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## Document Review – Comment Sheet

*Document commented: Common Safety Methods on the assessment of Safety Level and Safety Performance of railway operators at national and Union level (CSM ASLP)*

<i>Requestor:</i>	Consultation.ERA1219@era.europa.eu
<i>Deadline for submitting comments:</i>	17 March 2021

	<i>Reviewer 1</i>	<i>Reviewer 2</i>	<i>Reviewer 3</i>	<i>Reviewer 4</i>	<i>Reviewer 5</i>
<i>Date:</i>	17 March 2021				
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### *Document History*

<i>Version</i>	<i>Date</i>	<i>Comments</i>
0.1		
0.2		
0.3		

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*Conventions:*

<i>Type of Comment</i>		<i>Reply by requestor</i>	
<i>G</i>	General	<i>R</i>	Rejected
<i>M</i>	Mistake	<i>A</i>	Accepted
<i>U</i>	Understanding	<i>D</i>	Discussion necessary
<i>P</i>	Proposal	<i>NWC</i>	Noted without need to change

*Review Comments <if necessary add extra lines in the table>*

<i>N°</i>	<i>Reference (e.g. Art, §)</i>	<i>Type</i>	<i>Reviewer</i>	<i>Reviewer's Comments, Questions, Proposals</i>	<i>Reply</i>	<i>Proposal for the correction or justification for the rejection</i>
1.		G	NSA DE	The comments below do not only represent the opinion of NSA DE. For analysing the draft proposal for CSM ASLP and compiling the necessary comments, also members of DE railway sector were consulted and their contributions have been incorporated into this document as far as possible.	NWC	Noted

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2.		G	NSA DE	<p>The whole process of developing the CSM ASLP in the dedicated ERA Working Party (from Dec 2019) stood under high pressure to have the deliverables available per Dec 2020 (start of consultation). The necessary coordination to deliver contributions was severely limited. Sector and NSA repeatedly requested ERA and EC to review the project-planning. This also results in the draft document, especially the Annexes, not seeming to be mature enough.</p> <p>This also applies for all interfaces to existing legal texts like CSM RA, CSM SMS, CSM Monitoring, CSM Supervision or TSI OPE, which are not clear. The draft uses wordings and definitions similar to existing legal texts, which can lead to confusion and misunderstanding. For example, does the concept of building blocks used here fit to the bow-tie methodology used for AMOC under TSI OPE?</p>	NWC	<p>RISC Committee was informed in due time of the issues reported concerning the planning.</p> <p>As an agreed solution a phased implementation approach was decided.</p> <p>RISC Committee was informed about the issues raised concerning the interfaces with other legislation. The solution proposed by the Agency was to have a CSM ALSP not duplicating and not impacting any roles and responsibility established by existing legislation.</p> <p>The Building Block approach is fully compatible and can be used to develop bow-ties</p>

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3.		G	NSA DE	<p>A phased / staged application of the CSM ASLP seems to be agreed by all parties involved. Starting point should be the establishment of the Group of Analysts and the reporting of events. This would also limit the burden for rail operators, where especially SME are concerned.</p> <p>The Regulation should only contain what is applicable in the first phase of the implementation. Annexes dealing with later stages should be deleted for the first phase.</p> <p>This would offer the possibility to take into account experience from the first phase, optimize the draft Annexes, and implement them after a positive evaluation of the first phase.</p>	<p>A</p> <p>R</p> <p>NWC</p>	<p>The Article 11 has been redrafted to clarify the proposed phased approach.</p> <p>The phased approach is also used to prepare for the implementation of the next phases and also to offer a baseline for the work of the GoA.</p> <p>Therefore all the elements (but restructured) that have been developed with the working party are mature enough to serve as a baseline for the GoA.</p> <p>The learning process is embedded in the CSM proposal by the establishment of the GoA. The GoA will have all the opportunity in accordance with the CSM to make improvement proposals, at each stage.</p>

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4.		G	NSA DE	<p>NSA DE of course is supportive to the general aim of the CSM ASLP to foster information sharing and collective learning. However, also stemming from the mandate, this should be done in efficient way, balancing the costs and benefits for the operators, especially SME. As regards the foreseeable costs for all stakeholders, compared to the impact assessment carried out by ERA, we consider some cost-factors missing and some underestimated. The assessment of the collected data could support ERA/COM and national authorities to target their initiatives for safety improvements, however the benefits for each RU and IM are not clear. We see no convincing arguments that the approach will help railway operators to increase their safety level by the collection of data at Union level instead of national level, that would be more effective to reach this objective. It is to be noted that costs for railway operators are direct, substantial and certain, while the benefits are indirect, small and not certain. It should be avoided that operators (particular SME) are forced by external regulations to spend resources on tasks and measures that are not balanced by benefits in their own area of responsibilities, where those resources are not available for other safety relevant tasks.</p>	NWC	<p>A very large part of the CSM proposal is mainly structuring the information stemming for already existing requirements to be applied by the operators.</p> <p>A positive impact for the operators and other entities is to be able to share structured information. It facilitates collective learning at each level. Furthermore, the elements provided by the CSM (e.g. ROS which includes HOF and SMS elements) go beyond the current practice of many, if not most, operators and should guide and support them in improving their SMS. Apart from expected benefits linked to safety performance it is also likely that there could be benefits in terms of optimising the operators' application of their SMS of importance for operational performance. In both cases these benefits are estimated at a conservative level.</p> <p>The Impact Assessment is positive.</p>

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5.	Art. 2.1	G	NSA DE	<p>Broad scope seems out of the boundaries of the mandate and Directive 2016/798 as a legal basis. Proposal:</p> <p>This Regulation shall apply to <b>railway operators as defined in Art. 3.1</b>, to the sharing of data or information concerning the categories of events defined in this Regulation, their occurrence, their occurrence scenarios, their risk control measures or on safety performance management.</p>	NWC	The CSM proposal is fully in line with the Mandate requests.
6.	Art. 3 b)	P	NSA DE	<p>“in the context of this Regulation” to be deleted. This applies for all the definitions.</p>	A	deleted
7.	Art. 3 d)	P	NSA DE	<p>Delete Definition for Risk control measure. Use existing terminology from CSM RA instead. It must be avoided to have two different terms with exactly the same meaning. This applies for all items that concern interfaces to other existing legal texts.</p>	NWC	<p>It is already the current situation that both terms ‘risk control measures’ and ‘safety measures’ are used in existing EU legislation.</p> <p>The definition added in the CSM is needed to facilitate the implementation for all operators, confronted to this existing situation.</p>

8.	Art. 3 (i) and (j)	U/ P	NSA DE	<p>These definitions more or less repeat the definitions for serious / significant accident from Dir. 2016/798, but call that “event” instead of “accident”. This does not make sense and will create confusion and misunderstandings. To be deleted.</p>	NWC	<p>As you indicate, the definitions proposed do not repeat them but use the definition of accidents and incidents in a fully consistent manner.</p> <p>The CSM ASLP uses consistently pre-existing definition of Accident and Incident.</p> <p>Accidents have ‘harmful consequences’ however the word harmful is not defined by RSD.</p> <p>This is why the Cat A definition clarifies that the CSM considers a subset of accidents with ‘victims’ (fatalities or injuries) or ‘damages’ (to rolling stock, infrastructure or environment).</p> <p>This approach allows also to be consistent with the notion of serious and significant accidents. ‘serious accident’ means any train collision or derailment of trains resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure or the environment, and any other accident with the same consequences which has an obvious impact on railway safety regulation or the management of safety;</p> <p>‘extensive damage’ means damage that can be immediately assessed by the investigating body to cost at least EUR 2 million in total;</p> <p>‘significant accident’ means any accident involving at least one rail vehicle in motion, resulting in at least one killed or seriously injured person, or in significant damage to stock, track, other installations or environment, or extensive disruptions to traffic, excluding accidents in workshops, warehouses and depots;</p>
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						However, 'delays' and 'extensive disruption of traffic' are not included in Cat A. events, while Cat A events does not exclude events occurring in 'terminals'.
9.	Art. 4.1	G	NSA DE	<p>From this Article, it remains unclear what to report at which frequency. It is all in the Annexes. Basic requirements must be mentioned here, to give the railway operators that will have to apply the Regulation a good impression what is expected from them.</p> <ul style="list-style-type: none"> <li>- Detailed reporting for XXX within XXX days</li> <li>- Summary reporting for XXX within XXX days</li> </ul>	A	<p>Article 4 has been redrafted to directly specify what needs to be reported.</p> <p>It has the effect of simplifying the Annex I, where the 'sharing request' tables are not needed anymore.</p>
10.	Art. 4.1 a)	U	1	"any applicable occurrence in which the railway operator is involved" – does that mean directly involved? Should be clarified.	NWC	A definition of involved operator is provided by the CSM proposal (Art 3 (o))

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11.	Art. 4.2	U	1	<p>Right to request review of data should be limited for data in the respective authority's competence. It must also be clarified who must do the review (the operator that provided the information!). The request for review should be justified.</p> <p>Proposal:</p> <p>Each National Safety Authority, TDG Competent Authority and the Agency shall <b>in duly justified cases</b> be entitled to request <b>the reporting entity to perform</b> a review of reported data and information, <b>provided that the reporting entity or the reported data falls within the competence of that authority.</b> “</p>	A	<p>This covered by amended article 4(7) “...Each national safety authority, TDG competent authority and the Agency shall be entitled, in duly justified cases, to request the reporting operators to perform a review of reported data and information, provided that the requested operator and the concerned data and information <b>falls within the competence of the requesting entity</b>”</p> <p>It is confirmed by Article 7(15)</p> <p>‘Within the limits of the sharing rules established by the Appendix D, any entity shall be entitled to use the data and information from the Information Sharing System for which they have access rights <b>in order to fulfil the roles and responsibilities placed on them by the European Union legislation.</b>’</p> <p>Article changed in accordance with proposal.</p> <p>It reinforces the initial proposed approach.</p>

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12.	Art. 5.1	G / P	NSA DE	<p>It remains unclear when and in which intervals this assessment takes place. Such basics of the process must be contained here.</p> <p>“in due time” is not appropriate. Concrete timing to be specified.</p> <p>Clarification on timing shall be added</p> <p>“estimation of safety level” – to be replaced by “assessment of safety level”.</p> <p>‘Assessment of safety level’ is more accurate and shall be altered.</p>	<p>A</p> <p>NWC</p> <p>NWC</p>	<p>Estimation periods have been added in Article 5(2)(a) and (b)</p> <p>We prefer to fix the timing when this part of the CSM will be implemented, taking into account experience gained with the first phase.</p> <p>Estimation and Assessment have different meaning (estimation is to allocate a value to something / assessment is to compare this value with a referenc in order to take decisions) and the terms are properly used, in accordance with CSM RA and standards.</p>
13.	Art. 5.1	U	NSA DE	<p>“For this purpose, the Agency shall provide each railway operators with access to all the information applicable to it for the considered reporting period.” – How will this be done? Via the information system mentioned in Art. 7? Timing? To be specified.</p>	NWC	<p>This process is facilitated by the ISS. See response to comment 12 on the timing.</p>

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14	Art. 6	G / P	NSA DE	<p>Article should have the heading “Group of Analysts”. There is clarification needed if Group of Analysts will replace JNS. If so, some stipulations need to be added. Especially to aim at avoiding national measures for the time a specific problem is discussed in this forum. Proposal:</p> <p>Art. 6.5</p> <p>Any railway operator may classify a reported event to be urgently dealt with by the Group of Analysts. The Information Sharing System shall offer this possibility. The Group of Analysts will, potentially with the help of dedicated subgroups of specific experts, analyse the event and propose harmonised solutions acc. to Art. 6.4. These harmonised solutions shall preclude any non-harmonised measures to be decided by National Safety Authorities.</p>	<p>NWC</p> <p>NWC</p>	<p>The Group of Analysts (GoA) will integrate the current JNS workflow. This is currently described in the drafting of The GoA Working Arrangements.</p> <p>This possibility is covered by the GoA Working Arrangements, any entity can trigger an urgent JNS procedure, in the new context of the GoA.</p>
15.	Art 7.1	P	NSA DE	Replace “any party” with “any railway operator”.	<p>R</p> <p>A</p>	<p>It is a basic assumption of the Mandate to share information between parties.</p> <p>Clarification, taking also into account other comments received have been made in Article 2.</p> <p>Article 7.1 is deleted, while the possibility (not the obligation) to report safety relevant by any party information is kept in amended article 2.</p>



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18.	Art. 7.8	G/P	NSA DE	<p>We strongly advocate a decision per Member State, which reporting channel is chosen. Only by doing so, a harmonised application per Member State can be ensured, with NSA participation and involvement in the reporting process. This offers the possibility to clarify problems within existing and proven procedures on a national level, before data is entered in the ISS.</p> <p>Proposal:</p> <p>For the implementation of this Regulation, the Member States shall notify the Agency whether they will mandate the indirect sharing of information via a pre-existing system, or they will allow direct reporting to the Information Sharing System.</p>	NWC	<p>An EU harmonised regulation cannot call for nationally based rules.</p> <p>The CSM offers the two possibilities, and it is the responsibility of the EU-MS to consider the establishment of such a National rule.</p> <p>The Agency considers that it is not justified as precautions are taken to ensure the mirroring of data and information between parties. Therefore the two channels (direct or indirect) should be considered equivalent as the ISS will automatically mirror the data between systems.</p> <p>When operators operates in several countries, it is considered as a complexification of the CSM to potentially establish different rules to be followed by the same operator depending on the location an occurrence takes place.</p>
19.	Art. 7.10	P	NSA DE	<p>“The Agency shall not be responsible for any malfunction of indirect communications” – If the malfunction is within the Agency’s sphere of competence, it cannot be neglected. The Agency must take the responsibility for its part of the interface of indirect communication. The Agency must evaluate each change it proposes also regarding its effects on the interfaces and the interfaced systems.</p>	A	<p>We propose to add ‘due to connected systems’.</p>
20.	Art. 7.11	P	NSA DE	<p>Amendments of data must be tracked. Original data must remain available.</p>	A	<p>We propose to add ‘in a traceable manner’</p>

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21.	Art. 8	P	NSA DE	It must be clear which fees apply. Is it the hourly rate that also applies for VA and SSC?	NWC	<p>In theory, when the ISS is established, some operators may wish to use it voluntarily in an extensive way to fulfil specific needs (for examples detailed monitoring, operator's sensors feeding an automated specific monitoring).</p> <p>This article covers the situations where the voluntary use of the ISS by any party – for reporting non-mandatorily requested datasets - would result in increased ISS operation costs or even investment costs (bigger/quicker server needed).</p> <p>As it is impossible to define any voluntary use situation today, the article indicated that fee would be applied to cover voluntary and specific use of the ISS by an entity.</p> <p>This article protects both the entities and the Agency as in such case a specific agreement shall be negotiated.</p> <p>This is to be understood in the remaining context that the Agency is not entitled to make profit, thus fees would <u>only</u> cover the extra <u>specific</u> cost incurred by the Agency.</p>
22.	Art. 9.3	G	NSA DE	Character of the technical support documents is still unclear. Will they be mandatory? Will the opinion of the Agency amending the Documents be discussed in RISC?	NWC	The Regulation, including the Annex and Appendices, is binding in its entirety and modified in accordance with the Mandate by delegated acts.

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23.	Art. 11	G / P	NSA DE	The proposed staged implementation is supported and appreciated. However, it would be more straightforward to limit the Regulation to what is implemented in the first stage (reporting of safety information) and give dates for further ERA recommendations on the other topics. Those should be integrated in the Regulation at a later stage, based on further Recommendations from ERA, accompanied by an obligatory evaluation of the first stage. This would really allow for learning from the implemented parts.	NWC	The collective learning and the activities of the GoA will be facilitated if all the parts of the CSM have a reference baseline. The Agency finds the elements developed with the working party and based on previous harmonisation work mature enough to constitute a relevant baseline.  We consider it is necessary to capture the state of development agreed with the working party as a baseline, that will be the basis for GoA amendments proposals.  Even if not all the elements will be mandatory applicable it will allow operators and the NSAs to prepare for the next phases.
24.	Art. 11.3	U	NSA DE	What is the “immediately available solution”, that is to be used as long as the ISS is not available yet? Remains unclear.	NWC	The Agency is currently investigation the options that are available. As the first phase is very limited in terms of number of occurrence to be reported it can be implemented without an ISS.
25.	Art. 11.6	P	NSA DE	(See also No. 11) Unclear if entities must register actively or will be registered automatically. Proposal:  The entities... <b>shall register and connect...</b>	A	Modified as proposed

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26.	Annex I	G / U	NSA DE	<p><u>Whole Annex:</u></p> <p>Have responsibilities clear, passive wording like “shall be processed”, “shall be implemented” to be avoided.</p> <p><u>5.1.2.2</u></p> <p>What is “AIS”? To be clarified. Dir. 2016/798 defines serious injury (currently, not historically). CSM should not deviate from that.</p> <p>“soil pollution” is there twice, under environment and under operating services. Is that justified?</p> <p><u>7.2</u></p> <p>Definition of “high speed passenger train” and “dangerous goods freight train” missing.</p>	<p>NWC</p> <p>NWC</p> <p>NWC</p>	<p>The legal service of the Commission will review the text to ensure the wording that is used is legally correct.</p> <p>Abbreviated Injury Scale (AIS) Measures the severity of each injury on a scale from 1 (slight injury) to 6 (non-treatable usually fatal injury) for each of the 9 regions of the body (Head, Face, Neck, Thorax, Abdomen, Spine, Upper Extremity, Lower Extremity, External, other).</p> <p>This reporting is optional in the CSM.</p> <p>Soil pollution asked only once under ‘environment’ in the final proposal</p> <p>RSD defines the type of operation Article 3(31) ‘... passenger transport, including or excluding high-speed service’</p> <p>‘high-speed passenger train’ means a passenger train delivering high-speed service of passenger transport.</p> <p>‘Dangerous goods freight train’ is defined in the SRT TSI Article 2.4 “(e) Freight train: A freight train is a train composed of one or more locomotive(s) and one or more wagon(s). A freight train including at least one wagon carrying dangerous goods is a dangerous goods train”</p>

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27.	Annexes II-V	P	NSA DE	Annexes to be deleted. To be added after evaluation of preceding stages on recommendation from Group of Analysts.	R	Please see comment 23

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28.	Annex II	G	NSA DE	<p>As regards self-estimation, again there are questions regarding costs and benefits. It remains unclear what will happen with these results. The interface to other CSMs dealing with items like management review, monitoring, internal / external auditing, risk management is not defined. The process of the assessment of the safety performance, especially the self-estimation part cannot guarantee well based comparisons between different operators.</p> <p>Detailed questions:</p> <p>2.1 „...using the self-estimation tables in section 5...“ – there is no section 5. Which tables are referred to?</p> <p>3.4 What is “area P # 1..5“, „area C # 1..5“, „area A # 1..5“?</p>	<p>NWC</p> <p>A</p>	<p>An impact assessment was carried out. The assessment focused on setting positive and negative impacts per CSM ASLP element incl. operators’ self-estimation. The possible value of self-estimation has been mentioned drawing on existing studies into this approach.</p> <p>Overall, the aim of this part of the CSM is to provide a tool for the sector to improve the SMS of the operators, with a focus on the management of RCM:</p> <ul style="list-style-type: none"> <li>• <i>For the operators: helping them to self-assess their level of safety performance and find areas for improvement;</i></li> <li>• <i>For the authorities to improve the dialogue with railway operators</i></li> </ul> <p>Dataset to be reported clarified in Annex II with reference to Appendix B.</p>

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29.	Annex VI	G	NSA DE	<p><u>3.1 (table)</u></p> <p>Restricting the NSAs to data “in the targeted EU MS” might be too narrow. For NSA A being the lead NSA for an RU from MS A, it is also important what that RU does in MS B and MS C.</p>	NWC	<p>The rules is that any data ‘concerning one given operator’ is shared with ‘the authority(ies) from the EU MS where the targeted railway operator operates (NSA, NIB,TDG CA)’.</p> <p>It means that for an operator operating in several countries, in accordance with its single safety certificate, the authorities of all the MSs concerned will have access to the information.</p> <p>Note: it is proposed to clarify the text with ‘MS(s)’ in plural when applicable.</p> <p>The ISS might be designed to facilitate those information exchanges between NSAs.</p>

*Note: This table could be changed according to the requestor’s needs*

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