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ACCOMPANYING REPORT N. ERA-REC-115-2017/ACR TO THE RECOMMENDATION OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

on

THE REVISION OF THE COMMON SAFETY METHODS ON CONFORMITY ASSESSMENT AND THE COMMON SAFETY METHOD ON SUPERVISION

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Contents

1.	Executive summary	3
2.	Introduction	6
2.1.	Purpose and scope	6
2.2.	Background	6
3.	Workgroups.....	7
4.	Working method	8
5.	Content of the revision of the CSMs	10
5.1.	Objectives.....	10
5.2.	Structure and content	16
6.	Stakeholders' opinions.....	25
6.1.	Working party	25
6.1.1.	General opinion.....	25
6.1.2.	Minority opinions.....	25
6.2.	Public consultation.....	29
6.2.1.	General opinion.....	29
6.2.2.	Minority opinions.....	29
6.3.	NSA Network consultation.....	38
6.3.1.	General opinion.....	38
6.3.2.	Minority opinions.....	42
6.4.	Others.....	66
6.4.1.	Human Factors Network	66
6.4.2.	Group of Experts	66
7.	Annex 1: Abbreviations	82
8.	Annex 2: Reference documents	82
9.	Annex 3: Reference legislation.....	83
10.	Annex 4: Coordination on legal issues	84

1. Executive summary

In accordance with the Commission mandate [11], agreed by the Rail Interoperability and Safety Committee (RISC), Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates, Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (also named hereinafter the '**Common Safety Methods (CSMs) on conformity assessment**') and Commission Regulation (EU) No 1177/2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (also named hereinafter the '**CSM on supervision**') need to be revised in order to ensure that a more consistent approaches to conformity assessment and supervision are adopted by National Safety Authorities (NSAs).

Although the CSMs on Conformity Assessment have been applied for less than 7 years, (less than 5 years in the case of the CSM on supervision), the European Union Agency for Railways (also named hereinafter the '**Agency**') has, through a range of approaches, been able to analyse the information collected from various sources (e.g. the analysis of the results from the cross-audit programme of the NSAs, the dissemination activities, direct feedback on the practical application and use of the CSMs on conformity assessment and CSM on supervision or parts of it). After examining this data the Agency came to a conclusion that further harmonisation in the assessment of safety certificates/authorisations combined with effective post-award supervision is an absolute necessity to develop the Single European Rail Area and can only be achieved through the revision of the CSMs of conformity assessment and CSM on supervision.

During the initial development of the above CSMs, the aim was to develop high-level principles which could be handled with supporting guidance. This strategy gave a certain degree of flexibility while ensuring that the aims were met. The detailed guidance was to be developed by a task force composed of NSAs and chaired by the Agency. However, the development of such detailed process requirements and related application guidance for safety certification was only partially successful due to the current diversity of approaches to the application of the CSMs by NSAs and the different interpretation of the EU legal framework. The impact assessment undertaken by the Commission on the revision of the institutional framework also confirmed that there was a divergent interpretation of EU law. In addition, some NSAs found it difficult to use guidance to support the development of their decision-making as it was not a legal requirement.

As a consequence, in 2014 and more recently in 2016, the Agency has received the mandate to further harmonise conformity assessment approaches among Member States through the revision of the CSMs on conformity assessment and CSM on supervision. To that end, the Agency is requested to submit to the Commission its final recommendation on the revision of the above CSMs not later than 1 June 2017.

In the course of developing, discussing and agreeing this recommendation in the working party, all stakeholders have agreed on the overwhelming majority of the approaches underpinning the recommendation.

In some cases and on specific issues, a common position could not be reached with stakeholders. In particular, representatives of CER and ERFA had reservations about how the issue of human factors and safety culture is dealt with in the assessment criteria set out in the revised CSMs on conformity assessment. Their view is that some criteria added to the CSMs may lead to different interpretations and requirements by stakeholders, the Agency and NSAs, thus creating uncertainty and discrimination between railway undertakings to obtain single safety certificate. CER requests to clarify first what criteria are to be fulfilled and that can lead to refuse certification. In particular, CER promotes the creation of a specific Annex in the CSMs on conformity assessment to define more precise criteria in line with the proposal included in CER position paper published on 8 November 2016. It is essential for CER that presumption for conformity on human factors and safety culture criteria are further clarified. To that end, according to them, a guidance should be prepared taking into account UIC work, approved by NSAs and published before the start of the shadow running phase of the Agency programme for the implementation of the 4th Railway Package.

The integration of human factors and safety culture (even if not mentioned as such) is one of the major changes introduced by Directive (EU) 2016/798, in particular Article 9 thereof. From the very beginning of the revision work, the Agency mandated the Human Factors Network, composed of human factors and safety culture experts from the railway sector, including CER representatives, to identify what necessary amendments should be made to the CSMs under revision and also to help the Agency in building/ revising its guidance. At the very early stages of the discussions within the Human Factors network, it became obvious that separating out human factors requirements from other SMS requirements would be detrimental to the objective of Directive (EU) 2016/798 as it would then mean or be understood that human factors (and safety culture) are issues to be managed outside the SMS processes. Therefore, the Human Factors Network agreed that a new Annex in the CSMs on conformity assessment, as proposed by CER, was not the right approach. The Agency proposals for the integration of human factors and safety culture into the SMS reflect the opinion of the Human Factors network which was discussed and agreed with the working party. Other associations, such as ETF and EIM, were also supportive of that approach.

On several occasions, the working party stressed the need for the CSM assessment criteria set out in Annex II of the revised CSMs on conformity assessment to be supported by guidance explaining/clarifying what evidence is required to meet each of the elements. The Agency agreed that the CER proposals, including the UIC related work on safety culture, are relevant contributions for guidance as it helps clarify basic human factors and safety culture requirements. CER was also informed that the best way for them to address their concerns is by joining the work of the Human Factors network and assisting them in jointly writing the guidance that will underpin the text in the CSMs. CER and ERFA have not had the benefit at this stage of seeing the proposed guidance which it is hoped will address their concerns by providing more detail on what the expectation of compliance with the human factors requirements looks like. CER is encouraged to examine the future Agency guidance against its stated position to see whether it meets their expectations and to return to the Agency with an agreed common position harmonising the different views within CER and involving their representatives in the various related forums (i.e. working party, Human Factors network) which they attend.

Minority opinions stemming from the public consultation, NSA network consultation and discussions in other forums such as the Human Factors network and the Group of Experts are detailed in the present report (see section 6). These issues will be covered in the accompanying guidance to the CSMs where relevant.

In general, the feedback from the working party, NSA network, Human Factors network and the Group of Experts is considered positive. On several occasions, some stakeholders praised the Agency for way it had handled the revision work on the CSMs, in particular on how the Agency, in collaboration with the experts, improved the text.

In various forums (i.e. Group of Experts, working party, public consultation), NSAs have requested clarifications about the scope of their assessment and supervision with regard to the maintenance of vehicles, in particular when the Entities in Charge of Maintenance (ECMs) are not certified in accordance with Union law. The current legal framework does not identify a role for an NSA to assess/supervise ECMs and maintenance workshops unless the NSA is an ECM certification body. The Agency recognises this as an important issue to clarify. However, a final position cannot be reached before setting and agreeing on the scope of the ECM certification in the future revision of the ECM Regulation. The Agency has already agreed to provide further guidance on this issue when the revision of the ECM Regulation is completed or at least, when the scope of the ECM certification will be agreed by the different parties.

A few NSAs and representatives at the Group of Experts questioned the appropriateness of the railway undertakings providing assistance to victims following serious accidents, as part of their SMS, as referred to in the 3rd subparagraph of Article 9(5) in Directive (EU) 2016/798. This provision has been added in Annex II of the revised CSMs on conformity assessment in the emergency arrangements forming part of the railway undertakings' SMS. Some on the Group of Experts stressed on the one hand that their current national legislation gives that role to the authorities (local and regional governments) without specifically involving

the railway sector and others argued on the other hand that it may not be easy to determine whether the accident falls into the category of 'serious accident' in accordance with the definition given in Directive (EU) 2017/798, creating a big area for misunderstanding and discussions about whether actually railway undertakings performed well in terms of emergency management. In addition, it was noted that the railway undertakings may or not be responsible for the accident, taking the example of accidents caused by third parties at level crossings, which could therefore bring into question its role in the assistance to victims and also create problems when other institutions have already taken actions in this respect. This issue may need to be discussed again with the Group of Experts.

Feedback on the implementation of CSM on supervision and the objectives of the 4th Railway Package have shown the necessity of avoiding duplication of supervision between NSAs supervising the SMS of railway undertakings operating in more than one Member State. To address this specific issue, the Agency has proposed to identify a leading role for an NSA with the aim of coordinating the supervision of the SMS. The working party recognised the need for such a role but was split in how best to implement it, in particular who shall decide which NSA will take on this role and how the NSA should exercise it. The Agency agreed that criteria should be established by NSAs as part of their cooperation arrangements.

From previous coordination meetings with DG MOVE, it has been agreed that transitional provisions in the CSM on supervision are not justified (see Annex 4). During the public consultation, NSAs expressed the need to clarify that the SMS of the railway undertakings and infrastructure managers should be supervised against the requirements/criteria set out in the applicable CSM on conformity assessment at the time the Part A safety certificate was issued. The draft legal text of the CSM on supervision may need re-evaluation by the EC Legal Service in order to find the most suitable legal approach to this question, taking into consideration that NSAs have still to supervise during the transition railway undertakings and infrastructure managers for which a safety certificate (Part A and Part B) or a safety authorisation has been granted before 16 June 2019 in accordance with the old safety certification regime and that any enforcement action they may take to remedy non-conformities has to have a legal basis.

DG MOVE presented its views on the transitional provisions for the single safety certificate (and for the vehicle authorisation) at the Group of Experts in January 2017. The discussions within the Group of Experts were not closed and the way forward still needs further discussion and agreement. Therefore, the transitional provisions set out in the CSM on conformity assessment for the issuing of single safety certificates may need updating, consistent with the ones specified in the draft Implementing Act on the practical arrangements for safety certification as referred to in Article 10(10) of Directive (EU) 2016/798.

The Agency has conducted a Light Impact Assessment to help clarify if further harmonisation of assessment and supervision criteria and processes potentially represent an improvement or a burden to stakeholders, considering that the Railway Safety Directive 2004/49/EC already requires an SMS-based certification scheme. The approach for identifying relevant impacts is based on assessing what changes the implementation of the proposed measures for revising the CSMs could generate, compared to the current scenario where there is no consistent approach amongst NSAs due to insufficient harmonisation of assessment criteria and supervision procedures.

The Light Impact Assessment for the revision of the CSMs is based on a number of complementary stages for data collection and analysis in order to provide the required information for assessing the probable consequences. As an initial stage the members of the working party were invited to contribute to the Light Impact Assessment through a simple and short questionnaire. Data was also collected from a workshop, interviews and bilateral meetings, as well as from the review of relevant documents and case studies.

From the perspective of effectiveness and efficiency, the Light Impact Assessment concludes that a revision of the CSMs addressing the issues identified in the policy paper [1] and taking into consideration the new provisions of Directive (EU) 2016/798 is expected to address fully the problems experienced by stakeholders regarding safety certification and supervision inasmuch as these are linked to the three CSMs. The expectation is that this should result in at least the disadvantages from the revision being matched by

advantages, while possibly overall implying positive net-benefits. More details can be found in the Light Assessment report [4].

2. Introduction

2.1. Purpose and scope

The purpose of this document is to support the Agency recommendation on the revision of the CSMs on Conformity Assessment and the CSM on Supervision, including:

- › An outline of the objectives, consistent with the mandate given to the Agency [7], for carrying out this revision work and how these objectives have been met;
- › The working method in view of delivering the recommendation;
- › The results of the work of the relevant workgroups and in particular the different solutions and alternatives discussed and the reasons for choosing the proposed solutions;
- › The results of the consultations carried out within the network of the national safety authorities and in particular whether a consensus has been reached on the proposed solutions and, if not, the positions taken by Member State authorities that have opposed the recommendation or made other reservations;
- › The opinions expressed by the working party as referred to in Article 5 of the Agency Regulation [5];
- › The results of the consultation of social partners and users under Articles 6 and 7 of the Agency Regulation [5], including the opinions expressed by the stakeholders.

The results of the impact analysis carried out by the Agency under Article 8(1) of the Agency Regulation [5], including the methodology followed and the assumptions used, are documented in a separate report [4].

2.2. Background

Early 2014, the Agency has received a mandate from the European Commission [7], agreed by the RISC, for the revision of the CSMs of Conformity Assessment and CSM on Supervision under Article 6 of the Railway Safety Directive 2004/49/EC in order to ensure that a more consistent approach across NSAs is adopted. At the same time, the Agency has established a programme plan for the single safety certificate demonstrating its capacity to deliver a single safety certificate by 2018, consistent with the objective set in the mandate for submitting its final recommendation.

To support the Commission Mandate, the Agency has developed a policy paper [1] providing an analysis of the application of the above CSMs through a number of sources. This paper describes and analyses some of the key issues underpinning the current implementation and application of the safety certification regime within the European Union. It focuses on identifying the key areas and potential changes that need to be considered to existing safety regulatory framework and outlines a work plan satisfying the milestones set in the programme plan for the single safety certificate.

In April 2015, the Agency has requested the Commission to extend the time period for submitting its final recommendation in due consideration of the progress made on the technical pillar of the 4th Railway Package (4RWP) during the trilogue between the European Parliament, the Council and the Commission, in particular the new timescales for the delivery of a single safety certificate, and consistent with the programme set out to reach these targets. In turn, the Commission confirmed in a letter addressed to the Agency that a delay in providing the Agency recommendation could be considered justified without revising the current Commission Mandate.

From Mid-2015 onwards, the Agency has taken the decision to establish and manage a new programme [3], superseding the previous Agency programme for the single safety certificate, to be ready to effectively deliver its new tasks, as set out in the technical pillar of the 4RWP, by 2019. As part of its new tasks, the Agency is empowered to issue single safety certificates. The revision of the above CSMs has a direct link with

this programme and thereby becomes part of the portfolio of activities/projects necessary to achieve the 4RWP programme objectives.

In July 2016, a new mandate [11] has been adopted by the RISC to better anchor the role and objective of the revision of the above CSMs within the newly adopted legal framework of the 4RWP and make it consistent with its timeframes.

3. Workgroups

For drawing up its recommendation, the Agency has established a working party in accordance with Article 3 of the Agency Regulation and its internal procedure on working methods for workgroups.

The representatives from the following stakeholders were invited to join the working party and nominate competent experts:

- › National Safety Authorities;
- › Representative Bodies (i.e. ALE, CER, EIM, EPTTOLA, ERFA, ETF, UIP, UIRR, UITP and UNIFE).

When deemed appropriate, the Agency has also set up working party subgroups in order to focus in a short timeframe on well-identified topics with the most suitable experts in the field. By nature, the working party subgroup involves a limited number of experts, such as representatives of NSAs, representatives of Representative Bodies or independent experts or even a mix of them, and reports back to the working party.

The following table summarises in the chronological order the list of working party and working party subgroup meetings chaired by the Agency in view of developing its recommendation and future implementation guides.

Table 1: List of working party and working party subgroup meetings

<i>N°</i>	<i>Type</i>	<i>Date</i>
1	Working party (kick-off)	12-11-2014
2	Working party	19-02-2015
3	Working party	04-05-2015
4	Working party subgroup on the assessment criteria	30-06-2015
5	Working party	09-09-2015
6	Working party subgroup on the national requirements	28-10-2015
7	Working party subgroup on the assessment criteria	29-10-2015
8	Working party	17-11-2015
9	Working party subgroup on the assessment criteria	16-12-2015
10	Working party	16-02-2016
11	Working party	10-05-2016
12	Working party	13-09-2016
13	Working party	08-11-2016

The agenda items for each of above meetings are proposed in accordance with the project time plan. The agenda and the minutes of each meeting (including the list of participants and the follow-up of the action plan) are circulated to the meeting participants for adoption and registered on a specific workspace of the Agency Extranet.

4. Working method

The working method used for drafting the Agency recommendation is outlined in the project plan [2] and was agreed together with the working party at the kick-off meeting (i.e. first working party meeting).

The work on the revision of CSMs is broken down into manageable chunks to ease the monitoring and control of the project developments. Starting from the policy paper [1], different themes and related tasks are identified and grouped into work packages allotted to the project team members. The results of the work carried out under each work package are formalised in working papers and shared with the working party and where necessary, with a working party subgroup, for consultation. After collecting comments and inputs from the working party (subgroup), the working papers are revised accordingly and proposed for discussion at the agenda of a working party meeting. The different opinions of the working party are recorded in the minutes of meeting, including any decision taken. Each working paper concludes on a proposal for a policy change and/or on guidance information that will be used as a basis for developing future implementation guides. The different working papers can undergo several rounds of consultation as appropriate in order to meet the objectives set out in the policy paper [1].

Table 2: List of work packages

<i>Theme</i>	<i>ID</i>	<i>Work package</i>	<i>Subgroup (yes or no)</i>	<i>Policy change (yes or not)</i>
THEME 1 - SAFETY CERTIFICATION/ AUTHORISATION	1.1	Structured and auditable approach to certification	Yes	Yes
	1.2	SMS functions	Cancelled (used as input for 1.3)	
	1.3	Restructuring and reviewing of assessment criteria	Yes	Yes
	1.4	Harmonised national requirements	Yes	Yes
	1.5	Reviewing of CSM assessment criteria	Cancelled (merged into 1.3)	
	1.6	Decision-making criteria	No	No
	1.7	Conditions of application for safety certificates/authorisations	No	No
	1.8	Validity of safety certificates	Cancelled (irrelevant for the 4RWP)	
	1.9	Conditions for updating safety certificates/authorisations	No	Yes
THEME 2 - SUPERVISION	2.1	Harmonised approach to supervision (link with THEME 1 – decision-making criteria) (including scope for reassessment)	Yes	No
	2.2	Supervision strategy and plan	No	No

<i>Theme</i>	<i>ID</i>	<i>Work package</i>	<i>Subgroup (yes or no)</i>	<i>Policy change (yes or not)</i>
	2.3	Principles for coordinated and joint supervision	No	Yes
	2.4	Supervision techniques	No	No
THEME 3 – DECISION- MAKING	3.1	Risk based decision making model for enforcement (link with THEME 1 and THEME 2 – decision-making)	Yes	No
	3.2	Enforcement policy statement	Cancelled (priority given on 3.1)	
THEME 4 – COMPETENCE MANAGEMENT	4.1	Harmonised competence requirements	No	Yes

Based on the relevant working papers, the Agency elaborates a draft policy proposal and submits it for consultation to the working party. After collecting comments and inputs from the working party, the revised policy proposal is published on the Agency website for public consultation, targeting in particular social partners and organisations referred to in Articles 6 and 7 of the Agency Regulation [5]. At the same time, the representatives of the NSA network are informed about the start of the 3 month consultation and are also invited to submit their comments on the draft policy proposal (i.e. draft legal text). Considering the comments collected during the consultation phase, the Agency revises its policy proposal and arranges where appropriate a workshop with RISC and EC representatives in order to:

- › present the scope and content of the revised CSMs, as well as the results of the public consultation;
- › give the Member States the opportunity to share their opinions on the proposed texts;
- › anticipate comments and discussions between the Commission and the stakeholders (i.e. both the public and the group of experts appointed by the Member States during the comitology procedure) that usually occur once the Agency has delivered its recommendation to the Commission.

The outcome of the discussions at this workshop (if any) are reported back to the working party for discussion in order to agree on the necessary amendments. In the present case, in view of the timeframe, it was not possible to arrange such workshop.

Depending on the RISC rolling plan, the Agency presents the content of the final draft of the policy proposal to the ‘Group of Experts’ before submitting its final recommendation to the Commission.

The NSA Network, the Human Factors Network and the ‘Group of Experts’ are regularly informed about the progress of the project developments.

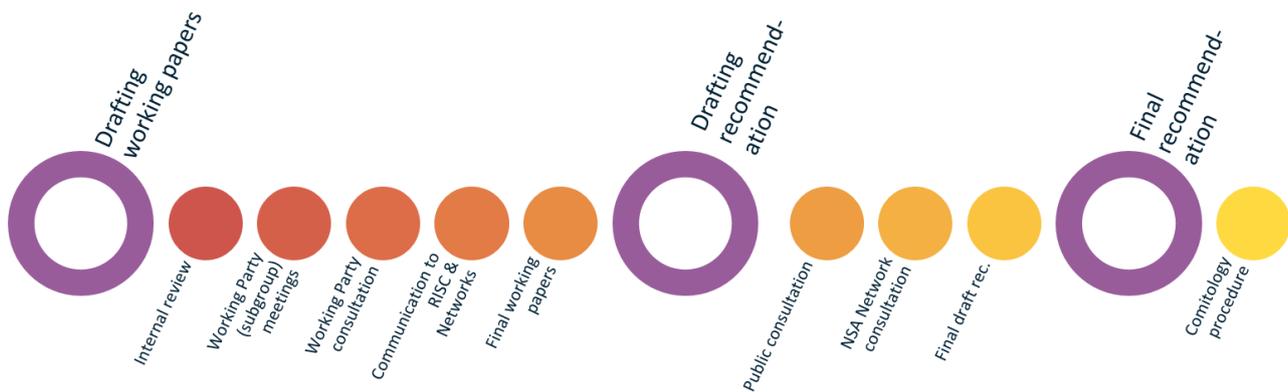


Figure 1: Working method

5. Content of the revision of the CSMs

5.1. Objectives

The main objective underpinning the revision of the CSMs is to ensure that a more consistent approach across NSAs is adopted. This need for harmonisation is not only restricted to the NSA decision-making criteria but also extends to the NSA processes in view of granting safety certificates/safety authorisations and also conducting their post-award supervision activities.

As described in section 4, the Agency has drawn up different work packages contributing to the achievement of this overarching objective. The following table summarises the purpose and scope of each work package, including the variety of sources used by the Agency to inform its developments and the proposed outputs expected from the relevant working papers.

Table 3: Description of work packages

Theme	ID	Work package	Purpose and scope / inputs / outputs
THEME 1 - SAFETY CERTIFICATION/ AUTHORISATION	1.1	Structured and auditable approach to certification	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Develop a safety certification scheme for NSAs to consistently approach applications from Railway Undertrackings and Infrastructure Managers <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › NSA cross-audit protocols › Documentation collected from previous cross-audits <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Annex I of the CSMs on Conformity Assessment could be revised to structure the existing requirements in accordance with the proposed framework › Model templates and forms supporting the proposed certification scheme
	1.2	SMS functions	Not applicable
	1.3	Restructuring and reviewing of assessment criteria	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Provide clear links between the assessment criteria (of the Annex II of the

Theme	ID	Work package	Purpose and scope / inputs / outputs
			<p>CSMs on Conformity Assessment) and the SMS requirements (or functions).</p> <ul style="list-style-type: none"> › Make the SMS more of a functional system than just a paper exercise › Clearer process link to Part B › Revise existing criteria that pose problems relating to their understanding or implementation › Consider human factors where relevant <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › Output from 1.4 on the harmonised national (Part B) requirements › Human Factors Network’s note (and future contribution) <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Revised criteria in Annex II of the CSMs on Conformity Assessment › Contribution to the revision of Annex III of Regulation (EU) 1158/2010
	1.4	Harmonised national requirements	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Clarify the link between Part A and Part B Certificate, and more specifically, to explain the link in more details between Part B requirements and the processes of the SMS › Develop a process which covers both the quality, consistency and level of detail required for Part B applications and the flexibility given to the NSAs in their decision-making process <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › Output from 1.3 on restructuring and reviewing the assessment criteria › Review of existing NSA practices › Review of the links to Regulation (EU) 2015/995 (TSI OPE) <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Revised criteria in Annex III of Regulation (EU) 1158/2010 › Contribution to the revision of Regulation (EC) 653/2007
	1.5	Reviewing of CSM assessment criteria	Not applicable
	1.6	Decision-making criteria	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Development of decision making requirements on how the assessment criteria should be used and be checked by the NSAs to ensure the RUs/IMs’ capability

Theme	ID	Work package	Purpose and scope / inputs / outputs
			to operate safely and to ensure consistency across NSAs <ul style="list-style-type: none"> › Defining major and minor non-conformities and how this links to the issuing of a certificate and an input into the supervision process <u>Inputs:</u> <ul style="list-style-type: none"> › Review of existing NSA good practice <u>Outputs:</u> <ul style="list-style-type: none"> › New definition of major/minor non conformities for Annex I of the CSMs on Conformity Assessment › New guidance with examples of what evidence could be considered and what major/minor non conformities might be to assist the NSAs › Input into the work of 2.1 on a risk based approach to supervision › Input into the work of 3.1 on risk based decision making for enforcement
	1.7	Conditions of application for safety certificates/authorisations	<u>Purpose and scope:</u> <ul style="list-style-type: none"> › Clarify the following notified issues: <ul style="list-style-type: none"> › Assessment of the Infrastructure Manager’s capacity to operate vehicles on its own network › Operations until the first station border under the same safety certificate › Contractual or partnership arrangements between Railway Undertakings › Case of shunting operators working in marshalling yards and train formation facilities (including shunting facilities) › Case of siding users <u>Inputs:</u> <ul style="list-style-type: none"> › Study on risks arising from shunting operations (provided by the NSA Netherlands) › SGS study on safety certification arrangements › Agency guide on issuing safety certificate/authorisation (incl. comments) <u>Outputs:</u> <ul style="list-style-type: none"> › Scope of application for safety certificate/authorisation (to complement the above Agency guide)
	1.8	Validity of safety certificates	Not applicable

<i>Theme</i>	<i>ID</i>	<i>Work package</i>	<i>Purpose and scope / inputs / outputs</i>
	1.9	Conditions for updating safety certificates/authorisations	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Criteria to assess major, substantial and significant changes and the nature of the changes as foreseen by the Safety Directive and other Regulations (i.e. major, substantial or significant) › Decision-making on process on when to update and what the update of a safety certificate/authorisation (i.e. partly or completely reviewed) should be › Avoid unnecessary update of safety certificates/authorisations <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › DV29 bis › CSM RA – and discussions on significant change <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Contribution to the revision of Regulation (EC) 653/2007
THEME 2 - SUPERVISION	2.1	Harmonised approach to supervision (link with THEME 1 – decision-making criteria) (including scope for reassessment)	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Set up the principles of using a risk based model to target the supervision activities: <ul style="list-style-type: none"> › Refining the various sources of data/information (ERA/GUI/04/2012/SAF) › How to process these data in the purpose of identifying areas for targeted supervision activities presenting the greatest risks (risk based model) <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › NSA good practice › Outcomes from the former task force on assessment and supervision › Relevant studies (e.g. TRL benchmarking study on the NSA enforcement powers) › Existing ERA guidance and training materials (dissemination) › Information collected by the ‘Matrix’ tool › Supplementary information from sub-group <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Contribution to the revision of the CSM on Supervision
	2.2	Supervision strategy and plan	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Set out the requirements for of the supervision strategy and plan by proposing how the risk based model should provide an input into their development activities

Theme	ID	Work package	Purpose and scope / inputs / outputs
			<p><u>Inputs:</u></p> <ul style="list-style-type: none"> › Output from 2.1 on the risk based approach to supervision <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Templates / forms for guidance purposes › Contribution to the revision of CSM on Supervision
	2.3	Principles for coordinated and joint supervision	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › More information and direction on co-operation and collaboration between NSAs for those railway undertakings operating in more than one Member States › Article 8 of the CSM on Supervision limitative to coordinated supervision <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › ERA guidance on common approach to supervision of railway undertakings operating in more than one Member States (incl. model template MoU) › Feedback from exchange of information between NSAs for the purpose of their supervision activities <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Update of Article 8 including overarching principles for coordinated and joint supervision › Revised Agency guide(s)
	2.4	Supervision techniques	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › A description of harmonised audit and inspection techniques for supervision to ensure that NSAs are consistent in their application. › Examples will be produced of when to use the techniques <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › ISO 17000 › TRL benchmarking study › VTT study on the review of audit techniques <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › New definitions for the CSM on Supervision › New guidance to support the requirements in the Regulation
THEME 3 – DECISION-MAKING	3.1	Risk based decision making model for enforcement (link with THEME 1 and THEME 2 – decision-making)	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › The development of an enforcement framework model on how NSAs can prioritise and focus enforcement action to ensure that they are targeted, accountable

Theme	ID	Work package	Purpose and scope / inputs / outputs
			<p>and proportionate in their treatment of RUs/IMs</p> <ul style="list-style-type: none"> › The harmonisation of NSA approaches to decision making and enforcement is needed to ensure that they take the similar decisions in similar circumstances (including possibly requirements for delivering enforcement) › The proposals will include sufficiently wide tools to response proportionality to different situations and could show a clear escalation in severity. hen to use the techniques <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › UK’s Enforcement Management Model and other good practice from NSAs › TRL benchmarking study <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › New annex to the CSM on Supervision or › New guidance to support the enforcement framework model
	3.2	Enforcement policy statement	Not applicable
THEME 4 – COMPETENCE MANAGEMENT	4.1	Harmonised competence requirements	<p><u>Purpose and scope:</u></p> <ul style="list-style-type: none"> › Proposals for a high level competence management system (CMS) which NSAs can use to manage and develop the competence of their staff › Development of a requirement for NSAs to have sufficient (and competent) resources to ensure that they can adequately monitor the safety performance of the sector <p><u>Inputs:</u></p> <ul style="list-style-type: none"> › Existing good practice on the development of CMS both from NSAs/sector and from other sectors <p><u>Outputs:</u></p> <ul style="list-style-type: none"> › Revised CSMs on Conformity Assessment and CSM on Supervision on a model CMS and competencies needed to fulfil the safety certification and supervision tasks › New guidance on how to apply the CMS and what to consider in relation to resourcing requirements

5.2. Structure and content

The structure and content of the existing CSMs on Conformity Assessment and CSM on Supervision have been revised based on the outputs of the different working papers for which a policy change is proposed (see Table 2: List of work packages). Particular attention has been paid to maintain a 'symmetry' between the CSMs on Conformity Assessment, consistent with the overarching objective of harmonisation of approach to safety certification, as these Regulations are to be applied by the same actors in the same way.

During the NSA Network dated 19-05-2015, the Agency shared its view on the potential to merge the CSMs on Conformity Assessment and the CSM on Supervision into one legal act. This proposal would have the merit to:

- › Offer a complete, coherent and consistent certification scheme, similar to the approach already promoted in ISO standards and ECM Regulation;
- › Clarify the interface between assessment and supervision;
- › Simplify the legal texts by using common articles and harmonised terminology;
- › Reduce the number of applicable regulations (legal framework) with one legal act to be maintained (instead of three) and to be applied by the relevant parties.

Representatives of NSA UK, NSA DK, NSA FI and NSA IE positively supported the reinforcement of the link between the CSMs and expressed interest in following how the Agency would merge them. Although the need to have a consistent and coherent certification process with a clear interface between assessment and supervision was recognised as a necessity, NSA DE and NSA FR expressed concerns about the Agency proposal, arguing that it could lead to confusion in the roles and responsibilities of the different parties involved in the process. Considering the lack of consensus on this issue, the Agency proposes to maintain for the time being three separate legal acts, though in its view roles and responsibilities of the different parties are clearly established in the recast Railway Safety Directive [6].

In addition, following coordination between the Agency and DG Move on legal issues (see Annex 4), it was agreed that CSM on supervision could apply anyhow (depending on the date of application set out in the Regulation) and irrespective of the CSM on conformity assessment in force at the time the safety certificate was issued (e.g. Part A/Part B safety certificate could be still valid after 16 June 2019 or not all Member States could have transposed Directive (EU) 2016/798 before that date). It was also recommended to avoid cross-references between revised CSM on supervision and revised CSM on conformity assessment in order to make it clear that the former can apply irrespective of the date of application of the latter. This recommendation may hinder the creation of a coherent and consistent certification process, as mentioned in the previous paragraph. Nevertheless, considering that in the revised CSMs cross-references are mostly limited to the definition of the interface between assessment and supervision, the risk of confusion (i.e. which CSM on conformity assessment the SMS must comply with) is somewhat limited and further information can still be given in guidance documents. The approach taken in the proposed CSM on supervision may need re-evaluation by the EC Legal Service.

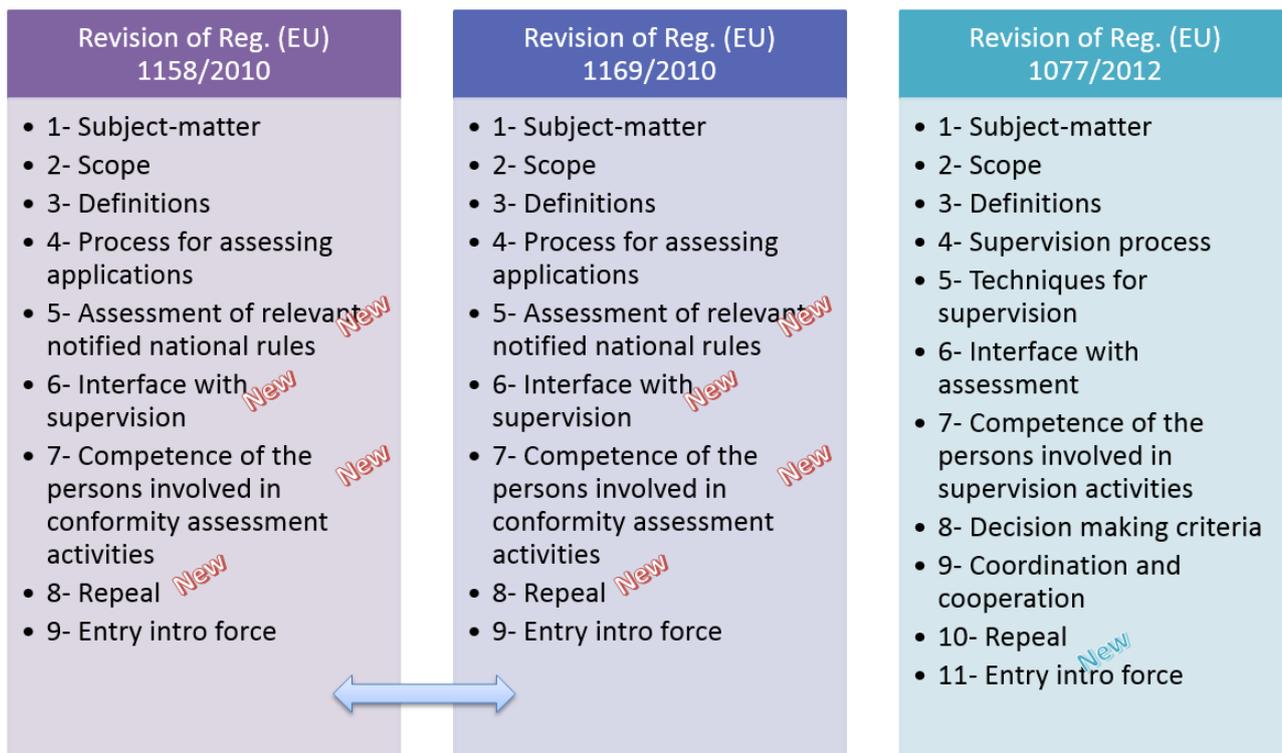


Figure 2: Overview of the structure of the revised CSMs and links to the different working papers as appropriate

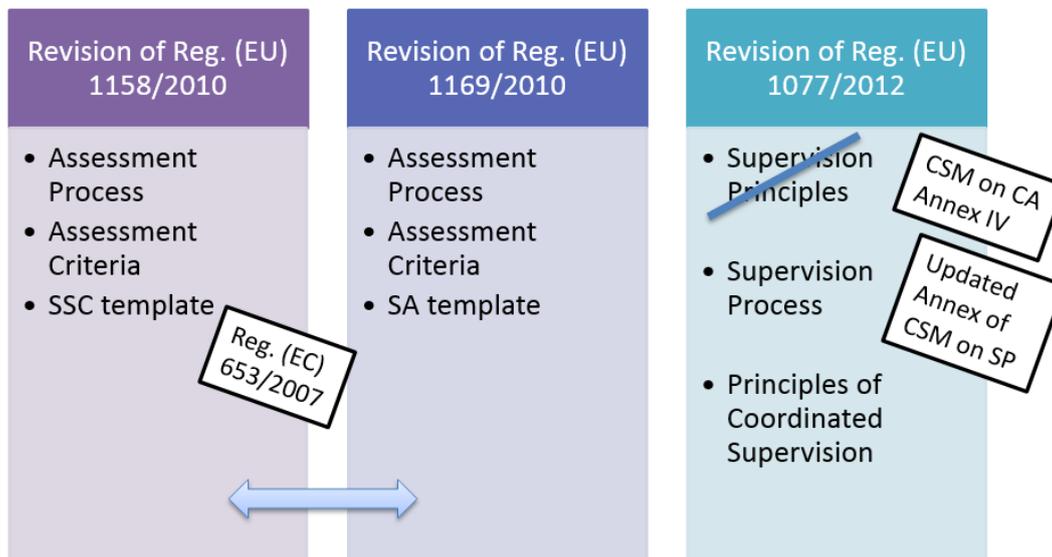


Figure 3: Overview of the structure of the annexes of the revised CSMs and links to the different working papers as appropriate

The following table provides a summary of the main changes¹ and the reasons for it:

Table 4: Summary of proposed changes to the Articles of the CSMs on Conformity Assessment and CSM on Supervision

¹ Excluding any editorial change and necessary adaptation of references to the new legal framework of the 4RWP (unless required for the ease of understanding of the readers).

Article / Annex	Summary of the change(s)
<i>CSMs on Conformity Assessment (unless stated otherwise, changes equally apply to both CSM Regulations)</i>	
1 (subject-matter)	Simplification of the text to avoid duplication of references to the process and assessment criteria (for assessing applications for safety certificates/authorisations) with those already present in Article 4.
2 (scope)	<p>New article added to clarify who shall apply the CSMs on Conformity Assessment, under what circumstances and for what purposes. For example, if the railway undertaking has an area of operation in more than one Member State, the Agency is responsible for the assessment of compliance with the legal obligation to establish a safety management system whilst the relevant NSA(s) of the Member State(s) concerned by the area of operation is (are) responsible for the assessment of compliance with the relevant national rules.</p> <p>In addition, the UK's Rail Safety and Standards Board (RSSB) escalated the following issue to the UK NSA: <i>"The CSMs require the NSA (ORR in the case of the Great Britain mainline railway) to scrutinise applications against the assessment criteria set out in Annex II to the CSMs. In effect, an IM or RU would need to comply with Annex II in order to allow the NSA to grant a safety authorisation or a safety certificate. However, there appears to be nothing that directly requires an IM or RU to comply with Annex II."</i></p> <p>A similar issue was also raised by some NSA representatives at the working party, mentioning appeal proceedings.</p> <p>During the NSA Network dated 19-05-2016, a representative of the NSA DK expressed the view that, though he was very supportive of the efforts to establish the transparency for companies regarding the requirements they have to fulfil, he did not support the idea of having those criteria's in the same legislative document as the one that sets out the criteria for the conformity assessment.</p> <p>The Agency's view is that the Safety Directive [6] provides sufficient legal grounds to request an applicant for a single safety certificate/safety authorisation to demonstrate compliance with the assessment criteria set out in Annex II of the CSMs on Conformity Assessment. Indeed, Article 10(3) states that the application file must comply with the requirements laid down in CSMs:</p> <p><i>"The application for a single safety certificate shall be accompanied by a file including documentary evidence that:</i></p> <p><i>(a) the railway undertaking has established its safety management system in accordance with Article 9 and that it meets the requirements laid down in TSIs, CSMs and CSTs and in other relevant legislation (...)"</i>.</p> <p>The term 'CSMs' encompasses the (assessment criteria of the) CSMs on conformity assessment. Therefore, the Agency proposes to include this clarification in the legal text.</p>
3 (definitions)	<p>(former Article 2 in existing CSM Regulations)</p> <p>Definitions in Article 3 of the Safety Directive [6] should also apply (e.g. type, extent and area of operation). On request of NSA BE, NSA LU and NSA IT (7th working party meeting dated 10-05-2016), the definition of 'dangerous goods' should be added as this term is referred to in the revised text (Annex II and Annex III). To address this request, the Agency proposes to refer to the definitions provided for in the the regulations concerning the international carriage of dangerous goods by rail (RID), appearing as Annex II to Directive 2008/68/EC.</p> <p>The following definitions are also added:</p>

Article / Annex	Summary of the change(s)
	<ul style="list-style-type: none"> › (Revised Reg. 1158/2010 only) Definition of ‘safety certification body’ is based on Articles 10(5) and 10(8) of the Safety Directive [6] where, depending on the area of operation, either the Agency or the NSA can issue single safety certificates. This term is referred to in Articles 4, 6, 7, 8 and Annex I; › Definitions of ‘human factors’ and ‘safety culture’ have been proposed by some representatives of the Human Factors Network (and its subgroup) based on a published RSBB guidance document (Understanding Human Factors -a guide for the railway industry). Both terms are referred to in Annex II; › (Revised Reg. 1158/2010 only) Definition of ‘frontier location’ is derived from TSI OPE. This term is referred to in Article 5.
4 (process for assessing applications)	<p>(former Article 3 in existing CSM Regulations)</p> <p>Minor amendments to clarify that the process set out in Annex I of the CSMs on Conformity Assessment also apply to renewal and update applications.</p> <p>Article 3(2) of existing CSM Regulations is removed as the risks relating to the use of contractors, including the exchange of information needed between the different parties to ensure safe operations, are managed in Annex II under the assessment criteria ‘contractors, partners and suppliers’ and ‘asset management’ (for specific considerations about maintenance).</p> <p>Following discussion at the NSA Network (subgroup) on cooperation agreements in November 2015, it has been acknowledged the numerous benefits of pre-engaging with the applicant as early as possible in the process and the Agency was requested to reflect on how best this could be included in its technical proposal. In response to this request, the Agency proposes to add a new provision, similar to the principle of transparency set out in the existing CSMs on Conformity Assessment (see the principles of supervision), where the applicant should receive upon its request the necessary help to understand what is expected of it.</p>
5 (assessment of notified national rules)	<p>New article added to clarify the scope of assessment of notified national rules by the NSA, in accordance with Article 10(3)(b) of the Safety Directive [6], with specific provisions (Revised Reg. 1158/2010 only) for the specific case of railway undertakings travelling to stations in neighbouring Member States with similar network characteristics and similar operating rules (i.e. the frontier location).</p>
6 (interface with supervision)	<p>(former Article 4 in existing CSM Regulations)</p> <p>The content of former Article 4 is taken out as the principles for supervision set out in Annex of existing CSM Regulations are moved into a new Annex of the revised CSM on Supervision.</p> <p>Instead, the new Article 6 identifies the need for exchanging information, including the type of information to be used, between those responsible for the assessment and the others responsible for carrying out supervision activities (interface assessment to supervision only).</p> <p>The content of the Article varies between the two CSMs on Conformity Assessment to take into account the single entry point of the one-stop-shop for submitting applications for single safety certificates. In effect, the application file, including a mapping of the evidence against each CSM assessment criterion, should be registered in the one-stop-shop and shared between the different bodies involved in the assessment, which include the NSA(s) that will conduct post-award supervision activities. However, additional clarification is necessary for</p>

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
	safety authorisation application where the one-stop-shop functionalities are not used.
7 (competence of the persons involved in conformity assessment activities)	<p>New article added to require those undertaking conformity assessment activities in view of granting single safety certificates/safety authorisations to establish a competence management system (entailing a minimum set of elements) and to hold minimum competencies requirements.</p> <p>The content of this Article aims at installing and ensuring mutual trust between the different authorities (i.e. the Agency and the NSAs), in particular when close cooperation is needed between them for the issuing of single safety certificates or in the case of cross-border infrastructure.</p>
8 (transitional provisions)	<p>New article to accommodate the transitional provisions and possible extension of the transposition period set out in Articles 31 and 33 of the Safety Directive [6] respectively. The cut-off date for the granting of single safety certificates/authorisations under the new regime corresponds to the date of entry into force of the Safety Directive plus 3 years (i.e. 16 June 2019). It also takes into account the different cases where applications for safety certificates are submitted to the NSAs before the cut-off date and also when not all Member States concerned by the area of operation have transposed the Safety Directive [6] (i.e. until the cut-off date plus 1 year).</p>
9 (repeal)	New article to repeal existing CSMs on Conformity Assessment.
10 (entry into force)	(former Article 5 in existing CSM Regulations) No change.
Annex I	<p>(former Annex I in existing CSM Regulations)</p> <p>The purpose of this annex is to develop a safety assessment process for safety certification bodies to ensure a consistent approach to applications from railway undertakings and Infrastructure Managers, respectively for the granting of single safety certificates and safety authorisations, providing assurance that they can take similar decisions in similar circumstances and that the assessment process is undertaken in a similar way by all relevant parties. This process gives flexibility to the NSAs and the Agency (as appropriate) to define their own organisational structure and associated roles and responsibilities for implementation. Similarly, the NSAs and the Agency (as appropriate) are free to establish their own information management system consistent with the proposed process (e.g. by defining a storage policy, including retention time and storage location, for records²). This is without prejudice to the practical arrangements referred to in Article 10(10) of the recast Safety Directive and the cooperation agreements referred to in Article 11 of the recast Safety Directive and should not be precluded from applying an audit framework as set out in ISO 19011³ and/or applying on a voluntary basis, partly or wholly, the requirements for bodies providing audit and certification of management systems as set out in ISO 17021⁴.</p>

² By definition, a record is a “document stating results achieved or providing evidence of activities performed” (ISO 9000:2005).

³ ISO 19011 provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well guidance on the evaluation of competence of individuals involved in the audit process.

⁴ ISO 17021 applies to third party certification bodies verifying the conformance of an organisation's management system(s) to a standard (e.g. ISO 9001). The ISO 17021 standard requirements are more

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
Annex II	<p>(former Annex II in existing CSM Regulations)</p> <p>On the one hand, the structure of Annex II of CSMs on Conformity Assessment is revised in order to:</p> <ul style="list-style-type: none"> › Ensure a structure consistent with the ISO High Level Structure, facilitating the integration of different management systems (as appropriate) which share the same core principles and requirements though the risk domains are different; › Ensure a structure consistent with the management function of the system of maintenance as set out in ECM Regulation, which has strong commonalities with the CSM CA assessment criteria; › Provide both the NSAs and the sector with a common structure between the CSM CA assessment criteria and the SMS guidance , which should facilitate the assessment and the development of the SMS respectively. <p>On the other hand, the content of Annex II of CSMs on Conformity Assessment is also revised in order to:</p> <ul style="list-style-type: none"> › Clarify links and avoid duplication with other EU Regulations; › Solve interpretational issues with existing criteria notified by NSAs; › Make it clearer that the SMS created as the core of the CSM CA procedure should form an integral part of an organisation’s overall business processes; › Reinforce the management system approach and facilitate its understanding (cross-references between the different processes); › Find commonalities with the requirements of the management function of the system of maintenance as set out in ECM Regulation; › Better consider human factors and safety culture where practicable. <p>The proposed restructuring and reviewing should not result in changing the railway company’s SMS but should bring more clarity and consistency for:</p> <ul style="list-style-type: none"> › NSAs in approaching the assessment; › RUs/IMs in adopting a management system approach for the development and implementation of their SMS; › RUs/IMs in integrating their SMS with other management systems. <p>The safety regulatory framework significantly changed since the entry into force of the Safety Directive 2004/49/EC and subsequent CSMs on Conformity Assessment (initiated in early 2007). In the meantime, new Directives and Regulations entered into force such as the Safety Directive [6], the Common Safety Method on Monitoring, the ECM Regulation, and existing Regulations were substantially revised such as the TSI OPE and the Common Safety Method on Risk Assessment. This new EU railway regulatory framework is then considered in the review process in order to avoid unwanted duplication of legal provisions across various regulations and also to ensure that links are made across all relevant requirements.</p>

stringent than those applying to the NSA. For example, certification bodies have to implement, under a predefined timeframe, a two-stage (initial) audit, surveillance audits and a recertification audit prior to expiration of certification. They have also to draw up the audit plan in accordance with the relevant guidance provided in ISO 19011.

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
	<p>New requirements/criteria relating to operational arrangements are identified in a way that does not preclude railway undertakings and infrastructure managers to have their own SMS framework.</p> <p>Cross-references are added between (set/type of) requirements/criteria to reinforce the management system approach and facilitate its understanding.</p> <p>To facilitate discussion on detailed proposals, the Agency decided to set up a Working Party subgroup to share views among experts and to actively contribute to the ongoing developments. The outcomes of the discussions at the Working Party subgroup were reported back to the Working Party. In addition, the Agency also mandated the Human Factors Network to reflect on the best possible approach to integrate human factors and safety culture into the SMS and to make some thoughtful suggestions concerning the way forward.</p> <p>During the discussion, it was agreed that the ISO High Level Structure (HLS) should be adopted. This approach would also provide strong support for RUs and IMs in developing their SMS. However, although a consistent stance with ISO management system standards is sought, it must be underlined that the CSM primarily serves the purpose of NSAs assessing applications for the granting of safety certificates or safety authorisations. By comparison, the standards are based on voluntary certification, equally apply to both the conformity assessment body and the applicant and involve some leaps of faith when interpreting them. Care then must be taken not to adopt a too broad perspective (similar to what exists in the standards) which could only be detrimental to the harmonisation of NSA’s decision making and not take benefit from the valuable experience gained by the NSAs since the entry into force of this safety certification regime.</p> <p>Most of the CSM assessment criteria equally apply to both RUs and IMs. In other words, only a small part of them are RU or IM specific. Whilst IMs are able to manage in essence a one-to-one relationship with their NSA, the latter has often to manage various applications from domestic and international RUs. Having all the players on the same level playing field and so, ensuring that everyone is treated the same (among NSAs and within each NSA) also requires from the NSAs a common approach to the safety assessment and the harmonised decision-making criteria. In practice, it is conceivable that IMs could cope with high level assessment criteria (based upon which they can check the adequacy of their SMS) whereas RUs would obviously need more direction in what is expected of them.</p> <p>The SMS must be integrated into the business of the organisation and then, must not become a paper based system specifically developed for demonstrating compliance with the regulatory framework. Criteria can be satisfied by a documented process (or procedure etc.) but they must also be contemplated within and across the various business areas of the organisation. For example, the NSA can check that a policy statement exists but has also to check the organisation’s commitment to apply it. A practical way to do this is for the NSA to check how it is monitored and reviewed at senior management level, how staff are involved in this and how this is communicated. Likewise, the organisation may not</p>

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
	<p>have a specific procedure to manage safety relevant information but has to describe how the relevant parts of the business manage it adequately (e.g. communication of safety-relevant information to the train driver).</p> <p>The Safety Directive [6] stipulates that, through its processes, the safety management system should ensure that human capabilities and limitations and the influences on human performance are addressed by applying human factors knowledge and using recognised methods. Article 9 of that Directive also provides specific provisions with regard to the integration of human factors and safety culture into the SMS. Following discussions with Human Factors experts, it is recognised that unintentional slips/lapses and mistakes are often predictable by risk assessment and best controlled by being designed out in planning. The group was supportive of a top-down approach consisting of (new) overarching criteria supplemented by additional proposals to prioritise human factors for some criteria and to underpin their systematic integration thereof. Further guidance is however needed to help understand the extent to which evidence fulfils the criteria.</p>
Annex III	<p>(former Annex I and Annex II in existing Regulation (EC) 653/2007)</p> <p>This annex includes a standard format of single safety certificates or safety authorisations, respectively for the revised Regulation (EU) 1158/2010 and Regulation (EU) 1169/2010.</p> <p>The new format of single safety certificates should repeal the existing format for part A and part B safety certificates included in Annex I and Annex II of Regulation (EC) 653/2007.</p> <p>The Agency proposes to include the standard format of single safety certificates in the revised Regulation (EU) 1158/2010 (and not the new Implementing Act on the practical arrangements for the safety certification as referred to in Article 10(10) of the Safety Directive) in order to ensure a ‘symmetry’ with the revised Regulation (EU) 1169/2010 (as already discussed at the outset of this section).</p> <p>The information contained in this new format of safety authorisations has been proposed by the NSA UK and is very similar to the one appearing in the standard format of single safety certificates.</p>
<i>CSM on Supervision</i>	
1 (subject matter)	Text adapted to consider the new legal base, in particular Article 17 of the Safety Directive [6] introducing new provisions on supervision activities conducted by the NSAs. Simplification of the text to avoid duplication with Article 17 of the Safety Directive.
2 (scope)	<p>(former Article 1 (or part of it) in existing CSM Regulation)</p> <p>The scope of the CSM is adapted based on Article 17(1) of the Safety Directive [6]. Reference is made to of the new Annex I which now sets out the principles for supervision (formerly in Annex of existing CSM Regulations).</p> <p>Following discussion at the NSA Network dated 18-05-2016 and at the 7th working party meeting dated 10-05-2016, it has been questioned whether the coordination of the supervision of the RU’s SMS should be performed by a leading NSA. Other NSAs, depending on the area of operation, could coordinate with that NSA to decide how to conduct supervision of the RU’s SMS (by opposition to the situation where each NSA supervises the RU’s SMS on its own and so, does not see the</p>

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
	importance of coordinating with other NSAs). The Agency believes that this approach goes in the direction of the 4 th Railway Package, which promotes coordination between different authorities, increase of efficiency by avoiding duplicate assessment/supervision among the different authorities and reduction of costs (e.g. no additional costs to be borne for translation) and proposes to clarify the scope of the supervision accordingly.
3 (definitions)	(former Article 2 in existing CSM Regulation) Specific definition of supervision can be removed as already included in the revised CSMs on Conformity Assessment.
4 (supervision strategy and plan(s))	(former Article 3 in existing CSM Regulation) To address a remark of the NSA FR, the Agency proposes to clarify that the supervision strategy shall be risk based.
5 (techniques for conducting supervision)	(former Article 4 in existing CSM Regulation) No change.
6 (interface with assessment)	(former Article 5 in existing CSM Regulation) This Article still identifies the need for exchanging information, including the type of information to be used, between those responsible for the assessment and the others responsible for carrying out supervision activities (interface assessment to supervision only). In addition, it clarifies that information collected during supervision activities can be reused for assessing update application (and not renewal application as stated previously). In addition, it sets out the purpose for exchanging this information and the coordination principles underpinning it. It also includes the minimum set of information to be considered during this coordination.
7 (competence of the persons involved in supervision activities)	(former Article 6 in existing CSM Regulation) This article is now mirrored with Article 7 of the revised CSMs on Conformity Assessment. It still requires the NSA undertaking supervision activities to establish a competence management system (entailing a minimum set of elements) and to hold minimum competencies requirements. The content of this Article aims at installing and ensuring mutual trust between the different authorities (i.e. the NSAs), in particular when close cooperation is needed between them for sharing information during the course of their supervision of railway undertakings operating in more than one Member State.
8 (decision-making criteria)	(former Article 7 in existing CSM Regulation) No change.
9 (coordination and cooperation)	(former Article 8 in existing CSM Regulation) Principles remain the same but are extended to the case of cross-border infrastructure. Cooperation and coordination arrangements have to meet the principles set out in the new Annex III of the CSM on Supervision.
10 (repeal)	New article to repeal existing CSM on Supervision.
11 (entry into force and application)	(former Article 9 in existing CSM Regulation) No change.
Annex I	(former Annex IV of existing Regulation (EU) 1158/2010 and Annex III of Regulation (EU) 1169/2010) Minor changes made to the content of the former Annex IV of existing Regulation (EU) 1158/2010 and Annex III of Regulation (EU) 1169/2010 in order to clarify the wording and also avoid duplication of provisions with other Articles of the CSM.

<i>Article / Annex</i>	<i>Summary of the change(s)</i>
Annex II	<p>(former Annex I of existing CSM on Supervision)</p> <p>Elements listed in former Annex I of existing CSM on Supervision are reordered for a better logic sequence of activities. The need to consider human factors knowledge and methods when planning supervision activities is also identified. On request of the working party, a flowchart has been added in appendix to ease the understanding of the supervision process and its interface with the assessment process (consistent inputs/outputs between the flowcharts of the revised CSMs on Conformity Assessment).</p>
Annex III	<p>Article 8 of the existing CSM on supervision requires co-ordination and co-operation between NSA's. Before the publication of this CSM, NSA representatives at the former "Task Force on Assessment and Supervision" agreed that a clear framework setting up the co-operation arrangements between NSAs for cross-border supervision should be developed, including the principles underpinning the model agreement.</p> <p>In 2013, the Agency guidance on a common approach to supervision of railway undertakings operating in more than one Member State was elaborated with the aim of achieving the above objective and published on the Agency website, with a model template of MoU for coordinated supervision enclosed. Until now, a few NSAs have signed off the proposed MoU or equivalent (e.g. France, Belgium, Luxembourg, Denmark, Norway and Sweden) while others have decided to informally apply its principles.</p> <p>Articles 17(8) to 17(12) of the Safety Directive [6] introduce new provisions for the coordination and cooperation between NSAs, including interface with the relevant bodies for the purpose of renewing single safety certificates (i.e. the NSA or the Agency in cooperation with relevant NSA(s)). In addition, Article 17(6) requires the NSA, in case of cross-border infrastructures as referred to in Article 12, to perform its activities of supervision in cooperation with other relevant NSAs.</p> <p>The purpose of this new annex is to elaborate further the principles and elements for the sharing of information between NSAs referred to in Article 8(1) of the (existing and revised) CSM on Supervision, in accordance with Article 17 of the Safety Directive, based on those already identified in the model template of MoU for coordinated supervision.</p>

6. Stakeholders' opinions

6.1. Working party

6.1.1. General opinion

Feedback from the working party is deemed positive as no significant issues have been raised during these meetings and in many cases, a position gathering a large consensus among participants was reached.

6.1.2. Minority opinions

The table below summarises the minority opinions expressed by the working party. Some of them have been clarified in the meantime during a coordination meeting with DG MOVE on 30 November 2016 [12].

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Table 5: Minority opinions expressed by the working party

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA IT	Revised 1158/2010 and 1069/2010 Art. 4(2)	Pre-engagement should be made mandatory for all parties (and not only on request of the applicant)	Pre-engagement is to be requested by the applicant. In some circumstances, it might not be needed, e.g. in case of renewal/update. The applicant shall take the responsibility to decide whether it starts pre-engagement or not.
NSA IT	Revised 1077/2012 Art. 2(3)	According to new mandate, there is a role of the Agency in supervision. This role is reflected also in Art. 17 of the recast RSD (i.e. ERA issuing guidelines). Guidelines should not be considered as general guides but as applicant specific ones. IT expects that the Agency will appoint the leading NSA for each certificate it issues.	Guidelines referred to in Article 17(9) (3 rd §) are to be understood as the guide(s) to be developed by the Agency in order to support the cooperation between NSAs during supervision. It has nothing to do with instructions to be given by the Agency to the supervising NSA(s) involved in the assessment where the SSC is issued by the Agency. The Agency has no role in the supervision and thereby, cannot take the responsibility to decide how RU/IM should be supervised by NSAs. Following discussions at the Working Party, it is promoted that supervising NSAs agree themselves, based on criteria, who should be leading.
NSA SE	Revised 1158/2010 and 1069/2010	Difficulty in managing the requirements of Directive 89/391/EC when different	The working party acknowledged the link between the SMS and the H&S and agreed that

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
	Recital + Annex II	authorities with different responsibilities are involved. In addition, it requires specific knowledge in health and safety matters.	duplication of assessment should be avoided. The Agency proposed to clarify by guidance the scope of assessment in relation to H&S issues. It was also clarified that if the NSA during supervision finds H&S issues it should notify the competent authority.
CER	Revised 1158/2010 and 1069/2010 Annex II	The text as proposed on the integration of human factors and safety culture may leave space for interpretation and so, may lead to different interpretations by NSAs.	The Agency, the NSAs and the HF Network always promoted an integrated approach (i.e. priority HF issues integrated in the various assessment criteria where appropriate). CER committed several times to provide the Agency with some proposals but to date, no contribution was received. Guidance will provide an indication of the evidence required to show how the criteria have been met. This should support consistent application by NSAs.
EIM	Revised 1158/2010 and 1069/2010 Annex II 3.1.1.1.b)	The inclusion of "and where relevant with" is essential here and should not be replaced by "set out in" since the risk assessment method set out in Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798 (CSM REA) is not applicable to evaluate the risks referred to in point (a) (that is "all operational (including human performance), organisational and technical risks relevant to the character and extent of operations carried out by the organisation"). The risk assessment method of CSM REA is applicable to significant technical, operational or	The CSM on risk assessment applies for all technical, operational or organisational changes. For each change, the applicant/proposer has first to decide if the change is significant or not. If yes, he will have to demonstrate that the risks related to the change are acceptable using one the principles described in the CSM and that the requirements issued from this demonstration are well implemented in the system under change. When the change is not significant (the subject of your comment), the applicant/proposer will have to document his decision. In this case, it is left to the applicant to choose the appropriate

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>organisational changes of the railway-system. Also, the risk assessment method of CSM REA may not be appropriate to evaluate the risks referred to in point (a) and it should be left to the organisation to choose and justify the appropriate methods.</p> <p>Because of the described scope in the CSM REA (Art.2.1: "This Regulation shall apply to the proposer as defined in Article 3(11) when making any change to the railway system in a Member State."), a reference to this CSM REA is appropriate only:</p> <ul style="list-style-type: none"> › In criterion 3.1.1.b) if the organisation chooses to apply the risk assessment method of CSM REA as an appropriate risk assessment method; › In criterion 3.1.2.1 when (3.1.2) Planning for a change. 	<p>risk assessment process for justifying that the risk control measures it puts in place are appropriate to control the associated risks to an acceptable level. This is what you are referring to in your comment and what is already set out in the CSM on risk assessment.</p>

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6.2. Public consultation

6.2.1. General opinion

6.2.2. Minority opinions

The table below summarises the minority opinions expressed by the social partners and users (under Articles 6 and 7 of the Agency Regulation [5]) during its formal consultation (17 November 2016 – 17 February 2017).

Table 6: Minority opinions following the consultation of social partners and users

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
CER Trenitalia ERFA	Article 3, definition of "Human factors", "safety culture" and "human centred approach" Annex II (1.2, 2.1.1.g and 2.1.1.e) (CSMs CA)	CER is worried that some criteria added to the CSM may lead to different interpretations and requirements by stakeholders, EUAR and NSAs, thus creating uncertainty and discrimination between RUs to obtain safety certificate. The criteria proposed in annex II of the draft CSM CA (version 0.13), if they are taken into account for granting safety certificate, shall become predictable. As such, the proposed criteria may not allow to define when the safety culture is so "negative" that it can create safety issues, when a strategy will bring insufficient human factor "knowledge"...	Art. 9 of Directive (EU) 2016/798 requires the integration of human factors (and safety culture) into the SMS. We then believe that proposing requirements apart from the key elements constituting the SMS will be detrimental to this objective of integration. We are currently developing guidance to explain the role of human factors and safety culture into the SMS and how the related requirements can be assessed. This guide is also of interest for the applicants. We will therefore consider the inputs provided in your position paper in order to work out our guide. The policy proposals with respect to human factors and safety culture have been elaborated by the Human Factors network and its subgroup

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>CER also noted that the provisions proposed in the CSM are not covering the entire scope of the RSD article 9(2) (e.g. promote mutual trust, ensuring confidentiality).</p> <p>CER ask to clarify first what are criteria to be fulfilled and that can lead to refuse certification. For this we suggest:</p> <ul style="list-style-type: none"> - Add at the end of annex II paragraph 2.1.1.g and 2.1.1.e. "The criteria set in annex IV shall serve as a reference to fulfill this criteria when applying for a single safety certificate" - Create an annex IV for the CSM defining more precise criteria in line with proposal included in CER position paper published on 8/11/2016 (see link) <p>It is essential that presumption for conformity on Human factor and safety culture criteria are further clarified. A guidance should be prepared taking into account UIC work. The guidance should be approved by NSAs and made available before the new safety certification process start shadow running.</p>	<p>and the results of this work reported back to the working party. UIC experts were present at both the Human Factors network and the subgroup meetings. These experts explained that the UIC paper, on which you position paper lays down, had a different objective than the one pursued by the CSMs and did not object to consider it for the guide as starting point.</p>
CER RFI	Art. 3 (CSM CA for SA)	<p>a) 'human factors' means all of the people or human performance issues that...</p> <p>b) 'safety culture' means ...</p> <p>c) 'human centred approach' means</p>	<p>The terms "people" and "human" have not specific meaning in the context of this CSM nor to a wider extent, in the field of railways. Therefore, we don't understand why a specific definition should be provided therein.</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>....</p> <p>e) infrastructure manager in terms of number of employees working in the railway sector.</p> <p>It should be given the definition of "people" and "human". See also the use in the ANNEX II (point 4.1.1) of word "staff", that in the ISO 9001 is "people".</p> <p>There should be consistency of terminology.</p> <p>Tha same concept for the "number of employees".</p>	<p>For the definition of "extent" (see bullet e) in your comment), we prefer keeping consistency with similar definition of "extent of operation" in Article 3 of the recast Safety Directive. I'm sure that it is not ambiguous that employees and staff mean the same.</p>
CER RFI	Art. 4 (CSM CA for SA)	It is not clear who makes the request.	The structure of the sentence makes clear that it is on request of the applicant.
CER	Art. 4(2) (CSM CA for SSC)	The pre-engagement process causes a lot of extra work in terms of coordination. Who will talk to whom, and in wish language?	Pre-engagement is for the whole benefit of the applicant in order to de-risk its project. It is up to the applicant to decide. Either the applicant is mature and in that case it does not need pre-engagement or it does not know what is expected of it and in that case requests for pre-engagement. The applicant is then driving the pre-engagement process and not the authorities. The need for coordination should reflect the status of the draft application file. For the first meeting, this should involve all relevant authorities and then, it can be decided who participates. The fees for the pre-engagement will be known in advance. The language for the coordination will be the same as the one used during the assessment.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
CER	Art. 4(3) (CSMs CA)	How can the RU ensure, that the NSA trust in that?	The relevant authority has to apply the presumption of conformity when applicable to avoid any duplication of assessment.
CER	Annex I (2.1) (CSMs CA)	The RUs prepared extensive reference lists for fulfilling the CSM criteria. By the fact, that the old and new Reg. 1158 is not comparable, the RUs need to create a new document. If so, there is a big cost and resources effort.	We disagree with that comment. Firstly, many NSAs require today that the applicant justifies how it meets the CSM assessment criteria. That is not new. We have then proposed to harmonise the approach to ensure the same level playing field. Secondly, everyone has to accept the changes. It is quite usual to continually improve and this is recognised by Article 6 of Directive (EU) 2016/798. As discussed during the working party, the Agency agreed to provide a correspondence table to facilitate the task of both the authorities and the applicant when adopting the new regime. Finally, this task must only be done once and the work does not restart from scratch.
CER	Annex I (3.4/3.3) (CSMs CA)	Who will decide which part shall be translated, how much of that, and legally correct? (Factor cost and resources)	The need for translation is described in the new Implementing Act on the practical arrangements for safety certification (see Article on language). Following discussions at the previous workshop on the single safety certificates, held earlier in December 2016, it has been agreed with the CER representative that only the part of the SMS relevant for the understanding of the national rules should be subject to translation when applicable. This approach has been reflected in the above Implementing Act.
ERFA	Annex I (3.4/3.3) (CSMs CA)	It reads "...check that the language is understandable." Should it not rather read	The term "language" is the right one. The term "content" may have a broader meaning and could be mixed up with the assessment itself.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>"... check that the content is understandable"?</p> <p>If considered, 3.5 needs to be amended as well.</p>	<p>Issues can be clearly explained in a language understandable to people but you still may not be satisfied with the content.</p>
CER	Annex I (4.13) (CSM CA for SSC)	<p>".... without causing unnecessary inconvenience to the applicant."</p> <p>What does that mean? The RU need to plan the resources for audits and inspections, there is always an unnecessary inconvenience.</p>	<p>You have to put §4.13 in context. If NSAs do not coordinate their approach, then there is a risk that each NSA decides to undertake audits on its own, possibly overlapping in scope what the other authority delivered or planned to deliver or even planning an audit at the same time or close to the one of another authority.</p> <p>Authorities can always decide to undertake audits or inspections. If they do so, we require that they coordinate their approach. In that respect, this provision is beneficial for the applicant.</p>
Trenord	Annex II (1.1 (b)) (CSMs CA)	<p>It seems that the organization take into account only the serious risks, while RU shall identify all the risks and classify them.</p> <p>Which is the definition of serious risk to be used?</p>	<p>The purpose of criterion 1.1 is to better understand the organisation and its environment. There is no intention here to provide a comprehensive list of risks (which would be the outcome of the application of a risk assessment process) but to present the 'high level' risks faced by the organisation with regard to the type and extent of its operations.</p> <p>Together with the working party, it has been agreed to clarify it in guidance.</p>
CER RFI	Annex II (2.3.4) (CSMs CA)	<p>It should be clarified what is meant by "delegated responsibilities" and what is the hierarchical level considered (up to what level it should get? Similar to the one Employer Job, as a Country Director, or</p>	<p>Ok, we will clarify it in the guide.</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		manager of a Work Center?). These questions then become essential when we have to provide evidence to the NSA	
CER RFI	Annex II (3.1.1.1 (a)) (CSMs CA)	Given the sensitivity of the subject is deemed appropriate to have more details on the requirement.	Ok, we will clarify it in the guide.
CER RFI	Annex II (3.1.1.2) (CSMs CA)	What are the requirements of the Council Directive 89/391/EEC? It would be specifically stated in this Regulation, where appropriate. The mere reference to the Directive does not encourage the transposition and application in the SMS: it is necessary to specify the articles of the Directive which is referred to.	The aim of this Directive is to introduce measures to encourage improvements in the safety and health of workers at work. It applies to all sectors of activity. It contains general principles of prevention. In that respect, we cannot refer to a specific article as the whole Directive applies. Note that this Directive applies since 12 June 1989, far before the entry into force of the present CSM. However, your comment gives the impression that it is something new for you.
Trenord	Annex II (3.2.1) (CSMs CA)	It seems more clear as follow: "improve the safety performance of the processes" instead of "improve its safety performance".	By definition, "performance" can relate to the management of activities, processes, products (including services), systems or organisations. It is not limitative to "processes". This can be clarified in the guidance. We however need to revise the sentence to improve clarity.
ERFA	Annex II (4.2.2 (d)) (CSMs CA)	Instead "ongoing": " adequate "; this seems to better reflect 4.2.2 (c) " <i>duration of the training and the frequency of the refresher training are appropriate for the training objectives.</i> "	Ongoing training is a concept of organisational learning (which is not only based on trainings) with the aim of maintaining the competence to the required standards and acquiring, where necessary, new competencies relevant for the post. The organisation can decide to arrange trainings at a given frequency to achieve that

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
			objective but it can be complemented by means other than trainings. So the term “ongoing training” does not mean that there should be “continuous” trainings but that the organisation has arrangements in place (e.g. trainings, coaching/mentorship, etc.) to ensure that staff remain competent for the job.
Trenitalia	Annex II (4.4.3 (g)) (CSMs CA)	Some clarity is needed on what is meant by the word ‘understood’. In 4.4.3 (g) of Annex II (Support)	Here the intention is that the organisation takes reasonable steps to make sure that necessary safety information is understood. For example for conversations between safety critical staff it is normal for people to repeat back messages or be asked to repeat back messages in order to check understanding. During safety critical briefings it would be normal to ask questions to check understanding rather than for example just asking people to sign a paper to say they were there. We will provide some further explanation in guidance along these lines.
Trenord	Annex II (5.1.3) (CSMs CA)	Add (h): Maintenance of vehicles using calibrated measurement instruments.	Maintenance aspects of vehicles are managed under 5.2 (asset management).
Trenitalia	Annex II (5.1.3 (b) & (c)) (CSMs CA)	Operations: Clarity is also needed in what is meant by ‘fatigue risk management,’ 5.1.3 (b) and development and implementation of train timetables’ 5.1.3. (c)	Fatigue risk management is the practice of local managers taking reasonable steps to ensure that their staff alert them to any issues which would result in them being made unfit to work through fatigue. Managers should also make sure that staff rosters are constructed to minimise the effects of changing shift work and regularly review

Organisation(s)/ Association(s)	Ref. to revised CSM/Art./Annex	Comment	Agency's response
			<p>arrangements. Risk assessments should look at the fatigue risk implication of the proposals.</p> <p>Implementation of train time tables is in the list of issues which need to be considered in terms of controlling risk since the timetabling of trains if not done with proper consideration can create risks which increase risks, for example the workload on signalling staff at certain times, thereby creating conditions in which an accident may occur.</p> <p>Guidance will be provided in the decision making criteria guidance.</p> <p>Note that for consistency sake we propose that this bullet point be incorporated in 3.1.1. (a). This is to avoid confusion as the other bullet points refer to operational aspects and not to a specific type of risk.</p>
Trenord	Annex II (5.2.4) (CSMs CA)	The sentence "To control risks where relevant for the supply of maintenance" is referred to <i>supplier of maintenance</i> or to <i>the execution of maintenance activity</i> too?	It does not only apply to "suppliers". It applies to the management and delivery of the maintenance activity, either performed by the organisation or by a contractor.
EIM	Annex II (3.2.2.a)) (CSMs CA)	Was there a specific reason to state "(where applicable)"? If not, it could be deleted.	From the CSM perspective, there should not be any obligation for the organisation to set strategic objectives (even if it is recognised as standard practice).
ETF	(CSM SUP)	In the CSM revision for supervision by national safety authorities we are missing provisions regarding the withdrawal of a safety	Noted, this will be covered within guidance for NSAs on how to use enforcement to manage deficiencies in applications.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		certificate or safety authorization. In Article 6 the CSM is only addressing the situation "prior to the renewal" or "prior to the up-date". What are the criteria and what is the procedure when a safety authority carrying out the supervision comes to the result that a withdrawal of the safety certificate would be appropriate?	<p>This approach will support Article 8 of the CSM which is about the Decision Making Criteria that the NSA uses for deciding on the effectiveness of safety management systems and for dealing with non-compliances.</p> <p>In the Practical Arrangements for Safety Certification and the Application Guide the procedure for taking this action will be indicated. In essence the line that is being taken is that national legal provisions will be used in the first instance to deal with non-conformities and then if this is not enough the Supervising NSA will request that the SCB which issued the Certificate considers its revocation providing suitable evidence to support this view. The SCB will then make a decision on revocation based on the available evidence.</p>
ETF	Annex III (CSM SUP)	It is necessary to mention the specific topic of working time rules and to specify how to ensure the cooperation. This is particularly relevant in cross-border cooperation for cross-border operations, which are reding working time not sufficiently addressed in Annex III.	Noted. In our view this is one risk among a number which could be mentioned specifically. What we have chosen to do in the CSM notably in Article 9 but also elsewhere is to make it clear that the NSA has to have a clear view on all the risks that exist within the system and target its resources to the supervision of the most important risks.. Working time is clearly a risk that the NSA will be aware of and will be checking to make sure that the Safety Management Systems of the actors involved actively cover it.

6.3. NSA Network consultation

6.3.1. General opinion

Since 2015, the Agency has reported back to the NSA Network the work progress on the project developments, pointing out the main issues discussed and conclusions reached within the working party.

During the follow-up discussions, a number of NSAs have raised findings on issues, previously discussed during the working party meeting(s), for which a common conclusion has been reached:

Table 7: Summary of findings raised during NSA Network meetings

<i>Organisation(s)</i>	<i># NSA Network</i>	<i>Comment</i>	<i>Agency's response</i>
NSA DK	41	<p>Our concerns addresses Article 2 (2) and Annex II in the latest draft for CSM on conformity assessment and supervision.</p> <p>We find the requirements set out in Annex II very relevant and useful, and we very much support the publication, but we fail to find the legal basis. To outline our understanding we would like to look back to the start of the work for revising the CSM, which was started based on RSD 2004/49.</p> <p>We read the legal basis in RSD 2004/49 the way that it contains no legal basis for enforcing requirements for the SMS to be implemented by the RUs and IMs other than those listed in Article 9 and Annex III. If more detailed requirements were to be established the MSs when implementing the directive should decide these.</p> <p>The new RSD 2016/798 has foreseen the need of such a Common Safety Method and states so in Article 9 (7). At RISC 76 the mandate for updating 1077/2010, 1158/2010 and 1169/2010 (CSM CA) was renewed.</p>	<p>The legal basis for drafting common safety methods is provided by Article 6(1) of Directive (EU) 2016/798.</p> <p>In the specific case of conformity assessment this is reinforced by Articles 9(1) and 10(3)(a) of the same Directive. The latter clearly state that the RU/IM's SMS shall ensure among others that the relevant parts of CSMs are applied. This can include requirements/criteria set out in Annex II of the CSMs on conformity assessment.</p> <p>Article 9(7) can be used when there are elements of the safety management system not included in article 9(3) which need to be harmonised at EU level. The intent is not to propose a CSM on how develop a SMS, the latter being redundant with Annex II of the proposed CSM on conformity assessment, but rather to develop/harmonise further specific SMS process(es). The CSM on monitoring and CSM on risk assessment are examples of CSMs that can be developed under Article 9(7).</p>

<i>Organisation(s)</i>	<i># NSA Network</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>To our understanding, the mandate (published 1 September 2016) does not include this reference, and thus the legal basis seems to be absent.</p> <p>As we see it there could be one of two possible solutions available,</p> <ol style="list-style-type: none"> 1. Obtaining a mandate based on the RSD 2016/798 Article 9 (7), and publish a separate CSM for these requirements. 2. Implementing the requirements through national implementation. 	
NSA NL	42	Requirements for running the test drives by the RUs – Specific certificate could be needed for confirming the ability of the RU to perform testing of vehicles	<p>The Agency agreed to clarify this issue by guidance without changing the SMS assessment criteria that are already deemed sufficient to manage risks relating to testing activities. This conclusion was also shared during the NSA Network. The Agency will reflect on whether the application form and the standard format of SSC should confirm that the SMS includes specific arrangements for testing.</p>
NSA IT	42	Requirements linked with Health and Safety issues in CSM – Health and Safety Directives should not be referred to in the CSM as the NSA may not be the competent body to check the compliance therewith.	<p>Requirements covering health and safety issues and transport of dangerous goods are present in current Safety Directive (Recital 12).</p> <p>The purpose of these provisions is to establish link between the Safety Management System and other safety relevant requirements and to give guidance to the applicant that they should be considered within the structure of the SMS.</p> <p>The NSA role is to check if the requirements have been taken into consideration in the structure of</p>

<i>Organisation(s)</i>	<i># NSA Network</i>	<i>Comment</i>	<i>Agency's response</i>
			<p>the SMS, not to check conformity with specific provisions setting those requirements. This detailed verification may be done by other competent authorities appointed at the MS level outside the SSC and supervision process.</p> <p>The working party acknowledged the link between the SMS and the H&S and agreed that duplication of assessment should be avoided. The Agency proposed to clarify by guidance the scope of assessment in relation to H&S issues. It was also clarified that if the NSA during supervision finds H&S issues it should notify the competent authority.</p>
NSA IT NSA DE	42	Concept of the leading NSA in the CSM on Supervision – NSA DE and NSA IT were against the leading role of the NSA for supervising the SMS of RUs operating in more than one Member State. NSA IT stressed the potential issue that for each application/assessment, the NSA would have to sign bilateral agreements with other NSAs.	<p>The Working Party agreed with the concept of the leading role to be taken by a NSA for the coordination of the supervision of the effectiveness of the SMS in order to avoid duplication of supervision among them. NSAs should decide who will take that role, preferably at the end of the assessment. More details are to be provided in the application guide.</p> <p>With or without the role of leading NSA, the NSA will have in any case to establish MoU with neighbouring NSAs. This is not a change as this is already required in the current CSM on supervision. The MoU should be valid for all applications. Therefore, there is no need to sign agreements between NSAs for each SSC application where residual concerns are to be deferred for later supervision.</p>

<i>Organisation(s)</i>	<i># NSA Network</i>	<i>Comment</i>	<i>Agency's response</i>
NSA IT	42	Interface between assessment and supervision – The CSMs should be more accurate about what information is to be exchanged between the different authorities	<p>The revised CSM on conformity assessment describes in its Article 6 the interface “assessment to supervision” whilst the revised CSM on supervision describes in its Article 6 the interface “supervision to reassessment”.</p> <p>Following the discussions at the 7th CSM Working Party meeting (May 2016), it was agreed the minimum list of information to discuss during coordination meeting between authorities. It was also requested by the CSM Working Party not to go for a prescriptive list of information. At the CSM Working Party meeting in September, It was also proposed to harmonise the template for the exchange of information (this only applies to the interface supervision to reassessment).</p>
NSA IT	42	Unclear in the CSMs how the NSA has to check the completeness of the file	<p>The purpose and details of the “Initial screen” stage are described in Annex I of the revised CSM on conformity assessment which was discussed together with the CSM Working Party.</p> <p>The Agency/NSA should check the completeness of the application file by analysing that basic information required in the CSM assessment criteria and relevant notified national rules have been submitted by the applicant.</p> <p>The Agency already started developing a new guidance to help the NSA (and also the Agency) in undergoing that task.</p>

6.3.2. Minority opinions

The minority opinions expressed by the NSA Network during its formal consultation (17 November 2016 – 17 February 2017).

Table 8: Minority opinions following the consultation of the NSA Network

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA ES	Recital (CSMs CA)	Health and Safety at work issues (risks arising from work activities, job design or workload) can go beyond the limits of NSAs competences. Therefore, the NSA may check in a very shallow way if Health and Safety Directive has been considered by the RU. For example, the NSA might not be able to check if the railway undertaking has identified health and safety risks properly or that the relevant risk control measures are in place. The scope of these checks needs to be clarified taking into account the limited powers of the NSA regarding these aspects.	<p>This is an issue for guidance. It should be noted that some NSA's have competence in this area and others do not. Those that do not should as you suggest seek evidence that workplace Health and Safety Directives are covered within the SMS of the applicant. They will not be required to check that the measures that the applicant says are in place do in fact deliver the level of safety claimed as this is a matter for the relevant labour authority.</p> <p>The purpose of this recital is to recognise that health & safety matters need also to be addressed in the SMS. It does not say that the implementation of related Directives must be checked by the NSA.</p>
NSA IE	Recital 14 (CSM CA for SA)	Does the IM have to be certified as an RU for this activity?	No it does not since an IM's role is not to transport passengers or goods in their own right from A-B but to maintain the infrastructure for which purposes it may run trains/vehicles of different types. We are saying that if you have an SA you do not also need to be an RU. Unless you have a sideline in transporting goods or passengers for their own sake.
NSA FR	Recital 18/16 (CSMs CA)	We do not understand the need to refer to train drivers whose certification process is sufficiently defined in other	A recital provides context to ease the understanding of the provisions of the Regulation. In the present case, the recital aims

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		texts (directive, decision and recommendations).	at clarifying Article 4(3) where it stated that there could a presumption of conformity with the CSM assessment criteria when certificates (etc.) are delivered in accordance with Union law. With the recital, we clarify that in the case of train driver certification, the certificate shows the ability of the RU to conform to the relevant competence requirements of the CSM.
NSA IE	Art. 2(3) (CSM CA for SA)	<p>In relation to “including the use of contractors”:</p> <p>In the case where the infrastructure manager itself operates inspection vehicles, on-track machines, or other special vehicles, the assessment for a safety authorisation can include assessment of conformity with the relevant requirements for obtaining a single safety certificate.</p> <p>However, in the case where the infrastructure manager contracts out such activities, the assessment for safety authorisation must assess the relevant requirements for management of contractors. As a separate legal entity, the Contractor would, in such circumstances, need to be assessed for conformity with the relevant requirements for obtaining a single safety certificate.</p>	<p>It depends. If the contractors sole job is to provide traction then it is likely that they will need to be an RU as defined since they are likely to transport goods from A-B. If they drive tampers for the IM for example then they don't technically need to be an RU for this bit but it would make sense to be so. If the contractors sole job is working for an IM then they do not need to be an RU as defined the expectation is that the IM covers this in their SMS through their contractual arrangements.</p> <p>This can be clarified in guidance. There are different options but in any cases, the assessment must cover the management of contractors. If this contractor is a RU, its safety certificate can provide a presumption of conformity. This is the reason why in 2.3 we do not specify “operates itself” to avoid entering into the specific cases.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		The foregoing needs to be made clear in this CSM.	
NSA IE	Art. 3(a) & (b) (CSM CA for SSC)	<p>(a) In relation to “by the use of the railway infrastructure”:</p> <p>The risk that has to be controlled is a function of traffic density (trains/hr; gross tonne-km, line speeds, etc.). If not more precisely expressed in the CSM, this should be clearly stated in the guidance document.</p> <p>(b) In relation to “length of railway track”:</p> <p>Perhaps this should be defined more precisely, i.e. route-km and running track –km (should siding tracks be included or not?) The definition should also include a reference to interfaces with contiguous networks</p>	<p>The purpose of the Article is to make it clear that the applicant must indicate the nature of their operation. At this stage it is not a question of risk which is covered in the Annex II requirements</p> <p>The purpose of the Article is to make it clear that the applicant must indicate the nature of their operation. At this stage it is not a question of risk which is covered in the Annex II requirements. We are not looking for an exact accounting here we are looking for a description that says this is us.</p>
NSA IE	Art. 6 (CSM CA for SSC)	Proposal to align this with Article 6.1 of the Safety Authorisation CSM.	This is clear to us. The two texts do have to be slightly different as the roles are different. Remember that when in Article 6.1 of the CSM CA SSC we are catering for both the SCB as ERA and SCB as an NSA whereas for the CSM CA SA the role is undertaken solely by the NSA. So in the latter case they can directly use information gained in assessment for supervision in the former it must be the case that the SCB passes relevant information to the NSA and they deal with it as they see fit.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA DK	Art. 7(2) (CSMs CA)	The competence levels are not defined clearly enough (how many years of experience etc)	Based on the list of minimum competency requirements, the NSA has to define the criteria necessary to meet these requirements, such as the number of years of experience. The objective is to ensure the same level playing field between authorities. Specifying a number of years or other limitative requirements would be detrimental to the recruitment process of the NSA (and the Agency) whereas the intent is to give a push for the authorities to get more competent resources.
NSA ES	Art. 8 (CSM CA for SSC only)	The transitional provisions need to be included again in the text to clarify the regime for the applications, especially for clarifying the different timing foreseen in this period.	It has been agreed with the Commission that transitional provisions for the safety certification regime will be introduced in the new Implementing Act on the practical arrangements for safety certification. There is no need to duplicate these provisions. Please also note that any decision for issuing Single Safety Certificate to be issued after 16/06/2019 should be made in accordance with Directive (EU) 2016/798.
NSA DK	Art. 8 (CSM CA for SSC only)	How are changes to SC issued before 16 June 2019 handled? In general we do not see this described. The "old" CSM CA must be valid for such changes.	You have a valid point. For the time being, it has been proposed to manage transitional provisions in the new Implementing Act on practical arrangements and to avoid duplication in the CSMs. However, discussions are still ongoing on the transitions (Cf. Expert Group in January). So the proposed text of the Implementing Act on practical arrangements may still be amended. If so, the CSM on conformity assessment for SSC

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
			must be made consistent with the Implementing Act.
NSA DK	Art. 8 (CSM CA for SA only)	How are changes to SA issued before 16 June 2019 handled? In general we do not see this described. The "old" CSM CA must be valid for such changes.	There should not be transitional provisions for safety authorisations because the relevant parts or Articles of the recast safety directive do not need further transposition by the Member States. Practically, it means that after 16/6/19 the new regime applies in all Member States. So any decision taken after that date shall be done in accordance with the recast Directive and subsequent Regulations. This can be explained in guidance.
NSA FR	Annex I (1.) (CSMs CA)	We do not agree with this new requirement of developing a "structured and auditable process" and we want the first sentence to be deleted.	This is not a new requirement. It exists as such in Annex I(1)(a) of Reg. 1158/2010 and 1169/2010. This was actually the purpose of the workstream 1.1 in our work plan of the revision of CSMs. It truly describes the objective behind Annex I. We therefore do not understand why this introductory sentence would not apply anymore.
NSA FR	Annex I (2.) (CSM CA for SSC)	According to Directive 2016/798 art 10.10, we consider that those requirements shall be in the PA and not in the CSM to comply with point b. and c.	The concept of "submission of application" and "resource assignment" are introduced in the PA SSC under another perspective and with a different level of details, e.g. the PA SSC focuses on when to submit an application, which is absolutely not developed in the CSM and the assignment of resources is described as part of the responsibilities of the Agency/NSA but it does not say when during the process this occurs. In the present Annex, we describe the stepwise approach. It is part of the general description of the step.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA FR	Annex I (3.4, 3.5 and 3.6) (CSM CA for SSC) (3.3, 3.4 and 3.5) (CSM CA for SA)	We consider that those articles do not have any added-value concerning the responsibilities of the SCB and we prefer to delete those parts in order to avoid any interference in the prerogatives of the SCB (we prefer not to describe too much detailed requirements like that because if something is missing, it would be more difficult to explain a rejection that would not be described here).	Stating for instance that “if an application is fundamentally deficient it can be rejected” does not impair the flexibility given to the safety certification body to take a decision. The § also identify the need to check that the file is understandable and that additional information should be requested where relevant. We do not understand where you lose the freedom of your decision here. These concepts are supported by the Directive when introducing the acknowledgement of completeness of the application.
NSA DK	Annex I (3.5) (CSM CA for SSC) Annex I (3.4) (CSM CA for SA)	The rejection must be given in the right way taken legal obligations into account. If this is described in a guide, also the part about “stating the reasons in writing” should be in the guide. Alternatively also references to “legal requirements” should be here.	The guide will describe what is the purpose of each CSM assessment criterion and what evidence can be expected of it. As proposed, any rejection must be justified and this justification must be based on the legal requirements (otherwise it would not be really justified). If this can help, we can clarify it in the guide.
NSA FR	Annex I (3.6 and 3.7) (CSM CA for SSC)	According to art 10.10 of RSD, we consider that this requirement should be in the Practical arrangement and not in the CSM.	This is a bit subjective. We do not see to which provision of Art. 10(10) you are referring to. It could be in one or the other. However, it is more appropriate in our view to have it in the CSMs as it gives a context to it (process based approach) and also , it allows a symmetry with the process for issuing safety authorisation.
NSA ES	Annex I (4) (CSMs CA)	The text that was included in Art. 6(5) of previous versions of the Agency proposal for the Commission Implementing Act on practical arrangements for issuing single safety certificates as referred to in Article 10(10) of Directive (EU) 2016/798, that is,	It is correct that during the review of the practical arrangements, I have said that this provision will be moved back to the CSM. Annex I of the CSM is sufficiently clear as it is clearly stated in Annex I.4.7 point (d) of CSM CA

Organisation(s)	Ref. to revised CSM/Art./Annex	Comment	Agency's response
		<p><i>“During the assessment, even if the application file is complete as referred to in point 2, either the Agency or the national safety authority (or authorities) may request at any time complementary information, setting a reasonable deadline for the provision thereof, without suspending the assessment unless required in accordance with 4.4 of Annex I of Commission Delegated Regulation (EU) No ../..”</i> needs to be moved to the CSM (with the appropriate adaptation). In this version of the CSM this provision is not included.</p>	<p>for SSC that you can request additional information.</p> <p>However, we can propose in point (e) that the authority specifies and also agrees with the applicant on a timeframe for compliance.</p> <p>In the subsequent provisions, in 4.8 and 4.9, it is explained under which conditions you can suspend the assessment. So it is clear that the assessment cannot be suspended unless these condition are fulfilled.</p> <p>So no information was lost from what was originally proposed in Art. 6(5) of previous versions of the practical arrangements and that is now removed in the Agency proposal for the practical arrangements.</p>
NSA ES	Annex I (4.3) (CSMs CA)	<p>The term “arrangements” may lead to misunderstanding as it may be interpreted as “agreements” or “measures, provisions” (as the cooperation agreements). It may be useful to replace it with a synonym.</p>	<p>This appears to us clear as the term is placed in the context of the NSA’s internal structures. Any change would be potentially more confusing.</p> <p>Note that “arrangement” has the meaning “the way things are done or organized”. For instance, you will find the term “arrangements” in the definition of safety management system in Directive (EU) 2016/798 with the same meaning.</p>
NSA DK	Annex I (4.4) (CSM CA for SSC)	<p>It doesn’t seem up-to-date to expect that evidence can be looked at as samples <i>by the desk far from the company</i>. Most companies today use IT based systems for storing data. Proposal for alternative wording: “..using sampling methods or audits where appropriate.”</p>	<p>In accordance with ISO 19011 and 17021, audits can be either off-site or on-site. Sampling is one of the audit technique. It is not limitative to off-site audit such as document review. We can clarify it in the guide.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA FR	Annex I (4.5) (CSM CA for SSC)	This point is redundant with article 12 of the PA. Moreover, the requirements are more detailed in the Practical arrangement, so we propose to delete it from the CSM.	We do not see any duplication here. Article 12 of PA is about the categorisation of issues which is a level of detail further. In the PA SSC, we explain how after the identification of issues these issues are to be managed in a consistent way by the different authorities. As for the previous comments, there are links (fortunately) but the assessment framework must provide the high level requirements. Where necessary, these requirements are further detailed in the PA SSC.
NSA DK	Annex I (4.5 and 5.1) (CSM CA for SSC)	The criteria for deciding and who to take decision upon minor/major concern and what can be deferred for supervision (after issue of SSC) must be clear. It should be stated that the decision should be taken in agreement with the supervising NSA(s).	We agree with you. This has been required in the Implementing Act on the practical arrangements (see Art. 11(4)(b)).
NSA LT	Annex I (4.8) (CSM CA for SSC)	Timeframe should be determined. E.g. 1 month.	It is not possible to impose a generic timeframe. No one size fits all. It must be determined on a case-by-case basis.
NSA ES	Annex I (4.9) (CSMs CA)	The sentence "if the applicant agrees" should be removed as there is no need to agree with the applicant in these particular cases. The applicant may be informed but the decision on the suspension of the timeframe belongs to the safety certification body in coordination with the NSA(s). (follow-up) From our point of view, the decision on the suspension of the timeframe belongs to the safety	The need for having an agreement of the applicant on the suspension of the assessment derives from discussions and agreements on the practical arrangements for vehicle authorisation at the related workshops. The approach to the suspension of the assessment should be the same for both vehicle authorisations and single safety certificates. In our view, that it is the right approach because the applicant should be responsible to decide whether it accepts that the application be

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>certification body in coordination with the NSA(s) and there is no need to agree with the applicant. But, if the approach to the suspension of the assessment that is considered to be right is that the applicant should be held responsible for deciding and, if appropriate, accepting the suspension (tacitly accepting that the timeframe can possibly be extended beyond 4 months depending on the timeframe needed to collect the required information), this needs to be explicitly explained in the text of the CSM. Moreover, what would happen if the applicant does not agree with the suspension?</p> <p>According to relevant legislation, in any case, the applicant is able to propose itself a rejection of the application at any stage of the process.</p>	<p>suspended or rejected otherwise. The applicant could indeed propose itself a rejection of the application. If it agrees with the suspension, it tacitly accepts that the timeframe can possibly be extended beyond 4 months (depending on the timeframe needed to collect the required information).</p> <p>(follow-up) This is already stated in § 4.8.</p> <p>If it does not agree, then the Agency/NSA can decide to reject the application. The same approach is proposed in the new Implementing Act on the practical arrangements for vehicle authorisation.</p>
NSA IE	Annex I (4.9) (CSMs CA)	What if the applicant does not agree? (See last line of paragraph 4.9)	The different options are described in §4.8. The SCB (and NSA for SA applications) is in charge of the process and responsible for ensuring that all matters which it considers as blocking the issue of a SSC (SA) are resolved. If they cannot be resolved either because the applicant is unable to resolve the matter to the satisfaction of the SCB(NSA) or they can't agree a timescale for the resolution of the issues the certificate does not get issued.
NSA ES	Annex I (5.1) (CSMs CA)	The residual concerns to be deferred to supervision should be agreed with the	We agree with your proposal but this is already stated in Article 11(4)(b) of the draft

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>representatives responsible for supervision in the NSA.</p> <p>We propose to modify the text as follows: Based on the conclusions of the completed assessment, a decision shall be made on whether to issue a single safety certificate or to refuse the application. Where a single safety certificate is to be issued, some minor non-compliances or residual concerns for consideration in later supervision may be identified and agreed with the responsible authority for supervision. A single safety certificate shall not be issued where serious non-compliance with the CSM assessment criteria is identified and not resolved during the assessment.</p>	<p>Implementing Act on the practical arrangements for safety certification as it relates to the coordination between the Agency as SCB and NSAs. So we don't need to duplicate it in the CSMs.</p>
NSA LT	Annex I (6.1) (CSMs CA)	This should also include that the fee (charge) must be paid before closing a file.	Fees and charges are dealt with in a new Implementing Act.
NSA ES	Annex I (7) (CSMs CA)	<p>The need to carry out a complete re-assessment must not be linked only to supervision aspects. It should be made possible a complete re-assessment:</p> <ul style="list-style-type: none"> - if applicant does not provide a good indication of the changes made to its SMS -during transitory situations: in the renewals of safety certificates previously issued according to Regulation 1158/2010. The applicant shall indicate 	<p>We have to distinguish what is required from the applicant before submitting a renewal/update application from the scope of the assessment itself.</p> <p>If the evidence provided is not good enough the application is not declared "complete" or gets suspended at a later stage during assessment (until enough evidence is provided) or possibly rejected.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		the subsequent changes following a new legal base but the railway undertakings are not included in the scope of the CSM so a re-assessment is needed in this case.	<p>Transitional issues are usually managed apart. We agree with your understanding. The current proposal does not preclude the Agency/NSA to re-assess the complete file where appropriate. Indeed, during the transition, the targeting of the assessment should also consider the change of legal framework and the need to re-assess the whole file or not. This is let to the responsibility of the concerned authority (or authorities).</p> <p>The two cases you refer to can be used as examples for the guide.</p>
NSA DK	Annex I (7) (CSMs CA)	A renewal should not be mixed up with "changes". Normal procedure for e.g. ISO certifications is that a renewal is done as for a new application for the document review. The aim is to see the system as a whole. The certificate holder might have made lots of changes during the period since last certification. A renewal process should aim at seeing that there is a complete system that fulfills all requirements. We would agree that the supervision activities could be planned based on "implementation history".	It is indeed clear that in ISO the renewal is a complete reassessment of the system in place. In the railway context, supervision is a continuous activity as referred to in Art. 17. The feedback on the implementation of Reg. 1158/2010 has also shown different approaches to renewal among NSAs. Following discussions at the working party, it has been agreed that renewal should not systematic lead to a full re-assessment. This does not mean that you can't do it but that your decision is justified by the extent of the changes. The applicant is asked to provide the full mapping of its documentary evidence against the CSM assessment criteria and to indicate where the changes are compared to the previous assessment. This approach appears to us a good compromise.
NSA DK	Annex I (8.) (CSM CA for SSC)	"Definition" of substantial change is different from today. Some changes could still be "substantial" even if they do not fit	We do not understand your comment. The provisions relating to substantial changes are the same in the recast Directive. Indeed, the change

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		into the defined category, e.g. change of the system that the certification was based upon.	of safety certification regime can be seen as a substantial change. However, this will not change that current safety certificates will have to be replaced by single safety certificates after 16 June 2019. It only changes the approach. As discussed during the OSS workshops, applicants will have the possibility to submit an update of their safety certificate in order to “convert” it to the new format. Because the change is substantial, it can be decided to opt for a full re-assessment.
NSA IE	Annex I (8.) (CSM CA for SSC)	<p>There is a need to include a requirement in 8.1 to update a single safety certificate whenever a material (substantial) change to the safety management system is proposed, i.e. a change in (a) the distribution of responsibilities within the organisation of the railway undertaking; (b) how control is ensured by the management on different levels; (c) how staff and their representatives on all levels are involved; (c) how continuous improvement of the safety management system is ensured; (d) the application of human factors knowledge and methods; or (e) the promotion of a culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety while ensuring confidentiality.</p> <p>Please include such requirement.</p>	We understand the rationale behind this suggestion however the specifics of the Directive only allow you to require an update of the single safety certificate if you alter the type, extent and area or operation. There is of course another lever here. An organisation proposing a substantial change to its safety management system would have to apply the CSM REA and the NSA could therefore use this lever via its scrutiny of an independent assessment report to make sure that the correct assessments of risk were carried out for such a change.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA ES	Annex I (8.3) (CSMs CA)	The term 'substantial change' should be clarified by defining it in Article 3 (Definitions).	<p>We have already explained what a 'substantial change' means in the current application guide (see Agency guide on issuing safety certificates/authorisations, available on our website).</p> <p>This issue has been discussed several times in the CSM Working Party. Outside the conditions under which there could be substantial changes (i.e. change in type/extent of operation, change of legal framework) set in the Directive, it is extremely difficult to come up with an harmonised comprehensive definition. This is why in the guide we have proposed examples of what could be considered as 'substantial changes'.</p>
NSA ES	Annex I (8.3); Annex I (8.5.b)(CSMs CA)	In case of an update application, the SCB and relevant NSA(s) shall consider the results of past supervision activities in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process but, it is important to also consider the outputs of applying this process for the substantial change proposed. As the substantial change shall be clearly described, the RU shall provide the results of applying its change management process to the particular substantial change and the potential safety risks and appropriate control measures that the RU shall identify before	Noted what you say is correct. Clearly it would be the intention that the description of the proposed change includes all the measures taken to mitigate the risks and which involve a change to the SMS arrangements. Nothing said here prevents this. Suggest that this might become clearer if we put some new information in guidance.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		implementing the change. This needs to be reflected in the text.	
NSA DK	Annex II (CSMs CA)	We find that it is unclear what needs to be documented. Annex II is to a wide range based on the organization being responsible, but in the requirements it is unclear what the expected level of documentation both in the SMS and for the resulting outputs from the system is. We support, that everything doesn't have to be documented, since leadership, culture etc are important and not always easy to document, but in a system that is based on assessment of "application file" (and not audits) it will be necessary to define clearly what documentation is necessary.	This approach is identical to the one in new ISO management system standards. We do not see it as a problem considering that the applicant is requested to provide a mapping table of its documentary evidence against each of the CSM assessment criteria (and national rules). Please note that audits are not excluded. Running a full off-site/on-site audit will be recommended for any new application.
NSA LT	Annex II (1.2) (CSMs CA)	There are specific criteria dedicated to risks, so this point seems redundant.	This § is about consideration of human factors in the SMS in general. It sets the framework to develop specific methods and techniques to manage human factors. Of course, there are connections with the risk assessment and other SMS processes. This § allows the organisation to recognise that human factors are a cross-cutting issue to manage.
NSA SE	Annex II (new 2.3.4/former 2.3.6) (CSMs CA)	For a better understanding of how the organisation is structured there should also be an organisation chart providing a better understanding of the organisation of the RU/IM and its responsibilities.	In our opinion, the organisation chart is the evidence you expect to fulfil § 2.3.4. This can be clarified in the guide.
NSA DE	Annex II (3.1.1 (a)) (CSMs CA)	Amend text:	When we refer here to interested parties, it cross-refers to 1.1 (c) which includes among others

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>“identifying and analysing all operational (including human performance), organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Operational risks shall include at least those arising from work activities, job design or workload and the activities of other interested parties (see 1. Context of the organisation) <u>and railway-related risks that concern staff or assets of third party contractors;</u>”</p> <p>Justification: Added text shall make clearer that IM is also responsible for safety-at-work for staff and material of third party contractors regarding dangers resulting from railway traffic.</p>	<p>contractors. I understand that your point is about staff and assets that do not appear explicitly in the text.</p> <p>The term ‘activities’ (of other interested parties) encompass staff and assets. This can be clarified in guidance.</p> <p>Note that your comment is not specific to IM’s contractors. It can also apply to RU’s.</p>
NSA ES	Annex II (3.1.1.2) (CSMs CA)	<p>In line with comment 2, the scope of the assessment of health and safety criteria should be defined. What are the evidences showing the fulfilment of this criterion? Would it be enough to include a mention to the related Directive? Should the NSA ask for the Safety and Health Plan? Or could a certificate issued by the competent body be considered as a proof of the ability of a RU to meet these requirements?</p>	<p>The NSA only has to satisfy itself that these requirements are considered. The competent authority will check that they are met. So they will need to mention that they are applying the relevant Directive and give some indication of how. They also should supply the H and S plan to demonstrate they have one.</p> <p>If there is a certification scheme in a member state which checks that appropriate workforce health and safety requirements are in place this would be good evidence of compliance. However, such certification scheme is not required for the sole purpose of showing compliance with the relevant CSM assessment criteria.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
			As discussed during the CSM Working Party, this will be further detailed in the guide on the decision-making criteria that the Agency is developing.
NSA CH	Annex II (3.1.2) (CSMs CA)	<p>In the new regulation (ex 1169/2010) the content of the old Criteria T is not explicitly visible. Proposal: add a new 3.1.2 (before the actual 3.1.2 planning for change, further numeration to be shifted as consequence).</p> <p>Content: Safe design of the infrastructure. The organisation shall establish procedures for a save design of the infrastructure troughout the life-cycle. Covering design, installation, monitoring, maintenance and change of the infrastructure taking into account relevant Norms and rules.</p>	<p>In our view, this is not necessary for the following reasons:</p> <p>T.1 is managed under 5.2.1. The infrastructure and its components/subsystems is an asset.</p> <p>T.2 is managed under 3.1.1 for the planning of change and 5.4 management of change</p> <p>T.3 is covered in 1.1.1 by the capture and implementation of legal and other applicable requirements. It is however not specific to the infra design.</p>
NSA DE	Annex II (4.1.1) (CSMs CA)	<p>Amend text:</p> <p>“The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system to ensure the safe operation and maintenance of its railway operations. This includes technical and medical experience from occupational health and safety specialists.”</p>	<p>In our opinion, this is already covered by 3.1.1.2.</p> <p>The purpose of this criterion, similar to ISO management system standards, is to ensure the available of staff and assets for achieving the objectives of the safety management system.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		Justification: Shall emphasize that aspects of occupational health and safety must be in the focus of the IM.	
NSA ES	Annex II (4.5.1.1 (f)) (CSMs CA)	§4.5.1.1(f) "reference to documented information required by this Regulation." Is this the mapping table cross-referencing the safety management system against the CSM criteria? It should be rewritten in order to be clearer.	Likewise ISO management system standards, no specific references to all applicable documents are identified. Usually, a general statement is used. We can propose in a guide, as it also done by ISO, to list those required documents (e.g. safety policy) with cross-references against the CSM assessment criteria.
NSA LT	Annex II (4.5.1.2) (CSMs CA)	Just a reference to the Safety directive should be enough, no need to repeat the content of the annual safety report.	The content of this provision is not a mere repetition of the Directive. Specific elements have been added on request of NSAs. In other terms, it elaborates further what is introduced in the Directive.
NSA ES	Annex II (5.2) (CSMs CA)	It needs to be clarified the definition of the term "asset" for this regulation in particular.	The term being not specific to railways, we do not see the need for a specific definition in the CSMs. If definition is needed, it can therefore be covered in the guidance on the Decision Making Criteria.
NSA IE	Annex II (5.3) (CSMs CA)	So monitoring of contractors, partners and suppliers is done by the railway organization Should there not be a requirement for self-monitoring for contractors, partners and suppliers. The old criteria C1 to C5 are much more specific for the organization to have control of contractors, partners and suppliers.	The monitoring has to be done by the RU/IM as this is the body applying for the SSC not the contractors, partners and suppliers. Clearly one method for the RU/IM to monitor them is to insist as part of the contractual arrangements that they self-monitor and supply the results to the RU/IM.

Organisation(s)	Ref. to revised CSM/Art./Annex	Comment	Agency's response
NSA ES	Annex II (5.4.1) (CSMs CA)	<p>According to Annex II 3.1.2.1. <i>“The organisation shall identify potential safety risks and appropriate control measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change), including consideration of the safety risks from the change process itself.”</i> This may suggest that section 5.4. Management of change applies to any safety related change (when making any safety related change to the railway system) but the text of section 5.4.1 states that the organisation shall implement and control changes <u>to the safety management system</u>, so this section seems to deal only with the changes made to the SMS.</p> <p>The scope of Annex II section 5.4 needs to be clarified.</p>	<p>It's the same thing. The SMS is the way that the whole system fits together to ensure safety. This means that when it talks about changes to the SMS it also means everything that the SMS covers including risk assessment etc.</p> <p>In addition, the Decision Making Criteria guidance will make it clear that all safety related changes need to go through the change management process.</p>
NSA DK	Annex II (5.4.1) (CSMs CA)	<p>The wording “.. changes to the safety management system ..” is misleading. All changes that the SMS will have to control is not changes to the SMS</p>	<p>The SMS is the way that the whole system fits together to ensure safety. This means that when it talks about changes to the SMS it also means everything that the SMS covers including risk assessment etc.</p> <p>In addition, the Decision Making Criteria guidance will make it clear that all safety related changes need to go through the change management process.</p>
NSA IE	Annex II (5.4.2 (a)) (CSMs CA)	<p>There is a need to include a requirement in 8.1 to update a single safety certificate whenever a material (substantial) change</p>	<p>We understand the rationale behind this suggestion however the specifics of the Directive only allow you to require an update of single</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		to the safety management system is proposed, i.e. a change in (a) the distribution of responsibilities within the organisation of the railway undertaking; (b) how control is ensured by the management on different levels; (c) how staff and their representatives on all levels are involved; (c) how continuous improvement of the safety management system is ensured; (d) the application of human factors knowledge and methods; or (e) the promotion of a culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety while ensuring confidentiality.	safety certificate if you alter the type, extent and area or operation. There is of course another lever here. An organisation proposing a substantial change to its safety management system would have to apply the CSM REA and the NSA could therefore use this lever via its scrutiny of an independent assessment report to make sure that the correct assessments of risk were carried out for such a change. This can be clarified in guidance. (e) is a copy-paste of Article 9 of Directive 2016/798. Note that this has been replaced in 2.1.1 by the promotion of a positive safety culture. In that case, we do not have to ensure confidentiality as the organisation applies a no blame reporting culture.
NSA DK	Annex II (5.5.1 and 5.5.3) (CSMs CA)	What is the relevance of TSI here?	TSI OPE provides provisions for the emergency response procedure such as the need for coordination between the different parties.
NSA ES	Annex II (5.5.9) (CSM CA for SSC)	Same as for Health and Safety issues, the competent authority for Regulation (EC) No. 1371/2007 on rail passengers' rights and obligations may not be the NSA. In the case of Spain, the responsible authority is the General Directorate of Land Transportation. Currently, in the SMS assessments, RUs are only reminded to have a plan of assistance to victims. It is necessary to clarify the scope of this checks, how this requirement may be assessed: could its compliance be	The NSA only has to satisfy itself that these requirements are considered. The competent authority will check that they are met. So they will need to mention that they are applying the relevant Regulation and give some indication of how. This will be further detailed in the guide on the decision-making criteria that the Agency is developing.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		demonstrated with a certificate issued by the competent authority for Regulation 1371/2007?	
NSA DK	Annex II (5.5.9) (CSM CA for SSC)	To manage guidance to victims is new in the SMS. We do not think that this should be managed through the SMS.	The idea was to reflect Art. 9(5) 3 rd subparagraph of the recast safety directive, which identifies a role for the RU: "In case..., the RU shall provide..." In our opinion, this has an impact on the emergency response procedures which are part of the SMS. This is also the reason why such provision is inserted in Article 9 which is about the SMS.
NSA DK	Annex II (6.) (CSMs CA)	It should be considered to integrate CSM Monitoring totally in the CSM CA. Monitoring is a natural part of management systems. And this revision of the CSM CA includes most of the requirements.	That is a valid point and this is exactly what we have been aiming at. Through numerous discussions within the working party, in particular with EIM, it was finally agreed that the relevant clause in ISO HLS could not be fully adapted to railways because of our specific legal framework, in particular the CSM on Monitoring. The aim of chapter 6 in the CSM is to reflect what is set out in the CSM on Monitoring. Internal audits and management review are tools serving the purpose of monitoring, for which it was deemed These requirements do not exist in the CSM MON.
NSA DE	Annex II (6.6.1 (a)) (CSMs CA)	Amend text: "to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety	Operational, organisational and technical safety measures refer to those measures resulting from risk assessment, as referred to in 3.1.1. In the light of our answer to your comment 2, this is intrinsically part of the risk assessment to consider also external parties. Therefore it is implicit that these measures do not apply only to

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>measures <u>and their application to all external staff and external assets</u>"</p> <p>Justification: Added text shall make clearer that IM is also responsible for safety-at-work for staff and material of third party contractors regarding dangers resulting from railway traffic.</p>	<p>the organisation itself but also to any other parties with shared interface with the IM.</p> <p>We propose to clarify it in the guide.</p>
NSA DK	Annex III (CSM CA for SSC)	<p>It is not clear how the certificate will be filled in. How and where are the relevant MS(s) supposed to be noted?</p> <p>Where can you include operations that are not passenger or freight transport or shunting (e.g. operation in connection with infrastructure maintenance etc?</p> <p>What is supposed to put under "Other operations"?</p>	<p>Explanations about the different fields will be provided in the guide.</p> <p>In the past, the working party and also the NSA Network discussed the need to distinguish those RUs performing testing of vehicles. Other NSAs were in the opinion that it could be useful to specify those RUs only performing testing of vehicles as core business. Other NSAs proposed to identify those RUs operating vehicles for the infra maintenance etc.</p> <p>As the working party could not agree on a specific list of operations, we gave the opportunity, as a compromise, to specify other types of operation in the certificate.</p>
NSA SE	Recital 11 (CSM SUP)	<p>"In accordance with Article 17(1) and Article 17(8) of Directive (EU) 2016/798, in the cases where railway undertakings and infrastructure managers are also entities in charge of maintenance that are not certified in accordance with Article 14(4) of Directive (EU) 2016/798, supervision activities carried out by national safety authorities with the aim of checking the</p>	<p>This issue has been raised by the NSA ES at the working party and also during the consultation. We recognise this is an important issue to clarify. However, this will depend on the scope of the revision of ECM Regulation.</p> <p>Indeed, the legal framework does not identify a role for a NSA to assess/supervise ECMs and maintenance workshops unless the NSA is ECM certification body. It is up to ECM Regulation to</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>application of the relevant CSMs referred to in Article 6 of Directive (EU) 2016/798 by entities in charge of the maintenance are justified means for supervising the effectiveness of the safety management systems of these railway undertakings and infrastructure managers.”</p> <p>Something is missing:</p> <p>Its not enough just to check fulfilment of CSM RA and CSM MON. NSA also need to supervise and check that RU /IM fulfill the obligations according art 14 for ECM without a certificate.</p>	<p>regulate it or at least to set the clear boundaries of NSA assessment and supervision with regard to the supply of maintenance, be the ECM certified in accordance with EU law or not.</p>
NSA SE	Art. 1 (CSM SUP)	<p>“This Regulation establishes a CSM for the supervision of the management of safety by national safety authorities of railway undertakings after they have been issued (single) safety certificates and infrastructure managers after they have been issued safety authorisations, or entities in charge of maintenance where appropriate as referred to in Article 6(1)(c) and Article 17(1) of Directive (EU) 2016/798.”</p> <p>NSE SE don't agree to delete above sentence</p> <p>NSA conducting supervise according to whole art 14 where appropriate not only CSM MON or CSM RA. Here is the mandate</p>	<p>This comment has also been raised by Italy at the Expert Group #2 and detailed in their subsequent comments.</p> <p>The legal framework does not identify a role for a NSA to assess/supervise ECMs and maintenance workshops unless the NSA is ECM certification body. It is up to ECM Regulation to regulate it or at least to set the clear boundaries of NSA assessment and supervision with regard to the supply of maintenance, be the ECM certified in accordance with EU law or not.</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>for NSA to act when a RU / IM use a not certified ECM.</p> <p>NSA need to check how the RU/IM secure fulfilment of art 14. It is not enough just to check fulfilment of CSM RA or CSM MON</p>	
NSA DK	Art. 2(3) (CSM SUP)	It must be defined clearly who should have the leading role for coordinating the supervision. What if a "decision" can't be agreed between relevant parties?	As discussed during the working party, this depends on many criteria and not necessarily where the undertaking has first established its operations. You could have cases where most of operations are conducted outside the Member State where the RU is established. In most cases, it will be however the "local" NSA in charge of supervising the RU's SMS, simply because of the language issue and the proximity.
NSA ES	Art. 6 (CSM SUP)	<p>Art. 6 (1) of the previous versions of the Regulation needs to be included again:</p> <p>1. The national safety authority shall use information gathered during the assessment of a railway undertaking's or infrastructure manager's safety management system for the purposes of its supervision of the continued application of their safety management system, in accordance with Article 17(11) of Directive (EU) 2016/798 and Article 6 of Commission Delegated Regulation (EU) No ../... or Commission Delegated Regulation (EU) No ../.. of .. on a common safety method for assessing conformity</p>	<p>Art 6(1) has been removed to avoid duplication with Article 6 in the revised CSMs on Conformity Assessment.</p> <p>Article 17 defines the bidirectional interface between assessment and supervision. For practical reasons, we have proposed to describe the interface assessment to supervision in the revised CSMs CA (as it is important to identify what comes from the assessment, in coherence with the process defined in Annex 1 of the revised CSMs CA) and the interface supervision to re-assessment in the revised CSM SUP (as it is important to define what comes from the supervision, in coherence with the process defined in Annex 2 of the revised CSM SUP).</p>

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		with the requirements for obtaining railway safety authorisation ⁵ respectively.	Please note that Article 6 of the revised CSM CA refers to Article 17(11) of Directive (EU) 2016/798.
NSA DE	Art. 6 (CSM SUP)	To be deleted here and transferred to CSM CA Annex I point 2.1. Justification: NSA does not have a current up-to-date overview of all major and minor non-compliances and their status of being resolved. NSAs would have to contact the RU/IM to get this information in order to transmit that information to the SCB. Therefore, it is more convenient for all parties to transfer this obligation to the RU/IM and its application.	Reference to "current" status of action plan(s) can be removed from the legal text. We also agree that the applicant has also the responsibility to provide a status of its action plan(s) when submitting its application. However, it is also part of the responsibility of the NSA undertaking supervision to monitor the implementation and effectiveness of the action plan(s).
NSA ES	Transitional provisions (CSM SUP)	The transitional arrangements need to be clear, it is not sufficient to put single between brackets in the title. It is necessary to add an article on transitional provisions.	This issue was discussed with EC legal service. Please refer to the note on legal issues circulated to the CSM Working Party and to the NSA Network. There are not two specific supervision regimes. The supervision principles have been maintained and improved where necessary. These principles apply irrespective of the type of certificates issued. Otherwise, the NSA would have the obligation to apply two CSMs on supervision at the same time, depending on the type of certificates issued.

<i>Organisation(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		(follow-up) Although the Agency legal service has stated that transitional provisions are not required in the revised CSM on Supervision, it needs to be clearly indicated in the CSM on Supervision that the RU/IM's SMS should be supervised against the requirements/criteria set out in the applicable CSM on conformity assessment at the time the Part A safety certificate was issued.	It is up to the Legal Service to confirm whether such clarification is needed. When we discussed the first time it was obvious to them that you supervise against the legal base used to deliver the safety certificate.
NSA PL	Annex III, point 3 (b) (CSM SUP)	Proposal to delete point b. Safety authorisation are to be notified to the Agency in the same manner as safety certificates, therefore it is unclear why only copies of the former are to be provided under framework for coordinate and joint supervision.	We added "where appropriate" because it only applies in case of cross-border infrastructure where NSAs have also to coordinate their supervision activities.

6.4. Others

6.4.1. Human Factors Network

From the very early stages of the project, the Human Factors Network has been consulted by the Agency in order to identify possible measures to support the integration of human factors principles and methods. For that purpose, the Human Factors Network has established a subgroup composed of human factors experts to develop further these measures, consistent with the work plan of the revision of the CSMs. The outcome of discussions at this subgroup has been reported back on a regular basis to the working party and considered when revising the CSM Regulations.

6.4.2. Group of Experts

The progress status on the revision of the CSM Regulations has been discussed with the 'EC RISC Working Group' in June 2015 and then, with the 'Group of Experts' in accordance with the new comitology procedure.

During the first ‘Group of Experts’ meeting on 8 November 2016, the Agency presented the remaining open issues stemming from the previous working party meeting (held earlier in September). The ‘Group of Experts’ positively welcomed the work accomplished so far and did not raise any significant matter of concern.

Before, during and after the second ‘Group of Experts’ meeting on 25 January 2017, the following issues have been raised:

Table 9: Specific issues raised before, during or after the second ‘Group of Experts’ meeting held on 25 January 2017

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency’s response</i>
Poland	Art. 5(2) (CSM CAfor SSC)	This article should be reworded in order to include also cross-border agreements.	It is not necessary as it is obvious that you have to take into consideration those agreements in accordance with Article 10(8) of Directive 2016/798.
Poland	Art. 6(1)(a) (CSM CAfor SA)	Letter (a) should be deleted. There is no need to automatically share the whole application file (which can be very large and parts of it might be legally protected) with other NSAs. Parts of it, referring to possible cross-border sections or cross-border cooperation, should be of course shared, upon request of the relevant NSA.	
Poland	Art. 7(2)(b) (CSM CAfor SSC)	Proposal to add at the end of the sentence here “including relevant technical competences and skills”. Point (e) in this article mentions “relevant non-technical competencies” – it is therefore unclear under which point “technical competencies” are covered. It should be clearly indicated that staff performing conformity assessment activities must have relevant technical competences.	Bullets (a) to (e) are technical competencies. Non-technical competencies, in the jargon of Human Resources, are soft skills. Please do not mix up competency requirements and criteria to select/recruit people. Based on the list of minimum competency requirements, the NSA has to define the criteria necessary to meet these requirements.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
Poland	Art. 8 (CSM CA for SA)	This article should be aligned with similar article in new CSM-CA for railway undertakings. It's unclear why this article does not refer to possibility to notify the Commission about prolongation of transposition.	This has been explained in the legal note prepared following coordination with DG MOVE and its legal service (see Annex 4). There is no need for transposition of Article 12. Therefore, there is no derogation for prolonging the transposition.
Poland	Annex I.3.2 (CSM CA for SA)	Proposal to add a sentence: "The information requested by the safety certification body should be precisely indicated and agreed with the applicant as to avoid misunderstandings concerning its content and unnecessary prolongation of the certification process".	Although the OSS won't be used for safety authorisation process), we have the provision of Annex I p. 4.9 explains what is expected from the SCB in terms of clarity of requests.
Poland	Annex I.3.3 (CSM CA for SSC)	Proposal to add a sentence: "The information requested by the safety certification body should be precisely indicated and agreed with the applicant as to avoid misunderstandings concerning its content and unnecessary prolongation of the certification process".	At the same time I believe that using the communication in the OSS will solve the problem as it will allow for more direct communication between assessors and applicant with use of the issues log not the formal administrative letters, so a part of the problem should be solved itself. Additionally in my opinion Annex I p. 4.7 explains what is expected from the SCB in terms of clarity of requests.
Italy	Annex I.3.7 (CSM CA for SSC)	After "Any supplementary information sent as part of the application" we propose to add the following sentence: "...and into the timeframe referred to point 3.6". The aim is to explain that obligations to share and keep any supplementary information is valid only if it is received in	It is clear that the assessment cannot start without the requested supplementary information. This means that the 4 month timeframe does not start until the requested information has been provided by the applicant in accordance with Art. 10(6) of Directive (EU) 2016/798 and also Article 6 of the practical

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		time. There should be no obligation for what is sent out of the timeframe.	arrangements. In our view, this repetition is not needed.
Poland	Annex I 4.7 (b) (CSMs CA)	Delete 'standards'. The proposed text does not anywhere mention 'standards' as a criteria against which compliance is to be assessed.	This is a misreading. The intention is that standards are used as part of the evidence of compliance not as criteria for assessment in themselves.
Italy	Annex I.7.3 (CSM CA for SSC)	The re-assessment is foreseen only in case of changes and based on the degree of changes proposed. For the Italian NSA, in case of the five-year renewal application of safety certification it would be appropriate to make a complete re-assessment of the documentation (as it is in the 1158 Regulation). The experience gained suggests to continue with this approach.	This decision is let to the responsibility of the safety certification body but there should not be full re-assessment unless justified (e.g. during transition period or following doubts identified during supervision) but the whole application file needs to be submitted in accordance with Article 4(3) of the Practical Arrangements for the Single Safety Certificate.
Poland	Annex I.8 (CSMs CA)	The process described in this section seems unclear, especially in context of analyzing the need to update the certificate. In our view a need to update the certificate is only when information contained therein is outdated. If change affects a parameter included in the certificate – there is a need for update. If not, there is no need. In our view there is hardly here a room for safety certification body assessment. Please note that it makes no sense to update a document, if there are no changes to its content.	think there is a misunderstanding. There will be more information on what is meant here in the Application Guide. In practice the update of the Safety Certificate should take place if there has been a substantial change to the SMS. This may not result in the certificate itself changing in content but does ensure that the applicants SMS continues to be fit for purpose which is the point of this system.
Poland	Annex I.8.1 (CSM CA for SSC)	Update is required in case of substantial change to type, extent or area of operations. In the template of safety certificate only type and area of operations	At the same time I believe that we may use information from the SMS summary explaining the profile of the company including type of its operations / etc. (p. 1.1 a and f of Annex II) but of

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		is indicated. Concept of extent seems therefore to be missing. Today it is attributed to the size of railway undertaking (number of employees), which was indicated in the application for safety certificate and later in the certificate itself. However in the new regime there is no indication about what exactly means 'extent' – in our view this should be clarified as it might later create difficulties and misunderstandings.	<p>course we will not have such detailed parameter as a number of employees there.</p> <p>Taking into consideration problems with interpretations that we may have, indeed it should be clarified but maybe in the guide not here.</p> <p>Type, extent and area of operation relate to the context of the organisation (see 1.1 in Annex II) and this will be covered in the Decision Making Criteria Guide.</p> <p>Note that the decision not to have anymore the extent of operation in the application form nor the certificate has been made within the working party. There was a desire to simplify the templates and also it was believed that the requested information (volume of transport, size of the company) were not relevant</p>
Poland	Annex I.8.5 (b) (CSMs CA)	Delete "(in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process)". Determining areas of particular attention should be left to the decision of the NSA.	We may underline the most important areas here, although – at the same time - for me it should be more risk management and change management process. I think this is a misunderstanding. What is being said here is that the question of how the organisation has validated its changes is a question of interest for the NSA/SCB. For example have they followed their own process? Some additional explanation necessary in Guidance.
Italy	Art. 9 (CSM CA for SA)	Italy proposes to add the same sentence used in the other CSM: "It shall apply from 16 June 2019 in respect of areas of operation in the Member States	This issue has been clarified in the note on legal issues the Agency circulated to the CSM Working Party and the NSA Network. In substance, transposition of Article 12, apart of par. 5, is an

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>that have not notified the Agency or the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall fully apply from 16 June 2020.”</p> <p>The entry in force timing should be aligned with the other CSMs, otherwise it would become not applicable or in overlapping with the previous CSM during the transitional period.</p>	<p>obligation dating back to 2006 and transposition deadline of 2004/49/EC. In other words, we presume these provisions have already been transposed. Once old Directive is repealed, new one applies ensuring the continuity. In conclusion, there is no need for any transitional provision.</p>
Germany	Annex II (3.1.1 (a)) (CSMs CA)	<p>Amend text:</p> <p>“identifying and analysing all operational (including human performance), organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Operational risks shall include at least those arising from work activities, job design or workload and the activities of other interested parties (see 1. Context of the organisation) <u>and railway-related risks that concern staff or assets of third party contractors;</u>”</p> <p>Justification: Added text shall make clearer that IM is also responsible for safety-at-work for staff and material of third party contractors regarding dangers resulting from railway traffic.</p>	<p>When we refer here to interested parties, it cross-refers to 1.1 (c) which includes among others contractors. I understand that your point is about staff and assets that do not appear explicitly in the text.</p> <p>The term ‘activities’ (of other interested parties) encompass staff and assets. This can be clarified in guidance.</p> <p>Note that your comment is not specific to IM’s contractors. It can also apply to RU’s.</p>
Poland	Annex II (5.5.9) (CSM CA for SSC)	<p>Proposal to delete this provision. This provision is too far reaching, can create serious repercussions for railway undertakings and is unnecessary.</p>	<p>This is right. We may have different national systems which are well recognised by the citizens and all emergency services. There is one communication pattern and one set of</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>Firstly it has to be noted that in Poland obligation to provide psychological assistance to victims is an obligation of local and regional governments under Emergency Management Act. There is no point therefore in organizing such help by railway undertakings, which will double the effort of local government.</p> <p>Secondly, it has to be noted that determination of whether an accident can be treated as 'serious' is sometimes very hard to be done right on accident's site. Accidents resulting from reasons other than train collision or derailment, which are explicitly stated in the definition of a 'serious accident', need to be evaluated by a criteria of 'having an obvious impact on railway safety regulation or the management of safety'. In case of countries like Poland where a significant number of accidents involves unauthorized persons or level crossing users (this means at least one person dead), it is hard to determine on-the-spot whether it is a 'serious accident' and we need to organize psychological help or not. This creates a big area for misunderstanding and discussions whether actually railway undertaking performed well in terms of emergency management.</p> <p>Thirdly, this imposes a demanding obligation, disregarding other factors like</p>	<p>responsibilities allocated to different public institutions irrespectively of the transport mode. Changing it may create mess. At the same time I understand the requirement based on Regulation 1371/2007. Maybe it should be softened in the guide specifying that if there is specific national path the RUs have to inform about it. Summarizing – I believe something should be done here (at least explanation form our side).</p> <p>We clearly need to keep the provision as its EU law. However, we could perhaps say that if national rules apply which have the same effect as Regulation 1371/2007 then these should be used and if not 1371/2007 and/or as suggested we could provide more in the Application Guide.</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		circumstances of the accident, role of the railway undertaking, the fact whether other institutions already had taken action in this respect etc. It can also create a disputable situation, when victims of level crossing accident are to be helped by railway undertaking.	
Germany	Annex II (6.6.1 (a)) (CSMs CA)	Amend text: <p>“to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures <u>and their application to all external staff and external assets</u>”</p> <p>Justification: Added text shall make clearer that IM is also responsible for safety-at-work for staff and material of third party contractors regarding dangers resulting from railway traffic.</p>	Operational, organisational and technical safety measures refer to those measures resulting from risk assessment, as referred to in 3.1.1. In the light of our answer to your comment 2, this is intrinsically part of the risk assessment to consider also external parties. Therefore it is implicit that these measures do not apply only to the organisation itself but also to any other parties with shared interface with the IM. We propose to clarify it in the guide.
Poland	Annex III (CSM CA for SA)	Since a change in extent of operations might require a new authorisation, extent should be indicated in the template of safety authorisation.	Unlike safety certificates, Article 12 of Directive 2016/798 does not refer explicitly to substantial change to the type or extent (of operation) as these terms are exclusively used for railway undertakings (see definitions in Article 3 of the same Directive). We have added definitions of similar terms for infra managers but to ensure consistency of approach in Annex II.1.1.
Italy	Art. 1, Art. 2(1)(b) (CSM SUP)	- Who is in charge of the supervision of certified ECM for freight wagons	1) In the working party on revision of CSM CA and SU and in NSA network, the Agency proposed to

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>(certification bodies: accredited bodies, recognised bodies or national safety authorities)?</p> <p>- Who is in charge of the supervision of not certified ECM (for other vehicles)?</p> <p>- What kind of supervision activities should be done in the different cases?</p> <p>For instance, in Italy ECMs are certified by Certification Bodies other than NSA, does it mean that Italian NSA is not in charge of ECMs supervision?</p> <p>Only the Certification Bodies will do supervision?</p> <p>How can the NSA maintain a complete overview on the safety of its railway system and relevant actors (IMs, RUs and ECMs)?</p>	<p>postpone the discussions on 'supervision of ECM' to the project of revision of ECM certification for ensuring consistency with the extension of scope to voluntary or mandatory ECM certification. Same regarding certification of maintenance workshops. Both working party and NSA network accepted the Agency proposal. Consequently a set of rules and guidance on 'supervision of ECM and maintenance workshops' will be discussed and agreed in the following year, thus well before the entry into force to the revision of the CSM on supervision.</p> <p>2) Art 16(j) of 2016/798 limits supervision to RUs and IMs in conformity with art 17. Art 16 does not mention any supervision of ECM.</p> <p>3) Art 17 (1)(c) extends the supervision to the implementation of CSMs on RA (402/2013) and CSM on MO (1078/2012) to ECM. Since Art. 17(1) is addressed to the supervision of RUs and IMs, it can be understood that the supervision of ECMs referred to in point (c) covers those RUs/IMs acting as ECMs and being not certified against ECM Regulation (any duplication with ECM surveillance activities has to be avoided). In that context, the supervision of the application of CSM RA and CSM MO should be done through the supervision of the RUs/IMs' SMS referred to in point (b).</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
			<p>4) Art 17(8) considers that “When supervising the effectiveness of the safety management systems of infrastructure managers and railway undertakings, the national safety authorities may take into account the safety performance of actors as referred to in Article 4(4) ...” It should be understood by all parties that NSAs may perform some supervision actions on RUs/IMs acting as ECMs, including their maintenance workshops, under the conditions that those ECMs are not certified, in order to consider their respective safety performances. But it can only be done as means that must be duly justified by NSAs for the purpose of supervising RUs SMS and IMs SMS. Therefore Art 17(8) does not provide an open door for systematic supervision of ECMs and maintenance workshops. In addition to that, as mentioned above, it would not be useful for NSAs to duplicate the surveillance activities of the ECM certification body.</p> <p>5) There is no legal requirements forbidding exchange between NSAs and ECM certification bodies.</p> <p>Conclusions:</p> <ul style="list-style-type: none"> - Discussions on the topic will be done in Agency works on revision of ECM certification in 2017.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
			<ul style="list-style-type: none"> - No systematic supervision of ECMs and maintenance workshops is imposed by Directive 2016/798 - Some supervision actions on ECMs (and their maintenance workshops), in the cases where the RUs/IMs are non-certified ECMs, can be done as justified means for supervising the effectiveness of RUs SMS and IMs SMS. - Duplication of NSA supervision actions with surveillance performed by ECM certification bodies must be avoided but exchange of information between them is not forbidden!
Italy	Art. 2 (CSM SUP)	<p>Italy expressed in the past its concerns in introducing the “leading NSA” concept. Firstly, because it is not directly foreseen by the Safety Directive. Secondly, because it seems to introduce an extra level of complexity in the process.</p> <p>Without any legal base, the resulting responsibilities and coordination activities between the concerned NSAs will be regulated through “commercial” agreements to be signed for each SSC, following the national legislations. This cannot be done “promptly”.</p> <p>Italy believes that the DA should define who designate the leading NSA (ERA in our opinion) and how it is nominated, clearly stating criteria, responsibilities and tasks.</p>	<p>Directive (EU) 2016/798 sets out high level objectives but do not define how these objectives should be achieved. Article 17(9) of the same Directive stipulates that duplication of supervision should be avoided by the cooperation between NSAs. In order to meet these objectives, we have proposed the appointment of a coordinator among NSAs (in charge of supervision of RUs operating in more than one Member State).</p> <p>This issue has already been discussed at the 8th CSM Working Party meeting and the outcomes of discussions at the CSM Working Party are reflected in our policy proposal.</p> <p>With or without the role of leading NSA, the NSA will have in any case to establish cooperation</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>Many examples of “open” operational issues could be done using the proposed approach.</p> <p>Without all the necessary clarifications into this Act on the use of the “leading NSA”, it is preferred to leave this approach, maintaining the “joint supervision” as is done now.</p>	<p>arrangements with neighbouring NSAs. This is not a change as this is already required in Article 8 of the current CSM on supervision. These arrangements should be valid for all applications. There is no need to sign off agreements between NSAs and certainly not, for each SSC application where residual concerns are to be deferred for later supervision. Therefore, there is no additional level of complexity added by this proposal. This should be part of the setting up and implementation of coordination arrangements between NSAs. As you mentioned at the end of your comment, it is up to the NSAs to decide whether on a case-by-case basis, based on their coordination arrangements, it is preferred or even possible to undertake joint or coordinated supervision. Please note that for many NSAs, the joint supervision is simply not possible because of limitative powers given to the NSA by their respective Member State.</p>
Italy	Art. 3 (CSM SUP)	<p>The CSM introduces some new elements. To avoid different interpretations in each MS and to have a common European approach, some definitions should be added.</p> <p>At least, the following:</p> <ul style="list-style-type: none"> - “Safety Performance”: in the safety directive and into the present CSM no indication is available on how to measure it and how to check it. 	<p>The terms “regulatory framework” and “safety performance” are already used in Directive (EU) 2016/798. The purpose of the CSM is not to provide definitions for general terms that have no specific meaning for the understanding of the CSM or more globally, in the field of railways</p> <p>Article 6(a) of the proposed revision for the CSM SUP explicitly defines “major non-compliance”, i.e. a non-compliance which may affect safety performance or create serious safety risks.</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>- "Major non-compliances": it does not seem the same used in the SSC CSM (different level and prioritization). To avoid that in each MS a different concept or meaning of "major non conformity" could be taken, a definition is needed.</p> <p>- "Safety regulatory framework": the "safety regulatory framework" is an element that should not be defined in an agreement between NSAs. It should be harmonized and clear for all.</p>	
Poland	Art. 7(2)(b) (CSM SUP)	<p>Proposal to add at the end of the sentence here "including relevant technical competences and skills".</p> <p>Point (e) in this article mentions "relevant non-technical competencies" – it is therefore unclear under which point "technical competencies" are covered. It should be clearly indicated that staff performing conformity assessment activities must have relevant technical competences.</p>	<p>Bullets (a) to (e) are technical competencies. Non-technical competencies, in the jargon of Human Resources, are soft skills.</p> <p>Please do not mix up competency requirements and criteria to select/recruit people. Based on the list of minimum competency requirements, the NSA has to define the criteria necessary to meet these requirements.</p>
Italy	Art. 9 (CSM SUP)	<p>- The foreseen obligation (shall) to sign and develop cooperation arrangements is new, not foreseen by the safety directive. Furthermore no legal base comes in support to sign arrangements with other subjects different from NSA/ERA (like NoBos and IBs), because this CSM is applicable only for NSAs.</p>	<p>The development of cooperation arrangements between NSA and Agency and between NSAs is referred to in Article 17(9) of Directive (EU) 2016/798.</p> <p>The need for cooperation with other competent authorities is already identified in Annex IV of Reg. 1158/2010 and Art. 8(2) of Reg. 1077/2012. No</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>- Based on the previous comment, has the Agency developed a cost/benefit analysis or at least a light impact assessment of that? By our NSA internal discussion, it seems that it will result in an increase of costs for all NSAs.</p> <p>- What happens if the mentioned arrangements are not in place for any reason?</p> <p>- The information sharing related to “serious safety risks” is mandatory and cannot be solved by a kind of “arrangement”. Other tools, at European level, have to be developed (as for common occurrences and safety alerts tasks).</p> <p>Furthermore, in this article, are completely missing the following points:</p> <p>a. The application of Article 15.4 of the Agency Regulation states: “... The Agency shall support, and upon request, coordinate the NSAs in the supervision of ECM...”.</p>	<p>change has been made in that respect for the current revision of the CSMs. In addition, Art. 17(4) of Directive (EU) 2016/798 also identifies the need for cooperation with other competent authorities. In term of supervision activities, there is a need to establish coordination with NIB (their findings being one of the elements the NSA should take into account when establishing its strategy for supervision). In addition to the need to avoid duplication of work, the same applies for certification bodies. It was not our intention to describe in the Act for each type of cooperation (Agency-NSA, NSA-NIB, NSA-labour inspectorate, NSA-ECM certification body etc.), all the information to be considered. This is a matter for the application guide.</p> <p>There should not be any increase of costs as these arrangements should already be in place since 7 June 2013, i.e. that date of application of Reg. 1077/2012.</p> <p>The terms “serious safety risks” as referred to in Art. 17(6) of Directive (EU) 2016/798 may be removed.</p> <p>The term “Arrangement” in Art. 9(2) has a broad meaning and does not mean that an agreement has to be signed between the Agency and the NSA. It means that they have to define the way they will</p>

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>Considering that the supervision activities have been extended also to ECMs, this article shall provide also for that and clarify how to fulfil this issue.</p> <p>b. No reference to the “guidelines” as stated in article 17.9 of the Safety Directive: “...The Agency shall assist such coordination activities by developing guidelines.”</p> <p>It states that the Agency has an active role in the coordination for supervision. We believe that guidelines issued for instance in relation to a SSC granted by the Agency, reporting the minimal useful information, can truly help NSAs to proceed in their supervision tasks.</p> <p>For instance, a guideline may report: what have to be checked on ECMs, where the RU organization is located, what “residual” non-compliances have to be checked/closed, indication of the leading NSA, etc..</p>	<p>communicate the information (how, to whom, what).</p> <p>The coordination referred to in Art. 15(4) of Agency Regulation is covered by the cases referred to in Art. 9(2) of revised CSM SUP. As mentioned above, it is not possible to describe in the legal act all interfaces between authorities and the purpose of each interface. This can be described in the guide. About what needs to be supervised for ECMs, this will be managed during the revision work of ECM Regulation and reflected in the guide.</p> <p>Art. 17(9) of Directive (EU) 2016/798 refers to guidelines to be developed by the Agency. This has not to be repeated in the CSM. For information, this guide already exists today. It needs update based on the relevant working paper developed together with the CSM Working Party. As clarified in the note on legal issues circulated to the CSM Working Party and the NSA Network, the term “guidelines” should not be confused with “instructions”. Basically, it refers to “application guides”.</p>
Poland	Art. 9(2) (CSM SUP)	Is the ‘cooperation agreement with the Agency’ mentioned in art. 9(2) the same cooperation agreement as the one under art. 76 of regulation 2016/796 (Agency	We refer here to cooperation arrangements and not agreements. Indeed, these arrangements are different from those specified in Article 11 of recast safety directive or Art. 76 of ERA regulation. However, there is no ambiguity as we do not refer

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised CSM/Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		regulation)? If not, we suggest to use another word.	<p>to one of the above Articles. If the meaning was the same, we would have the obligation to refer to the relevant Article of the recast Safety Directive or ERA Regulation.</p> <p>Note that Art. 17 refers to a lot of coordination/cooperation activities between authorities, which are also different from those set out in Art .12 of the same Directive.</p> <p>As the legal base for this CSM is Art. 17 and nowhere else we refer to Art. 12 of the recast Safety Directive, we believe there is no ambiguity possible.</p>
Italy	Annex II (CSM SUP)	As for annex I, also for this annex the supervision on ECM should be considered. No indication for ECM has been provided in Annex II	Supervision of application of CSMs REA and CSM Monitoring is one specific case while Annex I describes framework supervision principles. As mentioned before, duplication with other Articles of the CSM, in particular the article on cooperation and coordination, should be avoided therein.

7. Annex 1: Abbreviations

Table 10: Table of abbreviations

<i>Abbreviation</i>	<i>Description</i>
4RWP	Fourth Railway Package (i.e. its technical pillar composed of Directive (EU) 2016/797, Directive (EU) 2016/798 and Regulation (EU) 2016/796)
EC	European Commission
ECM	Entities in Charge of Maintenance
EU	European Union
CMS	Competence Management System
CSM	Common Safety Method
IM	Infrastructure Manager
MoU	Memorandum of Understanding
NSA	National Safety Authority
RU	Railway Undertaking
SA	Safety Authorisation
SMS	Safety Management System
SP (or SUP)	Supervision
SSC	Single Safety Certificate
TSI	Technical Specification for Interoperability
WP	Work Package

8. Annex 2: Reference documents

Table 11: Table of reference documents

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[1]	Policy paper for the revision of the Common Safety Methods on Conformity Assessment (Commission Regulations n°1158/2010/EU and 1169/2010/EU) and the Common Safety Method on Supervision (Commission Regulation n°1077/2012/EU)	<i>ERA-REP-109</i>	<i>1.0</i>
[2]	Project plan on the revision of the common safety methods for conformity assessment and the common safety method for supervision	<i>ERA-REC-115/PPL</i>	<i>2.0</i>
[3]	Programme Plan - Preparation and implementation of the 4th Railway Package at ERA	<i>ERA-PRG-005/PPL</i>	<i>1.1</i>
[4]	Light Impact assessment on the revision of the common safety methods for conformity	<i>ERA-REC-115 Light Impact Assessment</i>	<i>1.0</i>

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
	assessment and the common safety method for supervision		

9. Annex 3: Reference legislation

Table 12: Table of reference legislation

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[5]	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (Agency Regulation)	<i>OJ L 138, 26.5.2016, p. 1-43</i>	-
[6]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)	<i>OJ L 138, 26.05.2016, p. 102-149</i>	-
[7]	Commission Implementing Decision of 14.3.2014 on a mandate to the European Railway Agency for the revision of the common safety methods for conformity assessment and the common safety method for supervision	<i>C(2014) 1649</i>	-
[8]	Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates	<i>OJ L 326, 10.12.2010, p. 11-24</i>	-
[9]	Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	<i>OJ L 327, 11.12.2010, p. 13-25</i>	-
[10]	Commission Regulation (EU) No 1077/2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation	<i>OJ L 320, 17.11.2012, p. 3-7</i>	-
[11]	Commission Implementing Decision of 1.9.2016 on a mandate to the European Union Agency for Railways for the revision of the common safety methods for conformity assessment and the common safety method for supervision and repealing Implementing Decision C(2014) 1649 final	<i>C(2016) 5504 final</i>	-
[12]	Summary of legal issues relating to the development of Common Safety Methods on conformity assessment, Common Safety Method on supervision and Agency proposal of Implementing Act on the practical arrangements for safety certification	-	02/12/2016

10. Annex 4: Coordination on legal issues

The following table provides non-legally binding information as an outcome of the European Union Agency for Railways and DG MOVE coordination meeting held on 30 November 2016. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
<p>Transitional provisions for the revised CSM on supervision</p> <p>If the NSA has to supervise the SMS in accordance with the revised CSM on supervision from 16/06/19. It is not clear against which CSM on conformity assessment the SMS must comply with. If the Member State has transposed the recast RSD by 16/06/19, should the NSA consider that the SMS shall comply with the revised CSM on conformity assessment?</p> <p>Or is it the CSM on conformity assessment 1158/2010 against which the safety certificate Part A was issued (before 16/06/19)?</p>	<p>The Agency legal service prepared a note giving explanations why, according to their view, transitional provisions are not required in the revised CSM on supervision. Legal interpretation would be that the RU/IM's SMS should be supervised against the requirements/criteria set out in the applicable CSM on conformity assessment at the time the Part A safety certificate was issued (see Art 31(2) RSD 2016/798 and Art 8 draft rev. CSM CA SSC).</p> <p>During the CSM WP meeting in September, it was also proposed to manage the 4RWP as substantial change to the regulatory framework which would then require an update application – This approach is not retained.</p>	<p>CSM on supervision could apply anyhow (depending on the date of application set out in the Regulation) and irrespective of the CSM on conformity assessment in force at the time the safety certificate was issued.</p> <p>It is recommended to avoid cross-references between revised CSM on supervision and revised CSM on conformity assessment in order to make it clear that the former can apply irrespective of the date of application of the latter.</p>
<p>Transitional provisions for revised CSMs/Practical Arrangements</p> <p>It is not clear what happens if the MS transposes the recast RSD before 16/06/19. Would the new provisions of the RSD and the revised CSM for conformity assessment/supervision apply as soon as the RSD is transposed in their MS?</p> <p>What is the impact on the transitional provisions?</p>	<p>In theory, the Agency should be ready to issue SSC as soon as the first Member State has transposed the new Directives</p> <p>However, cooperation agreements between the Agency and NSAs are prerequisite for the Agency to issue a SSC in cooperation with NSAs</p> <p>Treaty on European Union also requires the different institutions/Member States to act and cooperate loyally (principle of sincere cooperation and art 4 TEU)</p>	<p>No, please see provisions of Article 31, paragraph 2. It is explicitly established that <u>safety certification</u> till 16 June 2019 remains under Directive 2004/49/EC conditions. However, this does not apply to other provisions of 2016/798, meaning if they are transposed before 16 June 2019 they can be applied.</p>

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
	Date of application of the new certification regime should be set and agreed in their cooperation agreements	
<p>Revised CSM on conformity assessment (revised 1169/2010) Are transitional provisions needed for the granting of safety authorisations in accordance with Art. 12 of Directive 2016/798?</p>	<p>According to Art. 33 of the recast RSD, Art. 12(1) to (4) does not need to be transposed though equivalent provision to Art. 12(1) in Directive 2004/49 has been amended.</p> <p>At the same time, Directive 2004/49 is repealed with effect from 16 June 2020 by Directive 2016/798 which requires a new transposition; it gives the impression that the MSs can decide themselves what they want with regard to Art. 12(1) to 12(4) (e.g. not changing their current transposition)!?</p>	<p>No, there is no choice given to MSs in this regard. Transposition of Article 12, apart of par. 5, is an obligation dating back to 2006 and transposition deadline of 2004/49/EC. In other words, we presume these provisions have already been transposed. Once old Directive is repealed, new one applies ensuring the continuity.</p> <p>However, MS are expected to transpose Article 9 on SMS.</p> <p>Commission will clarify in its transposition table that when transposing Art. 12(5) of recast RSD, MS shall also take care of the amendment made to Art. 12(1).</p>
<p>Revised CSM on supervision Art. 17(1) of Directive 2016/798 already defines the scope of the supervision. Would it be possible in the CSM to elaborate it further starting from the wording of the Directive?</p>	<p>New points are added in the CSM compared to the list provided for in Art. 17(1).</p>	<p>Yes, this can be further developed where appropriate.</p>
<p>Revised CSM on supervision Art. 2(3) <i>Comment from NSA IT as reported during the CSM Working Party</i></p> <p>According to new mandate, there is a role of the Agency in supervision. This role is reflected also in Art. 17 of the recast RSD (i.e. ERA issuing guidelines). Guidelines should not be considered as general guides but as applicant specific ones.</p>	<p>Guidelines referred to in Article 17(9) (3rd §) are to be understood as the guide(s) to be developed by the Agency in order to support the cooperation between NSAs during supervision. It has nothing to do with instructions to be given by the Agency to the supervising NSA(s) involved in the assessment where the SSC is issued by the Agency.</p> <p>The Agency has no role in the supervision and thereby, cannot take the responsibility to decide</p>	<p>The term “guidelines” is expressed in a context of assistance to be provided for by the Agency to help NSAs coordinate with each other when and where appropriate. The Agency shall deliver guidance document for that purpose.</p>

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
IT expects that the Agency will appoint the leading NSA for each certificate it issues.	how RU/IM should be supervised by NSAs. Following discussions at the Working Party, it is promoted that supervising NSAs agree themselves, based on criteria, who should be leading.	
<p>Revised CSMs on conformity assessment (Revised 1058/2010 & Revised 1169/2010) Art. 2(2) <i>Comment from NSA DK as reported during the NSA Network and before the 1st meeting of the GoE</i></p> <p>Our concerns addresses Article 2 (2) and Annex II in the latest draft for CSM on conformity assessment and supervision.</p> <p>We find the requirements set out in Annex II very relevant and useful, and we very much support the publication, but we fail to find the legal basis. To outline our understanding we would like to look back to the start of the work for revising the CSM, which was started based on RSD 2004/49.</p> <p>We read the legal basis in RSD 2004/49 the way that it contains no legal basis for enforcing requirements for the SMS to be implemented by the RUs and IMs other than those listed in Article 9 and Annex III. If more detailed requirements were to be established the MSs when implementing the directive should decide these.</p>	<p>The legal basis for drafting common safety methods is provided by Article 6(1) of Directive (EU) 2016/798.</p> <p>In the specific case of conformity assessment this is reinforced by Articles 9(1) and 10(3)(a) of the same Directive. The latter clearly state that the RU/IM's SMS shall ensure among others that the relevant parts of CSMs are applied. This can include requirements/criteria set out in Annex II of the CSMs on conformity assessment.</p> <p>Article 9(7) can be used when there are elements of the safety management system not included in article 9(3) which need to be harmonised at EU level. The intent is not to propose a CSM on how develop a SMS, the latter being redundant with Annex II of the proposed CSM on conformity assessment, but rather to develop/harmonise further specific SMS process(es). The CSM on monitoring and CSM on risk assessment are examples of CSMs that can be developed under Article 9(7).</p>	<p>Agree with the explanation provided.</p> <p>Art. 9(1) of recast RSD clearly states that the SMS shall comply with relevant parts of CSMs. This can include requirements/criteria set out in Annex II of the CSMs on conformity assessment.</p>

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
<p>The new RSD 2016/798 has foreseen the need of such a Common Safety Method and states so in Article 9 (7).</p> <p>At RISC 76 the mandate for updating 1077/2010, 1158/2010 and 1169/2010 (CSM CA) was renewed.</p> <p>To our understanding, the mandate (published 1 September 2016) does not include this reference, and thus the legal basis seems to be absent.</p> <p>As we see it there could be one of two possible solutions available:</p> <ol style="list-style-type: none"> 1. Obtaining a mandate based on the RSD 2016/798 Article 9 (7), and publish a separate CSM for these requirements. 2. Implementing the requirements through national implementation. 		
<i>The following issues have an indirect impact on the development and implementation of the revised CSMs:</i>		
<p>Recital 41 of Directive (EU) 2016/798</p> <p>In the event that the direct cause of an accident or incident seems to be related to human actions, attention should be paid to the particular circumstances and the manner in which routine activities are performed by staff during normal operations, including the design of the man-machine interface, the suitability of procedures, conflicting objectives, workload and any other circumstances which may have influence on the occurrence, including physical and work-related stress, fatigue or psychological fitness."</p>	<p>"man-machine interface" has the meaning of "human-technology interface".</p>	<p>Should the term be used, it is advised to use the term of the Directive.</p> <p>However, a clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p>
<p>Art. 7.1(a) of Directive (EU) 2016/798</p>	<p>"staff including the staff of contractors " has the meaning of "employees or contractors".</p>	<p>A clarification can be made to Member States in the transposition table to help them understand</p>

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
individual risks relating to passengers, staff including the staff of contractors , level crossing users and others, and, without prejudice to existing national and international liability rules, individual risks relating to unauthorised persons on railway premises ;	<p>“unauthorized persons on railway premises” has the meaning of trespassers.</p> <p>Reference to Annex I (category of users) could help understand that the above terms have the same meaning.</p>	and transpose the recast Directives in a harmonised way.
<p>Art. 9.3(e) of Directive (EU) 2016/798</p> <p>"procedures and methods for identifying risks, carrying out risk evaluation and implementing risk-control measures whenever a change of operating conditions or the introduction of new material imposes new risks on the infrastructure or the man-machine interface;"</p>	<p>“man-machine interface” has the meaning of “human-technology interface”.</p>	<p>Should the term be used, it is advised to use the term of the Directive.</p> <p>However, a clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p>
<p>Art. 9.3(i) of Directive (EU) 2016/798</p> <p>procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken</p>	<p>The list of SMS elements provided for in Article 9 still refers to “near misses” and “other dangerous occurrences” (in addition to incidents and accidents).</p> <p>The terms “near misses” and “other dangerous occurrences” are not defined in this Directive and furthermore, they are embedded in the definition of “incident”.</p> <p>There could be confusion in the CSM Regulation for Conformity Assessment with respect to CSIs, investigation and occurrence reporting. There is a risk that RU/IM does not monitor all events affecting safety but only what they consider as dangerous occurrence or near miss</p>	<p>The list provided for in Art. 9.3(i) is to be understood as a list of elements to be reported (etc.) but it does not mean that the list is limitative to these elements.</p> <p>A clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p>
<p>Art. 9.5 of Directive (EU) 2016/798</p> <p>Before 31 May of each year, all infrastructure managers and railway undertakings shall submit</p>	<p>After ERA undertaking the task to issue SSC, it would be advised to clarify the addressee of the annual safety report: Is it only the competent national authority (-ies) that supervise the RU or</p>	<p>It can be clarified that the annual safety report of a RU operating in more than one MS shall be addressed to all NSAs and at least include relevant information for the area of operation in</p>

<i>Issue description</i>	<i>Explanation</i>	<i>Conclusion</i>
to the national safety authority an annual safety report concerning the preceding calendar year. The safety report shall contain:	IM or ERA as well. These annual safety reports could serve as source of information for the renewal of a SSC.	<p>their respective Member State. In addition, it does not prevent the RU to provide relevant information for the area of operation as a whole.</p> <p>A clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p> <p>In addition, the Agency can clarify the issue in its guidance.</p>
<p>Art. 16.2 (i) of Directive (EU) 2016/798</p> <p>monitoring, promoting, and, where appropriate, enforcing and updating the safety regulatory framework including the system of national rules;</p>	CSM on Supervision (and other ERA activities deriving from it) refers to Art. 16(2)(f) of Directive 2004/49/EC which is now the new Art. 16(i). The different items of Art. 16 are now linked to other relevant articles in the recast RSD. However, no link is made between Art. 16(i) and Article 17 (Supervision). Only Art. 16(j) refers to Article 17. Note that Article 17 refers to enforcement of NSA decisions which could justify a link between Art. 16(i) and Art. 17. "	<p>Even if there is no explicit cross-referencing between Art. 16(i) and Art. 17, it is acknowledged the link between them, as enforcement can be the result of supervision activities as referred to in Art. 17(6).</p> <p>A clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p>
<p>Art. 17.9 of Directive (EU) 2016/798</p> <p>The national safety authorities may develop a common supervision plan in order to ensure that audits and other inspections are carried out periodically, taking into account the type and extent of transport operations in each of the Member States concerned</p>	Revised CSM Supervision refers to in its Article 8 to coordinated or joint supervision. The term "common supervision plan" could be understood differently in the different Member States.	<p>NSAs may develop a common supervision plan (in the meaning of "joint") as referred to in Art. 17(9) of the recast RSD. It represents one option but other options can be taken by NSAs to achieve the same goal, e.g. coordinated approach as described in the revised CSM on supervision.</p> <p>A clarification can be made to Member States in the transposition table to help them understand and transpose the recast Directives in a harmonised way.</p>