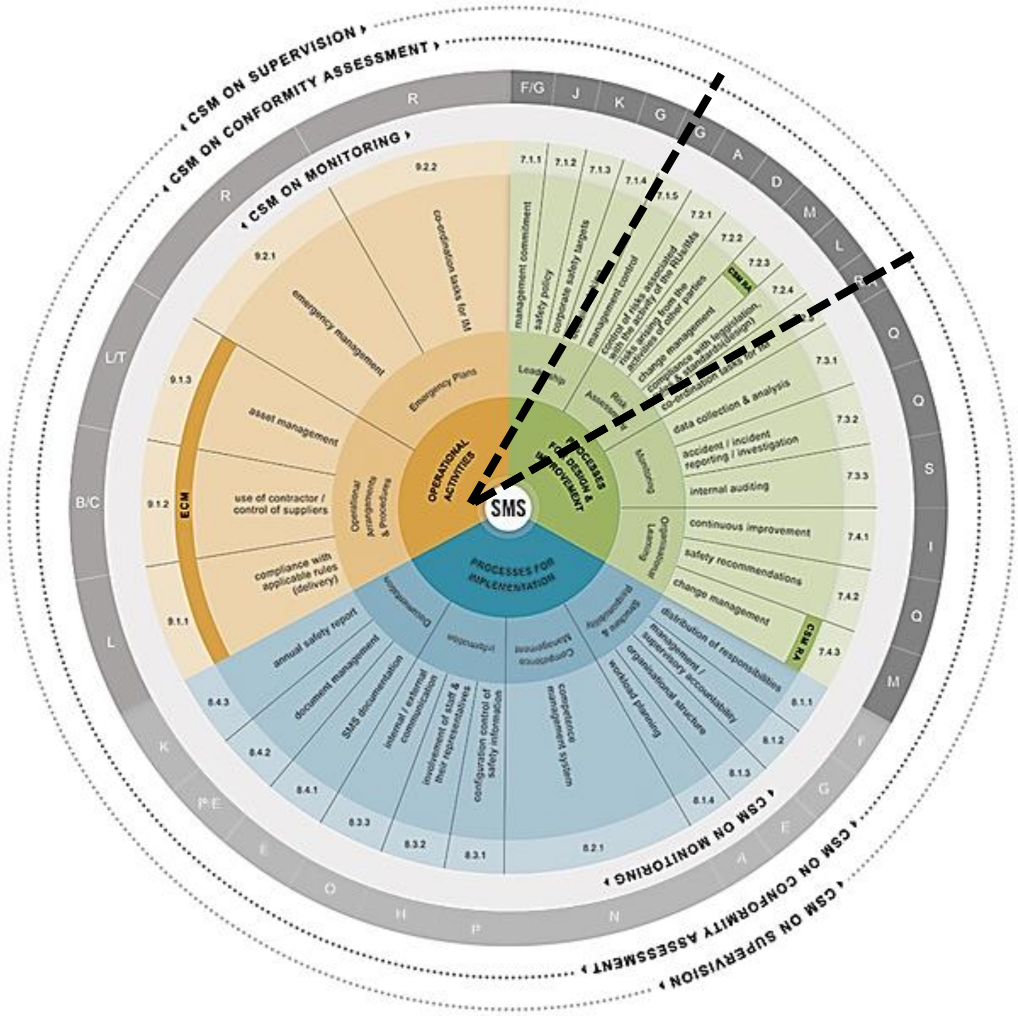

Figure 36: Risk Management Wheel (ERA, Website)[62]

The risk management process is defined as a key element of an effective SMS:

The responsibility for the safe operation of the railway system and the control of risks associated with it belongs to the infrastructure manager and the railway undertakings […] To achieve this, risk assessment (which is the overall process of risk analysis and risk evaluation) is a key element in any effective SMS (ERA, Website, SMS Wheel, Risk Assessment, Introduction).[63]

[62] http://www.era.europa.eu/tools/sms/Pages/default.aspx, Website consulted 26 March 2014.

[63] http://www.era.europa.eu/tools/sms/design-improve/risk-assessment/Pages/default.aspx, Website consulted 26 March 2014.

Such a process is composed of four steps (Figure 37):

1) Hazard identification – the possible side-effects of the performed activity are identified taking into account the interaction with the activities performed by other parties within the railway system. The definition of the ways in which such side-effects are identified is up to railway undertakings and infrastructure managers;
2) Risk estimation – for each identified hazard the frequency of the hazard and the severity of its consequences are estimated. In so doing, the hazard is transformed into a risk. The methodology to follow, as well as the data to use in order to establish the frequency and the magnitude of the identified risks, is defined by railway undertaking and infrastructure managers. In addition, the definition of the frequency and the magnitude of the identified hazards constitutes a criterion for prioritising the effort the railway undertaking and infrastructure managers should invest in dealing with the different risks they have to face:

   by estimating the consequence and probability of each of the identified risks, it should be possible to prioritise the key risks that need to be analysed in more detail.(ERA, Website, SMS Wheels, Risk Assessment, Control of risks with the activity of RUs-IMs);[64]

3) Evaluation of the acceptability of the identified risk – each identified risk is evaluated in order to establish if such risk is acceptable or not. The acceptability criteria should follow the general principles constituting the safety policy the railway undertaking and infrastructure managers intend to follow:

   during the risk analysis process, it is necessary to compare the estimated risks against risk criteria, which the organisation has established. Risk evaluation therefore, is used to make decisions about the significance of risks to the organisation and whether each single risk should be accepted or treated, by selecting and implementing measures (be it technical, human, organisational or any possible combination of these) to control

[64] http://www.era.europa.eu/tools/sms/design-improve/risk-assessment/Pages/default.aspx, Website consulted 26 March 2014.

the risk (ERA, Website, SMS Wheels, Risk Assessment, Control of risks with the activity of RUs-IMs);[65]

4) Identification of control measures in order to reduce the magnitude or the frequency of the risk under assessment – if the risk under assessment is classified as not acceptable, measures reducing its frequency and/or severity should be taken.

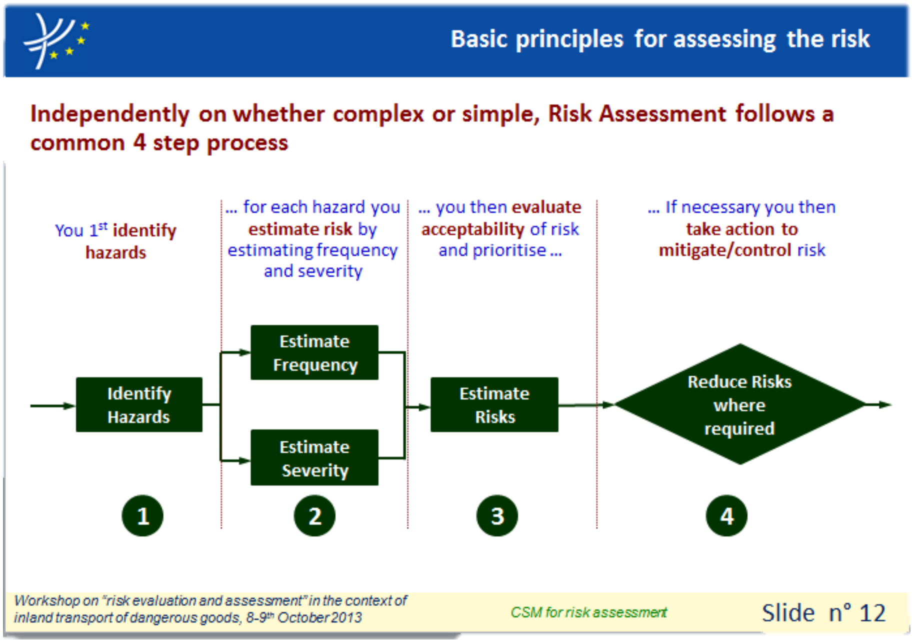

Figure 37: The main steps of a risk management process (ERA, slides: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9 October 2013, p. 12)

As mentioned, the risk management process described above is embedded within the SMS; another key element of the SMS is the definition and development of a monitoring strategy. Figure 38 shows where the monitoring processes are located in the SMS wheel. With reference to the risk management process, the monitoring strategy should 'ensure that desired performance is achieved' (ERA, Website, SMS

[65] http://www.era.europa.eu/tools/sms/design-improve/risk-assessment/Pages/default.aspx, Website consulted 26 March 2014.

Wheels, Risk Assessment, Control of risks with the activity of RUs-IMs).[66] Once again, the decisions about the way in which such monitoring activity is organised and implemented is up to railway undertaking and infrastructure managers. Mainly the monitoring process is meant, on the one hand, to verify that the adopted control measures are effective; on the other hand, to monitor that the risks classified as acceptable do not reach a level of unacceptability over time.

The risk management process promoted by the cost-benefit logic in order to guide the way in which regulated organisations manage their risk is close to the anticipation worldview of risk management. The proposed process fits into its main steps promoted by the COSO and ISO standards, considering the monitory step together with the process of risk management. (See Part 1, Chapter 1, Section 1.2.) So the cost-benefit approach corresponds very well with the phases defined by COSO and ISO standards in the risk management process.

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[66] http://www.era.europa.eu/tools/sms/design-improve/risk-assessment/Pages/default.aspx, Website consulted 26 March 2014.

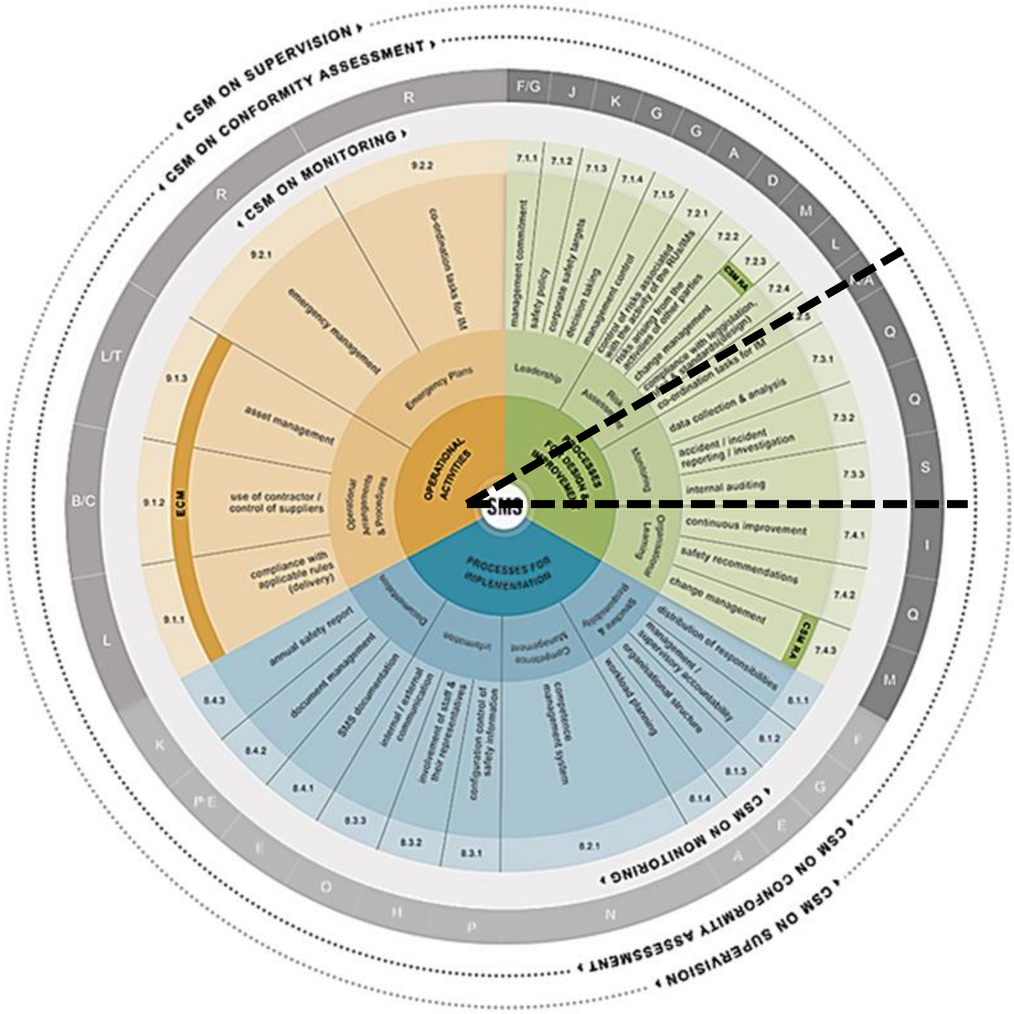

Figure 38: Risk Management Wheel (ERA, Website)[67]

Looking at the enforcement strategy promoted by the cost-benefit logic, there is not a formal check of the implementation of such processes and/or a system of sanctions in case of non-conformity. The SMS assessment is entirely delegated to the nation-state level and specifically to the NSAs. The strategies fostering and fostered by the cost-benefit logic are mainly training programmes through dedicated workshops, as well as informal information furnished during networking and working group activities. The strategy adopted in order to encourage the sector to develop a proper SMS is mainly to show the development of a proper SMS, which

[67] http://www.era.europa.eu/tools/sms/Pages/default.aspx, Website consulted 26 March 2014.

allows them not only to meet the safety objective, but also to meet and improve their business and quality objectives. One of the main assumption sustaining and sustained by the cost-benefit logic is that the safety and business objectives are not in contrast with each other, but that safety and business are in fact aligned. Thus, it assumes that in pursuing their business objectives, railway undertaking and infrastructure managers pursue their safety objectives as well, and *vice versa*. More specifically, the SMS and risk management processes described in it are presented as prerequisites for a company in order to stay in business (see Figures 39 and 40):

The overall purpose of the SMS is to ensure that the organisation *achieves its business objectives in a safe manner*. These objectives need to be fulfilled in today's ever changing and complex railway environment, giving evidence that the organisation complies with all of the safety obligations that apply to it. It is recognised that there are wide benefits of managing business in a structured way. It adds value helping to improve overall performances, introduce operational efficiencies, enhance relations with customers and regulatory authorities and build a positive safety culture (ERA, Application guide for the design and implementation of a Railway Safety Management System, 2010, p. 7, emphasis in the text).

Figure 39: SMS and business development (ERA slide, Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 48)

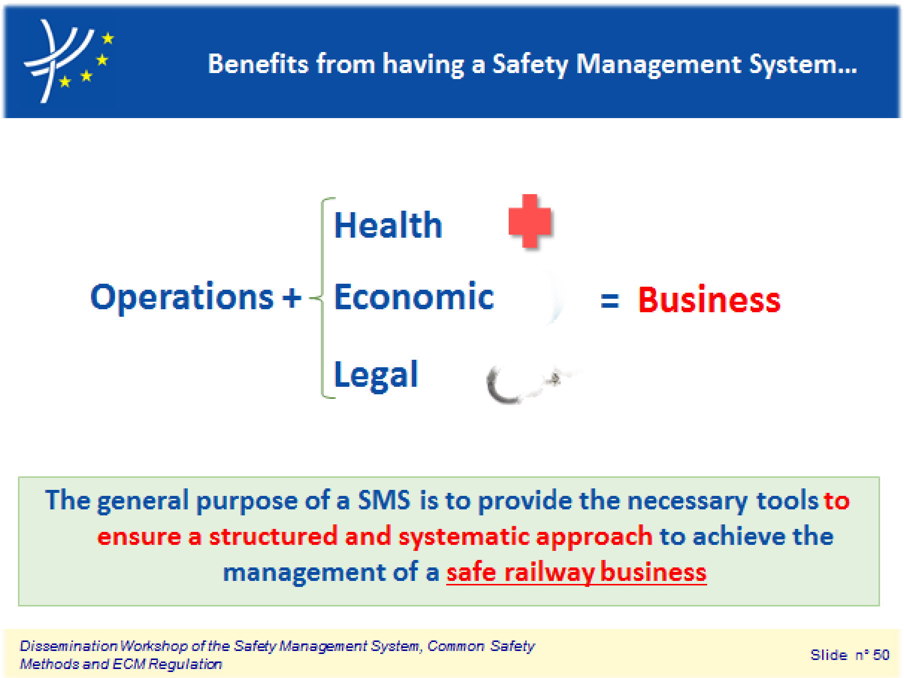

Figure 40: SMS – safety and business objectives (ERA slide, Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 50)

Thus, the enforcement process promoted by the cost-benefit logic is more oriented to persuade the regulated organisations, showing them that conformity to the process is in their own interest, rather than to sanction them.

To sum up, cost-benefit logic presents an imbalance in favour of the indirect risk management process, following the principle of regulating the ‘what’, but not the ‘how’. The direct risk management process of assessment of the Member States refers to ensuring that the level of safety is not decreasing, but is more related to the accountability of the regulatory activity toward public opinion, rather than as a strategy to improve and monitor safety performance. The definition and development of the legislative framework follows a direct risk management process, but the tangible outcomes of the process tend to avoid prescriptive and detailed regulation respecting the ‘what’ and ‘how’ boundaries. Such an imbalance toward indirect risk management and the recognition of avoiding detailed and binding rules, leaves decisions about ‘how’ to regulate to private organisations showing the close continuity between the cost-benefit logic and the risk-based approach to regulation.

Standard logic (NSA)

Standard logic presents a balance between direct and indirect risk management. The 'what' *versus* 'how' boundary stressed by the cost-benefit logic loses relevance. On the one hand, direct risk management processes maintain considerable importance. On the other hand, the tangible outcome of direct risk management processes present a mixture of detailed rules, process definitions and more general requests for analysing and developing control measures in order to face specific issues. In addition, during indirect risk management processes the regulators' intervention in decisions about risk acceptability, as well as the practical translation of the general framework offered by risk-based logic, tends to be more intrusive than the one promoted by cost-benefit logics. Standard logic promotes a middle ground to the risk-based and control-command approaches to regulation endorsing some of the principles and assumptions shaping and shaped by the risk-based logic, such as for example highlighting the full responsibility of the sector about risk acceptability decisions. But, at the same time, promoting and enforcing solutions closer to the control-command approach to regulation, *de facto* limiting such decisions: for example, in establishing specific limits on risk acceptability criteria, or in defining binding and detailed rules. Let us look closely at the processes of direct and indirect risk management shaping and shaped by the standard logic.

Direct risk management

The process of direct risk management promoted by the standard logic can be divided according to the source of the informational input used as a starting point of the process. More specifically, we can identify three main sources of information that are the starting point of three different processes of direct risk management: information coming from the sector or from third parties; information coming from the NIBs; and information collected directly by the NSA. A description of the three processes follows.

Information coming from the sector or from a third party

The process of direct risk management starting with information coming from the sector or from third parties, deals with accidents, incidents and near-misses analysis, which is a direct risk management process that is activated once a dangerous or potentially dangerous event occurs. One of the people employed in this activity using a football metaphor effectively describes such *ex post factum* process as follows:

> we are the coach that has to look again at the goal it took […] We are the ones who go and see what it is that didn't work to try and intervene, to try and improve the situation, which means that this thing has resulted in the goal, or the accident, or that you were about to face one and you didn't have the safeguards working. So we consider that part there (NSA, interview).

The development of the accidents, incidents, and near-misses process is not mandatory for the NSAs. Following the risk-based logic, the collection of data regarding accidents, incidents, and near-misses, as well as the detailed analysis of such data, is the responsibility of railway undertaking and infrastructure managers. The regulators supervisory activity can be limited to checking Safety Management System documentation and actual implementation; thus, being sure that the regulated organisations are analysing accidents, incidents, and near-misses by themselves, without directly examining such negative or potentially negative outcomes. Nevertheless, standard logic promotes the direct analysis of accidents, incidents and near-misses as a cornerstone of the supervisory activity regulators should ensure. Such activity is considered extremely relevant in order to fulfil the mission of the regulators' activities: guaranteeing the safety of the railway system. The assumption that the development of a Safety Management System should in principle guarantee that the railway undertakings and infrastructure managers are operating safely is recognised. But, at the same time, the importance of an additional check ensured by the regulators supervision on the outcomes of the railway undertakings and infrastructure managers' activities, is identified as a key strategy the regulators should develop in order to recognise and correct the possible lack of Safety Management Systems:

> the main principle of railway safety, […] is born from the fact that with the Safety Management System railway operators should be capable of managing safety problems themselves until they don't have them anymore – something that is anyway impossible, we could say. We do an additional intervention, we intervene in cases in which we think that they have to reinforce their defences and so they necessarily have to do something more (NSA, interview).

Let us examine the different elements of such a process following the definition of direct risk management proposed above – informational input, process, and tangible outcomes – in detail. (See Part 1, Chapter 1, Section 1.2.)

- Informational input

The informational input of the process dealing with accidents, incidents, and near-misses analysis comes from three main sources:

- The reporting of accidents, incidents and near-misses given by railway undertakings and infrastructure managers through a dedicated e-mail address. The reporting of potentially dangerous events should be done within 48 hours after the event occurred. The events that should be reported through the dedicated e-mail address are defined as 'all the accidents and incidents that compromised or could have compromised safety' (NSA, Document, Directive 4/2012, Annex 1, p. 26-27). The reporting is mandatory not only for incidents and for accidents, but also in the case of near-misses defined as 'events that didn't cause serious damage, but under slightly different circumstances could have done so' (NSA, Document, Directive 4/2012, Annex 1, p. 26-27);
- The events that caused at least an interruption of regular operations on the national railway infrastructure reported in a dedicated database managed by the infrastructure manager. The NSA has free access to the database that is updated about every two weeks;
- The reports of potentially dangerous events from third parties such as railway police, trade unions or private citizens. This additional source of information allows the NSA to know also about events that could not be reported by the railway undertakings or infrastructure managers. More specifically, the definition of the events that should be reported by railway undertakings and infrastructure managers as 'all accidents and incidents that compromised or could have compromise safety' (NSA, document, Directive 4/2012, Annex 1, p. 26-27) leaves space for subjective judgement. Thus, it could happen that the railway undertakings and infrastructure managers do not report events especially if the events have no consequences in term of injuries, damage to the infrastructure, or interruption of the service. Given the absence of evident consequences, these kinds of events are not detectable by regulators if the regulated organisations do not report them. This additional reporting channel involving railway police, trade unions or regular citizens permits the NSA to be aware of events classifiable as near-misses that the sector may not report.

- Process

All the reported events – accidents, incidents and near-misses – are examined one by one by a dedicated office in which three people are employed. The team is located within Unit 3 of the Agency: Management Standards (*Norme di Esericizio*). The infrastructure managers' database is examined on a monthly basis by the same office. The main focus of the direct risk management process is on the reported events rather than on the database examination. An analysis of the database is meant, on the one hand, to guarantee a monitoring of the trends rather than a one-by-one examination of events. On the other hand, the events added to the database are compared with the reported ones in order to intercept events that for various reasons could not be reported through the reporting channel. For example, near-misses not considered relevant when they happened and thus not reported within 48 hours after the event happened.

The one-by-one examination of reported events constitutes a key step in order to make a decision on the need to go further with additional action. This step filters the available information according to the method of reasoning (deductive – inductive) promoted by the standard logic. More specifically, the filtering process follows two main criteria: the frequency of the event (deductive reasoning), and the singularity of the event (inductive). Looking at the frequency criterion, if the reported event is known – meaning, the people examining it have already seen a similar event and in principle the causes of the event are known – the event is inserted within a category in which other similar events are collected. If the incidence of such a category of events increases reaching a certain frequency, further actions are taken in order to better understand and face the significant elements in the genesis of such types of events. The method of reasoning driving the event examined is deductive in this case: I have a theory in mind on what happened and I interpret reality through this theory. Consequently, I can classify the event in a category I already settled, collecting all the events responding to the available theory:

normally we do the first analysis at the beginning, when we see the type of event that has been reported. According to the typology of the event, we already know if we have to be on pre-alert and maybe send someone to see what happened and be in loco; or the thing we do more often [...] after we receive the first report, […] [is to] ask for [related] specific elements that allow us to identify what were the causes that led to the accident […] We need to go and see when there is a non-conformity. Where there are repeated non-conformities that are part of a branch that we are already aware of – because our history of activity starts quite a ways back: my personal one starts in 2002 and since 2002 I have dealt with accidents – we know where we should insert an event, and so we consider how we are safeguarding that activity and what the existing level of flaws are that emerge from our supervision […] So in that case what do we do, we go and look at the information that we have perceived from our experience and we try to see what actions we can perform (NSA, interview);

in global accident analysis we want to try to see the trends and try to see the macro numbers, the problems which [it pertains to], the principal trends to which the accident refers: if it's maintenance problems or the improper surpassing of a signal, third-party acts, the hydrological situation […] To try to intervene also on a macro level rather than on a single event because we are always trying to intervene on a level that is higher than our activity (NSA, interview).

In contrast, looking at the singularity criterion, if the reported event is not known: being completely new, it does not respond to any of the theories I have in mind, and a category in which to locate the event does not exist; thus, further analysis is developed in order to clarify the causes and the dynamics of the event. In this case, the method of reasoning driving the event examined is inductive. I do not have a theory in mind, but I look at the empirical evidence in order to develop a theory clarifying the event genesis:

the main criteria is recurrence […] for other things it depends on whether in the meantime they become significant enough to catch our attention, significant in the sense of recurring or new. Then we also have finite resources so it's not like we can (NSA, interview);

certainly, accidents and incidents are reported to us because it is their duty as undertakings and infrastructure managers. […][Our office] oversees this […] This specific office, then […] because, indeed, we are not obliged to investigate, we make a sort of statistical selection. I'll explain better: […] if that accident, let's call it that, I want to call it 'that event' because hazards and not just accidents are reported to us. If that event enters within the statistics that we have already noticed, that we are already following in a certain manner – malfunctioning doors, work site safety, right? – so let's say that it is not that interesting for us to go and see exactly what happened because we already know what the context is, they are already being monitored and we are proceeding in a certain direction […] In other cases instead it's a matter of singularities, singularities that attract our attention and which induce us to carry out, I don't want to call it an investigation, an in-depth analysis.. a single-case one. This analysis can be purely of a documentation character or in some cases we go on site (NSA, interview).

A new event is considered an important warning even if it leads to no consequences at all. In all the cases in which a new event occurs, further analysis is conducted in order to clarify the contributing factors in the event genesis. If the event is not new, but is part of a known type of events, the monitoring process focuses on the increasing frequency of the type of event, as main criterion, and on the severity of the consequence of the event. The possible consequences of an event are known on the basis of previous experience regarding the same events as well. Thus, given the frequency and singularity criterion, special attention is paid to events that in the past led to severe consequences.

Once the relevant events are identified, the second step of the process deals with the definition of the additional actions to take in order to face the identified issue. The possible steps are:

- If it is a new event, further analysis is done in order to clarify the causes and the dynamics of the event. It is possible that the location in which the event happens is examined and evidence is collected directly by the NSA. People from other units are involved according to the kind of event, and the needed expertise in order to understand the event's causes and dynamics. As soon as the causes and dynamics of the event are clarified an intervention with the railway undertakings or infrastructure managers follows;
- If it is a known type of event, two steps are possible: one internal and one external. The external option considers the cases in which the available information is deemed sufficient to formalise a tangible outcome for railway undertakings and infrastructure managers. The internal step regards the cases in which additional elements are needed in order to formalise a tangible outcome toward railway undertakings and infrastructure managers. In this case, other units are involved. On the one hand, it is possible that the problem requires further analyses through *ad hoc* inspections conducted by the Inspectorate and Controls Units. On the other hand, if the details of the type of events need to be further analysed, the expertise of other units is involved. For example, if the problem involves locomotive or track maintenance, the Technical Standard Unit is involved. Once the problem is better defined, the tangible outcome for the railway undertakings and infrastructure managers follows. Let us examine the tangible outcomes of railway undertakings and infrastructure managers generated by the accidents, incidents and near-misses analysis process in more detail.

- Tangible outcomes

The standard logic fosters different kinds of tangible outcomes of the accidents, incidents, and near-misses analysis process, which constitutes the input for the regulated organisations in order to solve the lacunas identified through the process. Looking at the outcomes shaping and shaped by the standard logic, a middle position of such logic between the risk-based and the control-command approaches emerges. (See Part 1, Chapter 1, Section 1.3.) More specifically, the content of the tangible outcomes can be:

- To ask the railway undertakings or infrastructure managers to examine and focus their attention on a specific phenomenon considered potentially dangerous according to the accidents, incidents, and near-misses analysis developed by the NSA. Such a solution is the closest to the risk-based approach allowing the railway undertakings and infrastructure managers to evaluate the hazards and identify the control measures to deal with the associated risks by themselves. The difference between standard, risk-based and cost-benefit logics refers to risk acceptability criteria. As already mentioned, the standard logic specifies the criteria through which regulated organisations should evaluate their risk through the definition of a mandatory frequency per magnitude matrix. (See Figure 15.) Consequently, if the hazard identified through the accidents, incidents, and near-misses analysis is not acceptable, given the criteria specified in the matrix, the regulated organisations are obliged to define control measures in order to decrease the frequency and/or the magnitude of the event. Nevertheless, the decision about which measures to undertake is still left to railway undertakings and infrastructure managers. The regulator proposes different solutions, but does not oblige the railway undertakings or infrastructure managers to adopt one solution over another. An example that goes in this directions refers to the following phenomenon: loss of material aboard trains while passing through train stations. An accidents, incidents and near-misses analysis identified such phenomena as increasing, thus a reaction on the part of infrastructure managers was undertaken. More specifically, the phenomenon was identified as unacceptable, thus the NSA asked infrastructure managers to develop control measures in order to reduce the magnitude of those events. In so doing, two different solution were proposed by the NSAs: to shift the passing trains to a dedicated track, far from the platforms in which passengers wait for trains, in order to reduce the probability that they can be hurt by the lost material; or to provide the train stations with sliding doors in order to regulate passenger access to the platforms and reduce the time exposed to the risk of being hurt by material coming from the passing trains:

faced with this objective onset – because it happened, there is a risk – we asked XXX to take action […] We hypothesised two scenarios, one scenario is to have passing-through trains instead of travelling on track one [...] [to travel] on the outer one. The difference is fundamental because in way stations, platforms one and two are dedicated to passengers; travellers mainly wait for trains on platform one, which is the main one, or on platform two. Instead there is platform eight, which is decentralised, and if the train loses a piece while it passes on platform eight, it is frankly unlikely that the piece will hit a passenger because there are no passengers on platform eight […] The other solution is what I call the 'sliding doors' one, that is, equip the station with automatic access for passengers: the doors open only when the train is stopped and when there is a train that is stopping the doors don't open and the passengers are held inside the station where they are protected (NSA, interview).

Nevertheless, the proposed solutions were presented just as possibilities, leaving infrastructure managers free to identify other control measures ensuring the same results. In brief, I identify this problem and you have to consider it because it is not within the acceptability limit, but you are free to decide what to do in order to bring it back within the acceptability limit. Such a decision is your free business decision and I cannot oblige you to adopt a specific control measure.

- To define mandatory norms, standards and control measures railway undertakings and/or infrastructure managers should follow in order to address the identified problem. Despite the non-binding and non-prescriptive regulatory strategy promoted by risk-based logic, following the standard logic, the definition of mandatory norms, standards, or control measures is still an option. Two examples of detailed prescriptions following accidents, incidents, and near-misses analysis deals with, for example, work sites on the railway lines and the blockage device for train doors:

another qualifying aspect of our regulatory interventions has been on the so called safety of work sites. Work sites are physical places along the line where maintenance work or the installation of a new structure is taking place […] So at a certain point each year 5 or 6 workers died at railway work sites hit by trains … But there's more, the trains not only ran over the worker but also the equipment, understand? At that point we acted, we made a specific decree on work site safety, it took 3 years eh … because the infrastructure manager questioned the technical legitimacy of our regulation, in the end in some way we managed to impose it […] One very simple thing existed before, done with the so-called 'sighting protection'.

> There were two workers that worked, one on the valley side and one on the mountain side. They placed themselves like that. It's not exactly technologically advanced. We said the sighting protection, even if it's done well, is not sufficient. You can set up work sites only where circulation is excluded […] Trains must not pass. Imagine that […] our decree […] says that 'when there is a space to respect of x metres blah blah blah' but the main principle is this, you mustn't do protection through sighting. Period (NSA, interview);

> with reference to measures of a technical nature, over the year 2008, the installation of the 'door blocking' system was completed on the entire pool of regional trains, while in 2009, following a specific request by this Agency, the installation of the so-called 'timed block' [doors] in cars destined for medium and long runs was completed (Intercity and Eurostar City). And within the end of 2012 the completion of the 'lateralisation' of the doors, even on the doors that today are equipped with 'timed block' doors, is expected to be completed. With the default of these technological adjustments, railway undertakings have been requested to adopt measures of an organisational nature to augment safety for the car boarding of passengers (NSA, Report on activities carried out by the National Safety Agency in 2012 and first elements on activities carried out in 2011up to 31 August, 2011, p. 34).

Thus, the practical translation of risk-based logic given by the NSA acknowledges the definition of a detailed prescription as a possible tangible outcome. In so doing, the standard logic gives room to solutions closer to the control-command approach to regulation, than to the risk-based one. Such solutions are still implemented within a risk-based framework and are considered as an extreme ratio to use only when solutions of compromise with the sector cannot be agreed upon.

If we look at the 'safety measures adopted […], with respect to analyses of accidents and after other events and factors' (NSA, 2012, Annual Report, p. 13) reported within the NSA annual report from 2010 to 2012, we can quantify the balance between risk-based and control-command tangible outcomes. The safety measures can be classified in three main categories: identification of a phenomenon on which an evaluation is asked by the sector; identification of a specific area on which to implement control measures in order to deal with a phenomena, for example, a request to intervene on freight maintenance, training, or a technical modification; identification of a technological device or emanation of a detailed rule the sector should implement/follow. Table 15 reports the number of safety measures classifiable within the three identified categories.

Tangible outcomes	*2010*	*2011*	*2012*	*Total*
Identification of a phenomenon on which an evaluation is asked	8	1	5	14
Identification of an area on which to implement control measures	3	6	5	14
Identification of a technological device or emanation of a detailed rule	8	4	3	15
Total	19	11	13	43

Table 15 Standard logic – tangible outcomes from 2010 to 2012 (Adapted from NSA, Annual report 2011, 2012, 2013)

Table 15 shows that the standard logic's tangible outcomes represent a middle ground between the risk-based and the control-command approaches to regulation. Assuming such a middle position, standard logic partially detaches itself from the principles and assumptions steered by the risk-based logic prevalent at the politico-economic level. Following risk-based logic, regulators should not enter into decisions about the acceptability of risks, or the control measures developed in order to reduce the frequency or the severity of such risks. In contrast, the tangible outcomes promoted by standard logic can also be extremely detailed and prescriptive. In substance, the practical translation of risk-based logic given by standard logic shows a balance between the risk-based and the control-command approaches.

Information coming from the NIB

- Informational input

A formal process through which the outcomes of the investigations conducted by the NIB constitute the input of the direct risk management process developed by the NSA, structures the relationship between the NIB and the NSA. More specifically, the results of the investigation process conducted by the NIB on accidents, incidents, and near-misses – an in-depth description of the investigation process is given later on in this section – are formalised in recommendations identifying improvement procedures to be undertaken in order to face the lacunas highlighted by the investigation. The recommendations should be directed by the NIB to the NSA, and not by the NIB directly to the sector. The NSA decides if additional actions should be taken towards the sector based on the actions already undertaken, as well as on the content of the NIB's recommendations. The NIB does not address recommendations directly to the sector, but it is the NSA that decides if additional requests should be made of the sector. Thus, the filtering process performed by the NSA becomes extremely relevant also with regards to the results of other regulators' activities.

- Process

The same unit of the NSA that conducts the accidents, incidents and near-misses analysis described above examines the recommendations given by the NIB and decides if additional actions should be taken or not. Such a filtering process *de facto* begins before recommendations are formally sent by the NIB to the NSA. Before closing the investigation and formalising *ad hoc* recommendations, the NIB should meet all the interested parties and exchange views on the investigation's results. Thus, the NIB and the NSA usually meet during the investigation process in order to discuss the issues emerging from the investigation. Thus, the filtering process *de facto* begins during those meetings in which the different views promoted by the two logics – standard and possibility – clearly emerge.

Let us take the example of the Lavino accident described above. As already mentioned, the cause of the railroad switch leading to the train derailment, which happened on 15 July 2012 near Bologna, was identified as an error which occurred due to a maintenance intervention that did not follow the maintenance procedure defined by the infrastructure manager. Following abductive reasoning shaping and shaped by the possibility logic, during the accident debate with the NSA, the NIB presented a different view of the event. More specifically, even if the crucial role of the maintenance procedure infraction was recognised, the main question posed by the NIB was: could this kind of error – incorrect positioning of the switch – happen even if the workers correctly followed the maintenance procedures provided? Following the inductive reasoning shaping and shaped by the standard logic, the NSA does not recognise the posed question as a relevant one, re-conducting the debate to the maintenance procedure infraction.

Basically, the possibility of the same error occurring if the maintenance procedure is followed was recognised, at the same time the statement that this alternative scenario did not actually happen was highlighted. Following inductive reasoning, any conclusions should be based on empirical evidence, thus, on what actually happened: taking action in the sector is justified only if an error scenario actually happened, and it is not justified if such a scenario is *de facto* possible, but does not actually happen. The method of reasoning promoted by the standard logic requires a focus on what actually happened and an intervention is not justified if there is not an event that can be directly related to the requirements addressed in the sector. In the Lavino case, the

NSA did not consider additional actions in order to face the alternative scenario fostered by the NIB, specifying such a position during the meeting.

As the infraction of the maintenance procedure is the only relevant recognised cause of the event under examination, the focus of the intervention promoted by the NSA toward the sector was limited to the reinforcement of the maintenance procedure. The exchange of views that occurred during those meetings, on the one hand, influenced the actions contextually, without waiting for the end of the investigation undertaken by the NSA, in the sector. This because the investigation times are quite long, thus, corrective measures are usually taken before an investigation ends. On the other hand, the exchange of views influences the NIB interpretation of the event as well, de-legitimising the possibility of addressing those alternative and hypothetical scenarios through *ad hoc* recommendations.

Consequently, the recommendations that the NSA formally receives, are a compromise between the two positions emerging during the meetings. The meetings are already a first filtering step in which the methods of reasoning promoted by the standard logic select the informational input emerging from a possibility logic point of view. A second filtering step occurs when the recommendations are formally received by the NSA. This step consists of an additional examination of the recommendations in order to consider the possibility of undertaking additional actions in the sector in order to address specific issues highlighted by the NIB, and not yet dealt with by the NSA. This additional examination following the criteria fostering and fostered by standard logic, filters out issues considered relevant from possibility logic's point of view. The description of such a process, given by the NSA, illustrates it is not common for additional analysis of the event and/or additional actions within the sector following an examination of the NIB's recommendations to occur:

> the recommendations are examined by me and [name of a person] and then, depending on the case, specific experts get involved […] To avoid making rash judgments we actually go through the most competent personnel that we have within the Agency […] Based on this we intervene because we know the state of the art. If someone tells us "no look, no" the investigative body says: "*It didn't happen".* But let's give an example: "You have to be more rigorous in the homologation of these rolling stocks because of the wheel arrangement problem." They tell me and I say: "Let's get the homologation sector interested." And the homologation sector tells us: "Look there are statistics, there is an international standard, we follow that and with this there is this, this and that". *Together we prepare the answer and we re-present it to the investigative body and we tell them if there is something more that they would like to highlight* (NSA, interview, my emphasis).

The role of the method of reasoning as a strong filter of information emerges in both the steps: during the exchange of views and meetings, and when recommendations are examined. In fact, additional actions are taken only if the recommendations are in line with the inductive-deductive approach promoted by the standard logic, and no actions are pre-emptively undertaken by the NSA in order to address the issue under examination.

- Tangible outcomes

The tangible outcomes of such a process are, on the one hand, a formal response to the NIB in which an explanation about the reasons why the decision of undertaking additional actions or not to, was made. On the other hand, if considered appropriate, an additional action within the sector is indicated. Through the NSAs' and NIBs' annual reports – from 2011 to 2013 – we can quantify the times in which additional actions in the sector followed the analysis of the NIB's recommendations. The actions following the recommendations analysis are classified in two main categories: no additional actions undertaken, this category also collects the recommendations considered by the NSA already included within the actions followed by other recommendations; and additional actions undertaken, this category also gathers the times in which the additional action was a reinforcement of an action already undertaken, or a commitment to monitoring the issue raised. Table 16 shows the quantification of such categories.

Measures	*2010*	*2011*	*2012*	*Total*
No additional actions undertaken	8	11	14	33
Additional actions undertaken	0	0	10	10
Total	8	11	24	43

Table 16: NSA's reaction to NIB's recommendations (Adapted by NIB's annual report 2011-2013, and NSA's annual report 2011-2013.)

Ten times out of forty-three, during the three years considered (2010-2012), actions within the sector were undertaken by the NSA following the NIB's recommendations.

Information collected by the NSA

The informational inputs collected directly by the NSA are the starting point of a process of direct risk management involving a unit of the NSA – Sector 6, Inspection and Monitoring – different from the one in charge of accidents, incidents, near-misses and NIB recommendations analysis. The informational input of this direct risk management process is information collected through the inspection activities carried out by the NSA on the infrastructure managers and railway undertakings' products. The product of the railway system is defined as the train in operation. Thus, inspections aim to check if the trains and the tracks on which the trains operate, which are the final product of the railway undertaking and infrastructure managers' activities, are operating ensuring transport safety:

> if I do it on the product, I go and look at what the conditions are of its functioning. For example the classic one for products is the one done on doors, so our inspectors get on the trains and select an important sample – for example regional transportation in Piedmont. Our inspectors, over the course of the week, distribute themselves on the trains and check the state of functioning of the doors: if they work, if the safety systems are working; then they have access to the on-board journals of the cars […] where you can see the recurrences, the repetitiveness of certain advisories, because in the on-board journal the train conductor has to indicate if there is an anomaly with a certain door, day to day, for every trip. If he sees that the door has an anomaly four days in a row, it means that it was never repaired. So that is a documentation inspection. Direct monitoring is done looking at the door, its functioning under that circumstance. Looking at the on-board journals I can be aware of the history of its functioning and the maintenance history of that door and this is product control (NSA, interview).

Inspections can deal with the state of the tracks and of the rolling stocks both on the technical and operational sides. For example, an inspection can check if the doors of a train are functioning well while that train is operating; if the tracks are correctly maintained, by checking the state of the tracks and comparing them to the fixed standards they should have in order to ensure the safety of the operation; if the train's axles are in good condition or need to be checked with an *ad hoc* maintenance intervention; if the train driver is driving the train properly and if he has the right licence to drive the train he is driving. The inspection activity leads to the identification of non-conformities. For example, the track measurements do not correspond with the standard one, or two doors were not functioning in a given train during operation, or the driver doesn't have the right license in order to drive the train, or an axle was not in the expected condition. The inspection activity does not look at the causes of such non-conformities, as well as at the processes contained in the Safety Management System (SMS) that could lead to the non-conformity under examination, but just registers the non-conformities. The inspection activity represents an additional check the regulator does on the output of the railway undertakings' and infrastructure managers' activities, aiming to check if the SMS actually gives the expected outcomes, but not if the SMS is well structured and following the prerequisites specified in the legislation:

I have a good system, a good process for which a safety certificate was issued. For me, the Agency, this is not enough. I want to come and verify your product because your piece of paper, which you wrote, is a document that remains over time, but the product is the result of not just pieces of paper, but also of the work of people and so the final point of connection: the product takes into account the entire organisation […] not only the parts that are a bit abstract, but the real parts that have an impact on people because, in the end, we are interested in the impact on people. Yes, you may have a well-done and well-structured process, but here guys the product doesn't work, here you are dangerous, here you don't do what you declared in your process. So that is what we go and verify, the compliance to criteria we require about system and process within the product. That is, are you doing what you declared to me you are doing? (NSA, interview).

Thus, once again, as in the case of accidents, incidents, and near-misses analysis, the role of the SMS to ensure the safety of the operation is recognised, but as a key element of the regulators activity, the inspections allow the actual functioning of the SMS to be double-checked. The non-conformities represent the informational input for another direct risk management process developed by the NSA. The inspections direct risk management process goes ahead parallel to the accidents, incidents and near-misses analysis. As mentioned previously, one of the possible tangible outputs of the accidents, incidents and near-misses process is undertaking a specific inspection activity. Nevertheless, the inspection activity is linked not only to the output of the accidents, incidents and near-misses analysis, and follows its own independent planning and management process. Let us examine the inspection process in-depth.

- Informational input

The informational input of the inspection process is the product of the inspections carried out by the NSA, thus the identified non-conformity. The inspection activity can be divided into two main types: routine and extraordinary. The routine inspection activity is the planned one: the inspections are planned on an annual basis and are meant to "take the temperature off the system" (NSA, interview); thus, to ensure a permanent and continuous surveillance of the product. This activity is linked to the deductive method of reasoning promoted by the standard logic. Basically, it is based on the assumption that the elements that could be critical in leading to a negative event are known. Thus, I can identify such elements and monitor them continuously in order to check the safety level of the railway system. Inspectors should follow detailed check lists containing all the components of the infrastructure and/or of the rolling stock that should be checked. The other criteria driving the planning of the routine inspections activity is the coverage of the entire railway system. In addition, attention is paid to the fair distribution of the inspections on all the railway undertakings operating on the national railway infrastructure. More specifically, the planned inspections should be proportional to the volume of transport carried out by the various railway undertakings operating on the national infrastructure:

> first of all, it's planned to try to cover the system. Obviously with the resources that we have it's impossible to be able to achieve total coverage, but we try to temporarily exclude parts that have just been monitored [in our inspections] and gave a positive result. If we have monitored that railway undertaking [...] we can concentrate on something else for the time being, until that undertaking is inserted again in the planning [...] but not on a sample based on a mathematical calculation because at this time it is impossible, we would need at least a thousand people to do this [...] To do this we would need many more resources (NSA, interview).

The extraordinary one is not carried out continuously, but constitutes a one-off activity fostered, for example, by an accident, incident, or near-miss analysis. Thus, it is linked to the inductive method of reasoning aiming to collect *ad hoc* evidence in order to clarify or monitor the trends affecting a specific technological component or activity. Another input of the extraordinary inspection activity can be the introduction of a new law or standard; in this case, the monitoring activity is meant to check if the sector correctly understood and is compliant with the new requirements.

The core activity of the unit is the routine inspection process. Routine inspections have been structured in order to guarantee the collection of standardised and representative data. On the one hand, the definition of detailed check lists (see Annex 3 for an example of a check list) ensures that all the inspectors will collect uniform and comparable data. On the other hand, the planning of the inspections is done in order to ensure the coverage of the system on a sample basis. The importance of the standardisation and of the coverage in order to ensure the usefulness of the collected informational input is stressed. The aim is not to know that door x of the train y is not working, but to be aware of the trends affecting the door functioning on the overall railway system. Given such an aim, it is seen as crucial to reduce the role of the subjective judgement of the inspector in order to ensure the homogeneity and the comparability of the collected data:

inspections have to be idiot proof, I can't send four people to do four inspections to check the Intercity doors […] They should look at different aspects that give me the results of non-conformities. They will take the identical form with codified checks in which they have to mark the conformity or non-conformity with an x because I need to then pull together the conclusions and do a sampling of this data. I'm not interested in knowing if the train had a faulty door, I want to know the average number of faulty doors that travel. Obviously, if I don't give these people a highly codified instrument to the extent of a capillary control, I risk having a series of impressions [...] that are not objective; I cannot sell it as objectivity. This doesn't stop anyone from accompanying their inspection activities with an additional report, a telephone call, an e-mail in which they highlight critical aspects in a more general manner, but I need forms, codes (NSA, interview);

we also worry about providing operators with a handbook on how to perform. First of all because we don't want the operator to go out and omit checks. That is, the fact of omitting a check isn't tolerated, all checks must be done. On the part of our operator there is first of all a signature and a form, which must be filled out that refers to this guide, on all the vehicles that are checked. And on each vehicle all of this series of checks must be done. Therefore, the moment that he is in charge of all the individual checks he did there is a traceability of the flow. So for the external operator who goes to perform an inspection, there is a form to fill out that refers to the guidelines, which refer to the procedures. There is the continuity of the process and then there is the part of inserting data. But why have they been codified like this? […] We conform to the evolution of the system, so we study the system to understand what to modify, the codes of non-conformity are tied, every single check is tied to a code of non-conformity, which is inserted into a database (NSA, interview).

The identified non-conformities are then collected in a dedicated database.

- Process

The process of direct risk management constitutes the processing and the evaluation of the information contained within the dedicated non-conformity database. Non-conformities contained in the database are analysed on a quarterly basis. The inspections activity is structured in order to ensure a decisional support system to the NSA's managers. (See Figure 41.) The idea is that the collected standardised and sample-based information can be analysed in order to produce synthesised and easy-to-read reports allowing the NSA's managers to make decisions on intervening in the sector or not.

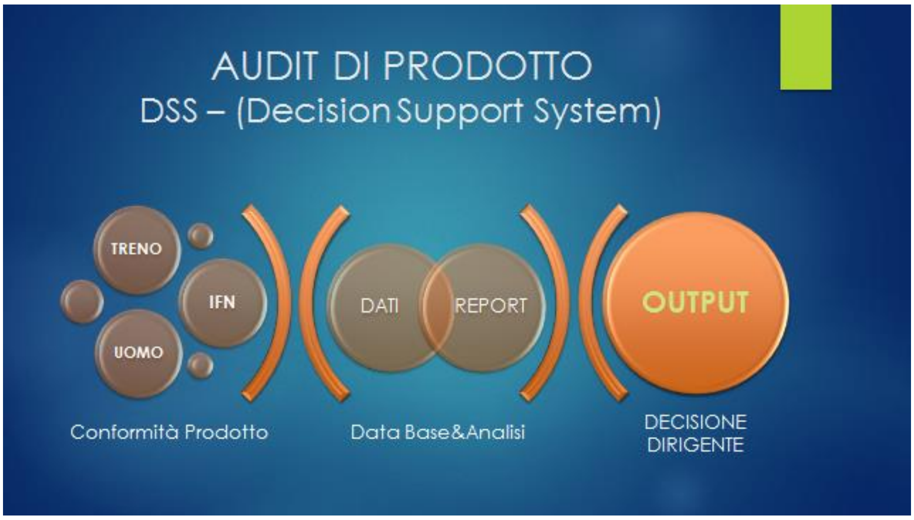

Figure 41: Inspections' Decision Support System (NSA, Slide: Inspection activities finalised to the identification of systematic lacunas, 2013, p.12)

The report synthesises the informational inputs through graphics (see for example, Figure 42), keeping the managers' attention on the non-conformities that reach a certain frequency across the entire system.

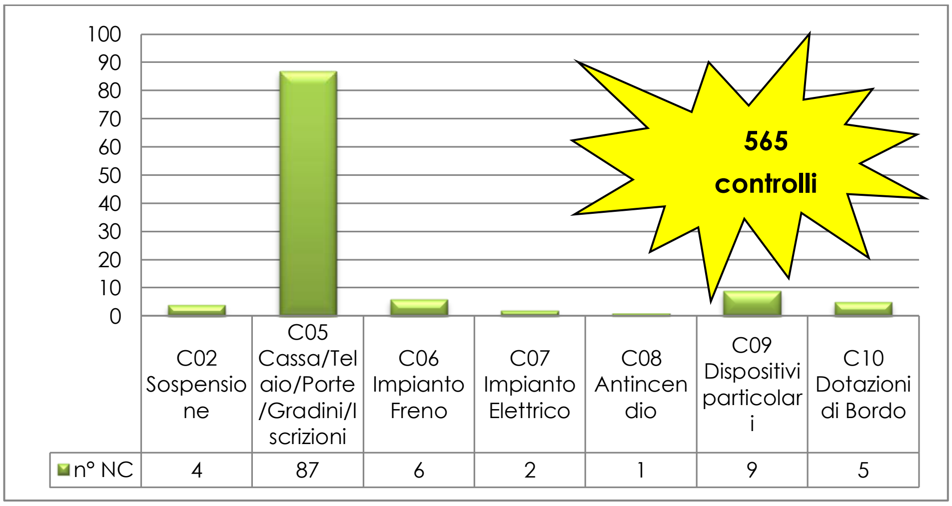

Figure 42: Example of graph contained in the quarterly inspection report (NSA, Trimester report on inspection activities on the rolling stock of railway companies 3rd trimester 2012, 2013, p. 13: Graphic 12 – no. NC on element C checks)

Thus, informational inputs are summarised and filtered through the frequency criterion that drives the undertaking of further actions within the sector. Here the method of reasoning steering the process is deductive and inductive: the monitored elements are identified through deductive reasoning, but the selection of the relevant issues is based on the empirical evidence that testifies to the actual relevance of the problem – inductive reasoning. Unlike accidents, incidents and near-misses analysis, given the previous selection of the relevant elements steering the process through the definition of detailed check lists, in the case of inductive reasoning, paying attention to a single new event is not possible and, more in general, it is not the aim of this activity:

the main objective of this inspection activity isn't "oh we found a train that has this problem let's quickly write the train company and stop this", the objective is to reach the end of the trimester or the end of the year with diagrams, diagrams that are as in depth as possible that will provide indications about where evidence of bad habits is emerging. Then it's up to who has to go and see why there is this peak of faulty doors in this trimester (NSA, interview);

there are some critical factors that occur instead in an entirely accidental manner. That is, it happened once. While there are other [cases] instead that denote troubling repetitiveness (NSA, interview).

- Tangible outcomes

As for the accidents, incidents and near-misses analysis, the results of the direct risk management inspection process can be internal or external:

- The internal result can be of two types. On the one hand, the identification of a frequent non-conformity can lead to an extraordinary inspection campaign aiming to collect additional information on the relevance of the non-conformity in a specific company or in the railway system as a whole:

  in the last two trimester reports, we found that the C05 indicator, which was 3 per cent three months ago, had risen to 13 per cent, so there was a variance of 10 points. What happened? So at this point, on this component in particular, we have to take focused action to understand. We focus on that single component not on the entire vehicle, but on the single component of 500 vehicles to have a more significant sample (NSA, interview).

  On the other hand, the output of the inspection activity can lead to the planning of an audit. The audit process will be explained later on in this section. An audit differs from an inspection because it does not focus specifically on the product, but considers the processes and the Safety Management System developed by the regulated organisations as well. Thus, the identification of a non-conformity could lead to the planning of an audit aiming to clarify the role of the processes developed by the regulated organisations within their SMS, which led to the identified non-conformity;

- The external result consists in actions within the sector. The actions can be a letter in which the regulators request the regulated organisation to pay attention to a frequent non-conformity, or again as an *extrema ratio*, the emanation of detailed rules to face the identified problems. Basically, the tangible outcomes of the direct risk management inspection process are of the same type as the accidents, incidents and near-misses analysis. The reason for such continuity is that the managers in charge of making decisions about the actions to undertake are the same. More specifically, even if the two processes are located in two different units, the head of the Management Standards Unit (*Norme di esercizio*) is the ad interim head of the Inspection and Monitoring Unit (*Ispettorato e Controllo*) as well.

In summary, there are three main lines of direct risk management: the accidents, incidents and near-misses analysis; the NIB recommendations analysis; and the non-conformities analysis. Through the three processes, the methods of reasoning the standard logic promotes, contribute to the filtering in and out of the informational input, which maintain attention on certain kinds of phenomena: the frequent and the new ones. Looking at the recommendations coming from the NIB, the methods of reasoning promoted by the standard logic encourage filtering out information about alternative scenarios that are possible in principle, but which refer to events that did not actually happen. The tangible outputs of such processes are midway between control-command and risk-based approaches to regulation. Thus, the tangible outcomes fostered by the standard logic partially detach NSA activities from the principles and assumptions shaped by risk-based logic at the politico-economic level. The risk management worldview closest to the direct risk management strategy promoted by standard logic is still, as in the case of the cost-benefit one, the anticipation worldview. (See Part 1, Chapter 1, Section 1.2.)

Indirect Risk Management

Indirect risk management processes, thus processes promoting specific strategies of risk management to the sector carried out by the NSA, are mainly three: certification, auditing, and training. Let us look closely at those processes.

Certification

The certification process is a conformity assessment on the documents containing a detailed description of the Safety Management System presented by railway undertakings and infrastructure managers in order to obtain a Safety Certificate/Authorisation allowing them to operate on the railway infrastructure. The Safety Certificate/Authorisation is divided into two main parts: Part A, which has value in all the European Union; and Part B, which contains the specific requirements in order to operate on the nation-state's network. As already mentioned in describing the indirect risk management processes promoted by the cost-benefit logic, the risk management process promoted by regulators toward the sector is part of the Safety Management System. The risk management process that regulators implement, should follow some mandatory steps: hazard identification; risk estimation; risk evaluation; implementation of control measures; and monitoring of the effectiveness of the selected control measures and of the identified hazards.

The NSA should check this process following the guideline referring to the safety certification release given by the ERA. As already mentioned, there is a key difference between the risk-based and cost-benefit logics and the standard one. The standard logic specifies the risk acceptability criteria regulators should follow in evaluating their risks. Those criteria constitute one of the requirements the railway undertakings and infrastructure managers should be compliant with, in order to obtain Part B Certificate/Authorisation, which allow them to operate on the Italian railway network. Risk acceptability criteria represent contents through which the process' 'risk evaluation' is filled. Thus, in defining mandatory criteria, standard logic oversteps the borders established by the cost-benefit logic between regulating the 'what' and regulating the 'how'. More in general, while Part A of the Certificate/Authorisation contains the processes regulators should follow, Part B of the Certificate/Authorisation, from the standard logic point of view, tends to define some of the ways in which regulators should fill in the contents of those processes:

the first part of Certification (Part A) relates to the general requisites from the SGS of the Company […] This attests to the company's acceptance of the SGS, but it's not enough to activate a railway service. Part B Certification […] is the part related to the adoption of measures to satisfy specific requisites for safe circulation on the NRI (National Railway Infrastructure given in concession to the *Rete Ferroviaria Italiana S.p.a.*) derived from management regulations, technical standards, and safety standards at a national level and in force when Certification is being issued (NSA, Document, Guidelines for the issue of safety certificate 2010, p. 5);

[whether] the procedure is good [or] it's not good, corresponds to technical requisites or non-technical [ones], [it] doesn't apply here [in Part A]. It refers to [another] evaluation that we do too, but which is finalised to the issuing of a Certification that is called Part B because we oblige them to comply with that table [Mandatory Frequency per Magnitude Matrix, See Figure 15] (NSA, interview);

okay so we can't ask them to do more, with respect to Part A of the Certificate, than what can be done, using the common sense of interpretation of this criteria. They don't find an obstacle in Italy different from what they would find in France, because I don't re-evaluate the Certificate released in France, so I have to be confident that the French Agency does the same job or, in any case, completely similar to mine. Instead, here in Italy, we have procedures specifically regarding risk analysis, and we apply those to Part B: the famous table, the matrix that is a national regulation [See Figure 15, p. 180]. So if a railway undertaking has Part A Certification in, say France, I don't know how their risk evaluation was conducted by the French Agency. To come to Italy you have to, in any case, demonstrate that all the risks you identified were evaluated as acceptable, not acceptable according to my national matrix, so I don't re-evaluate the procedure because the procedure is valid in Italy, France, Germany, Lithuania and Finland. But I re-evaluate the results because the results for me are linked to the regulations that I've established on my network […] Since it is, let's say, a technical rule of best practises, presumably they'll apply them in other countries as well, so this makes us feel confident pretty much, […] [that technical rule] refers to academic literature on risk analysis in the railway sector. That said, if this guy has invented another system and in his country they said it's okay, it doesn't matter to me, that is, they will be confident that by using that method things work there; but then you come to Italy to me and you have to demonstrate that using that method you are in compliance with my regulations, and my regulations tell me that you have to express your risk according to the categories in that matrix (NSA, interview).

The principle fostered by the risk-based and cost-benefit logics of preserving the free business decision is recognised, but the regulators' role is to bind such freedom in order to ensure the safety of their activities. Consequently, the free business decision is respected and ensured, but within the boundaries – processes, but also standards, risk acceptability criteria, and norms – fixed by the regulators:

I'm not going to enter into the merits of those activities [because] they are related to how you manage your safety. And safety, the management of safety, falls on undertakings and infrastructure managers: if I went into the merits of it, it [would be] like 'interfering' […] I don't have to tell you how you have to do it, I just have to make sure that what you have declared to me is coherent … is complete and coherent with what are the current regulations in place. The choice of how to do that is yours … Then over time we shall see. Of course if you make a choice that […] isn't foreseen by, if the regulation says you have to go on that line at 30 per hour, and you tell me you want to go 60, on that stuff then no (NSA, interview).

The tendency of regulating the content and not only the process of the risk management process promoted by the standard logic confirms the middle position the standard logic presents with reference to the risk-based and control-command approach to regulation.

The conformity assessment of the documents provided by the railway undertakings and infrastructure managers leads to the identification of the non-conformities the processes described by the applicant show. Such non-conformities represent mismatches between the presented processes and the ones described by the European and Italian legislative frameworks. The list of the non-conformities and an explanation of why the described processes do not match the requirements is sent to the applicants within four months after receiving the application. The applicant should change the processes judged non-compliant, and re-submit the documents to the NSA. This process can be repeated a maximum of three times. If the documents are judged compliant, the Safety Certificate/Authorisation is realised. Compliance of the described processes with the ones actually implemented is checked after the realisation of the Safety Certificate/Authorisation through the audit activity:

we go and see if activities are carried out safely and in conformity with what is declared in the documents. Over the period of the validity of the certificate, you have to go and look through certain key principles in the legislation through an audit – apart from transparency, equity, proportion, obvious things that, however, have to be declared. Moreover, [the audit has] to be linked to the conformity assessment. Points that leave margins of doubt etc., have to be transmitted to the office that does supervision because they are the ones that will have to be monitored. In the end, here it's the same group of people that does document analysis and audits – an audit of the safety management system: verifying conformity between management procedures in practise and those declared on the certificate; auditing processes;

processes for assembling the train, for example personnel training; material maintenance; operative practise execution; inspection activities done on single elements. It's called ‘product [auditing]’. Each of these elements contributes to say: ‘[They – the undertakings and infrastructure managers] can maintain the safety certificate’ [or] ‘Careful, there is something that isn’t working’ (NSA, interview).

Let us examine the indirect risk management auditing process in detail.

Auditing

The audit activity differs from the inspection one: on the one hand, the audit focuses on the processes and the Safety Management System as a whole. It focuses on the processes that led to the product ‘train in operation’. On the other hand, the aim of the auditing activity is not to identify non-conformities, but to help the regulated organisation in structuring an effective SMS by identifying gaps and agreements with the regulated organisation’s plans in order to fill those gaps. Thus, the focus is not on the whole system, but on a specific process in a specific unit of the regulated organisation. Like the inspection process, the auditing one can be routine or extraordinary. The routine audit aims to assess each railway undertaking and infrastructure manager at least once after the issuing of the Safety Certificate/Authorisation during the five years of validity of the certificate. This audit process focuses on the aspects upon which some doubts arose during the document conformity assessment.

The audit can also be a one-off activity, an extraordinary auditing process that arose due to gaps emerging from the inspections or the accidents, incidents and near-misses analysis. In this case, the audit is intended to explore the processes which, within the audited organisation, are linked to the increased non-conformity, or lacunas highlighted by the accidents, incidents and near-misses analysis. As already mentioned, an audit differs from direct risk management activities because the aim is not, or not only, to check if the regulated organisation is providing the expected outcomes, but also to help the regulated organisations to foster processes that can ensure reaching the expected outcomes. In this sense, it is closer to training than to an assessment. Both the routine and extraordinary auditing processes follow a detailed mandatory procedure. Firstly, a formal communication announcing the audit is sent to the audited organisation; the communication specifies which process the audit will focus on. The sites on which the audit will take place, as well as the dates, are agreed upon together with the regulated organisations.

The auditing procedure requires that the managers and employees of the regulated organisation follow the procedure and, if necessary, provide additional explanations about the audited activities. The auditing ends with a meeting in which the identified gaps are discussed and the strategies to correct them are agreed upon between the auditors and the representatives of the audited organisation. The auditing process ends with writing a shared document in which the interventions the audited organisation will put in place, as well as the timeline of such adjustments, are specified. Based on such documents, a follow-up audit is performed to ascertain whether timelines have been respected, and whether the agreed interventions have been put in practise, have been checked. From such interventions the middle position of the standard logic between the control-command and risk-based approach to regulation emerge once again. Although there is a cooperative effort to find solutions that are acceptable for both regulated and regulating organisations, the regulated organisations are not free to decide which measures to enact in order to remedy the detected gap:

you send a communiqué with all the information to the undertaking, a couple of weeks ahead. Then you go and do the audit and a document is put together in a standard format, which is called the audit report. There is a meeting for conclusions with the audited [party] and an agreement is made as much as is possible for commitments. If these commitments provide appropriate strategies to address the problems, then we write them and they become commitments. Because this document is signed by us too, and so [the terms] have to be okay for me. If we don't reach an agreement because maybe the process is so complicated, the non-conformity is so great that they, rightly so, take some time to consider. And there we write that 'you will have to communicate it to us.' And we will write about non-conformity number one: 'I expect that you will inform me about what you have decided.' And the commitments have to be all right for us in the first place, because having been the ones who found a non-conformity, we can say whether that commitment effectively addresses that issue. But there has to be adherence on their part too. I cannot tell them: "In three days' time you have to organise all the documents[…]It's an agreement, a conversation with respect to the urgency of the non-conformity, its gravity and in any case, the feasibility of the issues (NSA, interview).

The important aspect of indirect risk management auditing is that it is not just an assessment. In contrast, the audit is structured as a one-to-one training session in which the regulators help the regulated organisation to understand the legal framework and put it into place.

Training

Training activities through dedicated courses and workshops is seen as extremely important. Training has become particularly important given the significant changes that affect the organisations of railway safety regulation. Such changes are depicted as momentous compared with the previous approach to regulation. They have been specifically relevant in Italy where the Safety Directive has *de facto* introduced a risk-based approach to regulation in a legislative and cultural context in which the control-command approach had prevailed. The main changes on which the training activity has focused are: the responsibility of railway undertakings and infrastructure managers on the safety of their activities; the different relationships between regulated and regulating organisations in which regulators supervise, but try to avoid limiting regulated decisions through binding and detailed rules; and the concept of risk and risk management:

with the aim of supporting railway undertakings, the Agency described the new procedures, the evaluation criteria adopted and the new planning of risk management in an appropriate course held in the months of April and May 2010, and during a specific encounter on 26 November 2010. During 2010, meetings were also set up between Agency representatives and railway undertakings with Safety Certification or who had requested to obtain Safety Certification, or in some cases with associations that represent them, illustrating the principle novelties of the new regulatory context and the more delicate themes in terms of Security Management Systems that have emerged from the supervisory activities conducted by the actual Agency. (Report on the activities carried out by the National Safety Agency in 2012 and first elements of the activities carried out in 2011 until 31 August, p. 23);

we also saw this development as an epic one you know? From the introduction of Directive 49 and all the others that have followed, we also considered it necessary to try to better explain to railway operators as well, what the principles are, what the activities are, what the conditions are to be able to formulate and define a safety management system done in a certain way. What did this require? It required that over the years there have been various information sessions, various personnel training sessions for railway undertakings, there have been conferences, there have been moments to discuss maybe particular issues, above and beyond the regular meetings that we have had with single undertakings over the course of a process of issuing Safety Certificates. But there have also been more extensive moments (NSA, interview).

The changes are considered so relevant that the training of railway undertakings and infrastructure managers is seen as essential in order to agree upon a common language between regulators and regulated organisations:

> these courses we conduct are geared toward railway undertakings who, indeed, have the task of […] diffusing … the culture of safety. The culture of safety in a way that when, let's say, we are going to write these gentlemen, at least we are using the same language, we are speaking the same language. So we can say there are various moments (NSA, interview).

To sum up, standard logic presents a middle position between the risk-based and the control-command approach. The direct risk management processes play an important role, but there is also attention paid to promoting and enforcing the implementation of risk management processes toward regulated organisations. The indirect risk management process follows three main strategies: conformity assessment, auditing, and training. However, the tangible outputs of the direct risk management process – the definition of detailed rules as an option – as well as the content of the indirect risk management process – regulating the 'how' and not only the 'what' – show the persistence of some elements characterising the control-command approach to regulation.

Possibility logic (NIB)

The core strategy the possibility logic identifies in order to reach the end of guaranteeing the safety of the railway operations is direct risk management. In contrast, indirect risk management strategies promoted by risk-based and cost-benefit logic lose relevance. More specifically, the indirect approach to risk management is looked upon with a certain diffidence and considered not enough to ensure the safety of operations. Thus, possibility logic in its practical translation of the risk-based approach, presents an imbalance toward direct risk management, even operating within and recognising some of the assumptions and principles fostered by risk-based logic. The key direct risk management strategy promoted by the possibility logic is investigation. Let us examine the content of the investigation process and the position promoted by the possibility logic on the indirect risk management strategy in detail.

Direct risk management

- Informational input

The informational input of the investigation process is the events reported by railway undertakings and infrastructure managers. Railway undertakings and infrastructure managers should report all the events that led to dangerous consequences: deaths, injuries and/or material or environment damage. In addition, all the events that don't have dangerous consequences but which, under other conditions, could lead to dangerous consequences, should be reported as well. There is a dedicated e-mail address that is constantly monitored, that railway undertakings and infrastructure managers should use in order to report dangerous or potentially dangerous events. The events should be reported as soon as possible after they happen. If the event leads to relevant consequences there is a dedicated mobile phone allowing the investigation to be activated immediately even if the NIB's office is close.

- Process

Once the events are reported, all those events are in principle examined. There is no formal obligation to investigate events that have no dangerous consequences. More specifically, the events that should be mandatorily investigated are the ones that lead to a death, five injuries, or 2 million euros of damage. Despite the lack of obligation to investigate events that do not lead to dangerous consequences, possibility logic promotes an effort not to filter out events, but investigates as many events as possible even if they do not lead to consequences. The abductive reasoning shaping and shaped by the possibility logic encourages consideration of alternative scenarios, and not filtering events according to actual, but potential consequences.

Possibility logic pushes the NIB to go beyond its institutional mandate, which narrows their activities to the events that actually have adverse outcomes. Nevertheless, this effort is balanced with the limited resources available. Thus, the principle is to carry out as many investigations as possible, no matter whether they actually lead, or could lead to dangerous consequences, given the amount of resources attributed on an annual basis to the NIB by the government. If the budget is limited, priority is given to events that should mandatorily be investigated, thus the event that actually led to dangerous consequences. However, this choice is a mandatory one structured by the institutional mandate, rather than by the assumptions and principles fostering and fostered by the possibility logic.

Once the event is reported, an investigation team is nominated. The investigation team is composed of one investigator from the NIB and other experts selected from a pre-defined dedicated list of external investigators. The operative team of the NIB is extremely limited, with a total of six people, the chief executive included. Given the limited staff resources, a list of qualified investigators with different expertise has been defined. Once an event happens, external investigators are selected from the list according to the expertise required. External investigators receive an *ad hoc* mandate for the single event. The criteria by which the list is defined is expertise, but also independence. On the one hand, the *ad hoc* involvement of external experts allows the needed expertise for the event under examination to be selected:

railways are a complex system, they touch all sectors of engineering. There is no branch of engineering that touches all of these sectors. In fact this ‘summoning’ system isn’t bad, because it allows you to utilise a specialised person in an investigation, depending on the case. For example, there are accidents in which bridges have fallen, in that case, we are dealing with civil engineering (NIB, interview).

On the other hand, the need to monitor the independent attitude of the external investigators becomes especially relevant. As a general principle, investigators should not have a link to the sector, or to the NSA in order to maintain a fair attitude and not be ‘captured’ by the potentially involved parties:

for the investigators we are careful that they are not ‘captured’ by the controlled [or ‘investigated party’]. It’s one thing though if the people have a stable relationship with us, it’s different if I give an assignment to a person, but I can check the autonomy of that person with respect to the investigated [party]. For example, if my investigator the following month wants to be hired as a consultant with Trenitalia, it’s clear that we will have to go slowly the moment in which he must investigate an accident that is related to Trenitalia (NIB, interview).

Once the investigation team is nominated, the investigation begins. The investigation’s main aim is to identify the direct and indirect causes of the event. It differs from a juridical inquiry because the aim is not to identify how to fulfil responsibilities and determine guilt. In contrast, the aim is to identify the factors that led to the event and that can be corrected in order to avoid that the event will happen again, no matter who should be blamed for the event’s occurrence. The direct causes refer to the technical failures or human errors that triggered the event. The indirect causes refer to the assumptions that those technical failures or human errors happen within an organisational setting that can favour, instead of limit, the possibility of such technical or human failures. Thus, the inquiries do not stop once the trigger of the event is identified, but explore the factors that are not linked through a direct causal link to the event that makes the situation prone to the occurrence of the identified trigger.

For example, the direct cause of a door malfunctioning event, can be an error during the maintenance of the door. The investigation does not stop at identifying the maintenance error as a direct cause, but examines why this error was possible. Thus, it would consider whether the workers were correctly informed about the maintenance procedures, if a document exists in which maintenance plans are specified and if this document is actually available and easy to find by workers. All those factors that are not directly linkable to the maintenance error, but that could favour such an error, are indirect causes of the event the investigation aims to identify and correct. Basically the two main statements possibility logic identifies as key driving principles guiding the investigation process are, on the one hand, that the investigation is not the collection of evidence for a juridical trial and does not pursue the end of attributing blame and responsibility. On the other hand, the investigation does not stop once the technical failure and the human error are identified, but looks at the factors that favour the occurrence of such technical failures and human errors.

Considerable effort is made in order to ensure that the investigators fully understand the statements that should drive their view on the event during the investigation process. The process is not easy and the risk of focusing on blame attribution or direct causes still exists. The role of the internal investigators is to monitor the external investigators' activity in order to, if needed, reframe their views through those two principles. Nowadays, the training process is based on a one-to-one relationship between internal and external investigators. Nevertheless, given the observed difficulty to change investigators' approaches to those matters, the NIB is planning training programmes dedicated to external investigators:

> in the end having these problems with investigators we decided to take courses ourselves, geared toward two categories of people: investigators and trainers for investigators […] Now the approach is a bit one-to-one. In the course on investigative research, you try to correct the aim of the single investigator who reports to us. But it is something that takes time and so we decided to organise the course here (NIB, interview).

The investigation process is followed, through regular meetings, by all the NIB's staff. The external investigators in charge of the investigation under examination, the

NIB’s internal investigators, heads of units, and the chief executive attend those meetings. The event is discussed in detail and different opinions and views on the event’s causes, dynamics and possible alternative dangerous scenarios are examined. All the participants have an overall view of the event. Unlike the case of standard logic, the process does not synthesise or filter the available information in order to facilitate and support managers’ decisions, but the details of the event’s possible causes and dynamics are presented and discussed, and managers participate directly in the event analysis.

Before formally delivering the investigation report and the recommendations, the NIB meets all the interested parties such as, for example, the railway undertakings and/or infrastructure managers involved; if the event led to fatalities, the families of the victims; and the NSA. During such meetings, the identified causes of the event, as well as the different developed lines of inquiry, are presented and discussed. The meetings with the NSA are specifically relevant. As already mentioned, the recommendations are addressed to the NSA, and it is the NSA that decides if further action should be undertaken within the sector.

- Tangible outcomes

The tangible outcomes of the investigative process are the investigation reports in which all the identified causes and the event’s dynamics, and the recommendations that are suggested for improvement, with reference to the lacunas the inquiry highlighted, are presented.

Generally, the content of the recommendations, following the risk-based approach, tries to be sufficiently open in order to allow infrastructure managers and railway undertakings to make their own decisions on how the identified problem should be faced. Thus, for example, I can recommend that the way in which the maintenance plans are managed should be revised in order to facilitate the workers in consulting them, and guarantee that they are constantly updated. But I cannot ask them to manage those document in a specific way, such as to store the document in the maintenance workshop, according to the type of vehicle, or contact the producer every day in order to be sure that the maintenance plan is correctly up to date. As for the standard logic, sometimes recommendations can be quite specific, such as identifying a technological device to face this problem, or inserting a certain variable, in order to better calculate the maintenance plans. However, as a general trend, the principle fostering and fostered by the risk-based logic about the free decisions of railway undertakings and infrastructure managers in order to face the identified issue, is endorsed and translated into practise in defining the recommendation contents.

In conclusion, given the method of reasoning developed, the process of direct risk management developed by the NIB is closer to the imagination worldview on risk management than the anticipation one. (See, Part 1, Chapter 1, Section 1.2.)

Indirect risk management

Indirect risk management strategies promoted by the risk-based, cost-benefit and standard logics are generally seen from the possibility logic's point of view with certain diffidence and concern. A specific concern refers to the certification process, which promotes a focus on the form rather than the content that the possibility logic tries to avoid and discourage. In addition, the assumption that the SMS and the certification process assessing it can be a guarantee of the safe functioning of the operation promoted by the risk-based and cost-benefit logics, is questioned. More specifically, the fact that there is a certificate attesting that certain processes are developed, does not constitute a guarantee on the outcomes of such processes:

when something is certified, it's not enough for us. Certification occurs through formal processes. Safety Certification is a bit like the whole world of quality (ISO 9000 – 9001), quality control: for us it matters little, we are sceptical in that sense. We have an external vision with regards to certification […] We are aware that at a certain point the fact that a subject is certified tells me very little. For example for ECM (Entity in Charge of Maintenance) certification, the subjects that do maintenance are chosen by the Keepers (wagon owners), so I can choose a subject because it costs me x. Moreover, it ensures a revision, puts a stamp on and I'm okay. Consequently, I tend to take some distance from what I'm doing. If an element of the chain of responsibility [between the network of organisations involved in operating and certifying the railway sector] comes less because he's delinquent, I am unaware [of this] if I look only at the formal processes. With this certification system am I giving people safety? Obviously, there will be roles, profiles of responsibility, etc. But I am also risking that there are professional signers. Certifying can become a profession without anyone really knowing what is happening (NIB, interview);

regarding certification, the risk is that it becomes a bit like a quality brand for the company in the beginning. A consultant arrives that says: "You're missing a quality manual, here is your quality manual." You understand it's unlikely that the manual will be shared, it's not a product of the company, you risk losing the sense of the real content of the processes (NIB, informal talk).

The potential dangerousness of the focus promoted at the politico-economic level on regulating the process – the 'what' – rather than the content – the 'how' – as well as the need to look at the content rather than the process, is also stressed in official documents such as the annual report:

in 2013, the concept of quality certification is still defended despite repeated accidents that originated right in the heart of the ECM 'certified' [parties], continuing to reveal itself as a concept dangerously empty on a real level. The Investigation Body has in fact a real perception of the gaps still existing in the maintenance plan, being involved in investigative activities that blatantly have the same atavistic origin in the normative/regulatory gap, which came to the surface from the investigation into the Viareggio accident (NIB, Document, Annual Report, 2012, Director General's Preface, p. II);

I'm pushed to underline a principle that guides the recommendations which emanated after the Viareggio accident: it's not merely about perfecting a chain of operative praxis and so only 'better identifying a chain of responsibility' but it's about avoiding, in a concrete sense, that disasters of this magnitude can happen avoiding therefore the risk – *de facto* – of a 'chain of unloading' of responsibility through processes of certification that are vulnerable when not misleading or inconsistent (Annual Report NIB, 2011, p. 4).

In summary, possibility logic presents an imbalance toward the direct risk management approach and depicts the strategies of indirect risk management as potentially dangerous and not fitting for the purpose of ensuring the safety of the operation.

The three logics present three different equilibriums with respect to the direct and indirect risk management strategies. An examination of the tangible outputs of the direct risk management process, as well as of the content of the indirect risk management process, allows us to situate the three logics with respect to the risk-based and control-command approaches to regulation. More specifically, the cost-benefit logic is the one that offers a practical translation of the risk-based logic closest to this logic. On the contrary, both the standard and the possibility logics, offer a practical translation of such logic that is in between the risk-based and the control-command approaches, even if it recognises and implements some of the assumptions and principles fostering and fostered by risk-based logic.

Structure

In order to examine the structural indicators of the organisational component, we refer to the typology of coordination strategies described by Thompson (1967): coordination by standardisation, by plan and by mutual adjustment. (See Part 1, Chapter 2, Section 2.3.) First, we consider the coordination between the three organisations studied within the network, then we look inside each organisation. Given the prevalence of three different logics within the three organisations studied, an examination of the coordination strategies developed within each organisation is relevant in order to explore the contributing role in shaping the three context-specific logics, keeping in mind the various institutional orders' logics, and the organisational structure in which such logics interplay.

With reference to the coordination between the organisations studied, the railway regulatory network has a hierarchical structure in which the supra-national level tends to prevail on the national one. Nation-states should apply the regulations delivered at the European level and adapt the EU directives[68] delivering national implementation measures[69] that respect the principles and requirements specified in the directive. The NSAs and NIBs are linked at the national level to the nation-state government as well. In Italy, the Ministry of Infrastructure and Transport monitors the activities of the NSA and the NIB by receiving regular reports on on-going activities, as well as by giving some general indications about the objectives the NSA or the NIB should reach on an annual basis. This monitoring activity should not

[68]The definition of a directive given by the European Commission is 'EU directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so. Directives may concern one or more EU countries, or all of them […] Directives are used to bring different national laws into line with each other, and are particularly common in matters affecting the operation of the single market (e.g. product safety standards)' (European Commission, http://ec.europa.eu/eu_law/introduction/what_directive_en.htm, Website consulted 11 June 2014). The difference between directives and regulations is that regulations enter into force directly; directives should be adapted to the national legislative framework by the Members States through national implementation measures.

[69]The definition of national implementation measures given by the European Commission is 'texts officially adopted by the authorities in a Member State to incorporate the provisions in a directive into national law. All such texts sent to us by national authorities are scrutinised to ensure that they will actually implement in that Member State all the measures required in the directive' (European Commission, http://ec.europa.eu/eu_law/directives/directives_en.htm, Website consulted 11 June 2014).

conflict with the content of regulations and directives. Being a kind of technical unit of the European Commission, the ERA is the organisation in charge of coordinating the various NSAs and NIBs operating at the nation-state level. The main coordination strategy developed by the ERA is coordination by standardisation: definitions and enforcement of general principles, and processes.

The standardisation of the processes implemented by the various NIBs and NSAs refers, for example, to the specification of the elements that should be checked by the NSAs in order to deliver Safety Certificate/Authorisation. The standardisation of processes for realising a Safety Certificate/Authorisation is also considered a first step in order to reach a unique certificate valid across Europe without national specification, nowadays contained in the Part B Safety Certificate/Authorisation. Currently, the Part A Safety Certificate is still realised at the nation-state level, but it is valid across Europe. Consequently, a railway undertaking that obtains a Part A Safety Certificate in Italy, for example, and wants to undertake transport in Germany, does not need to be checked again on the pre-requisites affirmed in Part A of the Certificate, but only on Part B, which contains the specific requirements of the German railway network. Thus, the application of common processes for releasing Part A Certificate/Authorisation is seen as critical in order to maintain a common level of safety across Europe.

The standardisation of principles aims to create the basis for a common understanding and implementation – not all the activities and situations can be standardised by process specifications, thus the presence of common shared principles to refer to can orient decisions even when there is not a formal procedure to follow – of risk-based logic. Such common understanding and implementation is considered a prerequisite in order to ensure equal treatment of railway companies across Europe, as well as a guarantee in order to preserve free market entry for newcomers. The main strategies developed by the ERA in order to pursue a common standardised approach to regulation across Europe are:

- The networking – both NIBs and NSAs participate in dedicated networks organised and coordinated by the ERA. The NIBs and NSAs networks meet respectively four times a year. The idea of the networking activities was that over time the different NSAs and NIBs would converge on a common understanding and common implementation of the regulatory strategies adopted at the EU level. The network would work as a trigger for the exchange of best practises and practical implementation of EU legislation that would lead to a common EU approach to safety. Recently, this sort of natural convergence through networking has been put into question within the ERA given the persistence of important differences between various NSAs and NIBs;

- The definition of guidelines relating to NSA activities – the guidelines regarding conformity assessment and supervision. The guideline on conformity assessment defines what NSAs should check in order to realise Part A of the Safety Certificate. Conformity assessment should be based only on the documents the applicant submits describing its Safety Management System on paper. Guidelines on supervision refer to the methodology that NSAs should use during auditing activities, as well as the criteria upon which the audit activity programmed is based. The audit should follow the issuing of the Safety Certificate, and aims to check that the process described in the document submitted during the conformity assessment is actually developed in the everyday activities of railway undertakings and infrastructure managers;
- The definition of guidelines about how the NIBs should conduct investigations – which criteria should drive the opening of an investigation, as well as the information that the investigation report should contain;
- The training programme – different training programmes are realised in the different nation-states in order to explain and enforce the risk-based approach to regulation shaping and shaped by the risk-based logic. The training sessions are open to the sector and the regulators as well;
- The NSAs cross-audits and NIBs voluntary assessments – the audits and the assessments check the correspondence between the NSAs and NIBs activities and the specification about such activities given by regulations, directives and guidelines. The cross-audit program involves auditors from the ERA, as well as auditors from other NSAs. The purpose of such involvement is to increase the trust between NSAs in order to avoid that the requirements of the Part A Safety Certificate/Authorisation are re-checked when a company operating in a nation-state asks for a Certificate/Authorisation in another Member State. The NIBs assessment is made on a voluntary basis. This is because the ERA does not formally have a mandate from the Commission to monitor NSA and NIB activities. Some NIBs do not participate in the assessment program because it is seen as a threat to their independence. As investigators, they should be independent from the ERA as well, because an investigation could lead to a contestation of the EU legislative framework and such a legislative framework is *de facto* defined by the ERA. Consequently, an assessment of NIB activities performed by the ERA could lead to the anomalous situation in

which the monitored organisation checks the performance of the organisation in charge of monitoring its activity.

Standardisation pertains the information NSAs and NIBs should provide to the ERA as well. Both NSAs and NIBs should send a report to the ERA annually on their activities and on the nation-states' safety trends. The content of those reports are predefined by the ERA. The same pre-definitions affect the content of NIBs investigation reports. The information collected through this annual and investigation report is then published by the ERA in a dedicated database. All railway actors are free to consult those databases. The ERA does not analyse the content of such reports and investigations, but checks the conformity of the report with the requirements about what a report should contain. Therefore, the ERA's use of that information is limited to checking the standardisation of the NSAs' and NIBs' approaches, but not to considering the content of the reports as a starting point for a direct risk management process.

To sum up, the formal coordination strategy between organisations within the network is a top-down one, in which the organisation located at the top defines the standardised processes and principles the organisations located at the nation-state level should apply. Formally, a bottom-up coordination is not defined: there is not a distinct process within the network through which NSAs and NIBs can present issues to the ERA and, through the ERA, to the Commission. This top-down coordination strategy is linked to the deductive reasoning driving the implementation of risk-based logic: this is the best way in which things can be – common EU market open to competition with common safety standards – and those are the best ways to reach it – safety management system, anticipation approach to risk management; processes instead of detailed rules and definitions; responsibility of the safety of operation on infrastructure managers and railway undertakers; etc. Thus, here is where we should go and this is the way to go there. I do not need to check if the risk management process I define works, because this is the right way in which the possible side-effects of the railway transport should be managed. With this principle in mind, the cooperation of all the actors involved is pursued. The aim is to reach a shared approach in which all the actors give their contribution, but such a contribution should be driven by the principles and the ends fixed by risk-based logic.

Nevertheless, despite such a formal top-down approach, in the interstices of formal coordination strategies, a different form of coordination takes shape. These informal coordination strategies are close to Thompson's (1967) definition of the mutual adjustment coordination ideal-type. If we look at the relationship between the ERA and the Commission, as already mentioned, the starting point of any ERA activity can be exclusively a formal Commission input. The ERA can intervene only in the presence of such a formal mandate. Nevertheless, as already mentioned, it is *de facto* a two-way relationship in which the ERA can informally suggest to the Commission the need to work on a specific issue, or inform the Commission of on-going trends affecting the railway sector. Thus, informally the coordination between who decides – the Commission – and the implementation body – the ERA – follows a mutual adjustment coordination strategy.

The same process can affect the relationship between the ERA and NSAs and NIBs as well. The working groups, focus groups and network meetings are occasions in which NSAs and NIBs can raise issue that the ERA and the Commission should address. In this case, it is also an informal process, as the ERA has no formal mandate to present issues coming from NSAs and NIBs to the Commission. When this intervention is directly asked for by NSAs or NIBs, the formal answer of the ERA is always: our role is not to lobby the Commission about issues raised by NSAs and NIBs, you are invited to contact the representatives of your Member States for any issues you would like the Commission to consider. Again, in those interactions an interchange based on mutual adjustment coordination is *de facto* in place. Those interchanges are not formally recognised, thus there is no process to follow orienting the decision on which issues should be addressed and which should not. Consequently, those informal context-specific interactions are relevant in order to understand what is the degree of legitimacy of the available logics in filtering relevant issues in or out.

More specifically, which issues are filtered in, and which filtered out, during such an informal process of defining what is a relevant issue and what is not? In those interactions, conflict between the different logics becomes evident and allows the degree of legitimacy of the different logics to be explored. We come back to this conflicting logics interaction in the next chapter, dedicated to the coercive-normative component. Now let us look within the three organisations studied, in order to examine which coordination strategies are developed by the three organisations.

Cost-benefit logic (ERA)

The coordination strategies prevalent within the ERA are coordination by standardisation and mutual adjustment.

Given the variety of arguments that the ERA's activities could address, standardisation refers partly to the process to follow, but above all the principles and objectives that should lead those processes. Standardisation is pursued by enforcing standardised ends and clarifying the priority-scale of those ends: the end of any activity is the development of a common European market; in order to reach this end, the second order objectives to pursue are interoperability and railway market liberalisation and development. In pursuing these objectives, the current level of safety should be maintained. For example, if I am evaluating the adoption of a control measure that can reduce the frequency of a risky event, the first question I should answer is not whether this measure will improve safety levels, but if this measure is compatible with the objectives of interoperability and market development and liberalisation. If it is not, then I should evaluate whether the safety level will decrease without this measure. If not, even if the measure could guarantee an improvement of the safety level, I will not adopt it. Consequently, the safety objective in itself is a third-level objective after interoperability and market development. The priority-scale between potentially contrasting ends is clearly fixed, and the standardisation of this scale is one of the main ways through which coordination is pursued. The instrument through which such an evaluation of increasing/decreasing/stability of the safety level should be assessed is in the cost-benefit analysis.

In 2012, one hundred and thirty-nine people were employed by the ERA. They were divided into five operational units, one administrative unit and two units working closely to support the executive director (ERA, 2012, Annual Report, p. 83). The ERA's organisational chart shows (see Figure, 43) how the different ends shape the operational unit's task definition.

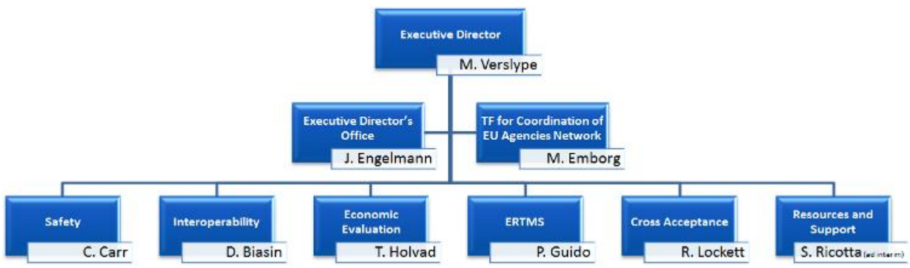

Figure 43: ERA's organisational chart[70]

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[70]ERA, http://www.era.europa.eu/The-Agency/About-ERA/Pages/Organisation.aspx, Website consulted 31 March 2014.

The economic evaluation unit is *de facto* transversal to other units operating in close continuity with them, in order to evaluate the economic impact of any recommendation the ERA sends to the Commission. Each unit has a point person in the economic evaluation unit that constantly cooperates with this unit. The interaction between different units is frequent, and it is based on coordination by mutual adjustment strategies. People working in the safety unit informally contact people working in other units quite often; the main close relationships are with the interoperability unit. This is in continuity with the priority scale the activities should follow in evaluating a safety measure: I should verify that it is not in contrast with the interoperability end. Even if coordination between units does not actually happen with informal or formal contacts, the coordination is still pursued by members of the safety unit by referring to the shared priority-scale: even if I do not meet with a member of the interoperability unit in order to evaluate a safety measure, I know that the measure should not conflict with the objective of such a unit.

Standard logic (NSA)

Within the Italian NSA, the main coordination strategies are coordination by standardisation and by plans. Coordination by mutual adjustment should ideally be limited to as little as possible. The importance of having standardised and planned activities is seen as extremely important: the proper way in which organisations should be coordinated. The organisation is divided into six main operational sectors: institutional relationships; operational rules; technical standards; certification and authorisation; inspection and control. (See Figure 44.) A total of 98 people were employed by the NSA in 2012 (NSA, 2012, Annual Report, p. 13).

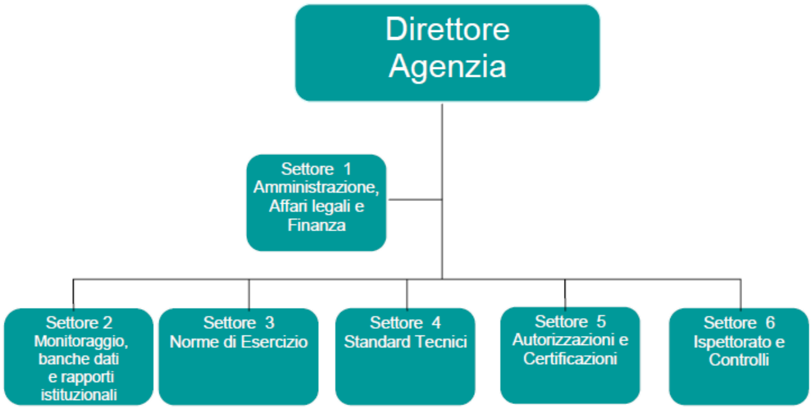

Figure 44: Italian NSA's organisational chart (NSA, 2012, Annual Report, Annex B1, p. 79)

All the activities are planned by the sector heads and approved by management; the activities carried out in cooperation with different units are coordinated through the definition of clear and fixed deliveries, standardised processes, and standardised instruments. For example, the assessment process for Safety Certificate delivery is shaped in different units each one in charge of checking the conformity of the processes described in the documents produced by the applicant with the requirements for a specific part of the certificate. For example, the assessment of the processes of risk management is done by a team located in the inspectorate and control unit. The responsibility of managing such activities is with the certification and authorisation unit, which is the unit in charge of Safety Certificate/Authorisation delivery. The management of this unit contacts other units, sending the documentation they are in charge of checking and the deadline by which it should be checked. Each unit involved sends back their feedback, following the deadline established by the certification and authorisation unit. The certificate and authorisation unit, after having evaluated all the feedback, decides if the Certificate/Authorisation can be delivered or not. The assessment activity is driven by standardised check lists, specifying all the elements that should be checked and which unit should check them.

The 'by plan' and 'by standardisation' coordination is linked with a strong centralised and hierarchical approach:

physically we are placed here where we are, we don't have a territorial structure. That is, there are outlying offices where we have colleagues distributed throughout Italy, but they have no autonomy for taking initiatives, that is, they are based there but what they have to do day by day always comes from here (NSA, interview).

The decisions are all made at the top-management level, the top managers decide on the basis of the information coming from the units in a synthetic manner and in a standardised form as much as possible. For example, we already mentioned the inspection report that is delivered every three months by the inspectorate and control unit. The report is defined in order to constitute a decisional support system, presenting the inspection results in an aggregate, synthetic and easy to read predefined form. All the relevant information should reach top management, in order to allow management to make decisions that should not be made at the lower level of the organisation: the decision is not a collective decision, analysis and decisions are both linked, but separate moments. For example, with regards to the decisions regarding interventions following incidents, accidents and near-misses analysis:

then the final decision rests with the section head, that is, this is all the evaluative part on which the section head decides whether or not to activate an inspection or an in-depth analysis. So there is a decisional process that is led by the responsibility [of the section head], but let's say on the basis of elements that every day are part of this job.
Question: And have you ever been held a different position on whether to do an in-depth study or an analysis, or not?
No, but since the decision isn't collegial, but a decision of who decides: the section head. Obviously, he is always in agreement with himself, so it's clear that the technician provides a whole series of elements then the final decision is made by the person who is responsible for doing it and so it is situated there. Then he can more or less take into account the technical part that is suggested to him, but he can also decide to do differently from what was proposed to him by the person who does the analysis. Normally it doesn't happen because these are people who do this as a job, but something different can happen and is indeed part of the prerogative of he who decides (NSA, interview).

The strong accent on hierarchy tends to discourage individual initiative leading to deference to the hierarchical roles that prevail on the ends of the regulatory activity. Employees located in the lower hierarchical positions should follow the opinion of the ones located in the higher ones:

obviously, you will know how to discern between those that are [official positions] and those that are my opinions, then I reiterate eh, reiterate, do as you're told regardless. So if my boss [...] I in any case how can I say, I allow myself to express these points of view, because they are the points of view. Then maybe I am emphasising them eh, but this is the position of the

Italian National Safety Agency. That is, if the director [...] – who is a person who is clearly keener than me – were here, he would tell you the same things, but clearly in less emphatic terms, but [he] would tell you the same things. If my director instead said: "But, instead we have to do it like this", I would tell you what my director would tell you. And it is all marginal the fact that I share [the opinion] or not, it doesn't mean being without an opinion, it means being respectful of the role (NSA, interview).

The discouragement of individual initiative and the importance of staying within the limits of each single role is defined and presented as the correct behaviour to follow. For example, the right behaviour of an investigator is to limit activities to the planned assessments and follow the pre-defined check-list. If investigators identify other elements that could be relevant for the regulatory activity during an inspection, they can report them, but this behaviour is not encouraged as the systematic organisation of the supervision activity should prevail over the intuition of the front-line operators. Thus, front-line operators can retroact on the structured activities, but such retroaction is discouraged and in any case should follow a formal mandate given by top managers:

Question: But, for example, can an inspector take his own initiative?
No let's hope not, let's really hope not. He can suggest a need to the branch in charge of his office [moving up the ladder] to the point of calling the section head and telling him: "In my opinion here there is this situation", but he doesn't decide where to go, absolutely not. This is because really it has to, in any case, fit into a mandate. So there has to be someone in charge that makes that decision […] I call my boss and I say: "I'll go take a look" after I've communicated this to my superior. Your superior will say: "Go have a look right away" rather than "let it go" rather than "help me understand better" […] If he finds himself, in his opinion, having to deviate from process in his own way, he shouldn't do it if he doesn't receive authorisation first […] We try as much as possible, especially regarding regular activities, to always monitor [what is being monitored by inspectors]. Then let's say there will always be a case we can't explain today, that a man who is there sees. He highlights it and was right to highlight it. But we tend to discourage this type of behaviour. You go and do your planned activity. If there are exceptional issues it has to really be common sense – it's no longer even a case of being an agency inspector […]. Because the problem is that for heaven's sake, we are good and keen but the Agency has objectives. If I go on my own initiative and look at what I want, I could instead underestimate something that instead should be important to check. Because in this business the activity doesn't stop there, it's not that I went there to say: "good" or "not so good", this is not the purpose, it's what comes after that. It's safeguarding safety. So it can't be left to the person who sees that little piece

of world, there has to be a decision from a senior position that says that little piece of world is together with a series of pieces of world (NSA, interview).

To sum up, the NSA’s main coordination strategies are by plan and by standardisation. In this case, the coordination strategies are linked with a strong emphasis on hierarchy and centralisation. Such an approach tends to discourage individual initiatives limiting the possibility for front-line operators to retroact, informing the standardisation of activities with new elements.

Possibility logic (NIB)

The main coordination strategy pursued by the Italian NIB is coordination by mutual adjustment. Formally, the organisations’ activities are separated into two divisions: international and institutional relationships and the database administration division; and inquiries on incidents and accidents division. (See Figure 45.) Hence, such a distinction is just a formal one because the employees assigned to the two divisions follow different tasks simultaneously. The organisation is composed of a very close and small group: four people employed in operative tasks plus the executive director in 2012. In addition, as already mentioned, a list of selected investigators is used on demand if additional expertise is required to investigate an accident, incident, or near-miss. Constant interaction and exchanges of information is the basis upon which coordination of the group is pursued. For example, there is no fixed procedure on the way in which an investigation should be conducted, or any pre-defined deadline. During the meeting in which the case under examination is discussed, the need to involve external experts or to investigate new aspects of the event is considered contextually. Proceding with the investigation process is based on information that emerges and is shared and discussed by the entire group.

Figure 45: NIB's organisational chart (NIB, 2012, Annual Report, p.2)

The emerging information and issues are constantly discussed within the group. During such discussions, conflicting views and opinions often emerge. The hierarchical element is not as stressed, as the management trusts the front-line operators and values their opinions. Interactions is described as even too frequent, the executive manager is involved in the everyday activities and follows the investigation process closely participating in meetings and, in some cases, also going to the incident scene with the investigators:

ok, the apexes are always placed there politically, but the apexes should have good advisors. For example, our Director is capable because he knows that on technical things he has to trust [others] (NIB, informal talk);

[with the Director] we have quite a few different points of view, especially with regards to technical things. He is not from the sector, the more he wants to be a technician the more difficulties there are. He should be a manager, if he lowers himself to my level there are problems, but it doesn't happen very often. For example, investigators […] come here and they show the different phases of the investigation, he participates because he's interested, this is a good thing. I think it's also a matter of the fact that our structure is very lean and interaction is maybe too easy (NIB, interview).

Individual initiative is encouraged, conflicting views are not seen as a problem, but as enriching. The constant interaction and the small dimension of the group creates the familiarity that makes the hierarchical differences less significant. Consequently, everyone can give his or her opinion, even if it contrasts with the opinion of one of the people with a higher role in the hierarchy. The expected behaviour is not to be compliant with the opinion of others, but to give one's own original contribution to the discussion. There is not one shared way of thinking, but a commitment to the core mission of the organisation:

there is a basic shared approach, but not a single thought. We disagree often and we often have different opinions, we have that independence that if [someone's proper name] finds something he doesn't like he can say it, and can do it, and can study it in depth, and is in the position that nobody can tell him: "You don't analyse this thing" […] We happily send each other to hell, we disagree very easily, we aren't a cohesive group in the sense of a single thought, but there is a shared basic approach, but not a common way of thinking. [someone's proper name] and me often disagree, we often have different opinions. If our group were very cohesive in my opinion, we should be worried. The process that is in place now is that individual independence is the responsibility of the Director General. This doesn't take away from the fact that we still have that independence so that if [someone's proper name] finds something he doesn't like, he can say it, and can do it, and isn't risking anything. He can do it (NIB, interview);

You see, what we say is never assertive, absolute. We proceed by successive conjectures, we discuss issues and cases together. Exchanges of opinion take place because that way we acquire other points of view and enrich ourselves on the content and, therefore, we write recommendations and we find ourselves advantaged by the exchange. It's a search for the central point, for successive conjectures: we look for a common point of view, full-formed and of greater substance (NIB, interview).

In summary, the Italian NIB strategies remind us of an organisation with the 'tight coupling around a small number of core values and loose coupling around everything else' described by Weick (2005: 433) as a prerequisite to imaginative reasoning. (See Section 1, Chapter 1, Section 1.2.)

This chapter shows that different logics are available within the network: the risk-based logic prevalent at the politico-economic level, and the cost-benefit, standard and possibility logic prevalent in the three organisations respectively studied at the inter-organisational level. Logics differ significantly between them. The cost-benefit logic is closer to the risk-based one; in contrast, the standard and possibility logics offer a different practical translation of this logic, which moves away from some of the principles and assumptions promoted by such a logic. The main difference between the national and supra-national level of governments are risk definitions and identified missions. More in general, the difference between the three logics has to do with the methods of reasoning, the strategies and processes developed in order to fulfil their mission, as well as the organisational structure in which such processes and activities are developed. The next chapter is dedicated to the degree of legitimacy of those logics by looking at the interplay between them in context-specific interactions.

2. Logics interplay and degree of legitimacy

The previous chapter described the content of logics prevalent within the railway regulatory network. Three different logics prevail within the three organisations studied. Those logics differ between each other conflicting on risk definitions, methods of reasoning, mission characterisation, as well as organisational processes and structures. Consequently, the three logics conflict with each other in orienting the network regulatory strategies. Here we aim to examine the logics interplay in detail in order to clarify which logic, of the three identified ones, tends to prevail on the others. First, we will discuss the prevalence of one logic over the other ones within the organisations. Then, we will examine the logics interplay by looking at the interaction between the three organisations studied. This will be done by taking into consideration the situated interactions between members of the three organisations, as well as the role of the network structure in favouring one logic over others, by assigning decision-making responsibility to the organisations in which the logic is prevalent.

Looking at the prevalence of one logic within one organisation, the term prevalence aims to stress that there is not only one available logic within the organisation, but even if all the logics are available within all the organisations, one of them is more legitimate and legitimised than the other ones. In all the organisations studied – the ERA, NSA and NIB – traces of all the identified logics – cost-benefit, standard, and possibility logic – are present, but one logic over the others deeply orients the regulatory approach. For example, saying that the cost-benefit logic is the prevalent logic within the ERA, does not mean that other logics are not present or available in this organisation. But it means that the cost-benefit one is the most legitimate and strongest one, and that it is the one that orients decisions and actions by prevailing when other points of view are expressed. The prevalence of one logic is not necessarily related to the number of people that sustain it. On the contrary, even if a limited number of people sustain one logic, the hierarchical position, or the personal recognition and charisma of such people can orient the organisation's decisions and actions following the specific logic they sustain. Thus, when a decision is made, their point of view counts more than that of the others.

The relationship between logics and people that support them, is a two-way street: the more a person sustains a logic, the more the logic is reinforced and, at the same time, the more the logic is reinforced, the more the person is reinforced as well. To establish the direction of such a link is extremely difficult. Also given the limited time of the research, it is very difficult to understand if it is the legitimacy of the logic that reinforces the position of the people that sustain it, or if it is the characteristics of the people that sustain a logic that gives legitimacy to that logic. In any case, once the mutual legitimacy mechanisms between logics and people starts, it tends to persist in orienting the organisations' approach, as well as the reputation and consideration for the people sustaining the orienting logic.

The characteristics of the people involved in this mutual legitimacy mechanism vary within the organisations studied. Within the ERA the people supporting the cost-benefit logic, whose opinion is more considered, are mainly professionals in the risk management field – engineering mainstream anticipatory approach to risk management (see Part 1, Chapter 1, Section 1.2) – and more generally people with an employment background in private companies especially from the railway sector. Legitimacy is linked with having a view closest to the sector's one, that is, being able to understand the value of the cost/benefit ratio for the company's survival and development. Within the NSA, logic legitimacy is closely related to the hierarchical position that the people that sustain it occupy within the organisation. The hierarchical superior promotes the logic others should follow. Within the NIB, the expected behaviour is to be compliant with the core value shared by the organisation, and perceive your work as a mission. Commitment to the work is the most valued element legitimating the expressed opinions. At the same time, if people supporting the prevalent logics are legitimate, people not fully committed to the prevalent approach are in some way marginalised, and their opinions and activities count less than the ones of the people sustaining the prevalent logic. In conclusion, despite the mechanism underlining the legitimisation process, a specific logic tends to orient actions and decisions in the three studied organisations. In order to understand which logic tends to orient decisions within the network, thus prevailing on the others, we decided to look at both the situated interactions between the three organisations studied and oriented by the three logics, as well as where the decisions are structurally located in the network.

The importance of situated interactions in order to understand the degree of legitimacy of the available logics is specifically relevant because it is an instance when two different logics conflict with each other in a situated interaction that, in accordance with the interpretations, actions or decisions that prevail, the force of one logic over another can be seen. Thus, we pay attention to the context-specific interactions between the organisations under study in order to understand which weight the available logics have in fostering regulation of the railway sector. Situated interaction is related to coordination by mutual adjustment within the regulatory network. We specifically examine the situated interaction, on the one hand, between the ERA and the Italian NSA, and on the other hand, between the ERA and the Italian NIB, which occurred during workshops, working groups, focus groups and NIB and NSA network meetings.

With reference to the interaction between the Italian NSA and NIB, we consider the meetings between the two organisations taking place before the formal emission of the recommendations following the investigation of accidnents, incidents and near-misses by the NIB. During those situated interactions, different opinions referring to the various logics emerge, and the prevalence of one opinion over another allows the strength and primacy of one logic over another to be understood.

An examination of the situated interactions indicates that the cost-benefit logic is the most resilient one, and tends to prevail over the standard and possibility logics when the organisations supporting such logics interact. Moreover, the standard logic tends to prevail over the possibility one. The prevalence of one logic over another depends on various factors affecting the situated interactions. During observation of those interactions, we identified some factors that contribute to the prevalence of one logic over the others:

- The charisma of the person who sustains a position supported by one logic, as well as the way in which the person is able to exert that charisma in presenting his or her argument within the specific context in which the interaction takes place. For example, the language used during the working groups, and NSA and NIB network meetings are mainly English and in some of the meetings French or German. Thus, the Italian NIB and NSA cannot promote their point of view in their mother tongue. The presented opinion appears confused and not well sustained because of the difficulty of expressing the concept in a language that is not the mother tongue. Consequently, the charisma of the person doing the speech, and the rhetorical quality of the given speech can be affected by this linguistic barrier. The way in which the opinion is presented affects the weight given to the content of the speech and consequently to the logic sustaining it;
- The audience attending the meeting in which the situated interactions happen. For example, if the meeting involves the sectors, the NSAs and the ERA, the positions of the sector and of the ERA tend to reinforce each other, thus the opinion sustained by the cost-benefit logic tends to prevail;
- The proximity of the logic with the politico-economic level logic – risk-based. The cost-benefit logic prevalence is related to the close continuity between such a practical translation of risk-based logic and risk-based logic in and of itself. Cost-benefit and risk-based logic share most assumptions and

principles. The politico-economic level constitutes a source of legitimisation of the context-specific logics, it being the general framework orienting the regulatory approach to the sector. Thus, reference to principles and assumptions fostered by risk-based logic constitutes a strong argument in order to support and pass on the expressed opinion or concern;

- The degree of legitimacy the principles and assumptions sustaining the logic have with reference to society as a whole. For example, some of the key assumptions of cost-benefit logic are that in order to present an issue or a problem, that issue or problem should be sustained by evidence and data. In order to be recognised and classified as an issue or problem, the issue presented should be based on certainty – deductive reasoning – or high probability – inductive reasoning, with a relevant number of empirical references. Such principles and assumptions are close to the one driving the hard scientific approach, and the definition of what is scientific and what is not. Consequently, such proximity retroacts on the cost-benefit logic, thus reinforcing it, and on the standard and possibility logic weakening them. This reinforcement process is quite strong and follows taken-for-granted ideas about what is scientifically grounded and, therfore, true, and what it is not, and therefore, false. To put it simply, it is common sense in this context to trust an argument or opinion more when expressed through data, evidence and numbers – deduction and induction with many empirical references, cost-benefit logic – than an opinion expressed on the basis of a single case – induction from a single case, standard logic – or than an opinion expressed through pieces of information, clues, and sensations – abductive reasoning, possibility logic. In addition, science reminds us that numbers are reassuring, and favours accountability;
- The possibility to argumentatively defend, a reasoning sustained by certain logics during a debate; inductive reasoning on a single case, and abductive reasoning, are less argumentative and defendable than deductive reasoning and inductive reasoning in many cases. Thus, cost-benefit logic tends to prevail. More specifically, cost-benefit logic allows the argument to be presented in a more systematic and simple way. The systematic and simple nature of the argument makes it easier to explain and easier to understand. If I have a likelihood, I can sustain my argument by presenting a number, if I do not have a likelihood I have to present a plausible scenario and make a specific effort to persuade the audience of the plausibility of my scenario, or of the possibility of generalising from my single case to others. In addition,

> when the different logics interact, if the audience is a cost-benefit logic audience, and the argument is presented referring to single case induction, or abductive reasoning, the audience reaction and the question that tends to be presented is: "Ok, you say that this is an issue, or a problem. Show me the evidence that it is, give me the likelihood of this phenomena." It is clear that if I'm following inductive reasoning on single case or abductive reasoning I do not have the likelihood, I just have one case, or nothing at all that actually happened, but signals that something could happen. A similar dynamic affects the interplay between the abductive and inductive approaches on one case reasoning, if the audience is a standard logic audience, and the speaker is a possibility logic speaker. The question that arises is: "Show me one case that actually happened that sustains the argument." The abductive speaker does not have a real case, but just a hypothetical plausible scenario, sustained by some pieces of information. Thus, it becomes very difficult for him or her to defend the argument, and the standard logic tends to prevail.

In summary, context-specific interaction, especially relevant to mutual adjustment coordination, shows that cost-benefit logic tends to prevail on the standard and possibility ones. Furthermore, standard logic tends to hold more weight that on the possibility one. Let us look at the structure in which the interactions took place, in order to understand if the places within the network in which decision-making is located favoured the organisations sustaining a specific logic. Here we look at the decision-making network structure in order to identify which organisations within the network can make decisions and look to the sector in order to face a problem or issue. Showing the organisation in charge of decisions, being that the three organisations support different logics, means understanding if the network structure sustains the prevalence of a specific logic. Thus, we aim to understand if the coordination – by standardisation and by plan – among the network shows a hierarchical configuration that allows certain interpretations to pass through and reach the regulators, or stops them by showing the prevalence of other interpretations sustained by other logics.

With reference to the relationship between the ERA and the NSA, the NSAs have a certain autonomy in decision-making. Nevertheless, such autonomy is limited by the market configuration. The market is *de facto* going toward a Europeanisation, thus national rules are progressively losing relevance. For example, a railway undertaking that is operating in Italy could use wagons rented from wagon keepers located in other countries. The wagon keeper can commit the maintenance of the wagons to different entities in charge of maintenance located in different parts of

Europe. Wagon maintenance can be performed by an entity in charge of maintenance that is certified in another country where the available logics are closer to the risk-based one. Thus, it is *de facto* not subjected to the national rules of the country in which the wagon maintained is operating. Another example is when a railway undertaking assigns transport to another railway undertaking from another country. The committed railway undertaking has its own Safety Management System certified in order to operate in a different country from the one of the commissioning railway undertaking. Thus, when executing the assigned transport, it operates in the country in which the railway undertaking that committed to the transport is certified, and it is classified as a supplier of the commuting railway undertaking. Therefore, the committed railway undertaking operates under the certificate of the commissioning railway undertaking.

Formally, if something happens the responsibility is still of the commissioning body, but a railway undertaking is actually operating on the national railway infrastructure following the principles fostered by the logic adopted within the country in which its certificate has been realised. Thus, with the market going toward Europeanisation, national rules tend *de facto* to lose relevance, because of the fact that companies referring to other nation-states' rules are operating in a national network in which other rules are in place. Despite the market modification, the hierarchical configuration of the network in which the ERA has a higher position than the national NSA, limits the autonomy of the national NSA's decisions. For example, the ERA is the only entity that can intervene in issuing technical specifications for interoperability (TSI). TSIs are 'the specifications by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and to ensure the interoperability of the trans-European high speed and conventional rail systems.'[71] TSIs are the only binding technical rules affecting railway transport in all of Europe today. It is the only type of rule in which technical details and specifications are given to the sector. The only entity that can decide upon TSIs is the ERA, thus, in order to take safety measures that affect all of Europe, an NSA must necessarily pass through the ERA. Consequently, the logic promoted by the ERA structurally prevails over the logics promoted by the NSAs. In addition, national safety rules are examined by the ERA and if they contrast with the interoperability or free market entrance principles, the NSA is invited to rewrite or

[71] ERA, http://www.era.europa.eu/Core-Activities/Interoperability/Pages/TechnicalSpecifications.aspx, Website consulted 14 June 2014.

rethink its position. Nowadays, such a process is affected by a certain flexibility about national specifications, but the idea is to completely suppress national rules over time. Thus, the ERA has *de facto* control over the decisions made by the NSAs. Consequently, cost-benefit logic tends to prevail, structurally, over standard logic.

With reference to the NIB, it does not have a direct relationship with the regulated organisations, and cannot intervene directly within the sector. Recommendations are sent to the NSA where a decision will be made on whether to undertake an action or not within the sector. Consequently, NIB conclusions are filtered by the NSA's logic. As a result, the structure of the network tends to favour the prevalence of the standard logic over the possibility one.

In summary, the way in which the regulatory network is organised tends to place decision-making on the ERA, favouring the filtering in or out of issues/problems through the cost-benefit logic. At the nation-state level, the way in which the relationship between NIBs and NSAs is structured tends to favour the filtering in or out of issues/problems raised by possibility logic through standard logic. Thus, the context-specific prevalence of the cost-benefit logic over the standard and possibility ones, and of the standard over the possibility one, tends to be reinforced by the organisational structure in which the three organisations interact.

Through an examination of the degree of legitimacy of the identified logics, we conclude the meso level analysis. The following part is dedicated to the macro and micro levels of analysis. More specifically, first we locate the identified logics within the inter-institutional system examining the role of the different institutional orders in the development of the three context-specific logics. Then, we explore the micro level by considering the focus of attention the different logics promote. In conclusion, considering the available insight about organisational accidents' genesis, we compare the focus of attention promoted by the logics and the relevant elements in organisational accidents' genesis in order to demonstrate whether they match or not: that is, whether the logics focus the attention of regulators on the elements relevant to the organisational accidents' genesis or not.

PART FOUR.

FINDINGS: COULD THIS NETWORK INTERCEPT AN ACCIDENT BEFORE IT HAPPENS?

1. FROM INTER-INSTITUTIONAL SYSTEM TO ORGANISATIONAL ACCIDENTS

The previous part focuses on a description of the logics shaping and shaped by the railway regulatory network considering the politico-economic and the inter-organisational levels – the meso level. This section focuses on the interaction between the macro and meso levels, and the meso and micro levels. On the one hand, by locating the context-specific logics identified at the meso level within the inter-institutional system – the macro level – and, on the other hand, by analysing the way in which the identified logics focus individuals and organisations' attention on certain phenomena instead of others – the micro level. Figure 4 (Part 1, Chapter 2, Section 2.3) offers a graphic representation of the levels of analysis considered. This section concentrates on the macro-meso levels interaction, whereas the next section focuses on the meso-micro levels.

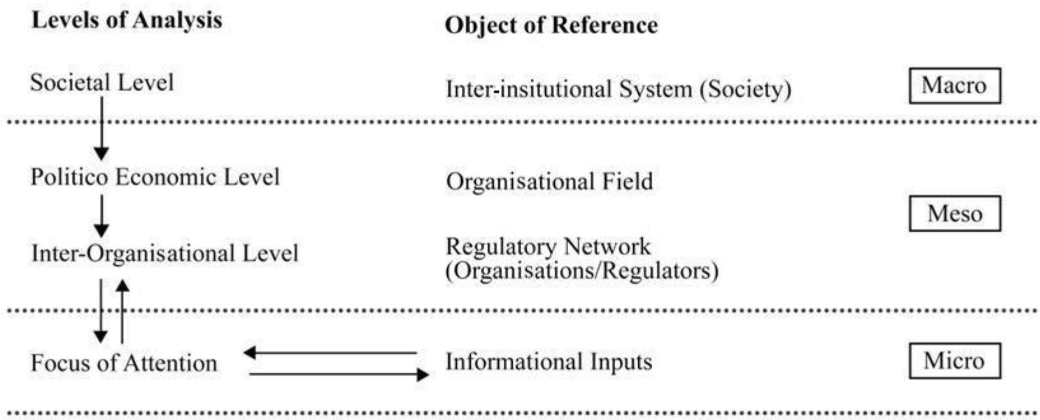

Figure 4: Levels of analysis considered in this dissertation (My elaboration.)[72]

As Figure 4 shows, the macro level corresponds with the societal level and the reference object is the inter-institutional system. Once the politico-economic and inter-organisational level logics are identified, this section aims to locate those logics within society as a whole, by considering the seven institutional orders composing the inter-institutional system: market, corporation, profession, state, family, religion, and community (Friedland and Alford, 1991; Thornton, 2004; Thornton, Ocasio and Lounsbury, 2012). Thus, the aim is, on the one hand, to

[72] For practical purposes and to allow for a better visual understanding of the levels of analysis considered, we utilise the Figure previously discussed in Part 1, Chapter 2, Section 2.3 here.

understand which institutional orders have a role in the available logics definition. On the other hand, it is to identify the weight of the different institutional orders in shaping the various context-specific logics identified at the politico-economic and inter-institutional levels.

Figure 46 shows the contributing role of the institutional orders as well as their different weight in shaping the logics identified: risk-based logic, at the politico-economic level, and cost-benefit, standard and possibility logics at the inter-organisational level.

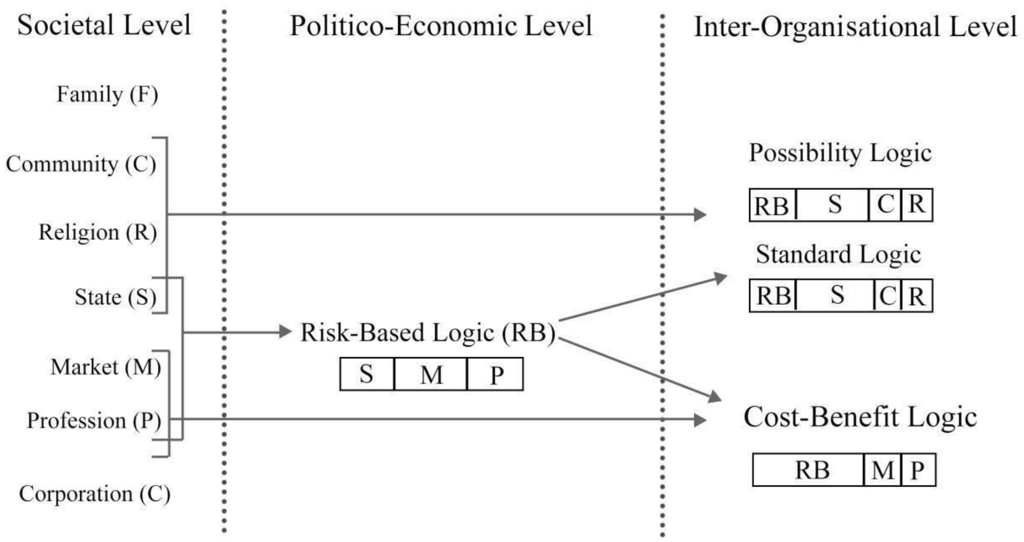

Figure 46: Logics of risk management and regulation and the inter-institutional system (My elaboration.)

More specifically, from the description of risk-based logic given in the previous section (see Part 3, Chapter 2, Section 2.1), the role of the market, state, and profession institutional orders, with the prevalence of the market one, can be identified. With reference to the inter-organisational level, the logics shaping and shaped by the three studied organisations present a mix of the risk-based logic with different institutional orders, as well as a different weight in the role of those orders. More specifically, the cost-benefit logic, prevalent at the European level of government, shows a mix of the risk-based logic with the market and profession institutional orders. Such a mix ensures a close continuity between the risk-based and the cost-benefit logics with a stronger characterisation of the role of the market and the profession institutional orders in defining some of the features of the cost-benefit logic. In contrast, the standard and possibility logics, prevalent at the Italian level of government, present a mix of the risk-based logic with other institutional orders. On the one hand, the logics show a stronger role of the state institutional order than in the cost-benefit and the risk-based ones. On the other hand, two institutional orders that are not relevant in shaping the cost-benefit and the risk-based logics have a role here: the religion and community institutional orders. Consequently, unlike the cost-benefit logic, the standard and the possibility logics detach themselves from the risk-based logic, presenting some specific and distinguishing features. Let us examine the influence of the different institutional orders on the context-specific meso level logics identified in-depth.

As already mentioned, looking at the politico-economic level, risk-based logic constitutes a mix of three institutional orders: state, market, and profession. Considering the state and market institutional orders, the risk-based logic presents an important influence of the market institutional order in reshaping the practical translation of the state one. More specifically, even if risk-based logic shapes and is shaped by a public regulatory network that is, by definition, closest to state institutional order; the concepts, principles and assumption promoted by the market institutional order favour the development of a specific definition of the role of the state in regulating the market. Such a balance in favour of the market institutional order promotes:

- A conception of regulation not as the effort of public agency to steer the market, avoiding and managing the market's possible side-effects, but as a cooperative activity in which public actors and the private sector co-participate;
- A closer attention paid by regulators on ensuring the condition for making free market decisions about risk acceptability by regulated organisations, business development and sustainability, and the liberalisation of the market. The decisions about implementing safety measures should take into account the sustainability of the economic enterprise;
- The adoption of 'light' regulatory strategies by considering the processes and procedures the sector should follow, rather than to fix strict and binding rules and limits, restricting business decisions.

The influence of the profession institutional order is related to the conception of regulation as a cooperative effort. With the adoption of a 'light' regulatory strategy, the responsibility of risk decisions is in the sector, and the conception of risk is viewed not as something that should be avoided, but as something that should be evaluated and managed. Those conditions promote and empower the profession institutional order and, more specifically, the profession developing around the field of risk evaluation and management. Those professions have progressively acquired power in defining the way in which risks should be managed, who should manage them, as well as which kind of indirect risk management strategies regulators should promote and enforce (Power, 1999; 2007). Therefore, the strategies of regulation and management shaping and shaped by risk-based logic give room to the mainstream approach to risk management formalised in standards such as the ISO and COSO ones. (See Part 1, Chapter 1, Section 1.2.)

In looking at the inter-organisational level, the context-specific logics shaping and shaped by the three organisations studied represent a redefinition and practical translation of the risk-based logic, creating a mix with other institutional orders – religion and community – or an enforcement of the institutional orders already composing such logic – state, market, and profession. Such a mix and enforcement vary according to the level of government. More specifically, at the European level, the cost-benefit logic presents a stronger role of the market and profession institutional orders. In contrast, at the Italian government level, the standard and possibility logics present a stronger role of the state institutional order, as well as the influence of the religion and community institutional orders that do not have a role in fostering the risk-based and cost-benefit logics.

Cost-benefit logic promotes a practical translation of the risk-based logic extremely close to such a politico-economic level logic, but it exhibits the stronger emphasis of the market and profession institutional orders. With reference to the market institutional order, the stronger role of such an institutional order is related to the adoption and the crucial emphasis placed on instruments and strategies linked to, and promoted by, this institutional order. A key example is the role of the cost-benefit analysis in fostering decisions about risk acceptability. In looking at the profession institutional order, the strong influence of the risk management profession affects the conception, promoted by the cost-benefit logic, regarding the proper strategies that should be adopted by regulated organisations in managing their risks. This influence is specifically forceful with reference to the indirect risk management strategies, promoted by this logic. More specifically, indirect risk management strategies follow the processes and assumptions promoted by the available mainstream standards about risk management closely. For example, the process of risk management promoted by the cost-benefit logic follows the same steps promoted by the COSO and ISO standards. (See Part 1, Chapter 1, Section 1.2.). In addition, a close continuity emerges with the principles guiding the development of the Enterprise Risk Management (ERM) that has established itself in today's mainstream formal process to manage risk. (See Part 1, Chapter 1, Section 1.2.) ERM aims to bring together different risk management lines of development, within a unique general frame of reference, thus developing a common approach to the management of different areas of risk (Dickinson, 2001; Dionne, 2013). A similar approach is promoted by the cost-benefit logic, stressing the need to bring together different lines of risk management by promoting the redefinition of the technological risk as a business one, and by encouraging the joint management of quality, environmental and technological risks.

The standard and possibility logics detach themselves from the risk-based logic through a stronger role of the state institutional order to the detriment of the market one. In addition, the crucial role of the community and religion institutional orders emerges, further detaching those logics from the politico-economic level one. The strong influence of the state institutional order fosters a different conception of the role of public agencies. More specifically, the role of regulators is linked to a view of the state as the entity in charge of containing the market and its externalities, safeguarding the interest of society as a whole. Thus, the main purpose of regulators' activities should not be the sustainability of the business, but the safety of the citizens. In addition, the guarantee of the physical integrity of citizens is seen as the main *raison d'être* of the state. Thus, the state is seen more as in opposition to the market's interests, rather than as a facilitator of such interests. Consequently, the guarantee of free market decisions, the sustainability of business, as well as the liberalisation of the market is put on the back burner with respect to the main purpose of guaranteeing the physical integrity of citizens. The community institutional order reinforces this element, emphasising the conception of the state as a community, and leading to a reinforcement of the conception of the role of regulators as protectors of the community as a whole, rather than of the business enterprise. This view on the role of the state and the need to guarantee citizens integrity is very salient in the Italian context, as reaffirmed in the Italian Constitution:

private economic initiative is free. It cannot be carried out in contrast to social utility or in a way that can cause damage to safety, freedom and human dignity. The law determines the opportune plans and rules so that they may be directed toward and in step with social ends (Italian Constitution, Art. 41).

Thus, a different ranking of priorities emerges: freedom of enterprise and business development is seen, on the one hand, as subordinate to the safety, freedom and dignity of human beings. On the other hand, it is seen as subject to the state's role of coordinating and fostering free enterprise toward the common good. The strong emphasis on the need to guarantee the physical integrity of citizens and, consequently, the establishment of causing damage to people as an un-crossable boundary in evaluating and managing risk, is reinforced by another institutional order: religion and, more specifically, the Catholic religion. The Catholic faith emphasises the conception of the sacredness of the human being, reinforcing the idea of the value of the life as a non-negotiable limit in evaluating the acceptability of risks. The influence of these different institutional orders on the standard and possibility logics leads those logics to detach the technological risk from business risk, and to redefine technological risk as the risk of causing damage to people. In so doing, it differs from the risk-based and cost-benefit logics.

The contribution of different institutional orders, as well as the different weight of the institutional orders affecting the available logics, allows the difference between the European and Italian levels to be explained. Nevertheless, the institutional orders cannot explain the difference between the two logics present at the Italian level of government. As already mentioned, logics are the context-specific product of the interaction between symbolic and material components (Jackall, 1988; Friedland and Alford, 1991). Thus, in order to explain the differences between the two logics present at the Italian level, we must focus on the interaction between the symbolic, cognitive and material analytical components analysed in identifying and describing the two logics. (See Part 1, Chapter 2, Section 2.3; and Part 3, Chapter 2, Section 2.2.) More specifically, the symbolic and cognitive differences affecting the two logics such as, for example, risk definitions (frequency per magnitude vs. possibility per magnitude), and methods of reasoning (deductive and inductive vs. abductive), are linked to the material ones regarding the organisational structure and coordination, shaped and shaping such logics. Given the influence of the same institutional orders on the two logics, the main source of variability between the two logics affecting the development of specific symbolic and cognitive components are the organisational structures and coordination strategies, shaping and shaped by the two logics. Let us look closely at this symbolic-material link.

The development of specific symbolic and cognitive components – mission, risk definition, and method of reasoning – of possibility logic, prevalent within the NIB, is favoured by the organisational structure and coordination strategy prevalent within this organisation – the material component. The development of a risk definition that looks at the possibility of adverse consequences rather than to the probability of such consequences; as well as the presence of abductive reasoning is specifically favoured by the organisational structure and coordination in which interaction takes place. More specifically, the coordination by mutual adjustment, the limited strength of the hierarchy, as well as the restricted group in which such interaction takes place, favours the presence and sharing of multiple and contrasting opinions and views encouraging a focus on the details and plural interpretations upon which abductive reasoning is based.

In contrast, the NSA's strong hierarchical structure, the prevalence of a coordination strategy based on standardisation, as well as the complex unit structuration of the NSA, does not favour the development of a plurality of views and of the 'thinking outside the box' that abductive reasoning requires. On the contrary, the categorisation processes that a standardised approach requires in order to render information easily synthesised and fitting for standardised documents and fixed forms, tends to limit the attention to details and the chance to develop alternative explanations. At the same time, the strong hierarchical separation between who collects and analyses information, and who makes the decisions supported by by standardisation coordination, favours a process of filtering the available information determined by the need for simplifying and synthesising that information. Consequently, information reaching the managers is partial, simplified, not detailed, and constructed using standardised documents. Such a process of simplification and synthesising focuses managers' attention – those who makes decisions – on the frequency of the event or on its novelty, rather than on its possibility and dangerous consequences. Thus, focusing managers' attention on the present rather than on the future, preventing the development of abductive reasoning. In addition, hierarchy means pressure to conform to standardised procedures, to respect hierarchy itself, and to play by the rules instead of proposing alternative explanations, or identifying new issues to analyse. This pressure to conform limits the possibility of generating alternative interpretations, and conflicting and multiple explanations, which are a crucial ingredient in order to develop abductive reasoning.

The role played by the organisational structure and by coordination strategies in shaping different symbolic and cognitive approaches is in line with the analysis proposed by Weick (2005) of American Intelligence and NASA. Weick's analysis shows how the characteristics of bureaucracies can prevent organisations from developing imaginative interpretations of the future and how, on the contrary, coordination by mutual adjustment and the presence of smaller structures favours organisations in developing an imaginative/abductive approach to risk management. (See Part 1, Chapter 2, Section 1.2.)

To sum up, in looking at the elements that contribute to the development of particular context-specific logics, we can identify two main effects:

- The macro-meso effect that refers to the different weight and kind of institutional orders that contribute in logics' definition. Such an effect is particularly relevant in differentiating the European level of government from the Italian one;
- The meso-meso effect linking the development of specific symbolic and cognitive features of logics to the organisational structure in which such logics take shape. The symbolic/cognitive-material effect refers to the differences between the two organisations located at the Italian level of government. Thus, given the role of the same institutional orders, the organisational structure and coordination strategy tends to favour the emergence of different logics.

This section shows how the inter-institutional system provides organisations with various ingredients that are then recombined at the meso level through the development of context-specific logics. In addition, it underlines the role of the organisational structure and coordination strategies in favouring the development of different context-specific logics given the influence of the same institutional orders. The next section looks in another direction, focusing on the effects of the presence of the available context-specific logics, rather than on the factors that contribute to the logics' development.

2. LOOKING AT THE EVENTS WEARING THE INSTITUTIONAL LOGICS' GLASSES

This section aims to examine the interactions between the meso and the micro level of analysis; more specifically, the purpose is to look at the consequences of the prevalence of the different identified logics on individual and organisational actions and decisions. Considering the interactions between logics and environmental stimuli, we aim, on the one hand, to identify the stimuli upon which the logic focuses regulators' attention. On the other hand, we seek to understand if environmental stimuli retroact on logic in activating them in different ways. Going from logics to environmental stimuli – top-down (see Figure 47) – the emphasis is on the way in which organisations and the institutions in which individuals operate, focus the attention of individuals on specific problems and solutions, and direct behaviour and action in certain directions instead of others (Simon, 1957; 1972; March and Simon, 1958; March and Olsen, 1976; Ocasio, 1997; Thornton and Ocasio, 1999; Thornton et. al., 2005; Cho and Hambrick, 2006; Lounsbury, 2007).

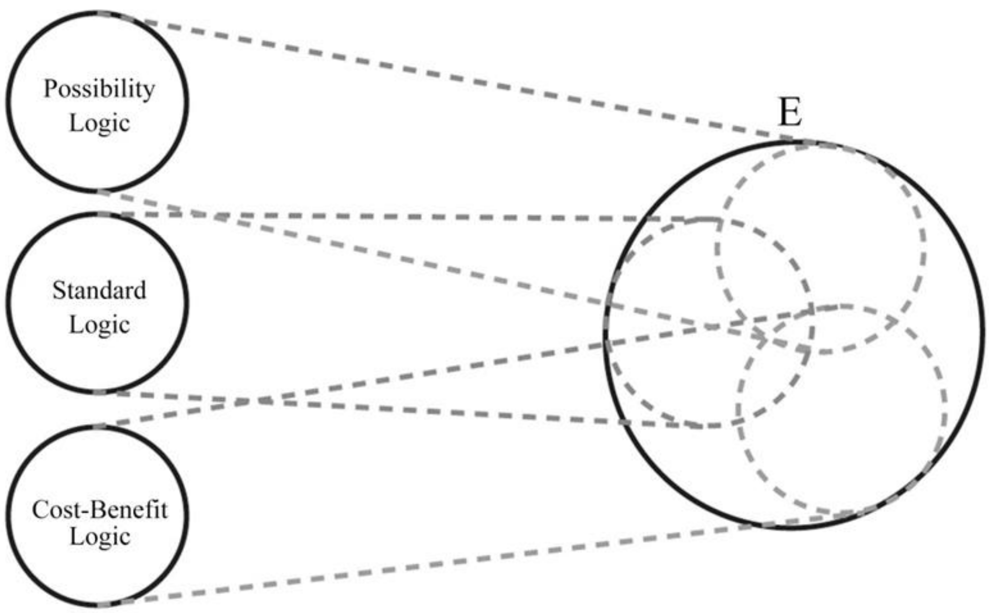

Figure 47: From logics to environmental stimuli (E) (My elaboration.)

Going from environmental stimuli to logics – bottom-up – the emphasis is on the situations in which the existing schemas are not appropriate in order to understand the available environmental stimuli. Consequently, the stimulus can activate the available logics in ways that vary from the expected schemas or structure-oriented behaviours (Hoffman and Ocasio, 2001; Fiske and Taylor, 2008; Nigam and Ocasio, 2010). An analysis of the micro-level effect of logics, as well as of the interactions between informational inputs – environmental stimuli – and logics, is the necessary next logical step in order to build the mental experiment through which we aim to answer the question: 'Why doesn't the (watch) dog bark?' On the one hand, the analysis of the micro level shows where regulators' attention is focused. Thus, in looking at the available information and environmental stimuli wearing the logics' 'conceptual lens' (Allison and Zelikow, 1999), the aim is to identify the phenomena upon which regulators' attention is focused: how regulators select, interpret and classify the available information, and in so doing, sort in or out potentially relevant information for preventing organisational accidents. On the other hand, the comparison between logics' focuses and the phenomena that previous studies have identified as relevant in organisational accidents' genesis, shows the gaps opened by the presence of specific regulatory logics. The mental experiment allows us to understand if the informational inputs that the logics classify as relevant are the ones that are, according to previous studies on organisational accidents' genesis, actually relevant in order to intercept an accident before it happens. Let us look closely at the railway regulatory network's logics, identifying which problem and solution regulators' attention is focused on.

With reference to the politico-economic level, risk-based logic focuses regulators' attention on specific problems and solutions in order to manage and regulate the possible side-effects of railway transportation activity.

Concerning the problems upon which risk-based logic focuses regulators' attention, the problem they should face is not to deal with the side-effects of the regulated activity, but to intervene in a manner that favours the regulated organisation. Such a focus detaches regulators' activity from the outcomes of the regulated area of human activities, and directs their effort on the processes the regulated organisations develop in order to deal with the possible side-effects of their own activity. Consequently, the regulators' role distances from the one of a watchdog on the possible dangerous outcomes of the regulated activity. In contrast, attention is focused on being sure that the regulated organisations are watching their own activity rather than on watching the regulated organisations' activity directly. Thus, regulators are distanced by the hazard sources and focused on the processes other organisations are using in order to identify and deal with such hazards. Consequently, regulators are watching the compliance of the process the regulated organisations have in place with the risk management process they are supposed to follow. The actual outcomes of such risk management processes move to the background and are not identified as a problem in need to be addressed.

The shift of the processes as a problem to focus on, rather than on the side-effects in and of themselves, has important consequences on the solutions risk-based logic identifies in order to face the identified problems. The solution risk-based logic offers to regulators in order to avoid, handle, and/or cope with the possible negative and unwanted outcomes of the regulated activities, follows the distinction between regulating the 'what' and regulating the 'how'. Regulators' activities should fix general principles and processes – what – the regulated organisations should develop – how – in order to manage their own risk. However, they should not interfere with the regulated organisations' decisions about how to apply those principles and processes. Regulators are not responsible for fixing criteria about risk acceptability, but decisions about risk acceptability and control-measure development are free business decisions the regulated organisations should make. Consequently, risk-based logic focuses regulators' attention on indirect, rather than on direct risk management solutions. The focus of attention affects the tangible outcomes of the risk management processes as well. As the regulators' role is fixing principles and processes, but not entering into the 'how' regulated organisations fill those processes with content, the tangible outcomes should not lead to the definition of a binding set of rules, but to non-prescriptive regulation aiming to empower regulated decisions rather than making decisions for them.

As the analysis of the inter-organisational level shows, the practical translation of the 'espoused theory' (Argyris and Schon, 1974) – risk-based logic – given in their everyday activities by the organisations studied leads to the definition of hybrid approaches to risk regulation combining a risk-based framework with elements closer to the control-command approach. If we look at the problem, the inter-organisational level's logic focuses the regulators attention directly on the outcomes of the regulated organisations as well: the three logics focus on both processes and outcomes, but to a different degree. The cost-benefit and standard logics focus on both processes and outcomes. Cost-benefit logic, closest to risk-based logic, presents an imbalance in favour of processes. Possibility logic – unlike risk-based, cost-benefit, and standard logics – focuses specifically on outcomes. The solutions in order to face the targeted problems vary from the ones of the risk-based logic, considering processes of direct risk management as well. The tangible outcomes of the regulators' activities represent a middle-way between the risk-based and the control-command approach. For example, standard logic fixes clear and detailed limits about the risks regulated organisations can, and cannot accept.

More in general, this logic allows the border between the 'what' and the 'how' to be crossed, for example, requiring specific control measures or imposing on the regulated organisations to implement control measures in order to face a risk classifiable as unacceptable.

Given the question this study aims to answer – 'Why doesn't the (watch) dog bark?' – it is important to identify the problems the different logics focus the regulators' attention on. The aim is to understand which informational inputs among the available ones are seen as problems, and to evaluate if the informational inputs classified as problems are relevant in order to intercept an organisational accident before it happens. In contrast, we do not consider the proposed solutions to the identified problems. Thus, the analysis proposed here can demonstrate whether regulators pay attention to information relevant to organisational accidents' genesis, but do not question if the measures undertaken, in order to face the identified problems, are effective or not. More specifically, we consider the direct risk management processes developed by the three logics in order to understand how the processes filter informational inputs in or out, defining some pieces of information as problems and some not. To put it differently, we aim, on the one hand, to show which phenomena are 'in sight' – visible – and which are 'out of sight' if individuals and organisations are wearing the logics' glasses. On the other hand, we seek to compare the 'in sight' phenomena with the relevant elements in organisational accidents' genesis in order to understand if those elements are among the 'in sight' or the 'out of sight' phenomena. To do that, we structure a 'mental' or 'conceptual experiment'. (See Part 2, Chapter 3.). More specifically, the analysis is structured as follows:

- First, we analytically define which are the informational inputs – outcomes of the regulated activity – available to regulators. Then, we separately wear the lenses of the three logics and we identify where between such inputs the regulators' attention is focused. The presence of different logics allows our thesis to be reinforced by a guarantee of counterfactual reasoning. More specifically, it shows that by changing the lens, the phenomena upon which the attention is focused, changes as well. Thus, the importance of the role of the logics in shaping the regulators' view is sustained by the possibility of seeing different logics in action. Subsequently, we consider the way in which the mechanism of normalisation of deviance affects the three logics;
- Then, considering the three logics separately, we compare the inputs upon which the three logics focus their attention, with the inputs the organisational accidents' studies recognised as relevant in order to intercept an accident

before it happens. The comparison is driven by the question: are the inputs relevant in order to intercept the organisational accidents among the ones upon which the logics focus regulators' attention?

- In conclusion, we insert the interaction between logics on the scene, by evaluating which logics prevail within the network. We are, thus, able to understand which inputs are finally dealt with and which ones are not considered. Therefore, we can consider whether, given the available logics and their different degrees of legitimacy, the network can or cannot see relevant informational input for preventing an organisational accident.

Focus of attention: informational input

In order to represent the focus of attention mechanism in a synthetic way, we start from an analytical representation of the environmental stimuli that inform the regulators' activities. Such environmental stimuli are the different dangerous or potentially dangerous events known by regulators. They can be considered as the informational input of the direct risk management processes activated by the risk management and regulation logics. Figure 48 offers a graphical representation of those events.

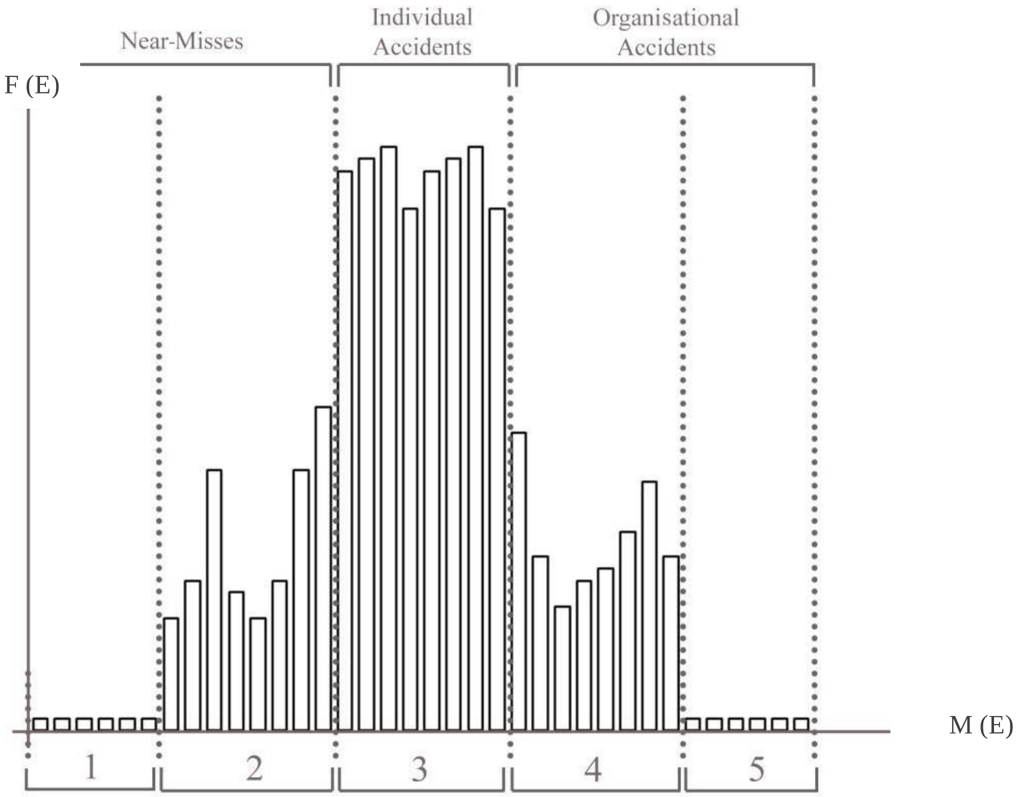

Figure 48: Informational input activating risk management process developed by regulators – a graphic representation (My elaboration.)

The x-axis represents the magnitude of the events – M(E) – the y-axis represents the frequency of the events – F(E). Each bar corresponds with a type of event. The numbers under the x-axis identify five categories of event in which the types of events – bars – can be aggregated:

1. One-off events without any consequences, but material damage or service delay; those one-off events represent emerging phenomena: events that did not happen, or were not noticed before. Thus, a type of event which cannot be categorised and for which a record of previous events of the same type, which occurred in the past, does not exist when the event happens. A train that enters the train station and does not stop before damaging the buffers located at the end of the tracks, without the passengers even realising that it happens, can be taken as an example of the events located in this category[73];

[73]The examples presented here are authentic ones that occurred during the research period.

2. Events without any consequences, but material damage or service delays occur, that are unlike the events in the previous category because they happened or were noticed before. Consequently, a type of event, which exists within the categorisation system, as well as a record of previous events of the same type exists. A railroad switch in bad condition or the detachment of wagons in motion can be taken as an example of this category of events;
3. Events with consequences for one person and with high frequency; level crossing accidents, or running people over are examples of events located in this category;
4. Events with consequences for more than one person that already occurred and, thus, a category of reference in which to classify them already exists; the train derailment that happened in France at the Bretigny-sur-Orge station in July 2013 in which six people died and many people were injured, can be taken as an example;
5. One-off events with consequences for more than one person; these events differ from the one in the previous category because of the catastrophic nature of the consequences, as well as the extremely low frequency. The Santiago de Compostela high-speed train derailment, which occurred 24 July 2013, is an example.

The five categories of events can also be combined into three categories that are more general:

- Near-misses: events without consequences, but with material damage that, under different conditions, could lead to an organisational accident – types 1 and 2;
- Individual accident (Reason,1997): accidents that affect a single person – type 3;
- Organisational accidents (Ibid.): accidents that occur to organisations – types 4 and 5. (See top of Figure 48.)

Now we will use the graph (Figure 48) in order to illustrate where the three identified logics focus regulators' attention. More specifically, an examination of the logics' focus of attention allows us to understand the way in which the available logics filter the events defining certain features as relevant information or problems, and others as irrelevant. In addition, we consider the interaction between events and focus of attention, taking into account if there are certain types of events that do not respond to available schemas or theories that, retroacting on the logics, activate alternative management or regulation processes – bottom-up effect.

Cost-benefit logics

Figure 49 demonstrates where attention is focused in wearing the cost-benefit logic's glasses.

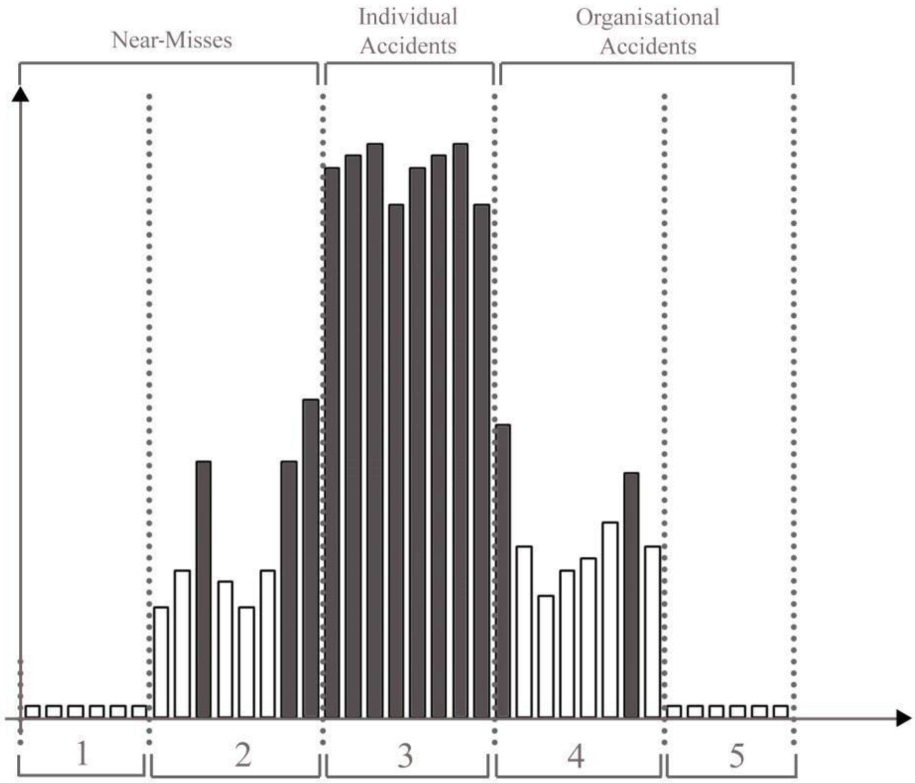

Figure 49: The cost-benefit logic's focus of attention – a graphic representation (My elaboration.)

The black bars identify the types of events on which the logic focuses the regulators' attention while the white bars show the types of events that the logic filters out. Let us go through the main assumptions and principles of the cost-benefit logic, once again, in order to explain why attention is focused on those black bars. Cost-benefit logic does not fix acceptability limits and, in principle, considers it up to the sector to decide about the acceptability of risk. Consequently, according to cost-benefit logic, deaths and injuries are in principle acceptable if the regulated organisations classify those events as within their acceptability level. For example, in exposing the risk definition cost-benefit logic promotes, we highlighted how the acceptability of death and injuries is stated in the reference example of the risk matrix given by the CENELEC standard to which the cost-benefit logic refers. (See

Part 3, Chapter 1, Section 1.2.) As a result, the consequences of the events are not a crucial development triggering the attention of regulators. Furthermore, the method of reasoning promoted by the cost-benefit logic – deductive or inductive, but only with high frequencies – promotes a key focus on the frequency of events.

More specifically, events are considered relevant and problematic only if they reach a certain frequency, without distinctions between near-misses, individual, or organisational accidents. One of the key assumption of the cost-benefit logic refers to the evidence that should justify any intervention. Thus, the events are classified as 'problems' only if there is congruous evidence supporting the classification of the event as a systemic event – present in more than one country or more than one company across Europe – and a frequent event. Consequently, events that do not reach a certain frequency, and a certain degree of certainty about their dangerousness, are not considered problems and, therefore, are filtered out by the risk management process or during situated interactions with other logics. The deductive or inductive reasoning, with the high degree of certainty promoted by the cost-benefit logic, leaves little room for bottom-up interaction.

Standard logic

With reference to standard logic, we can see a top-down effect of the logic, as well as a bottom-up effect in which a specific type of event activates the logic in a different way.

With reference to the top-down effect (see Figure 50), standard logic considers deaths or injuries as, in principle, unacceptable. Consequently, the logic focuses regulators' attention on all the events that lead to deaths or injuries – types 3, 4, 5.

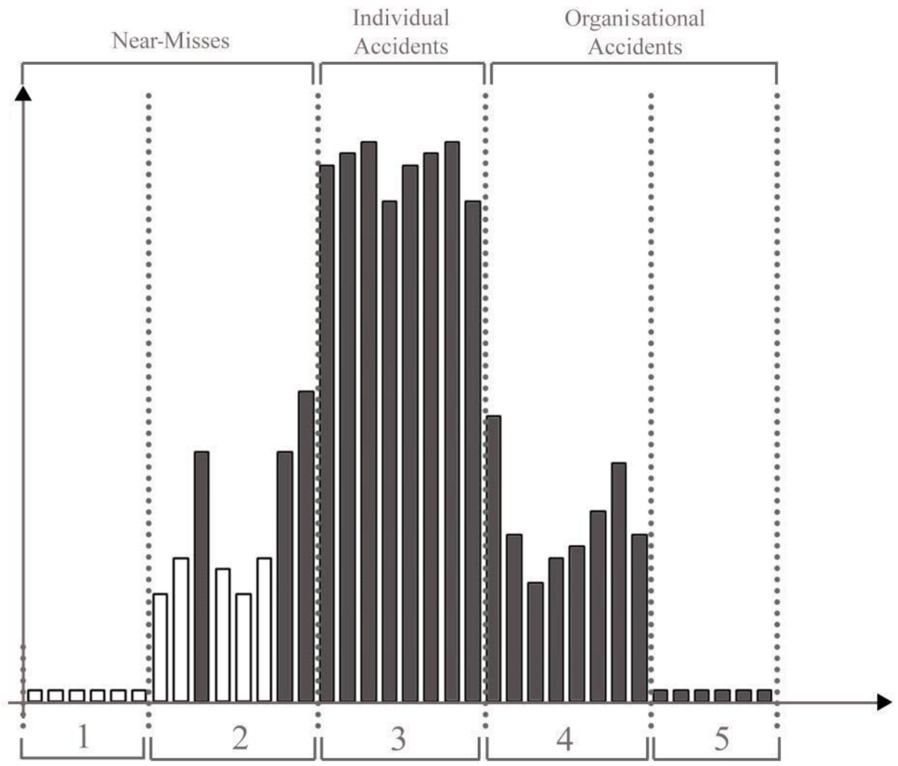

Figure 50: The standard logic's focus of attention – a graphic representation (My elaboration.)

With reference to the events that have no consequences on people, the main criterion is the frequency of the event. As accidents, incidents, near-misses and non-conformities analysis highlights, events that do not reach a certain frequency are filtered out by those processes. Thus, this top-down effect is close to the cost-benefit logic one. Nevertheless, standard logic presents a bottom-up effect as well. This bottom-up process refers specifically to accidents, incidents and near-misses analysis. If the event is a one-off event without consequences and does not fit within any of the available theories on possible accidents, incidents, or near-miss scenarios, the event is seen as a salient one. Thus, the logic activates inductive reasoning on a single case and focuses the regulators attention on the event. (See Figure 51.)

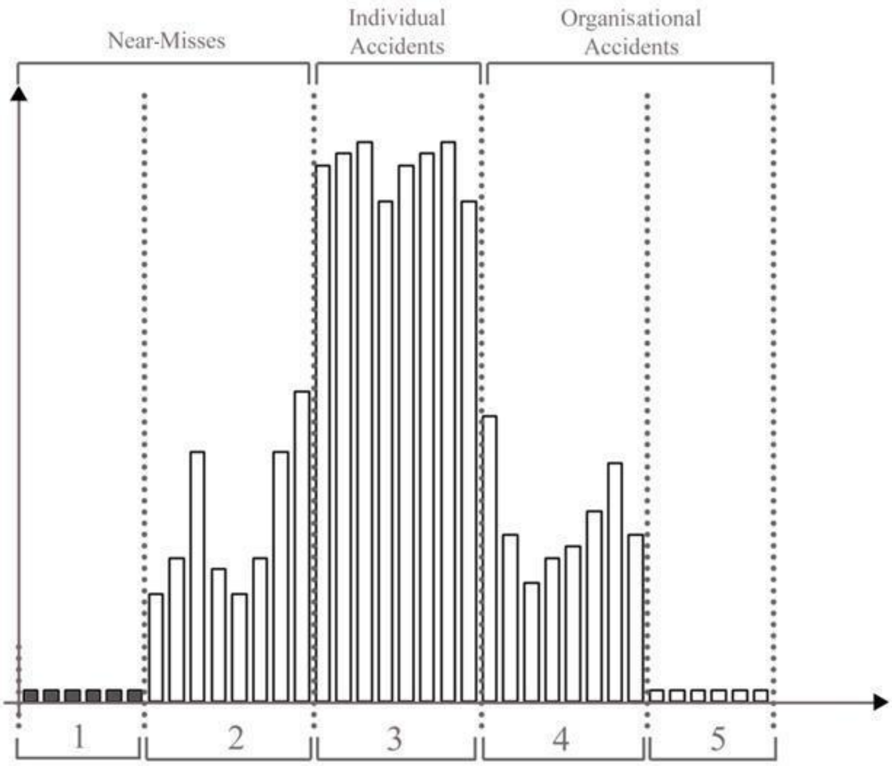

Figure 51: Standard logic – a graphic representation of the bottom-up effect (My elaboration.)

Possibility logic

Regarding possibility logic, as in the case of the standard one, events that lead to deaths or injuries are, in principle, considered because of the acceptability limit fixed by both logics. Nevertheless, the specificity of this logic, due to the application of abductive reasoning, is to go beyond the events that actually happen fostering alternative scenarios. From the available events, abductive reasoning cultivates a hypothetical future in which alternative accident precursors or scenarios are identified. Figure 52 provides a graphic representation of these events' projection. Thus, the logic focuses regulators' attention on a hypothetical future (HT) in which other possible informational inputs are identified – M(HE), the magnitude of hypothetical events, and the F(HE), frequency of hypothetical events – from the available fragmented pieces of information that the events that actually happened provide.

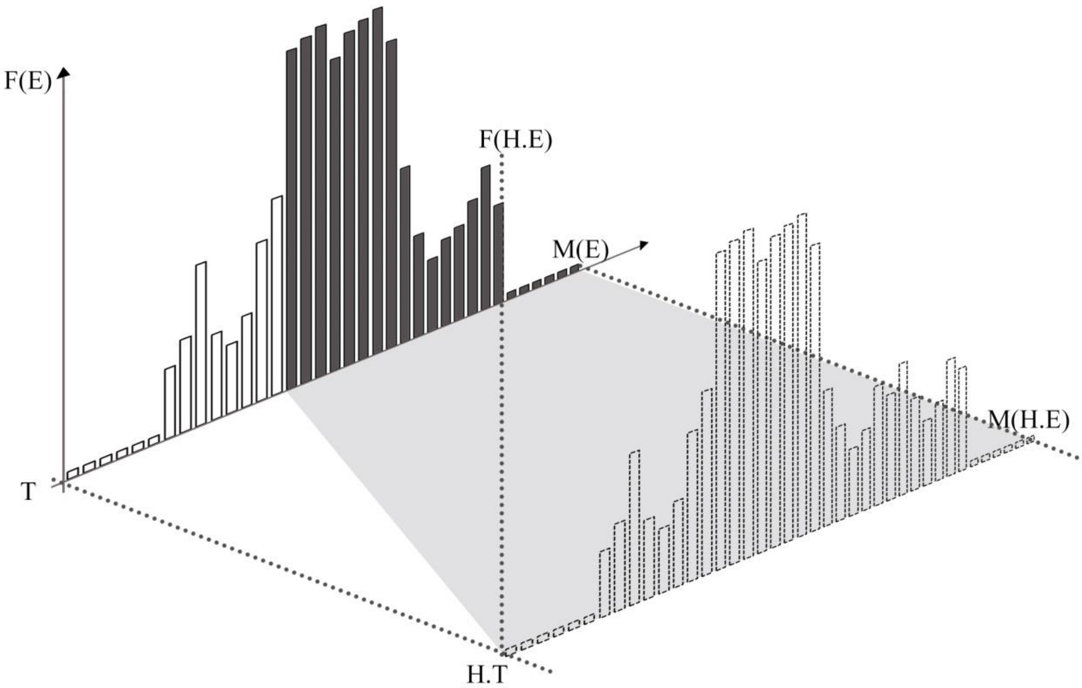

Figure 52: Possibility logic – a graphic representation (My elaboration.)

To sum up, the three logics differ between them in focusing regulators' attention on different types of events. Thus, by changing the logic, the types of events on which regulators focus their attention also changes.

Focus of attention: normalisation of deviance

The identified logics influence the way in which the normalisation of deviance (Vaughan, 1996) mechanism affects the regulatory activity as well. As already mentioned (see Part 1, Chapter 3, Section 3.2), Vaughan shows how the normalisation of deviance mechanism is linked to the specific way in which organisations construct their own principles and belief about how to make decisions and to act. Such principles and belief shaped by organisational processes affect the perception organisational actors have of the events and the phenomena they face : 'the explanation of the Challenger launch is the story of how people who work together develop models that make them blind to the consequences of their actions' (Vaughan, 1996: 409). Over time, dangerous signals and deviation from the expected outcomes or courses of events, loose relevance in people's eyes, becoming the expected outcomes and courses of events rather than deviations from the norm.

Consequently, events that for people external to the organisation could stand out as dangerous, are perceived as normal and not dangerous within the organisation. For example, the analysis of both the Challenger and the Columbia disasters shows that potentially dangerous events, but which have not led to negative consequences in the past, such as O-ring malfunctioning or foam detachment, were not classified by NASA as anomalies, but as part of the launch routine. Shared procedures, categorisation of events and principles driving risk evaluation, tend to favour the normalisation of deviance mechanism instead of preventing it. For example, the shared procedures about risk evaluation at NASA tended to minimise the risks depicting potentially dangerous events as residual and, thus, acceptable. Being that the normalisation of deviance mechanism is closely linked to procedures and belief shared within an organisation, the way in which such mechanism affects the functioning of organisations varies according to the procedures and belief shared by the organisations. Let us examine such variations in looking at the way in which the presence of different logics affects the way the normalisation of the deviance mechanism takes shape.

Cost-benefit logic

Cost-benefit logic views the types of events that the normalisation of deviance mechanism affects more in a particular manner. More specifically, the events that the cost-benefit logic tends to normalise are mainly the organisational accidents and their recognised precursors. Let us examine the principles and assumptions of the cost-benefit logic that sustain the normalisation mechanism:

- The contrast between proactive and reactive approaches; the cost-benefit logic insists on the need to develop a proactive approach to risk management. Risks should be managed systematically by identifying the sources of danger and evaluating them before accidents happen. This in contrast with a reactive approach in which, after the fact, the involved organisation reacts to the event modifying rules and procedures. Such a proactive approach tends to minimise the post-accident reaction. Consequently, accidents tend to be normalised: the focus is in defining formal procedures of hazard identification and risk evaluation, if something that does not fit with the formalised procedures happens – accidents – the logic tends to exclude it from the scene. On the one hand, accidents, and more specifically accident consequences, are seen as random events closer to fate than to risk, and thus, not preventable and not considerable at all as inputs for the formal evaluation procedures. On the other hand, if they are considered within the formal procedures, they have already been evaluated and addressed, and the fact that they happened is something that was already evaluated as acceptable. Thus, if an accident happens, it is because the formal procedure established that the risk associated with this accident was residual, not further reducible and/or extremely low. The formal procedure normalises accidents by defining the rational terms of their acceptability. The formal risk management procedures are the rational way of managing risks; in contrast, post-accident reaction is the irrational reaction, closer to the lay public sentimental approach rather than to the scientific and professional approach to risk management that regulators are supposed to have and promote. Consequently, organisational accidents are not the object of specific attention, and through the formal risk estimation processes they are located 'out of sight';

- The 'zero risk does not exist' statement; to state that zero risk does not exist means to state that the 'perfect operations' are the ones that represent deviations from the norm. For example, the normal state of maintenance of components is that a certain number of components could have weaknesses of maintenance, and not that all the components that are circulating are perfectly maintained. To state that perfection is not reachable – 'zero risk does not exist' – means to accept as normal and as the objective to reach, the 'imperfect conditions', rather than the 'perfect' ones. Thus, being no-reducible to zero, the imperfect conditions become residual, acceptable, and hence normal. Consequently, accidents' precursors are normalised as well;
- The cost-benefit analysis; in examining the Challenger and Columbia disasters Vaughan (1996; 2003) states that a cost-benefit analysis of those events would surely highlight the need to avoid the accidents: the extremely high cost of them generously justifies the development of control measures in order to avoid them. However, the problem of the cost-benefit analysis is that to do a cost-benefit analysis *ex post facto* does not take into account the 'before the fact' bias that affects it. The fact that the cost of the accident exceeds the cost of the control measures to avoid it is true, and demonstrable with a certain degree of certainty, only *ex post*. In performing a cost-benefit analysis *ex ante*, the attention is focused on the extremely low degree of probability that the accident will actually happen. To associate a number such as 10^{-9} to an event is equivalent to saying that it will never happen, or at least not before this technology will become obsolete and will be replaced by other ones. The idea of the cost-benefit analysis is to have a cost today in order to

have a reduction of cost tomorrow. However, if the cost I will have tomorrow is not certain, but extremely improbable, it is extremely improbable that my investment today will have a return tomorrow. In addition, the cost-benefit approach does not consider only one event, but it is a way of fixing priorities, given the finite available resources among different types of events. Therefore, given the finite resources, the resources should be used to face probable events even if they have minor consequences, rather than extremely improbable events with high consequences. A probable event with minor consequences ensures that an investment in control measures will give a return, because it is certain that they will happen. Thus, resources tend to be located on individual accidents rather than on organisational accidents, or more in general, on events whose frequency and magnitude are closest to the average than the ones of organisational accidents. The uncertainty surrounding the actual return of my investment concerning the organisational accidents makes the acceptance of those events the rational and correct behaviour. This is true especially if I can locate the same resources on other events that, given their higher probability, will ensure the return of my investment. Again the detachment from the norm is normalised: to face organisational accidents is not rational, the cost of a reduction is too high given the uncertainty surrounding such investment; consequently, the correct thing to do is to accept the risk associated with those type of events. In essence, through the formal evaluation processes, the fact that an event could happen once in five hundred years captures the attention, and the fact that this once could be tomorrow loses relevance. Therefore, events that do not reach a certain frequency tend systematically to receive less attention than more frequent events despite the nature of the possible consequences.

The cost-benefit analysis differs from the standard and possibility logics. Given the classification of death and injuries as not acceptable, those logics consider the accidents as a significant event. The accident constitutes a salient event that opens a re-discussion of the available assumptions and principles. Such re-discussion usually ends with a change of the available standard, norms, or more rarely, of the regulatory approach. The cost-benefit logic considers this reaction as an emotionally driven response that leads to disordered and irrational changes to regulation. In order to manage such an irrational post-accident reaction, a specific procedure has been developed: the quick response procedure. Basically, if an accident or an event that is classified as salient happens within the European railway sector, such an event should be reported to the ERA which then institutes a panel selecting representatives of the different stakeholders, NSAs, and NIBs. The panel should examine the accident/event, and decide if a quick and special intervention – post-accident reaction – is needed or not. The evaluation should follow a set of questions. Only a positive answer to all the questions can lead to a post-accident reaction. The questions guarantee a second rationally oriented reading of the event: going through the questions by re-affirming the principles and assumptions promoted by the cost-benefit logic, the normality of the event is re-built. In essence, the process guarantees a re-reading of the event from the point of view of the cost-benefit logic. The questions the panel should answer, classified through the main principles fostered by the cost-benefit logic, are:

- Evidence-based:

  Does the request contain *sufficient information*?
  Do the reported facts concern a *known risk on which there is sufficient knowledge*?
  Is *there sufficient knowledge / information on the problem to immediately define effective action(s)*? (ERA, 2013, October, Quick Response Procedure Draft, Annex 2, p.19-20, my emphasis);

- Systemic event:

  Do the reported fact(s) involve/concern/are of interest for *more than one country*?
  Do the reported fact(s) involve/concern/are of interest *for actors active on more than one country*?
  Can the reported fact(s) have a high safety risk on several stakeholders from different countries? (Ibid., my emphasis);

- Formal risk estimation:

  Is the *risk high*?
  The level of risk corresponds to the *severity multiplied by the frequency*. It can be either qualitative or quantitative risk analysis (Ibid., my emphasis);

- Sector responsibility on risk decision:

  Would the *foreseen immediate / short term action(s) suggested via this procedure have an effect on the problem within a short period of time*?
  Is it likely that the immediate measures taken by the involved actors will not mitigate or avoid the considered risk within a short time period?

(*If such measures are sufficient, the QRP is not applicable. If these are not sufficient, the QRP can be applicable*) (Ibid., my emphasis).

To sum up, the bottom-up reaction that, from the salience of the environmental stimuli, can lead to the questioning of the principles and assumption sustained by cost-benefit logic, is avoided through the definition of a specific procedure. The procedure allows the event to be re-normalised despite the post-accident reaction promoted by the other logics. The development of *ad hoc* procedures such as the Quick Response one makes the cost-benefit logic resilient, increasing its strength/legitimacy with respect to other available logics.

Standard logic

Standard logic favours a normalisation mechanism that is closer to the one described by Vaughan (1996; 2003) with reference to the Challenger and Columbia disasters. Here the events that the logic tends to normalise are especially the near-misses or accidents' precursors: potentially dangerous events that happened without catastrophic consequences in the past. Such events are known, and the organisation has theories of reference explaining them and categories of reference in which to locate them. Nevertheless, the fact that those events happened in the past without catastrophic consequences contributes to reduce the perception of their dangerousness, and in so doing normalise them. As for the NASA, even if not formalise in predefined categories, the standard logic distinguishes between events that are classified as 'in family' and events that are classify as 'out of family'. The 'in family' events are events in which the top-down process linking logic and environmental stimuli prevails. The 'out of family' events are the ones that, given the lack of a theories of reference and categories in which to locate the events, trigger a bottom-up process which, going from the environmental stimuli to the logic, demands further analysis and activates an induction on single case inference. The normalisation of deviance affects the 'in family' events. The normalisation process is limited to events that do not reach a certain frequency. This focus on the events' frequency is related to the hierarchical structure of the organisation in which the standard logic prevails. More specifically, the organisation presents a formal and marked distinction between who analyses the informational inputs and who makes decisions. The decisions are located at the top management levels, and the communications between 'front line operators' and management take place mainly through standardised and easy to read documents: for example, the inspection report that shows the trends about the observed non-conformity through standardised graphs. (See Figure 42.) The non-conformities are identified through codes, and the only parameter that is included in the graph is the frequency of such codes. Attention is drawn to the height of the bars rather than the events that they represent. Consequently, given the way in which the information is synthesised, management attention is focused on the frequency of the events rather than on their specificities and potential dangerousness. Focus on the frequency tends to put events that do not reach a certain frequency 'out of sight', and normalise them as background and not relevant information.

Possibility logic

Possibility logic is less subject to the normalisation of deviance mechanism than other logics. The possibility logic does not apply standardised processes and focuses on single events. There is not a formal process of categorisation and quantification of events, thus the normalisation of deviance has less room to affect the events' analysis. More specifically, there are two critical elements, differentiating the possibility logic approach to the events' analysis, that counter-act the normalisation of deviance mechanism:

- The attention is focused mainly on the singularity of the events, rather than on the patterns of events of the same type. The emphasis is on the specificities of the events; thus, the point of reference from which the analysis is structured is not the event type, but the event in itself. Consequently, the focus is on alternative precursors or consequences of the event under study, despite whether they really happened or not. The fact that the potentially dangerous precursors happened in the past without dangerous consequences, or that the event under examination did not have dangerous consequences is not relevant for the analysis. Thus, the normalisation of deviance has little room to affect the process;
- The logical process that drives the events' analysis and the comparison between events is not the classification and quantification, as it is for the standard and cost-benefit logics. In contrast, the logical process that drives the events analysis is the analogy. Events that are related to each other are not necessary events of the same type. The analogical process tends to favour cross-category references that focus on similarities between different events. The analogy sustains the identification of continuity between events that can be classified in extremely different categories. As already mentioned, the

example of the alarm procedure shows how the analogical process can work. In that case, two extremely different events, such as a derailment and the detachment of a door from a train in motion, were put together because in both the events, the suspicion that the alarm procedure was defective or inadequate arose, and a specific in-depth analysis was conducted on that element. The alarm malfunction is not linked to the main events, but represents a background detail that the analogical process highlighted. This inclination for analogy rather than categorisation and classification contrasts the structuration of processes that favour the normalisation of deviance mechanism.

To sum up, as regulated organisations, regulators are subject to the normalisation of deviance mechanism as well. Not all the logics are subject to the mechanism in the same measure, and the mechanism takes different shapes according to the prevailing logic. Cost-benefit logic's specificity is the normalisation of a specific type of events: organisational accidents. Standard logic follows the mechanism presented by Vaughan (1996; 2003) in analysing the NASA case closely. Possibility logic, by promoting non-standardised procedures and logical processes alternative to categorisation and quantification, leaves less room for the mechanism than the cost-benefit and standard logics.

Could this network intercept an accident before it happens?

Previous empirical studies about organisational accident genesis highlight near-misses and, more in general, accident precursors as crucial elements in order to intercept the organisational accidents before they happen. They also provide insight about the mechanism that can affect the possibility of paying attention to those near-misses and precursors: normalisation of deviance. In the preceding pages, we highlight how the available logics of risk regulation and management – cost-benefit, standard and possibility – focus regulators' attention and are affected by the normalisation of deviance mechanism. Now, by comparing the events upon which the logics focus regulators' attention on events relevant to intercept an accident before it happen, we can finally understand whether by observing reality through those logics, relevant events in organisational accidents' genesis can be seen. Let us examine each logic separately.

Cost-benefit logic focuses regulators' attention on individual accidents rather than on organisational accidents, and more in general, on events whose magnitude and frequency are closest to the average. The processes through which risk is evaluated and estimated – e.g. cost-benefit analysis – favour a focus on events that reach a certain frequency. Through the normalisation of deviance mechanism, organisational accidents, as well as near-misses and precursors, tend to be normalised if they do not reach a certain frequency and do not have a systemic value – e.g. affecting more than one country. Consequently, cost-benefit logic does not focus regulators' attention on events potentially relevant in order to prevent organisational accidents before they happen.

Standard logic exhibits a focus on organisational accidents, but does not focus regulators' attention on near-misses and accidents' precursors if they do not reach a certain frequency. Through the processes that bring information from the 'front line' to management, the attention focuses mainly on events that reach a certain frequency, normalising non-conformities that do not reach a certain frequency. Thus, there is a gap in the analysis of near-misses and precursors, and such a gap leaves room for organisational accidents.

Possibility logic focuses attention on events that have consequences in terms of deaths or injuries, but in analysing such events, it fosters alternative scenario and possible precursors. The focus on the singularity of the event, as well as the application of an analogical process, rather than a categorisation and quantification one, to analyse events, leaves little room for the normalisation of deviance mechanism. Abductive reasoning and the attention to details that this logic favours, allows regulators to see events or non-conformities that are not visible from other logics' points of view. Nevertheless, possibility logic considers a hypothetical future in which alternative precursors or accident consequences could happen, but this future is just plausible, neither real, nor probable. Thus, it is difficult to distinguish between what is plausible and could become real, from what is just plausible but will never become real. To put it simply, in looking at reality from the possibility logic's lens, there is the possibility of intercepting organisational accidents before they happen, but there is not the possibility to demonstrate that such a process actually works.

Now, if we look at the logics' interactions and degree of legitimacy, previous chapters show how the cost-benefit logic tends to prevail on the standard and the possibility ones, and the standard logic tends to prevail on the possibility one. Consequently, if we consider the logics' interaction and the hierarchical structure of the network, the logic that tends to prevail is the cost-benefit one; thus, the focus of attention affecting such logic affects the regulatory network as a whole as well. The regulatory network tends to focus regulators' attention on events that are not crucial in organisational accident genesis.

In conclusion, we show how logics and their interactions can prevent regulators from focusing on events that are relevant in order to intercept organisational accidents before they happen. Despite the presence of regulating organisations, accidents happen not because regulators are linked to regulated organisations by inappropriate relationships or conflict of interest (Froud et al., 2004; Hirsch, 2003; Citron, 2003); adopt unethical or immoral behaviour (Mintzberg, 2004; Froud et al., 2004; Williams, 2004a; 2004b; Ghoshal, 2005); are too close to regulated organisations or too far away from them, and thus, do not have sufficient or sound information (Vaughan, 1996; 2003; Reason, 1997); or, to go to *clichés*, they do not do their jobs, or are underqualified. On the contrary, accidents can happen because standardised processes, accurate categories, precise definitions, scientific rigor and market rationality can lead regulators to look away from events that are significant in organisational accidents' genesis. And even if other point of view are available, the high degree of legitimacy reinforcing such standardised processes, accurate categories, precise definitions, scientific rigor and market rationality, prevents other point of view from being considered.[74]

Finally, we can answer our question: 'Why doesn't the (watch) dog bark?'. The (watch) dog does not bark because the logics of risk regulation and management shaping and shaped by the regulatory activity, and the interaction of those logics leads organisational accidents 'out of sight', focusing regulators' attention on another type of phenomena: events closest to the average, with reference to their frequency and magnitude. Thus, the attention is focused on events with limited consequences but with high frequency. In effect, organisational accidents tend to be normalised and classified as random, residual, not further reducible and/or associated with an extremely low risk. Therefore, the (watch) dog does not bark because when the killer is approaching the victim, it is looking in another direction, whose it cannot see the killer, nor hear him approaching.

[74]This does not mean that elements, such as the one mentioned before, are not relevant, but they usually focus our attention, moving other elements to the background, such as the logics' role.

CONCLUSION

One of the first books examined when starting to work on this research project is *What is a case? Exploring the Foundation of Social Inquiry* edited by Ragin and Becker (1992). The book is the result of a broad debate, a series of workshops, and conversations centred on the notion of 'case' and the status of the 'case' in social sciences methodology. Some of the ideas emerging from this debate have remained, and have travelled along the research pathway. More specifically, Becker's ideas about the question '*What is this case a case of?*, effectively summarised by his co-editor Ragin, in the introduction of the book, particularly drew attention:

He persistently pulled the rug out from under any possible consensus about 'What is a case?' From his perspective, to begin research with a confident notion of 'What is a case?' (or more precisely, what this case – the research subject – is a case of) is counterproductive. Strong preconceptions are likely to hamper conceptual development. What it is a case of will coalesce gradually, sometimes catalytically, and the final realisation of the case's nature may be the most important part of the interaction between ideas and evidence. In short, Becker wanted to make researchers continually ask the question 'What is this case of?' The less sure that researchers are of their answer, the better their research may be. From this perspective, no definitive answer to the question 'What is a case?' can or should be given, especially not at the outset, because it depends. The question should be asked again and again, and researchers should treat any answer to the question as tentative and specific to the evidence and issue at hand. Working through the relation of ideas to evidence answers the question 'What is this case a case of?' […] Becker's concern [is] keeping the question alive. (Ibid.: 6-7).

Another important element that emerged from this debate was that, despite the extremely different positions of the scholars involved, they agreed on the statement that a case could be many different things. What the case is could change during the research process, as well as according to the different audiences looking at the same case:

While the answer to "What is a case?" were diverse […], [t]hey agree that cases may be multiple in a given piece of research: What the case is may change both in the hands of the research (during the course of the research and when the results are presented) and in the hands of the research's audiences (Ibid.: 7-8).

What was actually done in defining the research design of this research was to put the issues raised by this book in a corner, choosing a case in a quite preconceived way. Various cases of regulatory networks were examined reflecting deeply on the case selection, and finally, a case with specific criteria was chosen, following a precise idea about what we would like this case to be a case of. As already mentioned, a case was chosen that was meant to be a case of a risk-regulatory network, as well as an 'extreme case'; fitting for looking at logics' role in shaping regulators' attention. Nevertheless, despite such preconceptions, the issues about what this case is a case of, and for whom, risen by Ragin and Becker (Ibid.), still followed the research development. Over the course of time, the case has become many different things. Whether because it was looked at from another point of view, or because new evidence emerging from the field work pushed toward looking in another direction or, alternatively, because presenting the research during seminars, summer schools, and more in general, informal conversations, it became evident that the case became different things in the eyes of the different people involved.

Becker (1992) highlights the relationship between ideas and evidence as a key element progressively increasing the answer to the question 'What is this case a case of?'. During this study, the relationship between ideas and evidence has played a crucial role in forming the theoretical framework and the empirical results in the way they were presented here. On the one hand, new evidence led to the development of a new idea, and thus the search for new theoretical stimuli emerged. On the other hand, new theoretical stimuli encouraged the formation of new ideas and, consequently, the collection of additional evidence or the recognition of the actual value of the available evidence.

In reading the entire text once again before writing this conclusion, a realisation emerged that the various lines of development opened in the text, as well as the connections between the evidence presented and the contributions comprising the theoretical framework, can be effectively systematised by answering the question 'What is this case a case of?'. This effectiveness is probably related to the role that the question actually has had in driving the research pathway. Thus, the question arose once again: 'What is my case a case of?'. In answering the question, attention was also paid to the suggestion emerging from the debate mentioned above about the role of the audience in defining the case. Thus, there was a focus, on the one hand, on what this case could be for scholars from different fields and, on the other hand, on what this case could be for practitioners dealing with risk management and regulation. This not with the purpose of proposing recipes to improve the strategies of risk management and regulation in use, but with the aim of stimulating reflection and increasing awareness among practitioners about the issues, trade-offs and critical issues that this case highlighted. The final answer to the question *What is this case a case of?* follows.

This case is a case of risk perception

The classical psychometric paradigm dealing with the perception of the possible negative outcomes of human activities has historically drawn a strong distinction between public laypersons and experts (e.g., Slovic, 2000). The conclusion shaped by such distinctions can be summarised by the statement that public laypersons perceive risk – thus frame the relevance of the possible negative outcomes of human activities – following criteria such as the exaggeration of the relevance of unfamiliar negative outcomes (Slovic, 2000). In contrast, experts see reality as it actually is. A by-product of the institutional logics analysis here proposed is an additional move beyond such asymmetric assumption. More specifically, framing this case as a case of risk perception can give further evidence to the thesis, sustained by social scientists analysing risk, that 'all perceptions of risk, whether lay or expert, represent partial or selective views of the things and situations that threaten us' (Jasanoff, 1998: 91).

The analysis of the available logics shows that, on the one hand, experts even in the same regulatory network show a high degree of variability on the relevance they attribute to the possible negative outcomes of the regulated area of human activity, as well as on the more effective strategies to avoid, cope with and/or handle such undesired outcomes. On the other hand, the logics' focus of attention mechanism shows that experts also have preconceptions – assumptions and principles – leading to partial views on the phenomena they should deal with. Consequently, this case illustrates how the distinction between public laypersons and experts is not about who perceives reality and who sees reality in the way it actually is. In contrast, it is between two different ways of seeing reality linked to a different set of cultural, cognitive and structural factors, shaping and shaped by individuals and organisations' decisions and actions. The combination of those elements proposed by individuals, as well as the mix and the relevance of the various institutional orders available in a 'particular social world' (Jackall, 1988: 112) can vary. Nevertheless, despite such variability this process works for both public laypersons' and experts' 'particular social world' (Ibid.).

This case is a case of risk management

The definition of the research design – e.g. case selection – did not consider the risk management literature available. Nevertheless, the case shows how direct risk management processes – targeting the outcome of the regulated organisations - play a crucial role in regulators' activities, and are framed by the available logics as one of the appropriate means to pursue the identified missions. Consequently, the case shows another possible 'class of (similar) units' to which it can be related: risk management processes.

The analysis shows how the practical implementation of risk management processes given by the organisations studied, and promoted by the identified logics, are quite similar to the available theoretical-normative worldviews on risk management – anticipation, resilience, imagination, and auditability-accountability. (See Part 1, Chapter 1, Section 1.2.) More specifically, two of the theoretical-normative worldviews about risk management, find a close practical implementation within the railway regulatory network: anticipation and imagination. Such close continuity allows some of the findings about the effectiveness of those approaches to be extended to the larger population of anticipation and imagination approaches to risk management. The analysis of the risk management process filtering steps distinguishes relevant from irrelevant events, as well as the result of the comparison with the available knowledge about organisational accidents' genesis, allowing us to better understand the strengths and weaknesses of these two approaches to risk management.

Anticipation is particularly effective in dealing with individual accidents, rather than with organisational accidents. Anticipation tends to focus attention on phenomena closest to the average with reference to their magnitude, and that have a certain frequency. Nevertheless, anticipation tends to put outliers, such as organisational accidents characterised by extremely high magnitude and extremely low frequency, 'out of sight'. In addition, if anticipation is linked to strong deductive reasoning and the regulatory domain is framed as a closed system (cost-benefit logic), it tends to employ predefined categories through which events are classified and pre-selected. Consequently, it runs the risk of not allowing emerging phenomena to be seen. If such assumptions are relaxed, and the anticipation approach is combined with both inductive reasoning, as well as an open system view on the regulated domain (standard logic), increasing the sensitivity of the process to environmental stimuli, the possibility of catching emerging phenomena increases.

Imagination fostering alternative scenarios is more effective than anticipation in catching organisational accidents and organisational accident precursors. The plurality of views and the attention to details stimulating and stimulated by abductive reasoning, allows phenomena and emerging threats, not visible from anticipation's point of view, to be seen. Nevertheless, imagination fosters hypothetical futures in which alternative precursors or accident scenarios could happen, but this future is just plausible: neither real, nor probable. Thus, it is difficult to distinguish what, from being plausible could become real, from what is just plausible but will never become real. Such a gap between being plausible and becoming real is the main weakness of the imaginative approach. More specifically, the risk that the imaginative approach runs is to dedicate the finite amount of available resources to face events that, in any case, would never happen. In addition, another question arises, what is the limit to this reasoning? How far can we go in imagining alternative plausible futures? For example, once someone recounted a true story about a periodical car inspection that happened in Germany: the inspected car was quite old, but in good condition; the engine, the lights, the brakes, all were working properly, but the inspector saw a little hole in the body of the car. The interesting part of the story was the explanation the inspector gave of the reason why, given the hole, the body should be repaired or substituted, in order to allow the car to pass inspection: 'a kid – kids have little fingers – could insert a finger in the hole when you are stopping at the traffic light, you might not see him/her, you could restart the car, trail, and kill the kid.' Can we say that it is impossible? We cannot, but is it reasonable to close or to cover every little hole in any vehicle in the world because kids can insert fingers in it? Thus, imaginative risk management can be extremely useful in many situations. But a key question remains: what is the limit of it?

More in general, the analysis confirms that choices about risk management are not just technical ones (Jasanoff, 1993; 1998). Different risk management strategies, such as anticipation and imagination, present different pros and cons, and choosing one approach instead of another entails decisions about the amount and the allocation of resources society accepts to invest in avoiding, coping with or facing the side-effects of human activities. The choice does not refer just to the acceptability of risk, but it is embedded within the process itself: the relevant threats are filtered in or out through the process, not as a separate step in which decision are made. Thus, choosing an approach to risk management is not just a technical matter; but is an embedded political decision. This adds stimuli for reflection about the strategies and the organisations in charge of managing risk in our society. More specifically, to recognise the political component of risk management puts into question the attribution of responsibilities about risk decisions the risk-based approach to risk management fosters. The risk-based approach places decisions about risk within private companies and within public non-majoritarian agencies. Thus, decisions about risk, potentially affecting the whole society, are *de facto* made by non-elective and/or private organisations.

This case is a case of a risk-based regulatory network

The case was chosen ‘on paper’ for being a case of a risk regulatory network; this with the idea of enriching the knowledge about this widespread approach to regulation, by referring to the ‘larger class of (similar) units’ (Gerring, 2004: 342) of risk regulatory networks. Nevertheless, the empirical analysis revealed that the case was more complex than what the available contributions about risk regulation theorise. Thus, the reference to this broader population of cases became more complex as well. The case highlighted how the risk-based approach was widespread within the network, but as an ‘espoused theory’ (Argyris and Schon, 1974). The various organisations involved show differing and more blurred ‘theories in use’ (Ibid.). In order to see such variability the examination of the inter-organisational level was crucial. More specifically, this level of analysis allowed the variability affecting the practical translation of the risk-based approach given by the organisations studied, to be seen. Consequently, a discontinuity emerged in considering the politico-economic and inter-organisational levels. The Italian level presented a regulatory strategy still close to the control-command approach to regulation, leading to the implementation of hybrid approaches to regulation mixing the politico-economic level’s risk-based logic with assumptions, strategies and ideas closest to the control-command one. The contribution that this case gives to the risk regulation field is in looking at regulation from a lower level of analysis, to catch the variability within a regulatory network which, from a politico-economic level’s point of view, looks just like a risk-based one. Consequently, it highlights an area of variability not yet explored. In looking inside umbrella concepts such as ‘regulatory state’, previous studies identifying the general trend toward risk-based regulation, present a more blurred situation by looking at the differences between nation-states (e.g., Jasanoff, 2005a; 2005b), or within nation-states through different regulatory domains (e.g., Hood et al., 2001). By showing another area of variability, this study represents a further step in this direction: variability exists within the same regulatory domain and between different levels of government.

The importance of the level of analysis is relevant in looking at the macro level as well. More specifically, the study shows how the context-specific logics – cost-benefit, standard and possibility logics – constitute a mix between the risk-based logic and different institutional orders, as well as a different weight of the same institutional orders. In examining the purpose of creating a unique European railway market, this element shows the depth of the differences existing between the European and the Italian approach to risk regulation. Within the political arena, the objective of creating a similar approach to safety around Europe has always been framed as a 'methodological issue': the need to share the same safety methods or processes. Nevertheless, the analysis of the role played by the various institutional orders in shaping the context-specific logics, highlights how the distinction is not just about the 'methods in use'. Methods are embedded in cultural assumptions and principles linked to different conceptions about the role of the state, the mission regulatory agencies should pursue and the sacredness of human life. This allows the complexity of the objective to share a common approach to safety across Europe to be perceived and suggests the need to address the issue at a different level: it is more about the search for a common and shareable cultural background, than about the definition of processes and methods.

This case is a case of symbolic and material interaction

The institutional logic perspective defines logics as the context-specific product of the interaction between symbolic and material components. Thus, looking at the relationship between the symbolic and the material, allows the role played by those components in the definition of a context-specific logic, to be seen (Jackall, 1988; Friedland and Alford, 1991). The case of the Italian regulatory network has turned out to be an interesting one to explore how the material and symbolic interplay fosters context-specific logics. The interaction of the symbolic and material components is specifically relevant in the formation of the standard and possibility logics. The distinction between macro and meso level effects allows the meso-meso effects regarding the material and symbolic/cognitive components of those context-specific logics to be distinguished better and examined. More specifically, the case shows how, given the influence of the same institutional orders on the two logics (macro-meso interaction) – prevalence of the state on the market institutional orders, and influence of the religion and community ones – the main sources of variability between the two logics, shaping two different methods of reasoning and risk definitions, are the organisational structures and coordination strategies. Thus, given the influences of the same institutional orders, the organisational structures and the coordination strategies favour the development of different inference processes.

The analysis confirms Weick's (2005) thesis about the relationship between coordination and method of reasoning: a by standardisation coordination favours deductive reasoning, in contrast, a by mutual adjustment coordination favours abductive reasoning. The case of the Italian railway regulatory network constitutes a further empirical validation of Weick's theory. More specifically, Weick's analysis considers two main cases of organisational failure of imagination: the Challenger disaster, and the 9/11 terroristij attack. He shows how both NASA and US National Intelligence's failure of imagination were linked to a bureaucratic organisational structure coordinated through standardisation that favoured deductive reasoning. Then, assuming that the presence of abductive reasoning would allow the organisations studied to intercept the disaster and the terrorist attack before they happened, he identified, in the coordination by mutual adjustment, a way of favouring this method of reasoning. Thus, the analysis provided empirical evidence for the relationship between standardisation and deduction, but not for the relationship between mutual adjustment and abductive reasoning. On the contrary, the case of the Italian railway regulatory network allows us to compare two organisations in which, given the same set of assumptions and principles promoted by the same institutional orders influence, we can observe how two different material sets foster two different symbolic/cognitive approaches, providing empirical evidence for both the relationship: standardisation-deduction (standard logic) and mutual adjustment-abductive reasoning (possibility logic). Thus, this case can be considered a case of symbolic/material interaction confirming and giving additional empirical foundation to Weick's theory.

This case is a case of focus of attention mechanism

This case can be considered a case of focus of attention mechanism providing further insight into the relevance of such mechanism in affecting our view(s) on reality. Previous studies have highlighted how logics represent 'conceptual lenses' that are at the same time a way to see and a way not to see: logics focus individuals' attention on certain problems, but not on others, as well as on certain solutions despite the potential multiplicity of available solutions (March and Simon, 1958; Simon, 1962; March and Olsen, 1976; Ocasio, 1997; Thornton and Ocasio, 1999; Thornton et. al., 2005; Cho and Hambrick, 2006; Lounsbury, 2007). This study, by presenting an analytical representation of the available environmental stimuli regulators face, and by comparing the environmental stimuli on which logics focus regulators' attention, with the available insight on organisational accidents' genesis, allows the consequences of such mechanism to be explored. Thus, on the one hand, it shows the extent to which this mechanism can affect our view of reality, as well as the consequences of such a mechanism from a practical and concrete point of view. On the other hand, it offers further empirical validation on the relevance of the focus of attention mechanism; more specifically, the presence of three different logics, and the analytical representation of the available environmental stimuli, allows us to illustrate how by changing the logics' 'lens' the phenomena on which regulators attention is focused changes as well. Consequently, this case allows us to structure counterfactual reasoning: if x changes, y changes as well. This counterfactual statement constitutes a 'smoking gun' (Collier, 2011: 827) in sustaining the relevance of such a mechanism in shaping our views.

This research goes a step further with reference to the available explanations on regulatory failure by pointing out the intrinsic bias of any view on reality. The examination of the focus of attention mechanism shows how, despite the presence of regulating organisations, accidents happen not because regulators are linked to regulated organisations by inappropriate relationships or conflicts of interests (Froud et al., 2004; Hirsch, 2003; Citron, 2003), adopt unethical or immoral behaviour (Mintzberg, 2004; Froud et al., 2004; Williams, 2004a; 2004b; Ghoshal, 2005), or are too close to regulated organisations or too far away from them and, thus do not have sufficient or sound information (Vaughan, 1996; 2003; Reason, 1997). On the contrary, accidents can happen because standardised processes, accurate categories, precise definitions, scientific rigor and market rationality can lead regulators to look away from events that are significant in organisational accidents' genesis. And even if other points of view are available, the high degree of legitimacy reinforcing such standardised processes, accurate categories, precise definitions, scientific rigor and market rationality, prevents other points of view from being considered. The available logics and their interplay focus regulators' attention on events with limited consequences, but with high frequency. On the contrary, organisational accidents tend to be normalised and classified as random, residual, not further reducible, and/or associated with an extremely low risk. The study does not exclude other explanations of regulatory failure, but highlights a different, not yet explored, contributing factor. It does not allow us to establish the weight that those different contributing factors can have in compromising regulators' possibility to avoid a dangerous event. Nevertheless, it focuses our attention on the intrinsic and, as yet, unexplored limits of the ways in which regulators see reality.

More in general, the institutional logics perspective offers a different point of view on the understanding of the partial and selective nature of any perception and, more specifically, of the perceptions linked to possible negative and unwanted outcomes. The 'What-You-Look-For-Is-What-You-Find' principle (Hollnagel, 2009: 1) is not new: the partial and selective nature of perceptions has been stated by different disciplines such as cognitive psychology, cognitive and psychological engineering as well as cognitive philosophy. Such a principle underlines that our understandings and interpretations of reality are strongly influenced by the information we pay attention to and notice. In order to explain this selection of information, which shapes our understanding of the phenomena we face, different mechanisms have been identified, for example, schemata (e.g., Minsky, 1975; Rumelhart and Ortony, 1977; Rumelhart, 1980), heuristics (e.g., Pachur, 2012), or mental models (e.g., Johnson-Laird, 2010). Such mechanisms look at phenomena exclusively from a micro level point of view. In contrast, the institutional logic perspective allows for 'bringing the society back in' (Friedland and Alford, 1991: 232) and explains the selective and partial nature of our understanding of the world from a meso point of view. Thus, it permits us to recognise the social and structural basis of such cognitive mechanisms, as well as the way in which they are socially legitimised and strengthened. Research points out that looking at understandings and interpretations of reality from the institutional logic perspective allows us to specify the cultural, organisational and social basis of such selective perceptions identifying patterns affecting different organisations or different groups of people without being reduced to a deterministic or functionalistic interpretation.

This case is a case of normalisation of deviance

The analysis of the Italian railway regulatory network provides additional empirical evidence about the role of normalisation of deviance (Vaughan, 1996) in preventing organisations from seeing and classifying as risky, potentially dangerous event. The case shows some peculiarities that allow us to add some elements to the theorisation of the way in which such a mechanism works.

This case shows how the normalisation of deviance mechanism does not exclusively affect events that do not lead to dangerous consequences, but can affect the perception of events leading to extremely dangerous consequences as well. More specifically, the analysis underlines how the proactive approach, stress on the statement that 'zero risk doesn't exist', as well as the cost-benefit analysis instrument, sustained by the cost-benefit logic point of view, can lead to the normalisation of accidents as well. In this case, it is the extremely low frequency of the event, instead of the absence of dangerous consequences, which favours the normalisation of the events. More specifically, following the cost-benefit logic, accidents tend to be classified as normal accidents (Perrow, 1999), instead of as epistemic (Downer, 2011) or organisational (Reason, 1990; 1997; 2008). Thus, accidents tend to be seen as an intrinsic property of the system that, no matter what you do, cannot be avoided (zero risk doesn't exist). This case shows how the characteristics of the event interact with the logics through which events are classified and interpreted. Consequently, it shows the strong role of logic in the definition of the events that are normalised, as well as the less important role played by the events, in and of themselves, in this process.

This element shows the potential danger of considering the statement that 'zero risk doesn't exist' as an assumption on which to define procedures and management strategies. Even if, for example, the available study on organisational accidents confirmed that not all types of events are preventable (Power, 1999; Downer, 2011), to start from the statement that in any case we cannot prevent accidents before they happen, can be dangerous. The risk is to broaden more and more, over time, the scope of the range of the events classified as unavoidable, as well as to fail to recognise the organisational accidents even after they happen; losing a chance to improve the system and avoid further accidents of the same type in the future.

LIST OF FIGURES AND TABLES

Figure1: Social sciences and risk – an analytical map (My elaboration.) *39*

Figure2: Risk Management Process in ISO 31000 (IS/ISO 31000, 2009: 14) – the numbers show the overlapping with the COSO (2004) standards *62*

Figure 3: Institutional logics and the focus of attention: a graphical representation (My elaboration.) *121*

Figure 4: Levels of analysis considered in this dissertation (My elaboration.) *133*

Figure 5: Interaction/Connection – systems more vulnerable to normal accidents (Perrow, 1999) *139*

Figure 6: The latent factors model (Reason, 1997) *143*

Figure 7: Swiss Cheese Model (Reason, 2008) *144*

Figure 8: Heinrich's pyramid (Heinrich, 1980: 61) *147*

Figure 9: Risk-based regulatory network (The diagonal bars highlights the organisations, the point of view of which, this study aims to maintain.)(My elaboration.) *164*

Figure 10: The ends of risk-based logic (Document ERA, Slide: Dissemination of Commission Regulation on CSM on Risk Assessment, 2009, p. 16) *191*

Figure 11: Risk-based logic processes and strategies (Document, ERA, Slides: Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 2013, p. 13) *194*

Figure 12: European Railway Agency's foundational purposes (ERA, Slide: Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 2013, p. 14) *196*

Figure 13: The Italian Railway Regulatory Network *201*

Figure 14: Cost-benefit logic – risk definition (ERA, slides: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 11) *204*

Figure 15: Example of Risk evaluation matrix given in the EN50126 standard (from EN 50126-1, p. 21) *211*

Figure 16: Standard logic – the zero-risk objective (NSA, Slides: Analyses and evaluation of risks in the railway sector. The application of EN 50126, 2012, p. 18) *214*

Figure 17: Differences between the standard and the cost-benefit logics with respect to the reference to the EN50126 international standard (NSA, Slides: Analyses and evaluation of risks in the railway sector. The application of EN 50126, 2012, p. 23) *217*

Figure 18: Standard logic – risk matrix for risk acceptability evaluation (NSA, Document: R.F.I Provision 51/ 2007) *218*

Figure 19: Standard logic – accidents are not acts of God (NSA, Slide: Training session POLFER CAPS – Cesena Workshop – Module 2A, 2012, p. 5) *220*

Figure 20: Objectives steered by the cost-benefit logic (ERA, slide Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 12) *224*

Figure 21: Safety Harmonisation (ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 18) *226*

Figure 22: Objectives driven by the standard logic (NSA, Slide presentation: Agency training course for railway police, 2011, p. 5) *228*

Figure 23: Role of the regulators – Independency and transparency (NSA, Slide presentation: Agency training course for railway police, 2011, p. 7) *232*

Figure 24: Common Safety Methods on Risk Evaluation and Assessment: Risk Management process diagram (Regulation, 352/2009, Appendix, p. L 108/18) *241*

Figure 25: Old Scenario vs. New Scenario – reactive vs proactive approach (ERA, Slide: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 3) *245*

Figure 26: Reactive vs. Proactive approach (ERA, slide: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 68) *245*

Figure 27: Reactive approach: accident used to prevent accident (ERA, slide: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9th October 2013, p. 69) *246*

Figure 28: Viareggio accident: detached wheels-set (the white arrow indicate the axle.) 254

Figure 29: Example of a railroad switch..... 255

Figure 30: Safety indicators collected by Eurostat in each Member State (Regulation 93/2001, Annex H, p. 12) 260

Figure 31: Method for calculating the NRV (Commission Decision of 5 June 2009 on the adoption of a common safety method for assessment of achievement of safety targets, as referred to in Article 6 of Directive 2004/49/EC of the European Parliament and of the Council, p. L 150/15) 261

Figure 32: National Safety Performance Assessment Process (ERA, 2013, Assessment of Achievement of Common Safety Targets, Figure 1: Decision flowchart for the assessment procedure of CSTs, p.8) 264

Figure 33: Second step of the national safety performance allowing a safety deterioration of the 20% (ERA slide, Results of TF on CSM for CST, Working Parties Meeting, Lille, 1 October 2013) 266

Figure 34: Networking activity as a key role of the ERA (ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 25) 272

Figure 35: Cost-benefit logic – what, but not how indirect risk management strategy: (ERA, Slide: Dissemination of the Commission Regulation on Common Safety Methods (CSM) on Risk Evaluation and Risk Assessment, 2009-2011, p. 262) 277

Figure 36: Risk Management Wheel (ERA, Website) 281

Figure 37: The main steps of a risk management process (ERA, slides: Workshop on "risk evaluation and assessment" in the context of inland transport of dangerous goods - 8-9 October 2013, p. 12) 283

Figure 38: Risk Management Wheel (ERA, Website) 285

Figure 39: SMS and business development (ERA slide, Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 48) 286

Figure 40: SMS – safety and business objectives (ERA slide, Dissemination Workshop of the Safety Management System, Common Safety Methods and ECM Regulation, 12-13 February 2013, p. 50) 287

Figure 41: Inspections' Decision Support System (NSA, Slide: Inspection activities finalised to the identification of systematic lacunas, 2013, p.12) *305*

Figure 42: Example of graph contained in the quarterly inspection report (NSA; Trimester report on inspection activities on the rolling stock of railway companies 3rd trimester 2012, 2013, p. 13: Graphic 12 – no. NC on element C checks) *305*

Figure 43: ERA's organisational chart *326*

Figure 44: Italian NSA's organisational chart (NSA, 2012, Annual Report, Annex B1, p. 79) *328*

Figure 45: NIB's organisational chart (NIB, 2012, Annual Report, p.2) *332*

Figure 46: Logics of risk management and regulation and the inter-institutional system (My elaboration.) *345*

Figure 47: From logics to environmental stimuli (E) (My elaboration.) *352*

Figure 48: Informational inputs activating risk management process developed by regulators: a graphical representation (My elaboration.) *357*

Figure 49: The cost-benefit logic's focus of attention – a graphic representation (My elaboration.) *359*

Figure 50: The standard logic's focus of attention – a graphical representation (My elaboration.) *361*

Figure 51: Standard logic – a graphic representation of the bottom-up effect (My elaboration.) *362*

Figure 52: Possibility logic – a graphic representation (My elaboration.) *363*

Table 1: Insurance, business, finance, technology, work, natural phenomena and national security: the various meanings of risk (My elaboration.) *30*

Table 2: Four worldviews on risk management (My elaboration.) *68*

Table 3: Definitions of regulation over time (Adapted from Hutter, 2006: 203.) *89*

Table 4: Control-command vs. risk-based approach to the regulation of side-effects (My elaboration.) *92*

Table 5: Control components and regulatory regime content and context (Hood et al., 2001: 22) *99*

Table 6: The inter-institutional system (Thornton et al., 2012: 73) *115*

Table 7: Institutional logics' core meta-theory – differences between institutional logics perspective and institutional theories (My elaboration.) *117*

Table 8: Institutional logic – main proposed definitions.. *122*

Table 9: The logic content – empirical indicators (My elaboration.) *124*

Table 10: Methods of reasoning *126*

Table 11: Logics' legitimacy and interplay – the coercive-normative component (My elaboration.).. *131*

Table 12: Taxonomy of accidents (My elaboration.)... *146*

Table 13: Risk-based logic (My elaboration.) *188*

Table 14: The inter-organisational leve – cost-benefit, standard and possibility logics.. *203*

Table 15 Standard logic – tangible outcomes from 2010 to 2012 (Adapted from NSA, Annual report 2011, 2012, 2013) *297*

Table 16: NSA's reaction to NIB's recommendations (adapted by NIB's annual report 2011-2013, and NSA's annual report 2011-2013) *300*

ANNEX 1

Example of hazard log.

HAZARD LOG E DOCUMENTO DI VALUTAZIONE DEI RISCHI	RISPETTO ALLE SITUAZIONI PERICOLOSE
AGGIORNATO DA:	RIUNIONE ESPERTI DEL:
VERIFICATO DA:	VISTO DA:
APPROVATO DA:	
DATA:	

PREMESSA: a seguito di revisione periodica del DVR ed anche in relazione all'attivazione del servizio con materiale ordinario viaggiatori rimorchiato con auto al seguito (Autozug), nonché alle indicazioni di dettaglio fornite da ANSF sulle modalità di stesura dell'Hazard Log, si riporta di seguito il registro delle situazioni pericolose con la corrispondente analisi e valutazione del rischio in conformità a quanto previsto dalla Procedura PS002 e PS009 del sistema di gestione della sicurezza di . Il presente documento è stato quindi prodotto e revisionato a seguito di riunioni ed incontri con il gruppo di esperti nelle varie discipline ferroviarie.

LEGENDA: SP (situazione pericolosa), ICS (Indicatore Comune di Sicurezza), IPS (Indicatore Prestazionale di Sicurezza), PS (Piano Annauale della Sicurezza), CM (Coordinatore Manutenzione), PdC (Personale di condotta), PdA (Personale di accompagnamento), PdV (Personale di verifica), PdMan (Personale di manovra), PdO (Personale di officina), SCMT (sistema controllo marcia treno), SAMAC (sistema di acquisizione e mantenimento delle competenze), DPC (disposizioni particolari di circolazione), FL (Fascicolo Linea), SSB (sottosistema di bordo), IF (Impresa Ferroviaria), GI (Gestore infrastruttura); Personale SO (Personale Sala Operativa).

REGISTRO DELLE SITUAZIONI PERICOLOSE (HAZARD LOG) ED ANALISI							INTERVENTI DI MITIGAZIONE			
nr. prog.	Area	Situazione pericolosa	Conseguenze possibili	Personale coinvolto direttamente	Frequenza/ Gravità	Profilo di rischio esercizio	Azioni mitigative esistenti e valutazione	Frequenza / Gravità - post-mitigaz.	Rischio residuo	Effetto azione / note ed ulteriori attività mitigative
SITUAZIONI CRITICHE LEGATE AL SERVIZIO										
SP1	Materiale Rotabile	Spezzamento treni per rottura organi di aggancio	Arresto del materiale senza dare luogo ad eventi incidentali. Per le conseguenze derivate da una non corretta immobilizzazione si rimanda al punto successivo.	PdC/ PdV	remota/ insignificante	tollerabile	In riferimento alla tipologia di gancio (automatico) presente sui mezzi leggeri, ed in relazione ai dati disponibili maturati da nei servizi effettuati in doppia composizione, non si sono riscontrate criticità. Per quanto concerne il materiale ordinario, il PdC è istruito sul corretto utilizzo del rubinetto del freno (IEFCA) mentre il PdV è chiamato al controllo, durante le visite tecniche, dell'aggancio dei veicoli. I materiali sono manutenuti secondo quanto previsto dal Piano di Manutenzione. Inoltre, in caso di spezzamento, la condotta viene interrotta con frenatura ed arresto dei veicoli in composizione. I materiali sono provvisti di idonei strumenti di immobilizzazione (staffe).	improbabile/ insignificante	trascurabile	Prevenzione : corretto uso del rubinetto del freno come da normativa vigente (IEFCA) e corretta effettuazione delle visite tecniche di verifica. In caso di emergenza, intervento secondo l'IO-PS006-PEM e secondo regolamenti. Protezione: L'attuazione delle procedure previste da regolamento ferroviario (RS) e delle procedure di emergenza richiamate anche dall'istruzione Operativa IO-PS006-01 attuate dal personale in maniera efficace, possono escludere lo scenario conseguente ad urti e collisioni.
SP2	Personale	Non corretto stazionamento / immobilizzazione del treno	Può verificarsi che il treno, non correttamente immobilizzato, si muova	PdC/ PdA	remota/ critica	indesiderabile	Il personale viene formato ed istruito sul materiale rotabile. Il sistema di monitoraggio interno a prevede inoltre un controllo a campione sul comportamento del personale per lo stazionamento. Viene inoltre verificato che il materiale sia fornito dei dispositivi idonei all'immobilizzazione del materiale rotabile e che il personale sia formato sull'utilizzo degli stessi. Il materiale rotabile leggero è dotato di freno a molla che viene inserito dal PdC posizionando il treno in parking, con le modalità previste da manuale, oppure si attiva automaticamente in caso di intervento del vigilante.	improbabile/ critica	tollerabile	Prevenzione: Fermo restando l'attivazione delle attività mitigative, la frequenza non può essere ragionevolmente ridotta ad inverosimile. Il controllo delle SP viene effettuato da personale istruttore con affiancamento e scorte secondo SAMAC.

ANNEX 2

Example of check list for the issuing of the Safety Certificate Part A

NSA
Lista di controllo per la valutazione di conformità del Sistema di Gestione della Sicurezza – Parte A

Data	
Organiszazione controllata	
Finalità del controllo	
Documenti esaminati	
Esecutore	

Valutazione dei contenuti del sistema di gestione della sicurezza relativi alla Parte A del certificato ai sensi del D.L. 162/07 secondo i criteri di valutazione di cui al Regolamento (UE) 1158/2010

Norma di riferimento/ Requisito	**Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)**	**Proposta di interpretazione del criterio ERA**	**Rilievo**
D.L. 162 – Art. 13 - comma 2 Il sistema di gestione della sicurezza, tenendo conto delle dimensioni e della tipologia di attività svolta, garantisce il controllo di tutti i rischi connessi all'attività di GI/IF, compresa la manutenzione, i servizi, la fornitura del materiale e il ricorso ad imprese appaltatrici? Fatte salve le vigenti norme in materia di responsabilità, il sistema tiene parimenti conto, ove appropriato e ragionevole, dei rischi generati dalle attività di terzi?	***A. MISURE DI CONTROLLO DEI RISCHI PER TUTTI I RISCHI CONNESSI ALL'ATTIVITÀ DELL'IMPRESA FERROVIARIA***		
	A.1 - Esistono procedure in atto per individuare i rischi connessi alle operazioni ferroviarie, compresi quelli derivanti direttamente dalle attività lavorative, dalla progettazione del lavoro o dal carico di lavoro e dalle attività di altre organizzazioni/persone	L'IF deve descrivere in una procedura come identifica i rischi associati all'esercizio ferroviario in essere, alla attribuzione delle mansioni, ai carichi di lavoro, alle attività di altre organizzazioni (interne al sistema ferroviario) che influiscono sulla sicurezza. I fattori sopra elencati devono scaturire dalla descrizione del sistema che risponda a criteri di completezza ad esempio individuando tutte le funzioni svolte o tutti gli elementi costituenti o tutte le anomalie possibili con lo scopo di individuare i confini della propria parte di sistema e tutti i punti di interazione con altre organizzazioni o elementi esterni ad esso. Tra le altre, le evidenze relative alle assunzioni di responsabilità delle singole attività manutentive deve essere riportata nel registro degli eventi pericolosi del sistema (vedi punto B).	
	A.2 - Esistono procedure in atto per elaborare e attuare misure di controllo del rischio.	L'IF deve descrivere come dall'analisi (del punto A.1) scaturiscono le misure di controllo dei rischi e le relative modalità e responsabilità di attuazione.	
	A.3 - Esistono procedure in atto per controllare l'efficacia delle misure di controllo del rischio e per realizzare i cambiamenti, qualora richiesti.	L'IF deve descrivere in una procedura modalità e responsabilità per verificare che la combinazione tra probabilità ed entità delle conseguenze (livello di rischio) di ogni evento incidentale si mantenga al di sotto della soglia di accettabilità definita nell'hazard log. La verifica deve essere svolta monitorando che gli opportuni parametri critici (fattori causali, precursori, eventi statisticamente correlati agli inconvenienti) preventivamente individuati permangano entro i limiti prestabiliti. Questo processo deve consentire l'introduzione dei cambiamenti quando necessario.	

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	A.4 - Esistono procedure in atto per individuare la necessità di collaborare con altri organismi (come il gestore dell'infrastruttura, l'impresa ferroviaria, il fabbricante, il fornitore di servizi di manutenzione, l'organismo incaricato della manutenzione, gli addetti alla manutenzione dei vagoni, il fornitore di servizi e l'ente appaltante), ove opportuno, su tematiche di intervento comune, che hanno la probabilità di influire sulla messa in atto di adeguate misure di controllo del rischio, a norma dell'articolo 4, paragrafo 3 della direttiva 2004/49/CE.	L'IF deve aver una procedura per individuare le organizzazioni (GI, IF, costruttori, fornitori di manutenzione, ECM, detentori di veicoli, fornitori di servizi, appaltatori) la cui attività incide sui rischi della propria parte di sistema ferroviario ed il corretto interfacciamento con esse per sviluppare le necessarie cooperazioni al fine di gestire tutti i rischi derivanti dallo svolgimento delle attività di interfaccia con tali organiszazioni.	
	A.5 - Esistono procedure per la documentazione e la comunicazione concordate con gli organismi appropriati, compresa l'individuazione di ruoli e responsabilità di ogni organismo partecipante e le specifiche per lo scambio di informazioni.	La procedura del punto A.4 deve stabilire le responsabilità e modalità per definire gli accordi specifici sulla gestione dei rischi condivisi, come ad esempio quelli che scaturiscono dalla gestione dei service, dalla gestione delle interfacce. Devono essere stati elaborati tutti gli accordi necessari per l'attuazione di detta procedura (contratti o altri impegni formali).	
	A.6 - Esistono procedure per monitorare l'efficacia di queste disposizioni e ad attuare delle modifiche, ove necessario.	L'IF deve avere una procedura per il monitoraggio dell'efficacia degli accordi di cooperazione ai fini di apportare i necessari correttivi agli accordi quando questi non si rivelino efficaci (ad esempio per inadempienza o per inattuabilità di alcuni accordi). Il criterio deve considerarsi esteso anche ad accordi interni, nel caso di organiszazione complesse o articolate sul territorio (ad esempio accordi interdivisionali o tra impianti dislocati in aree geografiche diverse) L'elaborazione delle necessarie misure di mitigazione del rischio condiviso e per il corretto monitoraggio nel tempo della relativa efficacia ricade nel punto A.3.	
	B.CONTROLLO DEL RISCHIO CORRELATO ALLA FORNITURA DI MANUTENZIONE E MATERIALI		
	B.1 - Esistono procedure per ricavare i requisiti/gli standard/i processi di manutenzione dai dati relativi alla sicurezza e dall'assegnazione di materiale rotabile.	Deve essere presente una procedura che garantisca per ogni tipologia di rotabile utilizzato la determinazioni di: - modalità d'uso, - condizioni di esercizio, - piano e modalità di manutenzione. Tale procedura deve avere la finalità di mantenere i requisiti stabilito all'atto della autorizzazione della messa in esercizio Nel caso in cui l'entità responsabile della manutenzione è esterna all'IF, la procedura deve descrivere come l'IF acquisisce queste informazioni e come alimenta il responsabile della manutenzione in modo da garantire che i requisiti/standard/processi di manutenzione se ne prendano carico.	
	B.2 - Esistono procedure per adattare gli intervalli di manutenzione secondo il tipo e l'entità del servizio effettuato e/o i dati ricavati dal materiale rotabile.	In una procedura deve essere descritta la modalità di tenuta sotto controllo degli intervalli di tempo o percorrenza che non devono essere superati tra due successivi interventi manutentivi. L'IF deve descrivere le modalità per avviare un processo di adeguamento degli intervalli manutentivi secondo i dati e le informazioni derivanti dal servizio realmente effettuato dal materiale rotabile, individuando gli enti/organizzazioni (entità responsabile della manutenzione) che occorre coinvolgere allo scopo.	
	B.3 - Esistono procedure volte ad assicurare che la responsabilità della manutenzione sia chiaramente definita, a individuare le competenze richieste per i posti di manutenzione e ad assegnare livelli adeguati di responsabilità.	Deve essere descritta la pianificazione della manutenzione, sia internalizzata che affidata a terzi. In ogni caso deve essere specificata l'organizzazione, i ruoli, le responsabilità, le competenze nel processo manutentivo. Nel caso di affidamento a terzi tale regola deve essere trasferita all'organizzazione fornitrice e l'IF ha l'onere del controllo della corretta applicazione (audit, monitoraggi etc.). Per questo aspetto, effettuare una verifica con quanto emerso per il punto A.6.	

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	B.4 Esistono procedure per raccogliere informazioni sulle disfunzioni e sui difetti derivanti dal funzionamento quotidiano e per segnalarle ai responsabili della manutenzione.	Devono essere descritti i controlli da effettuare in esercizio e l'utilizzo di questi dati con opportuni strumenti di analisi al fine di rilevare l'efficacia della manutenzione. Tale evidenza dovrebbe essere riportata nella procedura connessa alla gestione delle non conformità e anomalie (ad esempio quelle definite nel libro di bordo).	
	B.5 - Esistono procedure per individuare e segnalare i rischi derivanti dai difetti e dalle non conformità o dai malfunzionamenti legati alla costruzione durante il ciclo di vita alle parti interessate.	Deve essere descritta la modalità con cui i difetti, le non conformità e i malfunzionamenti rilevati in esercizio durante l'intero ciclo di vita del materiale (che hanno origine nella progettazione e costruzione) sono identificati ed analizzati per determinare i rischi da loro originati. L'analisi dei rischi deve essere continuamente aggiornata con tali analisi. Tale evidenza dovrebbe essere riportata nella procedura connessa alla gestione delle non conformità e anomalie.	
	B.6 - Esistono procedure per verificare e controllare le prestazioni e i risultati della manutenzione per garantire che soddisfino gli standard aziendali.	Deve essere descritto nel piano di manutenzione e controllo (PMC) le modalità e i criteri di accettazione dei controlli interni (o sui fornitori) in merito alla conformità della manutenzione effettuata. Le prestazioni e i controlli della manutenzione devono essere soggetti a monitoraggio da parte della IF, anche attraverso la definizione di opportuni indicatori. Pertanto deve esserci una procedura che stabilisca come determinarli, verificarli e le responsabilità del loro controllo.	
	C. CONTROLLO DEL RISCHIO CORRELATO ALL'USO DI IMPRESE APPALTATRICI E CONTROLLO DEI FORNITORI		
	C.1 - Esistono procedure per verificare la competenza delle imprese appaltatrici (compresi i subappaltatori) e dei fornitori.	Devono essere definiti i criteri di qualificazione dei fornitori ed appaltatori (su processi che hanno impatto sulla sicurezza dell'esercizio). E' incluso anche il riesame dell'idoneità nel tempo del fornitore.	
	C.2 - Esistono procedure per verificare e controllare le prestazioni e i risultati legati alla sicurezza di tutti i servizi appaltati e dei prodotti forniti dall'impresa appaltatrice o dal fornitore per garantire che siano conformi ai requisiti stabiliti nel contratto.	Deve essere prevista una procedura per stabilire le modalità, l'estensione e le responsabilità dei controlli di conformità dei prodotti/servizi oggetto di fornitura o appalto.	
	C.3 - Le responsabilità e le attività legate a problemi di sicurezza ferroviaria sono chiaramente definite, conosciute e assegnate tra le parti contraenti e tra tutte le altre parti interessate.	Devono essere specificate le modalità e le responsabilità per trasmettere, alle organiszazioni esterne che interagiscono con la sicurezza dell'esercizio ferroviario dell'IF, i requisiti, le responsabilità e i compiti necessari per la fornitura di prestazioni inerenti alla sicurezza.	
	C.4 - Esistono procedure volte ad assicurare la tracciabilità di documenti e contratti relativi alla sicurezza.	Deve essere gestita formalmente (emessa, codificata, registrata, conservata) tutta la documentazione ed i contratti relativi a forniture che influenzano la sicurezza.	•
	C.5 - Esistono procedure atte a garantire che le attività legate alla sicurezza, compreso lo scambio di informazioni relative alla sicurezza, siano effettuate dalle imprese appaltatrici o dal fornitore conformemente ai relativi requisiti stabiliti nel contratto.	Laddove non siano applicabili le modalità di controllo finale delle prestazioni rese devono essere previste modalità di qualificazione dei processi, che fanno parte della prestazione fornita (ivi compreso lo scambio di informazioni relative alla sicurezza), attraverso la determinazione dei relativi requisiti ed il successivo controllo di questi ultimi.	
	D.RISCHI DERIVANTI DALLE ATTIVITÀ DI ALTRE PARTI ESTERNE AL SISTEMA FERROVIARIO		
	D.1 - Esistono procedure per identificare i rischi potenziali derivanti da parti esterne al sistema ferroviario, qualora opportuno e ragionevole.	Devono essere previste le modalità per individuare i rischi generati dall'attività di soggetti esterni al sistema ferroviario che siano rilevanti per la sicurezza dell'esercizio nella propria parte di sistema.	

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	D.2 - Esistono procedure per stabilire misure di controllo volte ad attenuare i rischi indicati al punto D1 per quanto riguarda le responsabilità del richiedente.	L'IF deve descrivere come dall'analisi (del punto D.1.a) scaturiscono le misure di controllo dei rischi in modo commisurato alle responsabilità del richiedente .	•
	D.3 - Esistono procedure per controllare l'efficacia delle disposizioni indicate al punto D2 e per attuare le modifiche qualora opportuno.	L'IF deve descrivere in una procedura modalità e responsabilità per verificare che la combinazione tra probabilità ed entità delle conseguenze (livello di rischio) di ogni evento incidentale si mantenga al di sotto della soglia di accettabilità definita nell'hazard log. La verifica deve essere svolta attraverso il monitoraggio della permanenza entro i limiti prestabiliti di opportuni parametri critici preventivamente individuati (fattori causali, precursori, eventi statisticamente correlati). Questo processo deve consentire l'introduzione dei cambiamenti quando necessario.	
D.L. 162 – Art. 13 - comma 3 Il sistema di gestione della sicurezza di ogni GI tiene conto degli effetti delle attività svolte sulla rete dalle varie IF e provvede affinché tutte le IF possano operare nel rispetto delle STI e delle norme nazionali di sicurezza e delle condizioni stabilite dai rispettivi certificati d sicurezza? Il sistema è concepito in modo tale da garantire il coordinamento delle procedure di emergenza del GI con quelle di tutte le IF che operano sulla sua infrastruttura?	Non ci sono criteri ERA specifici per questo requisito.		
D.L. 162 – Art. 13 - comma 4 Il sistema garantisce che ogni anno anteriormente al 30 giugno, tutti i GI e le IF trasmettano all'Agenzia una relazione annuale sulla sicurezza relativa all'anno precedente con tutti i contenuti previsti?	Eliminato in questa versione degli assessment criteria.	La raccolta dei dati per la definizione della relazione annuale si deve basare su un flusso informativo prestabilito in una procedura (fonti, modalità di raccolta, trasmissione, validazione, classificazione dei dati, cadenze di rilevazione, formati), che garantisca la correttezza e completezza delle informazioni relative al periodo di riferimento della relazione annuale.	
D.L.162/07 – All. III – comma 1 Il sistema di gestione è documentato in tutte le sue parti pertinenti?	***E.DOCUMENTAZIONE DEL SISTEMA DI GESTIONE DELLA SICUREZZA***		
	E.1 - Esiste una descrizione dell'attività che chiarisce il tipo, l'entità e il rischio del funzionamento.	Devono essere definiti servizi e prestazioni rese in termini di tipologia, estensione funzionale, caratteristiche peculiari, attività esternalizzate, risorse utilizzate, dimensioni dell'azienda. Elementi di maggior dettaglio (estensione geografica, dati dimensionali etc.) dovranno necessariamente essere inseriti nella definizione del sistema che fa parte dell'analisi e valutazione dei rischi (parte B).	
	E.2 - Esiste una descrizione della struttura del sistema di gestione della sicurezza, compresa l'assegnazione dei ruoli e delle responsabilità.	L'IF deve fornire la descrizione della struttura documentale del Sistema. L'IF deve fornire l'indicazione delle funzioni (organigramma), la descrizione di ruoli (compiti) e responsabilità di tutte le figure aziendali che contribuiscono al funzionamento del sistema di gestione della sicurezza ed i loro rapporti funzionali (descrizione o opportuna simbologia grafica/tabella/matrice) e gerarchici all'interno del sistema relativamente ai processi gestionali del sistema.	
	E.3 - Esiste una descrizione delle procedure del sistema di gestione della sicurezza richieste dall'articolo 9 della direttiva 2004/49/CE e dall'allegato III coerente con il tipo e l'entità dei servizi erogati.	Deve essere fornito un documento che elenchi tutte le procedure di funzionamento dell'SGS. L'elenco deve permettere l'associazione delle varie procedure ai singoli requisiti delle normativa richiamata (Art. 9 e all. III) in modo da verificarne la completa copertura. Il quadro sinottico, se opportunamente codificato, messo sotto controllo ed inserito nei documenti di sistema, potrebbe essere idoneo a soddisfare il requisito.	•

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	E.4 - I processi critici per la sicurezza e i compiti attinenti al tipo di attività/servizio sono elencati e descritti brevemente.	Deve essere fornito un elenco e una breve descrizione di tutti i processi essenziali per la sicurezza e dei compiti fondamentali per lo svolgimento di tali processi. La selezione dei processi deve essere motivata (ad esempio fornendo il criterio di individuazione dei processi critici o all'interno della mappatura complessiva indicando il percorso critico).	
D.L.162/07 – All. III – comma 1 Il sistema descrive la ripartizione delle responsabilità in seno all'organiszazione dell'IF?	***F.RIPARTIZIONE DELLE RESPONSABILITÀ***		
	F.1 - Esiste una descrizione di come viene assicurato il coordinamento delle attività del sistema di gestione della sicurezza all'interno dell'organismo, in base a conoscenze comprovate e a una responsabilità principale a livello di gestione.	Deve esistere all'interno dell'organizzazione una struttura preposta ad assicurare l'attuazione dell'SGS i cui componenti siano dotati di conoscenze appropriate e comprovate nonché di un responsabile. Per poter garantire la completa attuazione dell'SGS questa figura responsabile deve essere collocata opportunamente all'interno dell'organigramma in modo da poter avere la necessaria autonomia da tutte le altre funzioni aziendali coinvolte nell'attuazione.	
	F.2 - Esistono procedure volte ad assicurare che il personale con responsabilità delegate all'interno dell'organismo abbia l'autorità, la competenza e le risorse adeguate per svolgere il proprio compito.	Deve essere descritta la regola aziendale per la selezione del personale a cui affidare le responsabilità, per garantire che il personale abbia la necessaria autorità (da organigramma), conoscenza e disponga delle necessarie risorse per il corretto svolgimento dei compiti assegnati.	
	F.3 - Sono chiaramente definiti gli ambiti di responsabilità relativi alla sicurezza e la ripartizione delle responsabilità a funzioni specifiche ad essi associate, insieme alle relative interfacce.	Devono essere specificati in modo univoco e non ambiguo gli ambiti di responsabilità relativamente ai processi critici per la sicurezza, in modo che non ci siano sovrapposizioni o vuoti di responsabilità, ad esempio alle interfacce tra le funzioni.	
	F.4 - Esiste una procedura volta ad assicurare che i compiti correlati alla sicurezza siano chiaramente definiti e delegati al personale con competenze adeguate.	Deve essere descritta la regola aziendale per la definizione dei compiti correlati alla sicurezza e per garantire che questi siano assegnati a personale in possesso di competenze adeguate.	
D.L.162/07 – All. III – comma 1 Nel sistema è indicato come la Direzione garantisca un controllo a tutti i livelli?	***G. ASSICURARE IL CONTROLLO DA PARTE DELLA GESTIONE A DIVERSI LIVELLI***		
	G.1 - Esiste una descrizione di come vengono assegnate le responsabilità per ogni processo relativo alla sicurezza nell'ambito dell'organismo.	Per i processi relativi alla sicurezza deve essere descritto come si attribuiscono compiti e responsabilità al personale dell'azienda.	
	G.2 - Esiste un procedura per il controllo periodico dell'esecuzione dei compiti assicurato dalla catena di gestione, che deve intervenire se i compiti non vengono eseguiti correttamente.	Devono essere descritte le modalità con cui il management controlla ad ogni livello il corretto svolgimento dei compiti assegnati al personale.	
	G.3 - Esistono procedure per individuare e gestire l'impatto di altre attività di gestione sul sistema di gestione della sicurezza.	Nel caso l'azienda abbia un sistema di gestione integrato (sistema di gestione che contempera finalità ed obiettivi in campi differenti come sicurezza dell'esercizio, sicurezza del lavoro, ambiente, qualità, salute) deve essere definita una procedura per rendere compatibili e definire le priorità dei processi relativi alla sicurezza rispetto ai processi degli altri sistemi di gestione.	
	G.4 - Esistono procedure per rendere le persone che hanno un ruolo nella gestione della sicurezza responsabili delle loro prestazioni.	Deve essere descritto il sistema per valutare il livello di prestazione resa dal personale che ha un ruolo nella gestione della sicurezza (distinto per ogni singola funzione) rispetto agli obiettivi ad esso assegnati.	
	G.5 - Esistono procedure per assegnare risorse per svolgere i compiti nell'ambito del sistema di gestione della sicurezza.	Deve esistere la procedura per l'assegnazione delle risorse necessarie allo svolgimento dei compiti assegnati nell'ambito dell'SGS.	
D.L.162/07 – All. III – comma 1 Nel sistema è indicato come sia garantita la partecipazione a tutti i livelli del personale e dei rispettivi rappresentanti?	***H.COINVOLGIMENTO DEL PERSONALE E DEI LORO RAPPRESENTANTI A TUTTI I LIVELLI***		
	H.1 - Esistono procedure in atto volte ad assicurare che il personale e i rappresentanti del personale siano adeguatamente rappresentati e consultati per la definizione, la proposta, l'esame e lo sviluppo degli aspetti legati alla sicurezza delle procedure operative che possono coinvolgere il personale.	Deve esistere una procedura per garantire che tutto il personale sia adeguatamente rappresentato e consultato all'atto della predisposizione, dello sviluppo e del riesame degli aspetti di sicurezza delle procedure operative in cui è coinvolto.	
	H.2 - Il coinvolgimento del personale e gli accordi di consultazione sono documentati.	La partecipazione del personale ed i risultati di tale partecipazione (es. accordi sulle modalità di partecipazione) deve essere documentata.	
D.L.162/07 – All. III – comma 1	***I. GARANTIRE IL MIGLIORAMENTO COSTANTE***		

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Nel sistema è indicato in che modo è garantito il miglioramento costante del sistema di gestione della sicurezza?	Esistono procedure in atto volte ad assicurare, ove ragionevolmente possibile, il miglioramento costante del sistema di gestione della sicurezza; tali procedure includono: (a) procedure per revisioni periodiche del sistema di gestione della sicurezza, in funzione delle esigenze; (b) procedure per descrivere gli accordi relativi al controllo e all'analisi dei dati relativi alla sicurezza; (c) procedure per descrivere come vengono rettificate le carenze individuate; (d) procedure per descrivere l'attuazione di nuove regole di gestione della sicurezza basate sullo sviluppo e sulle lezioni apprese; (e) procedure per descrivere come vengono utilizzati i risultati degli audit interni per perfezionare il sistema di gestione della sicurezza.	Devono far parte del sistema un insieme di processi e procedure aventi come scopo il miglioramento continuo del sistema stesso. Tale miglioramento deve essere basato sulla ciclica applicazione di fasi di monitoraggio, controllo e riesame di tutti i processi di funzionamento del sistema. Il riesame suddetto deve essere in grado di fornire indicazioni sull'efficacia o sulla necessità di correggere i processi controllati (quelli direttamente connessi alla sicurezza dell'esercizio come ad esempio la condotta/preparazione/gestione del treno, la manutenzione dei componenti critici, ecc.) ma anche di migliorare l'efficacia degli stessi processi di monitoraggio e controllo. Per l'esecuzione del riesame deve essere predisposta una opportuna procedura che tenga conto dei risultati dei seguenti processi: - esecuzione del monitoraggio e dell'analisi dei dati relativi alla sicurezza secondo una procedura definita - attuazione delle opportune azioni correttive rispetto alle carenze rilevate secondo una procedura definita che preveda anche una verifica di efficacia dell'azione applicata; - attuazione delle opportune modifiche al sistema volte al miglioramento dello stesso in base alle esperienze acquisite, secondo una procedura definita; - utilizzazione dei risultati degli audit al fine di individuare ed applicare interventi migliorativi su tutti i processi dell'SGS secondo una procedura definita.	•
D.L.162/07 – All. III – comma 2.a Nel sistema è presente una politica della sicurezza approvata dal direttore generale dell'organismo? La politica è comunicata a tutto il personale?	***J. POLITICA DI SICUREZZA APPROVATA DAL DIRETTORE GENERALE DELL'ORGANISMO E COMUNICATA A TUTTO IL PERSONALE***		
	Esiste un documento che descrive la politica di sicurezza dell'organismo e che: (a)viene comunicato e reso disponibile a tutto il personale, ad esempio tramite l'intranet dell'organismo; (b)è adeguato al tipo e all'entità del servizio; (c)è approvato dal direttore generale dell'organismo.	Il documento deve essere emesso ed approvato formalmente dall'alta direzione (data e firma) e deve contenere i principi ispiratori dell'operato dell'azienda in materia di sicurezza espressi in maniera adeguata al servizio reso coerentemente alla sua descrizione contenuta nei documenti del SGS; devono essere definite le modalità di diffusione della dichiarazione al personale.	
D.L.162/07 – All. III – comma 2.b Nel sistema sono presenti obiettivi dell'organismo di tipo qualitativo e quantitativo per il mantenimento ed il miglioramento della sicurezza? Nel sistema sono presenti piani e procedure per conseguire tali obiettivi?	***K. OBIETTIVI DELL'ORGANISMO DI TIPO QUALITATIVO E QUANTITATIVO PER IL MANTENIMENTO E IL MIGLIORAMENTO DELLA SICUREZZA NONCHÉ PIANI E PROCEDURE PER CONSEGUIRE TALI OBIETTIVI***		
	K.1 - Esistono procedure per determinare gli obiettivi di sicurezza pertinenti in conformità con il quadro giuridico ed esiste un documento che descrive tali obiettivi.	Questa sezione deve necessariamente essere conseguente alla determinazione dei parametri del proprio sistema che si ritengono critici per la sicurezza (vedi punto A.1). In particolare è necessario descrivere all'interno di una procedura responsabilità e modalità di individuazione dei valori quantitativi o qualitativi con i quali confrontare i risultati del monitoraggio dei parametri relativi alle prestazioni dei processi del sistema verificando se sono all'interno delle soglie di rischio accettabili.	
	K.2 - Esistono procedure per determinare gli obiettivi di sicurezza rilevanti coerenti con il tipo e l'entità delle operazioni ferroviarie interessate e con i relativi rischi.	Nella procedura devono essere descritte le modalità per rendere evidente che il mantenimento dei rischi al di sotto della soglia di accettabilità (vedi A.1) è realizzato attraverso il raggiungimento degli obiettivi.	
	K.3 - Esistono procedure destinate a valutare regolarmente le prestazioni generali della sicurezza in relazione agli obiettivi di sicurezza aziendali e a quelli stabiliti a livello di Stato membro.	Nella procedura devono essere descritte le modalità per confrontare, con una frequenza congruente con la natura ed importanza della problematica trattata, i valori dei parametri critici per la sicurezza con gli obiettivi stabiliti nel proprio SGS in coerenza con l'obiettivo primario di sicurezza (tendere a valori nulli di incidentalità)	

Norma di riferimento/ Requisito	**Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)**	**Proposta di interpretazione del criterio ERA**	**Rilievo**
	K.4 - Esistono procedure in atto per controllare ed esaminare regolarmente gli accordi operativi: (a)raccogliendo dati importanti sulla sicurezza per ricavare delle tendenze nelle prestazioni di sicurezza e valutare la conformità con gli obiettivi; (b)interpretare i dati importanti e attuare i cambiamenti necessari.	Nella procedura SGS devono essere descritte le modalità per monitorare il livello delle prestazioni di sicurezza rese in base agli accordi per lo svolgimento delle procedure operative (almeno quelli stipulati con organiszazioni esterne) in modo che sia agevole confrontare tali prestazioni con gli obiettivi di sicurezza stabiliti. Deve essere previsto un processo formale continuo di revisione degli accordi che espliciti le figure responsabili e le modalità di interfacciamento tra l'azienda e le organiszazioni interessate.	
	K.5 - Esistono procedure messe in atto dal gestore dell'infrastruttura per sviluppare piani e procedure destinati a raggiungere i suoi obiettivi.	**C'è un errore,** si deve intendere non solo per il GI ma anche per le IF l'esistenza di procedure per la redazione di piani e progetti finalizzati al raggiungimento degli obiettivi di sicurezza stabiliti.	
D.L.162/07 – All. III – comma 2.c Nel sistema sono presenti procedure atte a soddisfare gli standard tecnici ed operativi in vigore, nuovi e modificati? Nel sistema sono presenti procedure atte a soddisfare altre prescrizioni contenute nelle STI? Nel sistema sono presenti procedure atte a soddisfare altre prescrizioni contenute nelle norme nazionali di sicurezza ? Nel sistema sono presenti procedure atte a soddisfare altre prescrizioni contenute in altre norme pertinenti? Nel sistema sono presenti procedure atte a soddisfare altre prescrizioni contenute in decisioni dell'Agenzia? Nel sistema sono presenti procedure volte ad assicurare la conformità agli standard e alle altre prescrizioni durante l'intero ciclo di vita delle attrezzature e delle operazioni?	***L. PROCEDURE ATTE A SODDISFARE GLI STANDARD TECNICI E OPERATIVI IN VIGORE, NUOVI E MODIFICATI O ALTRE PRESCRIZIONI***		
	L.1. - Per i requisiti relativi alla sicurezza attinenti al tipo e all'entità delle operazioni, esistono procedure atte a: (a) individuare tali requisiti e aggiornare le relative procedure per rispecchiare i cambiamenti apportati agli stessi (gestione del controllo delle modifiche); (b) attuarli; (c) controllare la conformità agli stessi; (d) intervenire quando viene individuata la non conformità.	Nella procedura devono essere descritte le modalità per: • individuare e tenere sotto controllo le fonti normative (nazionali ed internazionali), • analizzare tutti i cambiamenti introdotti dalle norme, • riesaminare ed eventualmente modificare il sistema delle procedure e dei processi aziendali in funzione di tali cambiamenti, • adeguare la pianificazione dei controlli (audit interni) da effettuare in base ai processi modificati, • verificare la corretta attuazione individuando le non conformità rispetto ai requisiti previsti attuando le necessarie azioni correttive.	
	L.2 - Esistono procedure in atto per garantire che vengano impiegati il personale, le procedure, i documenti specifici, le attrezzature e il materiale rotabile adatti allo scopo prefissato.	Devono essere descritte, in procedure di gestione dell'esercizio, le misure adottate per la corretta preparazione del servizio (es. procedure per utilizzazione materiale rotabile e personale, gestione dei moduli e documenti di servizio, controlli preventivi di idoneità sanitaria, circolabilità, conoscenza linee e mezzi, possesso competenze adeguate, ecc.), nei vari settori quali condotta, formazione treni, manovra, verifica, accompagnamento.	
	L.3 - Il sistema di gestione della sicurezza ha procedure in atto per garantire che la manutenzione venga eseguita conformemente ai requisiti pertinenti.	Devono essere descritte le modalità: • di pianificazione e controllo della manutenzione conformemente ai piani di manutenzione previsti dal costruttore, • per assicurare il rispetto delle scadenze manutentive, • per l'effettuazione dei controlli sulle operazioni di manutenzione svolte all'esterno dell'azienda.	
D.L.162/07 – All. III – comma 2.d Nel sistema sono presenti procedure e metodi da applicare per la valutazione del rischio? Nel sistema sono presenti procedure e metodi da applicare nell'attuazione delle misure di controllo del rischio ogniqualvolta un cambiamento nelle condizioni di esercizio comporti nuovi rischi per l'infrastruttura o per le operazioni? Nel sistema sono presenti procedure e metodi da applicare nell'attuazione delle misure	***M. PROCEDURE E METODI DA APPLICARE NELLA VALUTAZIONE DEL RISCHIO E NELL'ATTUAZIONE DELLE MISURE DI CONTROLLO DEL RISCHIO OGNIQUALVOLTA UN CAMBIAMENTO NELLE CONDIZIONI DI ESERCIZIO O L'IMPIEGO DI NUOVO MATERIALE COMPORTI NUOVI RISCHI PER L'INFRASTRUTTURA O PER LE OPERAZIONI***		
	M.1 - Esistono procedure di gestione destinate a introdurre cambiamenti nelle apparecchiature, nelle procedure, nell'organismo, nel personale o nelle interfacce.	Devono esistere procedure per individuare in base alle esigenze dell'impresa i cambiamenti da apportare agli elementi caratteristici del servizio di tipo tecnologico, (e dal 7/2012) organizzativo ed operativo, attraverso le opportune valutazioni sull'entità e sugli effetti delle modifiche; nel processo di individuazione devono essere coinvolte le figure aziendali più appropriate al fine di apportarvi tutte le necessarie competenze.	

Norma di riferimento/ Requisito	**Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)**	**Proposta di interpretazione del criterio ERA**	**Rilievo**
di controllo del rischio ogniqualvolta l'impiego di nuovo materiale rotabile comporti nuovi rischi per l'infrastruttura o per le operazioni?	M.2 - Esistono procedure di valutazione del rischio per gestire i cambiamenti e per applicare il metodo comune di sicurezza alla valutazione del rischio e alla valutazione come stabilito nel regolamento (CE) della Commissione n. 352/2009[75] ove necessario.	Deve essere presente una procedura che recepisca il regolamento 352/09 e che stabilisca in particolare i criteri di valutazione della rilevanza di una modifica.	
	M.3 - L'impresa ferroviaria dispone di procedure in atto per utilizzare i risultati della valutazione del rischio in altri processi all'interno dell'organismo e per renderli visibili al personale interessato.	Deve essere presente una procedura che stabilisca come le condizioni applicative, il campo di applicazione, le assunzioni alla base dell'analisi, le disposizione operative e manutentive sono rese disponibili a tutto il personale insieme alle norme di controllo dei rischi individuati.	
D.L.162/07 – All. III – comma 2.e Nel sistema è presente un'offerta di programmi di formazione del personale e di sistemi atti a garantire che il personale mantenga le proprie competenze e che i compiti siano svolti conformemente a tali competenze?	***N. OFFERTA DI PROGRAMMI DI FORMAZIONE DEL PERSONALE E DI SISTEMI ATTI A GARANTIRE CHE IL PERSONALE MANTENGA LE PROPRIE COMPETENZE E CHE I COMPITI SIANO SVOLTI CONFORMEMENTE A TALI COMPETENZE***		
	N.1 - Esiste un sistema di gestione delle competenze che comprende almeno: (a) l'individuazione delle conoscenze e delle competenze richieste per i compiti correlati alla sicurezza; (b) principi di selezione (livello d'istruzione di base, attitudine mentale e idoneità fisica richiesti); (c) formazione iniziale e certificazione delle competenze e delle capacità acquisite; (d) formazione continua e aggiornamento periodico delle conoscenze e delle capacità esistenti; (e) controlli periodici delle competenze ove opportuno; (f) misure speciali in caso di incidenti/inconvenienti o di assenza prolungata dal lavoro, ove necessario/opportuno; (g) formazione specifica sul sistema di gestione della sicurezza per il personale direttamente impegnato nel garantire che il sistema di gestione della sicurezza funzioni.	Gli elementi individuati dal criterio N1 devono essere applicati a tutte le figure aziendali sia direzionali che operative.	
	N.2 - Esistono procedure all'interno del sistema di gestione delle competenze destinate a: (a) l'individuazione dei posti che eseguono compiti di sicurezza; (b) l'individuazione dei posti che comportano responsabilità nelle decisioni operative all'interno del sistema di gestione della sicurezza; (c) il personale che abbia le conoscenze, le capacità e l'attitudine necessarie (mediche e psicologiche) adeguate ai loro compiti e periodicamente rinnovate/aggiornate; (d) l'assegnazione del personale con le competenze adatte ai rispettivi compiti; (e) il monitoraggio del modo in cui vengono eseguiti i compiti e attuazione delle azioni correttive ove necessario.	Si presume che gli elementi individuati nel criterio N2 siano applicabili al personale con compiti direttamente connessi con la sicurezza dell'esercizio ivi compreso quello con ruoli di coordinamento. Il monitoraggio delle prestazioni del personale deve essere presente come misura di controllo o mitigativa del rischio nell'hazard log (da riscontrare nel requisito A1).	
D.L.162/07 – All. III – comma 2.f Nel sistema sono presenti disposizioni atte a garantire un livello sufficiente di informazione	***O. DISPOSIZIONI ATTE A GARANTIRE UN LIVELLO SUFFICIENTE DI INFORMAZIONE ALL'INTERNO DELL'ORGANISMO E, SE DEL CASO, FRA GLI ORGANISMI CHE OPERANO SULLA STESSA INFRASTRUTTURA***		

[75] GU L 108 del 29.4.2009, pag. 4.

Norma di riferimento/ Requisito	Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)	Proposta di interpretazione del criterio ERA	Rilievo
all'interno dell'organismo e, se del caso, fra gli organismi che operano sulla stessa infrastruttura?	O.1 - Esistono procedure volte ad assicurare che: (a) il personale conosca e comprenda il sistema di gestione della sicurezza e le informazioni siano facilmente accessibili e (b) la documentazione adeguata sul sistema di gestione della sicurezza venga fornita al personale responsabile della sicurezza.	Devono essere disciplinate le modalità di redazione delle procedure aziendali che consentano la massima fruibilità nella consultazione delle stesse da parte del personale interessato, che deve essere individuato inequivocabilmente all'interno delle stesse, e fornite laddove necessario mediante l'ausilio di un opportuno piano di distribuzione. Devono essere stabilite le opportune modalità perché il personale possa visualizzare/capire la struttura del sistema nella quale la procedura di suo interesse è collocata.	
	O.2 - Esistono procedure volte ad assicurare che: (a) le principali informazioni operative siano pertinenti e valide; (b) il personale sia informato della loro esistenza prima che vengano applicate; (c) siano a disposizione del personale e ove necessario vengano distribuite ufficialmente delle copie.	Devono essere disciplinate le modalità per l'emissione controllata delle informazioni operative, quali gli ordini interni e tutte le comunicazioni contenenti indicazioni operative per lo svolgimento delle procedure di esercizio (es. programma di manovra, programma di verifica, prospetto delle chiavi, ecc.), la distribuzione tempestiva e controllata e la messa a disposizione a tutto il personale interessato secondo apposito piano di distribuzione o se più appropriato, almeno alla struttura (impianto o postazione) che svolge l'attività.	
	O.3 Esistono disposizioni in atto per la condivisione di informazioni tra gli enti ferroviari.	Devono essere disciplinati in appositi documenti modalità e formati per la tempestiva e efficace condivisione delle informazioni per lo svolgimento del servizio tra l'impresa ferroviaria e i suoi fornitori (ditte, GI, altre IF) e partner (altre IF), interlocutori in genere (es. GI). Le disposizioni devono essere esaustive rispetto alle tematiche di interfaccia dichiarate nella descrizione del proprio servizio (forniture, collaborazioni, service etc.).	
D.L.162/07 – All. III – comma 2.g Nel sistema sono presenti procedure e formati per la documentazione delle informazioni in materia di sicurezza e scelta della procedura di controllo della configurazione delle informazioni essenziali in materia di sicurezza?	***P. PROCEDURE E FORMATI PER LA DOCUMENTAZIONE DELLE INFORMAZIONI IN MATERIA DI SICUREZZA E SCELTA DELLA PROCEDURA DI CONTROLLO DELLA CONFIGURAZIONE DELLE INFORMAZIONI ESSENZIALI IN MATERIA DI SICUREZZA***		
	P.1 - Esistono procedure volte ad assicurare che tutte le informazioni essenziali in materia di sicurezza siano esatte, complete, coerenti, facili da capire, adeguatamente aggiornate e debitamente documentate.	L'IF deve aver definito quali sono le informazioni essenziali di sicurezza; tali informazioni devono comprendere, in ordine decrescente di essenzialità: - moduli di esercizio per la comunicazione di informazioni urgenti relative ai treni (restrizioni temporanee di velocità, presenza di merci pericolose, ecc.); - moduli di esercizio di prescrizione e comunicazione dati treno, programmi di manovra e verifica, ecc.; - documenti contenenti informazioni di esercizio a carattere permanente (ad esempio ordini di sicurezza permanenti, registri disposizioni); - informazioni più generali del sistema di gestione della sicurezza (ad esempio ritorni di esperienza, verbali di incontri, ecc..). Per ogni documento / tipologia di documento che contiene informazioni essenziali per la sicurezza devono essere chiaramente individuati i formati, i contenuti e devono essere definite le modalità e le responsabilità per la compilazione, trasmissione e archiviazione.	
	P.2 - Esistono procedure per: (a) organiszare, creare, distribuire e gestire il controllo delle modifiche apportate a tutta la documentazione essenziale in materia di sicurezza; (b) ricevere, raccogliere e memorizzare tutte le documentazioni/informazioni essenziali su carta o tramite altri sistemi di registrazione.	Devono essere definite le modalità per modificare i documenti contenenti requisiti o caratteristiche di sicurezza in modo da renderne consapevole l'organiszazione al fine di evitare l'uso improprio di documenti superati. Devono essere definite le modalità di ricezione, raccolta e gestione di tutte le informazioni essenziali per la sicurezza in appositi elenchi database (ad es.: elenco dei componenti e delle loro versioni, elenco dei moduli in vigore, elenchi degli elaborati tecnici) in modo che possano essere opportunamente fruibili per le pertinenti valutazioni quando necessario.	

Norma di riferimento/ Requisito	**Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)**	**Proposta di interpretazione del criterio ERA**	**Rilievo**
	P.3 Esiste una procedura per il controllo della configurazione delle informazioni essenziali in materia di sicurezza.	Devono essere chiarite le modalità per garantire che l'organiszazione operi su versioni appropriate di un documento. Ciò si può ottenere ad esempio definendo le modalità di emissione e distribuzione degli elenchi del punto precedente, i formati che consentano di individuare agevolmente le informazioni sulla validità di un documento e la possibilità di consultare elenchi ufficiali aggiornati di versioni dei documenti.	
D.L.162/07 – All. III – comma 2.h Nel sistema sono presenti procedure volte a garantire che gli incidenti, i "quasi incidenti" ed altri eventi pericolosi siano segnalati, indagati ed analizzati e che siano adottate le necessarie misure preventive?	***Q.PROCEDURE VOLTE A GARANTIRE CHE GLI INCIDENTI, GLI INCONVENIENTI, I "QUASI INCIDENTI" ED ALTRI EVENTI PERICOLOSI SIANO SEGNALATI, INDAGATI E ANALIZZATI E CHE SIANO ADOTTATE LE NECESSARIE MISURE PREVENTIVE***		
	Q.1 - Esistono procedure volte a garantire che gli incidenti, gli inconvenienti, i "quasi incidenti" ed altri eventi pericolosi: (a) vegano riferiti, registrati, studiati e analizzati; (b) vengano riferiti, ove necessario per la legislazione pertinente, agli organismi nazionali.	Devono essere stabilite le modalità per la rilevazione e la classificazione degli eventi in incidenti, inconvenienti, quasi incidenti ed altri eventi pericolosi. L'approccio a tali eventi deve essere disciplinato almeno nei seguenti elementi: • individuazione delle competenze necessarie per la corretta interpretazione degli eventi, • oggettività delle valutazioni ottenuta attraverso l'indipendenza dall'evento delle persone incaricate, • analisi delle cause, • eventuale quantificazione dei danni, • standardiszazione del processo d'indagine e di registrazione delle risultanze. Devono essere definite le modalità e le responsabilità con le quali l'impresa intende garantire i flussi informativi previsti dalle legislazioni nazionali pertinenti. Le modalità e le responsabilità per le comunicazioni verso l'NSA (comunicazione inconveniente e trasmissione documenti) e l'Organismo Investigativo (da verificare i flussi informativi instituiti dal Ministero) rientrano nella parte B.	
	Q.2 - Esistono procedure volte a garantire che: (a) vengano valutate e attuate le raccomandazioni dell'autorità nazionale preposta alla sicurezza, dell'organismo di indagine nazionale e delle indagini di settore od interne ove opportuno o richiesto; (b) vengano valutate e prese in considerazione le relazioni/informazioni pertinenti fornite da altre imprese ferroviarie, gestori dell'infrastruttura, gli organismi incaricati della manutenzione e detentori dei veicoli.	Il ritorno di esperienza di eventi incidentali (e non) deve essere garantito attraverso un processo aziendale formaliszato (ad es. come input dei processi di riesame direzionale, progettazione della sicurezza del servizio) che tenga conto di tutte le indicazioni o raccomandazioni (cogenti e non) che possono giungere dall'esterno, il processo coinvolgendo le figure aziendali appropriate deve garantire che siano effettivamente attuati gli opportuni provvedimenti migliorativi dei processi.	
	Q.3 - Esistono procedure per informazioni pertinenti correlate all'indagine e alle cause di incidenti, inconvenienti, "quasi incidenti" e altri eventi pericolosi da utilizzare per trarre insegnamenti e, ove necessario, adottare misure preventive.	Deve essere definite le modalità per elaborare documenti informativi interni in cui siano divulgati gli esiti dell'analisi sugli eventi incidentali (e non) effettuata da personale competente. Tali esiti devono essere tenuti in conto a tutti i livelli opportuni (ad es. nello svolgimento delle attività operative, nella modifica delle procedure e nel miglioramento dell'analisi del rischio).	
D.L.162/07 – All. III – comma 2.i Nel sistema sono presenti i piani di intervento, di allarme ed informazione in caso di emergenza, concordati con le autorità pubbliche competenti?	***R. FORNITURA DI PIANI DI INTERVENTO, DI ALLARME ED INFORMAZIONE IN CASO DI EMERGENZA, CONCORDATI CON LE AUTORITÀ PUBBLICHE COMPETENTI***		
	R.1 - Un documento identifica tutti i tipi di emergenze, comprese condizioni operative degradate ed esistono procedure in atto per identificarne di nuove.	Devono essere definite le modalità, responsabilità e competenze per l'individuazione delle emergenze e, come output, deve essere fornito almeno l'elenco delle stesse.	

Norma di riferimento/ Requisito	Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)	Proposta di interpretazione del criterio ERA	Rilievo
	R.2 - Esistono procedure in atto volte ad assicurare che, per ogni tipo di emergenza individuato: (a) sia possibile contattare rapidamente i servizi di soccorso; (b) i servizi di soccorso vengano forniti con tutte le informazioni in anticipo, per preparare la loro risposta di emergenza, e al momento di un'emergenza.	Devono essere definite le modalità per la redazione dei piani di emergenza in modo che siano garantiti in ciascun piano i contenuti riportati nel criterio R2.	
	R.3 I ruoli e le responsabilità di tutte le parti sono individuati e precisati in un documento.	Devono essere garantite nel piano di emergenza le informazioni riportate nel criterio R3.	
	R.4 - Esistono piani d'azione, allarmi e informazioni, che comprendono: (a) procedure per avvisare tutto il personale con responsabilità di gestione dell'emergenza; (b) disposizioni per comunicarli a tutte le parti, comprese le istruzioni di emergenza per i passeggeri; (c) disposizioni per contattare il personale competente immediatamente in modo da poter adottare le decisioni necessarie.	Devono essere garantite nel piano di emergenza le informazioni riportate nel criterio R4.	
	R.5 - Esiste un documento che descrive come sono stati assegnati i mezzi e le risorse e come sono stati individuati le esigenze di formazione.	Nella procedura di pianificazione delle emergenze (vedi R1 ed R2) devono essere specificate le modalità di assegnazione delle risorse e mezzi per affrontare le emergenze e individuate le necessità di addestramento del personale coinvolto nell'attuazione dei piani.	
	R.6 - Esistono procedure in atto per ristabilire le condizioni operative normali appena possibile	Devono essere previste le responsabilità e le modalità per coordinare gli interventi di ripristino delle condizioni normali di esercizio che gli organismi territoriali esistenti devono attuare.	
	R.7 - Esistono procedure per verificare i piani d'emergenza in cooperazione con altre parti per formare il personale, testare le procedure, individuare i punti deboli e verificare come vengono gestite le possibili situazioni di emergenza.	Devono essere previste le modalità per lo svolgimento di simulazioni, al fine di determinare la messa a punto dei piani di emergenza ed ottenere l'adeguato addestramento del personale, in cooperazione con tutti gli altri soggetti interessati (altri operatori od autorità pubbliche).	
	R.8 - Esistono procedure per garantire che il personale competente incaricato (specialmente per quanto riguarda i servizi per le merci pericolose), in possesso di adeguate competenze linguistiche, possa essere contattato facilmente e immediatamente dal responsabile dell'infrastruttura.	Devono essere definite modalità e responsabilità per la redazione dei piani di reperibilità del personale con adeguate competenze preposto ad essere contattato dal gestore dell'infrastruttura (specialmente per quanto riguarda i servizi per le merci pericolose).	
	R.9 - Esiste una procedura per contattare l'organismo incaricato della manutenzione o il detentore dei veicoli in caso di emergenza.	Attraverso la procedura di pianificazione delle emergenze devono essere garantite in tutti i piani di emergenza le modalità per contattare il responsabile della manutenzione od il detentore del rotabile.	
D.L.162/07 – All. III – comma 2.j Nel sistema sono presenti audit interni regolari del sistema di gestione della sicurezza?	***S.DISPOSIZIONI PER AUDIT INTERNI REGOLARI DEL SISTEMA DI GESTIONE DELLA SICUREZZA***		
	S.1 - Esiste un sistema di audit interno indipendente e imparziale che agisce in maniera trasparente.	Devono essere descritte le modalità di pianificazione degli audit interni in modo che l'attività sia assegnata a persone indipendenti dal processo verificato e collocate nell'organizzazione in modo da non essere coinvolte nelle mansioni oggetto di verifica.	
	S.2 - Esiste un programma di audit interni previsti che possono essere modificati secondo i risultati degli audit precedenti e il controllo delle prestazioni	Il programma degli audit deve essere definito in modo tale da evidenziare processi e funzioni su cui svolgere l'attività di verifica allo scopo di poter intervenire coi necessari cambiamenti in conseguenza delle risultanze di audit precedenti e di controlli prestazionali sulle funzioni aziendali. Le modalità di modifica del programma di audit secondo i criteri sopra definiti devono essere riportate in un'apposita procedura (procedura di audit).	
	S.3 - Esistono procedure in atto volte a individuare e selezionare responsabili dell'audit adeguatamente competenti.	Nelle modalità di pianificazione degli audit interni devono essere specificati i criteri e le modalità di individuazione e selezione del personale da adibire all'attività in base alle competenze possedute che devono essere specifiche per la conduzione dell'attività (conoscenza ed esperienza nell'attività di audit, conoscenza dei processi verificati).	

Norma di riferimento/ Requisito	Criterio ERA (traduzione in italiano del regolamento (UE) 1158/2010)	Proposta di interpretazione del criterio ERA	Rilievo
	S.4 - Esistono procedure in atto per: (a) analizzare e valutare i risultati degli audit, (b) consigliare misure di follow-up, (c) verificare l'efficacia delle misure, (d) documentare l'esecuzione e i risultati degli audit.	Devono essere descritte le modalità di registrazione delle risultanze dell'audit in opportuni report, le modalità di analisi di tali risultanze da parte delle funzioni coinvolte nell'individuazione delle azioni correttive, la pianificazione dei controlli di attuazione ed efficacia di tali azioni.	•
	S.5 - Esistono procedure per garantire che i livelli più elevati della catena di gestione siano informati dei risultati degli audit e assumano la responsabilità generale dell'esecuzione di modifiche al sistema di gestione della sicurezza.	Devono essere previste le modalità di analisi delle risultanze degli audit e delle azioni predisposte per l'individuazione delle necessarie modifiche al SGS da parte delle strutture competenti (es. nel riesame direzionale da parte del RSGS e dell'Alta direzione).	•
	S.6 - Esiste un documento che illustra come vengono pianificati gli audit rispetto alle disposizioni di controllo periodiche per assicurare la conformità alle procedure e agli standard interni.	Il programma di audit deve tenere conto in particolare delle cadenze dei controlli di conformità su personale ed apparecchiature (es. mantenimento competenze personale esercizio, scadenze dei cicli manutentivi, ecc.) verificandone il rispetto mediante opportuni audit effettuati secondo tempi adeguati.	

ANNEX 3

Example of check list: inspections of rolling stock

ANSF Agenzia Nazionale per la Sicurezza delle Ferrovie	Procedura per l'effettuazione dell'attività ispettiva sul sistema ferroviario	SIC.ISF.DOC.03

GUIDA AI CONTROLLI

SETTORE: **MATERIALE ROTABILE**

SOTTOSETTORE: **VERIFICA**

ELEMENTI CONTROLLATI: **VEICOLI IN COMPOSIZIONE A TRENI IN SOSTA**

T - VEICOLI CON CABINA DI GUIDA NON ADIBITI AL SERVIZIO VIAGGIATORI (tutti i veicoli, anche in composizione a complessi automotore, dotati di cabina di guida destinata alla condotta e non adibiti al servizio viaggiatori).

Controlli		Codice non conformità
T01	**Rodiggio**	
	Sale montate: assili, ruote (cretti, parti a contatto con l'assile, difetti vari), visibilità della linea di fede.	T0 1 01
	Cerchioni: contrassegni di riferimento (in presenza di cerchione riportato), difetti vari, superficie di rotolamento (presenza di solcature, sfaccettature e riporti di metallo, difetti vari).	T01 02
	Bordini: spessore, altezza, quota qR (limiti di usura, spigoli faccia attiva, sbavature, cretti, difetti vari). In caso di dubbi richiedere all'IF le opportune misurazioni.	T01 03
	Boccole: controllo visivo finalizzato al rilevamento di non conformità manifeste (perdita lubrificante, segni di accaloramento, mancanza di bulloni al coperchio boccola, fissaggio di eventuali organi applicati alla boccola, agi trasversali e longitudinali tra boccola e parasala).	T01 04
T02	**Sospensione**	
	Sospensione principale, organi di collegamento e ammortizzatori.	T02 01
	Sospensione secondaria, organi di collegamento e ammortizzatori.	T02 02
T03	**Carrelli**	
	Telaio (presenza di deformazioni o cretti).	T03 01
	Fissaggio di eventuali organi applicati al carrello.	T03 02
	A disposizione.	T03 03
T04	**Trazione e repulsione**	
	Organi della trazione (tenditore, gancio di trazione, ecc.).	T04 01
	Presenza e utilizzazione dell'alloggio di ricovero per tenditore non utilizzato.	T04 02
	Organi della repulsione (piatti, custodie, bulloni, altezza dei	T04 03

	respingenti, ecc.).	
	Accoppiatore automatico e presenza della maschera di protezione sull'accoppiatore non utilizzato	T04 04
T05	**Cassa/telaio/porte/gradini/iscrizioni**	
	Cassa (esterna, interna, telaio, finestrini, porte di testa, iscrizioni ecc.).	T05 01
	Parti amovibili e relativi dispositivi di bloccaggio (sportelli batterie, cartelli indicatori, fanali, carenatura, ecc.).	T05 02
	A disposizione.	T05 03
	A disposizione.	T05 04
T06	**Produzione aria e comando freno**	
	A disposizione.	T06 01
	A disposizione.	T06 02
	A disposizione.	T06 03
	A disposizione.	T06 04
T07	**Impianto freno**	
	Impianto frenante (distributore, cilindro del freno, serbatoi, leve, dispositivi vari, ecc.).	T07 01
	Maniglie di azionamento del freno di emergenza (presenza del sigillo).	T07 02
	Accoppiatori flessibili di testata e rubinetti d'intercettazione (integrità e loro posizionamento se non utilizzati).	T07 03
	A disposizione.	T07 04
	Suole freno (consumo, integrità, ecc.).	T07 05
	Freni a dischi (presenza di accaloramento, indicatori di stato, ecc.).	T07 06
	A disposizione.	T07 07
	A disposizione.	T07 08
	A disposizione.	T07 09
	A disposizione.	T07 10
T08	**Motore/riduttore/ponte/trasmissione**	
	Motore, riduttore, ponti, trasmissione (presenza di parti pendenti e/o distaccate, perdite di fluidi operanti).	T08 01
	Eventuali dispositivi anticaduta.	T08 02
T09	**Impianto elettrico**	
	Fanali e/o luci di testata/coda.	T09 01
	Organi di accoppiamento fissi e mobili della condotta A.T..	T09 02
	Presenza e ricovero degli accoppiatori non utilizzati.	T09 03
	Regolarità delle chiavi di blocco (chiave a bracciale non univocamente contrassegnata, ecc.).	T09 04
T10	**Cabina di guida**	
	Vetri frontali e laterali.	T10 01
	Corretta sonorità del fischio e della tromba.	T10 02
	Tergicristalli.	T10 03
	Corretta segnalazione degli strumenti di guida: manometri, strumenti di misura elettrici, segnalazione blocco porte.	T10 04
T11	**Pantografo**	
	A disposizione.	T11 01
T12	**Antincendio**	
	Estintori: rispetto scadenze.	T12 01
	Stato di carica, integrità del dispositivo di sicurezza, della maniglia di fissaggio e dei supporti.	T12 02
	Stato di carica della bombola estinguente.	T12 03
	A disposizione.	T12 04
	Pulsanti di scarico estinguente piombati.	T12 05

	Azionamenti manuali scarico estinguente e piombatura.	T12 06
T13	**Apparecchiature di sicurezza e ausiliarie**	
	Apparecchiatura SCMT, SSC, ERTMS, RS, piombatura CEA (libro di bordo).	T13 01
	A disposizione.	T13 02
	Dispositivo antipattinante, freno alta velocità, tachimetro, vigilante, DIS, GSMR.	T13 03
T14	**Dotazioni di bordo**	
	Presenza e regolarità delle dotazioni di bordo (torce di segnalazione emergenza, cavetto di shunt, ecc.).	T14 01
	A disposizione.	T14 02
	A disposizione.	T14 03
	Libri di bordo (presenza e corretta compilazione), guida depannage.	T14 04

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