

# Dissemination of the Commission Regulation (EC) No 352/2009/EC on Common Safety Method on Risk Evaluation and Assessment

Maria Antova, Dragan Jovicic, and Thierry Breyne

European Railway Agency, Safety Unit, Safety Assessment Sector,  
Rue Marc Lefrancq 120, F-59307 Valenciennes Cedex, France  
{maria.antova, dragan.jovicic, thierry.breyne}@era.europa.eu

**Abstract.** In order to support the market opening across Europe, the European Commission decided to define a common and harmonised approach for managing the railway safety. To take this forward, the EU Legislators have approved in April 2004 the railway safety directive 2004/49/EC. This directive allocates amongst others the task of defining a Common Safety Method (CSM) on risk evaluation and assessment to the European Railway Agency (ERA). The Regulation 352/2009/EC covering this CSM on risk assessment was published in April 2009 in the EC official journal. In order to support the railway actors in the implementation of this Regulation, as well as in order to gain inputs for its upcoming revision, the European Railway Agency performed a series of dissemination workshops for the CSM on risk assessment. The objective of this paper is to summarise and highlight some points from the dissemination of the Common Safety Method on risk assessment.

**Keywords:** EC, Regulation, Common Safety Method (CSM), Risk Assessment, Dissemination, Questions, European Railway Agency (ERA).

## 1 Introduction

The safety directive 2004/49/EC [1] in its Article 6(3)(a) requires the development of a harmonised approach for risk assessment. This development led to a Commission Regulation on a Common Safety Method on risk evaluation and assessment (EC) N° 352/2009 [2] published in the Official Journal of the European Union on 29th of April 2009. The risk assessment and risk management processes, which it describes, contain basically the following three steps:

1. identification of hazards;
2. risk analysis and risk evaluation based on existing risk acceptance principles, identification of safety measures and resulting safety requirements;
3. demonstration of the system compliance with the identified safety requirements.

Additional requirements for mutual recognition were included in the process: Hazard Management and independent assessment of the correct application and results of the CSM process performed by an Assessment Body. The process has to be applied to any safety related change of the railway system in a Member State, which is considered to be significant.

Due to the relative novelty of some aspects of the formal CSM process for risk assessment, this CSM Regulation will have a gradual implementation. From 19 July 2010, it applies:

- to all significant technical changes affecting vehicles as defined in Article 2(c) of Directive 2008/57/EC [3];
- to all significant changes concerning structural sub-systems, where required by Article 15(1) of Directive 2008/57/EC or by a TSI.

In order to give sufficient time to the concerned actors, where needed, to learn and apply the new common approach as well as to gain experience from it, the CSM Regulation remains voluntary with respect to the operational or organisational changes until 1 July 2012.

For the purpose of providing further support and detailed presentation on the CSM Regulation to all the actors from the European railway community, in the period of mid-2009 until mid-2010, the Agency has organised a series of CSM dissemination workshops. This dissemination exercise is also considered as a part of the activity related to the fulfilment of the requirement in Article 9(3) of the CSM Regulation. It requests ERA to monitor and collect feedback on the application of the CSM on risk assessment in order to make recommendations to the Commission with a view to improving it. The dissemination workshops were supported by a questionnaire, which was filled in by the participants of the workshop in advance. The purpose was also to allow the Agency to see, at an early stage, how the railway actors understand the concepts defined in the CSM Regulation to adapt the presentation to their needs and to collect feedback, ideas and suggestions how to improve the CSM in the scope of its upcoming revision.

## **2 Topics from the dissemination of the CSM on risk assessment and evaluation**

In the following sections there is a presentation of some questions, which have been discussed during the CSM dissemination workshops, which took place so far. It is to be paid attention that it is not possible to cover all the questions, within the scope of one single paper. All topics, which have been discussed during this series of dissemination meetings, are considered to be equally important.

The gained inputs are going to be considered in the scope of the revision of the CSM on risk assessment, the work on which is going to start at the beginning of 2011. The report for the revision of the CSM on risk assessment should be made by ERA and sent to the Commission by the end of 2011.

## 2.1 How should the requirements from the CSM Regulation be fulfilled

In order to enable the mutual recognition of the results of risk assessments and to ensure that the existing safety levels are maintained in the Community rail system, the CSM harmonises the process for risk assessment. It specifies *what* requirements must be fulfilled *without* specifying *how* to fulfil them.

This is an important property of the CSM, since the current practices for risk management vary between the different Member States. Usually, different tools are established and different practices for the assessment and evaluation of risks exist. Moreover, the specific physical and historical properties of the railways around Europe request different activities in their given context.

Therefore, it is necessary for the proposers to be able to comply with the CSM requirements, paying attention to their local particularities and adjusting their activities to the particular context of their work. In their activities, this freedom and flexibility are considered to be very important.

## 2.2 Significant change

The CSM on risk assessment shall apply to any safety related change of the railway system in a Member State, which is considered to be significant.

If there are no notified national rules defining whether a change is significant or not in a Member State, the proposer shall decide, by expert judgement, on the significance of the change. This decision is based on the following criteria that are provided in Article 4 of the CSM on risk assessment:

- failure consequence;
- novelty used in implementing the change;
- complexity;
- monitoring;
- reversibility of the change.

If the change is not significant, the CSM application is not mandatory, but the decision needs to be documented. This would allow the national safety authority to check it during its supervisions of the proposer's safety management system.

For non significant changes, attention on the possible additionality effects needs to be paid. This means that the expert judgement shall always evaluate, if when added up, the sum of all non significant changes since the last application of the CSM becomes a significant change.

In the scope of the dissemination of the CSM, discussions took place, on the question, if it is viable to provide a harmonised list of all changes in the railway system, which are considered to be significant. On one hand such a checklist would avoid the need to count on expert judgement when deciding on the significance of a change and would thus bring some strict rules to the answer of this question. On the other hand, having such a predefined list in a harmonised piece of European legislation would, by a way, take away the

responsibility of the proposer to decide if, based on its experience, the change is significant and would also have the effect that every time when a change is not published on the list, a Europe-wide solution of this problem will need to be sought. Further questions exist, on:

- is the development of such a list feasible;
- how can such a list take into account the different operators' expertise;
- would not it affect the cost of risk assessments for those railway actors who could have decided that the change is not significant;
- is it going to influence positively or negatively the process for answering to the question of the significance of a change and the demonstration of CSM compliance?

During the work on the development of the CSM Regulation, the solution to support the decision by the predefined criteria referred to above has been put in place. This seems to be a good compromise between setting up a too restrictive and inflexible framework or setting a question with a too wide spectrum of answers, without any further guidance on how to proceed with its answer. In the scope of the CSM dissemination workshops, with the help of the pre-workshop questionnaire, it has been confirmed that the criteria are used already nowadays by the railway actors in order to define whether a change, which they would like to introduce, is significant. Already before the CSM Regulation has come into force, the actors are answering to such questions, in order to define the way how to analyse their changes and the resulting hazards, in the scope of their safety management systems. They are used to applying this practice in their everyday work and are confident in knowing well its effectiveness level.

## 2.3 Hazard Record

The CSM Regulation requires that the proposer in charge of the risk management process maintains a hazard record. The hazard record is the document in which identified hazards, their related measures, their origin and the reference to the organisation, which has to manage them, are recorded and referenced.

It is clear that the hazard record is an important part of the hazard management process. It helps to document and support the decision making process, by providing transparency and consistency. Due its traceability, on one hand it allows corrective actions to be taken promptly and quickly, and on the other hand, it supports the exchange of information between the different actors. It gives them the possibility to contribute to the evidence of a continuous compliance with the relevant requirements. It does not need to be complicated, because it is mainly targeted on the key issues.

Whereas these advantages of the hazard records are obvious and clear for most of the railway actors, among them there are also such, who admit that they are not yet experienced in its usage. Therefore, advice on different questions often seems to be needed.

For example, for some actors it is not very obvious to know when the hazard record has to be updated. This is usually done whenever:

- a new hazard is discovered or a new safety measure is identified during the design phase;
- a new hazard is identified during the operation and maintenance of the system after its commissioning, so that the hazard can be assessed in compliance with the CSM as to whether it represents a significant change;
- it could be necessary to take into account accident and incident data;
- there are changes to the safety requirements or the assumptions about the system;

Additionally, it is good that a difference is made between the hazard records, which are mainly meant to be used in the preventive part of the railway safety, and the statistics from railway accidents and incidents, which every company is maintaining and is a typical reflection of the reactive part of the railway safety. Although, the prevention and the reaction are interconnected with each other, still, typically the hazard record is structured and maintained in a different way from the event statistics of the railway companies. Nevertheless, it is normal that it receives input for its updates, whenever such unwanted events occur, which lead to the recognition of new hazards, or to the change of some of the existing ones.

Another topic of particular interest is the maintenance of the hazard record in the typical situation when there are a number of actors involved in a certain significant change, each of whom has to have responsibility for his part of the system under assessment. In such cases, it is normal that each of the involved parties keeps a record of the hazards for their part of the assessed change or project. Usually there is one overall actor (proposer) who has responsibility for the main record. This main record covers all the necessary elements of the system under assessment. It does not have to contain all the information from the other actors, but it needs to keep the links and key safety related issues. The exchange of information gains more importance, if the hazard cannot be controlled by one actor alone.

The practice has shown that when classifying the hazards in the hazard records, every company is having its own logic. Even though, at the very beginning it might be a bit challenging to set up such a logic, which is adjusted to the company needs and is able to reflect its existing safety profile, once it has been set, it becomes a powerful support for the creation and the maintenance of the hazard records. Sometimes it might be hard to figure out the necessary level of detail for the documentation of the hazards. Nevertheless, by gaining more practice in the usage of the hazard record, the companies are gradually learning, which level of detail is most proper for their situation too.

Currently, there is no requirement in the CSM Regulation on the question how long to maintain the data from the hazard records. Therefore, also this decision lies in the responsibility range of the proposers.

## 2.4 Tools and Methods for risk assessment

During the CSM dissemination workshops, questions have been asked about when to use which risk assessment tools and where could more information on this topic be found.

Some of the European railway actors have requested further support and more detailed training on how the risk management and risk assessment process described in the CSM Regulation can be applied. For some part of them, the risk management and assessment concepts, as well as the respective terminology of a risk based approach seem to be new. Sometimes, even if the whole concepts are not new for them in theory, they confirm to be rather inexperienced in their practical implementation. It has been reported that it is often hard to find literature on these topics available in the own language and this implies an additional difficulty for the concerned actors.

Therefore, in order to assist them, the European Railway Agency has decided to elaborate with the support of a subcontractor a training material on the risk management and risk assessment techniques and tools.

For this purpose, a tender for a study has been launched in April 2010. The work on the study has started in August 2010. The estimated date for the completion of the activities lays in February 2011.

The aimed training material shall be supported by an analysis of advantages and disadvantages of the methods and tools used in the different steps of the CSM process. The risk management and risk assessment terminology, the different techniques, tools and methods that might be needed to demonstrate the compliance with the CSM Regulation, will have to be explained. Their use shall be illustrated with instructive examples of risk assessment, which are taken from different spheres of the work in the railway sector (construction of new lines, changes of existing lines, introduction of new and/or modified technical systems, operational changes, etc.).

The developed materials are going to be made available on the web page of ERA. Their exact dissemination modes are going to be proposed and defined in the scope of the work on their development.

## 2.5 Coordination between ERA and CENELEC

Currently, the CENELEC CLC TC9X Working Group 14 (WG 14) for safety-related standards is working on a combined revision of the following standards:

- EN 50126:1999 [4], which specifies the Reliability, Availability, Maintainability and Safety (RAMS) process for the railway system;
- EN 50128:2001 [5], which concentrates on the software in the signalling;
- EN 50129:2003 [6], concerning the safety relevant electronic signalling systems;
- EN 50155:2001 [7], which is about the electronic equipment used on rolling stock and does not have any special safety or software focus.

From the perspective of the railway community, the revision of these standards must reflect the European safety activities currently undertaken by non-standardisation bodies, one of which is ERA. For this reason, the new standards should provide to the users clear links with ERA's railway safety orientated perspective and activities.

Unlike the CSM on risk assessment, which is a mandatory element for the EU Member States, the compliance with the CLC standards is not mandatory. Nevertheless, they focus on the technical process and outcome in connection with the safety assurance of products and systems both across the EU and beyond. They are going to reflect among others also the risk acceptance principles and criteria, which are currently being developed as a part of the upcoming revision of the CSM Regulation.

The CENELEC standards and the EU regulations are complementary and collectively address broader aspects of safety assurance across the EU. Therefore, having recognised all these aspects of the current developments of both CENELEC and the ERA, a common active coordination activity has been set up between them. Its aim is to align the EN standards with the activities of the Agency and especially with the CSM on risk assessment and its revision, and to provide further a sound and safe basis for the European railways.

### 3 Conclusions and outlook

Shortly after the publication of the CSM Regulation in April 2009, the European Railway Agency has started a series of activities for its dissemination.

The first step in the CSM dissemination was represented by a series of workshops, which the Agency has held for all concerned railway actors around Europe. During them and with the support of the associated CSM guides [8], [9], the requirements of the CSM Regulation have been explained further and in more details.

With the support of railway sector organisations and national safety authorities, the Agency is going to continue the dissemination activity with the review of the feedback based on real case examples of changes to the railway system whereby the CSM process has been applied. Among others, this should allow to learn from different actors more about the gained experience and the encountered difficulties by the application of the CSM. In this way, these could be taken into account for the future revision of the CSM.

During the dissemination workshops, series of questions have been raised. Most of them were reflecting difficulties, which arise from the particular legal framework of the different Member States and are therefore not proper for a publication in a generalised paper. Nevertheless, there were also questions at a higher level, which have been asked repeatedly and whereby more guidance is necessary. Some of them have been summarised in the sections above. Others, like for example the questions, which consider the Independent Assessment Body for the application of the CSM process, and the questions about the

Risk Acceptance Criteria, which are to be applied for the aims of achieving mutual recognition whenever the third risk acceptance principle (the explicit risk estimation) is applied, are still under development, and are therefore going to be clarified at a later moment in time.

At this stage, it is important to underline that in order to help the actors from railway sector for the application of the CSM on risk assessment, the ERA has also issued the following two informative and not legally binding documents:

- Guide for the application of the Commission Regulation on CSM on risk assessment [8];
- Collection of examples of risk assessments and some possible tools supporting the CSM [9].

These two documents are translated in all EU languages where Member States operate railway and have been made available on the web site of the Agency. Thus, they are meant to represent the first emergency help for the railway actors, who encounter difficulties in the application of the CSM Regulation.

## References

1. Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)
2. Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council
3. Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community
4. EN 50126:1999 - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)
5. EN 50128:2001 - Communications, Signalling and Processing Systems - Software for Railway Control and Protection Systems
6. EN 50129:2003 Railway Applications - Communication, signalling and processing systems - Safety Related Electronic Systems for Signalling
7. EN 50155:2001 Railway Applications - Electronic equipment used on rolling stock
8. Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of the Railway Safety Directive, Version 1.1. from 06/01/2009
9. Collection of examples of risk assessments and of some possible tools supporting the CSM Regulation, Version 1.1 from 06/01/2009



FORMS/FORMAT 2010

Formal Methods for Automation and Safety in Railway  
and Automotive Systems

Schnieder, E.; Tarnai, G. (Eds.)

2011, XI, 257 p., Hardcover

ISBN: 978-3-642-14260-4