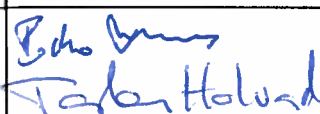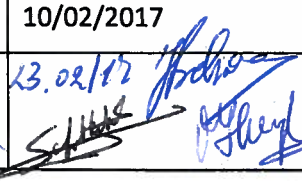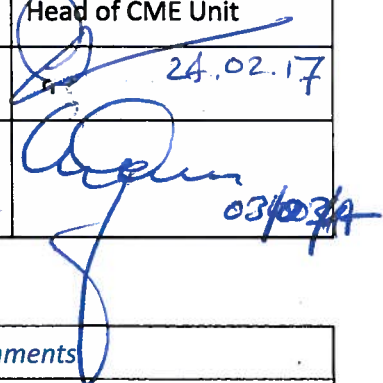EUROPEAN
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Light Impact Assessment

Revision of the Common Safety Methods on Conformity Assessment and the Common Safety Method on Supervision

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Date	10/02/2017	10/02/2017	24.02.17
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Document History

Version	Date	Comments
0.1	03/11/2016	Preliminary version of LIA report
0.2	09/12/2016	Incorporation of comments from WG members
0.3	16/01/2017	Incorporation of final comments from Safety Unit
0.4	23/01/2017	Quality check EcoEv
0.5	27/01/2017	Updated version addressing Quality check EcoEv
1.0	10/02/2017	Final version

Contents

1. Context and problem definition

1.1 Problem and problem drivers	**Context**: Article 16(2) of Directive 2004/49/EC, Railway Safety Directive (RSD) listed the tasks that National Safety Authorities (NSAs) should carry out without determining how this should be done. The EU legal framework regarding the Common Safety Methods (CSMs) for on Conformity Assessment (CA) and Common Safety Method (CSM) on Supervision (SP) is interpreted and applied in a different ways across Member States (MSs). The guidance developed, as a non-legally binding support, did not lead to a sufficient level of harmonisation.

Problem: The degree of harmonisation and consistency of assessment and supervision processes performed by the NSAs is currently insufficient at EU level.

Main consequence: The problem is likely to compromise, to a considerable extent, the achievement of the Single Safety Certificate (SSC) and the accomplishment of a Single European Railway Area (SERA), with negative consequences on the competitiveness of the railway sector.

More specifically, the main issues in the scope of the problem, as well as their specific consequences are displayed below:

Issue	**Consequence**
Issue 1: The assessment of part A/part B diverges between NSAs	Concerns regarding the cost and time for Safety Certificates (SCs)/ Safety Authorisations (SAs), especially for RUs operating cross-border
Issue 2: Some NSAs tend to 'over-regulate' the Part B regarding the compliance with network specific rules	Lack of confidence in the Part A process and a devaluation of the Part A of a EU-valid SC, lengthy processes, arbitrary decisions, risk of discrimination between applicants
Issue 3: Some NSAs believe the safety responsibility of railway undertakings (RUs) lies with the train path ownership, irrespective of existing contractual arrangements or partnerships	Missed opportunity from the shared use of (Part B) SCs, which can allow quick and effective operations between partner RUs
Issue 4: There is limited proactive targeting of high-risk activities based on the collection and analysis of data	Reacting and fixing are merely a short-term solution and may not identify fundamental issues.
Issue 5: National requirements have either not been reviewed or replaced by the new requirements in the CSM on Supervision	RUs working in several MS will thus experience different supervision methods and requirements
Issue 6: There is no common approach on the transparency and accountability regarding the decision making process for NSAs	NSAs may not sufficiently prioritise and focus enforcement actions such that there is a risk that they are not targeted, accountable and proportionate in their treatment of RUs/IMs

	Issue 7: There is significant variation with some NSAs having a competence management system and other NSAs having an ad-hoc approach only	This may result in risks regarding adequate resources and / or competent staff restricting the NSAs taking forward their activities
1.2 Main assumptions	The issues presented in section 1.1 were identified in the Policy Paper for the revision of the three CSMs[1], including experiences and perceptions by the concerned stakeholders. The Policy Paper provides also the basis for the work on developing specific proposals for revising the CSMs.	
1.3 Stakeholders affected	Each organisation has a different perspective of the problem. The Agency and the NSAs will issue SSCs while the NSAs only will issue SAs. The railway undertakings (RUs)/infrastructure managers (IMs) will apply for those SSCs or SAs, as a legal requirement to develop their businesses. Likewise NSAs will carry out supervision activities to verify that the obligation to implement a Safety Management System (SMS) is complied with and RUs/IMs will be subject to those supervision activities. Despite the different perspectives, all involved organisations are directly and strongly affected by the problem. The following table indicates the level of importance for each of these stakeholders.	

Category of stakeholder	*Importance of the problem*
Agency	5
NSAs	5
RUs/IMs	5

It is essential, both for the Agency/NSA and for the RUs, that there is consistency and transparency in the process for issuing SSCs. A detailed standard process for the application and the issuing of SSCs, applicable either by the Agency or the NSAs, will ensure that RUs are subject to the same agreed fundamental elements. Consistency and transparency will also be required on how NSAs approach and carry out their supervision activities.

To the RUs, the priority is to avoid differences in the assessments carried out by the NSAs, with different decisions being taken in similar circumstances. This strongly affects RUs, which also fear too costly and lengthy processes to obtain SSCs. RUs are also affected by the approach by the NSAs, which may not take market needs sufficiently into account. The low probability of RUs operating in different MS being subject to a similar application and assessment process in each of the MS, impacts their business of RUs and may demotivate potential new entrants.

This perspective is also valid for IMs with particular focus on cross-border infrastructure, where the concerned NSAs according to Article 12 of the recast RSD shall cooperate in order to issue safety authorisations. Indeed, any significant differences in processes for assessment, supervision and decision-making between NSAs could undermine this cooperation.

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[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)

1.4 Evidence and magnitude of the problem	The main evidence for the problem definition comes from the Agency's Policy Paper on the revision of the CSMs for CA and the CSM SP, drawing on several sources, including:
	- *Agency's paper and consultation work on the migration towards a SSC[2]*
	- *EU Commission's IA support study on the revision of the institutional framework of the EU railway system, with a special consideration to the role of the European Railway Agency[3]*
	- *Several external studies commissioned by the Agency (e.g. TRL study on the benchmarking of NSA enforcement powers[4])*
	- *Cross-audit Programme (set up by the NSA Network, supported and resourced by the Safety Unit of the Agency)*
	- *The Matrix evaluation initiative (Guide and Procedure).*
1.5 Baseline scenario	The likelihood that the problem would persist if no action is taken is high. If no action is taken:
	- *there would be a growing divergence in approaches among NSAs, leading to an increase of financial and administrative burden for obtaining a SSC or a SA;*
	- *difficulties felt by many NSAs in carrying out supervision activities are likely to increase. Some NSAs will hardly be able to establish a risk-based supervision strategy targeting their activities at areas with greatest risk and prioritising the use of their resources.*
	- *RUs may be led to prefer continuing with the system in place previously to the RSD or simply to adapt their business to the requirements of each MS altogether (e.g. creation of new companies in some of the MSs where RUs wish to operate, therefore leading to the multiplication of SSC)*
	- *the creation of SERA may be compromised if harmonisation of safety certification and supervision is not achieved at EU level.*
1.6 Subsidiarity and proportiona-lity	The **subsidiarity principle** does not apply in this case, as the solution needs to be identified at EU level (Art 6(1b) and Art 6(5) of the recast RSD).
	The proposed revision of CSMs is mandated by the EC to the Agency (mandate from 1st of September 2016), with the final objective of maintaining safety and where reasonably practicable continuously improving it.
	The drafting, adoption and review of the CSMs take however into account the opinions of NSAs and stakeholders, including sector associations.
	The **proportionality principle** is applied as the solution ensuring the most effective response to the problem and taking into consideration the effects for all parties involved (including consideration to any additional administrative burden) will be proposed. This should ultimately alleviate the financial and administrative burden for companies in the railway sector.

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[2]   Report on the 2012 consultation with stakeholders on proposals for migrating to a single EU safety certificate, 01/06/2012

[3]   Final report, June 2012 (http://ec.europa.eu/transport/modes/rail/studies/doc/2012-06-ia-support-study-era-final-report.pdf

[4]   Benchmarking study of NSA enforcement powers, ERA/2011/SAF/OP/03, 06/07/2012 (http://www.era.europa.eu/Document-Register/Pages/Benchmarking-study-of-NSA-enforcement-powers.aspx)

2.   Objectives

2.1.	**Strategic and specific objectives**	Mark below the **strategic objective(s) of the Agency** with which this initiative is coherent: ☒ Europe becoming the world leader in railway safety ☐ Promoting rail transport to enhance its market share ☒ Improving the efficiency and coherence of the railway legal framework ☒ Optimising the Agency's capabilities ☐ Transparency, monitoring and evaluation ☐ Improve economic efficiency and societal benefits in railways ☒ Fostering the Agency's reputation in the world **General objective:** To ensure that a more consistent approach among NSAs is adopted as regards decision-making criteria and processes for issuing SSCs/SAs In the context of the 4th Railway Package (4RWP): to ensure a clear framework for the Agency's future assessment activities and consistency on how NSAs conduct their supervision activities. **Specific objectives**: 1. To ensure harmonized, efficient and effective safety certification/ authorisation processes for the RUs and IMs across EU 2. To ensure harmonized, efficient and effective assessment of the country-specific rules for the RUs across the EU 3. To ensure an efficient and effective system of assessment and supervision at NSA level 4. To ensure the alignment with the relevant provisions of the 4RWP (as regards SSC).
2.2.	**Link with Railway Indicators**	The Agency has defined a set of (outcome) monitoring railway indicators (RIs) for the four Operational Activity Areas (OA), incl. the Harmonised Safety Framework (OA1). These indicators are being monitored in order to assess how Agency's outputs contribute to outcomes linked to moving towards a Single European Railway Area (SERA). As part of the impact assessment template within the context of formulating objectives, information should be included about whether achieving the defined objectives for an initiative may be detectable through any of the railway indicators. This information is mainly for internal use, but may also be of interest to external stakeholders. In the case of the Harmonised Safety Framework the following indicators have been defined: - RI 1.1 (Licensed RUs holding a safety certificate) - RI 1.2 (Improvement of safety maturity level in MS' authorities) - RI 1.3 (Improvement of safety maturity level of sector) - R 1.4 (Improvement of Railway Safety Performance) - RI 1.5 (Proportion of RUs applying for Part B Certificate in other MS and reporting problems)

	- RI 1.6 (Train Drivers with a European License in accordance with the Train Drivers Directive) - RI 1.7 (Infrastructure Managers with Safety Authorisation). For this particular initiative the following railway indicators would be relevant: 1.1, 1.2, 1.3, 1.5 & 1.7. It should be noted that any linkage between the revised CSMs and these indicators may be difficult to determine given that other factors would also be of importance. It is foreseen that further refinement of the railway indicators will take place in the coming period (e.g. RI 1.5 would need to be adjusted as Part B Certificates will disappear in the new framework being introduced with the 4RWP). More information about the complete set of indicators is available in the Agency's Railway System Report, issued for the first time in September 2016 reporting on the pilot phase findings (see the following link: www.era.europa.eu/Document-Register/Documents/Railway%20System%20Report%202016.pdf).

3. Options

3.1.	**List of options**	**Option 0** (baseline) – No revision is performed
		Option 1 – The revision is limited to make the CSMs **compatible with the relevant provisions of the 4RWP**
		Option 2 – The revision is limited to all relevant issues within the theme of **safety certification/authorisation of RUs and IMs**
		Option 3 – The revision covers all relevant issues within the four themes - **safety certification/authorisation, supervision, decision-making and competence management**
		Option 4 – The revision considers all relevant issues within the four themes **safety certification/authorisation, supervision, decision-making and competence management** + the relevant provisions of the 4RWP.
3.2.	**Description of options**	Option 0 (baseline) was described in section 1.5.
		Option 1 – The revision is limited to make the CSMs **compatible with the relevant provisions of the 4RWP**
		In this option, the CSMs on CA and on SP are revised only to the extent required by the relevant provisions of the Technical Pillar of the 4RWP, in particular those regarding the process and timeframe for delivering SSCs. The revision of the CSMs would become one of the projects necessary to achieve the programme objectives of the 4RWP. A direct link would be established between the objective of the revision of the CSMs and the new legal framework of the 4RWP, in full consistency with the provisions of the latter. The issues within the four key themes identified in the Agency's Policy Paper would not be addressed.
		Option 2 – The revision is limited to all relevant issues within the theme of **safety certification/authorisation of RUs and IMs**
		Issues addressed are identified in the Agency's Policy Paper underpinning the initiative for revising the CSMs for CA and CSM on SP. This includes: 1) structured and auditable approach to certification/authorisation, 2) restructuring and reviewing of assessment criteria, 3) harmonised national requirements, 4) decision-making criteria, 5) conditions of applications for safety certificates/authorisations, 6) conditions for updating safety certificates/authorisations.
		Option 3 – The revision covers all relevant issues within the four themes - **safety certification/authorisation, supervision, decision-making and competence management**
		In addition to the proposals listed above (Option 2) this option would also encompass proposals for: 1) harmonised approach to supervision, 2) supervision strategy and plan, 3) principles for coordinated/joint supervision, 4) supervision techniques, 5)

	risk-based decision making model for enforcement, 6) harmonised competence requirements.
	Option 4 – The revision considers all relevant issues within the four themes **safety certification/authorisation, supervision, decision-making and competence management** + the relevant provisions of the 4RWP.
	This option combines Option 1 and Option 3.
3.3. Uncertainties/risks	Overall, it is expected that there would directly be a relative low level of uncertainties/risks for the project, given that all three CSMs are already in place. The main issues to be monitored carefully would be how the complete framework for safety certification/authorisation and supervision will work in the future, as adjusted in accordance with the 4RWP, and the future cooperation between the Agency and the NSAs.
	This issue is not specifically linked to the CSMs revision but rather to the complete change of the framework for safety certification/authorisation and supervision activities carried out by the NSAs and/or the Agency.

4. Impacts of the options

4.1.	Impacts of the options (qualitative analysis)	Impacts are generated because the options will lead to changes in how safety certification/authorisation and supervision activities are carried out by NSAs (and from 2019 on, also by the Agency for safety certification), which in turn will have implications on the parties applying for SSCs/SAs and/or being supervised (RUs and IMs).

The following aspects should be taken into consideration in the assessment of impacts:

1. The impacts are limited to the revision of the CSMs and should not include the impacts from introducing the CSMs as such

2. Impacts of other changes deriving from the 4RWP are out of scope of the assessment of the revision of CSMs, e.g. One Stop Shop (OSS) practical arrangements, SSC.

3. Other ongoing proposals (linked to the 4RWP) may though have linkages with the revision of the CSMs in terms of overall system changes for safety certification/authorisation and supervision. Any such significant linkages will not be considered in this impact assessment but will, as far as relevant, be taken into account in the other work streams of the Agency.

Option 1 – The revision is limited to make the CSMs **compatible with the relevant provisions of the 4RWP**

Category of stakeholder		
RUs/IMs	(+)	- RUs/IMs may benefit to a limited extent from the CSMs being amended to be consistent with the 4RWP provisions which would facilitate somewhat their preparations for applying for SSCs and SAs respectively - Relative low one-off costs related to familiarisation with amended framework
	(-)	- RUs/IMs will experience differences between NSAs in their approach towards applications for SSC and SA (notably of importance for RUs with operations in several MS) - RUs/IMs will continue to face variation regarding the NSAs' approach to the delivery of supervision activities. The same would be the case for NSA decision-making, including transparency and accountability - Costs and time resources for RUs/IMs likely to remain unchanged with respect to their applications for SSCs/SAs as well as for their preparation of NSA supervision

			- Limited entry of new RUs to the market and delayed achievement of SERA.
	NSAs	(+)	- The CSMs are compatible with the 4RWP provisions which would somewhat facilitate their activities regarding assessment of applications for SSCs and SAs (e.g. no reference to Part A / Part B of the safety certificates) - Possibly lower one-off costs linked to the revision of the CSMs, including lower effort required for harmonisation re. assessment and supervision.
		(-)	- Variation in approach to safety certification/authorisation and in the delivery of supervision activities may result in additional resources for coordinated or joint supervisions among NSAs - limited mutual trust among NSAs due to lack of a common approach for NSA decision-making and of a consistent approach for safety certification/authorisation and supervision - NSAs may retain ad-hoc approaches due to lack of provisions on competence management.
	Agency	(+)	- CSMs are compatible with 4RWP provisions thereby benefitting the Agency's new activity of assessing SSCs in terms of legal certainty.
		(-)	- Lack of consistent NSAs' approach to safety certification/authorisation could make the Agency's role of issuing SSCs more complicated (risk of dual systems) - Lack of progress on harmonising the NSAs' approach for delivering supervision activities could result in additional Agency costs to manage the interface between assessment and supervision - Any one-off costs for the preparation and implementation of the frameworks to be used by the Agency for issuing SSCs directly influenced by the specific approach adopted in the revised CSMs.

Option 2 – The revision is limited to all relevant issues within the theme of **safety certification/authorisation of RUs and IMs**

Category of stakeholder		
RUs/IMs	(+)	- RUs/IMs will experience a consistent approach by NSAs in their approach towards applications for SSC and SA (notably of importance for RUs with operations in several MS). This could reduce

			their uncertainty as they prepare SSC / SA applications - Costs and time resources for RUs/IMs likely to decrease with respect to their applications for SSCs/SAs
		(-)	- RUs/IMs will continue to face variation regarding the NSAs' approach to the delivery of supervision activities. The same would be the case for NSA decision-making, including transparency and accountability - Costs and time resources for RUs/IMs likely to remain unchanged with respect to their preparation of NSA supervision - One-off costs linked to familiarisation with revised CSMs and adaptation of existing procedures and arrangements (e.g. changes to the SMS documentation). - limited entry of new RUs to the market and delayed achievement of SERA.
	NSAs	(+)	- A consistent approach to safety certification/authorisation may contribute to enhanced mutual trust between NSAs regarding issued SSCs. In particular, if all issued SSCs have been based on a harmonised approach it would be easier for a NSA to have confidence in a SSC issued by another NSA.
		(-)	- One-off costs linked to the revision of the CSMs which would involve resources on training and adjustment to current procedures and arrangements - Lack of compatibility with 4RWP provisions would lead to problems for NSAs in their practical implementation of tasks, concerning safety certification and authorisation.
	Agency	(+)	- A consistent NSA approach to safety certification/authorisation would facilitate the Agency's role of issuing SSC. As a result, implementation costs are likely to be lower (compared to Option 1) and the transition period could possibly also be shorter.
		(-)	- Any one-off costs for the preparation and implementation of the frameworks to be used by the Agency for issuing SSCs directly influenced by the specific approach adopted in the revised CSMs - Lack of compatibility with 4RWP provisions would lead to problems for the Agency in its implementation of tasks, concerning SSCs.

Option 3 – The revision covers all relevant issues within the four themes - **safety certification/authorisation, supervision, decision-making and competence management**

Category of stakeholder		
RUs/IMs	(+)	- RUs/IMs will experience a consistent approach by NSAs in their approach towards applications for SSCs/SAs (notably of importance for RUs with operations in several MS). This could reduce their uncertainty as they prepare SSC / SA applications. - RUs/IMs will benefit from a more harmonised approach by NSAs regarding their delivery of supervision activities. The same would be the case for NSA decision-making, including transparency and accountability - Costs and time resources for RUs/IMs likely to decrease with respect to their applications for SSCs/SAs, as well as for RUs/IMs resources incurred in connection with NSA supervision activities. This would in particular be the case for RUs, whereas costs are more likely to remain stable for IMs - Incentivising for the entry of new RUs to the market as well as moving towards a Single European Railway Area.
	(-)	- One-off costs linked to familiarisation with the revised CSMs and adaptation of existing procedures and arrangements (e.g. changes to the SMS documentation)
NSAs	(+)	- A harmonised interface between assessment and supervision, as well as a harmonised cooperation framework between NSAs, may help to facilitate coordination activities between the NSAs after the granting of the SC/SA - A common approach for NSA decision-making may result in improved mutual trust among NSAs. A similar argument is valid concerning a consistent approach for safety certification/authorisation and supervision. - Provisions on competence management would contribute to ensure that all NSAs address this area, thereby reducing/eliminating any risks concerning NSA staff competencies.
	(-)	- One-off costs linked to the revision of the CSMs which would involve resources on training and adjustment to current procedures and arrangements - Possibly additional resources for competence management to fulfil the requirement for NSAs to have sufficient (and competent) resources

			- Lack of compatibility with 4RWP provisions would lead to problems for NSAs in their practical implementation of tasks concerning safety certification, authorisation and supervision.
	Agency	(+)	- A consistent NSA approach to safety certification/authorisation would facilitate the Agency's role of issuing SSCs. As a result, implementation costs are likely to be lower (compared to Option 1) and the transition period could possibly also be shorter - Progress on harmonising the NSAs' approach for delivering supervision activities may result in somewhat lower Agency costs to manage the interface between assessment and supervision.
		(-)	- Any one-off costs for the preparation and implementation of the frameworks to be used by the Agency for issuing SSCs directly influenced by the specific approach adopted in the revised CSMs - Lack of compatibility with 4RWP provisions would lead to issues for the Agency in its practical implementation of tasks concerning SSCs.

Option 4 – The revision considers all relevant issues within the four themes **safety certification/authorisation, supervision, decision-making and competence management** + the relevant provisions of the 4RWP.

Category of stakeholder		
RUs/IMs	(+)	- RUs/IMs may benefit from the CSMs being amended to be consistent with the 4RWP provisions which would facilitate somewhat their preparations for applying for SSCs and SAs respectively - RUs/IMs will experience a more consistent approach by NSAs in their approach towards applications for SSCs/SAs (notably of importance for RUs with operations in several MS). This could reduce their uncertainty as they prepare SSC / SA applications. - RUs/IMs will benefit from a more harmonised approach by NSAs regarding their delivery of supervision activities. The same would be the case for NSA decision-making, including transparency and accountability - Costs and time resources for RUs/IMs likely to decrease with respect to their applications for SSCs/SAs, as well as for RU/IM resources incurred in connection with NSA supervision activities. This

			would in particular be the case for RUs, whereas costs are more likely to remain stable for IMs - Incentivising for the entry of new RUs to the market as well as moving towards a Single European Railway Area..
		(-)	- One-off costs linked to familiarisation with the revised CSMs and adaptation of existing procedures and arrangements (e.g. changes to the SMS documentation) - There could also be challenges linked to the practical implementation of Human Factors and safety culture into the SMS.
	NSAs	(+)	- A harmonised interface between assessment and supervision as well as an harmonised cooperation framework between NSAs may help facilitate coordination activities between them after the granting of the SC/SA - A common approach for NSAs' decision-making may result in improved mutual trust among NSAs. A similar argument is valid concerning a consistent approach for safety certification/authorisation and supervision. - Provisions on competence management would contribute to ensure that all NSAs address this area, thereby reducing/eliminating any risks concerning NSA staff competencies - The CSMs are compatible with the 4RWP provisions which would somewhat facilitate their activities regarding assessment of applications for SSCs and SAs (e.g. no reference to Part A / Part B of the safety certificates).
		(-)	- One-off costs linked to the revision of the CSMs which would involve resources on training and adjustment to current procedures and arrangements - Additional resources for competence management to fulfil the requirement for NSAs to have sufficient (and competent) resources may be needed.
	Agency	(+)	- A consistent NSAs' approach to safety certification/authorisation would facilitate the Agency's role of issuing SSC. As a result, implementation costs are likely to be lower (compared to Option 1) and the transition period could possibly also be shorter - Progress on harmonising the NSAs' approach for delivering supervision activities may result in somewhat lower Agency costs to manage the interface between assessment and supervision

			- CSMs are compatible with 4RWP provisions thereby benefitting the Agency's new activity of assessing SSCs in terms of legal certainty.
		(-)	- Any one-off costs for the preparation and implementation of the frameworks to be used by the Agency for issuing SSCs directly influenced by the specific approach adopted in the revised CSMs
4.2.	**Impacts of the options (quantitative analysis)**		The current Impact Assessment is a Light Impact Assessment (LIA) as the foreseen impacts are likely not to be significant nor is the project considered complex/controversial. On this basis, it does not contain a specific quantitative analysis of the foreseen impacts. The following considerations are however put forward: Overall, relative limited (positive and negative) impacts are expected as a result of the proposed revision of the three CSMs. It is likely that option 4 will be at least benefit-cost neutral and possibly with small positive net-benefits On the basis of the available information option 4 is expected to perform better than the other options considered in terms of benefits compared to costs. As such none of the other options address fully the issues identified in terms of safety certification/authorisation or supervision Core (quantifiable) impacts would concern changes in the resources required for the different stakeholders involved in safety certification/authorisation and supervision as well as any one-off costs due to the revision Although limited cost information is available concerning safety certification/authorisation and supervision, indicative UK information about the average cost provides a useful insight (see GL Noble Denton 2010 study for ORR): *Development of SMS for passenger RU: €57.000* *SMS maintenance per year for passenger RU €45.000* *Safety certification (initial application) passenger RU €24.000 (incl. RU resource costs but not fees and charges to NSA)* *Safety certification (initial application) freight RU €60.000 (incl. RU resource costs but not fees and charges to NSA)* *Safety certification (amendment cost) passenger RU €5.400.* Overall these estimates suggest that relative limited costs would be incurred by RUs for their application for SSCs. Indeed, with assumptions concerning a number of RUs in Europe it would be possible to derive an order of magnitude cost estimate regarding safety certification. A similar analysis could be developed with respect to the other stakeholders.

5. Comparison of options and preferred option

5.1. Effectiveness criterion (options' response to specific objectives)

		Option 1 *Revision limited to relevant provisions of 4RWP*	Option 2 *Revision limited to the theme of safety certification/ authorisation*	Option 3 *Revision considers all (4) themes from CSM Policy Paper*	Option 4 *Revision considers all (4) themes from CSM Policy Paper and relevant provisions of 4RWP*
	Ensure harmonized, efficient and effective safety certification/ authorisation processes for the RUs and IMs across EU	2	5	5	5
	Ensure harmonized, efficient and effective assessment of the country-specific rules for the RUs across the EU	2	5	5	5
	Ensure an efficient and effective system of assessment and supervision at NSA level	1	3	5	5
	Ensure the alignment with the relevant provisions of the 4RWP as regards SSC	5	1	1	5
	Overall	**12**	**14**	**16**	**20**

For objective 1 ("Ensure harmonized, efficient and effective safety certification/ authorisation processes for the RUs and IMs across EU") it is observed that options 2 to 4 all achieve the highest possible response. This is because even option 2, which has the most limited scope, aims at creating conditions for the NSAs to assess the sufficiency of applications in a proportionate, consistent and targeted way. Option 1 scores lower, as the mere alignment of the CSMs with the main provisions of the recast RSD on safety certification/authorisation (e.g. Articles 10 to 12) does not seem sufficient to achieve this objective.

As to objective 2 ("Ensure harmonized, efficient and effective assessment of the country-specific rules for the RUs across the EU") it is found that options 2 to 4 all achieve the highest response. These options address how (harmonised) national requirements is integrated within the overall assessment framework for safety certification / authorisation. Option 1 has a lower score, as the mere alignment of the CSMs with the main provisions of the recast RSD on safety certification / authorisation (Articles 10 to 12) does not seem sufficient to achieve this objective.

In the case of objective 3 ("Ensure an efficient and effective system of assessment and supervision at NSA level") it is verified that options 3 to 4 reach the same highest response. The reason for this is that these options both are addressing key issues raised concerning the NSAs activities regarding assessment of applications for safety certificates and safety authorisations as well as supervision. Option 1 receives the lowest score as the mere alignment of the CSMs with the main provisions of the recast RSD on safety certification / authorisation and supervision (Articles 10 to 12 & 17) does not seem sufficient to achieve this objective. Option 2 is achieving an intermediate score as it focuses exclusively on addressing the issues concerning safety certification / authorisation.

As to objective 4 ("Ensure the alignment with the relevant provisions of the 4RWP as regards SSC") it is found that options 1 and 4 both reach the same highest response. The reason behind is that both options aim at making the provisions of the CSMs fully compatible with the relevant provisions of the Technical Pillar of the 4RWP, in particular those regarding the process and timeframe for delivering SSCs. Options 2 and 3 receive the lowest scores.

Overall the analysis indicates that option 4 reaches the highest performance in terms of fulfilling the four objectives, followed by option 3. Option 4 seems thus the best placed to achieve the defined objectives, whilst complying with the applicable legal provisions [recast RSD and Regulation (EU) 2016/796] and with the mandates from the EC for the revision of the CSMs. Option 1 has the lowest overall score with respect to the specified objectives. As regards option 2, the findings clearly underline that a revision limited to the issues within the theme of safety certification/authorisation, even if this is a key element to facilitate business for RUs/IMs and thus to create a Single European Railway Area, would not help to achieve all the specified objectives.

Option 3 reaches the second highest overall score after option 4 with the difference being caused by not addressing specifically the objective concerning alignment with the relevant 4RWP provisions.

	Option 1	Option 2	Option 3	Option 4
*Effectiveness (average score)**	**3.0**	**3.5**	**4.0**	**5.0**

*The values presented have been converted to a 5-point scale.

5.2.	Efficiency (B/C ratio) criterion	On the basis of the available information, option 4 appears to have the highest performance with respect to efficiency in terms of the balance between costs and benefits. In particular, this option is expected to address fully the problems experienced by stakeholders regarding safety certification and supervision inasmuch 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. The other options are likely to be ranked lower in terms of efficiency considerations: • *Option 1 is inferior to Option 4 as it does not necessarily address the problems identified concerning safety certification/authorisation and supervision which may result in additional costs for stakeholders* • *Option 2 is inferior to Option 4 as it only addresses those issues that are linked to safety certification/authorisation, but none of the problems in terms of supervision, decision-making or competence management. Moreover, the inconsistencies with provisions of the 4RWP may also lead to additional costs being incurred* • *Although Option 3 addresses the problems identified regarding safety certification/authorisation as well as supervision, decision-making and competence management which could provide net-benefits, these may be eroded due to the possible inconsistencies with 4RWP provisions and therefore additional costs compared to Option 4.*
5.3.	Summary of the comparison	Please see sections 5.1 and 5.2.
5.4.	Preferred option(s)	From a perspective of effectiveness and efficiency, **option 4** would be the preferred choice.
5.5.	Further work required	Not foreseen at this point.

6.   Monitoring and evaluation

6.1. Monitoring indicators	In accordance with the EC Better Regulation Guidelines {COM(2015), 215 final} the monitoring and evaluation arrangements should be outlined in the (*ex-ante*) impact assessment reporting, in order to facilitate future analyses of whether the measures adopted actually deliver the intended results and also to inform any future revisions of the measures. Particular attention should be given to setting out monitoring indicators, frequency of data collection and data sources for these indicators. Below, a tentative (non-exhaustive) list of monitoring indicators is given. This list of indicators should be further elaborated as required. Subsequently, considerations concerning frequency of data collection and data sources are presented. The following section 6.2 outlines whether future *ex post* evaluations are envisaged and under what conditions (triggers). **CSMs on CA** Preliminary proposal for headline indicators: *Overall level of correct implementation of CSMs* *Number of major non-compliances for safety certification and authorisation per country and per application* *Number of new, updated, renewed (single) safety certificates (including number of certificates with area of operation in two or more Member States)* *Number of safety authorisations issued* *Number of revoked (single) safety certificates/authorisations.* Preliminary proposal for in-depth information requirements: *Overall perceptions and experiences of safety certification and authorisation by stakeholders (NSAs, RUs / IMs) with particular focus on any changes* *Views on specific elements of the CSMs on CA (what are the problems, advantages etc.)* *Implementation costs (this should focus on obtaining practical-based information about costs incurred by the different parties* *Perceptions among RUs /IMs whether there are changes in resources used on safety certification and authorisation (this could be supported through specific examples)* *Perceptions among NSAs whether costs for their assessment work have changed (this could be supported through specific examples)* *Examples where the CSMs on CA has been an influencing factor for RUs decision to enter a new market.* **CSM on SP** Preliminary proposal for headline indicators: *Overall level of correct implementation of CSM*

	• *Number of supervision activities (audits, inspections) undertaken according to the applicable risk-based plan* • *Number of identified major non-compliances in the application of the SMS of RUs/IMs.* Preliminary proposal for in-depth information requirements: • *Overall perceptions/experiences with the CSM on SP by concerned stakeholders* • *Views on specific elements of the CSM by NSAs, RUs / IMs* • *Costs of supervision activities for NSAs* • *Possible implications on railway safety.* **CSMs on CA and CSM on SP** The expected frequency for the measurement linked to the headline indicators could be annual (provided the data are readily available, e.g. already included as part of the NSA's annual reporting to the Agency), whereas for the more detailed (and resource intensive) information requirements biennial data collection would be appropriate. Key-data sources would include: (1) annual NSA reporting with respect to safety certification/authorisation and supervision; (2) information gathered through the monitoring of NSAs' activities by the Agency according to the recast RSD; (3) dedicated interviews/surveys issued through the NSA Network, as required.
6.2. Future evaluations	Based on the monitoring indicators and other relevant information, future *ex post* evaluations of this initiative may be considered as required.

7.   Annex 1: Abbreviations

Table of abbreviations

Abbreviation	Description
4RWP	Fourth Railway Package (i.e. its technical pillar composed of Directive (EU) 2016/797, Directive (EU) 2016/798 and Regulation (EU) 2016/796)
CA	Conformity Assessment
EC	European Commission
EU	European Union
CSM	Common Safety Method
IA	Impact Assessment
IM	Infrastructure Manager
MS	Member State
NSA	National Safety Authority
OA	Operational Activity Area
ORR	The Office of Rail and Road (UK safety and economic regulator for Britain's railways)
OSS	One Stop Shop
RI	Railway Indicator
RSD	Railway Safety Directive
RU	Railway Undertaking
SA	Safety Authorisation
SC	Safety Certificate
SERA	Single European Railway Area
SMS	Safety Management System
SP	Supervision
SSC	Single Safety Certificate
TSI	Technical Specification for Interoperability