EUROPEAN UNION AGENCY FOR RAILWAYS

Making the railway system work better for society.

COR – Risk Profiling

COMMON OCCURRENCE REPORTING PROGRAMME

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Contents

1. Introduction

1.1. This document sets out a framework and approach to be adopted by the Agency to develop Risk Profiling (which in time may lead onto organisational profiling. However, this is not discussed in this document) to assist the railway sector operating in the European Union's single market in improving its safety performance. While the European Railway Sector has a good overall performance when compared with other high-risk sectors, e.g. Aviation and Road transport the statistics relating to significant accidents and the fatalities and serious injuries resulting from them show there are still areas where railway safety could be improved without significantly impacting on the financial / overall performance of railway companies. Equally, we must distinguish between high risk and high potential hazard sectors – the rail sector in Europe can also be considered to be within the group of industrial sectors where high potential hazards exist, e.g. Chemical, Nuclear, Oil exploration, etc.

1.2. The idea of a risk profile of the railways is not new. The first mention of this goes back to the second Safety Performance report published in 2009[1]. This reference confirmed that the "…railways are generally safe for passengers and employees…" but there were still a "…large number of fatal accidents occur, mainly to unauthorised users (mainly trespassers) and level crossing users." The report went on to provide a simple profile of fatalities occurring on Europe's railways. A decade later these general conclusions remain valid. In terms of actually producing risk profiles only the work undertaken for the Inland transport of Dangerous Goods has been completed (Inland TDG)[2].

1.3. The Agency has been a party to the development of the EU Risk Management Framework for the transport of dangerous goods[3]. This document touches briefly on this framework.

1.4. Additionally, while the Agency has published the trend findings and made comparative studies, e.g. Priority Countries Programme, it has not made the fullest possible use of all the data that it has available to it. The Agency's current approach has been to examine results of safety performance at the level of the Member State, whereas it may be more appropriate to examine performance by line of route or by company. This report focusses on the potential offered by more detailed risk profiling allied to risk modelling for improving railway safety outcomes such that Europe becomes the leader in railway safety. Both risk profiling and risk modelling are explained within the paper.

1.5. The use and development of risk profiling enables the better understanding of the risks faced in the SERA, their magnitude and gives indications of where mitigations might be effective. Through understanding the sector risk register and its relationship with sector operator's SMS it should be possible, through the Agency's sector monitoring programmes, to create a "living" risk profiling process that enables the evaluation of the current risk controls. The Agency can then respond to changing operational environment and emerging risks.

1.6. In developing the 'Sector Risk Profile (SRP)' better collaboration and 'engaging more' with all stakeholders is necessary to increase understanding, promote safety improvement opportunities, and work on solutions together. This approach must be underpinned by creating a culture that encourages open and honest communication, listening to others, showing respect and maintaining trust.

2. Background

2.1. In general, the industrial sectors, in order to improve their safety performance have moved away from reactive approaches towards a more pro-active approach based on the understanding of risks facing the particular sector and then trying to manage those risks to levels of tolerability.

2.2. The Agency, as the technical and safety regulator for railways in the European Union has been developing the competences to be able to independently challenge the railway sector. Key stepping stones required are an understanding of the risk profile(s) faced by those railway organisations, particularly the Railway Undertakings and Infrastructure Managers. In moving towards a Common Occurrence Reporting (COR) system for the railways operating in the Single European Rail Area (SERA) the Agency needs to build upon the work that it has already completed. This would include work that is currently being researched or that it hopes to achieve in the next two to three years and would include use cases for the COR data. An initial, but in the end unsuccessful, study on the potential use of "Big Data" approaches was started. Whilst collaboration with the railway sector was good it became apparent that they too were only in the initial phases of exploiting such data.

2.3. Since the formation of the Agency here have been periodic excursions into the development of risk profiling. From the evidence, while these have provided a definition, they have not substantially developed the data that enables an understanding of the risk profile faced by Europe's railways.

2.4. However, more mundane approaches may also yield beneficial results towards this end. These include better statistical analyses, different approaches using the Common Safety Indicators (CSIs) allied to research derived from the Accident Investigation Reports contained within the ERAIL database and historical research. From such research it may be possible to develop a risk profile for Europe's railways based upon a risk profile framework. The framework would incorporate a series of methods and analytical tools that will be relevant to address the issues and give greater understanding to the actors and regulators involved in the safety of railways. This approach was used to establish the Inland Transport of Dangerous Goods (TDG) risk management framework[4]. Recently, a tool, the 'risk management platform' has been described by the Agency along with an impact assessment. Such a framework could be extended to non-TDG risk situations. The extension of the risk framework will be analysed to determine the optimal allocation of resources and workload. This can only be examined at a later stage in the process.

2.5. The failure to address the lessons of accidents through self-regulation has typically lead to the establishment of a "safety regulator" or the strengthening of one that is already in

[1] European Railway Agency. The Railway Safety Performance in the European Union, ERA (Valenciennes) 2009
[2] See: https://www.era.europa.eu/activities/transport-dangerous-goods/inland-tdg_en.
[3] See https://www.era.europa.eu/activities/transport-dangerous-goods_en.
[4] See: https://www.era.europa.eu/activities/transport-dangerous-goods_en.

existence. But there is an issue of what constitutes a failure to address or learn lessons from accidents.

2.6. Safety can be defined as freedom from risk. If you want to increase safety, you must first consider risk. Risk is the "…the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of and the degree of severity of that harm." Risk can be avoided by pre-emptive action, e.g. Behaviour modification can increase safety. This is due to the fact that safety and risk have an inverse relationship. When one goes up, the other goes down. To increase safety, you need to decrease risk. The safety indicators, i.e. the statistics, help map the changing relationship between safety and risk.

2.7. There was a concern in the late 1980's and early 1990's that as the liberalisation of railway markets proceeded there would be the risk that railway safety would deteriorate. The European Union in setting up the Agency in 2005 gave the oversight of railway safety in European Union Member States to the Agency recognising that:

> *"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, which will separate functions of previously integrated railway companies and move the railway sector further from self-regulation to public regulation. 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." .*

2.8. The current recast Safety Directive states:

> *"Safety levels in the Union rail system are generally high especially when compared to road transport. Railway safety should be generally maintained and, when practicable, continuously improved, taking into account technical and scientific progress, and the development of Union and international law. Priority should be given to the prevention of accidents. The impact of human factors should also be taken into consideration." .*

2.9. However, merely analysing the CSIs, which record the statistics on "significant" accidents, alone are not enough. The Agency developed database systems (ERAIL) to record the occurrences of more serious accidents, their investigation and reporting along with the recommendations that come from the reporting. The data gathered by this system have now developed to the point whereby they might be used in a more pro-active way to assist the sector and the NSAs in producing a better safety performance – particularly in the development of risk profiling.

2.10. The current legislative framework for railways in Europe is already built around the Safety Managements Systems. Each of the players in the railway sector typically follows such systems to identify the hazards faced and to manage the risks associated with the identified hazards. Reporting of safety indicators and the measurement of performance against agreed targets has now been in place for nearly a decade.

2.11. The Agency is also covering the concern of 'What railway safety looks like when done badly or not at all' as this could indicate underlying cultural issues. Through the work on European Rail Safety Culture Declaration the Agency has engaged the sector to improve safety records, encourage pro-active thinking, responsible behaviour, and staff engagement. Having improved registration of occurrences will be a pre-requisite for developing the risk profiles.

2.12. The current framework relating to data concerning accidents and incidents are in the main lagging indicators, i.e. looking back at past performance. It should be noted that the CSIs are reported between 9 and 21 months after occurring. They provide a history of what has occurred but provide no insight as to what might occur in the future. The slowness of reporting deters from the development of effective policy and strategic actions. In the case of more serious occurrences, while the decision to investigate can be initially notified quickly (averaging 57 days from the occurrence), the investigations take much longer averaging 419 days. By determining the risks likely to be faced by railway undertakings and infrastructure managers we are at least trying to bring about better foresight of the potential safety risks faced by these actors.

3. Purpose and Scope of this technical document

3.1. This technical document sets out what risk profiling is and how it will be of use to the Agency and the actors that work with it. These actors are critical to the development of the risk profile for the Single European Railway Area (SERA) in that they, the Railway Undertakings, Infrastructure Managers and others will provide the data from which risk profiles can be measured and built.

3.2. This is the first introductory document on risk profiling. A further detailed planning assessment of the requirements, resources required and deliverables still need to be made.

3.3. There are two main elements that would arise from the risk profiling approaches and that could be used ahead of the implementation of COR. These are:

1. Early warning indications (leading indicator(s)), and
2. Ability to learn lessons from actual precursor data that enable the prevention of future more serious incidents or accidents.

4. Basic definitions

4.1. ***Risk –*** *according to Knight (1921)[5] risk is something that you can put a price on, e.g. with a contract for insurance. An insurance underwriter will assess the risks and hazards and price the insurance contract accordingly. The Common Safety Method on Risk Assessment (CSM on RA) defines risk as "…the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of and the degree of severity of that harm. This is sometimes referred to as impact x probability. The CSM on RA goes on to define a number of other terms that will be used in this report. These are shown in paragraphs 2.10.2 to 2.10.6 below. The ISO standard on risk management ISO 31000:2018 defines risk as "…the effect of uncertainty on objectives…".*

4.2. ***Risk analysis*** *means systematic use of all available information to identify hazards and to estimate the risk;*

4.3. ***Risk evaluation*** *means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;*

4.4. ***Risk assessment*** *means the overall process comprising a risk analysis and a risk*

[5] Frank H Knight, Risk, Uncertainty and Profit. (New York: Riverside Press, 1921) See: https://mises.org/sites/default/files/Risk,%20Uncertainty,%20and%20Profit_4.pdf

evaluation;

4.5. ***Safety means freedom from unacceptable risk of harm; Risk management*** *means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;*

4.6. ***Profile*** *– a list, report or sketch summarising a situation and enabling comparison;*

4.7. ***Risk profile*** *can be defined as the result of an assessment of:*

- *the nature and level of the railway safety risks faced by an organisation/MS;*
- *the likelihood of adverse effects occurring;*
- *the effectiveness of controls in place to manage those risks*
- *the enabling of effective comparisons, and*
- *the level of disruption and costs associated with each type of risk.*

4.8. ***Uncertainty*** *– according to Silver (2012)6 risk that is hard to measure. It will be possible to know some of the incidents, accidents or occurrences but there will be no data or measurement of the risks to ascertain the timing or frequency of them happening; Granularity - the scale or level of detail in a set of data. The lower the granularity of the data, the less information is contained within the data. The higher the level of granularity the more information is contained within the data;*

4.9. ***Bayes*** *– Thomas Bayes (1701 – 1761) was an English statistician who is known for formulating a specific case of the theorem, relating to probabilities, that bears his name: Bayes' theorem.*

4.10. ***Bayes' theorem –*** *In probability statistics, Bayes' theorem (alternatively Bayes' law or Bayes' rule, also written as Bayes' theorem) describes the probability of an event, based on prior knowledge of conditions that might be related to the event. For example, if train accidents are related to train kilometres operated, then, using Bayes' theorem, train kilometres operated can be used to more accurately assess the probability that there would be a train accident, compared to the assessment of the probability of train accident made without knowledge of the train kilometres operated.*

4.11. ***Benchmarking –*** *generic term used to describe the measurement against a particular level, e.g. measurement of performance against the "best in class".*

4.12. ***Black box modelling –*** *a method of modelling where we do not know the internal structure (links between causes, consequences and other contributing factors) of the system being modelled.*

4.13. ***White box modelling*** *- a method of modelling where we do know the internal structure of the system being modelled.*

4.14. ***"Grey" or "Gray" box modelling*** *- a method of modelling that is a combination of white-box and black-box modelling, e.g. some parts of the internal structure of the system may be known. In relation to railway safety this approach may be the most useful as certain*

[6] Nate Silver, The Signal from the Noise. The Art and Science of Prediction. (London: Allan Lane, 2012) p.29

components of the internal system will be known, e.g. permitted line speed for different classes of train, train weights and composition, infrastructure formation and location, etc.

4.15. ***Information Asymmetry*** *occurs when a party has more relevant information about its actions or intentions party than the other(s). Under such situations the party with more relevant information has a tendency or incentive to behave inappropriately from the perspective of the party with less information*

4.16. ***Moral hazard*** *means lack of incentive to guard against risk where one is protected from its consequences, e.g. by insurance, Government guarantee.*

4.17. ***Principal - Agent*** *- means a relationship between two parties and is an arrangement in which one entity legally appoints another to act on its behalf, e.g. The European Commission mandates the European Union Agency for Railways to oversee and improve railway safety on the railways in the SERA. As noted above a moral hazard may also arise in a Principal - Agent relationship. The agent may have an incentive to act inappropriately (from the viewpoint of the principal) if the interests of the agent and the principal are not aligned.*

4.18. ***Sector Risk Profile (SRP)*** *- SRP is the characterisation of a risk picture specific to a sector, achieved by assembling all available information on the sector in terms of its characteristics and exposure to unsafe events, estimating the likelihood and severity of the event outcomes under the current risk controls and crafting optimal risk responses including additional risk treatments[7].*

4.19. ***Regulator*** *– a person or organisation that supervises a particular industry or business activity*

5. Risk profiling – What is it and how can it be used by the Agency

5.1. A Risk Profile can be defined as a list of risks or unwanted events to which the entity is exposed at a given point in time and which may lead to an accident. Therefore, by understanding the risk profile of an organisation, company, entity, etc., it may be better placed to control the risks that have the potential to lead to accidents. Defining a risk profile is already a Safety Management System requirement (Paragraph 6.2.7 SMS Requirements). A risk profile is differentiated from the hazard log or list in that it contains qualitative or quantitative data that allows it to be applied in the everyday work of administrative bodies or railway operators concerning railway safety. Risk profiling is one of possible ways of using the occurrence data.

5.2. Industries such as maritime and shipping, railways, mining, chemical, aviation, oil and gas exploration, nuclear and space have all developed their safety regimes based upon an understanding of their risk profiles. In their nascent phase the typical response to accidents

[7] X.G. Lin, F. Fernandes, S.M. Duffield and J. Codyre, The development of the sector risk profiling methodology for Australian civil aviation activity and its application to the small aeroplane transport sector. Given at 22nd International Congress on Modelling and Simulation, Hobart, Tasmania, Australia, 3 to 8 December 2017, see http://www.mssanz.org.au/modsim2017/

will be re-active, i.e. "…this is what happened in the accident, we must legislate and set rules to ensure that it never happens again…".

5.3. In the modern era we have seen many of these sectors move towards a risk based approach in which the risk profile of the industry is used to direct future safety effort. The willingness to consider different levels of risk as acceptable by companies working in a particular sector is dependent upon the understanding by the companies of the risks they face, the degree to which they can mitigate those risks internally and the level of insurance that they can achieve to restore, where possible, the situation before an accident. The use of the risk profile, developed from the past experience, can then be used to understand and mitigate the risks by changing processes and systems.

5.4. A necessary prerequisite of the risk based approach, common to any sector, is the competence of the regulator (National or European). Regulators need to be competent such that independent constructive challenge can be undertaken. In order to do this any regulator requires an understanding of the current and future risk profile of the industry. Understanding of risk is only as good as the data used in determining the magnitude and consequences of the risk being measured.

5.5. Risk based regulatory regimes require an effective means of regulation, concentrating on the areas of highest risk and not consuming time and energy on risks that are negligible. However, to work effectively both the regulator and those actors who are regulated require an accurate view of the current and possible future risk profiles. These will be subject to variable uncertainty. What is proposed here would be to adopt a common approach to risk profiling and reduce uncertainties by building on this existing Risk Management Framework.

5.6. An approach based on high levels of risk needs therefore to be supplemented with a monitoring of the perceived negligible risks to ensure that they remain negligible. One source of this would be a comprehensive incident and near miss database, i.e. the reporting of all occurrences that might in some way lead to an accident. It is fully accepted that it is difficult obtaining accurate near miss data. This is a clear limitation of a risk based regulatory framework. Nevertheless, while the current ERAIL database does not provide reporting for all occurrences it at least provides some of the elements that help in the construction of a risk profile – the data that currently exist being used to set the boundaries within which the current safety performance is expected to be. This database may provide at least part of the foundations (particularly the data contained within the database concerning serious accidents) for the development of a future Common Occurrence Reporting (COR) system.

5.7. An overall picture of risk requires input from many sources of data, the reliability and consistency of which may be variable between data sources, especially of data that relies on human reporting. Incident data in particular can often suffer from under-reporting and for this reason a proportion of the regulatory activity should remain inspection based rather than risk based to identify any emergent areas not detected in the risk data. However, it should be borne in mind that occurrence reports represent only one share of safety data. Accident investigation reports, audit findings, quality of SMS manuals, positive findings, safety culture etc. are also critical inputs for overall picture of safety.

5.8. Currently, the CSIs provide the means of assessing the safety performance of the railways operating in the SERA. They contribute to aspects of the risk profile on the EU railways. It must be noted that the current CSIs are only a set of statistics. There is no occurrence detail contained within the CSIs, e.g. time manner place, F&SI, etc. However, it is known from the previous papers on the development of COR that a considerable further amount of work would be required to create a consolidated risk picture of EU railways. It should be noted that a decision was made to develop the TDG occurrences reporting in line with the new occurrence reporting regime. The work is expected to start in 2019 or 2020. A first step would be to establish whether the data from current incident reporting could be used in either preparing the risk profile or reaching an understanding of what the risk profile looks like. It is the second of these two approaches that is further examined in this paper.

6. Risk profiling versus risk modelling

6.1. There is a significant difference between risk profiling and risk modelling. It is possible to produce a profile of the risks from a sample of the data. Our current CSIs allow us to develop a very high-level profile. The ERAIL investigations data allow us to develop the next level down in the profile, e.g. we may be able to say “With a certain level of statistical confidence, x is likely to happen.” We may be able to develop modelling type approaches that are based upon the risk profile that enable the development of forecasts concerning future risk events.

6.2. Risk modelling uses all of the available evidence and data available describe the risks faced by the railways in the SERA. The structure of such a model would be to describe the possible situations that lead to occurrences. It can be allied to statistical modelling to ascertain probable outcomes. It would enable a better understanding and reduction of uncertainty leading to a better understanding of the risks faced.

6.3. A Risk Model for Europe’s railways would take as its starting point a risk profile for the whole railway network and its operation. Much useful foundation work has been established by the Inland transport of dangerous goods risk management framework. It would underpin the evidence derived from the sector and regulators of their risk-based approach to safety management.

6.4. It would provide a starting point for quantified risk analysis. For example, it could be used to assess incremental or major changes proposed to the railway network, e.g. the rate of implementation for European Train Control System (ETCS), fitting of barriers at ungated level crossings etc. Railway undertakings would be better able to understand the safety of their operations. Infrastructure Managers could manage risks associated with their infrastructure, e.g. infrastructure collapse, occurrences at level crossings or Signals Passed

at Danger (SPADs). Other players would be able to assess their contributions to railway risk, e.g. the Safety Risk Model (SRM)[8] developed by the UK's Railway Safety Standards Board. This, in their words, "…provides a network-wide view of risk and is used by companies and projects to support risk-based decision making.".

6.5. Such risk modelling would help to focus collaborative cross-industry effort, e.g. between Manufacturers of equipment, railway undertakings and infrastructure managers to bring about better safety on Europe's railways

7. Relationship between risk profiling and benchmarking

7.1. A bench mark is a geographical or surveying term describing a fixed reference height that has been chiselled or marked into a stone structure (one that is solidly fixed), providing a stable elevation point. It is a spot height taken in reference to other Benchmarks locally or from a fundamental Benchmark, e.g. Mean sea level. In the context of this work we use the term in the measuring sense, e.g. to gauge safety performance by Member States or Railway companies against one another or against an agreed and defined standard.

7.2. The benchmarking process determines:

- What organisations set the safety or performance standards - who is 'best-in-class'?
- Where can we identify safety or technical advantage within the rail system?
- What performance standards / targets are?
- And how do we quantify these standards / targets?
- How do 'best-in-class' organizations reach these standards or targets?
- What outstanding practices can organisations adapt into their safety or system framework to improve safety or services, identify potential cost savings and enhance their safety or strategic planning?

Benchmarking requires correct comparisons, e.g. apples versus apples comparisons. This requires detailed definitions of indicators being compared and in the more complex exercises the ability to influence performance.

7.3. In railway safety we already carry out basic benchmarking, e.g. where we compare the performance of Member States and a European Union Average (See figure 1 below). However, the Agency and the Commission have also undertaken benchmarking exercises using "Stochastic Frontier", and "Data Envelopment" analyses[9]. These and other methods such as "Free disposal hull" analyses allow complex analyses to better understand the efficiencies that might be gleaned from the railways, their organisations, their structure and where these might be useful for improving safety.

[8] See: https://www.rssb.co.uk/safety-risk-model/risk-profile-bulletin, accessed 07/08/2018

[9] See: ERA Report on technical benchmarking of European Railways, 2011 and see: https://ec.europa.eu/transport/sites/transport/files/modes/rail/studies/doc/2015-09-study-on-the-cost-and-contribution-of-the-rail-sector.pdf While these studies benchmark technical efficiency and overall contribution of the railway there is no reason why safety and risk performance could not also be analysed.

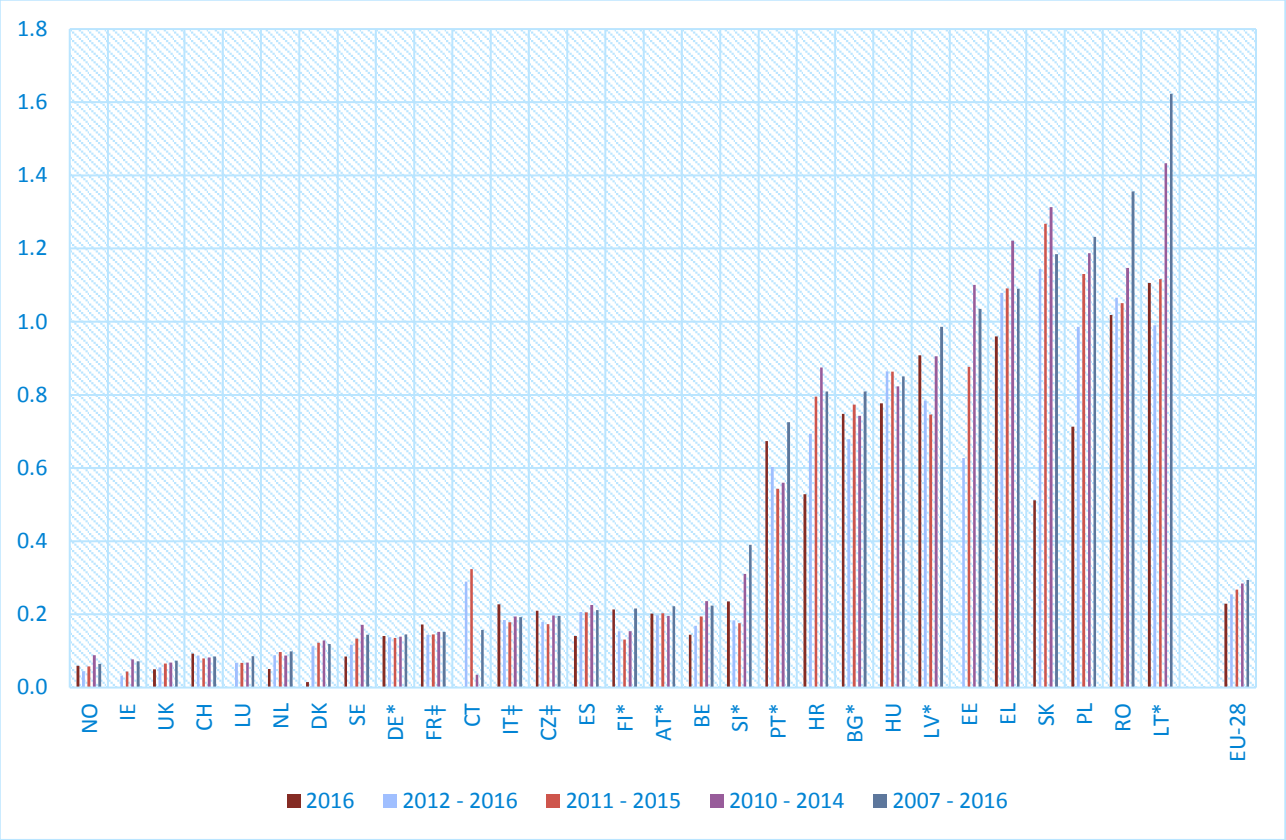


Figure 1 **Railway fatalities per million train kilometres – 2016, 3 x 5-year means and 10-year mean. (The order of Member States is based on 2016 performance). Sorted on the basis of the 10 year mean.**

8. Safety performance, safety levels and risk profiling

8.1. The Agency has reported on the safety performance in the SERA[10] from 2006 through the analysis of the CSIs. In 2010, harmonisation was achieved in the definitions used for the collection of indicators. This is now aiding the development of useful comparative analyses.

8.2. In the SERA safety performance has improved: there are fewer significant accidents, fewer fatalities and fewer serious injuries in 2017 than there were in 2006 (not shown) and in 2010 (See figure 2 below). The diagram below illustrates the numbers of significant accidents, fatalities and serious injuries at the EU-28 level from 2010. However, as can be seen from the data the number of significant accident indicator fluctuates up and down though with a general downward progression over the whole period and increases in the number of fatalities and serious injuries in 2016 and 2017 that are of concern.

[10] Directive 2012/34/EU Establishing a Single European Railway Area.

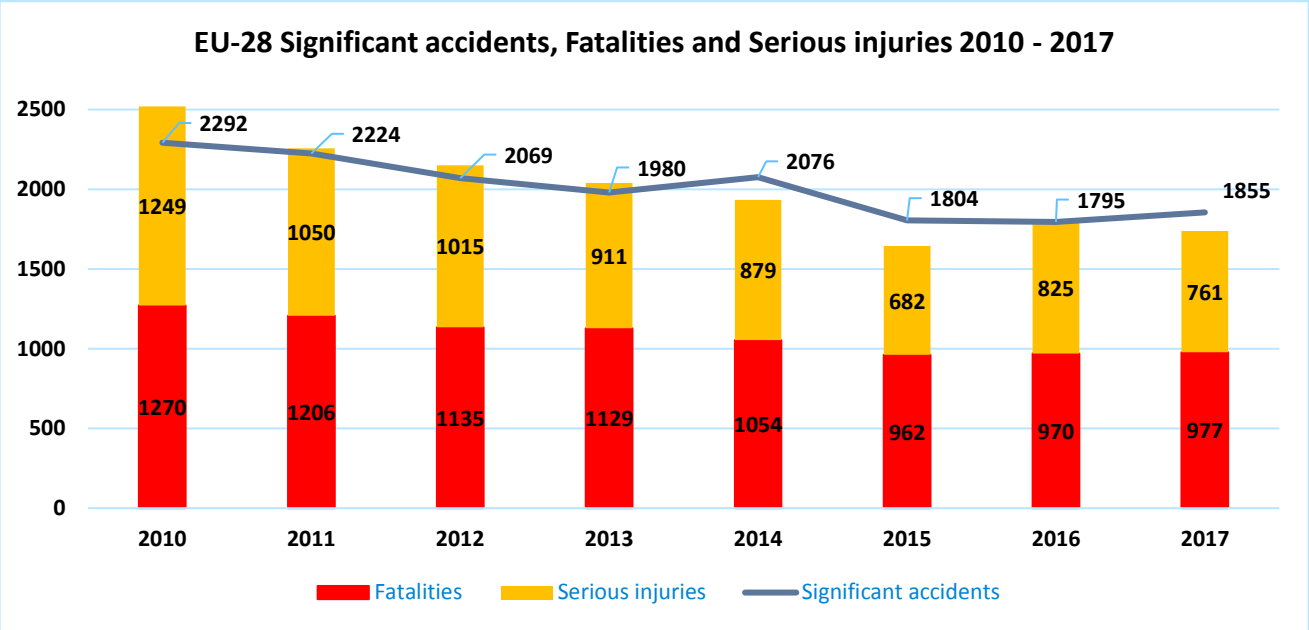
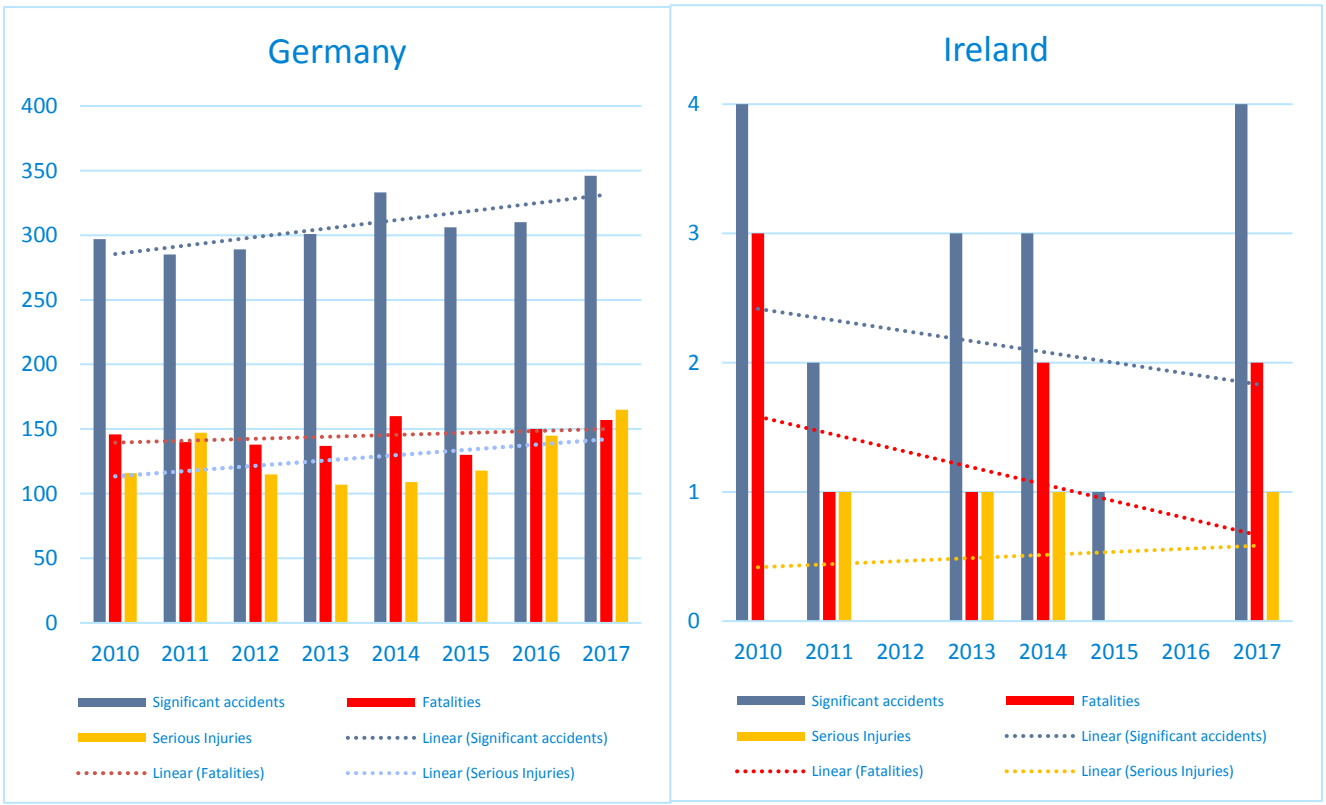


Figure 2 **Numbers of significant accidents, fatalities and serious injuries occurring on the railways in SERA 2010 – 2017.**



Figures 3 a & b **Numbers of significant accidents, fatalities and serious injuries occurring on the railways in selected Member States DE and IE 2010 – 2017 and average (2013 – 2017). Linear trend line for each indicator is shown.**

8.3. The data for Germany and Ireland shown in figure 3 a and figure 3 b show fluctuations between years. These fluctuations are what is termed "noise". We need to be able to extract any signal that might be present in our indicators from the noise. Noise in the statistical sense is random. This "statistical" noise happens, and is difficult to do much about, e.g. the change in weather from one day to the next and from one year to the next. However, by understanding the sources of statistical noise at least, it is possible to control for. A number of further questions arise from this including, but not limited to, how precise can a signal be when extracted from the indicators.

8.4. Also, if the Agency is going to collect more information, the question must be asked, what can it do with more, "better" and perhaps earlier information? The example that falls into this category are the Agency's Internal briefing notes prepared after serious accidents have happened.

8.5. Apart from such alarm bells, if they have sounded, what are the roles and responsibilities that arise after the alarm bell has been sounded? It is here that having a sector risk profile (SRP) may enable better safety outcomes[11]. The diagram below (Figure 4) shows the steps that have to be taken to establish a risk profile for the railway sector. The starting point for working through this diagram is in the top left – "Establish the (Sector) Context".

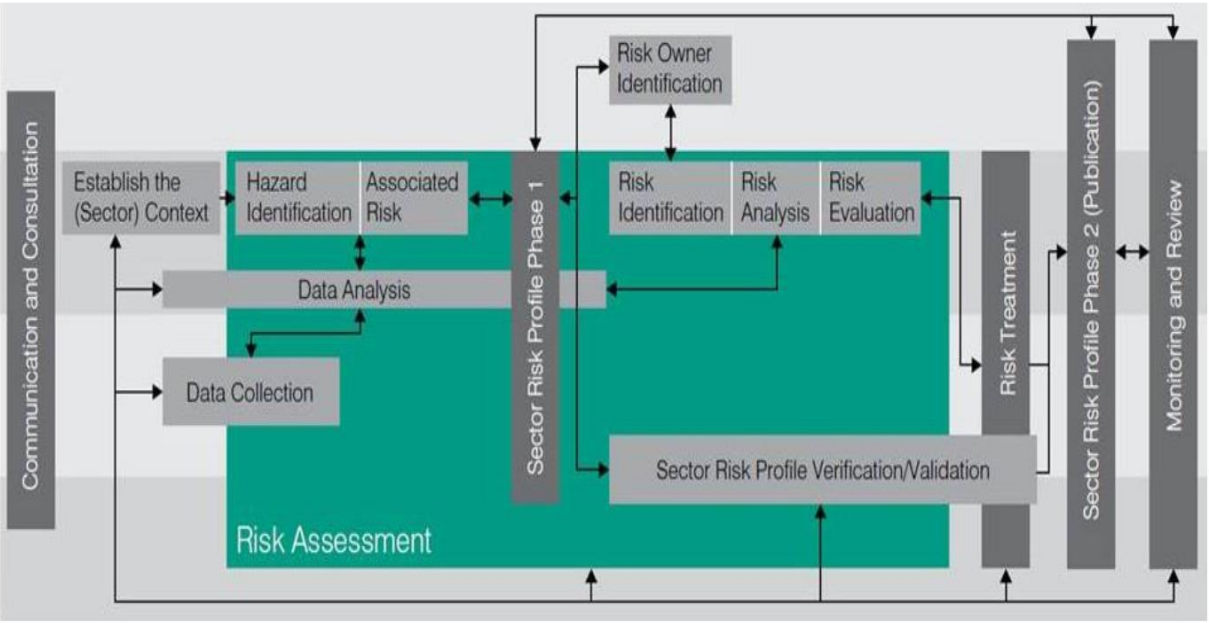


Figure 4 **Sector Risk Profile process as set out in the Lin (2017) paper[12]. Note that the start-point for tracing through the process is "Establishing the (Sector) context" box in the top left of the diagram. Establishing the sector context or, as used in the Inland TDG RMF "Describing a risk situation" sets out the risks faced and any data related to the situation.**

[11] Profiles could be developed for Member States (MS profile) or individual companies (CO profile)

[12] X.G. Lin, F. Fernandes, S.M. Duffield and J. Codyre, The development of the sector risk profiling methodology for Australian civil aviation activity and its application to the small aeroplane transport sector. Given at 22nd International Congress on Modelling and Simulation, Hobart, Tasmania, Australia, 3 to 8 December 2017, see http://www.mssanz.org.au/modsim2017/

8.6. The data must be converted into a common risk currency to enable them to be compared and consolidated into the overall risk picture.

8.7. The development of audit frameworks has also progressed despite some reluctance on the part of some of the players. What is now suggested is the development of the Sector Risk Profile (SRP) that brings about a greater understanding of the risks faced, that understands the underlying risks and is specific in the targeting of risk minimisation. Lin and colleagues (2017) showed how the Australian Civil Aviation Safety Authority (CASA) did this for the small aeroplane sector in Australia. Figure 5 below sets the SRP in the wider context.

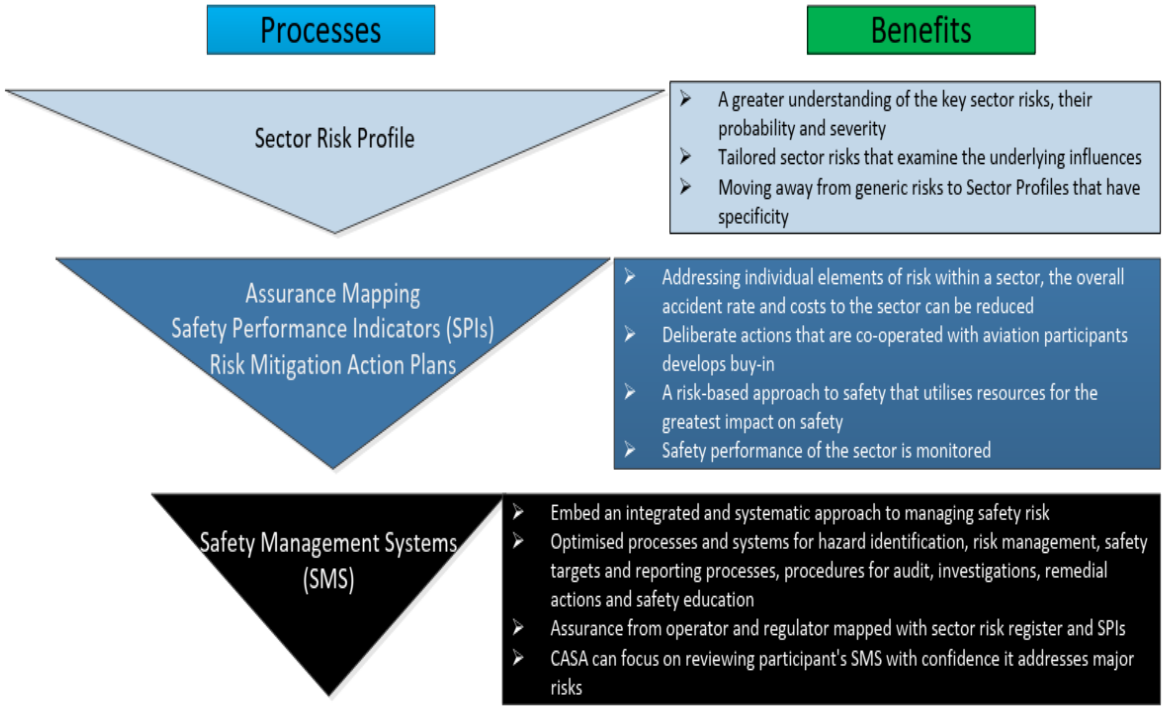


Figure 5 Sector Risk Profile in context after Lin (2017)

8.8. **All of the critical aspects and elements to develop the risk profile are currently in place for the railway sector.** The aspects of different geographic conditions, different types of signal systems, signalling control plant and railway infrastructures can be taken into account through the development of the Register of Infrastructure (RINF). **The Agency is therefore able to build upon the foundations that have been laid since inception in 2004 to create, with the railway sector players, a sector risk profile.**

8.9. Lin and colleagues (2017) followed the principles set out in ISO 31000:2009[13] and showed how qualitative and quantitative could be used to develop the SRP. The SRP was developed:

8.9.1. In consultation with the sector's subject matter experts;

8.9.2. To produce a sector risk register which includes all risk attributes such as causes, current controls, future treatments, ownerships, etc.;

8.9.3. Through an assurance mapping process which contains a gap analysis of the sector risk register and each sector entity's risk register; and

8.9.4. By introducing a new concept of the "living risk profile" through implementation and integration of the risk register into the sector entity's Safety Management System (SMS) and into the authority's safety surveillance program to responding to emerging risks.

Processes	ERA has:	Does ERA do this?	Is it within the current RSD (or other) legal framework?
Sector Risk Profile	A greater understanding of sector risks	Partially	Preamble (30) and article 4 (c)
	A greater understanding sector risk probabilities	No	Articles 4 (d) and 6.1
	A greater understanding of sector risk severities	Yes	Articles 4 (d) and 6.1
	Tailored sector risks to examine underlying influences	No	Article 4.1 (f) and (g)
	Moved from assessing generic risks to a specific sector risk profile	No	Articles 4.4 and 4.5
Assurance mapping Safety Performance Indicators Risk Mitigation Action Plans	Addressed individual elements of risk within sector	Yes	Article 4.5
	Addressed overall accident rate	Yes	Articles 5.1 and 5.2 (Annex 1)
	Addressed overall costs of accidents with a view to reducing costs	Partially	Articles 5.1, 5.2, 19 (Annex 1)
	Developed deliberate actions in co-operation with railway sector "buy-in"	Recently started	Article 4.2
	Developed risk-based approaches to safety utilising resources to target the greatest impact on safety	Partially	Article 6.1
	Safety performance of the sector is monitored	Yes	Articles 5.1 and 5.2 (Annex 1)
Safety Management Systems (SMS)	Embedded an integrated and systematic approach to managing safety risk	Partially	Articles 4.1 (d) (iii) and 9.1
	Optimised processes and systems for hazard identification	Yes	Article 9.3
	Optimised processes and systems for risk management	Yes	Articles 9.4 and 9.5
	Optimised processes and systems for safety targeting and reporting	Partially	Articles 1 (c) and 9.1
	Optimised processes and systems for safety auditing	Recently started	Article 9
	Optimised processes and systems for safety investigation	Yes	Articles 20, 21 and 23
	Optimised processes and systems for developing safety remedial actions	Yes	Articles 24, 25 and 26
	Optimised processes and systems for developing safety education	Partially	Agency Regulation Article 13?
	Developed assurance from railway sector operators and national regulators mapped to the sector risk register and Safety Performance Indicators	No	Agency Regulation 13.2?
	Focussed on reviewing participants SMS with the confidence that they address all major risks	No	Agency Regulation Article 13.4

Table 1 Mapping of requirements set out in Lin (2017) against what ERA currently does in respect of risk profiling for the SERA and the legal framework.

[13] See http://ehss.moe.gov.ir/getattachment/56171e8f-2942-4cc6-8957-359f14963d7b/ISO-31000

9. Data granularity and risk profiling

9.1. Data granularity describes the scale or level of detail in a set of data, e.g. the CSIs are merely statistical numbers, they describe only the number of occurrences, fatalities, serious injuries, precursors and normalising values, network, train, passenger and freight-tonne kilometres.

9.2. At the present time the CSIs, provided to the Agency, have the lowest level of data granularity for describing the railway safety performance of the SERA. Some precursor incident statistics are also collected.

9.3. However, the accumulation of the CSI data since 2006 now enables the Agency to determine trends and to understand those trends along with the likely variability within the data in a statistical manner. With a long enough run of statistics we might make an estimation of the numbers of significant accidents and in consequence the likely numbers of fatalities and serious injuries from this estimation.

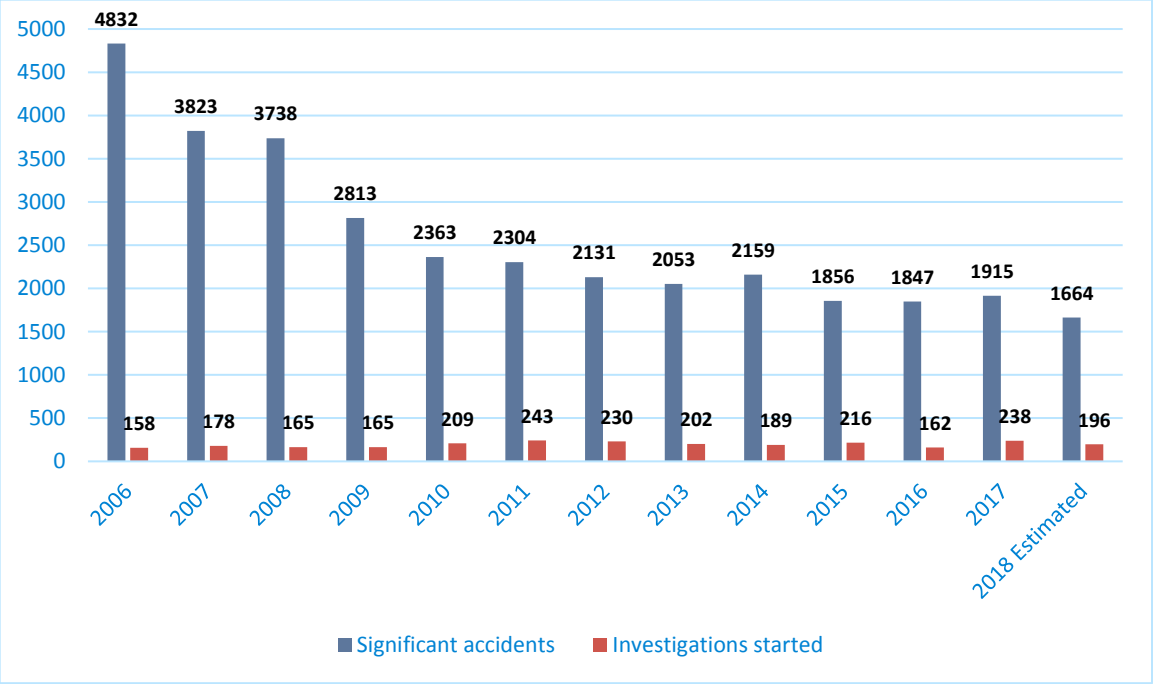


Figure 6 Extrapolation of numbers of significant accidents occurring on the railways in EU – 28, Norway and Switzerland 2006 – 2016 and extrapolation based upon existing trends 2017 - 2018 along with reports and notifications of occurrence in ERAIL 2006 – 2017 and extrapolation based upon 2018 Q1 ERAIL notifications.

9.4. While it is possible to test the estimation, and it may be useful to understand that an estimation is merely based upon the expectation of the trends that have been seen since 2010 are continuing, all other things being equal, into 2018, for which we have not yet seen the data (figure 6). The estimation does not take account of the wide range of factors that might influence railway safety performance. However, with the more detailed occurrence data and a slightly different, but still statistically rigorous, approach we may be better placed to make more meaningful estimations.

9.5. In regulatory terms the Agency's reporting constitutes "sunshine"[14] type regulation. By shining a light on the safety performance of railways in Europe, the railways operating in the SERA and their national regulators are encouraged not to neglect safety.

9.6. The data contained in the Investigations part of ERAIL have a higher level of detail and hence a higher level of granularity. These occurrences tend also to be the more serious cases and the ones that we most want to avoid because they have the highest costs in terms of fatalities, serious injuries and damage. So while the level of granularity in the data is higher, compared to the CSIs, the lack of full coding of the causes, consequences and learning prevent the better exploitation of the data within this database.

10. Past history versus predictive capability

10.1. Predictions of future railway safety performance are subject to considerable uncertainty, for two main reasons: Future factors that may influence railway safety — such as the adoption of Automatic Train Protection systems—while planned, are subject to budgetary constraints and are therefore uncertain; and knowledge of how strongly the railway system responds to external influences, particularly public concern, is incomplete.

10.2. An approach to using past history to predict future events is to use a Bayesian model. One of the significant properties of the Bayesian approach is that it takes account of prior information and allows the updating of model parameters through incorporation of new data or information. The power of the prediction can therefore be tested against the actual experience and this information used to assist further prediction. The mentioned Bayesian approach can be successfully used also in the evaluation of the safety targets. It makes possible to take into consideration different amount of occurrence data, which result from different sizes of member states or companies when evaluating any kind of general targets.

10.3. This approach moves away from the "estimation based upon historical trends" to the more nuanced "prediction based upon known prior data, its statistical characteristics and probabilities of events within the data happening. By using the Bayesian statistical framework we would be able to develop an inference model in which Bayes' theorem is used to update the probabilities for a hypothesis as more evidence or information became available. The starting point for such an inference model would be the F/N Curve, which is discussed further below.

11. Preventing rather than predicting

11.1. The recent recast of the Railway Safety Directive has placed the emphasis on preventing accidents. The Agency is working to do this by:

- Making available information about railway safety performance in the form of:
    - Common Safety Indicators published in the Safety Performance Reports and Railway Systems Report;
    - Analysing safety performance against safety targets;
    - Developed Common Safety Methods which describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed;

- Require the development of Safety Management Systems by Railway Undertakings and Infrastructure Managers
- Publishing information relating to the most serious accidents including details of the occurrence, causation, reports and recommendations, and
- Conducting audits, cross audits, i.e. producing technical opinions.

All of the above requirements are included within the recast Railway Safety Directive.

11.2. The recent recast of the Railway Safety Directive has placed the emphasis on preventing and mitigating accidents. Prevention has three roles:

- Primary prevention: removal of circumstances causing the accident – e.g. removal of level crossings, putting in pedestrian underpasses, etc;
- Secondary prevention: reduces severity of accidents should an accident occur – e.g. designing rail vehicles to absorb crash energy – thereby reducing the accident forces, installing passive safety measures within rolling stock to reduce the severity of casualties, installing passenger alarms enabling the signalling of problems and issues relating to railway safety, and
- Tertiary prevention: enabling optimal access to the railway following an accident – e.g. in order to provide effective first aid to those injured and speedy access for those requiring hospital care, thereby mitigating the consequences of an accident.

11.3. The Agency, in its role as technical and safety regulator has set the legal and safety framework for railways in the SERA as noted in paragraph 9.1 above. It has already specified the Inland TDG Risk Management Framework, which is a full safety risk profiling approach corresponding to what is proposed here for railways in general in this document. Such approaches assist the railway sector by:

- Identifying the critical hazards at a European level;
- Highlighting preventative measures (see above);
- Developing common methodologies for measuring and monitoring the hazards and evaluating the effectiveness of measures taken (see above);
- Presenting and sharing risk minimisation strategies, e.g. Safety Performance workshop;
- Collaborating with other agencies and bodies, EASA (Aviation), EMSA (Maritime), Eurostat (Statistics), ENISA (Network and Information Security) etc;
- Promoting accident prevention education and training, e.g. accident investigation training, etc.;
- Research, e.g. risk minimisation concerning the transport of Dangerous Goods, and

- With the Commission assisting in the development of policy making for railway safety, e.g. European Railway Safety Culture Declaration[15] – concerning the development of safety culture for railways in Europe.

11.4. The development of predictive methodologies can be considered as complementary to preventive approaches, e.g. monitoring and supervision, on the basis that if you can predict you may be able to prevent. The development of the sector's risk profile would enable better railway safety outcomes through the integration of the risk profile into the sector entity's Safety Management System (SMS) and into the Agency's NSAs safety supervision and surveillance programmes designed to respond to emerging risks. As well as extrapolation and scaling to achieve prediction, part of the future work of the Agency will need to examine emergent "artificial intelligence" approaches developing as part of "big data". The Agency has undertaken initial high level studies in co-operation with some railway sector actors to look at some of the issues that might be raised by "big data".

12. Black box (regulatory blind), White box (operational model) and evolution, if any

12.1. In developing a model and to assist in preventing accidents it would be better that we used a "White box" approach rather than a "Black Box". In the white box approach the operational model is known, e.g. the approach would be to model all events – both the safe ones, where nothing untoward happens, and the unsafe ones, where there is an occurrence which is not safe.

12.2. However, the Agency, to date, has worked in a "black box" environment – we do not have detailed knowledge of the operational model of the European railway sector. The level of detail regarding occurrences is limited by what is provided within the legislation. Therefore, there exists a degree of asymmetry between the railway sector and the national safety and investigation bodies in regard to the safety regulation of the SERA.

12.3. The agency understands the context in which the railways are operating and interfaces and tries to ensure that they work as expected. As long as safety / functionality of interfaces remains unchanged, or does not deteriorate then the directive requirements are met. While the Agency is "regulatory blind" it is nevertheless able to provide external perspective to the safety performance of the railway sector and the national regulatory and safety investigation bodies. Because of the legal requirements set out in the Railway Safety Directive some of the asymmetry is ameliorated.

12.4. However, some of the disadvantages of the black-box approach are:

- It is limited to the indicators that are collected and the manner in which they are collected;
- As noted, the Agency is blind in its coverage since the Agency has only a limited knowledge about the detailed "normal" functioning of the railway sector, and
- It is inefficient due to Agency's lack of knowledge about the processes of the players in the sector.

[15] For more information see: https://www.era.europa.eu/activities/safety-culture_en

12.5. At the other end of this spectrum a "white box" approach would remove much of the "regulatory blind" situation, i.e. regulators by their very nature do not have detailed knowledge of all operations, that we now see. A safety regulator will only see the aftermath of accidents, not the "normal operations" that had preceded it. Transparency regarding occurrences, whether normal or unsafe, offers benefits to those who are regulated and the regulators. The assumption regarding the white box approach is that the moral hazard implicit in the Principal (the Agency) and the Agent (the railway sector and the national regulators) is overcome because the incentives of both sets of players are aligned – all want safer railways. However, the white box approach will not be achieved instantly and therefore the risk profiling approach is a way to move from the current black box approach to a white box situation.

12.6. The situation within the Agency is that since inception we have tried to move away from the black box approach towards the white box, and in reality have ended up in a "grey box" area. We know something of the "operational" models used in the railway sector but are at some remove from the operating interface. An example of this approach was trying to develop Derailment Models using big data approaches.[16]

13. Assessment of risk profiling:

13.1. The outcome of risk profiling will enable risks to be identified and prioritised for action. This, however, may not be sufficient for efficient improvement actions: these actions should be focused on highest risk reduction potential and not on highest risk as such. It would also inform decisions about what risk controls measures are needed. The Agency has sought to develop better safety attitudes and behaviours through greater transparency of railway accidents, incidents and precursors and transparency of safety issues through the publication of reporting on the most serious accidents along with recommendations that arise from such accidents. The Agency has had in place targets for a number of critical target areas for Member States to measure their performance.

13.2. The resources required to undertake risk profiling are still to be determined.

14. Examples of applications

14.1. Risk profiling is in common use in the following industrial sectors:

- Aviation;
- Nuclear;
- Oil and Gas exploration;
- Chemicals;
- Mining;
- Environment;
- Pipelines, and
- Construction and Building.

14.2. The use of risk profiling is emerging in a number of sectors, including Health, Medicines, Food processing and Metropolitan railways.

[16] Jason Sadler and others, GeoSRM – Online geospatial safety risk model for the GB rail network. IET Intelligent Transport Systems: RRUKA Conference Special Issue (2015).

14.3. The railway sector, while coming late, nevertheless has through the development of Safety Management many of the foundations in place that will enable it to catch-up quickly with sectors such as aviation and nuclear.

14.4. At the present time the resources involved in risk profiling in these sectors have yet to be determined.

15. Use cases

15.1. At a generic level, the use cases of risk profiling follows from the provisions in the Safety Directive regarding the roles and responsibilities of the different stakeholders (Article 4) with respect to developing and improving railway safety in Europe including risk management. In particular, roles are set out for:

- Member States (Article 4(1))
- The Agency (Article 4(2))
- Railway undertakings and infrastructure managers (Article 4(3))
- All other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers (Article 4(4))

15.2. We note from the Aviation sector that EASA does risk profiles at the European level, Member States bring the profiles to national level and Companies take risk profiles into consideration in their Safety Management Systems (SMS). The possible outcome of this work, if agreed and accepted would be that the Agency would follow a similar process path.

15.3. As such the use cases of risk profiling should be linked to these roles and consideration given as to how risk profiling tools can support the stakeholders in fulfilling their responsibilities at individual and system levels.

15.4. The conduct and use of Risk profiling consists of three interrelated aspects:

Conduct of risk profiling

- Construction and development of risk profiles through data collection and other information sources.

Use of risk profiling

- Analysis and assessment of information contained in the risk profiles, and
- Specification of relevant action plans as required. The stakeholders identified above can make use of risk profiles and risk profiling to determine what they can do to minimise the concerned risks.

15.5. Specifically, the outputs from risk profiling can assist the stakeholders to:

- identify and understand safety risks;

- ensure relevant risks are incorporated in the risk management framework used by the stakeholders (for RUs and IMs risk profiling should be incorporated into their SMSs);
- identify system vulnerabilities which can inform the stakeholders where to target its resources;
- reduce safety risk among stakeholders, and
- maintain confidence of the public and key stakeholders

15.6. Stakeholder-specific use cases can be based on the objectives included in the COR Impact Assessment Report as follows:

15.6.1. European Commission:

Support impact assessments and decision making regarding proposals for new railway legislation and railway projects funding where safety aspects may be of relevance

15.6.2. The Agency:

Development of risk based regulation, e.g. to support the revision/refinement of the technical/ operational/ geographical scope of the TSIs including referenced standards on a risk informed basis so that they are not overly prescriptive in areas of low risk and insufficiently prescriptive for areas of high risk and support other Agency recommendations, opinions and advices.

Enable early identification of emerging safety issues and target appropriate proactive interventions and measures, e.g. to be able to collectively analyse occurrences and precursor data across the EU Member States with the view to receive an enhanced picture of emerging catastrophic risks that require actions on EU level

Support Agency operational tasks relating to railway safety or interoperability e.g. system authority for ERTMS, NSA monitoring, safety certification or vehicle authorisation

15.6.3. National Safety Authority:

Improve risk based supervisory activities (CSM supervision), e.g. increase efficiency of supervision by focusing supervision on those areas or actors at greatest risk, support better coordination between NSAs regarding supervision strategy for RUs operating in several Member State

Improve the NSA's understanding of the national risk profile when approving the SMS of a RUs/IMs during certification of RU/IM

Help to monitor, promote, and, where appropriate, enforce the safety regulatory framework

15.6.4. Member state:

Support the Member State for setting up the national safety plan as required by Safety Directive and help achieve at least CSTs, e.g. by benchmarking between Member States, ensure that current safety level is maintained or improved

Develop better national legal framework in terms of risk management, including national rules

Improve risk based decision making and prioritisation of investments decided by the Member State

15.6.5. RUs or IMs:

Support SMS development and monitoring (CSM on SMS), e.g. to facilitate the adaptation of their SMS. Particularly if area of operation is extended (RUs only), support prioritization of risks and allocate resources accordingly when risk control measures are implemented,

Support monitoring of low frequency high consequence risks and establish proper monitoring systems (CSM on monitoring)

Support decision making on significance or not of a change (CSM Risk Assessment)

Reduce administrative burdens for International RUs operating in several MSs e.g. they have to comply with different reporting requirements from one MS to another

Improve collaboration on identifying and managing shared risks, share experience and good practices between the railway operators, e.g. to support creating, sharing hazard and risks log identified from accidents and incidents between operational actors and provide ability for benchmarking and sharing taken safety measures

15.7. As such, risk profile(s) and risk profiling can be undertaken at different levels of aggregation including by specific operational activity, e.g. track worker protection, by individual companies, at national and European level as well as for different segments of the rail market, e.g. distinguishing between passenger and freight (or within passenger transport: local, regional, interregional). This raises an important dimension of risk profiling in terms of cooperation and sharing among the relevant stakeholders. The advantages of risk profiling are expanded in a context where stakeholders collaborate more' and 'engage more' with all stakeholders to increase understanding, promote safety improvement opportunities, and work on solutions together.

15.8. This improved understanding can then be taken forward by the individual stakeholders to improve their risk management approaches. Such a comprehensive approach involving all stakeholders would facilitate:

- A greater understanding of the key railway sector risks, their probability and severity;
- Tailored railway sector risks that examine the underlying influences, and
- Moving away from generic risks to Railway Sector Profiles that have specificity.

15.9. In this context, consideration could also be given to development of 'living risk profiles' whereby a railway sector risk register that includes all risk attributes such as causes, current controls, future treatments, ownerships is taken forward in the risk management frameworks of individual companies. Incorporation of increasing number and detail of risk attributes can be useful and relevant as long as these attributes allow aggregation ('summing') of (numbers of) occurrences. This could cover both integration into RUs / IMs SMSs and into NSAs supervision strategies to respond optimally to emerging risks. This could be part of an approach for continuous update of the risk profile and overall improvement in risk management.

16. Next steps

16.1. In the current situation, because of the need to report CSIs and investigations following the more serious accidents and incidents into ERAIL, risk profiling activities at company, member state and Agency / Commission levels are already being undertaken. However, given the lack of sharing of occurrence-related data the outcome of risk profiling is relatively limited in scope. This also applies to the advantages that might be delivered. This is especially so at European level and in those Member States with only basic national occurrence reporting schemes in place. Current examples of "high-level" risk profiling at national and European levels include:

- NSA annual reports to the Agency;
- Agency Safety Performance reports;
- Agency workshop on Safety Performance;
- Network of National Safety Authorities, and
- Accident Briefing Notes, etc.

16.2. A possible direction towards enhanced risk profiling prior to the implementation of improved occurrence reporting (COR) could be the introduction of consistent railway sector risk profiling[17], see Lin et al. (2017). We know that the majority of the sector players utilise risk profile type information. If there was consistency in use the sector would undoubtedly benefit. Emphasis in sector risk profiling is on engaging with sector stakeholders to consult and review all available information on the sector to develop the risk picture, optimal risk responses for risks of significance can be collectively identified and ownership assigned for implementing responses.

16.3. Sector risk profiling is largely qualitative but can also benefit from quantitative data. However, a qualitative description of risks it is hardly possible without evaluation of quantitative data. Sector risk profiling involves the following three phases (that can be repeated at regular intervals):

Phase 1: Establishes the sector context to assist with data collection and analysis, i.e. the Agency, and other regulators sit down with the sector to identify the hazards and associated risks for the sector;

Phase 2: Develops a sector risk register based on the hazards and associated risks where it is also possible to revise risk register, and

Phase 3: Consists of sector assurance mapping, including conducting a gap analysis between the sector risk register and each company's risk register.

[17] Lin, X.G., Fernandes, F., Duffield, S.M.and Codyre, J. (2017) The development of the sector risk profiling methodology for Australian civil aviation activity and its application to the small aeroplane transport sector.

16.4. Common Occurrence Reporting development would be done on the basis using the available / shared data among stakeholders. It would be strengthened per CSI accident and incident (rather than only aggregated data) as well as information about identified causes for the occurrences. By this process the scope and outcome of risk profiling would be significantly improved at all levels. Implicitly, COR promotes sharing, engagement and cooperation with all stakeholders. As such, this is taken further through the planned implementation of a network of safety experts (drawing on the experience from EASA). A further development could be to utilise the methodology of sector risk profiling as described in section 8 above. In fact, this could be one way of formalising the reflections and discussions within the Network of Safety Experts.

16.5. It is argued in this document there is a difference between accident prediction and prevention. An "added benefit of detailed risk profiling" must be the ability to specify what level of prediction, and what level of actual prevention, is intended to come out of it. Clearly, the level of detail necessary for predicting that "x accidents will occur at level crossings", is different than the level of prediction that says "an accident will occur at this specific level crossing". The former should be a profile that could be produced from the ERAIL System. The latter may even be impossible to achieve even with COR.

16.6. The risks associated with adopting risk profiling still need to be determined. This would be done as part of the detailed planning. If this document were to be accepted then the detailed planning could begin.

Annex 1. Current use of ERAIL and differences if it was fully exploited

The ERAIL (European Railway Accident Information Links) system is currently used to collect Common Safety Indicator (CSI) data along with the recording of the investigations undertaken by National Investigation Bodies (NIBs) into the more serious accidents that occur on the railways in the SERA. The system is now in daily use for the reporting of serious accidents in accordance with the legislative framework. The Agency has also seen a number of the NIBs using it as an information sharing tool for investigations of groups of accidents where they see common factors.

The CSI data has long been used to provide the data for the biennial Safety Performance Report required by the directive. The Agency also developed its Interim Report published in the intervening years. From 2018 the Safety Performance Report was incorporated into the new Safety and Interoperability Report which also contained the biennial report on railway interoperability and the railway systems report, see:

https://www.era.europa.eu/sites/default/files/library/docs/safety_interoperability_progress_reports/railway_safety_and_interoperability_in_eu_2018_en.pdf .

In moving towards the development of risk profiling we need to consider how to use the data from within ERAIL to develop the risk profile. If we consider risk at its most strategic level then we are looking at the risks to “society” of having a railway system. We can present “Societal” risk by F/N curves, which are plots of the cumulative frequency (F) of various accident scenarios against the number (N) of casualties associated with the occurrences and incidents that have taken place or might take place. The plot is cumulative, for each frequency, N is the number of casualties that could be equalled or exceeded. Often ‘casualties’ are defined in a risk assessment as fatal injuries, in which case N is the number of people that could be killed by the incidents.

Table 2 below shows the frequency and equivalent periodicity of having an accident in a given time period. However, the frequency cannot be discussed out of any decision-making context without understanding the method which was used to obtain it and the limitations of its use. The best, out of context, answer to the limitation is to say that it could happen tomorrow and also the day after tomorrow again if the barriers to prevent such event happening are not properly maintained. Thus, the frequency of an accident of 1,0E-05 has the equivalent periodicity of 1 in an month, etc. This scale allows to understand the frequency of accidents with different number of fatalities, which vary greatly in how often they can take place in the railway system.

Frequency	Equivalent Periodicity 1 in
1,0E-05	monthly
1,0E-06	yearly
1,0E-07	10 years
1,0E-08	100 years
1,0E-09	1,000 years
1,0E-10	10,000 years
1,0E-11	100,000 years
1,0E-12	1,000,000 years
1,0E-13	1,000,000,000 years

Table 2 **Frequency of occurrence and equivalent periodicity measured in accidents/fatalities 1 per number of months or years.**

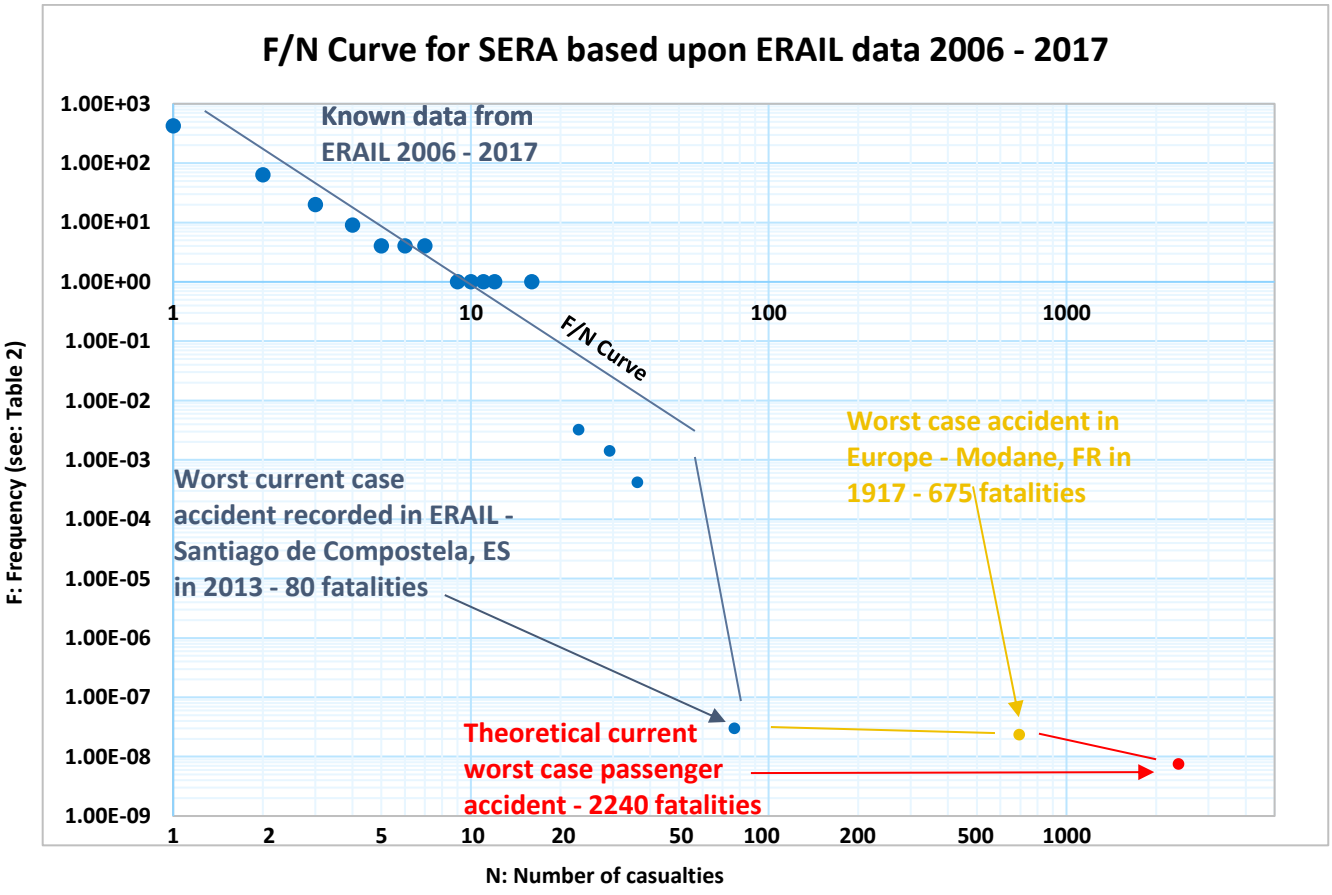


Figure 7 **The proposed SERA F/N curve based upon ERAIL 2006 – 2017 Investigation data. Sources: ERA (ERAIL database) and Kitchenside (1997)[18]**

[18] Geoffrey Kichenside, Great Train Disasters. The World's worst railway accidents, Siena Imprint, Parragon (Bristol), 1997.

F/N curves are a way of describing information about fatal accident frequencies and their distribution. They show fatal accident data graphically as might a statistician or analyst using exploratory data techniques. Once an F/N curve has been produced criteria can be set by which to determine whether the system risks illustrated in the F/N-curve are tolerable or not? These are sometimes called 'societal risk criteria'. A critical point is to decide where the line of the criteria runs, e.g. there may be the tendency to say that where a system's F/N curve lies wholly below the line, the situation could be regarded as tolerable and equally if any part of the F/N curve is above the line, the situation could then be regarded as intolerable. Safety measures to lower the F/N curve could then be required. However, this is a simplistic view. Nevertheless such analyses may be informative.

By understanding how the current F/N curve behaves or is likely to behave we may be able to define the area that is currently "considered acceptable" in terms of the ALARP principle (As Low As Reasonably Practicable). The ALARP principle is that the residual risk shall be reduced as far as reasonably practicable. Figure 7 illustrates the F/N curve for the SERA based upon an examination of information within ERAIL as well as historical sources. Basing on the number of accidents with a given amount of fatalities, the frequency of each type was calculated and the results presented on the figure. The F/N curve thus presents the frequency F (y-axis) of accident scenarios depending on the number of casualties N (x-axis).

The worst case theoretical passenger accident is determined by the limit set in the Common Safety Method for Risk Assessment (CSM RA) and assuming two of the highest capacity trains in current use and maximum formation were involved in an accident and all occupants were fatalities. While this is an extreme assumption it nevertheless conforms to the current limits set out in the CSM RA.

Residual risk is the risk or danger of an action or an event, a method or a (technical) process that, although being abreast with science, still conceives these dangers, even if all theoretically possible safety measures would be applied (scientifically conceivable measures); in other words, the amount of risk left over after natural or inherent risks have been reduced by risk controls.

The concept of "reasonably practicable" involves weighing a risk against the trouble, time and money needed to control it. We know, because of the public concern raised after the accident at Santiago de Compostela, in Spain, in which there were 80 fatalities, that at the frequency indicated there is a wish that this should not happen again. Setting this limitation we can create the individual Member State (MS) F/N curves, we can then start to define the potential risk profile for each MS.