



**Agency report**

**on**

**the experience with the existing regulation (EC) N°  
352/2009 on a common safety method on risk evaluation  
and assessment**

**and**

**on the revision of that regulation**

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## Referenced Documents

**Table 1 – Table of reference documents**

N°	Description	Reference	Version
/1/	Mandate to the European Railway Agency for the revision of the common safety method on risk evaluation and assessment	C(2010) 6931 final	final
/2/	Directive 2004/49/EC on safety on the Community's railways (Railway Safety Directive)	OJ L220, 21.6.2004, p.16 (Corrigendum)	
/3/	Regulation 881/2004 establishing an European Railway Agency (Agency Regulation)	OJ L220, 21.6.2004, p.3	
/4/	Definition of RAC for technical systems		2.0
/5/	Note on Assessment Bodies roles and responsibilities in the CSM on risk assessment		3.1
/6/	Change Requests for the Commission Regulation (EC) N°352/2009 on the CSM on risk evaluation and risk assessment		1.0
/7/	Economic Evaluation: Methodology Guidelines (ERA Economic Evaluation Unit – still in draft state)	061108 EE methodology guidelines.doc	2006
/8/	European Commission: Impact Assessment Guidelines.	SEC(2005) 791	2005
/9/	Final report of impact assessment		1.0
/10/	Commission Regulation (EC) on a common safety method on risk evaluation and assessment	352/2009	24 April 2009
/11/	Executive Summary concerning the "proposal for risk acceptance criteria to be included in the scope of the revision of regulation 352/2009/EC"		2.0
/12/	Proposal for RAC definition: " definition of RAC for failures of functions of technical systems, which are covered entirely by a technical solution"		3.0 May 2011
/13/	Final report Final Report – Risk Acceptance Criteria for Technical Systems and Operational Procedures	DNV 24127328/03	January 2010
/14/	Final report - Elaboration of training material on risk assessment techniques and tools-	ARC-296-004-R003	May 2011
/15/	General framework for the risk acceptance criteria within the CSM on risk assessment (Explanatory note on the development of RAC)		2.0, December 2010



## 1 INTRODUCTION

Following

- Directive 2004/49/EC on railway safety in the Community (Safety Directive - /2/),
- Regulation (EC) No 881/2004 establishing the European Railway Agency (Agency Regulation - /3/),
- The mandate to the European Railway Agency for the revision of the common safety method on risk evaluation and assessment- C(2010) 6931 final - of 12.10.2010

This mandate to the European Railway Agency, as referred to in Article 6(2) of Directive 2004/49/EC concerns the revision of the Commission Regulation (EC) N° 352/2009 on a common safety method on risk evaluation and assessment and a report that includes the feedback on the experience and on the effectiveness of the CSM on risk assessment, as referred to in Article 9(4) of that regulation.

The Agency shall submit to the Commission its final recommendation on the revision of the CSM on risk evaluation and assessment not later than 30 April 2012.

The Agency shall submit the report referred to in Article 9(4) of Regulation (EC) N° 352/2009 to the Commission by 31 December 2011 at the latest.

The present document provides:

- Part 1: the summary of the collected experience with the use of the existing regulation N° 352/2009. This part contains thus the Agency report under Article 9(4) of Regulation (EC) 352/2009 on the overall effectiveness and experience with the application of that Regulation, and;
- Part 2: the development process applied for the revision of that regulation based on further developments in two dedicated taskforces (see next sections of this document).

### **Part 1: Feedback on experience and on effectiveness of CSM on risk assessment**

- An analysis of the experience with the application of the CSM on risk evaluation and assessment /10/, including cases where the CSM has been applied by proposers on a voluntary basis before the relevant date of application provided for in article 10
- An analysis of the experience of the proposers concerning the decisions related to the level of significance of the changes
- An analysis of the cases where codes of practice have been used as described in section 2.3.8 of Annex I of /10/
- An analysis of overall effectiveness of the CSM on risk evaluation and assessment

Basically the gathering of experience with the application of the CSM on risk assessment has been done till now through:

- the annual safety reports of national safety authorities. A dedicated section has been introduced for that in the template of the annual safety report to be used by the NSAs;
- presentations by working group experts of the cases where the method was applied by their company or in their country, and finally;



- 
- the workshops on the dissemination of the Commission Regulation (EC) N° 352/2009 on a common safety method on risk evaluation and assessment.

## **Part 2: revision of regulation 352/2009 /10/**

In addition to cover the results of the analysis by the Agency under Article 9(4) of Regulation (EC) 352/2009 of the overall effectiveness and experience with the application of that Regulation, the revision work of the CSM on risk evaluation and assessment integrates the results of further developments led by the Agency since 2007, with the support of three dedicated taskforces and the working group on CSM on risk assessment. The following main requirements were targeted:

- experience with the application of the existing Regulation (EC) N° 352/2009 on risk assessment;
- specific requirements for the roles and the responsibilities of the assessment body referred to in Article 6 of the Regulation (EC) N° 352/2009. The revision clarifies the qualification requirements (to be checked by relevant authorities through an accreditation/recognition scheme) to be fulfilled by the assessment body for carrying out its tasks specified in the CSM regulation. The main objectives are to improve clarity, to avoid different independent assessment works by the different assessment bodies and to facilitate the mutual recognition of the independent safety assessment report across the Member States;
- a proposal for additional risk acceptance criteria to be used for assessing the acceptability of a risk during explicit risk estimation and evaluation.

**Note:** in spite of all indications from the sector how important this development is, it has not been possible to receive enough inputs to allow for an agreement within the working group on this topic. Therefore, this work needs to be continued and included in a following revision of the Regulation (EC) N° 352/2009. Consequently, with respect to the risk acceptance criteria, no proposal for change to the existing regulation has been made and the existing texts remain unchanged.

The present report describes the following for the revision of the regulation 352/2009:

- the changes made to the existing regulation in order to reflect those additional developments;
- the process of drafting the revision of the Regulation 352/2009;
- the result of the related impact assessments (one for the topic of the assessment bodies and one for the topic of the risk acceptance criteria);
- the minority opinions on certain requirements of the recommendation;
- the reported mistakes of translation of Regulation (EC) N° 352/0009 into some other EU languages: see ANNEX II and Table 8.

The Agency's recommendations are summarised in the last chapter.

The latest draft of the revised CSM on risk assessment is provided as a separate document delivered to the European Commission at the same time as the present report.



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## 2 PART 1 – FEEDBACK ON EXPERIENCE AND ON EFFECTIVENESS OF CSM ON RISK ASSESSMENT

### 2.1 Analysis of the collected experience

As explained in the introduction of this report, the gathering of experience with the application of the CSM on risk assessment has been carried out through:

- the members of the working group who presented a few cases of application of the method either by their company or in their country;
- the workshops on the dissemination of the Commission Regulation (EC) N° 352/2009 on a common safety method on risk evaluation and assessment;
- the annual safety reports of national safety authorities.

At every meeting of the working group on the CSM on risk assessment, the Agency invited the members to present the cases where their company or sector organisation applied the CSM on risk assessment /10/. With the exception of two cases presented by the Italian CER representative, the other working group members did not present any practical case where the relevant Commission regulation was applied. The two Italian cases did not show any particular problem with the application of the requirement in /10/.

Similarly at every dissemination workshops, the Agency invited the participants to present their cases of application of a risk assessment. However as the workshops took place before the mandatory application of the regulation 352/2009/EC, only a few cases were presented. Two cases were in line with the CENELEC EN 50 126 standard. The third one was the same Italian example as the one presented at the working group. All presented cases did not show any particular difficulty in applying the risk assessment process.

In order to complement those inputs, the Agency also analysed the content of the annual safety reports from the national safety authorities for 2010, first year of mandatory application of the CSM on risk assessment. The table in the ANNEX I gives the information related to the CSM on risk assessment from the annual safety reports of the respective member states.

Based on those annual safety reports of the national safety authorities, the following can be concluded:

- Analysis of the experience with the application of the CSM on risk evaluation and assessment reported by Member States.

Some countries (AT, DE, UK) drew up guides supplementing the Agency guides to regulation 352/2009 or organised briefing sessions (UK, AT, ) or published on their website the guide developed by the Agency (PL). But until the moment when the annual safety reports had to be submitted to the Agency there had not been observed real cases where the regulation was actually applied, because when the regulation became mandatory, the existing projects were at an advanced stage with respect to the entry in force of it (Channel Tunnel, UK, FI).

Some countries (ES, IT) described the application of the CSM by RUs and IMs for different projects.





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Other countries have no information available for this point (EL, NL, NO, SE).

Some countries do not mention anything (FR, RO, LT).

- Analysis of the experience of proposers concerning the decisions related to the level of significance of the changes.

Austria reported that the railway organisations made the distinction between significant changes or not significant ones (twelve changes were non-significant and three significant ones were technical and operational changes).

German NSA describes that a lot of workshops have been organised with the German railway industry representatives to discuss the definition of significant changes and on the practical application of the concepts. The embedding of different processes of authorisation brings difficulties with the application of the CSM on risk assessment. The current experience shows that the decision on the significance of a change is not very easy to be taken.

The Agency assumes that the German railway industry fears if they classify changes as "non-significant" ones and thus do not apply the Regulation (EC) N° 352/2009 but other risk assessment methodologies, their NSA might question their decision at a late moment in the process of authorisations of placing into service structural sub-systems. Consequently, the German NSA and German railway industry would prefer that an EU legal text clearly states which changes must be considered as significant. But as it was explained in the Accompanying Report of the Agency recommendation for the Regulation 352/2009, that cannot be done. It would be counterproductive as it would impose the use of the CSM even in the cases where the proposer could have judged it non-significant and would have kept the risk under control.

- Analysis of cases where codes of practice have been used.

There is nothing reported in the NSA annual safety reports on this topic.

- Analysis of overall effectiveness of the CSM on risk evaluation and assessment

The NSAs do not have enough feedback on the application of the CSM to be able to analyse the overall effectiveness.

## **2.2 Need for additional training material, tools and instructive examples of application of the risk assessment process**

In order to help the railway actors with the application of the regulation N° 352/2009 on CSM on risk assessment, the Agency accepted to collect examples of application of that method in order to make it available, e.g. through the Agency web site, to all railway actors who might need it. Consequently, as explained earlier, at every working group meeting, the Agency invited the participants to present their experience with the method either in their company or in their country. With the exception of two cases presented by the Italian CER speaker, the other working group members did not present any practical case where this CSM regulation was applied. These two Italian cases did not show any particular difficulty with the application of the requirements in the existing CSM on risk assessment.





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In the meantime, at several dissemination workshops organised in 2009 and 2010 to help the railway actors with the application of the CSM on risk assessment, it appeared that some of the European railway actors do need further support and more detailed training on how the risk management and risk assessment process in the CSM regulation N° 352/2009/EC can be applied. Indeed, for many of encountered railway actors, risk management and assessment concepts, as well as the subsequent terminology of a risk based approach, are quite new.

### **Training material and tools for risk assessment**

In order to assist those railway actors, the European Railway Agency decided to elaborate with the support of a Contractor (Abbott Risk Consulting Limited – Arc Abbott) detailed training material on risk management and risk assessment techniques and tools. This training material aimed to cover, as the minimum, all the steps of the risk assessment process in the regulation 352/2009/EC.

This training materiel on risk assessment techniques and tools was developed by Arc Abbott between August 2010 and May 2011. It describes for every step of the CSM process possible techniques and tools usable for fulfilling the requirements of the regulation. A pilot workshop with experts from the working group was also held in April 2011 in Lille. The purpose was to obtain their opinions with the aim to revise the training material. The participants of the pilot workshop were designated by their company at the working group meetings on risk assessment. Evaluation forms were distributed and used to collect their feedback on the training material. The overall participant feedback was positive, rating the "training techniques and tools" at a "good" level.

More details about the training material and risk assessment techniques and tools can be found in the reference /14/.

### **Instructive examples of risk assessment – Link with the training material and tools**

To illustrate the training materiel developed by Arc Abbott and in order to provide additional practical information to the railway actors, the Agency has launched a second study in 2011. The selected contractor is Det Norske Veritas (DNV). The purpose of the study is to:

- collect concrete examples of application of the CSM Regulation by the different railway actors across the whole Europe;
- make those examples instructive for educating railways actors with strong technical railway competence but inexperienced in risk management and risk assessment techniques, to start assessing and managing risks using the risk based approach in the CSM regulation;
- provide the links between the process in the CSM regulation, the training material and tools developed by Arc Abbott in the scope of the first study (see point here above) and the steps in the documented examples of collected risk assessments.

Targeted instructive examples are expected to include the following cases:

- construction of new lines or changes of existing lines;
- introduction of new and/or modified technical systems;
- operational changes (such as new or modified operational rules and maintenance procedures);
- organisational changes;



- other examples to be approved by the Agency.

This study takes place between January 2012 and December 2012. The results will be made available through the Agency web page.

## 2.3 Conclusion for the experience with the application of the CSM

Discussions within the working group and information gathered via the annual safety reports of the national safety authorities indicate that the CSM concepts are progressively being set up among the railway actors through Europe. The experience and the understanding of the method and of its requirements are progressively growing. Nevertheless significant disparities are still visible throughout Europe or among railway actors in the same country. There is thus not a lot of experience available for the moment that would justify additional modifications to the existing Regulation (EC) N° 352/2009 than those mentioned in section 1 of this report. One of the possible reasons might be the advanced stage of many projects with respect to the date of entry into force of the Commission regulation N° 352/2009/EC or the fact that its application is mandatory only since July 2010 for technical equipment only.

The Agency has organised dissemination workshops on the CSM on risk assessment during 2009 and 2010, i.e. before the CSM entered into force. However, despite those efforts, during the workshops the Agency is currently organising on the safety management systems, the CSM for conformity assessment and the ECM Regulation 445/2011, many railway actors are requesting the Agency to reopen and continue further the dissemination work on risk assessment. The same need has been observed also at the workshop the Agency organised for the representatives of Member States to discuss the revision before finalising and sending the revised CSM on risk assessment to the Commission. Many participants from the railway sector joined the workshop in order to receive early information about the scope of the revision of the CSM on risk assessment. The European railway sector is asking for repetitive workshops, additional training material to be developed and many examples of application of the risk assessment process to be collected and made available.

Consequently, the Agency suggests continuing further the education and training of the stakeholders by additional dissemination workshops and/or by developing a training programme in the next years. This will be certainly reflected on and suggestions on how it can be done will be provided to the European railway stakeholders.

## 3 PART 2 – REVISION OF REGULATION 352/2009

### 3.1 CSM Team and ERA Working Group for the revision of the regulation 352/2009

The CSM team was composed of a Head of Sector supported by one senior project officer and by three junior project officers. Due to the turnover, two new junior project officers integrated the team: one in 2009 and another in 2010. The third came from the safety reporting team.

*Table 2 – Members of ERA's staff working on revision of CSMs*

Member of staff	Role	Activity
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**Table 2 – Members of ERA's staff working on revision of CSMs**

Member of staff	Role	Activity
Thierry BREYNE	Project Officer – former Head of Sector and currently Head of Safety Unit	CSMs
Dragan JOVICIC	Project Officer - CSM WG Administrator	CSMs
Maria ANTOVA	Project Officer - RAC Administrator (took over the project from Marcus Andersson in 2009)	CSMs
Nathalie DUQUENNE	Project Officer - AB Administrator	CSMs
Suzanne KALLMAN	Project Officer	CSMs
Wouter MALFAIT	Project Officer from Economic Evaluation Unit responsible for the impact assessment on changes related to RAC-TS	Economic Evaluation
Torben HOLVAD	Project Officer from Economic Evaluation Unit responsible for the impact assessment on changes related to Assessment Bodies	Economic Evaluation

Internal consultation and reviews involving the whole team are carried out when relevant activities or outcomes have to be decided upon.

### 3.2 Meetings and Working methods

In 2005, in accordance with the Article 3 of the Agency Regulation 881/2004/EC, the Agency established working parties (also called working groups) for drafting the existing regulation 352/2009/EC. The Agency worked with the same working group to revise the regulation based on the inputs previously described.

The working group is composed of delegates of national safety authorities and railway associations notified by the railway interoperability and safety committee (RISC). Those delegates are railway experts of different parts of the railway sector. They contributed actively to the revision of CSM regulation with their knowledge in respect of their professional origin and affiliation to a railway sector organisation.

(a) This working group supported the Agency for the revision of the CSM regulation on risk assessment. It is composed of 14 National Safety Authorities and 5 sector organisations who did nominate experts. The following table shows the institutions/organisations which are to date represented in the CSM working group and the names of the respective representatives.

(b)



**Table 3 – Institutions/Organisations represented in the working group for CSM on risk assessment.**

<b>Institution/Organisation</b>	<b>Delegate</b>
NSA of Austria	Mr Gerhard DOTZER
NSA of Belgium	Mr Rene DEMULDER
NSA of Denmark	Ms Diana Rose JØRGENSEN who replaced Ms Pia MESSEL who replaced Ingemar INGEMARSON
NSA of Finland	Ms Sanna STRÖM who replaced Ms Mira LEINOEN
NSA of France	Mr Frédéric HENON who replaced Mr Thierray SAULE
NSA of Germany	Mr Frank LEISSNER
NSA of Italy	Mr Christian LUSI who replaced Gianluca CUTRERA
NSA of Latvia	Ms Jelena STEPANOVA
NSA of Norway	Ms Gunhild HALVORSRUD
NSA of Poland	Mr Pawel MICHALCZYK
NSA of Romania	Mr Ioan BUCIUMAN
NSA of Spain	Mr Ignacio ALONSO
NSA of Sweden	Mr Robert BYLANDER
NSA of United Kingdom	Mr Simon D'ALBERTANSON
Community of European Railway and Infrastructure Companies (CER)	Ms Anne-Lise JOLY - Mr Marc GEISLER - Mr Hans VOGT – Ms Liz DAVIES
European Rail Infrastructure Managers (EIM)	Mr Johan Larsen AASE – Mr Jonathan ELLIS who replace Brian TOMLINSON
UNIFE	Mr Pascal GUESDON – Mr Jens BRABAND – Mr Paul SELLER who replaced Mr David BEACHAM
UIP	Ms Valerie NICAISE

### **3.3 Process for drafting the revision of the regulation N° 352/2009 on the CSM on risk assessment**

#### **3.3.1 Introduction**

To prepare the revision of the regulation, the Agency organised during 2009 and 2010, two specific taskforces. One taskforce worked with the Agency on the roles and responsibilities of the assessment bodies and another one worked on the harmonisation of the risk acceptance criteria (RAC) to be used for quantitative explicit risk estimation. The outputs of the two taskforces provided two important documents that were taken into account for the revision of the CSM on risk assessment:

- note on the Assessment Body roles and responsibilities in the CSM on risk assessment /5/.



- proposal for harmonised risk acceptance criteria to be included in the scope of the revision of regulation 352/2009/EC. This proposal is based on two explanatory notes (/12/ and /15/) describing the way how the proposal was developed and one executive summary note /11/, which summarizes the proposal from the two notes in a short comparison with the relevant existing texts of the regulation.

During 2009 and 2010 the results of these two taskforces were regularly reported and presented to the whole working group in order to collect their suggestions and comments for further development in the respective taskforces. At the end of 2010 and beginning of 2011, the notes on the "roles and responsibilities of assessment bodies" and the explanatory notes on the development of the proposal for risk acceptance criteria were formally reviewed by the whole working group in order to take their latest remarks into account before launching the revision of the regulation N° 352/2009 on the CSM on risk assessment.

As a result of that process, the Agency and the working group decided in December 2010 to set up a new taskforce for drafting the revision of the regulation 352/2009. This taskforce was led by the Agency and composed of experts of the CSM WG.

In accordance with the scope of the Commission mandate, the revision taskforce took as basis for its work the inputs from the dissemination workshops and the finalised two notes of the dedicated taskforces on assessment bodies and RAC reviewed by the working group. Based on these inputs, the taskforce identified what parts of these two notes had to be included in the legal text of the revised CSM on risk assessment and what parts should be contained in the associated guidelines.

### 3.3.2 Dedicated taskforce for the revision of the CSM on risk assessment

The revision taskforce issued middle of 2011 a first draft of the revision. The revised CSM was then reviewed a first time and discussed within the whole working group at the plenary meeting of 14 September 2011.

The revision taskforce met 5 times in 2011.

**Table 4 – Meetings of the revision taskforce.**

Date	Subject of discussion
02/02/2011	<p>The main purpose of this first meeting was to present and agree with the taskforce on the plan for the revision of the CSM on Risk assessment. The different inputs and the time schedule associated to this taskforce were also presented and agreed on.</p> <p>As explained here above, the inputs used for the revision were formally reviewed beforehand by the working group. It was explained and agreed at this first taskforce meeting that the taskforce will not question and discuss again the technical content of the notes on the "roles and responsibilities of assessment bodies" and "proposals for harmonised RACs".</p> <p>The agreed inputs for the revision work are thus:</p> <ul style="list-style-type: none"> <li>• the note on the "roles and responsibilities of assessment bodies";</li> <li>• the note on the "proposal for harmonised RAC for technical systems";</li> <li>• the change requests collected during the dissemination workshops on the</li> </ul>



**Table 4 – Meetings of the revision taskforce.**

Date	Subject of discussion
	existing regulation N° 352/2009 on CSM on risk assessment.
09/03/2011	The first version of the revised text was discussed and amended.
04/05/2011	The taskforce completed the revised text and detailed further some requirements.
16/06/2011	The taskforce prepared the version to be sent to the working group for informal comments.
13/10/2011	Discussion on the comments from the working group members and agreement on how to take them into account the final draft.

### 3.3.3 Contribution of the whole working group

The results of the revision taskforce were periodically presented to the whole working group. In addition to that two reviews were done with the whole working group:


- 1°) An informal review on the first draft version (version 1.0) during summer 2011, followed by a working group meeting on 14 September 2011;
- 2°) A formal review on the final draft in October 2011, followed by a working group meeting on 23 November 2011.

**Remark:** as the validation by CER of the harmonised risk acceptance criteria (RAC) required more time (see in next sections of this report), that part of the CSM was not discussed in details at the WG meeting of November. In agreement with the Commission and the working group, the delivery of the revision was delayed by two months to finalise that validation work and to discuss and agree on the results among the sector organisations;

- 3°) In February 2012, a third formal review was done. It focussed to the revisions related to values of the harmonised risk acceptance criteria proposed by the sector organisations on basis of the CER validation work. In addition to the RAC part, many of working group members took the opportunity to review the whole document. The review comments were discussed and agreed at the working group meeting of 21<sup>st</sup> February 2012.

For all three reviews, the Agency applied a formal review process with the working group, using documented "comment sheets". This consisted in collecting reviewers' comments, answering them and returning to the reviewer the answered comment sheet for agreement. Usually this is followed by a phone conversation with the reviewer in order, on the first side to agree on the comments which could not be solved by e-mail, and on the other side to identify the major points to be discussed with the whole working group during the next plenary meeting. With a few exceptions, these phone calls were not necessary. Instead of that all received comments were presented, discussed and agreed with the whole working group on whether and/or how to take them into account.

The comment sheet template represented in Figure 1 was used to process the received comments and remarks.


Safety Unit

**Conventions :**

Type of Comment	Assessment	Comment from author
G General	CN Correction necessary	R Rejected
M Mistake	CE Correction expected	A Accepted
U Understanding	+ Major	D Discussion necessary
P Proposal	- Minor	NWC Noted without need to change

**Review Comments (if necessary add extra lines in the table) :**

N°	Reference (e.g. Art. §)	Type/ Assess	Reviewer's Comments, Questions, Proposals	Comm. (Author)	Proposal for the correction or justification for the rejection (by the Author)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.	End		End of comments		

Ref.: <Document Reference\_Document Version\_COMT\_XY>

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 Template Document Review Comments v0.2.docx

**Figure 1: Example of comment sheet used for the formal review process.**

In total, the revision of CSMs on risk assessment was presented and discussed with the whole working group five times: see table below.

**Table 5 – Working Group Meetings for the revision of the CSM on risk assessment.**

Date	Subject of discussion
13/04/2011	Presentation of the first results of the taskforce dedicated to the revision 352/2009 and collection of suggestions and remarks for improvement.
14/09/2011	<p>Presentation and discussion of informal review comments on the first draft of the revised CSM sent for review by the working group in July 2011.</p> <p>Comments were received from Spanish, Belgian and Austrian NSA, as well as from UIP, CER and some other members of the working group (Jens BRABAND and Marc GEISLER). All received comments were presented and discussed with the whole working group.</p> <p>The Agency and working group agreed what comments have to be dealt further within the revision taskforce on 13<sup>th</sup> October 2011.</p>
23/11/2011	Presentation and discussion of the formal review comments on the final draft of the revised CSM, sent for review by the working group after the revision





**Table 5 – Working Group Meetings for the revision of the CSM on risk assessment.**

Date	Subject of discussion
	<p>taskforce meeting of 13<sup>th</sup> October 2011.</p> <p>Comments were received from Austrian, German and UK NSAs, as well as from UNIFE, UIP, RSSB from UK, RFI from Italy, VDV from Germany (included in German NSA comments) and Marc GEISLER (DB). All received comments were presented and discussed with the whole working group.</p> <p>The Agency and working group agreed what comments to take into account within the document before submitting to Public Consultation.</p>
21/02/2012	<p>Presentation and discussion of the formal review comments on the modifications related to the harmonised risk acceptance criteria resulting from the "validation work by CER of the RAC values proposed by the taskforce on RAC" as well as on other parts of the revised CSM. The review request was sent to the working group on 8<sup>th</sup> February 2012, after the coordination meeting with the sector organisations on 1<sup>st</sup> February 2012.</p> <p>Comments were received from Austrian, Danish, Finnish, French, German, Romanian and Spanish NSAs, as well as from EIM, UNIFE, UIP an RSSB. All received comments were presented and discussed with the whole working group.</p> <p>The Agency and working group agreed what comments to take into account within the document before submitting to Public Consultation.</p>
31/05/2012	<p>Presentation and discussion of the results from the Public Consultation, the NSA Network and the workshop with RISC committee members, NSAs and railway sector organisations.</p> <p>All received comments were presented and discussed with the whole working group. The Agency and working group agreed how to take into account the comments within the document before delivering the recommendation to the Commission.</p>

### 3.3.4 Public Consultation

In compliance with Article 4 of the Agency Regulation /3/, on 8 March 2012 the Agency sent the revised CSM on risk assessment for Public Consultation by the trade unions, social partners, NSA network, railway sector organisations, including ETF and EPF, European Commission, as well as by the other units and the legal adviser of the Agency.

The Agency applied the same "formal review process" as the one used with the working group. A formal review request was sent to all reviewers. They were asked to provide comments back to the Agency using the comment sheet template represented in Figure 1.

The Agency collected all comment sheets, answered them and returned the completed comment sheets to the reviewer for agreement. As explained below, the received comments were presented for discussion in the working group at the plenary meeting of 31 May 2012 in order to agree on how to take them into account.



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The following comments are the main outcomes from Public Consultation and those meetings:

- (a) as it is proposed in the revised CSM both the accreditation and recognition schemes shall coexist for the acknowledgement of the assessment body competence;
- (b) the following requirement shall be added in Annex II of the revised CSM on risk assessment: *"To be accredited or recognised, the assessments body shall have knowledge, experience and competence in national technical and safety rules, as well as of the National Reference Document of each Member State involved with change"*. This specific point will be logged in the "minority opinion" section of this report;
- (c) concerning the mirrored requirements for the accreditation and recognition schemes, the following two diverging opinions were raised:
  - (1) many reviewers support the obligation for identical requirements and the same harmonised framework regardless whether accreditation or recognition is used;
  - (2) only the German NSA expressed that the national safety authority NSA shall not be requested to demonstrate to anyone its competence when the national safety authority is acting as either the recognition body or the assessment body. The Member State deciding on the use of the recognition scheme shall be responsible for its decision and endorse the NSA ability to perform the necessary work of either recognition body or assessment body. This specific point will be logged in the "minority opinion" section of this report;
- (d) before deciding on the use of the recognition scheme, Member States should consider whether it is not easier and simpler to use only the accreditation scheme, leaving thus the work to the professionals of the National Accreditation Bodies;
- (e) the revision of the legal text should strengthen the requirement to avoid the NSA, notified body, designated body or ECM certification body redoing the work of the assessment body as well as to avoid the assessment body redoing the work of the NSA, NoBo, DeBo or ECM certification body;
- (f) the accreditation/recognition of the assessment body cannot be considered as the ultimate solution for an automatic and full recognition of risk assessments. As there are often national specificities to fulfil, additional risk assessment and safety demonstration are necessary to be able to operate abroad. The accreditation/recognition is thus only a first step towards a long term objective;
- (g) Article 6(3) of the existing Regulation N° 352/2009 which lists the cases where the NSA may act as assessment body shall not be deleted in the revised text;
- (h) it is necessary to clearly state whether accreditation, recognition or both schemes are possible in a MS, as well as whether it is possible not having any assessment body in a Member State;
- (i) it would have been preferable to list in Annex II all the criteria to be fulfilled by the assessment body instead of referring to the ISO/IEC 17020 standard requirements and complement them with specific extra criteria in Annex II;
- (j) additional harmonised modules to be used by the assessment body should be developed to support further the accreditation/recognition and mutual recognition of the independent safety assessment report and of the results from the risk assessment;



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- (k) CER, UNIFE, EPTTOLA and UIP request that additional harmonised RAC are included in the current revision of the CSM while some NSAs estimate that additional RAC shall only be included in the CSM when agreement is reached within the railway sector;
  - (l) as Regulation (EC) N° 352/2009 extends to operational and organisational change in July 2012, does not the revision arrive too early? Maybe, it would have been better to gain experience over all type of changes (i.e. technical, operational and organisational) before revising more deeply the CSM on risk assessment;
  - (m) some minor comments are related to corrections of mistakes of references or textual changes to provide greater clarification (rewording etc.);
  - (n) finally, there were some comments on the understanding of the revised CSM. These are expected to be addressed in the guidelines for the application of the CSM on risk assessment.

The points on which consensus could not be reached in the working group are summarised in section 6.2.

### 3.3.5 NSA Network and NRB Network

The Agency reported regularly to the NSA network the progress with the developments of:

- the taskforce on the roles and responsibilities of the assessment body;
- the taskforce on the harmonisation of risk acceptance criteria;
- the taskforce on the revision of the CSM on risk assessment.

The comments and suggestions collected at NSA network meetings on those developments were regularly reported to and discussed in the working group in order to agree on how to take them into account. In particular, at the NSA network meeting of 6 and 7 September 2011, the following requests were raised:

- (a) by German NSA: in order to enable the Member States to put in place the accreditation and recognition schemes for the assessment body, the revised CSM shall allow a transition period of at least 1 year. This request was accepted in the working group;
- (b) by German NSA: when the internal assessment body of a railway undertaking (RU) or an infrastructure manager (IM) is recognised by the NSA, the NSA shall be allowed to amend the RU Safety Certificate or IM Safety Authorisation at its next renewal to include the statement that the RU/IM is able to act as assessment body. This request was accepted in the working group;
- (c) by UK NSA: (flexibility) when a significant change is not to be mutually recognised (e.g. for domestic market where the interoperability requirements do not apply), it is helpful to request the application of the CSM and to use the assessment body. But in order to avoid the costs of the accreditation/recognition, the CSM should relax some of the criteria to be fulfilled by the assessment body.

The working group accepted the idea and proposed that the assessment body shall *"fulfil at least the competency, independency and impartiality requirements of Annex II. The other requirements of Annex II may be relaxed in agreement with the national safety authority in a non-discriminatory way"*;



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- (d) by German NSA: when the NSA is acting as assessment body the CSM shall remove the obligation for functional independence of the NSA vs. the other functions assigned to the NSA in Article 16 of Directive 2004/49/EC. The working group accepted to delete the need for independence;
- (e) by German NSA: the existing text in Art. 7(2) is too weak: "... *the safety assessment report shall be taken into account by the NSA in its decision to authorise the placing in service of subsystems and vehicles*". Although the working group estimated the existing text sufficiently clear, the Agency proposed to change the requirement into: "...*the safety assessment report shall be accepted by the NSA in its decision to authorise the placing in service of subsystems and vehicles. The NSA may not request additional checks or risk analyses unless it is able to demonstrate without prejudice to Article 16 of Directive 2008/57/EC the existence of a substantial safety risk*". The working group accepted this modification of the text;

The scope and content of the revised CSM, as well as the results and comments of the public consultation, were presented and discussed at:

- **the NSA network meeting of 22-23 May 2012:**

The German NSA strongly supported that the revision and adoption of the revised CSM on risk assessment takes place as soon as possible as it clarifies some of the important points left open in Regulation (EC) N° 352/2009. For example, the accreditation/recognition of the assessment body answers the questions related to the check of the assessment body competence as well as the obligation of mutual recognition by the NSA of the safety assessment report of the assessment body.

The German NSA reminded their comments raised through the Public Consultation: see points (b) and (c)(2) above.

The Spanish NSA asked for clarifications on the accreditation/recognition schemes, on the coexistence of those two schemes in the same Member State, on the criteria in Annex II of the CSM, on whether the CSM for conformity assessment or CSM for supervision need to be revised to reflect the requirements for additional assessments/supervision by the NSA of the RU/IM ability to act as assessment body. The Agency committed to answer all those comments through the comment sheet received at the NSA network meeting.

The Slovenian NSA asked whether the revision was supported by an impact assessment, especially the costs of the accreditation/recognition vs. the criteria in Annex II of the CSM.

The Italian NSA underlined the conflicts of interests when the NSA is recognising assessment bodies and at the same time being their competitor when the NSA is acting itself as assessment body. The NSA also requested that when the assessment body is internal to the RU/IM, it shall always be recognised by the NSA who will check its independence.

The UK NSA reminded the need of relaxed criteria for the assessment body who will work on changes for which the interoperability requirements to not apply and where there is no need for mutual recognition of its results.

The UK and Danish NSAs asked what is the further process for harmonising additional risk acceptance criteria.



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- **the NRB network meeting of 29 May 2012:**

The railway sector insisted that the Agency continues the harmonisation of additional risk acceptance criteria. For the moment only one risk acceptance criterion is contained in Regulation (EC) N° 352/2009 (RAC-TS of  $10^{-9} \text{ h}^{-1}$ ). But the sector does need additional values for lower risk categories. Those are also necessary for safety related functions defined in TSIs, e.g. in LOC & PAS TSI.

- **the workshop with the RISC Committee members on 30 May 2012:** see section 3.3.6.

The results from the Public Consultation, as well as those additional comments raised at the meetings above, were presented and discussed at the working group meeting of 31 May 2012 in order to agree on the way to take them forward in the revised CSM on risk assessment.

### 3.3.6 Workshop with the RISC committee members and the European Commission

Before delivering the revised CSM on risk assessment to the Commission, on 30 May 2012, the Agency organised a workshop with the European Commission, the members of the RISC committee, the NSAs and representatives from railway sector organisations in order to:

- (a) present to the Member State represented in the RISC committee the scope and content of the revised CSM, as well as the results from the Public Consultation;
- (b) give the Member State and NSA representatives the possibility to raise questions and comments to be reported to the working group for discussion in order to agree on the necessary modifications;
- (c) anticipate the comments and discussions between the Commission and RISC that usually occur once Agency recommendations are delivered to the Commission;

There were not really new inputs or comments raised at the workshop. There was a repetition of comments already reported either through the NSA network or through the Public Consultation. The following main outcomes can be summarised:

- (a) the German NSA reminded their request to relax the requirements for the NSA when acting as either assessment body or recognition body;
- (b) the Austrian NSA, German NSA, CER and UNIFE representatives asked for explanations in the application guideline for the checks to be performed by the assessment body in relation with Articles 6 and 7 of the final draft of the revised CSM on risk assessment;
- (c) the French NSA underlined the ability of the assessment body to understand (*if it does not have knowledge, experience and competence in*) national technical and safety rules, as well as the national reference document of each Member State involved with change, in order to check the proposer's demonstration of the safe integration;
- (d) check the right version of the ISO/IEC 17020 standard to be referred to in Annex II of the revised CSM;
- (e) it is necessary to continue further with the harmonisation of the risk acceptance criteria for lower level severities. They are necessary for specifying safety related functions in TSIs (e.g. in LOC & PAS TSI).



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As explained above, the comments from the workshop were presented and discussed at the working group meeting of 31 May 2012 in order to agree on the way to take them forward in the revised CSM on risk assessment.

### **3.3.7 Final discussions and agreements in the working group**

In order to deliver the revised CSM on risk assessment to the European Commission, the Agency wrote a recommendation that encloses as appendix the revised CSM.

The Agency organised also a final working group meeting on 31 May 2012 in order to:

- (a) present to the working group the results from the Public Consultation, as well as the additional comments and remarks received at the NSA network and NRB network meeting and at the workshop with the European Commission and the RISC members;
- (b) agree on how to reflect the related comments and requests in the final draft of the revised CSM to be delivered to the European Commission by end of June 2012;
- (c) explain the content of the draft of the Agency recommendation which will enclose the revised CSM on risk assessment;
- (d) check whether the working group does not have additional comments on the impact assessment works on the roles and responsibilities of the assessment body and on the additional risk acceptance criteria.

The agreements reached in the working group are reflected in the final draft of the revised CSM on risk assessment. The other points on which consensus could not be reached are logged in the minority opinion section 6.2 of this report.

### **3.3.8 RISC Committee and delivery of the Agency recommendation to the EC**

Before delivering the Agency recommendation to the European Commission, with the appended revision of the CSM on risk assessment, the Agency presented the work and the associated feedback from the Public Consultation, NSA and NRB networks and workshop to the RISC committee on 6 June 2012.

Germany questioned the appropriateness of the revision work, suggesting that it could have been better to postpone it until having more experience on the use of the existing Regulation (EC) N° 352/2009. Such feedback could have included the experience with the use of the method for operational and organisation changes where its application will be mandatory from 1 July 2012. Then a deeper revision work could have been done.

Sweden and UK underlined the necessity to arrive very soon to an agreement on additional risk acceptance criteria because they are necessary for specifying safety related functions in TSIs (such as in the LOC & PAS TSI) and within the process of authorisations for placing into service structural sub-systems. France added nevertheless that the RAC topic is so important that we should not impose in hurry values that are not enough safe or on the contrary too costly ones for the railway sector. RACs should be set at the tight value and this requires time for validation and agreement among the sector organisations and the NSAs.





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UK and the European Commission added that if an agreement cannot be reached in the working group, then a political decision by the Commission and RISC shall be envisaged based on a proposal from the Agency.

A second Agency internal consultation was then organised with the support of all the operational units and the Legal Advisers of the Agency, as well as a coordination meeting with the Commission Legal Service. The first internal consultation took place during the Public Consultation described at step 3.3.4.

The Agency recommendation, with the revised CSM as appendix, was then signed by the Executive Director, and delivered to the European Commission early July 2012.

## **3.4 Other meetings and studies**

### **3.4.1 Meetings**

In addition to the meetings here above, the Agency took the opportunity to have some face to face coordination meetings to exchange information and to discuss some contentious details on the content of the recommendation. The following meetings have been held:

- 27/04/2010 - meeting on the topic of the CSM on risk assessment and the RAC in Paris with the CER/UIC-SSMG working group;
- 17/02/2011 – Coordination meeting with the European Co-operation for Accreditation (EA) in Vienna on the topics of accreditation and recognition of the assessment body;
- 16/03/2011 – Meeting with CER on the topic of RAC in Brussels;
- 29/03/2011 – Meeting with SNCF on the topic of RAC in Paris;
- 02/05/2011 – Coordination meeting with the French Ministry and the French National Safety Authority (EPSF) – Paris on the topic of mutual recognition of the safety report and work of the assessment body;
- 10/06/2011 – Meeting with CER on the topic of RAC in Brussels;
- 12/07/2011 – Visit to the CIM – Explanation of the application of the CSM;
- 07/09/2011 – Workshop on the accreditation and recognition schemes during the NSA Network 24<sup>th</sup> plenary meeting;
- 29/09/2011 – Meeting with CER on the topic of validation of the harmonised RAC in Brussels;
- 22/11/2011 – Meeting with CER on the topic of validation of the harmonised RAC in Lille;
- 15/11/2011 – Meeting with EIM to discuss their comments and questions related to the revision of the CSM on risk assessment in Brussels;
- 11/01/2012 – Meeting with UNIFE and CER on the topic of validation of the harmonised RAC in Brussels;
- 19/01/2012 – Meeting with EBA on the topic of RAC in Lille;





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- 01/02/2012 – Meeting with CER, UNIFE, EIM, UIP on the topic of validation of the harmonised RAC in Lille;
  - 27/03/2012 – Meeting with EBA to discuss their comments to the revision of the CSM in Lille;
  - 09/05/2012 – Meeting with UNIFE and CER on the topic of validation of the harmonised RAC in Brussels;
  - 30/05/2012 – EC workshop with the representatives of the Member States, NSAs, representative organisations and other railway actors;
  - Various ERA internal meetings for coordination on the LOC & PAS TSI, as well as two meetings of CSM working group experts and LOC & PAS TSI experts to discuss on the safety related open points of the LOC & PAS TSI (on 15/02/2011 and 19/01/2012);
  - Coordination with the working group for the revision of the OPE TSI is taking place. Based on this, the WG is now having a risk based approach for developing the revision;
  - Coordination with the ERTMS DMI working group for ensuring consistency with the CSM on risk assessment;
  - Coordination for ensuring that the Freight Wagon TSI is in line with the CSM on RA.

The Agency also participated regularly to NSA network meetings and to RISC in order to present the progress of the revision of the CSM on risk assessment. At the NSA Network meeting in September 2011, the Agency organised a dedicated workshop on the accreditation and recognition schemes to be put in place for the assessment bodies of the CSM regulation. During the RISC meetings, one of the main points highlighted was the role and responsibilities of the CSM assessment bodies. The development of the Risk Acceptance Criteria was presented also at NSA network meetings.

### **3.4.2 Seminars**

In order to ensure that the CSM on risk assessment is well understood, supported and correctly put in place, it is essential that the Agency participates to seminars to share and exchange information with the future users of the method. Therefore, the Agency participated, since beginning of 2010, to the seminars listed here below:

- 02-03/12/2010 – FORMS/FORMAT International Symposium, Braunschweig;
- 06/05/2011 – Seminar on "Liberalised rail - safer railways", Brussels;
- 23-24/05/2011 – WCRR, Lille;
- 04-05/11/2011 – "20<sup>th</sup> International Scientific Conference Transport 2011", Sofia Bulgaria;
- 25-30/06/2012 - ESREL Helsinki – Two presentations: one on open questions related to the further RAC development and another one on the revision of the regulation with focus on the assessment bodies N° 352/2009.



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### **3.4.3 Study on Risk Acceptance Criteria for Technical Systems and Operational Procedures used in various industries**

This study was performed in 2010. Its objective was to identify the types of Risk Acceptance Criteria (RAC) that are used throughout different industries, including if any in the railway field. The obtained inputs informed the Agency thinking mainly on the use of RAC within the other industrial sectors. The main conclusions of the study are summarised here after.

Harmonised Risk Acceptance Criteria (RAC) are used in aviation, nuclear and maritime sectors. Pan-industry RAC are also defined in a number of Member States

The report notes the existence of two options for setting RAC, as follows:

- RAC that are "evidence" based. Such RAC are based on historical evidence derived from an analysis of previous safety performance (possibly with an improvement factor built in).
- RAC that are aspirational or "technology-driving". Such RAC are normally set regardless of whether experience indicates they are currently attainable.

The results of the report indicate that evidence based goals are the norm when setting industry RAC. In fact all the industry schemes reported here (aviation, maritime) as well as the UK national scheme, are all set based on an analysis of past performance.

Such evidence based schemes are usually accompanied by a requirement to demonstrate that risks have been managed to a level where they are insignificant, or to a level where the benefits of further risk reduction are outweighed by the resources needed to implement them.

A number of variants of Safety Integrity Level (SIL) based techniques are used within industry for various purposes.

The detailed report of this study is uploaded on ERA's web site, as well as on the Extranet: see /13/.

### **3.4.4 Study on the assessment and acceptance of risks related to human activities within the European railways**

As described in this report, the work for the development of further harmonised RAC to be included in the CSM regulation has focused mainly on technical risks. Thus, as a second stage, in the next years, the topic of the acceptability of risks related to actions performed by human operators will also need to be addressed. These are often seen as risks arising from organisational and operational changes but they may also arise from technical changes as soon as the technical system needs to be integrated into the operational environment, to be operated and maintained by a human and similar. Therefore, since December 2011 (and expectedly until December 2012), the Agency is having a study performed by an external contractor in order to provide inputs on this topic and by doing so, in order to support this upcoming development.

Focused on the current practices of the railway actors within the European Union, this study seeks to give answer to the following questions about the state-of-the-art:

- How are the risks related to actions performed by human operators considered and assessed?



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- How is risk acceptance achieved and granted when considering risks related to actions performed by human operators?
  - How to compare formally between the mostly used approaches for granting of acceptance for risks related to actions performed by human operators?

Whereas the study will provide a list of appropriate formal comparison criteria for the investigated approaches, it will explicitly not make any recommendation on any preferable approach. Thus, the results of the study will be overtaken by the Agency future working groups and will be used, in order to take decisions on common proposals for these types of risks.

In order to ensure the acceptance of the results of the study, as well as their appropriateness in the current context, the study meetings with the contractor are supported by the participation and reviews of a group of experts (3 from CER, 1 from EIM, 1 from UNIFE, 1 from UIP and 1 from the Danish NSA). Additional coordination with the OPE TSI is made. As of today, the study seems to have a very good progress. Data has been collected and will be analysed in the next step of the study.



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## 4 CONTENT OF THE REVISION OF THE EXISTING REGULATION

### 4.1 Introduction

Originally, the main revisions to existing regulation N° 352/2009 on CSM on risk assessment were intended to be related to additional requirements on the assessment bodies and to the introduction of new categories for the harmonised risk acceptance criteria (RAC). Consequently, the introduction of new categories for harmonised RAC has been cancelled for the scope of this revision and only the additional requirements on the assessment bodies remained in the proposed revision text.

In addition to this, a few other revision requests were collected through comments received during the dissemination workshops or when presenting to the NSA networks the progress on the revision work of the regulation. These have also been addressed in the proposed revision text.

Finally, during the informal review process by the working group carried out during summer 2011, UIP reported that the entities in charge of maintenance shall be explicitly recognised in the CSM on risk assessment as actors who may act as a proposer. This has been reflected in the revised text, including the possibility to have an internal assessment body.

### 4.2 Revisions for assessment bodies

#### 4.2.1 Existing requirements

The existing regulation N° 352/2009/EC on risk assessment requires the assessment body to fulfil the criteria in Annex II of that regulation, but the regulation does not state who shall check the compliance with those criteria. This open point could lead to a lack of trust in the work performed by the assessment bodies, especially when the results from the risk assessment and the safety assessment report of the assessment body have to be recognised by another assessment body according to Article 7(4) of the Regulation N° 352/2009/EC.

One of the main objectives of the revision of the existing CSM on risk assessment is to establish, based on the results of the taskforce on the roles and responsibilities of assessment bodies, a common framework for evaluating and supervising the ability of assessment bodies to carry out their independent safety assessment of the correctness of the application of the CSM regulation by the proposer. To achieve this main goal, the Article 6 and Annex II had to be amended accordingly. In addition to that, a new Annex III had to be created in order to specify a harmonised structure for the safety assessment report to be written by the independent assessment body.

#### 4.2.2 Proposed modifications

##### **Article 6: Independent Assessment**

Based on the results of the taskforce on the roles and responsibilities of assessment bodies, as well as on a strong cooperation with the European cooperation for Accreditation (EA), the taskforce



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decided to request the compliance with the standard ISO/IEC 17020:1998 for the accreditation of the CSM assessment bodies.

Although the accreditation is the preferred scheme, it is not obligatory. Compliance with the European regulation 765/2008/EC enables also the use of a recognition scheme. However, the requirements for the accreditation and the recognition must be the same. Both of these two schemes were thus proposed in the revised CSM on risk assessment.

## **Annex II**

In addition to the requirements of the ISO/IEC 17020:1998 standard, the following additional requirements for the assessment body were specified in Annex II:

- competence in risk management process: knowledge and experience of the standard safety analysis techniques and of relevant standards;
- technical competence relevant to the type of change under assessment: knowledge of the component and/or subsystem under assessment;
- competence in the correct application of safety and quality management or in auditing management systems.

By analogy to Directive 2008/57/EC where NoBos are notified for areas of responsibility, the assessment bodies shall be accredited or recognised for the areas of competence or parts of it for which an essential requirement of safety exists.

In addition to the areas of responsibility mentioned in Directive 2008/57/EC and taking into account the requirement of demonstration of the safe integration within the process of authorisation for placing in service, the competence for covering the overall consistency and check of system approach for the risk assessment was added.

## **Annex III**

In order to facilitate the mutual recognition of the independent safety assessment report of the assessment body by another assessment body, it was important to specify a common structure for the safety assessment report. The associated requirements were laid down in this new Annex III.

### **4.3 Revisions for the harmonised risk acceptance criteria (RACs) – not included in the final Agency recommendation for the revision**

#### **4.3.1 Existing RAC in regulation 352/2009/EC**

The CSM on risk assessment provides only one harmonised "risk acceptance criterion", which refers to failures of functions of technical systems with a credible direct potential for catastrophic consequences. It can be found in paragraph 2.5.4 in Annex I of the existing regulation N° 352/2009/EC on CSM on risk assessment:

*"Where hazards arise from failures of technical systems not covered by codes of practice or the use of a reference system, the following risk acceptance criterion shall apply for the design of the technical system:*



*For technical systems where a functional failure has credible direct potential for a catastrophic consequence, the associated risk does not have to be reduced further if the rate of that failure is less than or equal to  $10^{-9}$  per operating hour."*

Already by the time when developing the Regulation N° 352/2009/EC, it was clear that further harmonised RAC (for lower severity consequences and further types of risks) will have to be provided. This is why, already in April 2007, an Agency taskforce was created, as a subordinate expert group to the CSM working group. This taskforce had the aim to work on further explicit RAC, with the initial objective to cover all (as many as possible) types of risks and consequence severities.

### 4.3.2 Initial proposal for further RAC

Based on the existing risk acceptance criterion, until May 2011, the work of the dedicated taskforce on the development of an extended set of harmonised risk acceptance criteria has led essentially to propose further RACs, to be applied also for other types of failure consequences.

The set of four RAC proposed by that taskforce is summarised in the table below.

**Table 6 – Taskforce RAC Proposal for the link between severity and acceptable rate of occurrence**

Severity of the estimated consequences	Acceptable rate of occurrence (R) of the analysed unwanted direct consequence (e.g. of an accident with catastrophic consequences)
multiple fatalities	$R \leq 10^{-9}/h$
single fatality and/or multiple serious injuries	$10^{-9}/h < R \leq 10^{-8}/h$
single serious injury and/or multiple light injuries	$10^{-8}/h < R \leq 3 \times 10^{-7}/h$
single light injury	$3 \times 10^{-7}/h < R \leq 10^{-5}/h$
non safety related consequence	not applicable

Further information on the approach and arguments for the above RAC definition can be found in /11/ (mainly) and /15/ (more generally).

An executive summary and a comparison with the existing CSM RAC is provided in /12/.

The above proposal and the two notes, which describe it (/11/ and /15/) have been regularly presented to the CSM working group. Before finalising them, they have also been formally reviewed by the working group, using the ordinary formal review template, in which the actors are able to give their comments, and where the Agency gives its answers. All actors and organisations have been offered phone calls for the finalisation of the documents. Finally, the documents have been agreed by all involved parties. Whenever possible, they have been presented also at NSA Network meetings.



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### 4.3.3 Main particularities of this initial RAC proposal

For the purpose of the current report, the most important particularities are summarised:

- The above set of RACs refers to failures of functions of technical systems. A human cannot be a cause of or a contributor to such a failure.

For various reasons, the sector has never been able to provide inputs on RAC for operational, organisational or in general "*risks related to actions performed by human operators*". *This is why the above proposal from the RAC taskforce and CSM working group does not refer to such types of risks. It is proposed to address them in eventual further revisions of the CSM on risk assessment. As described in point 3.4.4 of this report,* to support this future development, the Agency has already launched a study with the support of an external contractor. The aim of this study is to collect information on current practices and to provide formal comparison criteria, which can be used as a basis for the future discussions.

- The above initial proposal on RACs included a change of the existing term "catastrophic consequence", which is presently defined in Article 3(23) as "*fatalities and/or multiple severe injuries and/or major damages to the environment resulting from an accident*":
  - Due to lack of inputs on the RAC for *risks which lead to damages to the environment*, the above RAC proposal did not refer anymore to such type of consequences. Nevertheless, CER and some NSAs insist that RACs need also to be developed for such types of consequences. The reason for this is that for the normal freight traffic it is typical that the incidents and accidents often lead to more considerable damages to infrastructure and environment rather than fatalities and injuries (there are no passengers on the train). *Therefore, RAC for risks, which lead to damages to the environment need to be a subject of a future development;*
  - As a consequence of the work on the definition of the supplementary RAC, as well as in accordance with all inputs received from the representative organisations and the NSAs during the formal reviews, the above proposal puts the multiple severe injuries at a less demanding level for the frequency of occurrence of the associated failures.
  - After many discussions, it was suggested to remove the term "catastrophic consequence" from the definitions of the Regulation and start referring in Annex I of the Regulation and to precise text descriptions of the relevant severities of the assessed failures by integrating them in the RAC definitions themselves. This trick will avoid mistranslations and most importantly - misinterpretations of the short wording "catastrophic consequences", indications for which have already been received many times.

**Note:** On one hand side, people seem to make a shortcut and read and use only the term "catastrophic consequences", without referring to its definition, which is actually very precise. On the other hand, the Agency has spent many hours to argue with manufacturers who for various reasons tend to misinterpret the definition – even the legal advisors of the Agency had to be activated, in order to clarify better the hot discussions.

- There was an on-going discussion whether in the definition of the RACs to refer to minimally acceptable "points" (like the point of  $10^{-9} \text{ h}^{-1}$  in the current regulation), or to





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introduce “acceptability intervals” as shown in the above table (the acceptable frequency is e.g. " $10^{-9}/h < R \leq 10^{-8}/h$ ").

In the initial proposal of the taskforce, the solution with the “intervals” was chosen. Later on, in February 2012, the solution with the “points” was preferred back again. The opinion of the Agency is that none of the two solutions can solve the problem of not mature railway sector or NSAs or assessors who might expect a too precise evaluation. Both solutions are thus having a very comparable effect. Thus, other (better) solutions (e.g. dissemination, or similar) to the actual problem need to be sought.

- Linked to the proposed set of RAC was also a new proposal for definition of the term light injury. According to it, "*lightly injured person*" means any person injured who is hospitalised for less than or equal to 24 hours as a result of an unwanted occurrence, excluding attempted suicides. This definition is resulting mainly from the definition of seriously injured person, which is included in the CSI directive.

Many actors have hesitations about the usability of this definition because it is questionable if in a predictive study it can be foreseen whether due to an injury someone will stay in a hospital for less or more than 24 hours. Often this issue depends also on other types of national legislation (e.g. existence of rules for a minimum duration of a hospital stay under different types of circumstances). Nevertheless, the railways were given a sufficient opportunity to bring in a better proposal for this definition and none could suggest anything different.

The Agency recognises that it is hard to use the same definitions for the same terms both in the reactive part of safety (investigations, CSI, CST, etc.) and in the predictive/proactive part of safety (risk assessment). Nevertheless, the railway actors did not propose any better alternative. The only other imaginable solution would have been a suggestion for an improvement of the existing definition in the CSI directive, which would distinguish between a dead and seriously injured person not in the criterion of how long a person staid in a hospital, but on the criterion of what is an actual serious injury (badly burned, broken, etc. parts of the body, and similar).

- In accordance with the RAC defined in the current version of the CSM regulation 352/2009/EC, the above proposal for further harmonised RAC continued referring to functional failures with direct consequences. As a supplement to this, the proposal added also explicitly the option that if barriers exist outside the system under assessment, then the proposer could take them into account and derive a less demanding RAC for demonstration. The proposed definition of the term "barrier" was "*physical and/or non-physical means to reduce the frequency and/or the severity of the consequences of potential undesired events*". Later on, this proposal has been improved as a result of the RAC impact assessment.
- After long discussions it has been decided not to limit the above RAC proposal only to failures of electrical/electrical/programmable equipment or systems (shortly E/E/PES) (to which the standards EN 50126, EN 50128, EN 50129 typically refer) but to keep it open also for other types of systems (e.g. mechanical parts or systems. UNIFE gives general examples of cases when they have applied quantitative explicit risk estimation to mechanical parts or systems. Nevertheless, EIM, parts of CER, and some NSAs insist that for them it is not acceptable to refer the RAC proposal also to mechanical parts or systems if their applicability for these cases is not sufficiently validated. The Agency position on this item is that the proposer should retain his freedom (as this is allowed in Regulation N° 352/2009) to choose his approach for the explicit risk estimation. This freedom exists also



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nowadays and the Agency sees no arguments why this freedom should be removed and why innovation should possibly be stopped. Consequently, as the proposer is free to choose what risk acceptance principle to apply for controlling the identified hazards and risks, quantitative risk estimations will not be explicitly forbidden nor requested in the proposed changes to the CSM on risk assessment.

#### **4.3.4 Difficulties for agreeing on the RAC proposal**

##### **4.3.4.1 Discussions in the period December 2011 - 21<sup>st</sup> February 2012**

As explained in section § 5.3, in order to be able to agree with the working group on the figures to be proposed for the harmonised risk acceptance criteria, it was decided to use the impact assessment work for validating the figures developed by the taskforce on the risk acceptance criteria.

The impact assessment work on the risk acceptance criteria was launched in June 2011 with a deadline for 15 September 2011. At that time, at a meeting with the Agency, CER announced they would hardly be able to finish the impact assessment exercise with a common position on the topic until 15 September 2011. An agreement was met that CER can provide their feedback in two steps:

- 1<sup>st</sup> step: CER can answer a selected set of questions until 15<sup>th</sup> September, and;
- 2<sup>nd</sup> step: CER can get an extended deadline until 15 December 2011 for answering all remaining questions, as well as for providing the CER organisation position on the proposed risk acceptance criteria.

In order to follow the CER progress with this validation exercise, the Agency had two coordination meetings with CER (in September and November 2011). During these two coordination meetings, CER demonstrated a big progress with the review of the current practices for accepting risks related to functional failures of technical systems. Very interesting discussions on the faced challenges took place.

Similarly to CER, also EIM requested additional delay for delivering their results from the impact assessment. They were expected to be delivered before the end of December 2011. Nevertheless, until February 2012, when the Impact Assessment had to be officially declared as “closed”, EIM have never submitted an answer/position to this topic.

UNIFE submitted a filled-in impact assessment questionnaire, which is not supported by an organisation position paper. UNIFE answers showed that the manufacturers did not analyse the requirements from their contracts. On the contrary, UNIFE provided rather theoretical answers to most of the questions. By that time, in their answers, among others they have even pointed out their general fear that adding-up to the existing CSM regulation N° 352/2009/EC the proposed RAC for severities of different types than the "catastrophic consequence" one, might in some very special cases lead to an increased administrative burden. This position of theirs has changed significantly in the period since February 2012. Now UNIFE is one of the biggest defenders of the need for harmonised RAC.

During the coordination meeting with CER in November 2011, it became clear that the time until the end of December 2011 would not have been sufficient to achieve an agreement with all representative organisations and the CSM working group on the final RAC proposal. The Agency and CER estimated important to share the obtained results from the CER impact assessment (and



validation) exercise and to discuss them with the other representative railway organisations: EIM, UNIFE and UIP. CER requested a few weeks more to finalise the validation work and to be able to provide their organisation position paper on the proposed RAC.

Consequently, in order to give a chance to include in the current revision of the CSM on risk assessment the proposed RAC, after coordination with the EC, it was decided in December 2011 to postpone the delivery of the revised CSM on risk assessment by two months. This additional delay should have given sufficient time to all the sector organisations to finalise their impact assessment work and to provide their positions on the proposed RAC during the first two months of 2012. It was planned to organise an additional working group meeting in February 2012, in order to present and discuss the reached agreements with the whole working group (including thus also the national safety authorities), as well as to try to agree on "common harmonised risk acceptance criteria" to be reflected in the current revision of the CSM on risk assessment.

**On 15 December 2011**, CER sent their answers to the RAC Impact Assessment Questionnaire, as well as their position paper and results of half a year validation work of the risk acceptance criteria proposed by the taskforce on the RAC (refer to section § 4.3.2). CER proposals include:

- proposals for changes to the text for the RAC in the revision of the Regulation 352/2009/EC. These proposals suggest design targets less demanding than those initially proposed by the RAC taskforce and CSM working group, and;
- requests for additional explanations to be included in the guidelines supporting the revised CSM on risk assessment.

**On 11 January 2012**, CER and the Agency participated to a coordination meeting organised by UNIFE in order to discuss and agree on the RAC proposals. The following happened:

- CER presented to UNIFE their position on the proposed RAC. CER and UNIFE came upon some commonly agreed improvements of CER initial proposals to be shared with the Agency and the other sector organisations;
- Those CER-UNIFE agreed proposals were then discussed and amended further with the Agency already at the meeting, and later on off-line through e-mails.

**On 2 February 2012**, the Agency organised a coordination meeting with all sector organisations represented in the working group (CER, EIM, UNIFE, and UIP). The purpose was to find a common agreement on the final risk acceptance criteria to be proposed for formal review by the whole working group.

CER and UNIFE confirmed their position in support of the new proposals of CER. Although the present individual experts from EIM and UIP agreed with the discussed and proposed RAC, they could not yet provide their organisation official position. Shortly after the meeting, UIP confirmed their support to the commonly agreed text. EIM agreed with the proposed text but preferred to have it only in a guideline, for non-mandatory application and for validation.

The following proposals for revising the text in section §2.5 of Annex I of the existing regulation 352/2009/EC were agreed among the sector organisations:

*2.5.4. The following design targets shall apply to failures of functions of technical systems for which probabilistic targets can be demonstrated:*

- (a) For a failure that has a typical credible potential to lead directly to an accident affecting a group of people and resulting in fatalities, the*



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*frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than  $10^{-8}$  failures per operating hour appropriate to the assessed function.*

- (b) For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in fatality, or affecting a group of people and resulting in serious injuries, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than  $10^{-7}$  failures per operating hour appropriate to the assessed function.*
- (c) For a failure that has a typical credible potential to lead directly an accident affecting an individual person and resulting in a serious injury, but not fatality, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than  $10^{-6}$  failures per operating hour appropriate to the assessed function.*

*These design requirements shall be referred to as harmonised risk acceptance criteria for technical systems. The achievement of these design targets results in acceptable levels of safety when the safe integration of the technical system into the railway system has been demonstrated.*

*In (a) to (c) above, the term 'directly' means that no consideration is given to barriers external to the technical system that can reduce the frequency of the failure, or mitigate the severity of its consequence.*

*2.5.4a The harmonised risk acceptance criteria are required to be used only where mutual recognition is being sought, or where they are necessary to achieve a national level of safety. They represent the most demanding design targets that can be required. The proposer is also free to choose to use more demanding design targets for his own purposes.*

*2.5.4b When estimating the typical severity of the consequences of the analysed functional failure in order to derive which of those harmonised risk acceptance criteria is applicable for the assessed risk, the proposer shall apply the following conditions:*

- (a) If no trustworthy statistical data or expert estimates are available, then a more demanding but credible severity of consequence shall be chosen.*
- (b) The outcome to consider shall be an outcome greater than the average but not the worst case event.*

*2.5.4c For the case where failures of functions have external barriers affecting the frequency or consequence of the hazard then these can be considered and used to develop less demanding design targets. In this case, the mutual recognition, may still be possible, but is not automatic.*

*2.5.5. Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a more demanding criterion may be requested, through a national rule, in order to maintain a national safety level. In the case of additional authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.*

*2.5.6. Whenever the proposer demonstrates compliance with a harmonised risk acceptance criterion defined in point 2.5.4, the principle of mutual recognition of Article 7(4) is applicable for the acceptance of the assessed risk.*



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*Nevertheless, if the proposer can demonstrate that the national safety level in the Member State of application can be maintained with a less demanding criterion for risk acceptance than a harmonised risk acceptance criterion, then this less demanding criterion can be used instead of the harmonised one. However, in this case, the mutual recognition, which is applied whenever harmonised risk acceptance criteria are demonstrated, is not automatic.*

In addition to these agreed changes to the legal text, the Agency and sector organisations agreed also on the additional explanations to be included in the associated guidelines to help understanding how to use the proposed risk acceptance criteria.

#### **4.3.4.2 Working Group meeting of 21<sup>st</sup> February 2012**

The proposals agreed among the sector organisations at the coordination meeting of 2<sup>nd</sup> February 2012 were distributed for formal review and comments by the whole working group members on 8<sup>th</sup> February. The Agency processed the returned working group formal comments and presented them for discussion at the working group meeting of 21<sup>st</sup> February 2012.

Note: although the formal review was limited to the changes related to harmonised risk acceptance criteria, the working group examined again the unchanged text, agreed at the working group meeting of 23<sup>rd</sup> November 2011. The Agency analysed all comments in order to check whether some of comments were worth to be taken into account despite a previous review exercise.

During the meeting, to help the working group agreeing on the harmonised RAC, the Agency presented the latest feedback from the on-going impact assessment on RAC.

The meeting discussions between the sector and national safety authorities represented in the working group were quite animated as the new values agreed within the sector organisations (see section §4.3.4.1) are by one order of magnitude less demanding than the ones originally proposed by the RAC taskforce and working group. No one disagreed that CER have made an impressive validation work of the currently used figures for the risk acceptance. However, from the perspective of some NSAs the carried out work cannot be taken as representative for whole Europe. It gives a picture for the analysed functions within the few railway companies that took part in the validation exercise. Without additional time for reviewing the work and documentation produced by CER, the NSAs explained not to be able to give their position. Some NSAs also said that the presented validation from the sector was not “sufficient”. Nevertheless, they did not really manage to define clearly what could actually be “sufficient” for them.

Most of the meeting time was thus spent on trying to find an agreement on harmonised RAC. Due to lack of time, the other comments on the text agreed at the November working group meeting could not be discussed.

Despite all the efforts and intensive CER validation work on RAC, it was not possible to have a common view on harmonised and agreed RAC among all representatives in the working group for CSM on risk assessment. Consequently, the Agency could not make any proposal for further harmonised RAC to be included in the current revision of the CSM on risk assessment.

#### **4.3.4.3 Discussions in the period 21<sup>st</sup> February 2012 – end of June 2012**

After the working group meeting on 21<sup>st</sup> February 2012, as announced during the meeting:





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- the Agency has taken into account in the revised CSM the comments from the last discussions in the working group meeting;
  - the Agency has excluded from the revised CSM all parts related to further harmonised RAC; and;
  - the Agency has sent the revised CSM for Public Consultation on 8 March 2012 (i.e. without new RAC values).

After the decision not to include any new RAC text in the revision has been communicated, a series of actions have been taken by CER and UNIFE to jointly try to change the Agency and <working group position. These can be summarised in the following:

- 22<sup>nd</sup> February – A phone call from UNIFE and CER stating the disagreement with the decision and asking for more time for convincing those NSAs who disagreed with their proposal;
  - 23<sup>rd</sup> February – Official letter from ERA to CER and UNIFE saying that additional delay would not be possible;
  - 29<sup>th</sup> February – Official letter from UNIFE and CER asking that the RAC development is not stopped and that UNIFE and CER are given a 2 weeks' delay to build up a common RAC proposal;
  - 7<sup>th</sup> March – Official written answer from the Agency that the development is not stopped but due to the topic of the assessment bodies it would not be possible to tolerate a further delay of the revision;
  - 4<sup>th</sup> - 5<sup>th</sup> April - CER and UNIFE send in an e-mail their common proposal on RAC. As compared to the proposal from 21<sup>st</sup> February, the main new change of this new proposal is that it separates the most demanding consequence category (current RAC-TS) into two RAC, lowering by that the requirements for fatalities, which might occur in certain types of situations;
  - 18<sup>th</sup> April – The Agency sends an official answer by asking for justification of the proposal and asking for the answer to a few particular questions, which have remained unanswered also during the last working group meeting. ERA invited the two organisations to present their validation work and proposal at the workshop with the EC and the Member States on 30<sup>th</sup> May 2012;
  - 19<sup>th</sup> April – CER and UNIFE send to the Agency their official common proposal in a Word file, including also the details on texts that need to be included in the guideline documents. Shortly after the receipt of this e-mail, an e-mail from an individual expert from CER was sent to show his personal disagreement with some of the concepts of the CER/UNIFE proposal. The Agency answered right away, attempting to understand whether the position is agreed in the organisation or the organisations need more time to come to a common proposal;
  - April – The Representative Organisations UNIFE and CER, supported by EPTOLLA have submitted in their review comment sheets of the Public Consultation of the revision where they suggest that their proposal for RAC is included in the current revision;
  - 9<sup>th</sup> May – The Agency participates in a UNIFE meeting in Brussels, where also CER members are present. The CER/UNIFE proposal and parts of the presentations of CER for the workshop were discussed;
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- 18<sup>th</sup> May – CER and UNIFE send an official letter with their final text proposal. They confirm that they will present their work and proposal at the workshop on 30<sup>th</sup> May;
  - 30<sup>th</sup> May – Workshop of the EC on the revision of the CSM Regulation with the Member States, NSAs and the railway representative organisations. The afternoon was dedicated to the RAC topic. After a short introduction by ERA, CER presented the common CER/UNIFE proposal, giving various examples from their validation work and presenting answers to the questions from the Agency letter of 18<sup>th</sup> April.

The presentation was surrounded by a lively discussion with various participants. Various arguments were presented to answer to various questions. Nevertheless, many questions and arguments against the proposal were presented also by SNCF who officially never agreed with the CER proposal. Finally, after following the discussions for more than 1,5 hours and after seeing that there is no common agreement or convergence of the different points of view, the Agency decided to close the discussions. The arguments, questions and answers were clearly showing that the proposal is not mature enough to be acceptable for too many of the concerned parties. Consequently it was not possible to include the CER/UNIFE RAC proposal into the current revision. Further work needs thus to be done on this subject;

- 31<sup>st</sup> May – Meeting of the working group for the revision of the CSM regulation. Unexpected long discussions took place during this meeting. Most of the actors (except the German NSA) shown their willingness to search for a compromise and a common position. Nevertheless, a tour de table amongst the NSAs showed also that the majority of the NSAs have so far been only passive observers of this development and found it hard to give any comments or position on the topic. Even in this situation, the working group members expressed their willingness to try to find a solution before the adoption of the revision text (and after the Agency recommendation is sent to the Commission). The Agency confirmed once again that the revised CSM will not include any RAC amendments. It announced that the Agency will reflect internally on a possible way forward and will inform the working group members as soon as more information is available.

This was the last action concerning the proposal for further harmonised RAC to be included in the revision of the CSM regulation. The Agency confirms that this is a difficult development and it does not want to make proposals, for which it does not feel to have a sufficient validation. It is obvious that the sector is very far from any type of consensus on the subject and thus the topic has to be continued in order to achieve a trustable proposal.

#### **4.3.4.4 UNIFE position received just before finalising the accompanying report**

Before finalising this accompanying report, the Agency received the position of UNIFE on the harmonisation of further RAC values.

UNIFE wants to underline the importance of progressing in the field of common risk acceptance criteria for technical system across Europe. UNIFE estimates the upcoming revision of the CSM on risk assessment should be used to make some progress in that respect.

UNIFE therefore asks as minimum to have 2 categories, which only set targets for typical multiple fatalities and typical single fatality, as suggested below:





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- (a) *For a failure that has a typical credible potential to lead directly to an accident with ~~catastrophic consequences~~ multiple fatalities, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to  $10^{-9}$  failures per operating hour appropriate to the assessed function.*
  - (b) *For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in fatality ~~or serious injury~~ the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to  $10^{-7}$  failures per operating hour appropriate to the assessed function.*

The regulation should also explicitly add the information that this categorisation with (a) and (b) is not exhaustive. As soon as the railway sector is in a position of further evolution, UNIFE suggests having three risk acceptance categories where (b) also includes multiple serious injuries and (c) defines single serious injury at  $10^{-6}$  failures per operating hour. This would create the following three categories:

- (a) *For a failure that has a typical credible potential to lead directly to an accident with ~~catastrophic consequences~~ multiple fatalities, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to  $10^{-9}$  failures per operating hour appropriate to the assessed function.*
- (b) *For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in fatality ~~or serious injury~~, or affecting a group of people and resulting in serious injuries, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to  $10^{-7}$  failures per operating hour appropriate to the assessed function.*
- (c) *For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in a ~~serious~~ minor injury, but not fatality, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to  ~~$10^{-5}$~~   $10^{-6}$  failures per operating hour appropriate to the assessed function.*

As conclusion, UNIFE position is that the differentiation between different risk acceptance criteria is urgently needed by the railway sector (e.g. function essential to safety in the LOC & PAS TSI new draft).

Therefore UNIFE strongly suggests to the Agency to make sure that a step forward is taken in this revision of the regulation, and that complete set of RAC will be found as soon as possible.

UNIFE also expects this position to be part of the present accompanying report to the Commission.

The Agency position with respect to this latest UNIFE letter is that for the reasons previously described, the current revision cannot include any additional RAC for technical system. The first step in the UNIFE proposal was already discussed at the working group meeting of 31 May 2012. But an agreement could not be reached on the proposal for a RAC for a single person fatality. Consequently, the Agency does not recommend any change in the current revision of the CSM on risk assessment.



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## 5 SUPPORTING IMPACT ASSESSMENTS

### 5.1 Introduction

The revised CSM on risk assessment is accompanied by an impact assessment. The scope of the impact assessment is limited to the modifications of the existing regulation N° 352/2009 on CSM on risk assessment. The purpose is to evaluate the impacts of using accredited/recognised assessment bodies for significant changes and of introducing other categories than the RAC-TS for the harmonised risk acceptance criteria for technical systems.

The impact assessment has been developed by the Economic Evaluation Unit of the Agency in cooperation with the CSM team. The methodology for the impact assessment follows the ERA Economic Evaluation Guidelines /7/ and the EC guidance document on Impact Assessment /8/.

Both the method and the results of the impact assessment were presented and discussed several times both within the revision taskforce and the CSM working group.

Questionnaires have been sent to all members of the CSM working group and their respective organisations in order to support the evaluation of the potential positive and negative impacts of the modifications related to the assessment bodies and the introduction of new categories of risk acceptance criteria in the revised CSM on risk assessment.

### 5.2 Impact Assessment on changes related to Assessment Bodies

Concerning the changes to the existing regulation N° 352/2009/EC on the roles and responsibilities of assessment bodies, the Notified Bodies and Independent Safety Assessment companies have also been consulted for their opinions.

As explained in section § 4.2, the main modifications in the revised CSM are related to the accreditation and recognition schemes for the assessment bodies. Consequently, the impact assessment questionnaires aimed to collect the costs and benefits from these two schemes.

The conclusions from the questionnaire can be summarised as follows:

- for the majority of the respondents the two schemes bring added value;
- the dominant view is that the revised CSM would contribute to solve current problems regarding mutual recognition. The existing regulation N° 352/2009/EC on the CSM on risk assessment does not specify how and who shall check the requirements from existing Annex II and how to guarantee the same quality of the independent assessment work regardless which assessment body is appointed for that ;
- both accreditation and recognition schemes should be available according to the view of most of the respondents.
- the possibility for recognition of in-house assessment bodies was highlighted by several sector respondents as an important asset.

The SWOT (strengths, weaknesses, opportunities and threats) analysis suggests that trading-off is occurring with:

- the accreditation scheme is the preferred one among the respondents who put a high value on ensuring the mutual recognition than on the cost implications;



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- the recognition scheme is the preferred option for those respondents who place a high value on limiting the cost implications of the independent assessment work.

This result from the impact assessment provides an important justification for including both the accreditation and recognition scheme in the revised CSM on risk assessment.

The development of the accreditation scheme could be important with respect to increasing trust between the stakeholders. The implications for the NSA approval process with respect to rolling stock was highlighted as one important source of benefits derived from this proposal.

The results of the impact assessment suggest that these two schemes are likely to be of benefit for the sector in terms of contributions towards progress on mutual trust, reduction in redundant assessments and enhanced scope for cross acceptance. In this context, it is important to allow for both accreditation and recognition in order to address the different stakeholder needs.

The impact assessment has been largely qualitative due to the difficulty of providing precise quantitative information in this area. Quantitative estimation of the impacts would be subject to substantial uncertainty. However, some quantitative analysis has been performed and these confirm the finding that the benefits are likely to outweigh the costs.

The impact assessment findings finally suggest that it is likely that the benefits of the revision of the regulation 352/2009/EC will outweigh the costs over the medium to long term.

## 5.3 Impact Assessment of the RAC proposal

### 5.3.1 Purpose

The intention of this impact assessment was to use it amongst others also as an important mean for validating the proposal for harmonised risk acceptance criteria for lower risk consequence severities.

The impact assessment asked the railway actors to explain their current practices for accepting risks related to functional failures of technical systems:

- What requirements do railway undertakings and infrastructure managers specify in their contracts for functions of technical systems similar to those that should be proposed in the revised CSM on risk assessment?
- What do manufacturers receive as requirements whenever they sign a contract with a customer?

### 5.3.2 Main discussions around RAC Impact Assessment and validation

The expected inputs on the above two questions should have allowed the Agency to adapt its proposal and to be sure that it refers to the currently acceptable levels of risk.

Nevertheless, the received inputs on these questions were disappointing.

The main difficulties with this validation exercise were caused by the fact that most of the companies did not do any analysis and did not provide any data on the questions.



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Also the NSAs have often either left the important fields asking about the RAC values empty or answered only on a general basis, without really looking at what they really observe and experience as current practice e.g. within the processes of authorisations for placing into service.

Additionally, the work performed by CER showed that even when the companies chose to analyse the same functional failures retrieved from their real-life contracts, these functional failures are a part of a whole big system, which includes additional barriers dependent on the operational conditions of the particular company. Thus, the fact that presently the proposed RAC do not offer any harmonised approach for assessing barriers have made the comparison of the core results very resource demanding and difficult. It was also very hard to find failures of functions with direct consequences.

Concerning the topic of how to take barriers into account, from the very beginning the Agency proposed to suggest this development to CEN/CENELEC and to define only the requirement in the regulation that barriers can be taken into account. Nevertheless, from the validation exercise the involved organisations have requested the Agency to already develop more guidance both on the permissible types of barriers and on the question *"how to take them into account"*.

Further guidance seems to be needed also on the question *"what is the difference between the proposed harmonised RAC and other types of risk acceptance criteria defined at company levels or at national levels"*.

In the scope of the impact assessment of the RAC proposal, it could be observed that some actors are not sure whether the least demanding RAC category ( $10^{-5} \text{ h}^{-1}$ ) should exist. So far, this uncertainty is coming from some actors from CER, UNIFE, EIM and UIP. The Agency thinks that the category should not be excluded only based on the argument that *"now it is uncertain how often it will be used"*. Nevertheless, at the coordination meeting of 2<sup>nd</sup> February 2012, the represented sector organisations (CER, EIM, UNIFE and UIP) expressed their fear that a RAC for this least demanding category could create too much administrative burden. This point of view was shared and agreed on at the working group meeting of 21<sup>st</sup> February 2012. There was no NSA disagreeing that there shall not be any requirement for that category of severity in the current revision of CSM on risk assessment. Thus, the idea of proposing a RAC addressing "light injury" or "light injuries" had to be abandoned.

Based on different fears about NSAs interpretation of the proposed risk acceptance criteria, actors from UNIFE and some actors from CER are laying importance on the discussion on the usage of the alternative terms "multiple" (fatalities or injuries) and "more than one" (fatalities or injuries) within the RAC definition. Also terms like "a few" (fatalities or injuries) and "many" (fatalities or injuries) are thrown in the discussion. An intermediate compromise has been reached to refer to failures, which "would typically lead to multiple" fatalities (or injuries). "Typically" is explained as "a typical bad outcome", which is an outcome worse than the average but not the worst case event. The Agency has received a position from UNIFE that this was an acceptable compromise for them.

Concerning the discussion about the applicability of the discussed RAC also to mechanical parts and systems, the impact assessment has brought examples from different types of railway actors that they do perform quantitative explicit risk estimation also for this type of systems. Thus the Agency position on this subject is strengthened by this fact.



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### 5.3.3 Main conclusions from the RAC Impact Assessment and validation

The final report of the RAC impact assessment offers in a concise form all most important conclusions and discussions that are linked to its answers. Since it is not an aim of this report to repeat them one by one, it is recommendable to refer to the impact assessment report for more information.

Nevertheless, it is worth to mention that via the RAC impact assessment the agency received a qualitative indication, showing that harmonised RACs will:

- lower the amount of explicit risk estimations to be redone due to different RAC-requirements. Less redesigns of technical systems, as well as less paper work for safety cases are expected;
- improve cross-acceptance of technical systems.

Actors have indicated that the use of harmonised RACs for technical systems, which are not perfectly fine-tuned for all Member States, could lead that Member States could need to require more or less demanding values through Notified National Safety Rules (note: this is valid also with the current Regulation):

- this could on one hand side lead to administrative costs for the Member States if such notifications are needed;
- on the other hand side, this would lead to clear rules and transparency of the safety requirements for technical systems;
- it would also allow for the monitoring of notifications, the analysis of which would give feedback to the EC whether the RAC are set at the best level. Such a monitoring would allow for future fine-tuning of the proposed values.

The impact assessment received very limited information on the question of costs related to the harmonised RAC. Thus, the main identified costs are related to the process of defining appropriate RAC-values and getting them validated. Further costs could not be predicted by the railways.

Finally, the impact assessment showed that including harmonised RAC in the CSM regulation will further increase transparency on safety requirements and, if set at appropriate level, improve cross-acceptance of technical systems for explicit risk estimations. If no agreement could be found for the current revision, then the involved actors must imperatively agree on their actual criteria on the question “what sort of validation do they consider sufficient/acceptable”.



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## 6 WORKING GROUP OPINIONS

### 6.1 Working Group expectations - General opinions

The railway sector organisations (CER, EIM, UIP and UNIFE) regret that the working group could not agree what harmonised values to set for the risk acceptance criteria for lower level severities of risks. This resulted in cancelling from the scope of the current revision the changes previously proposed and discussed for those additional risk acceptance criteria. The railway sector organisations stress the need for additional criteria in order to help with the specification of safety related functions in TSIs (e.g. in LOC & PAS TSI) and facilitate the process of authorisations for placing into service structural sub-systems through the use of harmonised risk acceptance criteria. The sector organisations see a big advantage for the railway competitiveness to have more harmonised risk acceptance criteria for the technical systems and for the cross acceptance. Although this opinion was shared by the NSAs, the NSAs estimate nevertheless that additional validation work on RAC for lower level severities of risks is necessary to ensure that the existing level of safety is not decreased in the European Union railways.

Concerning the other changes to Regulation (EC) N° 352/2009, i.e. basically the revisions related to the assessment body, with the exception of the German NSA<sup>(1)</sup>, the other members of the working group support the revised CSM on risk assessment. The proposed requirements answer the questions left open in Regulation (EC) N° 352/2009 in relation to the checks of the assessment body competence as well as on the obligation for mutual recognition by the NSA of the safety assessment report of the assessment body. The sector organisations expect thus the revised CSM to enhance the mutual recognition of the application of the CSM and of the results of the risk management process specified therein, leading to less paper work and less additional demonstrations when applying for operation in other Member States.

Specifically in relation to the requirements on accreditation and recognition of the assessment body, the working group members estimate that<sup>(2)</sup>:

- both accreditation and recognition shall coexist in order to address different needs of different stakeholders of the railway sector;
- the same requirements and same framework shall be applied for both accreditation and recognition in order to provide the same quality of the independent assessment regardless whether the appointed assessment body is a recognised or an accredited one;
- if it is not already specified in existing national or European legislation, the proposer shall be free to appoint the assessment body he wants provided the assessment body fulfils the requirements of the revised CSM on risk assessment.

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<sup>(1)</sup> At the NSA Network meeting of 22-23 May 2012, the German NSA expressed nevertheless the opposite stressing on the importance to proceed with the adoption of the revised CSM on risk assessment as soon as possible to answer the points left open in Regulation (EC) N° 352/2009 on the checks of the competence of the assessment body and the requirement for mutual recognition by the NSA of its safety assessment report in the process of authorisations for placing into service structural sub-systems.

<sup>(2)</sup> Refer to "minority opinion" section below for the German NSA position.





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The working group acknowledges that a transition period is necessary to stakeholders for understanding and implementing the accreditation and recognition requirements in compliance with Article 7 and Annex II of the revised CSM. They welcome the trainings the Agency will provide to the National Accreditation Bodies and recognition bodies on the CSM on risk assessment, the ISO/IEC 17020 and ISO/IEC 17011 standards during this transition period.

To help further the sector with the application of the revised CSM on risk assessment, the working group requested the update of the application guideline with additional explanations for the revisions of Regulation (EC) N° 352/2009.

## 6.2 Minority opinions on certain contents

As described above, all revisions were not agreed unanimously by the CSM working group. Some members expressed divergent opinions for the following items.

### **1. By default the change shall be significant unless ... (German NSA)**

As described in section § 2, the Agency was not able to collect a lot of experience on the application of Regulation (EC) N° 352/2009. Consequently, due to this lack of usable information, the Agency was not able to include in the scope of the revision any modification of concepts for assessing the significance of the change under assessment.

German NSA request: to drive the proposer in deciding easier that the change is significant rather than non-significant, the logic for entering the risk assessment process shall be reversed. Instead of applying Article 5 and Annex I only when the proposer decides that a change is significant using Article 4 (i.e. as specified in existing text), the German NSA requires to replace the logic by the following requirement: *"If an authorisation for placing into service a structural sub-system, a safety certificate or a safety authorisation is required the change shall be significant unless the proposer can prove applying Article 4 that the change is not significant"*. At least in those cases, the proposer would always be obliged to apply fully the risk management process of the CSM. The fear is that manufacturers who do not have obligation for having an SMS would not perform any risk assessment in case the change is not significant in the process of authorisation of placing into service a structural sub-system.

This concern is shared by neither the Agency nor the other members of the working group, although some other NSAs acknowledge the difficulties and hesitations of proposers in deciding that only some of their daily changes are significant and need full application of the CSM on risk assessment. In 2007, the "taskforce on the significant change" checked whether a new authorisation for placing into service structural sub-systems, an update or renewal of an RU safety certificate or an IM safety authorisation are always a significant change. This taskforce concluded that sometimes there is indeed some overlap between a "significant change" under the meaning of the CSM on risk assessment and "a substantial or major change" in the sense of Articles 10 and 11 of Directive 2004/49/EC or "a major modification, upgrade or renewal of a structural sub-system" in the sense of Directive 2008/57/EC. But all those cases are not equal. Consequently, it was decided that it is not possible to state in the legal text that every "substantial or major change" in the operating conditions or every "major modification, upgrade or renewal of a structural sub-system" is significant from the CSM on risk assessment point of view. For example there are technical changes not safety related that require a new





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authorisation for placing in service structural sub-systems but where no risk assessment is needed. For example, for some technical compatibility requirements or when changing the numbering of wagons, the change is not impacting safety (so risk assessment is not necessary) but a new authorisation for placing in service is required.

The Agency position is that as long as sufficient experience is not available on the application of the CSM on risk assessment, the concepts in Article 4 of the CSM for assessing the significance of changes shall not be modified. Such an unjustified requirement would create additional costs to the railway sector while there is no need for applying the CSM.

## **2. Assessment body competence in national safety rules (German NSA)**

To enable the assessment body to check the correct application of the CSM risk management process described in Annex I as well as the appropriateness of its results, the following criterion (d) shall be added in point (1) of Annex II of the CSM: *"the assessment body shall have knowledge, experience and competence with the National Technical Rules, the National Safety Rules and the National Reference Document of every Member State involved with the change"*. This point of view was initially also shared by the French NSA. However, the French NSA agreed with the latest modifications of Annex II of the CSM at the working group meeting of 31 May 2012 and agrees that those criteria are now fulfilled.

This German NSA point of view was shared by neither the Agency nor the other members of the working group. The Agency position is that:

- (a) the assessment body shall not redo the work already performed by the notified body or the designated body: refer to Article 6(3) of the revised CSM;
- (b) the assessment body competence in different areas of the railway system, including the system approach view, listed in Annex II cover also the ability of the assessment body to understand any relevant national safety or technical rule related to the area of competence in which the assessment body is accredited/recognised. Consequently, the assessment body is expected to fulfil the need expressed by the German NSA at the extent required for the assessment body;
- (c) the accreditation of the assessment body against any set of national safety or technical rules is contradictory to basic Regulation N° 765/2008 on the accreditation. By principle an accredited assessment body shall be able to deliver his services in whole Europe while an accreditation against national rules will restrict his area of action solely to the Member State whose rules the assessment body knows;
- (d) it is unclear in what sharing of responsibilities between the proposer and the assessment body this requirement would result. Assigning responsibility for safety to the assessment body is against article 4(3) of Directive 2004/49/EC which sets the responsibility for the safe operation and control of the associated risks on the railway undertaking and infrastructure manager. The primary and main responsible for the correct implementation and demonstration of compliance with national safety and technical rules is the proposer. It is the responsibility of the designated body to check the compliance with the national safety and technical rules;
- (e) the CSM on risk assessment does not require the assessment body to act as a "validation or approval" authority for the correct implementation of the national rules. The assessment body shall not replace any function from the former homologation process in the CENELEC 5012x standards.



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In compliance with section 10 of the ISO/IEC 17020 standard referred to in Annex II of the CSM, the assessment body is required to check, based on sampling and audit assessment techniques, whether the risk assessment results are suitable to achieve safely the objectives of the change. That work will thus cover the check of how the proposer demonstrates compliance with the applicable national safety rules. There is thus no need for the assessment body for having beforehand specific "knowledge, experience and competency with the national safety rules and the national reference document of each Member State involved with the change;

- (f) any additional help of how the requirements in the CSM regulation can be achievable can be provided in the associated guideline for the application of the CSM.

### **3. NSA acting as recognition or assessment body should not demonstrate their competence (German NSA)**

The German NSA requires the withdrawal of the recognition scheme for the NSA when acting as either the recognition body or assessment body. The NSA shall not be asked to demonstrate his competence for those functions because Directive 2004/49/EC does not require such a demonstration of competence by the NSA. The Member State is kept for responsible for the NSA competence for any function the Member State would assign to the NSA.

Those concerns are shared by neither the Agency nor the other members of the working group. The Agency and working group position is that:

- (a) the work of a recognition body and of an assessment body require additional competence to the ones fulfilled by the NSA to carry out the tasks in Article 16 of Directive 2004/49/EC, in ECM Regulation N° 445/2011 and in Directive 2008/57/EC within the process of authorisations for placing into service structural sub-systems. Consequently, in order to ensure the same quality of work of the assessment body (if it is the NSA or recognised by the NSA) and permit the mutual recognition of its independent assessment, the same requirements shall be fulfilled by the NSA as by any other actor carrying out the same work;
- (b) the impact assessment of the assessment body revisions show that the same mirrored requirements shall apply for both accreditation and recognition regardless who will fulfil the specified functions. Except from the German NSA, there was not request to relax the requirements and criteria for the NSA. The NSA must be competent to fulfil the functions of recognition or of an assessment body, otherwise it is questionable how could the results of its work be cross-accepted by other parties;
- (c) in addition to that, the basic Regulation N° 765/2008 on accreditation explains that accreditation is the preferred Commission approach. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, in case of recognition, by virtue of article 5(2) of the Regulation 765/2008/EC the Member State shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the recognition body it selects for the implementation of the European Union harmonised legislation. In order to achieve a similar level of quality and trust as expected through accreditation, the requirements and



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rules for the evaluation and surveillance of assessment bodies in case of recognition should be equivalent to those used for the accreditation.

- (d) any additional help can be provided in the guidelines for the application of the CSM.

#### **4. Further harmonised modules for accreditation/recognition (German NSA)**

The German NSA, supported by the Spanish NSA, proposes to develop further harmonised examination modules to support the national accreditation bodies and recognition bodies in ensuring that the competence of all assessment bodies is acknowledged on exactly the same criteria, same principles and in a similar manner in all Member States. Those modules would increase the trust between Member States and facilitate further the mutual recognition of the work of the assessment body.

The Agency position is that the requirements in the revised CSM should not be changed. The Agency coordinated with the European Cooperation for Accreditation (EA) in order to check whether the requirements and criteria defined in the revised CSM on risk assessment are clear and sufficient to permit the accreditation (and recognition) of the assessment body. Specifying stricter and more detailed criteria would reduce the number of possible assessment bodies which would fulfil all needed criteria. The effect with more detailed criteria would be negative and counterproductive for the European railway sector. The possible divergence between the different national accreditation and recognition bodies is mitigated through the "peer evaluations", and the subsequent alignment on the harmonised assessment techniques, that will be ensured by EA for the accreditation scheme and by the European Railway Agency for the recognition scheme. The accreditation and recognition bodies will find answers to their questions in Annex II of the revised CSM, in the ISO/IEC 17020 and ISO/IEC 17011 standards.

Consequently, the Agency recommends that the requirements on both the competence of the assessment bodies and on the modules to be used by accreditation/recognition bodies are not changed. The danger is to block the whole process and to lead to a serious lack of competent assessment bodies on the European railway market.

The Agency recommends also monitoring the experience with the application of the provisions in the revised CSM in order to check whether accreditation and recognition schemes deliver the expected results and to collect the difficulties, missing requirements or over specifications. It is only through the use of those proposed schemes that sufficient information can be gathered to improve the method in a future revision exercise.

#### **5. More detailed criteria to be fulfilled by the assessment body**

The German and Austrian NSA, as well as CER and UNIFE, suggested defining more detailed criteria for the assessment body than the ones provided in Annex II of the revised CSM.

Based on the information from coordination with the European Cooperation for Accreditation (see point 4 above), the Agency position is that specifying stricter and more detailed criteria would reduce the number of assessment bodies, leading thus to negative and counterproductive effects on the European railway sector. Divergences between the ways of working of different national accreditation and recognition bodies can be mitigated through the "peer evaluations", and the subsequent corrective measures towards harmonised assessment techniques. Those peer evaluations will be organised by EA for the accreditation scheme and by the European Railway Agency for the recognition scheme.



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The Agency will also organise trainings for national accreditation and recognition bodies in order to explain what they have specifically to check for the CSM on risk assessment. In addition to that, the accreditation and recognition bodies will find answers to their questions in Annex II of the revised CSM, in the ISO/IEC 17020 and ISO/IEC 17011 standards. Any additional explanations can also be included in the updated guidelines for the application of the revised CSM on risk assessment.

Consequently, the Agency recommends that the requirements on both the competence of the assessment bodies are not changed. The danger is to block the whole process and to lead to a serious lack of competent assessment bodies on the European railway market.

### 6.3 Other points

The Agency would like to underline the following last points.

#### **1. Lack of independence of the NSA between the different functions performed by the NSA**

During the development of the roles and responsibilities of the assessment body and later on during the revision of the CSM on risk assessment, it was clearly pointed out that the national safety authority shall be able to act as assessment body. However, in that case the Agency and the associated taskforces estimated important to request the same criteria for competence and independence of the NSA as for any other assessment body. This independence was judged particularly important in the following cases if the NSA acts as the assessment body:

- (a) where a vehicle needs an authorisation (or additional authorisation) for placing in service according to Directive 2008/57/EC;
- (b) where an authorisation for placing in service a structural sub-system is necessary as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC;
- (c) where a safety certificate/authorisation has to be updated or revised following:
  - (i) an alteration of the type or extent of the operation;
  - (ii) in case of substantial changes to infrastructure, signalling, energy supply, or the principles of its operation and maintenance;
  - (iii) in case of substantial changes to the safety regulatory framework.

At least in such cases, there should be clear separation in the functions of the NSA as the authorisation body as defined in Article 16 of Directive 2004/49/EC and in Directive 2008/57/EC and its functions as assessment body. This requirement was questioned several times by the German NSA of the CSM working group. At the NSA network meeting of 6-7 September 2011, the German NSA representative also requested to remove this obligation for functional independence of the NSA acting as assessment body vs. the other NSA functions.

The comment was finally presented and discussed at the working group meeting of 14 September 2011. The Agency position was that if the same NSA staff is deeply involved as assessment body in those cases and also issuing the authorisation for placing into service structural sub-systems, the NSA might oversee potential problems that it could identify if the NSA was fulfilling this requirement for independence. But this point view was not shared by the other members of the working group. During a "tour de table" all working group members explained that we should trust the NSA in managing this independence without imposing it explicitly by law. The working



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group accepted thus to delete from the revised CSM the requirement for independence when the NSA is acting as assessment body.

In addition to that, during the internal Agency consultation, some concerns have been raised in relation to the multiple roles being assigned to the NSA by the European railway legislation. The NSA may act as both "recognition body" and "certification body" in addition to their roles defined in Article 16 of Directive 2004/49/EC and in Directive 2008/57/EC. That might create different situations of conflicts of interest or possible discrimination in the railway market. For example:

- (a) an NSA might be in the position of evaluating the work performed by the NSA itself (e.g. NSA both assessment body and authorizing body for a structural sub-system);
- (b) an NSA might be at the same time a "competitor" and "supervisor" of an assessment body it has recognized;
- (c) the NSA could be in a situation to act as designated body, while the safe integration is checked by an assessment body recognised by the NSA, and the NSA has to issue an authorisation for placing into service a structural sub-system.

Because of those complex situations, independence and separation of functions between the different roles of the NSA would have been preferable. But as the working group did not support the Agency position, the Agency recommends to monitor the experience with the application of the CSM on risk assessment and to check whether this independence is naturally managed by the NSA when fulfilling all the functions described above. Then based on such a feedback changes of requirements and improvements of the CSM on risk assessment can be imagined for those parts.

## **2. Requirement for surveillance of assessment body by the recognition body**

During the coordination with the EC Legal Service and the Agency internal review before the signature of the Agency recommendation by the Executive Director, the lawyers noticed that:

- (a) the CSM on risk assessment allows the use of a recognition scheme for acknowledging the competence of the assessment body whereas the preferred European solution for that should be the "accreditation" governed by the Regulation 765/2008;
- (b) Regulation 765/2008 allows other means of achieving the same requirements, e.g. the use of recognition. However, in case of recognition of the assessment body, the lawyers point out that by analogy to the accreditation scheme defined in the basic Regulation 765/2008, the recognition shall be requested explicitly to perform surveillance and, if needed, to revoke the recognition.

This requirement was considered initially by the taskforce on the roles and responsibilities of the assessment body which recommended using the ISO/IEC 17011 standard. The actual use of this ISO/IEC 17011 standard by the recognition body is then to be checked during the coordination meetings with EA (for the accreditation scheme) and peer evaluations (for the recognition scheme). This will be described further in the guideline.

Consequently, as from the legal point of view, the revised CSM left implicitly freedom for interpretation on whether surveillance is mandatory in case of recognition, in order to ensure that it provides also credible results, the lawyers suggested including requirements for surveillance and revocation of recognised assessment bodies. Consequently, the following text was added in Article 7 of the final draft after the working group meeting of 31 May 2012:





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*By analogy to the requirements in Article 5(3) and 5(4) of Regulation (EC) 765/2008/EC for accreditation, the recognition body shall ensure the following:*

- (a) conduct periodic surveillance in order to verify that the assessment body it recognised still satisfies the criteria set out in Annex II during the validity of the recognition;*
- (b) if the assessment body no longer satisfies the criteria set out in Annex II, limit the scope of application of the recognition, suspend or withdraw the recognition, depending on the degree of non-compliance.*

The details for the “general requirements for the accreditation bodies accrediting conformity assessment bodies” are provided in the ISO/IEC 17011 standard. As the explicit reference on the use of this standard in the revised CSM was not discussed in the working group, the Agency proposed to quote the standard in the application guideline. Indeed, by analogy to accreditation, the ISO/IEC 17011 standard can also be used by the recognition body to understand among others how they have to be organised, what they have to check when recognising an assessment body, how to conduct the assessment activity, how to implement the surveillance and how often, etc.

Before delivering the recommendation to the Commission, the Agency consulted the working group by e-mail. With the exception of Germany which answered that explicit requirements for surveillance and revocation of recognition are not necessary (they are already part of the German national law), none else disagreed to add the requirement in the final draft of the revised CSM.

### **3. Links between the recognition of the assessment body by the NSA and the CSM for conformity assessment and CSM for supervision (Spanish NSA)**

The Spanish NSA requested the update of the CSM Regulations N° 1158/2010 and N° 1169/2010 for conformity assessment and the upcoming CSM for supervision with the additional criteria to be checked by the NSA within the RU and IM safety management system when they want to act as assessment body. It could be necessary also to modify Annex III of Regulation 653/2007 in order to include in the Application Form the provisions adopted by the railway undertaking to meet the requirements to become an assessment body.

The Agency explained that all requirements to be used for both accreditation and recognition are already included in the revised CSM on risk assessment. They cover both the initial assessment of the assessment body and periodical surveillance to be carried out by the national accreditation body and the recognition body. Additional details are provided in the ISO/IEC 17020 and ISO/IEC 17011 standards on how national accreditation and recognition bodies have to be organised, what they have to check when assessing an assessment body, how to conduct the assessment activity, how to implement the surveillance and how often, etc. Those will also be explained further in the updated guidelines for the application of the revised CSM on risk assessment. Consequently, the Agency position is that there is no need for revising with further details the existing regulations on CSM for conformity assessment and CSM for supervision.

Concerning the update of the form/template of the safety certificate in Annex III of Regulation 653/2007, although it might be a possibility the existing template contains a spare field where the NSA can register the RU ability to act internally as assessment body. Consequently, the Agency suggests for the time being not amending Regulation 653/2007.



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#### **4. Case assessment body work is part of the tasks of the notified body (Spanish NSA)**

In Article 8(3) of the revised CSM, it is written that *"if a risk assessment is required by a relevant technical specification for interoperability (TSI) ... the independent assessment shall be part of the task of the notified body, unless otherwise prescribed by the TSI"*.

In relation to that, the Spanish NSA asked for writing that "it could be part of the notified body work" instead of "it shall be part of the notified body word". Its point of view is that the CSM assessment tasks (safety essential requirement as required in the TSI) shall not be restricted only to a NoBo. The Spanish NSA does not understand why in the case of the Control Command Signalling TSI (CCS TSI) the proposer is not free to choose the assessment body (NSA, notified body, designated body, an in-house independent safety assessor or an external independent safety assessor) and why the proposer must use a NoBo. Is there any reason for that?

The Agency understands the arguments given by the Spanish NSA. However, in case compliance with the CSM on risk assessment or with risk management standards (such as for example CENELEC 50126, 50128 and 50129) is required in a TSI, the basic legislation in Interoperability Directive 2008/57/EC gives the role to the notified body to verify the conformity with the TSI requirements, including thus compliance with safety requirements. Consequently, the secondary legislation (CSM on risk assessment) cannot change this responsibility.

If the TSI requires the use of the CSM, the responsibility to check the correctness of the application of the CSM on risk assessment and of the appropriateness of the results falls on the notified body. Consequently the word "shall" must remain in the text.

How to deal if the notified body does not have the competence required in the CSM to perform the independent assessment work? This is already described in the existing guidelines for the CSM on risk assessment.

Practically, as the applicant/proposer is appointing both the notified body and CSM assessment body, the applicant/proposer can solve this legal obligation through contractual arrangements. The applicant/proposer can thus ask the notified body and the assessment body to find an agreement on who will do what part of the work and who will mutually recognise the work of who. In practice this should not be a real problem.





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## 7 CONCLUSIONS

### 7.1 Part I: experience with the existing regulation 352/2009/EC

Discussions within the working group and information gathered via the annual safety reports of the national safety authorities indicate that the CSM concepts are progressively being set up among the railway actors through Europe. The experience and the understanding of the method and of its requirements are progressively growing. Nevertheless significant disparities are still visible throughout Europe or among railway actors in the same country. There is thus not a lot of experience available for the moment. One of the possible reasons might be the advanced stage of many projects with respect to the date of entry into force of the Commission regulation N° 352/2009/EC or the fact that its application is mandatory only since July 2010.

The Agency has organised dissemination workshops on the CSM on risk assessment during 2009 and 2010, i.e. before the CSM entered into force. However, despite those efforts, during the workshops the Agency is currently organising on the safety management systems and CSM for conformity assessment, many railway actors are requesting the Agency to reopen and continue further the dissemination work on risk assessment. The European railway sector is asking for repetitive workshops, additional training material to be developed and many examples of application of the risk assessment process to be collected and made available.

In addition to that, very often explanations about the scope and the applicability of the CSM on risk assessment are requested during brainstorming on other Agency developments or for example when dealing with DV 29.

Consequently, the Agency suggests continuing further the education and training of the stakeholders by additional dissemination workshops and/or by developing a training programme in the next years. This will be certainly reflected on and suggestions on how it can be done will be provided.

### 7.2 Part II: revision of the regulation 352/2009/EC

Concerning the revisions for the roles and responsibilities of assessment bodies, the Agency believes the revised CSM on risk assessment clarifies important points left open in Regulation (EC) N° 352/2009. The accreditation and recognition schemes provide an answer on who can check and how to check the competence of the assessment body. The relation between the work of the assessment body and the obligation for mutual recognition by the NSA of the safety assessment report of the assessment body are clarified.

Although the development was regularly presented at the NSA network and RISC meetings without major comments, because the received comments were taken into account in the revision, during Public Consultation and at the NSA network meeting of 22-23 May 2012, the German NSA raised the comments presented in section § 6.2.

The Agency would like also to highlight the following two points:

- it is necessary to have a reflexion on the possibility to provide trainings to address the sector difficulties in applying the CSM on risk assessment and in finding appropriate competence for assessment bodies on CSM on risk assessment;



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- when the recognition scheme is applied for recognising assessment bodies, it necessary to organise the necessary peer evaluations among the recognition bodies. Indeed, following the discussions with the European Co-operation for Accreditation (EA), it is important to have a mirror between the accreditation and recognition schemes. The peer evaluations organised by EA in case of accreditation among the "National Accreditation Bodies" should be implemented by an entity that shall ensure at the end the same quality of the recognised assessment bodies as the accredited ones. This "facilitator role" has been allocated to the European Railway.

Concerning the proposal for further harmonised risk acceptance criteria for technical systems, the development work is finished. The figures proposed by the dedicated taskforce (refer to section § 4.3.2) are in line with those provided in the existing version of the CENELEC EN 50 12x standards. However, the risk based approach is a new concept for many actors. Many of them seem not to be mature enough for adopting the notion of "risk acceptance". Consequently, as explained in section § 4.3.4.1, as a first trial the Agency decided in December 2011 to delay by two months the delivery of the revised CSM, in order to try to reach a consensus with the sector organisations and the NSAs represented within the working group on whether to include in the current revision a proposal for RAC, or not. A consensus has been reached with CER, UIP and UNIFE on the proposed RAC, as well as the EIM expert represented at the coordination on 2<sup>nd</sup> February 2012.

Despite all the efforts and intensive CER validation work on RAC, it is still very difficult to have a common view on harmonised and agreed RAC among the majority of representatives in the working group for CSM on risk assessment. Consequently, the Agency cannot yet make any RAC proposal that could be included in the current revision of the CSM on risk assessment.

However, the railway sector organisations stress the need for additional criteria in order to help, amongst others, with the specification of safety related functions in TSIs (e.g. in LOC & PAS TSI) and facilitate the process of authorisations for placing into service structural sub-systems through the use of harmonised risk acceptance criteria. The sector organisations see also a big advantage for the railway competitiveness to have more harmonised risk acceptance criteria for the technical systems and for the cross acceptance.

### **7.3 Co-ordination with CEN/CENELEC**

The Agency is having regular meetings with the chairman of the working group 14 of CEN/CENELEC in order to share the progress of development of the CSM on risk assessment. The objective is to permit CENELEC to include in the on-going revision of the EN 50 12x standards tools and techniques that can be applied to address the requirements of the CSM on risk assessment.

The coordination between the Agency and CEN/CENELEC has started. But it is not yet sufficient. For example, at the last coordination meeting, it appeared that CENELEC does not provide yet any guidance on how to perform operational and organisational risk assessments, which seem to be the most difficult areas where the railway sector would need the greatest help.

Consequently, the started coordination with CENELEC must be continued and indeed intensified.



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#### **7.4 Mistakes in translation of existing Regulation N° 352/2009**

In the scope of the revision work of the CSM on risk assessment, members of the working group have reported to the Agency about important inconsistencies in the translations of different terms from Regulation N° 352/2009 in their mother languages.

In order to inform the Commission about those problems, the Agency provides in ANNEX II of the present report the mistakes that were reported in the working group on the CSM on risk assessment.



## ANNEX I: EXPERIENCE WITH THE USE OF REGULATION 352/2009 IN THE NSA ANNUAL SAFETY REPORTS

The table below gives the extracts of the experience with the application of the CSM Regulation N° 352/2009 in the European Member States.

**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
AT	<p>As an aid to help and support users of the "Common Safety Method on Risk Evaluation and Assessment" and so that these common safety methods should be used in a uniform manner throughout the country, the Federal Ministry of Transport, Innovation and Technology (BMVIT) drew up a "Guide to Regulation (EC) N° 352/2009" (Leitfaden zur Verordnung (EG) Nr. 352/2009 [available only in German]):</p> <p>Website: <a href="http://www.bmvit.gv.at/verkehr/eisenbahn/sicherheit/gmethoden/index.html">www.bmvit.gv.at/verkehr/eisenbahn/sicherheit/gmethoden/index.html</a></p> <p>In their safety reports railway organisations reported <b>twelve changes</b> which they did not regard as significant. The majority of these referred to operating changes.</p> <p>The criteria of Article 4 para. 2 of Commission Regulation (EC) N° 352/2009 on risk evaluation and assessment were used. For example, risk was assessed on the basis of a risk matrix.</p> <p><b>Three changes (technical and operational)</b> which were regarded as significant were reported in safety reports.</p> <p>Because of the short time that application of the risk management process has been obligatory, there are as yet no meaningful reports or experience on the method.</p>
BE	Not applicable in 2010
BG	Nothing is mentioned in the report
Channel Tunnel	As Eurotunnel’s work on construction SAFE stations in the tunnel was begun before the CSM came into in force for rolling stock in 2010, it was not used as the basis of its risk evaluation and assessment. There is thus no experience available on the method.
CZ	Nothing is mentioned in the report
DE	<p>Regulation (EC) N° 352/2009 is compulsory applicable from 01.07.2012. However, it has been applied, from 19.07.2010 to significant changes, to rolling stock and for significant changes that affect the structural subsystems and where it was requested Article 15, paragraph 1 of Directive 2008/57/EC or by a TSI.</p> <p>For projects completed in 2010, it was still the transitional provision for projects in advanced stages of development in accordance with Article 2, paragraph 4 of Regulation (EC) N° 352/2009. The method was thus not applied.</p> <p>The application of Regulation (EC) N° 352/2009 has been discussed in workshops with representatives of the companies and organizations of the German railway</p>



**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
	<p>sector benefits. As a result of this work, the EBA has produced a guide, the beginning of July 2010 under the title "Notes on the application of Regulation (EC) N° 352/2009".</p> <p>As part of the workshops with the German industry, the representatives presented themselves in particular the definition of significant change and its practical application proved to be problematic. But the embedding of the processes after the CSM risk evaluation and assessment in the overall process of authorizing the placing of structural subsystems brings difficulties, both in the internal process for applicants and in conjunction with the Authority.</p>
DK	Nothing is mentioned in the report
EE	<p>The Common Safety Methods (CSM) Regulation was adopted on 24 April 2009 and its transposition into national legislation is organised in cooperation with the Ministry of Economic Affairs and Communications.</p> <p>There was one serious accident in Estonia in 2010 giving rise to the obligation to fit on-board devices of new rolling stock with extra safety functions and to a review of the railway undertaking’s safety processes. No important amendments were made in the railway sector in 2010 that would have required the assessment of risks related to implementation pursuant to the risk management process described in Article 5.</p>
EL	There is no information available on feedback with CSM on risk assessment.
ES	<p>In Spain, on 10 December 2008, the Department of Railway Infrastructure approved an internal legal document based on the existing draft version of Regulation N° 352/2009 available at this date:</p> <p>Circular Decision (10/2008) on the validation procedure for applications for authorisation of the placing in service of modified rolling stock, in accordance with Order FOM/233/2006 on the conditions for approval of railway rolling stock.</p> <p>The aforementioned decision regulates the procedure for authorising the placing in service of rolling stock which has already been authorised and subsequently modified. This new procedure introduces the most important aspects of Common Safety Method risk assessment and analysis.</p> <p>With the entry into force of part of Regulation N° 352/2009 in mid-2010, the drafting of a new circular decision was initiated with the aim of amending the existing Circular Decision (10/2008), adapting it to the CSM Regulation for Risk Assessment. Its publication is planned for early 2011.</p> <p>Listed below are several notable examples of the application of Circular Decision No 10:</p> <ul style="list-style-type: none"> <li>▪ Modification of vehicle gauge:</li> <li>▪ Change of variable gauge bogies to Spanish fixed gauge.</li> <li>▪ Adaptation of Iberian gauge to UIC gauge of 1 435 mm (modifying brake and running gear).</li> </ul>



**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
	<ul style="list-style-type: none"> <li>▪ Introduction of communication systems into vehicles (GSM-R).</li> <li>▪ Introduction of Spanish train protection and radio communication systems into vehicles originating from another Member State. The driver selects the systems to be used by means of a switch (‘country switch’) when passing from one network to another according to the interoperability instruction in force.</li> <li>▪ Adaptation of electric vehicles for operating on tracks without a catenary (diesel-electric operation).</li> <li>▪ Installation of devices for signalling incorrect pressure in bogie brake cylinders. This is intended to warn the driver of abnormal situations (like residual pressures in brake cylinders) in order to prevent placing the train in motion in such circumstances and so that the appropriate corrective measures can be adopted.</li> <li>▪ Introduction of a system for resetting alarm devices by remote control. The purpose of this modification is that, after a passenger emergency alarm has been activated, the driver may look at the situation and depending on a series of factors, may pinpoint which handle has been pulled and move the train to a safer place or situation and, once the train is stopped, reset the emergency alarm handle or handles that have been activated. The aim of this is to avoid significant risks in certain situations for trains, as for example, stopping in tunnels, on bridges, faced with a fire in the coaches, etc.</li> <li>▪ Adaptation to the service of lines supplied with a catenary voltage of 1.5 kV DC. A push-button has been installed in the cab for changing from the 25 kV AC voltage service to the 1.5 kV DC voltage service.</li> <li>▪ Introduction of hook movement restriction in locomotives so that they can travel on international gauge tracks. For this, all that is needed are changes in the running gear and bogie chassis so that they are suitable for running on international track gauge.</li> <li>▪ Software modifications in vehicles of a different type, such as:               <ul style="list-style-type: none"> <li>▪ Software for changing speed on passing through gauge changers.</li> <li>▪ Access door control software.</li> <li>▪ Software that affects several systems regarded as non-critical from the safety point of view, which improve operational efficiency, reliability and maintenance.</li> <li>▪ Traction control software.</li> </ul> </li> </ul> <p>Finally, it should be pointed out that the Department of Railway Infrastructure (DGIF), acting as the Spanish national safety authority and, waiting for conditions for accreditation and/or recognition of assessment bodies to be defined, recognises safety assessors as laid down in Annex II to (EC) Regulation N° 352/2009.</p>
FI	<p>In 2010 CSM on risk evaluation and assessment was not applied in Finland. Application of CSM on risk evaluation and assessment has been mandatory on significant technical changes affecting vehicles or significant changes concerning structural subsystems since 19 July 2010. There have been above-mentioned significant changes on Finnish railways but those projects have been at an advanced</p>





**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
	stage of development on the date CSM regulation entered into force. Because of that the application of CSM on risk evaluation and assessment hasn't been mandatory and the actors have not applied it.
FR	Nothing is mentioned in the report
HU	During 2010 the CSM on risk evaluation and assessment was not applied in Hungary.
IE	<p>A safety standard to implement the requirements of Commission Regulation N° 352/2009 was submitted by Iarnrod Eireann to the RSC as part of their application for Safety Certificates Part A and B and Safety Authorisation in December 2010.</p> <p>The pre-existing National Rule requires a risk assessment but does not prescribe the method. The Common Safety Method on risk evaluation and assessment became binding on the national network from 19th July 2010, but it will be a voluntary code of practice for light railways, metros and heritage railways.</p>
IT	<p>4 applications of the regulation by trenitalia : changes in training programs for staff engaged in operations (drivers, etc.),</p> <ul style="list-style-type: none"> <li>- Implementation of a new service of transportation;</li> <li>- Application of rules defined in order to have a single driver even in some types of rolling stock in which they were not applicable;</li> <li>- Cancellation of a company division which was engaged in operations.</li> </ul> <p>2 projects from IM: one for interlocking and another one for a technical project of screen</p>
LT	Nothing is mentioned in the report
LU	Neither the railway undertakings nor the infrastructure managers have reported to the NSA in their annual reports on the experience with the use of the CSM on risk assessment. Nevertheless, the NSA reminded many times through letters and meetings that the regulation 352/2009 is to be applied for any significant change related to structural sub-systems of the European railway system.
LV	<p>Railway undertakings, infrastructure managers and maintenance and construction companies adhere to the European Commission (EC) Regulation N° 352/2009 (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, which from 19 July 2010 applies to all significant technical changes affecting vehicles and to all significant changes concerning structural subsystems, where required by Article 15(1) of Directive 2008/57/EC or by a TSI. All the authorisation processes provide for assessment of substantial changes of the basic requirements.</p> <p>In 2010, such substantial changes were not established in any of the systems</p>
NL	No report received



**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
NO	No reporting in 2010.
PL	<p>As a result, in 2010, operators were not obliged to report their experience with the CSM in the assessment and methods of risk evaluation. The report mentions that five railway have sent their experience with risk assessment. As it is clear from the submitted documents, after assessing the potential impact of changes on the safety of the railway system - in any case the change was not considered "significant change" - in the meaning of 4 of the regulation.</p> <p>In addition, entities required to develop documented "Safety Management Systems" (SMS) include in there risk management requirements that are defined in Commission Regulation (EC) No. 352/2009.</p> <p>In order to fully understand and practice the correct application of the provisions of the above Regulation on the website of the Office for Railway Transport, has been published documents developed by the European Railway Agency:</p> <p>"Guide for the application of Commission Regulation N° 352/2009 of 24.04.2009 on the adoption of safety assessment methods for evaluation and assessment risks referred to in Article. Paragraph 6. 3 point. a) Directive 2004/49/EC of the European Council ",</p> <p>"Examples of risk assessment and possible support tools to Regulation on the adoption of safety assessment methods for evaluation and assessment risks referred to in Article. Paragraph 6. 3 point. a) Directive 2004/49/EC of the European Council ".</p>
PT	No application of the regulation 352/2009
RO	Nothing is mentioned in the report
SE	The reporting has been voluntary until 2010. Nothing to report for 2010. Transportation Board will ask questions to the railway undertakings and infrastructure managers about their experiences in applying CSMs from next year's collection of safety.
SI	Slovenia implemented the Directive 2008/57/EC, as well as the Regulation 352/2009 and the Commission Decision 2009/460/EC.
SK	Nothing is mentioned concerning the regulation 352/2009
UK	<p>Since 19 July 2010 the CSM on risk evaluation and assessment has applied to significant technical changes affecting vehicles or significant changes concerning structural subsystems where required by Article 15(1) of Directive 2008/57/EC or by a Technical Specification for Interoperability (TSI).</p> <p>ORR is not aware that this CSM has been applied by any railway undertaking, infrastructure manager or manufacturer during 2010. Many rolling stock and infrastructure projects were at an advanced stage when the Regulation came into force and therefore existing domestic processes for assuring safety including safety</p>



**Table 7 – Application of the regulation 352/2009 found in NSA’s 2010 annual safety reports**

Country	Application of the regulation 352/2009
	<p>verification and Interoperability authorisation would have been applied.</p> <p>ORR continued to engage with the GB rail industry on this CSM throughout 2010. We organised briefing sessions to ensure that stakeholders were aware of the implications of the CSM coming into force, and outlined the differences between safety verification, the current process for introducing new or altered vehicles onto the GB rail network, and the processes laid down by the CSM.</p> <p>ORR have published guidance on the CSM for GB industry, which supplements the ERA guidance and supports the application of the CSM by stakeholders.</p> <p>During 2011 ORR will be engaging with industry on possible changes to GB legislation to amend the requirement for safety verification of technical projects. This will simplify decision-making for these projects as the CSM on risk assessment and evaluation becomes more widely applied.</p>



## **ANNEX II: DISCOVERED INCONSISTENCIES OF TRANSLATION OF TERMS FROM ENGLISH TO MEMBER STATES' LANGUAGES**

In the scope of the work on the revision of the CSM regulation, members of the CSM working group have reported about important inconsistencies in the translations of different terms from the regulation in their mother languages. The first such report came from the German language speakers within the working group, where the representatives of Germany, Austria and Switzerland (via CER) have asked the Agency what could be done in the case, which they have observed.

The answer from the Agency was that the Member States have to use their official ordinary procedures for approaching the Commission with the issue of these translation inconsistencies. As of the present moment, the Agency does not have any means for assisting better the Member States for this question.

The discussion of the working group showed that members of the working group consider it helpful to add to this current report this *informative* annex, which is *fully non binding* and *without any possible requirements to the Commission*, informing the Commission about inconsistencies discovered in the translations of regulation 352/2009/EC in different languages.

The information from the underneath described inconsistencies has been provided by the members of the working group in a very systematic way, only after checking how the questionable words and phrases have been translated also in other EU legislation, which contains them. Consequently, translations to languages, which are spoken by more than one Member State (German, French, Dutch) have been discussed and agreed by all concerned parties that were represented in the working group. Thus, the underlying table contains only translation proposals, which have been agreed by all concerned working group members.

Whereas the working group members have the hope that the Commission might have resources and means to address this issue, still they are fully aware that this underlying table cannot guarantee that the proposals contained within this Annex will be implemented in practice and that if they want to ensure this happening, then they have to use the official processes for addressing this issue.



**Table 8 – Agreed proposals for improvement of translation of terms in other EU languages**

Nr	Original term in English as in the CSM on RA	Translation in the other language	Language	Translation of the term in the RSD or other EU legislation (indicate also which)	Explanation why the term is considered to be wrongly translated	Suggestion for alternative translation
1.	Expert	Sachverständiger	DE	According to our check, this term is currently used only in the CSM on RA.	“Sachverständiger” has in German a legal connotation such as a chartered or certified expert. This is not intended by the CSM RA.	Fachmann, Experte
2.	Expert judgement	Sachverständigenurteil	DE	According to our check, this term is currently used only in the CSM on RA.	Similar to the above, knowing the technical and legal meaning of the original text, the correct translation is “Expertenbeurteilung” or “Expertenbewertung”. The term “Sachverständigenurteil” suggests a very different meaning of the text and might impose costly new requirements, which do not exist in the original text and are not really meant by the legislator.	Expertenbeurteilung Expertenbewertung
3.	Code of Practice	Anerkannte Regel der Technik	DE	According to our check, this term is currently used only in the CSM on RA.	“Anerkannte Regel der Technik” usually means a standard or norm in German. This is not intended by CSM RA.	Regelwerk
4.	Broadly acceptable	Weitgehend akzeptabel	DE	According to our check, this term is currently used only in the CSM on RA.	“Weitgehend akzeptabel” means in German “almost acceptable” but not “acceptable with out any additional measures” as the English term and the intent of the CSM RA.	Allgemein akzeptabel
5.	Safety acceptance (and “acceptance” in general – see also next line)	Approvazione di sicurezza	IT	- CSM on RA itself: Ex.: Annex I §2.1.5 (risk acceptance principle → Criterio di accettazione dei rischi) - 2004/49/EC (Ex.: Art. 10.2.a), 11.1.a)) - EN 50126	Has to be changed in all appearance within the translation of the CSM on RA. “Accettazione” and “Approvazione” are not synonyms in Italian. “Accettazione” should be used to be consistent within the document and with other EU legislation.	Accettazione di sicurezza
6.	- “To accept” and its derivatives - “Accepted” - ...	- Approvare - Approvato - ...	IT	Idem	Idem  All appearances of the term acceptance and its derivatives (accepted, etc.) have to be changed from “approvare” to “acceptare”, etc. in the whole CSM on	- Accettare - Accettato - ...



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					RA translation in IT. <ul style="list-style-type: none"> <li>• acceptance (en) = accettazione(it)</li> <li>• to accept(en) = accettare(it)</li> <li>• accepted(en) = accettato(it)</li> </ul> Explanation: approvato(it), approvazione(it), approvare(it) have a different italian meaning with respect to accettato (it), approvazione (it), approvato (it): especially from a legal point of view they are not sinonimous.	
7.	the suitability of a system	capacité	FR	CSM-RA only Art 3 §14	Understanding in French	aptitude
8.	code of practice	code de pratique	FR	CSM-RA - in the whole regulation	Usual term in French	règles de l’art
9.	shall ensure	veille	FR	CSM-RA only Art 5 §3	Incorrect translation with a meaning more weak than in English	s’assure
10.	shall be taken into account by	tient compte du	FR	CSM-RA only Art 7 §3	Incorrect translation with a meaning more weak than in English	doit être pris en compte par
11.	shall start from	se fonde sur	FR	CSM-RA only Annex I §1.1.1	Wrong meaning in French	doit commencer par
12.	shall in turn inform the actor	informe l’acteur	FR	CSM-RA only Annex I §1.2.3	Wrong meaning in French	informe à son tour l’acteur
13.	classified	classifiés	FR	CSM-RA only Annex I §2.2.2	Wrong meaning in French	classés
14.	be relevant for	présenter un lien	FR	CSM-RA only	Wrong meaning in French	être pertinent pour
15.	shall not result in	n’engendrent pas	FR	CSM-RA only Annex I §2.3.2b	Incorrect translation with a meaning more weak than in English	ne doivent pas générer
16.	This Regulation shall enter into force on the 20 <sup>th</sup> day following its publication in the Official Journal of the European Union	Le présent règlement entre en vigueur le jour suivant celui de sa publication au Journal officiel de l’Union européenne.	FR	CSM-RA only Article 10 – Entry into force	Factually changed sense of the translation.	Le présent règlement entre en vigueur le 20 <sup>ème</sup> jour suivant celui de sa publication au Journal officiel de l’Union européenne.
17.	Code of practice	Código práctico	ES	<i>In Agreement with DE check, this term is currently used only in the</i>	“Código de prácticas” is a more correct translation. “Código práctico” could	Código de prácticas





**Table 8 – Agreed proposals for improvement of translation of terms in other EU languages**

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				CSM on RA.	mean “Practical code”.	
18.	Broadly acceptable	Riesgo aceptable en términos generales	ES	<i>In Agreement with DE check, this term is currently used only in the CSM on RA.</i>	Proposed translation could clarify the current one, even if it’s not wrong.	Riesgo generalmente considerado aceptable
19.	To identify	-Determinar -Indicar	ES	<i>Broadly used term with different meanings depending on the context</i>	Proposed translation generally fits better with the intended meaning and it would facilitate understanding.	Identificar
20.	Operation	-Operación -Servicio -Funcionamiento -Explotación ...	ES	<i>Broadly used term with different translations used. Depending on the context sometimes correctly chosen and sometimes not.</i>  <i>The term can be found in: CSM on RA, 2004/49/EC, Regulation 1149/2009, EC decision 2010/409/EU, 2008/57/EC, OPE TSI, 2007/59/EC, etc.</i> <i>In general, it seems to be translated quite chaotically and inconsistently in all these documents. The correct translation should be with the railway term “Operación”. It fits to all contexts that could be encountered.</i>	The proposed translation (operación) fits always with the intended meaning of the term “operation”, independently of the given context, so it is preferable to be used. <u>Request:</u> - Replace all mentionings/translations in the CSM on RA with the translation “Operación” and - Pay attention that “Operación” is the correct railway term and start using it correctly in the future, e.g. for the translation of the upcoming CSM on Monitoring, etc.; - Please try to correct the term translation in other EU legislation (e.g. see list on the left) whenever possible, e.g. on revisions, or similar.	-Operación
21.	Significance	Importancia	ES	<i>According to our check, this term is currently used only in the CSM on RA.</i>	“Importancia” means “importance” while significance just refers to the Regulation particular definition of “significant”, so it better fits with the term “Significación”	Significación
22.	Hazard log	Registro	ES	<i>According to our check, this term is currently used only in the CSM on RA.</i>  <i>Furthermore, the term is widely used and well established standard EN 50126 already translates the term as “Registro de peligros”</i>	Current traslation: “Registro” just means “Register”. “Hazard” traslated as “de peligros” should be added.	Registro de peligros
23.	... the TSIs may be considered as codes of practice	..deze verordening vastgestelde	NL	Only in the CSM Regulation, Annex I, point 2.3.3.	Typing error during the translation	..deze verordening vastgestelde risicobeheerproces



**Table 8 – Agreed proposals for improvement of translation of terms in other EU languages**

Nr	Original term in English as in the CSM on RA	Translation in the other language	Language	Translation of the term in the RSD or other EU legislation (indicate also which)	Explanation why the term is considered to be wrongly translated	Suggestion for alternative translation
	for controlling hazards, provided requirement (c) of point 2.3.2 is fulfilled...	risicobeheerproc es moet worden toegepast, kunnen de TSI's, <u>indien</u> zij voldoen aan de eisen in punt 2.3.2, onder c),...				moet worden toegepast, kunnen de TSI's, <u>indien</u> zij voldoen aan de eisen in punt 2.3.2, onder c),...
24.	.... The hazard record shall track the progress in monitoring risks associated with the identified hazards.....	In de gevaareninventari s wordt de voortgang van de monitoring van de aan de geconstateerde gevaaren verbonden risico's vermeld.	NL	Only in the CSM Regulation, 4.1.1 in Annex I	The translation can be improved	In de gevaareninventaris wordt de voortgang vermeld van het toezicht op de risico's verbonden aan de <u>identificeerde</u> gevaaren.
25.	Interfaces	Liitännät	FI	The term is used in some TSI's but the meaning in TSI's is different compared to CSM on RA.	The term describes technical interfaces thus it is too narrow. The term suggested includes environment and other parties.	Rajapinnat
26.	Codes of practice	Käytännösäännöt	FI	According to our check, this term is currently used only in the CSM on RA.	The term is not decent Finnish.	Toimintaohjeet
27.	Significant change	väsentlig ændring	DK	Only in the CSM regulation in appendix in Annex 1.  This term has earlier been changed. Only one place in the text (appendix in Annex 1) was mistakenly not corrected.	<i>Wrong translation only at one place in the text.</i>  The Danish language terminology was changed previously, but the wording in the <u>appendix in Annex I</u> was mistakenly not corrected.	signifikant ændring
28.	Codes of practice	adfærdskodekser	DK	Only in the CSM regulation in appendix in Annex 1.  This term has earlier been changed. But one place in the text – appendix in Annex 1 – was mistakenly not corrected.	<i>Wrong translation only at one place in the text.</i> The Danish language terminology was changed previously, but the wording in the <u>appendix in Annex I</u> was mistakenly not corrected.	anerkendt praksis
29.	Credible (worst case scenario) in article 4 (2 a)	sandsynligt	DK	Only in the CSM regulation. In article 4 (2 a)	<i>Wrong translation only at one place in the text.</i> 'Sandsynligt' may be understood both as 'probable' and 'likely', the latter suggesting a fair-sized chance of a certain outcome which should be expected, whereas 'realistisk' suggests a conceivable	realistisk



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					scenario.	
30.	Hazard	fare	DK	Only in the CSM regulation. “Hazard“ is also used in the Interoperability directive, but in a more general way – we are okay with the translation in the Danish version of the directive.  <i>Term generally translated wrongly in CSM-RA</i>	<i>Term generally translated wrongly</i> “Hasard” is already used as an expression when discussing risks in the Danish railway industry.	hasard
31.	Hazard record	fareregister	DK	Only in the CSM regulation (see above). A general problem.  <i>Term generally translated wrongly in CSM-RA</i>	<i>Term generally translated wrongly</i> “Hasardregister” is already used as an expression when discussing risks in the Danish railway industry.	hasardregister
32.	Hazard identification	fareidentifikation	DK	Only in the CSM regulation (see above). A general problem.  <i>Term generally translated wrongly in CSM-RA</i>	<i>Term generally translated wrongly</i> “Hasard” is already used as an expression when discussing risks in the Danish railway industry	hasardidentifikation
33.	“Risk control measures” in article 3 (11)	risikokontrolforanstaltninger	DK	Only in the CSM Regulation. In article 3 (11). The suggested translation “risikostyringsforanstaltninger” is already used three places in the Danish translation of the Railway safety Directive: - in section (5) in the preamble - article 4,3 in chapter II; - article 2,d) in Annex III;	<i>Wrong translation only at one place in the text.</i> The word “kontrol” in Danish has a slightly different meaning than “control” in English. The word “styring” works better here.	risikostyringsforanstaltninger
34.	“Risk Control Management” in the heading of article 8	ledelse af risikostyring	DK	<i>Wrong translation only at one place in the text.</i>  Only in the CSM Regulation. In the heading of article 8.	<i>Wrong translation only at one place in the text.</i> The word: “ledelse” is usually used when discussing “corporate management” or similar. The correct wording should be “styringssystem”.	risikostyringssystem
35.	“Broadly acceptable risk” in the Appendix in Annex I and in 2.2.2 and 2.2.3 in Annex I.	stort set acceptable risici	DK	Only in the CSM Regulation. In the Appendix in Annex I and in 2.2.2 and 2.2.3 in Annex I.	<i>Wrong translation at a few places in the text.</i> The wording ”stort set” implies that the risks are more or less accepted. Alment implies that they	alment accepterede risici



**Table 8 – Agreed proposals for improvement of translation of terms in other EU languages**

Nr	Original term in English as in the CSM on RA	Translation in the other language	Language	Translation of the term in the RSD or other EU legislation (indicate also which)	Explanation why the term is considered to be wrongly translated	Suggestion for alternative translation
				<i>Wrong translation in a few places in the text.</i>	are generally accepted.	
36.	“design”	udformning	DK	In the CSM Regulation, in article 3 (22). The word “Design” is used circa 40 times in the Interoperability directive. It is used to describe (planning, lay-out, development etc.) In the Danish version it is translated into more than 5 different Danish words, but the translations aren’t consistent with the intended meaning of “design” in the English version. We therefore have quite a lot of suggestions for changes in the wording in the Interoperability directive.	<i>Wrong translation at two places in article 3 (22)</i> In Danish the word “design” means “style=udformning” more than “development=udvikling”. In definition 22 “technical system” “udvikling” is a better word, as the English word: “Design” in this context means development and not “style”	udvikling
37.	“to be handled”	“må tages fat på”	DK	Only in the CSM Regulation, Annex 1(1.2.1)	Wrong translation	skal håndteres
38.	... under assessment and without prejudice to specifications <b>of</b> interfaces defined in ...	af	DK	Only in the CSM Regulation, “of” in 1.2.1 in Annex 1	Wrong translation	for
39.	...level of detail necessary to identify <b>where</b> safety measures...	at	DK	Only in the CSM Regulation, “where” in 2.2.5 in Annex 1	Wrong translation	hvor