EUROPEAN UNION AGENCY FOR RAILWAYS

Making the railway system
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Review of EU legislation related to occurrence reporting

COMMON OCCURRENCE REPORTING PROGRAMME

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1.0	27/09/2016	Consultation document
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2.1. Reference Documents

Table 1: Table of Reference Documents

[Ref. N°]	*Title*	*Reference*	*Version*
[1]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)	2016/798	OJ: L138/102 of 26/05/2016
[2]	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast)	2016/797	OJ: L138/44 of 26/05/2016
[3]	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) N° 881/2004	2016/796	OJ: L138 of 26/05/2016
[4]	Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation	1077/2012	OJ: L320/3 of 17/11/2012
[5]	Commission Regulation (EU) No 1078/2012 of 16 November 2012 on the common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and entities in charge of maintenance	1078/2012	OJ: L320/8 of 17/11/2012
[6]	Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	1169/2010	OJ: L327/13 of 11/12/2010
[7]	Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety certificate	1158/2010	OJ: L326/11 of 10/12/2010
[8]	Commission Directive 2014/88/EU of 9 July 2014 amending Directive 2004/49/EC of the European Parliament and of the Council as regards common safety indicators and common methods of calculating accident costs Text with EEA relevance	2014/88/EU	OJ:L201/9 of 10/7/2014
[9]	Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (Text with EEA relevance)	445/2011/EU	OJ: L122/22 of 11/5/2011
[10]	Commission Regulation (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union	2015/995/EU	OJ: L165/1 of 30/6/2015
[11]	Directive 2008/68/EC of the European Parliament and of the council of 24 September 2008 on the inland transport of dangerous goods	2008/68	OJ : L260/13 of 30/9/2008
[12]	Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products	85/374/EEC	OJ: L 210 of 07/08/1985
[13]	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety	2001/95/EC	OJ: L 11/5 of 15/01/2001
[14]	Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007	376/2014/EU	OJ L 122, 24/04/2014
[15]	Prospective Study into Harmonized Train Accident Precursors Analysis and Management, Study by TRL for the ERA, 2013	PPR665	Final
[16]	DNV-GL Study – Review of Data quality and approach of the Agency annual report on safety		2015-12-09

Table 1: Table of Reference Documents

[Ref. N°] *Title*	*Reference*	*Version*
[17] COR project plan	Project Plan ERA-PRG--004	V1.0

2.2. Definitions and Abbreviations

2.2.1. Standard Terms and Abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary. Furthermore, a glossary of railway terms that focuses primarily on safety and interoperability terminology, but also on other areas that the Agency can use in its day-to-day activities as well as in its Workgroups for the development of future publications, is available on the Agency website.

2.2.2. Specific Terms and Abbreviations

Table 2: Table of Terms

Term	*Definition*
Agency	The European Union Agency for Railways such as established by the Regulation (EC) No 2016/796 of the European Parliament and of the Council of 11 May 2016
Defect	A type of nonconformity occurring when a product or service fails to meet specified or intended use requirements. (ISO 9000 2015)
Hazard	A condition that could lead to an accident (Art.3.(13) of Regulation (EU) 402/2013 – CSM for Risk Assessment).
Monitoring	The arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective. (Art. 2.(b) of Regulation (EU) 1078/2012 [5] - CSM on monitoring)
Occurrence	Occurrence means any safety-related event which endangers or which, if not corrected or addressed, could endanger a train or any rolling stock, its passengers, staff or any other person, and includes in particular an accident and incident.
Risk	The frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm. (Art.3.(1) of Regulation (EU) 402/2013 – CSM for risk assessment)
Safety	Freedom from unacceptable risk of harm. (Art.3.(5) of Regulation (EU) 402/2013 – CSM for risk assessment)

Table 3: Table of Abbreviations

Abbreviation	*Meaning*
ECM	Entity in charge of maintenance
COR	Common Occurrence Reporting
GPSD	General Product Safety Directive
IM	Infrastructure Manager
MS	Member State
NSA	National Safety Authority
NIB	National Investigation Body
NOR	National Occurrence Reporting
OR	Occurrence Reporting
RU	Railway Undertaking
SMS	Safety Management System
CSI	Common safety indicators

3. Purpose of the document

This document provides a comprehensive overview and analysis of all relevant applicable EU legislation that relates to occurrence reporting in European transport.

This document forms part of the Common Occurrence Reporting Project and should be read in conjunction with the Project Plan. This second version of the paper reflects comments received during the workshop held on 25th and 26th October 2016, and as part of the written consultation carried out between 15/09/2016 and 16/11/2016.

4. Scope and objectives

This deliverable identifies and analyses the regulatory requirements applicable to the different actors in the European Union as defined in the Directive (EU) 2016/798 on railway safety [1], Directive (EU) 2016/797 on interoperability [2] and Regulation (EU) 2016/796 on the European Union Agency for Railways [3], which relates to sharing information on safety-related occurrences.

The review concerns these three main EU legal acts ([1], [2] and [3]) and other EU legal acts that stem from them (in particular the regulation (EU) 1078/2012 on a CSM for monitoring [5]). The latest available versions of the relevant legal acts are considered – see reference documents.

The scope of this paper further extends to consider general EU product liability legislation and legislation for other transport modes.

The objective is to determine and provide a common understanding of all legal requirements in relation to the reporting and analysis of safety occurrences, and to identify the potential for any new legislation. This second version of the document incorporates consultation responses and proposals from stakeholders (NSAs, NIBs, Ministry, OTIF, and Railway sector organisations (CER, UNIFE, RSSB, EIM)). This in turn will help to determine the right set of tools and requirements for any potential European Union (EU) wide occurrence reporting.

5. Background - Current legal provisions regarding occurrence reporting

5.1. General requirements for authorities and regulators

5.1.1. Occurrence reporting at European level

The main direct requirement clearly requiring data reporting to the Agency is set by the Directive (EU) 2016/798 on railway safety [1]. It requires that Member States collect CSIs through reports to the NSAs (Art 5, Art 19.a and Annex I), which are then reported annually to the Agency. Nevertheless, it is important to note that the purpose of the CSIs is for "*monitoring of the general development of railway safety*" (art. 5), and do not provide for the collection of detailed information for each occurrences.

Please refer to the paper on phasing for further detailed information regarding the current reporting scheme and process of CSIs.

Furthermore, article 25 of the Directive (EU) 2016/798 on railway safety [1] requires that the national investigations bodies, "*within 7 days of the decision to open an investigation, inform the Agency thereof. The information shall indicate the date, time and place of the occurrence, as well as its type and its consequences as regards fatalities, injuries and material damage*". Additionally, the same article demands that "*The investigating body shall send the Agency a copy of the final report referred to in Article 24(2) and of the annual report referred to in Article 24(3)".* Therefore, all occurrences[1] subject to investigation by a national

[1] Note: the term occurrence is not defined in the current EU railway legislation. Please refer to Annex II of this document regarding a proposal for a definition

investigation body are already reported to the Agency by the national investigation bodies, via the ERAIL database.

Besides, the most relevant general requirement is a universal principle, stated in the articles 4.1 and 4.2 of the Directive (EU) 2016/798 on railway safety [1], that all Member States and the Agency "*shall ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, […], and giving priority to the prevention of accidents.*"

The highlighted focus on the prevention of accidents is of crucial importance, as the overall objective of occurrence reporting is better management of the risk of accidents through a specific focus on the collection of precursors of accidents. This should be seen in conjunction with the adoption of a system approach to safety management at EU level, which requires in its most basic principle the implementation of a Plan-Do-Check-Act cycle in order to manage safe railway operations. Therefore, this general requirement regarding the maintenance and improvement of safety implies a basic need for some form of occurrence reporting, sharing and analysis at European level, since it constitutes a major aspect for the checking activities of PDCA-based approach at European level.

In addition, the Regulation (EU) 2016/796 on the European Union Agency for Railways [3] provides some related tasks to be performed by the Agency. This concerns in particular: the contribution to "*a high level of railway safety" (art. 2),* the promotion of the sharing of information on *"safety-related accidents, incidents and near misses" (art. 18),* and "*monitoring progress of railway safety"* through the collection of *"relevant data on accidents and incidents" (art. 35).* These tasks required by the legal framework can be seen as a mandate for the Agency to collect, or gain access to, safety related data allowing identification of safety trends and better understanding of the safety risk profile.

Nonetheless, the Regulation (EU) 2016/796 on the European Union Agency for Railways [3] requires also that the Agency has to perform other tasks such as developing the railway regulatory framework and providing safety recommendations and opinions to the Commission (art. 13 and 19). Safety occurrences that might be collected through COR would serve a better achievement of these tasks as well.

Despite those indirect calls for having access to safety related occurrences in order to achieve the above mentioned tasks, there is no specific legal requirement to report safety occurrences at European level, other than the annual collection of Common Safety Indicators (CSIs) and the report by NIBs of occurrences that are subject to investigation. However, CSIs' collection does not allow the achievement of all the objectives mentioned by the Directive (EU) 2016/798 on railway safety [1], the Regulation (EU) 2016/796 [3], as CSIs were designed only for the specific purpose of statistical monitoring of the general development of railway safety2. Therefore, the Agency considers that there is a need for a Common Occurrence Reporting Regime at EU level for these purposes.

5.1.2. Occurrence reporting at Member States level

As NSAs have to report CSIs to the Agency through their annual report (as described in the previous section), NSAs must collect the necessary data from RUs and IMs in accordance with article 9.6 of Directive (EU) 2016/798 on railway safety [1].

Besides, articles 16 and 17 of the Safety Directive [1] describe the tasks the NSA shall perform. Carrying out these tasks, in particular the supervision of the railway undertakings and the infrastructure managers and the monitoring and enforcement of the regulatory framework, indirectly requires that the NSA has access to safety occurrences reported by RUs and IMs, and some Member States have chosen to establish a national occurrence reporting system, mandated by the national legislation, for these purposes. In addition, Regulation (EU) 1077/2012 on a CSM for supervision [4] provides that, in the framework of their supervision

[2] Directive 2016/798 [1], article 5

tasks, NSAs shall consider the "use of data/information from a variety of sources as an input to the strategy and the plan. Sources could include […] accident/incident reports or data" (Annex I of CSM Supervision). To this end, NSAs need to have access to data related to occurrences for the planning and targeting of supervision activities and for the continuous supervision of the effectiveness of the RUs/IMs Safety Management systems. Further explanations about the use of safety data for this purpose will be provided in the paper related to the roles, use of data and governance.

Article 20 of Directive (EU) 2016/798 on railway safety [1] requires that NIBs shall investigate "any serious accident" and "may also investigate accidents and incidents which under slightly different conditions might have led to a serious accident". In order to carry out these tasks, article 22.3 of Directive (EU) 2016/798 on railway safety [1] provides also that "Member States shall provide for railway undertakings, infrastructure managers and, where appropriate, the national safety authority to be obliged to immediately notify the accidents and incidents referred to in Article 20 to the investigating body and to provide all available information.".

NIBs have therefore to be informed of these occurrences in order to be able to decide whether to investigate or not. Access to these reported occurrences could be done in a variety of different ways in each Member State (access by NIB to operators' database, dedicated database for NIB, database shared between NSA and NIB, etc).

To perform these tasks, some Member States have chosen to put in place a national reporting system in order to collect and share a wider set of occurrences than the CSIs, allowing authorities (NSAs, NIBs, Ministry) as well as the operators to access these data. Nevertheless, these reporting schemes have been implemented at national level only, and according to non-harmonised definitions of reportable occurrences, use of the data, and other practical or legal aspects.

Moreover, according to article 10 and 12 of Directive (EU) 2016/798 on railway safety [1], NSAs have to grant safety authorisations and safety certificates to IMs and RUs, and in accordance with the related Common Safety Methods ([6] and [7]). To carry out these certification tasks, in particular in case of renewal of safety certificate/authorisation, NSAs have to take into the outcomes of the supervision activities. Indirectly, the collection and analysis of safety-related occurrences may also participate to the certification tasks today done by NSAs.

It is important to note that the inappropriate use of individual company data to determine or support assessment of certificate applications or supervision plans is likely to have negative effects, such as a decrease of confidence from companies to report occurrences to authorities, and therefore to impede the development of a stronger reporting and safety culture in Europe. Reporting will become primarily a compliance activity, rather than one motivated by learning and improvement. Developing more positive safety cultures is precisely one of the objectives of the COR project. Eventually, since a part of the certification tasks is now allocated formally also to the Agency by article 10 of Directive (EU) 2016/798 on railway safety [1], it is necessary to clarify further the relevance of using data coming from COR for certification purposes.

All these issues related to the roles and the use of safety occurrences data for the certification of RUs/IMs and authorisation of vehicles will be considered further in the working paper related to "Roles, use of data and governance", as established in the Project plan.

Additionally, Annex C of the COTIF regarding the Regulations concerning the International Carriage of Dangerous Goods by rail[3] (RID), made applicable also within the EU legal framework by the Directive 2008/68/EC, requires in its section 1.8.5 that "If a serious accident or incident takes place during loading, filling, carriage or unloading of dangerous goods on the territory of a RID Contracting State, the loader, filler, carrier, consignee or if the case may be the railway infrastructure manager, respectively, shall ascertain that a report conforming to the model prescribed in 1.8.5.4 is made to the competent authority of the RID

[3] RID 2015

Contracting State concerned at the latest one month after the occurrence." Therefore, the requirement to collect and report occurrences related to dangerous goods transport already exists today from a legal perspective. A separate work stream lead by the Agency is currently on-going through the TDG roadmap workgroup4, which aims, in particular, to potentially revise this requirement and improve its implementation. The final strategy for the COR project regarding the legislation will therefore take into account the results of this working group. Links between this two Agency's projects have already been identified by the relevant project's team.

5.2. Requirements at the level of operational actors

5.2.1. Legal requirements from Railway legislation

Article 9.3.i of Directive (EU) 2016/798 on railway safety [1], requires that RUs and IMs' SMS shall contain "*procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken*". This means that RUs and IMs are required to put in place internal occurrence reporting within their company, as part of their SMS, and to use information coming from these data for learning purposes and improvement of railway safety. The level of complexity of the established system is defined by the operator and generally depends on the extent of its activities. Nevertheless, it indirectly requires that a large amount of safety occurrences have to be reported and recorded at company level.

This principle is to be supported by the monitoring process put in place according to the CSM on Monitoring [5], which applies also to ECMs. The monitoring process required by the CSM shall contain "*collection and analysis of information*" (art. 3.2), confirming that each operator already collects and records information regarding safety occurrences for the aim of better definition of strategic priorities for safety management improvement. Similarly, the ECM Regulation [9] requires explicitly in paragraphs 3.2 and 4(e) of its Annex III that ECM shall collect, report and analyse "*accidents, incidents, near-misses and other dangerous occurrences*".

Here there is a clear link between the data collected internally by RUs/IMs and the data expected to be collected for COR. The Agency's view is that most, if not all, of the data relevant for COR should be, or are already, collected at operational level. It is expected that the data relevant for COR should be seen as a subset (regarding their scope) of the data that a company needs to perform its own monitoring activities.

A more specific requirement for reporting is in article 4.5 of Directive (EU) 2016/798 on railway safety [1] and in Article 4.2 of CSM on Monitoring [5] obliging the operational actors to "*report a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems to the relevant parties involved***"**, in order to enable them to take any necessary further corrective action to ensure continuous achievement of the safety performance of the Union rail. It is notable that this requirement concerns safety risks of specific operational actors and has a limited scope as it concerns technical failures only and not necessarily operational accidents and incidents (although, in practice, it will be difficult to provide a useful and comprehensive report about a technical failure, without describing the operational context, such as maintenance and type of use). The requirement of Article 4.1 of the CSM on Monitoring [5] is limited to three specific operational actors and the exchange of the similar information between them, whereas the Directive (EU) 2016/798 on railway safety [1] extends this obligation to all relevant actors having a potential impact on the safe operation of the Union rail system. Similarly, article 5.5 of ECM Regulation [9] requires that "*all contracting parties shall exchange information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences*". It can be assumed here that it is expected that the information shared will also concern technical failures and defects (from which accidents and incidents may occur).

[4] Link to ERA Extranet space related to TDG roadmap workgroup

The way this information is exchanged is not prescribed by the legislation. The Agency is required by article 4.5.b of Directive (EU) 2016/798 on railway safety [1] to establish a tool[5] that "*facilitates the exchange of information among the relevant actors*" to support this obligation.

The requirements above introduce a general principle that information about hazards, accidents and incidents that have the potential to prevent accidents, should be shared among railway actors. This sharing is most closely related to the work on "Safety alerts", as mentioned in the project plan of COR project.

5.2.2. Legal provisions from product liability legislation

According to EU legislation, producers can be held liable for defects to products they place on the EU market. In addition, the EU product safety legislation aims to prevent injury from products by requiring producers to place on the EU market safe products. Injured persons or relative(s) of deceased persons injured/deceased because of and by defective products may claim damages with regard to products put on the EU market. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products establishes the principle of objective liability imposed to European producers or importers. By application of this Directive, a product is defined as movables, with some exceptions (Art. 2).

The key principle is that the producer shall be liable for damage to life, health and property caused by a defect in his product (Art.1) that the producer sold to the customer or manufactured. Liability, or the responsibility to pay damages, is placed on the producer. The injured party is required to prove the damage, the defect in the product, and the causal relationship between the two.

Producer is defined as the producer of a raw material, the manufacturer of a finished product or of a component part; the importer of the product; any person putting their name, trade mark or other distinguishing feature on the product; any person supplying a product whose producer or importer cannot be identified (Art. 3).

Railway subsystems and any railway components are in the scope of this EU product liability legislation and manufacturers/producers of these sub-systems/components are therefore responsible to put on the market railway vehicles and components that are "safe".

In summary, the EU product liability Directive (and its transposed national legal requirements) implies in practice that producers and / or manufacturers of railway components have the duty to take preventive action or corrective measures in case of detected defective products, in order to manage this liability risk. Therefore, to perform efficiently such corrective program (for instance through recall of products from users or withdrawal from the market) producers should be able to trace products and users and communicate accordingly.

The setting up of a COR (in particular regarding the function related to safety alerts) would help the efficiency of recall (withdrawal) of a particular component to reduce further possible liabilities of the producer, as it would provide a tool allowing a better identification of hazards from users as well as a way of warning the potential users of a railway product presenting a serious risk.

5.2.3. Legal provisions from product safety legislation and market surveillance

Besides the product liability legislation, there is General Product Safety legislation, established in the General Product Safety Directive (GPSD) 2001/95/EC. For the purpose of this Directive, the term product is defined as "*any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is*

[5] Link to Safety Alerts IT tool

supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned."

Thus, the GPSD applies to manufactured products that can be directly used by consumers, such as garden machinery, lamps, consumer electronics, and household appliances, etc.

Since the components of railway technical sub-systems are not meant to be used directly by consumers, the GPSD legislation is not applicable for railway products.

Additionally, the Regulation EC 765/2008, setting out the requirements for accreditation and market surveillance, contains also provisions related to the carrying out of market surveillance obligations by Member States. The provisions related to the principle of market surveillance of products apply only to products subject to "*Community harmonisation legislation*" (Art. 15) and in so far as there are no specific provisions with the same objective in "*Community harmonisation legislation*".

"*Community harmonisation legislation*" is defined in the article 2 of the Regulation EC 765/2008 as "*any Community legislation harmonising the conditions for the marketing of products*". Considering this, railway products are in the scope of the market surveillance obligations provided by this regulation, as these railway products are subject to a dedicated legislation (Directive (EU) 2016/797 on the interoperability of the rail system [2]) as regards as their placing on the market.

Besides, the Directive (EU) 2016/797 on the interoperability of the rail system [2] requires explicitly that Member States shall ensure that interoperability constituents are "*placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements*". However, this Directive does not contain any particular provisions regarding the way the market surveillance of interoperability constituents by Member States should be carried out. In this context, the provisions of Article 15 to 26 of the Regulation EC 765/2008 should therefore apply to the market surveillance of interoperability constituents, and also consequently to market surveillance of railway sub-systems and vehicles.

In particular;

- The requirement for market surveillance authorities to alert users of hazards identified (art. 19)
- The power for Member States to take restrictive measures, pursuant to "Community harmonisation legislation", such as withdrawal or recall from the market of a product presenting a serious risk (art. 20)
- The requirement for economic operators to communicate to Member States "any voluntary measures taken" regarding products made available on the market and presenting a serious risk (art. 22)
- The requirement for Member States to exchange information through the RAPEX system[6], in particular about measures taken about prohibition or restriction, as well as measures taken by economic operators (art. 22)

In conclusion, the market surveillance provisions provided by the Regulation EC 765/2008 are applicable to railway products/equipment in the scope of the Directive (EU) 2016/797 on the interoperability of the rail system [2]. Nonetheless, as the Rapex system is to be used by the market surveillance authorities to alert the users of a product, there is no requirement foreseeing a direct exchange of information between actors (manufacturers/users) whereas it is explicitly required by article 4.5 of the Directive (EU) 2016/798 on railway safety [1]. **Therefore, the setting up of a COR as described in the project plan (especially the part related**

[6] The RAPEX system (Rapid Alert System for dangerous non-food products) has been established under the framework of the GSPD legislation (Directive EC 2001/95) and aims to help the co-ordination of national market surveillance efforts to take rapid measures against unsafe consumer products which could have been made available on the market of several Member states, supporting for instance the withdrawal of unsafe products.

to Safety Alert) will not duplicate an existing obligation developed in the context of the general legislation about safety of products, but aim to reinforce the means given to manufacturers to fulfil their duty to monitor and potentially call-back or withdraw railway products/equipment from the market.

5.3. Conclusions

In summary, EU legislation explicitly requires operational actors (in particular RUs, IMs and ECMs) to ensure internal occurrence reporting, as part of the monitoring process of their Safety/Maintenance Management System. Collection of occurrences is therefore already done at company level, but varies in the way occurrences are defined, reported to authorities and shared with other actors. Therefore, the additional burden of putting in place a harmonised EU reporting are potentially already covered by existing practices, at least partially. However, this will be further assessed by the future impact assessment that will support the future comprehensive proposal for the COR system.

EU legislation also requires reporting of all relevant occurrences to NIBs and, potentially, to NSAs, although the national occurrence reporting system implemented in each Member States for these purposes may widely differ from one to another regarding the scope, the level of detail or the roles of the authority. A non-harmonised approach on reporting to the national authorities (NSAs and NIBs) risks duplication of reporting to both national and EU systems and limits the ability for national authorities to share amongst other EU national authorities.

As set out in sections 5.1 and 5.2, the current EU legislation analysed requires sharing and analysis of occurrence information at EU level, since only by analysing the occurrence information, can the risks be adequately identified, determined and understood. Eventually, if the wider obligations placed at an individual company, national and European level to continuously improve safety are to be realised, a system for sharing and analysis of this information at European level is required.

Nevertheless, there is no direct basis for establishing a COR system at EU level in the current legislation, as regarding the occurrence reporting obligations towards the Agency and the sole existing requirement is put on the NSAs to report on CSI statistics and on the NIBs to report on investigated occurrences.

A summary of these existing reporting requirements from the current legislation is provided in the table in Annex III of this document.

6. Analysis of existing legislation of other transport modes

6.1. Example of legislation established for aviation sector

The aviation sector is usually considered as being one of the leaders in the matter of safety occurrences reporting. It is useful to consider the framework for reporting in aviation as well as the lessons learned in the context of establishing a reporting system for railways.

The aviation sector has developed a common taxonomy since the 1970s at UN level, adopted through the so-called ADREP (Accident/Incident Data Reporting) taxonomy of ICAO (International Civil Aviation Organization). This facilitates a lot the achievement of a common understanding and alignment of practices across the world. This taxonomy has been used since then for occurrence reporting and analysing purposes and the European Union has also kept the same approach in the latest development lead by the European Aviation Safety Agency (EASA).

The occurrence reporting in aviation at EU level is enforced by regulation EC 216/2008 which contains specific reporting requirements, by Regulation EU 376/2014 which further develops the standards for reporting safety information and by Regulation EU 2014/1018 which lays down a list classifying occurrences to be mandatorily reported. The focus of this occurrence reporting in the aviation sector is put not only on the

learning from accidents and incidents, but also on the detection of potential safety hazards and proactive approach (article 1 of Regulation EU 376/2014). These objectives are similar to those followed by the COR project.

The mandatory reporting regime in aviation is therefore enforced by EU legislation mentioned above by:

- Defining which occurrences have to be collected by the operators and companies and reported to the authorities
- Defining the list of information to be included in the reporting (taxonomy)
- Defining the timeframe of reporting following an occurrence
- Defining a risk classification scheme (under development)
- Establishing an European central repository and related access and use rules
- Defining the IT tools to put in place, at company, national authorities and EASA levels and the technical and practical (timing) arrangements to be done for reporting, transferring and storage of occurrences into the databases, especially towards the European Central Repository
- Defining the process of reporting occurrences and which entity shall report to which other entity
- Defining the rules on the use and protection of data, and for confidentiality
- Defining the need of analysis and follow-up of these occurrences at all levels (by the companies, by the authorities and by EASA)
- Establishing a network of safety analysts, organised by EASA, to provide analysis of occurrences, support the European aviation Safety Plan, and information for EASA annual safety plans

A voluntary reporting regime is also established in order to report other types of occurrences.

These different topics and the way they have been implemented will also be further analysed in the context of the COR project if the decision is taken (following the Impact Assessment) to seek a mandate for supporting legislation.

6.2. Example of legislation established for maritime sector

A common taxonomy and related reporting requirements have also been put in place in the maritime sector and therefore provides useful learning and analysis for the establishment of a railway common occurrence reporting system.

Similarly to the aviation sector and due to the international nature of these transport modes, safety requirements have been established at international level, under the framework of IMO (International Maritime Organisation) which aims at harmonisation of approaches, in particular for accident investigation, where certain occurrences must be reported to flag authorities.

Since the establishment of the European Maritime Safety Agency (EMSA) through the regulation EC 1406/2002, some requirements have been put in place in the field of accident and incident reporting at EU level. The Directive 2009/18/EC establishing the fundamental principles governing the investigation of accidents in the maritime transport sector, requires especially that Member States be notified by the parties involved of marine accidents and incidents and to notify the European Commission of marine casualties and incidents. This last part of the requirement is done via EMCIP (European Marine Casualty Information Platform), the IT tool provided by EMSA to store and analyse casualty data and investigation reports provided by the Member State. The overall aim of the maritime reporting system as provided by the Directive 2009/19/EC is to "*reduce the risk of future marine casualties, by facilitating the holding of investigations and proper analysis of maritime casualties and incidents in order to determine their causes*".

For the occurrence reporting in maritime sector, no set of reportable occurrences have been established, meaning that each occurrence related to marine casualties and incidents, and falling in the scope (in term of type of ships involved) of the Directive 2009/18/EC has to be reported to the investigation body, which then notified them to the EMCIP database.

In addition and similarly to aviation, the Directive 2009/18/EC provides also:

- Rules of confidentiality to be respected in the context of occurrence reporting
- The process of reporting occurrences (which entity reports to which other entity)
- The setting up by EMSA of the European database for marine casualties (EMCIP)
- The format of occurrence notification (taxonomy) used by the national investigation bodies to notify through EMCIP
- The need of analysis and follow-up of these occurrences (by investigation bodies)
- The setting up of a permanent cooperation framework between the national investigation bodies and EMSA, in particular in order to share information related to occurrence analysis

6.3. Example of legislation established for road

The EU policy regarding road safety has also led to the setting up of a Common Database at EU level. Indeed, under the Council Decision 1993/704/EC, Member States have the obligation to communicate to the Commission data on road accidents resulting in death or injury that occur within their territories, with a view to setting up a "Community database".

This database established at EU level (so called "CARE" - Community database on Accidents on the Roads in Europe) aims to collect data in view of identifying and quantifying road safety problems, evaluating the efficiency of road safety measures, determining the relevance of Community actions and facilitating the exchange of experience in this field, through the use of an evidence-based approach. The data collected serve in particular the actions performed as part of the European Road Safety Observatory[7].

7. Need of legislation for COR?

The decision to propose or not legislation imposing a future COR system at EU level will be taken later in the project, in accordance with the project plan which foresee a comprehensive proposal for the system in 2017. This proposal will be based on the outcomes of the different consultations carried out in 2016 and early 2017 and will be accompanied with an impact assessment of different possible options identified. Proposal to develop or not a legislation will be part of the different options as well as the benefits and drawbacks associated and a consultation of the stakeholders will be carried out regarding this comprehensive proposal for the system. If, in time, the option retained is to support the development of legislation for COR, such legislation will have to follow the appropriate legislative procedure, depending on the type of legal act needed. Nevertheless, this paper aims also to identify what legislation could be useful or necessary to support European COR, considering the current provisions that already exists as stated in the section 5 of the present document.

7.1. Voluntary approach

For the time being, even if there are requirements or tasks that call indirectly for collecting and analysing of safety related data at EU level, there is no direct mandate for establishing a Safety Management Data Reporting regime at EU level. In this context, a voluntary approach could be considered as a possible option and would potentially allow a shorter implementation timescale.

[7] European Road Safety Observatory

Nevertheless, by having a voluntary approach, there are potential limitations on the efficiency of the COR. Indeed, a voluntary approach could undermine the quality and quantity of data reported, limiting the ability to draw conclusions and improve safety risk management.

Please refer to the paper on phasing for more details about a voluntary approach.

7.2. Mandatory approach

A mandatory approach for COR at EU level is another option of establishing a Safety Management Data Reporting regime at EU level . This would need to be considered against the potential additional burden on stakeholders of a requirement to change / increase their existing reporting systems.

In any case, such a mandatory approach would need to be supported by dedicated legislation stating the technical aspects of the system, as well as the roles of the future users. Lessons learned and inspiration from other sectors, in particular aviation and maritime will be taken into account for the definition of potentially additional legislation for COR.

7.2.1. Opportunities and future needs for COR

The Directive (EU) 2016/798 on railway safety [1] requires in its article 29 that the Agency "*shall evaluate the development of a safety culture including occurrence reporting. It shall submit to the Commission, by 16 June 2024, a report containing, where appropriate, improvements to be made to the system. The Commission shall take appropriate measures on the basis of these recommendations and shall propose, if necessary, amendments to this Directive*".

The COR project aims to take part to this evaluation of the efficiency of the occurrence reporting in the EU the report required by the Directive will also aim to identify what would be the need for further legislation, considering the development of the COR project at that time. Nevertheless, as explained in the section 5 of this document, the other tasks set out in the current legislation could not be achieved without common occurrence reporting. And as stated in the COR Project plan, the most visible added-values of setting up a Common Occurrence Reporting system at EU level will appear by ensuring common definitions and quality of data as well as sufficient consistency of the collection of occurrences across Europe. Basically, the clearest way to ensure these consists in the implementation of dedicated legislation, with the aim to establish the putting in place of the system by defining the set of occurrences to be reported and the related taxonomy, the roles of each bodies regarding the system and the different rules that would be necessary to ensure the proper operation of the system. The current existing legislation, in particular concerning CSIs collection and report, does not provide any of these requirements, and therefore would need to be amended.

Besides, the Directive (EU) 2016/798 on railway safety [1] introduces that new CSMs can be developed in order to define "*the methods for assessing the safety level and the safety performance of railway operators at national and Union level*"[8] or to define "*any other methods covering a process of the safety management system which need to be harmonised at Union level*"[9].

Considering the different objectives, and in combination with the reporting needs already identified in the existing EU legislation (as explained in the section 5.1 of this document), it could be envisaged to develop any new legislation supporting COR through one or both of these potential new CSMs.

Indeed, the assessment of safety level and performance of railway operators (meaning mainly IMs and RUs) as expected in the article 6.1.d of the Directive (EU) 2016/798 on railway safety [1], should be done on the basis of safety related data. As already stated, current CSIs allow only a reactive view of safety performance

[8] Directive 2016/798 [1], article 6.1.d
[9] Directive 2016/798 [1], article 6.1.f

and do not support proactive and preventative safety management at Member State and EU level. Therefore, there would be a need to collect more data, as defined in the paper "*Designing the common occurrences and taxonomy for COR*[10]" which is part of the COR project, to reach this objective. In addition, the article 6.1.f of the Directive (EU) 2016/798 on railway safety [1] may also provide the legal basis to develop the procedures and provisions potentially needed for a future harmonised reporting regime.

Such new CSM could therefore define what occurrences should be mandatorily reported and the reporting regime allowing a proper and harmonised collection and use of the information reported.

According to article 6 of the Directive (EU) 2016/798 on railway safety [1], CSMs are established by means of EU Regulations. The whole process of development of such new legislation, from the setup of the mandate by mean of implementing act, the establishment of a dedicated working party to elaborate the draft recommendation to the Commission and the adoption of a delegated act by the Commission, will have to be considered. Nevertheless, the current work done by the Agency for the COR project, in consultation with the relevant stakeholders, would serve as a strong basis to define what should be introduced in the legislation and therefore help to speed up the process for reaching a consensus. It shall be considered also that such new legislation will surely introduce the necessary transition periods allowing migration towards the future COR system.

If a dedicated legislation for COR will be established, some adjustments to the existing legislative framework (as described in the section 5 of this document) might be necessary. In particular, a review of the current Annex I of the Directive (EU) 2016/798 on railway safety [1] would need to be considered as poor implementation of new and additional legislation could result in requirements to report two sets of data, one for CSIs as today, and one for safety management data reporting, whereas such double regime should be avoided. Moreover, as Annex of a Directive, the review of the Annex I is to be done following the ordinary legislative procedure of the European Union. This means that considering the current legislative planning of the Commission, the launching of a new procedure of revising the Directive cannot start before 2019. In the meanwhile, the Agency and the Commission will consider all the works done in the framework of this project as the main inputs to a potential future proposal for legislation.

Depending of the choice made later in the COR project, these aspects will have to be taken into account for the phasing stages - please refer to the document on phasing for further details

8. Conclusion – Summary of main implications on the development of COR

The current EU legislation includes already several requirements that RUs/IMs and ECMs implement monitoring processes of their safety/maintenance management systems on the basis notably of safety data collected at operational level. This implies that occurrences related to safety management data are therefore already collected by the operators.

Furthermore, the operational actors (as defined in article 4 of recast RSD) have legal obligation to report defects, non-conformities or malfunctions of technical equipment, including those of structural subsystems to the relevant parties involved. This requirement of "safety alerts" cannot be practically fulfilled in the absence of an EU-wide tool accessible to all relevant operational actors. This tool may be developed by the actors alone, or delivered by the Agency, as required by the recast Safety Directive. Similarly, considering the current state of legislation, the railway actors are not obliged to fulfil their legal reporting obligation with the use of a tool prepared/managed by the Agency.

In addition, a mandatory reporting of relevant occurrences by RUs/IMs towards NIBs already exists. Indirectly, some existing requirements lead also that some Member States put in place requirements for

[10] ERA-PRG-004 - Designing the common occurrence and taxonomy for COR

reporting of relevant occurrences by railway operators to NSAs for the sake of their certification/authorisation and supervision tasks as well as part of the information needed to ensure the continuous maintenance and improvement of the safety level. Nevertheless, this reporting is today organized at national levels, with heterogeneity as regards of the detailed and types of information to be reported and thus not ensure a harmonized approach on safety. This is likely to hinder the general improvement of the safety levels across EU and the achievement of a common understanding of the risks.

Besides, considering also the provisions requiring the Agency to have a strengthened role regarding the continuous improvement of safety in EU, an access for the Agency to a more detailed occurrence information and data will be objectively needed in the future in order to effectively accomplish its duty. This is also relevant regarding the Agency's tasks of assistance to the Commission for development of the safety regulatory framework. These confirm the necessity to develop a COR at European level.

It shall be considered that, as some of the certification tasks nowadays performed by the NSAs will be allocated to the Agency by the latest development of the EU legislation, there is a need to explore and clarify further the relevance and the appropriateness of the use of data for individual company assessment in the context of safety certification assessment. This will be covered in the next steps of the COR project.

Eventually, supporting legislation in this area would potentially bring a lot of benefits, but will need to take into account the different needs of the actors and the potential migration of existing reporting systems. The current work carried out in the context of the COR project, developed in a close cooperation with the relevant stakeholders will allow to already define most of the needs of requirements that should be part of a dedicated legislation. Nevertheless, the decision to impose or not further legislation will be based on the conclusion that could be drawn from the COR project work for 2016, in particular following the work on phasing and options. At the latest, it has to be kept in mind that the decision to establish further legislation remains to the European Commission.

9. Outcomes from the consultation

The first version of the paper on legislation was elaborated by the Agency and provided for comments to railway stakeholders (including railway operational actors and authorities) from 15/09/2016 and 16/11/2016. A dedicated workshop was organized by the Agency on 25th and 26th October 2016 in its Valenciennes premises to support the consultation.

This second version includes the comments received as a result of the consultation, and also those provided during the above mentioned workshop.

The Agency appreciates all received comments and proposal from the various railway organisations and authorities. This consultation provided a general view to the Agency of stakeholders expectations and raised questions and issues which should be tackled for the future development and implementation of the COR project. A significant number of the comments received were related more to issues linked with papers and discussions coming later in the project (e.g. roles and governance issues, IT architecture and compatibility with existing national occurrences reporting systems). Therefore, these comments are not reflected in this revised version of the paper, but will be taken into account at the right stage of the project.

To support the consultation, the Agency raised six main questions regarding the first version of the proposed paper related to the legislation. The following table provides the most common views and outcomes provided in the course of the written consultation or during the supporting workshop:

Question raised in the paper	Stakeholders' views	Agency's views and conclusions
1. Is the analysis of legislation by the Agency in line with the	The analysis provided by the Agency in the paper was broadly	The Agency will use this paper as a basis for the next paper on roles, use of data and

understanding of the stakeholders	supported and agreed by the stakeholders.	governance. Its conclusions will also be used for the design of the different options that will be considered in the impact assessment that will support the comprehensive system proposal the Agency will provide in 2017.
2. Are there any other aspects regarding the legislation analysis that should be considered?	Stakeholders proposed that the Agency performs a deep analysis of the national reporting legislation and schemes. Stakeholders also requested improvements on the section related to the enforcement and supervision role of the NSAs. It has also be highlighted by the stakeholders that the implementation of the current legislation should be assessed before taking the decision to introduce a new one for COR.	The Agency would welcome any support from the stakeholders in the analysis of the current national reporting legislation. Part of this work has been already done through the study produced by DNV. However, the Agency stressed that a deeper analysis would require a translated version of the relevant legislation or guidelines related to national occurrence reporting systems. Regarding the improvement of the section related to the enforcement and supervision role of the NSAs, the Agency has taken into account this request and provides additional details in the updated version of the paper. Regarding the implementation of the current legislation, the Agency considers that this aspect will be part of the monitoring of NSAs which is now requested by the 4th railway package. Relevant outcomes from this monitoring will be taken into account for the development of a new legislation, if any.
3. How nowadays railway manufacturers fulfill their responsibilities to warn users when a potential safety risk related to a defective product has been identified?	No clear view on this question was provided, even though some stakeholders raised the need to explore deeper the legislation related to the responsibility of manufacturer as regard their role in a COR system.	The Agency considers that the paper provides already explanations about the general product legislation applicable to manufacturers. It provides also Agency's understanding regarding how this legislation articulates use of a COR system,

		in particular the part related to the safety alert IT tool.
4. Is a new legislation for COR strongly expected by the stakeholders? Why? Timeframe? 5. What would be the expected benefits of developing a new legislation? 6. Are there areas that strongly need to be covered by a legislation? Which areas should not be regulated by the legislation?	There is a general acceptance among stakeholders that a mandatory system is eventually inevitable. However most of the stakeholders agree on the fact that starting with a voluntary system will help to create a more agile setup of the system itself and allow better learning and make changes to the system easier, if needed. It is proposed that the Agency explores deeper what could be achieved through an application guide or a MoU. However, the stakeholders recognised that a voluntary approach will limit the benefit and the use of the data as the consistency of the report should be eventually ensure using the legislation.	Developing or not a new legislation and the related identified pro and cons will be part of the different options the Agency will explore in the impact assessment that will support the comprehensive system proposal.

Table 4 Consultation overview

10. Next steps

This is the updated proposal aiming to achieve a common understanding of the existing legislative requirements and the potential for further legal provisions that might be necessary for the setting up of the future COR regime. It should be noted that the interpretation given in this proposal has been developed by the COR project team, complemented by the views provided by a wide range of stakeholders and experts in order to find common ground between all parties. The objective of this document is to serve as a common basis for the other deliverables of COR project, in particular the definition of the different options for the impact assessment that will support the comprehensive system proposal which will be provided in 2017.

The COR project plan sets out in detail the other planned work packages, as well as the timing and content of an overall review, followed by a comprehensive proposal for a European COR system, in 2017 which will be supported by an impact assessment. In time, if a decision is taken by the Commission to propose a mandate for legislation, considerable work will be needed, working with stakeholders, to develop, and agree as far as possible, a recommendation, according to the Agency normal working procedures.

Annex I - Relevant excerpts from EU legislation

EU legislation relevant to occurrence reporting

Railway Safety Directive [RSD]

Art.4(1)

1. With the aim of developing and improving railway safety, Member States, within the limits of their competences, shall:

(a) ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and international legislation and of technical and scientific progress, and giving priority to the prevention of accidents;

Art.4(2)

The Agency shall ensure, within the limits of its competences, that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and of technical and scientific progress and giving priority to the prevention of serious accidents.

Art. 4(5)

Railway undertakings, infrastructure managers and any actor referred to in paragraph 4 who identifies or is informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems, shall, within the limits of their respective competence:

(a) take any necessary corrective measure to tackle the safety risk identified;
(b) report those risks to the relevant parties involved, in order to enable them to take any necessary further corrective action to ensure continuous achievement of the safety performance of the Union rail system.

The Agency may establish a tool that facilitates this exchange of information among the relevant actors, taking into account the privacy of the users involved, the results of a cost-benefit analysis as well as the IT applications and registers already set up by the Agency.

Art. 6(1d)

The CSMs shall describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed, including, where appropriate, through an independent assessment body, by elaborating and defining:

(d) the methods for assessing the safety level and the safety performance of railway operators at national and Union level;

Art. 9(1)

The safety management system shall contain the following basic elements:

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;

Art. 9(6)

Before 31 May of each year, all infrastructure managers and railway undertakings shall submit to the national safety authority an annual safety report concerning the preceding calendar year. The safety report shall contain:

(b) an account of the development of national safety indicators, and of the CSIs referred to in Article 5, in so far as it is relevant to the reporting organisation;

Art.17 – Supervision

1 National safety authorities shall oversee continued compliance with the legal obligation incumbent on railway undertakings and infrastructure managers to use a safety management system as referred to in Article 9.

For that purpose, the national safety authorities shall apply the principles set out in the relevant CSMs for supervision referred to in point X of Article 6(1), ensuring that supervision activities include, in particular, checking the application by railway undertakings and infrastructure managers of:

(a) the safety management system to monitor its effectiveness;

(b) the individual or partial elements of the safety management system, including operational activities, the supply of maintenance and material and the use of contractors to monitor their effectiveness;

(c) the relevant CSMs referred to in Article 6. The supervision activities relating to this point shall also apply to entities in charge of maintenance.

5 If, during supervision, a national safety authority identifies a serious safety risk, it may at any time apply temporary safety measures, including immediately restricting or suspending the relevant operations.

7 When supervising the effectiveness of the safety management systems of infrastructure managers and railway undertakings, the national safety authorities may take into account the safety performance of actors as referred to in Article 4(4).

8 The national safety authorities of Member States where a railway undertaking operates shall cooperate in coordinating their supervision activities concerning that railway undertaking to ensure that any key information on the specific railway undertaking is shared, particularly on known risks and its safety performance.

22 (3)
Member States shall provide for railway undertakings, infrastructure managers and, where appropriate, the national safety authority to be obliged to immediately notify the accidents and incidents referred to in Article 20 to the investigating body and to provide all available information. Where appropriate, this notification shall be updated as soon as any missing information becomes available.

Article 25 - Information to be sent to the Agency

1. Within seven days of the decision to open an investigation, the investigating body shall inform the Agency thereof. The information shall indicate the date, time and place of the occurrence, as well as its type and its consequences as regards fatalities, injuries and material damage.

2. The investigating body shall send the Agency a copy of the final report referred to in Article 24(2) and of the annual report referred to in Article 24(3).

Art.28(2) - Report and further Union action

The Agency shall evaluate the development of the safety culture including occurrence reporting. It shall submit to the Commission, not later than five years following the transposition of this directive, a report containing, where appropriate, improvements to be made to the system. The Commission shall take appropriate measures on the basis of these recommendations and shall propose, if necessary, amendments to this Directive.

ANNEX I – Common Safety Indicators

Common safety indicators (CSIs) shall be reported annually by the national safety authorities.

Agency Regulation [AR]

Article 2 - Objectives of the Agency

The objective of the Agency shall be to contribute to the creation further development and effective functioning of a single European railway area without frontiers, by guaranteeing a high level of railway safety and interoperability,…

Art.10 - Opinions

1 The Agency shall issue opinions at the request of the one or more national regulatory bodies referred to in Article 55 of Directive 2012/34/EU of the European Parliament and of the Council, in particular concerning safety- and interoperability-related aspects of matters drawn to their attention.

Art. 12 - Technical support – recommendations on railway safety

2 The Agency shall address recommendations to the Commission, at the request of the Commission or on its own initiative, on other measures in the field of safety, taking into account the experience gained.

Art.16a - *Exchange of information on safety-related accidents*

The Agency shall encourage the exchange of information on safety-related accidents, incidents and near misses, taking into account the experience of the railway actors referred to in Article 4 RSD. Such exchange of information shall lead to the development of good practices at Member State level.

Art.33 - Monitoring progress of railway safety and interoperability

1. The Agency, together with the national investigation bodies, shall collect relevant data on accidents and incidents, taking into account the contribution of the national investigation bodies to the safety of the Union rail system.

2. The Agency shall monitor the overall safety performance of the Union rail system. The Agency may in particular seek the assistance of the bodies referred to in Article 36, including assistance in the form of the collection of data and access to the results of the peer review in accordance with Article 22(7) RSD. The Agency shall also draw on the data collected by Eurostat and shall cooperate with Eurostat to prevent any duplication of work and to ensure methodological consistency between the CSIs and the indicators used in other modes of transport.

4. The Agency shall monitor progress on the safety and interoperability of the Union rail system. Every two years it shall present to the Commission, and publish, a report on progress on safety and interoperability in the single European railway area.

6. The Agency shall, at the request of a Member State or the Commission, provide an overview of the safety and interoperability level of the Union rail system and establish a dedicated tool for that purpose, in accordance with Article 51(3) of Directive …./…/EU

ECM Regulation 445/2011

Art.5(5) and Art.5(2) and its Annex III(I7.4j)

"All contracting parties shall exchange information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences as well as on any possible restriction on the use of freight wagons."
"All parties involved in the maintenance process shall exchange relevant information about maintenance in accordance with the criteria listed in sections I.7 and I.8 of Annex III."

(ii) urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several types or series of vehicles"

CSM on monitoring (1078/2012)

Art.4(1)
"Railway undertakings, infrastructure managers and entities in charge of maintenance, including their contractors, shall ensure through contractual arrangements that any relevant safety-related information resulting from applying the monitoring process set out in the Annex is exchanged between them, to enable the other party to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system."

If, through the application of the monitoring process, railway undertakings, infrastructure managers and entities in charge of maintenance identify any relevant safety risk as regards defects and construction non-conformities or malfunctions of technical equipment, including those of structural sub-systems, they shall report those risks to the other parties involved to enable them to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system.

Annex

2.4. The monitoring strategy and plan(s) shall define either quantitative or qualitative indicators or a mixture of both that can: (a) give early warnings of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned; (b) give information about unwanted outcomes; (c) support decision making.
3.2. For each defined indicator referred to in point 2.4, the following shall be carried out: (a) a collection of necessary information

CSM on Supervision (1077/2012), Annex 1(e)

NSA shall use data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations to bring subsystems or vehicles into service, national investigation bodies accident reports/recommendations, other accident/incident reports or data, a railway undertaking's or an infrastructure manager's annual reports to the national safety authority, annual

maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources.

CSM on CA (1169/2010)

ANNEX II : Criteria for assessing conformity with the requirements for obtaining safety authorisations to be issued in accordance with Article 11(1)(a) and (b) of Directive 2004/49/EC

Q.1. There are procedures to ensure that accidents, incidents, near misses and other dangerous occurrences:

(a) are reported, logged, investigated and analysed;

(b) are reported, as required by relevant legislation, to national bodies.

Q.2. There are procedures to ensure that:

(b) relevant reports/information from other railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account

Annex II - Defining safety occurrence

The EU legislation uses the term occurrence, however, it does not include its definition. Nevertheless, the definition could be derived from other applicable definitions of accidents and incidents and could also be "transposed" from similar legislation such as aviation.

The terms accident and incident are defined in the Directive (EU) 2016/798 on railway safety [1] (Art. 3; 11,13). An incident is defined as "*any occurrence, other than accident or serious accident, affecting the safety of railway operations*". An accident is defined as "*an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions; derailments; level crossing accidents; accidents to persons involving rolling stock in motion; fires and others;"*

Under the requirements set up in the article 9.3 of the Directive (EU) 2016/798 on railway safety [1] on SMS and under the requirements on monitoring process set up in Annex 2.3 of the CSM on Monitoring [5], the occurrences to be reported are "*accidents, incidents, near misses and other dangerous occurrences"*. This implies that all events listed are considered as being occurrences, but also that there are other types of occurrences (those that are "dangerous") than those listed. Nevertheless, terms dangerous occurrence and near-miss are not defined in EU railway legislation.

Besides, the term occurrence is then used extensively under the article 24 of the Directive (EU) 2016/798 on railway safety [1] on NIB accident investigation, referring to all types of accidents and incidents investigated by the NIB, but the Directive does not define the term occurrence as such.

In summary, the EU legislation for railways do not provide a conclusive definition of the term occurrence. It is nevertheless possible to assume that it includes at least the accidents and incidents (as defined in article 3 of the Safety Directive [1]) and other events that affect or may affect safety of railway operation.

EU legislation in the area of aviation safety contains a clear definition of an occurrence, as follows:

"Occurrence means any safety-related event which endangers or which, if not corrected or addressed, could endanger an aircraft, its passengers, staff or any other person, and includes in particular an accident and incident." (Regulation 376/2014 – Article 2 (7))

This definition could be applied to railway safety occurrences per analogy as follows:

Occurrence means any safety-related event which endangers or which, if not corrected or addressed, could endanger a train or any rolling stock, its passengers, staff or any other person, and includes in particular an accident and incident.

It should be noted that nowadays only occurrence types with the most significant hazard are defined under EU railway legislation. Defining "other types of occurrences" to be reported, is one of the key tasks of the COR programme, since common definitions are needed to enable common reporting and analysis. This is further explored in the paper related to "Designing the common occurrences and taxonomy for COR". It is therefore proposed to use the definition of the occurrence above (in bold) for further development of the COR.

Following the consultation of the stakeholders, a few of the consultees asked for the deletion of this annex, considering that a definition of occurrence would need to be further discussed and refined. However, this definition has been left in this paper for the purpose of consistency with the other papers drafted in this first phase of the project, in which the same definition has been used. This definition intends to provide a common understanding as well as to limit the scope of what has to be reported, because no definition of occurrence

is provided by the legislation to date. Nevertheless, we also recognise that what defines best the reportable occurrence are the occurrences themselves, as defined in paper on taxonomy, making the need for a commonly agreed and definitive definition less urgent and obvious at this stage. The need or not to define occurrence and exact definition if needed will be further discussed and agreed within a dedicated working group, if eventually a mandate to develop a COR legislation is given to the Agency.

Annex III – Summary of existing reporting requirements

Table 5: Summary of existing reporting requirement and role of actor from the current legislation

Actors involved in OR	**RUs/IMs**				
What are the requirements related to OR?	**Internal reporting for SMS monitoring purpose**	**Reporting of safety occurrences to NIBs**	**Reporting of CSIs to NSAs**	**Reporting of other relevant occurrences to NSAs**	**To alert other relevant actors in case of identification of technical defects / malfunctions / non conformities**
EU Legal reference	Safety Directive [1]: art. 9.3 + CSM Monitoring [5]: art. 3.2	Safety Directive [1]: art. 22.3	Safety Directive [1]: art. 9.6	Safety Directive [1]: art. 4.1	Safety Directive [1]: art. 4.5 + CSM Monitoring [3]: art. 4.2
National legislation?	/	Relevant safety occurrences are regularly reported to NIB through national provisions (IT system when it exists, access to RUs/IMs database, other procedures)	Relevant safety occurrences are regularly reported to NSA through national provisions (IT system when it exists, access given to NSA to RUs/IMs database, other procedures)		/
What does it mean in practice?	Procedures for internal Safety occurrences collection and analysis (often stored in a database)	Operational procedures are set to identify and report serious accident and other occurrences to NIBs	Procedures for collection and report to NSA of CSIs data, through annual report and (often) regularly through NOR system	Procedures to report to NSA the relevant occurrences	Procedures to ensure that relevant defects which are identified are properly shared with other actors (safety alerts are sent out - using when relevant the Safety alerts IT tool provided by the Agency)

Actors involved in OR	**ECMs**		**Other actors**
What are the requirements related to OR?	**To alert other relevant actors in case of identification of technical defects / malfunctions / non conformities**	**Internal reporting for monitoring and continuous improvement purposes**	**To alert other relevant actors in case of identification of technical defects / malfunctions / non conformities**
EU Legal reference	Safety Directive [1]: art. 4.5 + ECM Regulation [9]: art. 5.5	ECM Regulation [9]: Annex III, sections 3 and 4	Safety Directive [1]: art. 4.5
National legislation?	/	/	/
What does it mean in practice?	Procedures to ensure that relevant defects which are identified are properly shared with other actors (safety alerts are sent out - using when relevant the Safety alerts IT tool provided by the Agency)	Procedures for internal Safety occurrences collection and analysis (often stored in a database)	Procedures to ensure that relevant defects which are identified are properly shared with other actors (safety alerts are sent out - using when relevant the Safety alerts IT tool provided by the Agency)

Actors involved in OR	**NIBs**		**NSAs**			
What are the requirements related to OR?	**To investigate serious accidents and relevant accidents/incidents**	**To inform the Agency within 7 days an investigation is opened + sending a copy of the final report to the Agency**	**To collect CSIs from RUs/IMs through their annual report** **To report annually CSIs to the Agency in annual safety report**	**To certify RUs/IMs**	**To supervise RUs/IMs**	**To ensure that safety level is maintained and improved at MS level**
EU Legal reference	Safety Directive [1]: art. 20	Safety Directive [1]: art. 25	Safety Directive [1]: art. 9.6, art. 19.a, Annex I	Safety Directive [1]: art. 10,12	CSM Supervision [4]: art. 1 + Annex 1.(c)	Safety Directive [1]: art. 4.1
National legislation?	Relevant safety occurrences are regularly reported to NIB through national provisions (IT system when it exists, access to RUs/IMs database, other procedures)		Relevant safety occurrences are regularly reported to NSA through national provisions (IT system when it exists, access to RUs/IMs database, other procedures)			
What does it mean in practice?	To be immediately informed by RUs/IMs of serious accidents + To be regularly reported of safety occurrences by RUs/IMs	NIBs report to the Agency through ERAIL database	CSIs collected by NSAs on an annual basis (annual report) and often on a on-going basis (IT system when it exists, access to RUs/IMs database, other procedures) CSIs transmitted to the Agency on an annual basis, through NSA's annual safety report	To collect sufficient information on safety performance to support risk-based decisions	To collect sufficient information to support risk-based decisions and targeting of supervision activities.	To collect sufficient information on safety occurrences to support risk-based decisions

Actors involved in OR	**The Agency**					
What are the requirements related to OR?	**To collect and report CSIs from NSAs annual report and calculate CSTs**	**To collect investigation report from NIBs**	**To certify RUs**	**To ensure that safety level is maintained and improved** **To promote sharing of information on accidents/incidents** **To monitor progress of railway safety**	**To make safety recommendations**	**To provide a tool for safety alerts**
EU Legal reference	Safety Directive [1]: art. 5, 7, 19.a, Annex I	Safety Directive [1]: art. 25	Safety Directive [1]: art. 10	Safety Directive [1]: art. 4.2 Agency Regulation [3]: art. 2, 18, 35	Agency Regulation [3]: art. 13, 19	Safety Directive [1]: art. 4.5 Agency Regulation [3]: art. 16.a
National legislation?	/	/	/	/	/	/
What does it mean in practice?	Record of the CSIs through NSA's annual reports + To analyse and report the results in ERAIL and to the RISC	Record of NIBs' investigation report in ERAIL	To collect sufficient information on safety performance to support risk-based decisions	To collect sufficient information to support risk-based decisions and targeting of supervision activities.	To collect sufficient information to support risk-based decisions	Establishment of a Safety Alert IT tool to be used on a voluntary basis + integrated as part of the COR project

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