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Accreditation & recognition schemes: CSM on Risk Assessment	
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	Prepared by	Reviewed by	Approved by
Name	T. Holvad	N. Duquenne, D. Jovicic, T. Breyne	A. Magnien
Unit	Economic Evaluation Unit	Safety Unit	Head of EE Unit
Date & Signat.			

European Railway Agency

Accreditation & recognition schemes: CSM on Risk Assessment

AMENDMENT RECORD

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SUMMARY OF FINDINGS

Background

The Agency's proposals on accreditation / recognition of assessment bodies in the context of the Common Safety Method on Risk Assessment (CSM RA) are accompanied by an Impact Assessment Report in order to inform the decision-makers about the options available and their consequences. Our findings from this work has been based on a comprehensive questionnaire completed by the concerned stakeholders, interviews to provide more in-depth information and reviews of relevant secondary information sources.

Brief overview of content of Recommendations

According to the current CSM regulation [5], an assessment body has to fulfil the criteria of Annex II of the regulation, but it is not stated in the regulation who has to check that the assessment body fulfils these criteria. This open point could lead to a lack of trust in the work performed by assessment bodies. This is currently a concern especially for the cases in which this work has be to recognized by another assessment body according to art 7 §4 of the CSM regulation. The proposed amendment to the CSM regulation establishes a common framework for evaluating and supervising the ability of assessment bodies to carry out CSM application assessment. Within this framework, two different alternative options are envisaged:

- The assessment body is accredited by a national accreditation body, according to a specific accreditation scheme covering the CSM application assessment activity;
- the assessment body is recognized by the Member State, according to similar requirements as those used in the accreditation scheme.

Freedom should be left to choose between either of these options; however the same criteria as well as a similar control of their fulfilment should be applied in all cases in order to provide equivalent guarantees regarding the quality of the work performed by assessment bodies (as stipulated in Commission Regulation (EC) N° 765/2008).

Impact assessment results

Our conclusions from the questionnaire can be summarized as follows:

- For the majority of the respondents the scheme (whether accreditation, recognition or both) brings added value.
- Furthermore, the dominant view is that such a scheme would contribute to solve current problems regarding mutual recognition.
- Both accreditation and recognition should be available according to view of most respondents.
- The importance of inclusion of the possibility for implicit recognition of (in-house) assessment was highlighted by several sector respondents
- Among NSA respondents the general perception was that this scheme could have a positive influence on the authorisation process implying reduced costs and time involved.

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

- Accreditation being the preferred among respondents putting a higher value on ensuring mutual recognition than on the cost implications
- while (implicit) recognition is the preferred option for those respondents placing a higher value on limiting cost implications.

This provides an important justification for including both types of scheme. Findings from the interviews include:

- Flexibility for ABs required regarding the choice between recognition and accreditation
- Both recognition and accreditation should be available (incl. recognition through the safety certification process)
- Stakeholder needs vary
- Development of accreditation scheme could be important with respect to increasing trust between stakeholders.

- Implications for NSA approval process with respect to rolling stock was highlighted as one important source of benefits derived from this proposal

Quantitative aspects

The quantitative aspects of this impact assessment has focussed on determining likely costs for assessment bodies becoming accredited / recognised and the costs involved for the accreditation bodies. Additional work has examined the possible benefits of accreditation including a tentative quantification. As always quantification of benefits (and costs) is difficult and uncertain, although rather conservative assumptions have been used throughout. The indicative quantitative analyses suggest that the order of magnitude of the annual benefits could be in the range from 5,7 to 11,5 ME due to avoided duplicative work in the risk assessment and associated independent safety assessment process. These benefits should be compared to the cost of accreditation / recognition. These costs are likely to be in the range from 2,5 to 3,4 ME in the case of accreditation (and between 0,3 and 0,4 ME for recognition). Therefore, overall it appears likely that costs incurred for assessment bodies seeking accreditation would be outweighed by the benefits; indeed it is the choice of an assessment body to become accredited which should ensure the viability of such decision.

Conclusions

Our work suggests that these schemes are likely to be of overall benefit for the sector in terms of contributions towards progress on mutual trust, reduction in redundant assessments and enhanced scope for cross acceptance. Indeed, our tentative quantification of the impacts suggest that the Benefit Cost ratio is likely to be significantly higher than 1 (a low estimate of 1,7 and a high estimate of 4,6). In this context, it is important to allow for both accreditation and recognition in order to address the different stakeholder needs. Therefore, there is a need to ensure that both accreditation and recognition are perceived as valid and equivalent options. This would require that in the implementation phase and in the initial period afterwards there are monitoring arrangements put in place to ensure that the relevant stakeholders have confidence in the developed schemes.

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1. INTRODUCTION

1.1 Context

- 1.1.1.1 The CSM on risk assessment [5] requires that the risk assessment process to be applied by a proposer for a significant change shall be assessed by an Assessment Body appointed by the proposer. At this point the Agency is putting forward additional details regarding: (1) who can be assessment body; (2) what the assessment body should do and when it should perform the work; (3) how the work of the assessment body interacts with other assessment, certification and authorisation processes; (4) how the assessment body should perform the work & (5) accreditation or recognition schemes for assessment bodies. These details are presently not set out in the CSM on risk assessment [5]. As such this may cause confusion and uncertainty among the stakeholders leading to different interpretations and problems regarding trust thereby limit the extent to which the harmonisation efforts in this area generate the benefits from mutual recognition.
- 1.1.1.2 The proposals are based on work developed by a dedicated task force and are set out in an explanatory note [2] and proposed as part of the planned revision of the CSM on Risk Assessment Regulation [6]. In particular, the plans regarding accreditation / recognition schemes for assessment bodies have been considered as part of an impact assessment in order to inform the decision-makers about the options available and their consequences. As such, the outcome of the impact assessment is no pass / fail criterion for whether the Agency Recommendations should be taken forward or not as other elements may be important in this regard.
- 1.1.1.3 The present document outlines the key findings of the impact assessment. Our approach for the impact assessment is structured in accordance with the EC Impact Assessment Guidelines [4] and the Agency general evaluation guidelines [3]. The details for the methodology to be used for this work were specified in the applied guidelines document [7]. In particular, the work involves the following steps:
- Problem description
 - Definition of objectives
 - Specification of scenarios
 - Analysis of impacts

- Monitoring and evaluation arrangements.

1.1.1.4 The impact assessments have been developed by ERA's Economic Evaluation Unit (EE) in conjunction with the ERA Safety Assessment Sector.

1.2 Structure of document

1.2.1.1 Overall, the IA report is structured as follows:

- References, terms and abbreviations used in this document are presented in Section 2
- Section 3 describes the problems experienced in the context of assessment bodies. The basis for EU action in this area is set out in Section 3.3
- In Section 4 specific objectives for the proposals regarding accreditation / recognition schemes are described.
- The scenarios considered in the impact assessment are outlined in Section 5. The so-called reference scenario provides the benchmark against which the alternative (project) scenarios have been assessed.
- Section 6 provides a summary of the methodology used for the impact analysis. In particular, the general principles are specified in Section 6.2 and the key stages of data collection and analysis are set out in Section 6.3.
- In Section 7 the results of the impact assessment for the proposals re. accreditation / recognition are presented. The section covers the following items: findings from questionnaires and interviews, stakeholder perspectives, costs, benefits, competition assessment, administrative burden issues, transition and implementation considerations and uncertainties /robustness of findings.
- Section 8 provides an overview of plans regarding monitoring and evaluation in order to facilitate anticipated ex-post evaluation. This covers the following elements: prerequisites, efforts and results.

2. REFERENCES, TERMS AND ABBREVIATIONS**2.1 Reference Documents**

Ref. N°	Author	Title	Last Issue
[1]		EC Directive 2004/49 Safety Directive as amended by Directive 2008/110	2008
[2]	ERA Safety Unit	Note on Assessment Bodies roles and responsibilities in the CSM on risk assessment – summary	2009
[3]	ERA Economic Evaluation Unit	Economic Evaluation: Methodology Guidelines	2007
[4]	European Commission	Impact Assessment Guidelines. SEC(2009) 92	2009
[5]		CSM Regulation (Risk assessment)	2009
[6]	ERA Safety Unit	Proposed revision of CSM Regulation (Risk assessment)	2012
[7]	ERA Economic Evaluation Unit	Applied Methodology Guidelines – Accreditation & recognition schemes: CSM on Risk Assessment	2011
[8]		Commission Regulation (EC) N° 765/2008 requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	2008
[9]	ISO (International Organisation for Standardisation)	ISO 17020 - General criteria for the operation of various types of bodies performing inspection	1998
10	ERA	Report on railway vehicle authorization	2011

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2.2 Definitions and Terms

Table 1 : Definitions and Terms

Term	Definition
AB	Assessment Body
CBA	Cost-Benefit Analysis
CSM-RA	Common Safety Method on Risk Assessment
CSM AB	CSM Assessment Body – as defined in the CSM Regulation [5]
DeBo	Designated Body – as defined in the Interoperability Directive
EA	European co-operation for Accreditation
ECM	Entity in Charge of Maintenance
ESG	Economic Survey Group. The group has been set up by ERA and is managed by its Economic Evaluation Unit. ESG is considering the impact assessment work undertaken for the different recommendations of ERA, from the particular point of view of methodology (definition, usage and improvement)
IM	Infrastructure Manager (as defined in Article 3 of Directive 91/440/EEC)
NoBo	Notified Body (as defined in the Interoperability Directive 2008/57/EC)
NSA	National Safety Authority (as defined in Directive 2004/49/EC)
RU	Railway Undertaking (as defined in Directive 2004/49/EC)
SD	Safety Directive (2004/49/EC) as amended by Directive 2008/110
SME	Small and Medium sized Enterprises

3. PROBLEM DESCRIPTION

3.1 Overview of content

- 3.1.1.1 This section outlines our considerations regarding problems experienced in the context of risk assessment and mutual trust between the stakeholders concerned. It will be determined who is affected by the problems and the scale / importance of the problems and possibly also outlining ways that those problems can be addressed.
- 3.1.1.2 As such our considerations on this issue build on information gathered through questionnaire and discussions / interviews with the stakeholders (see Section 6 for the details regarding data collection).

3.2 Problems experienced regarding assessment bodies

- 3.2.1.1 The CSM on risk assessment [5] aims to harmonise the processes for risk assessment in order to enable the mutual recognition of the safety assessment reports and to ensure that the existing safety levels are maintained in the Community rail system. This should facilitate the acceptance of the risk assessment results by different Assessment Bodies or NSAs. As such the CSM regulation [5] requires that a safety assessment report concerning a system that has been accepted following the risk management process in the CSM regulation [5] shall, under certain conditions, not be called into question by any other assessment body assessing the same system (or part of it).
- 3.2.1.2 However, a significant potential barrier towards mutual recognition is the possible lack of trust between stakeholders with respect to the risk assessment results. Instances of lack of trust in the use of the risk management process and risk assessment results (incl. the safety assessment report provided by a CSM Assessment Body) are likely to be more frequent if the roles and responsibilities of CSM assessment bodies vary (incl. differences concerning scope of work, working practices and competences). In particular, lack of trust could be a current issue because the CSM Regulation [5] is not stating who has to check that the assessment body fulfils the criteria set out in Annex II of the Regulation. It should be mentioned that lack of trust for using of the risk management process and the risk assessment results has several dimensions as there may be issues both with regards to confidence to stakeholders within a given country as well as organisations from different countries. A formal

framework for accreditation and recognition aims to avoid as much as possible different interpretations of the regulation by the concerned actors. Further details regarding objectives are given in Section 4.

3.2.1.3 The possibility for introducing an accreditation or recognition scheme is being considered as a way to ensure that the competences of CSM assessment bodies (CSM AB) are evaluated within a common framework. This will contribute towards ensuring consistency of scope and depth of competences among assessment bodies – Notified Bodies (NoBo), Designated Bodies (DeBo), national Assessment Bodies (AB) – which carry out evaluation of risk assessment process and results and as a result enhance trust between stakeholders (incl. CSM assessment bodies in different countries).

3.2.1.4 The issues concerning lack of trust was examined as part of the impact assessment questionnaire. In particular, assessment bodies (NBRAIL members) were asked about the extent to which they have confidence in the assessment performed by another Assessment Body. Below, statements from the responding assessment bodies are listed:

- *High level of confidence, confidence is particularly based on the experience and know-how of the AB*
- *High level of confidence*
- *Medium level of confidence. The main problem for confidence is that often the complete assessment reports are not provided, but only conclusions or short versions.*
- *It depends on the assessment body as well as the particular safety assessor who produced the report.*
- *Medium level of confidence. To specific topics the assessors have not enough knowledge of the railway system.*
- *Low level of (or no) confidence*
- *Not sure, Depends on assessment body*
- *Not sure, No own practical experiences with it till now. The cases are at the beginning.*
- *Not sure, we haven't had a lot of experience of other people's reports.*

3.2.1.5 The listed statements provide an insight into the extent to which lack of trust in the work of other assessment bodies is present. The main finding seems to be that there are varying degrees of confidence in assessment reports produced by other assessment bodies.

3.2.1.6 Additional evidence on this issue was available by asking these respondents to state how often they have concerns about assessment reports from other assessment bodies:

- 4 replied sometimes,
- 1 replied very seldom
- 2 replied never.

3.2.1.7 Although the sample is limited the responses received do indicate that a number of assessment bodies have from time to time concerns about assessment reports from other assessment bodies.

3.3 Basis for EU action

3.3.1.1 The legal basis for these proposals is provided through Commission Regulation (EC) No. 352/2009 (CSM on Risk Evaluation and Assessment) [5] as the Whereas 15 mentions that: *'This should allow the European Railway Agency to assist such applications, where possible, and to propose improvements, if appropriate, to that CSM before 1 July 2012'*.

3.3.1.2 In practice, a solution through European based legislation is also required given the extent of differences regarding assessment bodies and their competences. In particular, as the problem concerns the interactions between stakeholders (often located in different countries) provides a rationale for seeking a European based solution. As such the scope of the problem (across borders) renders national based solutions ineffective.

4. OBJECTIVES FOR ACCREDITATION / RECOGNITION SCHEME

4.1.1.1 The key objectives for having an accreditation / recognition scheme in the case of the CSM Assessment Bodies regarding the application of the CSM for risk assessment [5] are the following:

- Trust in the competences of the CSM Assessment Bodies and their ability to apply those
- Confidence in the effectiveness the application of the CSM regulation [5] by the proposer and therefore in the risk assessment results
- Promote mutual recognition of safety assessment reports and facilitate the acceptance of the proposer risk assessment results
- Reduce time and costs for Proposers applying the CSM for risk assessment [5] by avoiding duplicative / repetitive assessments managed by different types of assessment bodies, (CSM AB, NoBo, DeBo, national AB)

4.1.1.2 Introduction of an accreditation / recognition scheme would imply that a common framework for assessing competences of the CSM Assessment Bodies would be established whereby these should fulfil a harmonised set of criteria, incl.:

- Competence
- Independence
- Impartiality
- Consistent and reproducible approach across projects
- Re-usability of the assessment report , for mutual recognition across countries

4.1.1.3 This approach could contribute towards a higher level of confidence by the stakeholders (incl. Proposers and regulators) towards the services provided by CSM Assessment Bodies as well as between CSM Assessment Bodies. In turn this would enhance the possibility for mutual recognition, thereby leading to reduced time and costs for Proposers in cases such mutual recognition is needed. An important consideration would also be to ensure that the accreditation / recognition framework does not go beyond in complexity with what is required in order to achieve the objectives behind this initiative, i.e.

proportionality. In this respect it could be of importance to allow both accreditation and recognition whereby Proposers could have the choice between the two options according to their requirements regarding level of trust. This would add flexibility to the proposed scheme. A Proposer's choice of CSM assessment body would most likely be based on considerations to quality, time and costs according to its preferences and needs. It should be noted that this is fully in line with the provisions in EC Regulation 765/2008 [8] where Article 5 do not mandate Member States to use accreditation. The recognition scheme should though fulfil the same requirements as in place for accreditation.

5. SCENARIOS / OPTIONS

5.1 Overview of content

5.1.1.1 This section will outline the reference and project scenarios that together form the basis for the impact assessments for the proposals regarding accreditation / recognition schemes for CSM Assessment Bodies.

5.1.1.2 The key issues concern consideration to the different variants and combination that could be foreseen regarding accreditation / recognition. The outline follows the specification included in the applied guidelines document [7].

5.2 Reference scenario

5.2.1.1 The impact assessment requires specification of two types of scenarios:

- Reference scenario (Business-As-Usual)
- Project scenarios (Do-Something)

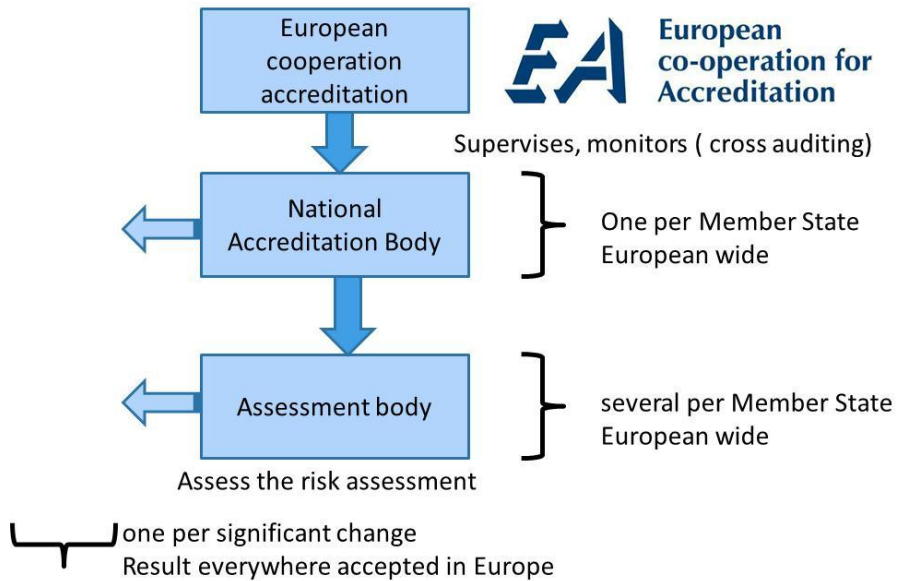
5.2.1.2 Impacts would be determined through the comparison of the project scenario(s) and the reference scenario. The reference scenario would be the situation without (mandatory) accreditation / recognition scheme for CSM Assessment Bodies. This follows the principles embedded in the EC Impact Assessment Guidelines, where the option of 'no change' should be included in the analysis unless relevant legislation lay down a specific obligation to act [4]. In particular, the proposed Reference Scenario will be based on a Business-as-Usual (BaU) approach, i.e. the collection of current practice across Member States and companies is in this case assumed to continue (regarding the evaluation of risk assessment process and results). In practice, as there is currently substantial country variation regarding these activities it will not be possible to take into account directly all arrangements in the reference scenario. Instead these differences will be picked up through the comparison between project and reference scenario. For some countries the reference scenario would be identical to the project scenario because these countries have already in place the elements contained in the project scenario.

5.3 Project scenarios

5.3.1.1 Several project scenarios can be identified reflecting the various possibilities regarding the situation with a mandatory accreditation / recognition scheme for CSM Assessment Bodies. Below, these are briefly outlined:

- Project scenario 1: Accreditation scheme
- Project scenario 2: Recognition scheme

5.3.1.2 Project Scenario 1 involves accreditation whereby assessment bodies would be accredited by a National Accreditation Body. The accreditation would be valid throughout the EU such that accredited assessment bodies can undertake work in each of the EU Member States if accreditation has been obtained in any of the countries. An overview of the different entities involved in the accreditation scheme is provided in the chart below. Further details on the accreditation scheme are available in [2].



5.3.1.3 In the case of Project Scenario 2 assessment bodies would be recognised in a given Member State. Within this scenario a distinction should be made regarding:

- direct recognition by the Member State of a national safety authority, an organisation or a part of it or an individual
- recognition (by the NSA) through the SMS for the appointment by RU/IM of internal assessors (as part of the safety certification award process).

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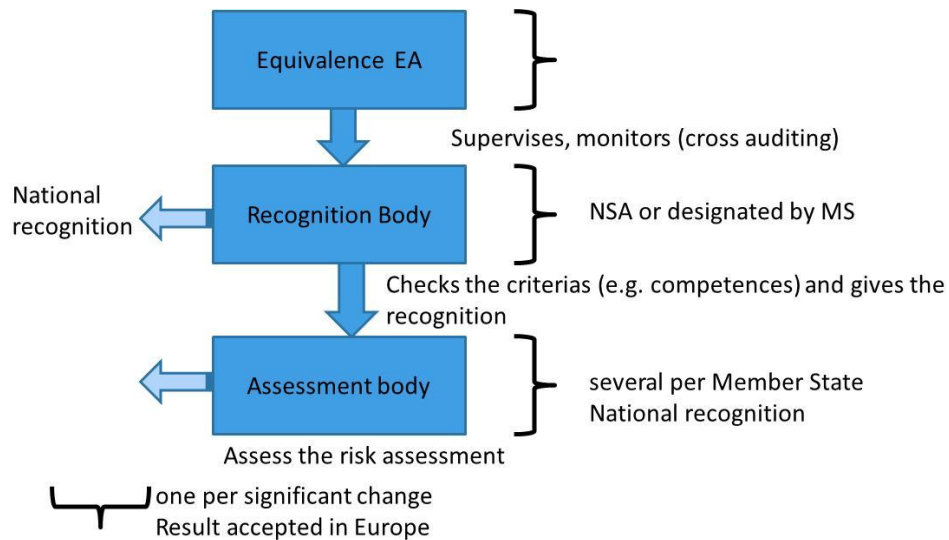
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- recognition of an organisation or an individual by the certification body through the assessment and surveillance of the maintenance system of an entity in charge of maintenance.

5.3.1.4 The case of the NSA acting as assessment body should also be considered within this scenario. Our findings regarding this are reported in Section 7 of this document.

Specific consideration here is also given to the possibility for allowing for different frameworks under recognition depending on whether changes concern domestic and cross-border / international changes. In the latter case the recognition scheme would mirror the accreditation to give the same level of confidence in the results. For domestic operations only it has been considered whether the MS could decide on the criteria to apply for recognizing the assessment body (such recognition would eventually be more limited compared to accreditation). The findings for these aspects are included in the impact assessment (see Section 7 of this document).

5.3.1.5 An overview of the different entities involved in the recognition scheme is provided in the chart below. Further details on the recognition scheme are available in [2].



5.3.1.6 The detailed specification of these scenarios will take into account Regulation (EC) No. 765/2008 [8] setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. For further details regarding the approaches for accreditation and recognition schemes the reader is referred to the detailed documentation prepared by the Agency's Safety Unit as part of the work on roles and responsibilities of assessment bodies in the context of the CSM

Regulation [2] and also the proposed revision of the CSM on risk evaluation and assessment [6].

- 5.3.1.7 These Project Scenarios have been compared to the Reference Scenario as part of the impact assessment work and full documentation are provided in Section 7. Our approach allows for a comparison of the different Project Scenarios such that it can for example be determined how a scheme based on accreditation only compares to the case where both accreditation and recognition are possible.

5.4 Practical analysis of scenarios

- 5.4.1.1 These scenarios have informed the impact assessment work. However, in practice it has not been possible to elaborate on all aspects in a detailed scenario analysis due to time constraints. The focus has been on the most important elements distinguishing the situation with a mandatory accreditation / recognition scheme compared to the situation without such a scheme in place. Specific considerations on differences between accreditation and recognition have been highlighted when relevant. This includes also the implications of having a combined solution with both accreditation and recognition available. The implications concerning the NSA acting as assessment body have been considered as part of the work though without formally analysing it as a separate scenario. Similarly, the aspects evolving around possible differential (lower) requirements for assessment bodies dealing with pure domestic changes have been assessed but without use of a specific scenario.

6. SUMMARY OF METHODOLOGY FOR IMPACT ANALYSIS

6.1 Overview of section

- 6.1.1.1 In this section a summary of the methodology used for the impact assessment will be set out. This includes information about the general principles for the assessment and data collection and analysis methods.

6.2 General principles for assessment of impacts

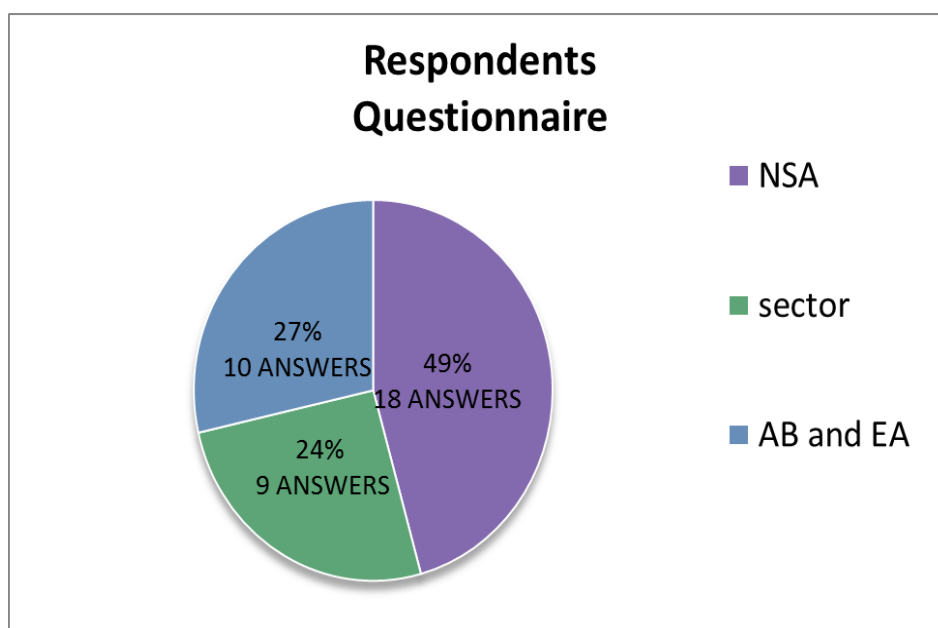
- 6.2.1.1 The impact assessment for considering the implications of a recognition / accreditation scheme is based on the following principles (in accordance with established Agency practice):
- Comparison of the reference scenario (Do-nothing or Do-minimum) with several alternative scenarios (as outlined above)
 - Assessment based on a cost-benefit analysis (CBA) perspective involving a consideration to the advantages and disadvantages generated relative to the reference scenario
 - Use of quantitative and qualitative analyses. Whenever possible quantitative information will be provided to supplement the qualitative considerations.
 - Examination of main benefits and costs for different categories of stakeholders (e.g. railway undertakings, infrastructure managers, rail manufacturers, government, assessment bodies)
 - Assessment of implications at European and country-specific level (or groups of countries)
 - Competition assessment (including assessment of consequences for Small and Medium sized Enterprises, SMEs)
 - Consideration to timing issues regarding speed of implementation
 - Consistent application of case study examples to illustrate potential consequences of accreditation / recognition schemes
 - Analysis of robustness of key findings in order to ensure their validity

6.3 Impact assessment questionnaire

- 6.3.1.1 A key element of the data collection consisted of a questionnaire. The questionnaire had two key purposes:
- To collect basic information about stakeholder views
 - To facilitate further data collection among stakeholders
- 6.3.1.2 It was decided that data collection based on a questionnaire would be relevant for basic information concerning stakeholder views. More in-depth information would though not be feasible to collect through questionnaires but could instead be obtained through interviews, bilateral meetings and review of available literature. Quantitative data on costs and benefits, for example, are more likely to be provided through interviews. Therefore, it was decided to include a question in the end of the questionnaire for respondents to indicate whether they would be prepared to be involved in further discussions with the Agency on the accreditation / recognition of assessment bodies.
- 6.3.1.3 The questionnaire was distributed to the stakeholders most likely to be affected by the proposals on a mandatory accreditation / recognition schemes, i.e.:
- Sector organisations and their members (CER, EIM, UNIFE and ERFA)
 - Assessment Bodies (via NBRail)
 - National Safety Authorities (NSAs)
- 6.3.1.4 In addition, the questionnaire was distributed to EA (European co-operation for Accreditation) and national accreditation bodies. However, following discussion with EA it was agreed to limit responses to EA only.
- 6.3.1.5 Apart from dedicated questions to the different stakeholders the questionnaire also contained a set of general questions covering the following issues:
- SWOT (Strengths, Weaknesses, Opportunities and Threats) questions
 - Value-added assessment
 - Preferred type of scheme
 - Views on NSA as CSM assessment body
 - Views on accreditation / recognition scheme solving any current problems

- Views on higher need for mutual recognition by freight operators / rolling stock manufacturers
- Views on relaxing requirements re. domestic only changes
- Changes in costs for the work of ABs

6.3.1.6 The questionnaire achieved some 37 responses providing a rich source for the impact assessment work. In the following chart a break-down of those responses is provided.



6.3.1.7 The Diagram shows that 18 NSAs responded to the questionnaire (49% of sample), 10 sector answers (27%) and 9 answers from assessment bodies (27%) have been received.

6.4 Interviews

6.4.1.1 A series of interviews and bilateral meetings have been undertaken in order to complement the information provided through questionnaires and explore issues more in-depth. Furthermore, quantitative information on costs would be cumbersome and unlikely to obtain through questionnaires. These interviews have been organised through conference calls, although face-to-face meetings have also been used.

6.4.1.2 The interviews focussed on the following main issues:

- In-depth understanding of how the proposed schemes will address current problems in relation to mutual recognition

- Improved understanding of cost drivers from introduction of accreditation / recognition scheme. What are the cost-differences (if any) between the two schemes
- To what extent are the costs created matched by benefits of accreditation / recognition scheme
- The scope and possibilities for relaxing the criteria if required
- Among these issues particular importance will be given to quantification of benefits and costs (order of magnitude).

6.4.1.3 Interviewees were encouraged to provide quantitative estimates of likely costs and benefits involved as well as to provide relevant case study examples that convey practical issues of importance for the impact assessment. The interviews have contributed towards a comprehensive understanding of the issues regarding risk assessment and the roles and responsibilities of assessment bodies.

6.4.1.4 Some 7 interviews have been carried out. These interviews cover the perspectives from the following categories of stakeholders:

- National safety authorities
- Railway undertakings
- Infrastructure managers
- Rail manufacturers
- Assessment bodies

7. ASSESSMENT OF IMPACTS

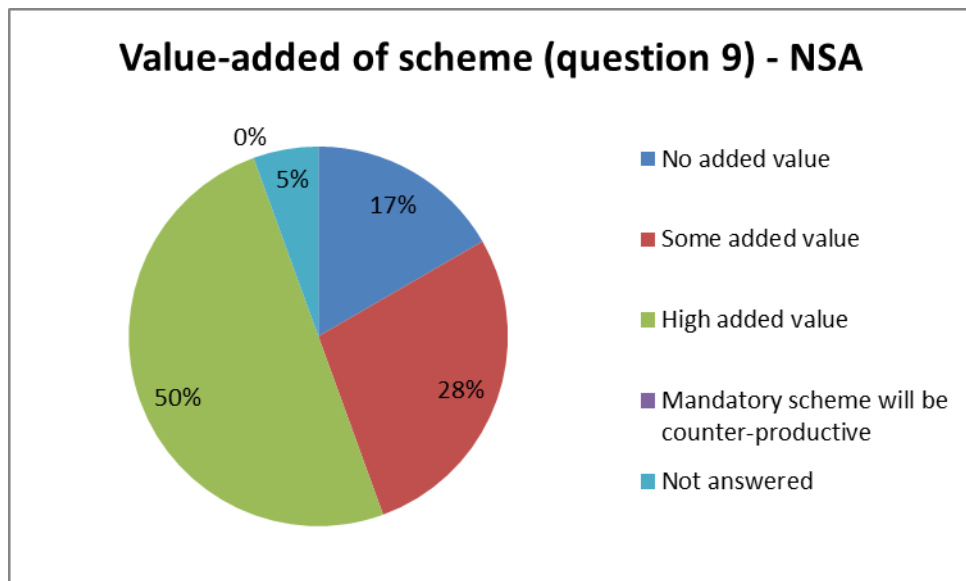
7.1 Overview of section

7.1.1.1 The findings regarding expected impacts from adopting and implementing the CSM on monitoring is presented in this section. In particular, the section will detail out the questionnaire and interview findings followed by a review of cost and benefit considerations. The remaining sub-sections outline issues on: competition assessment, administrative burden, transition and implementation aspects as well as robustness of results.

7.2 Questionnaire and interview findings

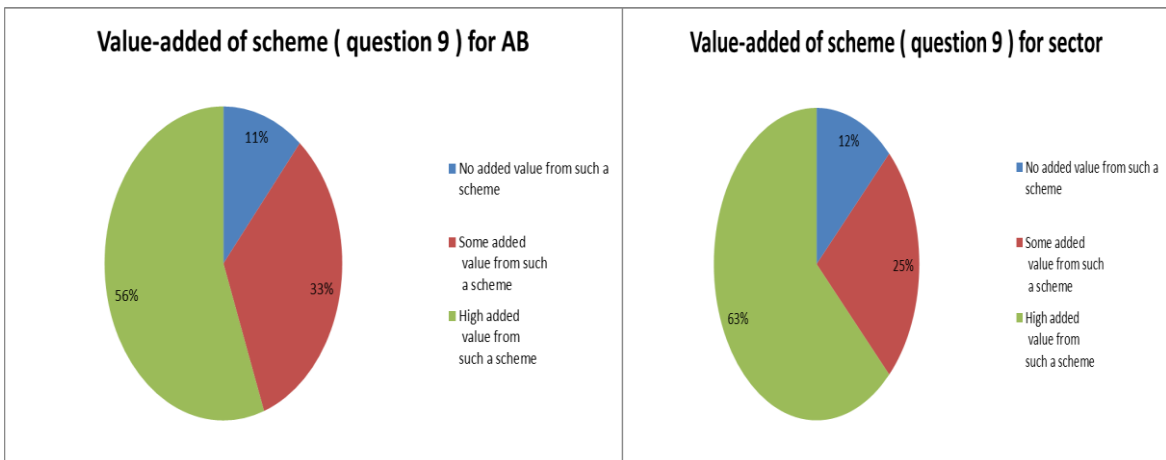
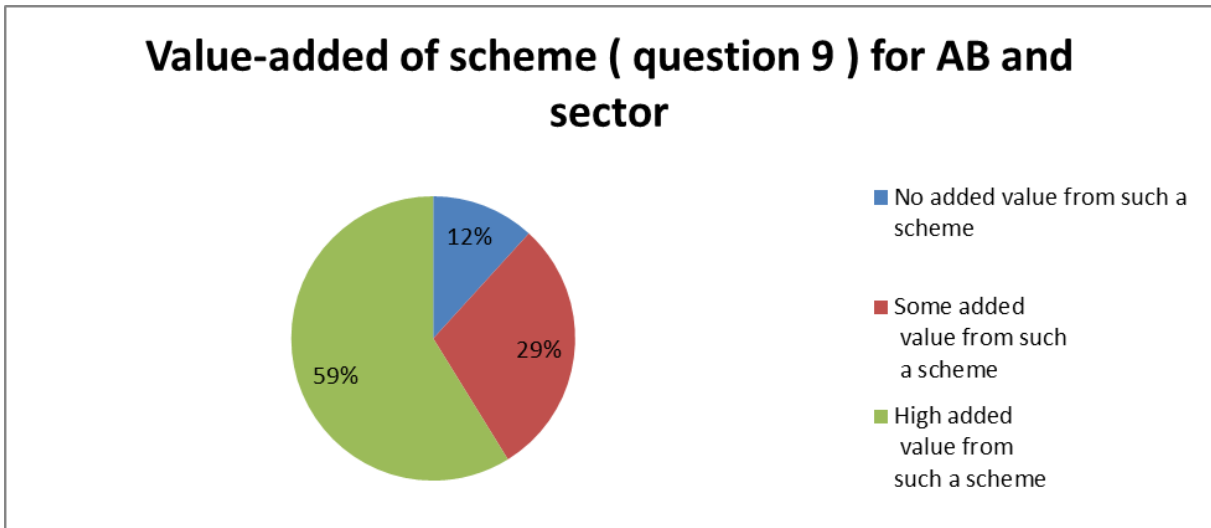
7.2.1 Value-added of accreditation / recognition scheme

7.2.1.1 Among the NSA respondents a substantial majority indicated that an accreditation / recognition scheme would have some (28%) or high added-value (50%), a total of 78%. Only 3 respondents out of 18 (17%) indicated that there would be no added value from such a scheme. It should be noted that one respondent indicated that the positive assessment related to recognition scheme only. Furthermore, as some respondents clearly prefer either accreditation or recognition only, it should be examined further whether the positive assessment is linked to the type of scheme adopted or whether it reflects a general view.



7.2.1.2 Reasons put forward for the indications of added value include: positive impact on safety, implications for mutual recognition, easier to identify suitably qualified organisations, assessment of significant changes (infrastructure) will be considered by an accredited / recognised assessment body. It should be mentioned here that for the minority of NSAs seeing no added value the view was that the proposed scheme would not contribute to enhance mutual recognition and reduce problems linked to cross-acceptance.

7.2.1.3 A similar distribution of answers appears for assessment bodies and the sector as indicated in the following chart. The majority of respondents considers that an accreditation / recognition scheme would be of some or high added-value.



7.2.1.4 Reasons behind the view of added value of such a scheme included among others the following:

- *Added value in sense of harmonization and cross acceptance.*

- *Higher acceptance and transparency of safety assessments.*
- *The added value by accreditation against recognition is expected to be higher. But for internal CSM AB the most added values are expected by recognition through the safety certificate. As processes are in place to fulfill the requirements of the regulation, the quality of the safety assessment is per RU/IM high. And the recognition is implicitly done by the NSA without additional effort in order to become a CSM AB.*

7.2.1.5 However, there were respondents who indicated that there would be no added value of such a scheme because they did not foresee any need for cross-acceptance for these types of stakeholders.

7.2.1.6 One respondent perceived that such a scheme would increase cost but considered that it would nevertheless be of high-added value:

- *Although more regulation will increase costs, quality of CSM assessment will be increased due to processes enforced by EC. This will also affect safety in a positive way.*

7.2.2 Impact on current problems regarding mutual recognition

7.2.2.1 The responses here can provide some information regarding the extent to which a formal accreditation / recognition is viewed as a help in solving any problems on mutual recognition. Overall, a clear majority of the NSAs that responded agree that a formal (mandatory) accreditation / recognition scheme would solve problems currently faced regarding mutual recognition. 56% strongly agree and a further 12% somewhat agree on this. It should be mentioned that none of the respondents strongly disagree but some 13% somewhat disagree. It should also be noticed that these responses do not imply that all current problems will be sorted in this way and further analysis of how this scheme will assist is required through case studies and illustrative examples. A tentative understanding can be formed from the additional comments received, although only few respondents provided further explanations. Possible reasons behind such a scheme solving current problems were expressed as follows:

- *This is important in an authorisation for placing into service situation. And also when accepting with part A safety certificates.*
- *Definitely, accreditation / recognition guarantee a greater confidence in the assessments.*

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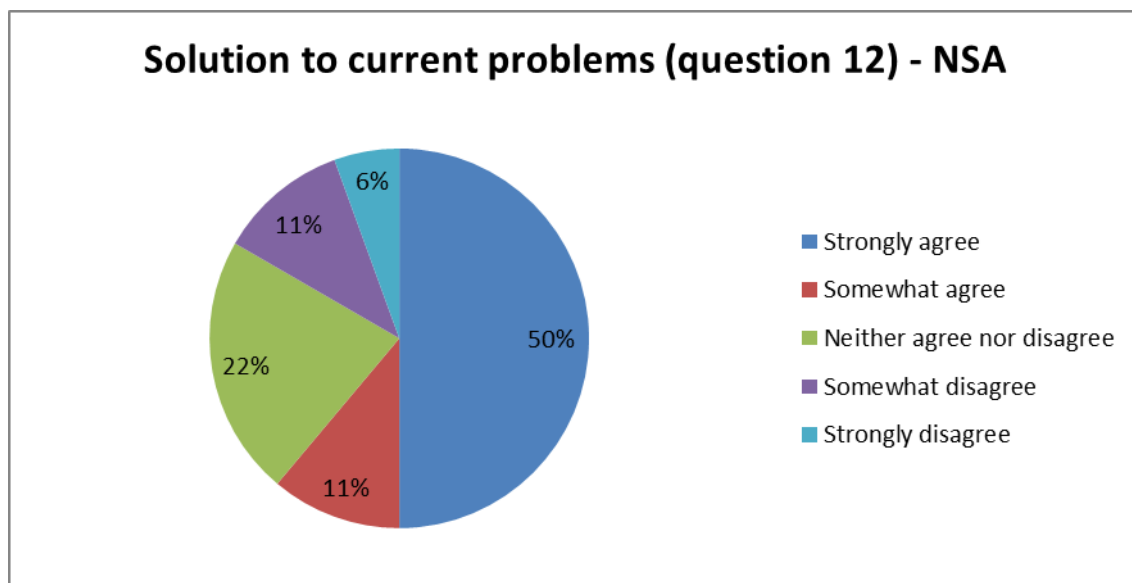
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7.2.2.2 These indications provide hints regarding the benefits of a formal accreditation / recognition scheme.

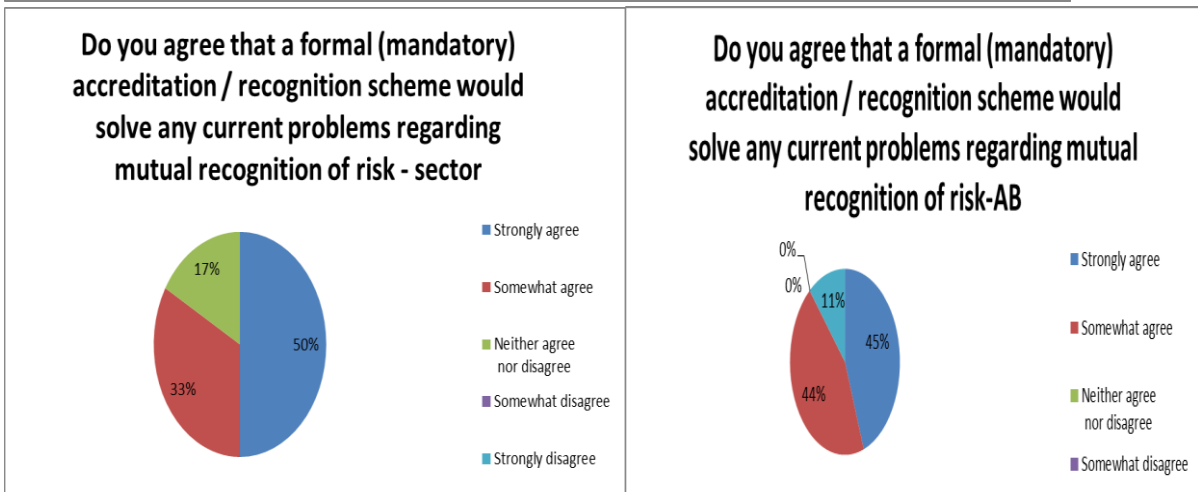
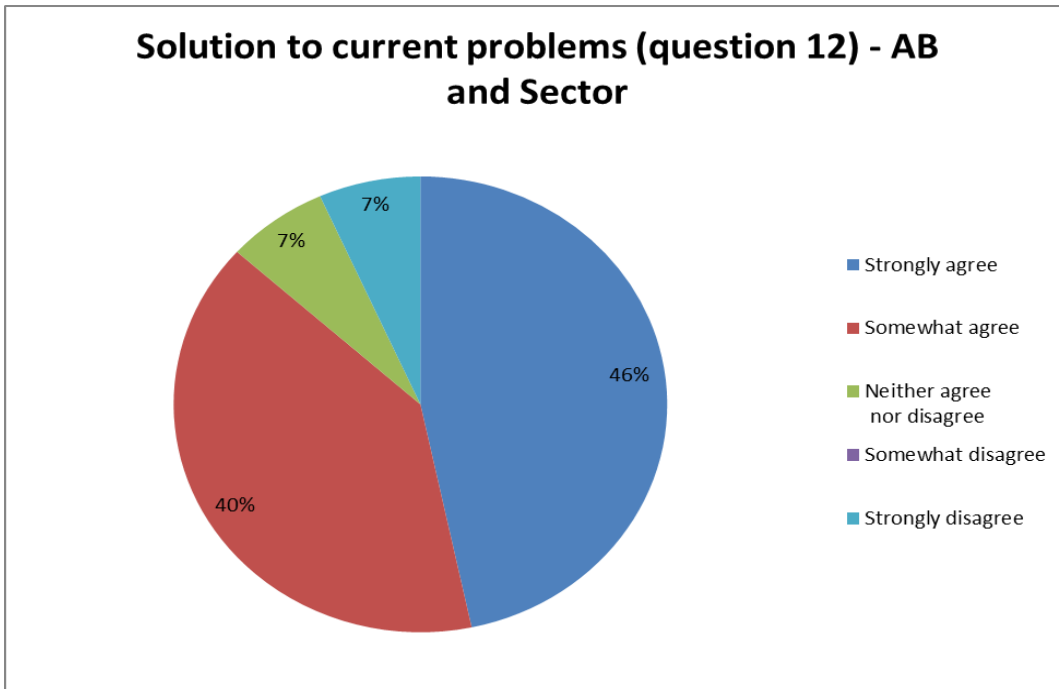
7.2.2.3 On the other hand one respondent which neither agrees nor disagrees on this issue stated that:

- *The answer to question 2 explains our reservations about the effectiveness of an assessment body in ensuring cross-border acceptance. Some of these difficulties are cultural in origin and some are due to concerns about importing risk that may be risk aversion or well founded in genuine concern. Moreover, the interface issue would still require an infrastructure manager to carry out some checks of their own when new equipment is proposed for use on a network. Quite where the boundary between assessment and this lies I am not sure and will probably need working out over time.*

7.2.2.4 This highlights some of the challenges that need to be addressed in order to capture the potential benefits of such a scheme.



7.2.2.5 The responses from assessment bodies and the sector also point towards the possibility that an accreditation / recognition scheme can provide a solution to problems concerning mutual recognition. For this group of responses the overall proportion of strongly agree and somewhat agree is though significantly higher – 86%.

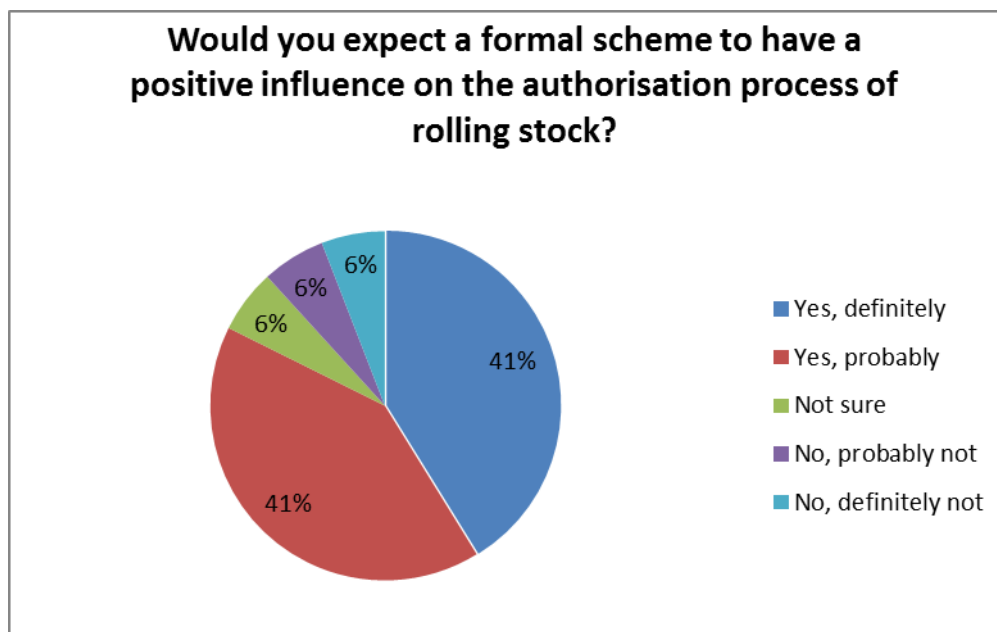


7.2.2.6 Two examples of the additional comments received from this group of respondents:

- *One thinkable problem can be cross acceptance, for this a formal accreditation can be a solution, at least part of a solution. The main part for mutual acceptance in my opinion depends on the underlying standards and a similar interpretation of them.*
- *If a formal accreditation/recognition scheme would not solve any current problems regarding mutual recognition of risk assessments, then such demanding scheme shall not be implemented. Mutual recognition will be possible if everybody follows the same rules but also if equal possibilities for claims are available.*

7.2.3 Influence on authorisation process

7.2.3.1 This question was addressed to the NSA respondents only (as they are in charge of the authorisation process). The results are shown in the following chart.



7.2.3.2 A substantial number of these respondents expect a formal scheme for accreditation / recognition of assessment bodies to have a positive influence on the authorization process of rolling stock. 41% definitely anticipate a positive influence, while another 41% answered that there probably would be a positive influence – in total some 82% of respondents expecting (with varying degrees of certainty) a positive influence. This is an important result as key benefits of the proposed scheme are foreseen here through reduced duplication of assessments leading to lower costs and shorter time for completion of the authorization process.

7.2.3.3 Below, examples of comments from the NSA respondents are provided supporting their answers:

- *Yes, because it will support and make easier the mutual recognition of rolling stock.*
- *This is absolutely necessary to ensure XA.*
- *It puts all the assessments in the same context and situation, as it is performed by a party whose main task it is to perform such assessments...*
- *Definitely, accreditation / recognition guarantees a greater confidence in the assessments made.*

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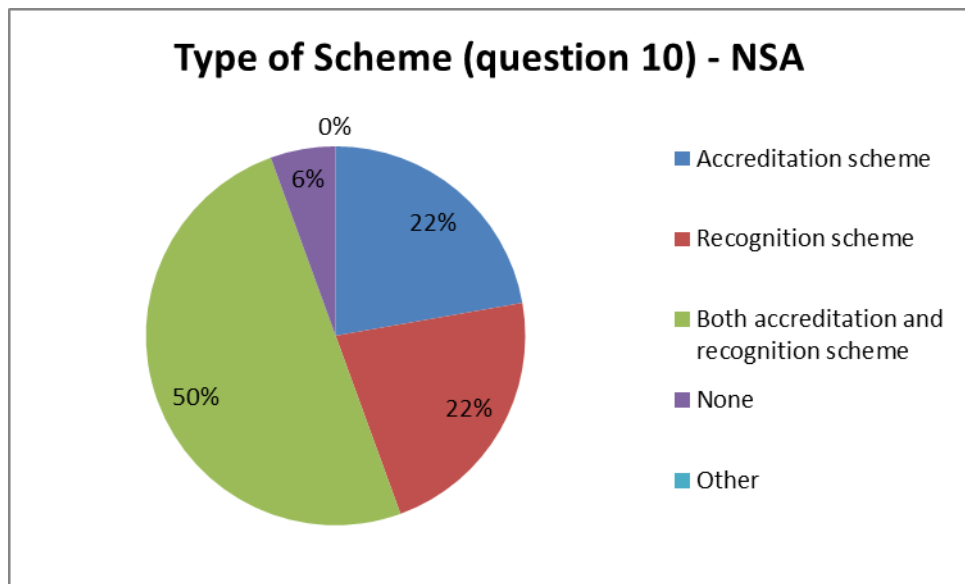
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- According to our opinion it shall have a positive influence on the process

7.2.3.4

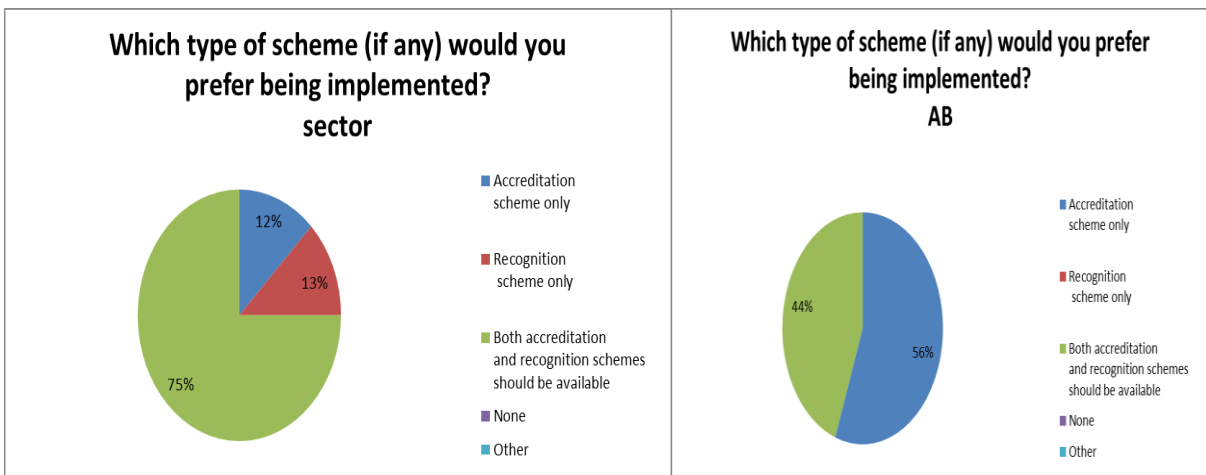
7.2.4 Preferred scheme

7.2.4.1 Consideration to scheme preferences was included in the questionnaire. Below, the results are shown for NSAs, respondents from the sector and assessment bodies. A majority of the NSA respondents preferred that both accreditation / recognition should be available (50%). On the other hand 22% would prefer accreditation only while 22% are in favour of recognition only.



7.2.4.2

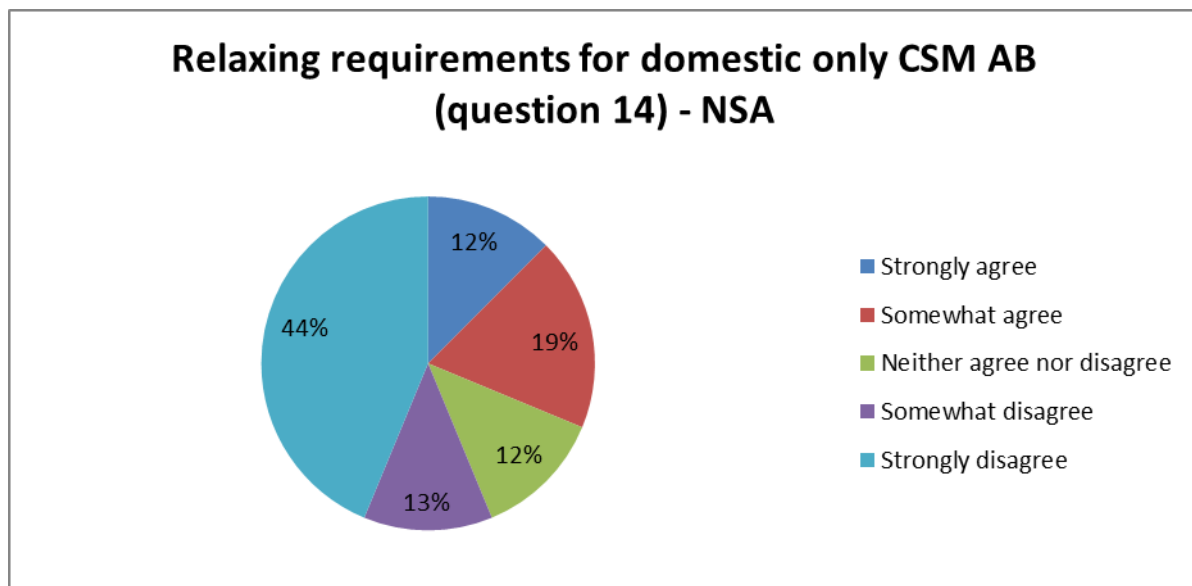
7.2.4.3 The view is consistent with the position among sector respondents, whereas preference among assessment bodies is towards a scheme based on accreditation only.



7.2.4.4 The views expressed in the questionnaire highlight the importance of a flexible approach regarding the scheme selection and would support the possibility for both accreditation and recognition to be available.

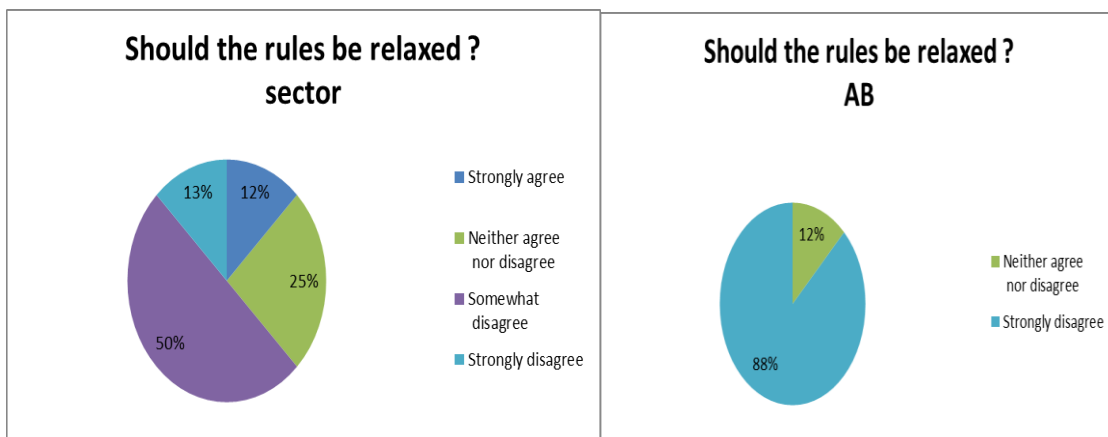
7.2.5 Attitudes on the relaxation of requirements for purely domestic changes

7.2.5.1 The possibility for relaxing requirements in those cases that involve purely domestic changes were considered in the questionnaire. On this issue the perception among NSAs, sector respondents and assessment bodies is overall rather similar as for all three groups a majority either somewhat disagree or strongly disagree.



7.2.5.2

7.2.5.3 The strongest opposition comes from assessment bodies (88% disagree) followed by sector respondents (63%). For NSA some 57% of the respondents disagree with this possibility.



7.2.6 SWOT analysis

7.2.6.1 SWOT (Strengths, Weaknesses, Opportunities, and Threats) questions were asked in the questionnaire (separately for accreditation and recognition). In the following, we review the main types of items mentioned. Overall, especially NSAs differentiated only to a limited extent in their answers between recognition and accreditation schemes.

Accreditation

Strengths

- Harmonisation of working methods/requirements of ABs (NSA, Sector)
- No advantage (NSA)
- Independence of staff and organisation from NSA (Sector)
- Mutual recognition (Sector, ABs)

Weaknesses

- Loss of flexibility (NSA)
- Costs (NSA, Sector, ABs)
- Slower process (NSA)
- Need of expertise (NSA, Sector)
- None (Sector)

Opportunities

- Harmonisation of working methods/requirements of ABs (NSA, ABs)
- Trust in AB's work (NSA)
- Clarification of roles and responsibilities in sector (Sector)
- Avoid heterogeneity of working methods, requirements (Sector)
- Mutual trust (Sector)
- Cross acceptance (Sector)
- Open market for ABs (ABs)

Threats

- Costs (NSA, Sector, ABs)
- Exclusion of certain AB (bodies) from activity (NSA)

Recognition

Strengths

- Harmonisation of working methods/requirements of ABs (NSA)
- Flexibility in employment of Abs (NSA)
- Further level of control (NSA)
- Same strength as accreditation (if scheme is mirrored) (Sector)
- Flexibility in employment of ABs/ in-house expertise (Sector)

Weaknesses

- No weaknesses as compared to current system (NSA)
- Questionable mutual recognition (NSA)
- Same weaknesses as accreditation (if scheme is mirrored) (Sector)
- Access to specific knowledge and skills (Sector)
- Rules & working methods would not be harmonised across EU (ABs)

Opportunities

- Harmonisation of working methods/requirements of Abs (NSA)
- Increased willingness of mutual recognition (NSA)
- Recognition easier than accreditation (NSA)
- Cross acceptance (Sector)
- No main opportunities – system already established (ABs)

Threats

- Administrative burden (NSA)
- Low level of mutual recognition (NSA)
- Less clarity of role of AB (Sector)
- Weakening of current arrangements (Sector)
- Mutual recognition might be rendered more difficult (Sector)

7.2.6.2 This summary clearly suggests that key advantages from a formalised scheme come from the possibility for harmonisation of working methods / requirements for ABs, trust in the work of assessment bodies and mutual recognition. These elements are linked such that the harmonisation of approaches would facilitate trust in the work of assessment bodies which in turn would promote mutual recognition. On the other hand there are concerns about cost implications expressed by all three types of stakeholders. Obviously, any costs incurred by this scheme should be contrasted with the likely benefits of the scheme as highlighted by the abovementioned advantages in terms of value-added, possibility for solving problems of mutual recognition and the positive influence on the NSAs authorisation process.

7.2.6.3 In the choice between accreditation and recognition the SWOT analysis seems to indicate that trading-off is occurring with accreditation being the preferred among respondents putting a higher value on ensuring mutual recognition than on the cost implications while the opposite is the case for those preferring recognition. In particular, the possibility for recognition through the SMS process was seen as important for the sector respondents in terms of minimise cost implications. Validity and trust among the stakeholders concerned towards both recognition and accreditation will be a critical issue in order to ensure that a proposer has a real choice of type of assessment body.

7.3 Stakeholder perspectives

7.3.1.1 In this section we will briefly outline the perspectives for the key stakeholders affected by this proposal. This outline will be based on the information provided through the questionnaire, interviews and available literature. In subsequent sections these elements will allow an overall assessment of benefits and costs (incl. implications on administrative costs). The main stakeholders affected by the proposals for a mandatory accreditation/ recognition scheme for CSM ABs are (as defined in the CSM Regulation [5]):

- Proposers
- Assessment Bodies
- National Safety Authorities
- National Accreditation Bodies (and recognition bodies as appropriate)

- 7.3.1.2 For **Proposers** the main advantages of this proposal are linked to the possibility to limit duplicative work building on increased trust in the work of CSM ABs and enhanced scope for mutual recognition of assessment reports from CSM ABs. As such accreditation would bring a high degree of trust of particular importance when Proposers are dealing with systems that require cross accepting or move across borders. On the other hand using an accredited assessment body involves costs which may not be justified in all cases (this would depend on the importance for cross acceptance). For these cases Proposers may rather choose a recognised AB. In this context RUs / IMs may in fact choose to use their internal AB which could then be recognised by the National Safety Authority as part of its assessment and approval of the SMS. This route should lead to lower cost implications while still ensuring the mutual recognition of assessment reports.
- 7.3.1.3 **Assessment bodies** planning to work as CSM AB need to be accredited or recognised. The proposal sets out clear and transparent criteria that CSM Abs should fulfil. It would be a business decision whether an AB chooses accreditation or recognition. As such the main advantage of accreditation would be linked to its European wide validity providing the opportunity for business on a larger scale compared to the situation without accreditation. This may be relevant for both ABs that are part of a Proposer's company (internal ABs) and for other types of ABs. On the other hand these business opportunities should be contrasted with the costs incurred for accreditation by the AB.
- 7.3.1.4 **National Safety Authorities** may be affected in three possible dimensions: (1) involvement in the recognition of Proposer's internal AB via the SMS assessment; (2) NSA could be a CSM AB as provided for under the CSM Regulation [5]; (3) NSAs process for the authorisation of the placing in service of subsystems and vehicles. As for the first item it would be required that this aspect will form an integral part of both the initial assessment of the SMS as well as any supervision activities following the award of the safety certificate / safety authorisation. If a Member State decides that the NSA is an assessment body it would require relevant competencies are in place along with necessary changes in organisational structure (separate section responsible for the activities of assessment body). In relation to the authorisation of the placing in service of subsystems and vehicles one possible advantage of the proposal is that NSAs should have more confidence in the assessment reports provided

by ABs. This may contribute towards reduced NSA resources for the authorisation of the placing in service related to significant changes.

- 7.3.1.5 **National Accreditation Bodies (NAB) (and recognition bodies)** need to be having competencies in place to evaluate whether companies satisfy the criteria for being accredited CSM ABs. As such under Regulation 765/2008 the NAB activities are regarded as public authority activities (not-for-profit) such that costs incurred through accreditation tasks are matched by fees from the companies applying for accreditation.

7.4 Consideration to benefits of proposals for accreditation / recognition of assessment bodies

- 7.4.1.1 Accreditation of an assessment body would signify that it meets the requirements set by harmonised standards as well as any specific requirements in the case of examining the application of the CSM for risk assessment. It is an attestation of the competences of the assessment body by a neutral party (National Accreditation Body being the sole body in a Member State that performs accreditation with authority derived from the State) in accordance with Regulation (EC) n^o 765/2008. A given accreditation is valid in all EU Member States and not restricted to the country of the national accreditation body that issued it in the first place.
- 7.4.1.2 Recognition of an assessment body also involves attestation with respect to its competences although not carried out by the national accreditation body as such recognition falls outside of Regulation (EC) n^o 765/2008 (see article 5).
- 7.4.1.3 For both accreditation and recognition a common framework for evaluation of competences of assessment bodies would be facilitated which in turn may lead to enhanced trust of the conclusions of the CSM ABs' safety assessment report.
- 7.4.1.4 Key benefits of an accreditation / recognition scheme is then linked to the possible improved conditions for mutual recognition which may result in time and cost savings due to avoided duplicative work in the risk assessment and associated independent safety assessment process. This may be of particular importance in those cases where a significant change also involves authorisation for placing in service of subsystems or vehicles where use of accredited / recognised assessment bodies could lead to shorter time involved and lower costs. Furthermore, as a possible side-benefit the introduction of a common framework for competence evaluation could contribute towards ensuring a high level of railway safety. The possibility for these benefits

occurring are supported by the findings from the questionnaire and interviews, in particular respondents perceived that the proposed scheme will be adding value and the dominant view among respondents was also that it would contribute to address the problems related to mutual recognition.

7.5 Consideration to costs of proposals for accreditation / recognition of assessment bodies

7.5.1.1 Possible disadvantages of establishing a (mandatory) accreditation / recognition scheme are mainly linked to the costs involved. The impact assessment has considered both implementation costs as well as on-going costs for all stakeholders that could be affected by such schemes (incl. proposers, assessment bodies, NSAs, accreditation bodies etc.). In particular, it has been assessed whether there are particular issues for SMEs in this respect (see sec. 7.6). Implications of higher costs could arise in different forms including: (a) increased costs for Proposer when implementing significant changes projects; (b) postponement or cancellation of projects with significant changes; (c) cancellation of other initiatives (in order to provide the resources required for the significant change project).

7.5.1.2 In the following we will outline the possible orders of magnitude related to accreditation under ISO 17020 covering:

- Costs for an assessment body to prepare for accreditation
- Costs for an assessment body to prepare for surveillance audit by the accreditation body
- Cost for the National Accreditation Body of accrediting an assessment body

7.5.1.3 It should be mentioned that the cost figures given are only indicative.

7.5.1.4 The costs for an assessment body to prepare for accreditation will depend on several factors. These factors include size of organisation and scope of activities as well as whether the organisation is already accredited under similar system (e.g. EN 45011). Our available information from the questionnaires and interviews suggest the following ranges as typical:

- 5,000 – 25,000 Euros (for organisations already accredited under similar system, e.g. EN 45011)
- 10,000 – 37,000 Euros (for other organisations)

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7.5.1.5 On this basis, an average of around 15,000 Euros (for organisations already accredited under similar system) and 23,500 Euros (for other organisations) would seem likely. It is possible that for very large organisations the costs involved would be above these ranges. It should be noted that these figures do not include the fees to be paid to the accreditation body.

7.5.1.6 Limited information about the costs for assessment to prepare for surveillance audits by the accreditation bodies (during the validity period of the accreditation) is available. However, some indications from the questionnaire suggest between 1 and 2 weeks for one person per year. As one respondent stated *'There is a continuous maintenance of the inspection processes; so there are only few costs especially for the audits'*.

7.5.1.7 Our available information concerning the costs incurred by the National Accreditation Body to perform an initial accreditation of an organisation under ISO 17020 indicate the following range:

- 6,000 – 15,000 Euros

7.5.1.8 This would point to an average of around 10,000-11,000 Euros. These figures are consistent with the fees published by the different National Accreditation Bodies as regard to inspection bodies. For example, in the following the charges from 2011 for the Irish National Accreditation Body are given (for laboratories and inspection bodies):

Fees	Euros
Application fee	€950.00
Pre-assessment fee	
- To include one assessor day on-site	€2,107.00
Initial assessment or annual management fee	
- To include INAB fee and one lead assessor for 1 day assessment on-site	€5,007.00
- Each additional assessor	€2,107.00
Additional visit fee	
- Each assessor day on-site	€2,107.00

Source: Irish National Accreditation Body (2011)

- 7.5.1.9 Overall, the likely average costs incurred by an organisation preparing and applying for accreditation could be around 25,000 Euros (already accredited against similar standard) and 34,000 Euros (not accredited against similar standard already). As most NoBos (80%) are accredited it can be expected that for these organisations the typical costs are likely to be closer to 25,000 Euros than 34,000 Euros. Indications from the UK National Accreditation Body (UKAS) suggest that costs in terms of fees are of similar magnitude in case of re-accreditation. Costs for preparing for re-accreditation may though be lower.
- 7.5.1.10 In comparison, it is expected that the costs for recognition via the SMS by the National Safety Authority would be significantly lower. In particular, the costs relating to the fees to the accreditation body would be avoided, while the costs of ensuring that the criteria of Annex II mirroring ISO 17020 are fulfilled can be integrated as part of the preparation of the SMS for NSA conformity assessment and supervision. In this case the costs involved for such an assessment body could be up to around 2,500 Euros (using the lower estimate given for the costs for preparing for accreditation and assuming half the number of work days required). As usual the uncertainty of such figures should be noted.

7.6 Balance between benefits and costs

- 7.6.1.1 In section 7.4 an overview of the sources of benefits was given highlighting the possible advantages gained through avoided duplication of work due to enhanced trust in assessment reports and increased mutual recognition of the assessment results. Furthermore, there is a strong possibility for a positive influence on the NSA procedure for authorising the placing in service of rolling stock. As such this could bring significant benefits to the sector that would outweigh the costs identified in Section 7.5. Indeed, Agency work regarding the scope for reduced costs and time involved for the procedure for authorising the placing in service of rolling stock [10] confirms the possible benefits. Two remarks: (1) this proposal may only be a necessary condition rather than a sufficient condition for cross-acceptance; (2) risk assessment elements represent only one of the cost drivers in relation to the placing in service of rolling stock procedure. Tentative quantification of the impacts does point towards the possibility that benefits could be significantly higher than the costs involved. In particular, these analyses suggest that the order of

magnitude of the annual benefits could be in the range from 5,7 to 11,5 ME. These benefit estimates are based on figures included in the abovementioned report [10] regarding the total costs of an additional authorization for a locomotive / fixed formation type, break-down of the cost drivers (incl. those linked to risk assessment) and number of authorizations per type in the most recent year (2009). The latter choice will result in underestimating the benefits as the number of authorizations per type was lower in 2009 compared to earlier years due to the macroeconomic conditions. Costs are likely to be in the range from 2,5 to 3,4 ME in the case of accreditation (and between 0,3 and 0,4 ME for recognition). These (total) cost estimates are based on the information given in Section 7.5 on the cost of accreditation / recognition per assessment body and consideration to the likely number of assessment bodies. On this basis our tentative quantification of the impacts suggest that the Benefit Cost ratio is likely to be significantly higher than 1 (a low estimate of 1,7 and a high estimate of 4,6). The uncertainty of such calculations should though be noted.

7.7 Competition assessment

- 7.7.1.1 In this section attention will be given to the possible implications on competition related aspects. In particular, it will be examined whether there are likely to be disproportionately adverse effects on SMEs and new entrants. There appear to be two sets of issues of importance. Firstly, the possible variation in impacts on railway undertakings acting as Proposers, where there may be differences according to whether the RU is an incumbent or a new entrant (similarly there could be variation linked to the size of the RU). Secondly, there could be issues linked to the market for CSM assessment bodies.
- 7.7.1.2 As for the first dimension it should be mentioned that the analysis should not consider implications linked to requirement regarding use of assessment body for a Proposer as this is already established by the CSM Regulation [5]. The analysis should focus on how different types of RUs (as Proposers) will be affected by the requirement that the assessment body used is accredited or recognised. Small RUs (in particular those that are new entrants) are probably less likely to have an internal department that could perform the role of assessment body (compared to larger RUs). Therefore, these types of RUs would then have to use an external assessment body (but this would already be the case without the proposal for accreditation / recognition). In this case, it is likely that the proposal would in fact improve the situation for small RUs

because all assessment bodies available would satisfy minimum criteria and the risk of assessment reports being called in question reduced, thereby reducing costs. The important element would then be to ensure that Proposers have a real choice among assessment bodies and to prevent that the market for CSM assessment bodies is not dominated by a few companies.

- 7.7.1.3 The last point brings the analysis to the second issue regarding the implications of the proposals for the market for CSM assessment bodies. On the positive side the proposal should clarify how a company can become a CSM assessment body (by defining the criteria to be fulfilled against the ISO 17020 standard and the additional requirements for CSM ABs). Furthermore, accreditation / recognition is delivered by an independent party (the National Accreditation Body or the recognition body). This should contribute to ensure that this market is in principle open with transparent access conditions. These elements should stimulate interest among relevant companies and facilitate their entry to this market. On the other hand there may be companies that initially have an advantage in fulfilling the criteria for accreditation / recognition (e.g. NoBos where some 80% already are accredited under relevant ISO or EN standards). In such cases, the resources required for such companies to become accredited / recognised are likely to be lower compared to other companies. This initial advantage needs to be monitored closely by the relevant national competition authorities in order to ensure that such companies are not dominating the market for CSM assessment bodies.

7.8 Administrative burden issues

- 7.8.1.1 As part of the impact assessment consideration has been given to the implications on administrative costs. This is based on the concepts put forward in the EC Impact Assessment Guidelines [4] where Annex 10 provide detailed information regarding administrative cost and administrative burden. In particular, administrative costs are defined as *'the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties'*. Administrative burden concerns *the part of the information collection and provision which is done solely because of a legal obligation* (in contrast to those elements that would be done by entities even without the legislation).

7.8.1.2 Overall, the CSM Regulation [5] already requires a Proposer to use an assessment body. Therefore, this aspect should not be considered here in terms of changes in administrative burden.

- 7.8.1.3 The additional administrative costs incurred by the proposal would concern:
- Accreditation bodies shall, when requested by an assessment body, evaluate whether the AB is competent to be a CSM AB. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to the AB. An equivalent task would be performed recognition bodies
 - Similarly, NSAs shall, when the Proposer is an RU or IM and it chooses recognition through the SMS process, undertake its assessment and supervision of the safety management system and determine whether the RU / IM is competent to be an assessment body. If this is the case the statement of recognition for a railway undertaking or an infrastructure manager shall be displayed on the relevant safety certificate or safety authorisation.
 - Accreditation bodies are required to perform monitoring audits of the accredited assessment bodies during the validity period as well as re-accreditation audits at the time of renewal. Equivalent tasks are to be performed by recognition bodies. When NSAs recognise (internal) assessment bodies of RUs and IMs through the SMS, the supervision activities will have to include this aspect to ensure that the provisions in the SMS are applied properly.
 - National Accreditation Bodies shall take part in peer evaluation activities in line with the EA Multilateral Agreement (MLA). An equivalent peer review activity will be set up for recognition bodies.
 - Assessment bodies seeking accreditation / recognition will have to prepare for the audits / inspection and provide the required information to the accreditation / recognition body

7.8.1.4 These administrative costs should be contrasted with the anticipated benefits (as outlined in the previous sections). In particular, although there are administrative costs associated with accreditation (and recognition) it is likely that there will be matching benefits due to less re-examinations, duplicative tests and doubts regarding assessment reports. In fact, it is likely that the proposals should result in net-savings regarding administrative costs. The likelihood of net-savings is strengthened by the flexibility given to the

Proposer in terms of the choice of assessment body. It should be mentioned that as these possible net-savings depends on trust in the different scheme elements by the concerned stakeholders, appropriate arrangements regarding implementation need to be ensured.

7.9 Transition and implementation issues

7.9.1.1 The key implementation issue arise from the point where CSM ABs need to fulfil the ISO 17020 requirements and Annex 2 of the proposed revision of the CSM RA Regulation [6] for accreditation or satisfy equivalent criteria under recognition. Otherwise, ABs not being accredited or recognised cannot be used by a Proposer. The accreditation scheme has therefore to be available to the National Accreditation Bodies (NABs) such that it can be integrated in their activities. Co-operation with EA is facilitating the appropriate practical development of such a scheme. Similar, arrangements need to be established for recognition bodies in order to ensure that this option is available to Proposers. Attention needs to be given to the possible role of NSAs in the scheme in order to ensure that appropriate competencies are in place. This refers primarily to the situation when NSAs is having the role of (implicit) recognition body through the SMS process. Also, there will be implementation issues in those cases where NSAs are planning to act as assessment bodies. As part of the development of the accreditation / recognition scheme consideration should be given to arrangements to ensure that there is sufficient choice for Proposers regarding selection of assessment body. This will be supported through the practical development of the schemes to be used by the accreditation / recognition bodies (as described above).

7.9.1.2 The abovementioned points reflect concerns raised by some respondents to the questionnaire and highlight the importance to proper implementation arrangements to ensure that the apparent scheme benefits are captured. As such it is critical that the proposal envisage dissemination / training activities of the relevant stakeholders as well as introduction of peer reviews among the recognition bodies (similar to those in place via EA for accreditation bodies).

7.10 Robustness of results

7.10.1.1 The impact assessment indicates that the benefits of the proposals are likely to outweigh the costs incurred. Although quantification of benefits is difficult and uncertain the inherent structure of the scheme in terms of the flexibility

provided suggests a strong possibility for benefits being higher than costs from a global perspective. This finding is supported both by the quantitative analyses and the questionnaires / interviews undertaken. Two important caveats has to be mentioned: (1) appropriate implementation arrangements need to be ensured in order to achieve the highest possible trust in the scheme by the different stakeholders for both accreditation and recognition; (2) the market for CSM ABs need to be monitored by the relevant competition authorities in order to avoid market dominance. These items put emphasis on careful monitoring and evaluation arrangements following the adoption of this proposal.

8. MONITORING AND EVALUATION

8.1 Overview

8.1.1.1 According to the EC Impact Assessment Guidelines [6] ex-ante impact assessments should include consideration to the monitoring and evaluation arrangements to be put in place for adopted policy actions. These types of activities will facilitate the update of the impact assessment in the course of the preparation of proposals, or after their entry into force. Monitoring and evaluation should check three related elements: (1) prerequisites, (2) efforts and (3) results. Each of these is defined and outlined in the following paragraphs with reference to the proposals regarding the mandatory accreditation / recognition schemes for CSM ABs. This forms the basis for the Agency's anticipated ex-post evaluation work.

8.2 Monitoring prerequisites

8.2.1.1 Pre-requisites refer to issues that support the accreditation / recognition schemes and will have an influence on changes observed but are not part of the schemes. Overall, limited monitoring activity is foreseen in this area. However, possible items to consider are identified in the report accompanying the revision of CSM RA Regulation. These includes would include among others: (1) other revision elements of the CSM RA (notably RAC), (2) adoption of CSM on monitoring and CSM on supervision, (3) implementation of ECM Regulation.

8.3 Monitoring efforts

8.3.1.1 This concerns the efforts to implement the (adopted) Recommendation, and the observed obstacles, for the EU Member States. A number of elements are already provided for in the proposed revision of the CSM RA Regulation [7], including (some of the information outlined may be made available through a change in the scope of ERADIS):

- Choices of Member States regarding the bodies responsible for accreditation / recognition of assessment bodies
- Identity of assessment bodies that have been accredited or recognised in Member States

- Frequency of the NSAs being assigned as CSM AB
- Preparation of ABs and NABs in terms of human and financial resources (the former should pay attention to the extent to which staff competences are sufficient, incl. extent of staff training)
- Information concerning assessment bodies involved in purely domestic changes to see if it will be possible to relax some requirements
- Activity level of assessment bodies and national accreditation bodies in each country according to relevant data.

8.3.1.2 Indicators regarding the activities performed in this context would form the basis for monitoring the efforts to ensure implementation of the mandatory accreditation / recognition scheme.

8.4 Monitoring results

8.4.1.1 This part of the monitoring will comprise indicators regarding the actual results or effects brought by the introduction of the mandatory accreditation / recognition scheme for CSM ABs. In this case it would be relevant to collect information from:

- Railway undertakings, infrastructure managers
- Railway manufacturers
- ECMs (Entity of Charge of Maintenance)
- National Safety Authorities
- Assessment bodies
- National accreditation bodies
- Recognition Bodies
- European co-operation for Accreditation

8.4.1.2 These stakeholders are the ones that would be most directly concerned by the introduction of this scheme. These stakeholders should be asked about:

- Overall perceptions / experiences of the accreditation / recognition scheme (how does it compare to situation without such a scheme at pan-European level)
- Actual use of accredited assessment bodies relative to recognised bodies
- Views on specific elements of the scheme

- Implementation costs
- Changes in on-going costs for using assessment bodies
- Implications on mutual trust
- Consequences on authorisation for the placing in service of vehicles

8.4.1.3 In part, this information will be supplied from the NSAs annual reporting which will include experiences of the proposers regarding the application of the CSM RA Regulation.

ANNEXES

**Annex 1 – Questionnaires for IA for accreditation / recognition of CSM
Assessment Bodies**



Questionnaire for
CSM - AB