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ACCOMPANYING REPORT TO FINAL RECOMMENDATION OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

on

*Common Safety Methods for the assessment of safety level and
safety performance of operators at National and Union level
(CSM ASLP)*

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1. Introduction

The European Commission implementing decision adopted on the 7 January 2019 [c(2018)8887/F1] gives the mandate to the European Union Agency for Railways to draft **common safety methods for assessing the safety level and the safety performance of railway operators at national and Union level**.

The mandate requires the Agency to deliver a recommendation by 31 December 2020¹.

The mandate documents were addressed to the Agency and published on the register of Commission documents, publically accessible at this [address](#).

It is also indicated that other recommendations may follow, in case of need, concerning the revision or repeal of existing legislation related to the future CSM ASLP and on the development of a technical system supporting the future implementation thereof.

For the preparation of the recommendation and in accordance with the Mandate, a Working Party (WP) was established.

On the 25 October 2019 the Agency requested the National Safety Authorities (NSA), the National Investigation Bodies (NIB) and Representative Bodies (RB) to nominate their representatives and alternates before the 22 November 2019.

The WP members have been appointed in accordance with the rules of procedures for managing working parties and workgroups.

On 26 February 2020, the NIB network notified the Agency with its decision not to be represented in the development work, for the sake of independence, but to nominate the Belgian NIB as an observer to the working party meetings on behalf the entire NIB network.

On 24 March 2021, the Working Party was counting 57 members and deputies from 17 countries (BE, DE, DK, EE, ES, FI, FR, IE, IT, LU, LV, PL, PT, RO, SE and CH and NO) and 4 sector associations (CER, EIM, UNIFE, UIP).

An Extranet workspace dedicated to the development of the common safety methods was used to facilitate the work of the WP meetings.

2. Structure of this report

In accordance with the requests of the Mandate, this accompanying report is structured as following:

The organisation of the development work, the evolutions of the CSM text as well as the solutions developed with the working party members on the issues raised until the final draft proposal are presented in **section 4**.

The results of the consultations and discussions carried out within the network of the national safety authorities and in particular the proposal amendments that were implemented based on this input are presented in **section 5**. This section is supplemented by the results of the consultation of the TDG Competent Authorities and OTIF contracting parties.

¹ On 18 March 2019, the European Commission asked the Agency to deliver a draft recommendation in February 2020, earlier than the original mandate deadline of December 2020. In the planning of the CSM development the Agency proposed to deliver a preliminary recommendation by end April 2020 based on the concept 'Big Picture' document, taking into consideration the complexity of the mandate and the other Agency's activities, as presented at its Management Board.

The results of the formal consultation of social partners and users under Articles 6 and 7 of Regulation (EU) 2016/796, including the opinions expressed by the stakeholders are presented in **section 6**.

The results of the impact assessments are presented in **section 7**.

Section 8 suggests possible follow-up recommendations in accordance with the possibility offered by section 2.2 of the Annex to the Mandate.

3. Presentation of results achieved by the CSM ASLP working party and groups

Without prejudice to the working method requirements specified in the mandate, the Agency started with the development of the so-called concept document 'Big Picture', suggesting possible methods for assessing operators and for establishing well-structured collective learning on railway incidents and accidents.

This document had the advantage of presenting a comprehensive approach of the methods, trying to obtain an overall sustainability of a possible future legal framework, indicating a list of potential benefits for the railway actors, as well as the consistency of the proposed approach with the existing railway legislation.

This approach was discussed and broadly supported by NSA and NRB representatives at two dedicated meetings in October 2019. Following these meetings with the NSA and the NRB representatives, the 'Big Picture' document (see [ERAEXT-472347183-1](#)) was finalised and delivered to the European Commission DG MOVE (C2) on 31/10/2019 and discussed at the 86th session of the RISC in November 2019.

The RISC 86th session concluded favourably on the follow-up development of the CSM ASLP along the lines described in the 'Big Picture', however several participants indicated that the mandate deadline was too short to allow sufficient discussion with stakeholders, as it should be the case for such a complex and important mandate.

3.1. Work of the Working Party

During the whole development phase of the CSM, the same issue with the tight planning remained, however, the deadline was not amended and the mandate remained fully binding for the Agency, without amendments.

Thus, it is in this extraordinary context of pressure that the Agency had to undertake the development of the CSM legal text with the help of the Working Party members, somehow facilitated by the agreed baseline provided by the 'Big Picture' document.

Therefore, in practice and as agreed preliminary, the development of the CSM text consisted mainly to convert the 'Big Picture' overall vision into legally coherent but also practicable methods, that will benefit the overall safety management of the European railway system.

The Working Party started to work in December 2019 and had two physical meetings. Due to the Covid pandemic the Agency had to organise all the consecutive meetings in remote mode.

It should be noted that while it was a new way of working, after a short period of adaptation of all the participants and of the Agency, the organisation of remote meetings actually allowed to organise detailed discussions on many technical topics that would have not been possible to organise physically in such a condensed manner.

Combined with the need to produce a text in a very short timeframe, the organisation of remote meetings allowed for the facilitation of many focussed technical meetings, many more than usually organised for the development of a CSM, providing the possibility to go into very depth technical discussions. However, the negative effect was that, despite the discussions were progressing well and were constructive, the pace of the work made it difficult for the WP members to coordinate with their counterparts and/or concerned stakeholders between each meetings, which is normal practice.

The progress of the work was also presented at RISC meetings 86 (November 2019) to 90 (February 2021), highlighting orientations taken, difficulties and proposed solutions.

The final CSM recommendation was addressed on 18 May 2021, approximately 4.5 months after the initially requested deadline of 30 December 2020, mainly due to the complexity of the discussions.

The results achieved by the WP were developed around several milestones, as following:

- The preliminary draft CSM ([ERAEXT-1284009250-75](#)), associated with the first consultation and an accompanying report ([ERAEXT-472347183-2](#)) suggesting ways forward for the WP discussions,
- The improvement of the CSM draft with WP discussions, focussed technical meeting, informal consultations and bilateral discussions from the 2nd to the 4th draft CSM text,
- The publication of the final draft CSM text ([Final Draft CSM](#)) for [formal consultation](#) in accordance with Article 6 and 7 of the Agency Regulation,
- The consultation comments and answers (link to publication page) and the follow-up discussions with the working party and with the NSA Network,
- The final CSM recommendation addressed to the European Commission (link), accompanied with the final Impact Assessment report (link) and this accompanying report (link).

In the following sections of this report, we summarise the evolution of the text towards the final CSM recommendation, per topic of interest.

3.2. Evolutions of the CSM text

Considering the number of technical requests contained in the Mandate, it was immediately considered that the CSM would have to cover several technical topics of very different nature and thus should be organised with a high level core text supplemented by specific technical annexes covering the Safety level and Safety performance assessments. This approach allowed to cover with the same legal text the support to collective learning by railway actors, including the reporting of occurrence scenarios and risk control measures, as well as the rules which should govern the exchange of data and information (sharing) between actors, taking into account the full respect of the EU legislations on the protection of personal and specific interest data and on the transparency of information.

A first working document scoping a possible content of the future CSM ([ERAEXT-1284009250-24](#)) was discussed at the 1st WP meeting (5-6 December 2019). This document was used to trigger the discussions on the different topics mentioned in the previous paragraph and to collect a 1st set of comments from the WP members concerning the structure and content the future CSM should have.

Based on the comments received and on the discussions at the 2nd WP meeting the Agency submitted a second working document for comment ([ERAEXT-1284009250-74](#)) on the 13/03/2020, containing only the core articles of the CSM, supplemented on the 23/03/2020 with technical annexes consisting in the preliminary draft CSM ([ERAEXT-1284009250-75](#)). This preliminary draft contained 8 articles (Subject matter / Scope / Definitions / Collection of data used for the assessments / Assessment of Safety Level and Safety Performance / Information sharing system / Collective learning / Control mechanisms / Entry into force and application) and 7 annexes.

The 3rd WP meeting (14-15 April 2020) was the first meeting organised remotely due to the Covid pandemic. The discussions at this meeting entailed the review of comments submitted by the WP members on the

preliminary draft and on the organisation of the future discussions, taking into account the pandemic. It was agreed to organise 16 bilateral remote meetings with each of the WP members that provided comments.

An additional meeting was organised on 13/05/2020 and specifically dedicated to debrief with the whole WP the results of the bilateral discussions.

Based on the above, the Agency addressed to the European Commission, on the 28 May 2020, the preliminary recommendation with an accompanying report ([ERAEXT-472347183-2](#)) describing, in its section 6, the remaining work to be developed with the WP members, taking into account the comments received, in order to finalise the recommendation. In particular, it was possible to clearly identify the remaining concerns and solutions that should be developed with the WP members in order to finalise the CSM.

The following meetings were organised, trying to solve the identified issues, using the following detailed contributions to continue the development of solutions with the WP members:

- Preparatory discussion on Safety Performance (03/06/2020) (ERA)
- Smart reporting criteria for maximizing reporting added value (10/06/2020) (ERA)
- Safety Performance roles and responsibilities (10/06/2020) (ERA)
- Orientation note for sharing rules (10/06/2020) (ERA)
- Applicable EU legislation on the protection of personal data / transparency (10/06/2020) (ERA)
- Proposal – Definitions SL occurrences (12/6/2020) (NSA ES)
- Example of data protection treatment in a legal text (16/06/2020) (ERA)
- Draft list of reference events (16/06/2020) (ERA)
- Safety performance – preparatory discussion on elements of proof (18/06/2020) (ERA)
- Accident reporting in CSM ASLP (18/06/2020) (presentation by Siemens)
- Practicalities in reporting more type of events – aggregation methods (18/06/2020) (Renfe)
- Linking of event type and risk control measures (18/06/2020) (ERA)
- Safety Level assessment (23/06/2020) (presentation by NSA CH)
- Statistical assessments for Safety level (23/06/2020) (Siemens)
- Practicalities in reporting more type of events – aggregation methods (23/06/2020) (Renfe)
- Potential aggregation of Safety Performance results (25/06/2020) (ERA)
- Data and information sharing rules (25/06/2020) (NSA NO)
- Assumptions for Bayes – SL Assessment (26/5/2020) (NSA CH)
- Group of Analyst activities (30/06/2020) (ERA)
- Testing of event reporting and occurrence scenario reporting (30/06/2020) (CER-EIM)
- Introduction of smart reporting criteria to reduce impact of data collection (30/06/2020) (ERA)
- Safety level potential assessment methods (30/06/2020) (NSA FR and NSA CH)
- Safety performance mapping SMS requirements (30/6/2020) (NSA ES , NSA BE)
- Reference list of events to be reported (30/06/2020) (ERA)
- Safety performance assessment and Elements of proof (01/07/2020) (ERA)
- Comments on elements of proof (6/7/2020) (NSA FI / NSA BE)
- Draft CSM annex VI on information sharing rules (07/07/2020) (ERA)
- Generic data and information management (07/07/2020) (ERA)
- Smart reporting (07/07/2020) (ERA)
- SL workshop recommendations (07/07/2020) (Siemens and NSA CH)
- Presentation test of CSM Annex I and III – Safety events and RCMs (07/07/2020) (CER and EIM)
- SP elements of proof (07/07/2020) (ERA)
- Linking of events example concerning scenario reporting (07/07/2020) (ERA)
- Comments on elements of proof (6/07/2020) (NSA EE, NSA BE, NSA IE, NSA FI, and ERA compilation)

All the above elements and related discussions were thoroughly considered by the Agency before issuing a 2nd draft on 30/07/2020, including possible solutions to the issues raised with the preliminary draft CSM.

Compared to the preliminary draft, the 2nd draft was the first almost complete text, except the annex concerning the activities of the future Group of Analysts supporting collective learning. This draft contained a sets of recitals, a fully rationalised method using ‘datasets’ and ‘sharing requests’, facilitating the future control exchange of data and information with ICT solutions. It also contained a first version of the rules to be applied for sharing data and information between operators, authorities, and any other entities.

From this stage of development, the 6th, 7th and 8th WP meetings, as well as six (6) additional focussed technical meetings were used to refine the proposed solutions and the quality of the CSM text.

During those meetings the following contributions were discussed:

- Link of event examples (update for scenario reporting) – (09/09/2020) (ERA)
- Group of Analysts workflows (09/09/2020) (ERA)
- Group of Analysts mind map (09/09/2020) (ERA)
- Comments on Impact Assessment (09/09/2020) (CER- EIM)
- Implementation testing Annex I – Occurrence reporting (09/09/2020) (EIM-CER)
- Taxonomy attempt (10/09/2020) (NSA SE)
- Group of Analysts discussion – Focus meeting (15/09/2020) (ERA)
- Information Sharing System functions (15/09/2020) (ERA)
- Visio process for collective learning v10 (15/09/2020) (ERA)
- Visio process for collective learning and change control management (16/09/2020) (ERA)
- GOA focussed meeting outcome process description (17/09/2020) (ERA)
- Collective learning on events (22/09/2020) (ERA)
- NSA SE – Taxonomy Attempt (causal tree) (22/09/2020) (NSA SE)
- Outcomes Test Annexes I and III CSM ASLP (24/09/2020) (CER-EIM)
- Framework of human functions (28/09/2020) (Renfe)
- GOA focus group input to discussion (29/09/2020) (ERA)
- GOA focus group after discussion (29/09/2020) (ERA)
- Presentation Safety monitoring tool (2/10/2020) (NSA CH)
- Risk Overview-IU-NSA CH (2/10/2020) (NSA CH)Taxonomy – NOR- CH (2/10/2020) (NSA CH)

The Agency used the above discussions and the written comments received until 25 September 2020 on the 2nd draft to issue the 3rd draft on 9 October 2020 accompanied with an improved taxonomy of events that became afterward the Appendix A. It contained also a first draft framing the activities of the future Group of Analysts devoted to continuously improved EU railway safety in a collective manner, using the harmonised datasets that would become available with the future CSM. This draft was discussed at the 7th WP meeting (14-15 October 2020).

Compared to the 2nd draft, the 3rd draft introduced clarifications on the following points:

- It developed a generic approach to set the requirements in terms of data to be collected and the conditions under which the data shall be exchanged called ‘sharing requests’,
- The process for the Group of Analyst to address proposals to the Agency and the possibility for the Agency to recommend CSM improvements according to the needs, in order to legally take into account the improvements developed with the Group of Analysts,
- The technical documents which needs particular attention and regular updates because the harmonised technical support they provide to the railway actors to implement the CSM (taxonomies, safety performance self-estimation questionnaire, detailed SL and SP assessment process and formulas, ISS detailed functional description),
- The introduction of the phased application of the CSM, as requested by the sector and the NSAs, taking into account the need for a well-functioning ISS in order to fully implement the CSM, the need to complement the technical support documentation on the detailed SL and SP assessment process, as well as allowing time for the adaptation of the sector and authorities to the new CSM requirement

- in terms of harmonised data exchange, including the connection of pre-existing systems and registration of entities implementing the CSM,
- Further improvement of the requirements concerning the reporting of occurrence scenarios,
- An update of the requirement concerning the reporting of TDG occurrences, in order to ensure a clear, easy and non-duplicated link with TDG EU legislation in case of reporting of TDG occurrences,
- An improvement of the text concerning the SL and SP assessment methods,
- An improvement of the annex concerning the rules applicable for sharing information between entities, including the full respect of the relevant EU legislation (personal data, specific interest, transparency of information) taking into account the national obligations established by the Member States,
- The introduction of a process overview of the data and information exchanges between any entities subject to the implementation of the CSM.

The Agency received an additional set of comments on the 2nd draft on 22/10/2020, taken into account for the preparation of the 4th draft, in addition with the results of the 7th WP meeting. In parallel, every contributors received on 30/10/2020 detailed answers to each comment they made on the 2nd draft, by the way also explaining the improvements made on the 3rd draft.

Before the 8th working party meeting the WP members received an update of the Impact Assessment accompanied with the 4th draft proposal. The Agency received several inputs, for improving the draft taxonomy (Appendix A) (CER-EIM) leading to a few amendments of this part, the final results of the tests made by CER EIM on the implementation of annex I (Simple and Detailed reporting), an EIM evaluation of the time/date related request items (constraints) based on Annex VI, as well as a detailed evaluation report on the Bayes Safety level estimation by NSA CH.

Compared to the 3rd draft, the 4th draft introduced clarifications on the following points:

- Two new whereas were introduced: 1) for clarifying the need to use harmonised taxonomies for sharing comparable data and information and to provide a baseline for the work of the Group of Analysts, 2) for indicating that further recommendations may be issued by the Agency to complement the answers to the requests of the mandate, in particular to take into account the identified possibility to simplify the future regime of CSI/CST with the help of the CSM ASLP implementation,
The other whereas were improved in accordance with the discussions held at the 7th WP.
- The improvement of the definition of Safety Level, in accordance with the WP discussions,
- The improvement of the definition of Category A events,
- The introduction of 4 definitions helping the clear setting of the occurrence reporting thresholds (definition of 'significant' and 'serious consequences') and the notion of 'involved operators' as well as 'interested party',
- The improvement of the application scope of Article 4, introducing the notion of operator 'involved' in an occurrence,
- The clarification, in the same article, that supervising authorities would systematically receive the assessment results sent to the operators they supervise,
- The clarification, in the Article 6, of the Group of Analysts' legal status as an ERA working party and consequential simplifications concerning the composition of the Group of Analysts, not duplicated in the CSM text as already covered by the Agency Regulation,
- The clarification, in the same article, of the possible actions from the Agency which could take place based on the Group of Analysts proposals, namely, publication of informal safety-related information, technical opinions or recommendations,
- Several clarifications on the requirements for use of the ISS in Article 7,
- Details on the phasing to be applied for the CSM application in Article 11,
- Clarifications introduced in the Annexes in accordance with WP discussions as well as a simplification of the annex VI governing the rules for sharing data and information.

The 8th working party meeting consisted into a detailed reading of each paragraph of the 4th CSM draft, leading to some additional, but limited, changes agreed with the WP members during the meeting. One pending issue was the clarification of the status of the technical supporting documents as 4 separated appendices. However, taking into account the discussions at the 8th WP meeting, and in particular the legal status which should be given to those Appendices, those were reintegrated into the final draft for consultation in order to clearly establish them as equally legally binding as the other part of the CSM text.

For the finalisation of the draft before the formal consultation the Agency also considered the following extra inputs:

- CER EIM views – SR fatalities and serious injuries – RCM types – OR gates (10/12/2020) (CER – EIM),
- CER EIM – using undeveloped event-gate instead of OR-gate (10/12/2020) (CER-EIM), as well as
- A joint proposal for final changes on Annex IV on SL assessment from NSA SE and NSA CH.

3.3. Resolution of issues raised on key CSM elements during the drafting period

The following solutions were developed, based on the WP member's discussions and contributions, in order to solve the issues expressed during the CSM development:

On the Safety performance assessment, the comments to the preliminary recommendation suggested that the elements of proof should be reviewed to ensure a strict consistence with the requirements of the CSM on SMS, the robustness of the assessment scoring method, and also ensure a clear compatibility with Certificate and Authorisation assessments.

The WP members improved the Safety performance assessment in clarifying the following:

- The whole process is delivered in two steps:
 - The self-estimation of their own performance by the operators themselves, including the provision of reference allowing the NSAs to check the correctness of the self-estimation.
 - An assessment of the operators based on their self-estimation, using harmonised indicators
 - The self-estimation steps was discussed in depth to ensure with the WP members that the requested elements of proof are fully consistent with the already existing applicable legislation and also with the so-called Maturity Model developed by the Agency with the NSAs and already used by some of them.
 - The assessment indicators, initially called 'scoring method' has been reviewed, simplified and clarified. In particular 1) no more aggregation is proposed between the PDCA areas of assessment 2) in the usability of aggregated indicators is considered feasible by some, but not by all WP members, and the meaning (relevance) of those indicators is still under discussion. As a solution, the detailed description of the estimators and of their relevance/uncertainty is given as a task for the Group of Analysts for complementing the Appendix C - Part C. This has no impact on the implementation of the first and second phases of the proposed CSM but will have to be finalised before the application of the third phase and in accordance with the agreed framework provided by Appendix C - Part B.
 - The interface with the processes of Safety Certification (SSC) and Safety Authorisation (SA) is covered in the following point.
- **On the respective responsibility of the NSAs and ERA in terms of safety performance assessment**, it was clarified that some NSAs did not foresee to use the harmonised Safety Performance assessment provided by the CSM ASLP to support their supervision role while other NSAs considered

that they will use it also in this context but they may need to exercise a review to obtain a genuine and acceptable ‘assessment’ in the context of their supervision.

The discussions were also related to the potential relationship between the Safety performance self-estimation and the processes of Safety Certification and Safety Authorisation. It was clarified that the CSM ASLP do not, and cannot, replace Safety Certification and Safety Authorisation because:

- It is limited to the ability to control risks with risk control measures, which only partly covers the requirements of the CSM SMS,
- It does not cover the entire scope used for Safety Certification and Safety Authorisation,
- It is a snapshot used to help the identification of possible improvements.

The consensus agreed in the working party consisted in the following improvements:

- To clearly distinguish the Safety Certification and Safety Authorisation processes from the CSM ALSP requirements and to reinforce the idea that the main objective of the CSM ASLP is to support the operators to identify possible improvements, the operators have to report **self-estimations**.
- This is to be understood in the context where the NSAs can always request a review of the self-estimations, in application of their supervision role established by the CSM on Supervision (complementarity of the two CSMs),
- This is also reinforced by the requirement in section 5 of Appendix C –Part B that the CSM shall be complemented by the Group of Analysts proposals describing the practical detailed implementation of the Safety performance assessment to be reported in Appendix C – Part B, defining exactly the harmonised method the Agency will have to implement to each operator and with the help of the future Information Sharing System, without making own judgement, in a traceable manner.
- To clearly indicate that the CSM ASLP is an harmonised assessment, to be considered as a support to NSAs’ supervision role but not as a replacement of it, the whereas (3) was introduced,
- To explicitly allow the NSAs to request a review of the Safety performance assessment inputs (self-estimation of operators) for those NSAs desiring to use the CSM ASLP assessment results as a support to their supervision decision-making (see Article 4.6).
- To confirm that ERA would strictly apply the harmonised method defined in the CSM ASLP without making own judgement at the place of the NSAs supervision, so the result of the CSM ALSP assessment is directly resulting from the inputs delivered by the operators self-estimation (see Article 5.5)

- **On the Safety level assessments** it was confirmed that at least two methods for which some WP members have already a strong experience (over ten years implementation), could be used based on the reporting of the occurrence of certain category of events. After long and repeated discussions the same arguments were still opposing basically the two possible methods for estimating safety levels 1) a frequentist approach using the frequency of occurrence of events and 2) a Bayesian approach using both the frequency and the severity of occurred events.

The initial proposal from the Agency allowed in principle the two methods, however WP members’ views were quite strong and remained opposed one the method to choose while both methods have been applied with relevant experience clearly demonstrated for both. Due to the lack of time, while having the assurance that both methods can be used for the CSM objective, it was not possible to detail further how each of the method or the both methods could be used (or combined) in practice, in the context of the CSM for the safety level assessments.

The solution adopted consisted in the following elements:

- In agreement with the WP members, NSA Sweden and NSA Switzerland made a last amendment proposal received by the Agency after the 8th WP meeting. It was including a

broader mathematical description of the Safety Level estimation, clearly framing the foreseen estimation while leaving the possibility for the Group of Analyst to further detail the practical application of the two possible methods. In turn, it is a solution allowing more time to finalise the details of the assessments while they are actually framed by the CSM. It does not compromise the implementation phasing of the CSM, as in any case, it will actually be practically feasible to implement those assessment to each operator (in practice >1000 x 4 assessments per year in EU) only when the Information Sharing System will be made available. The proposed amendments were integrated in the CSM recommendation by the Agency.

- In order to formalise the detailed application of Safety level estimation framework defined by Appendix C – Part A, the WP members agreed to clearly request the Group of Analyst to complement the Appendix C with the description of the detailed application of the Safety Level assessment. This is reflected in section 7.2 of Appendix C – Part A.
- At the request of CER and EIM the initial proposal was also completed by a process of allocation of occurrence causes in order to fully ensure the applicability of the Safety Level estimation, including a fair treatment of operators and a better comparability of the results. The relevant rules are reflected in the proposed CSM by the Section 5.1.3 of Appendix C – Part A.
- Finally, the WP members noted that for small operators the Safety level methods could only be applied if enough events could be reported, meaning that in practice the Category B events should be used and that Category A events may not be statistically significant to assess operators who would not have a sufficient volume of operation.

- **On the reporting of individual occurrence**

The main identified issues resulting from the consultation on the preliminary draft, concerned mainly the assurance the CSM could provide on the clarity of the reporting requests and on the overall quality and comparability of the Safety Level assessments based on occurrence reporting and at the same time the limitation of the number of occurrence to be reported.

The solution adopted to improve the initial draft progressed in the following way:

- In depth discussions on the current practice of the NSAs and operators in regards the CSIs reporting took place. It resulted in a better view of difficulties for the NSAs to collect and check correct reporting, showing that already with the current CSIs uncertainties exist and that NSAs had difficulties to reduce those uncertainties despite their efforts. The obvious conclusion was that uncertainties shall be taken into account for Safety level estimations and this was clearly indicated in the Safety level assessment requirements. In addition it was demonstrated that statistical methods exists to take uncertainties into account.
- It was also considered that the clarity of the reporting request could help at the source of the reporting. The WP recognised that the current RSD definitions of the significant and serious accidents are complicated to understand because they combined criteria concerning the type of operation, the type of accidents and the extent of severity. This is why the CSM ASLP is proposing to use unbundled definitions for 1) event type 2) seriousness and 3) category of operations, fully consistent with RSD but which can be used in a more flexible way to define which occurrence shall be reported.
- In complement, the concept of ‘smart criteria’ reporting was proposed, consisting in targeting better the type of events for which it is not necessary to repeat indefinitely the collection of information as it would lead to low benefits compared to similar reported events. The ‘smart criteria’ concept was introduced in the CSM in the form of so-called

‘reporting on request’. The reporting on request is based on a clearly defined occurrence collection process ensuring a fair and proportionate application on operators (automatic selection by the information sharing system independent from the operator concerned).

- The establishment of a harmonised taxonomy was based on past EU projects, including COR project, as requested by the Mandate. Despite several requests for additional input to improve the harmonised taxonomy, the Agency received only few proposals. The Agency considers therefore that it shows the proposed taxonomy can serve as a decent baseline for the future work of the Group of Analysts.
- The ‘baseline’ harmonised taxonomy will be supportive to further harmonisation and will help non-discriminatory application of the reporting criteria. This baseline taxonomy will also allow establishing an improved level of comparability throughout the Union, while nowadays operators have also to comply with several national obligations, diverging from this harmonised taxonomy or supplementing it. As a consequence, it is clearly identified that a ‘transition period’ will exist where national legislations will have to progressively converge toward a better harmonised situation to the benefit of the operators and a reduction of their effort to comply with the applicable legislation.
- The transition period will be helped, based on collective improvement by the Group of Analysts, including NSAs representative and the sector, as establish by the proposed CSM. In case of need, for example if a systematic issue in the comprehension of a type of event is identified, or if a type of event to be reported nationally would qualify for further integration into the harmonised taxonomy, it would be possible to update the harmonised taxonomy.
- It is also identified that the Group of Analysts will have to supplement the taxonomy with a definition for each applicable event type. As only one WP member has proposed extensive definitions, it is suggested to start further work on the taxonomy with this basis, but using the collective Group of Analysts process.

- **On the reporting of occurrence scenarios**

- The harmonised reporting of occurrence scenario is the most powerful element for both individual and collectively learning on the reasons leading to the occurrence of accidents and is already a requirement for individual operators to investigate occurrence in accordance with the CSM on Safety Management System. At the same time it was reported as to be the most complicated exercise by the operators.
- The harmonisation method was tested by CER and EIM on several examples and was improved following these tests and the comments reported by UNIFE and the discussions at the working party meetings. Based on this the Agency checked the applicability of the method on >50 NIB reports and on complicated cases, gaining the assurance that the reporting of scenarios, as proposed by the CSM is applicable, consistent with existing norms, and can be used in consistency with Regulation (EU) 2020/573.
- Thus, the Agency considers, in line with the Mandate, that the reporting of the occurrence scenarios (causal chains and underlying/systemic factors) is not only the main room for collective learning but it will also be applicable by all parties, allowing to use a harmonised ‘language’ for discussing the cause of accidents and to prevent their reoccurrence.
- It must also be noted that the reporting of scenarios has no direct impact on the assessments of operators, thus it can be fully and only considered as a support to the prevention of reoccurrence of their relevant accident types.
- However, it was acknowledged that this exercise remains difficult at every level (operators, NSAs, NIBs, JNS) and the Agency agreed that the process for reporting occurrence scenarios described in the CSM should be assisted by guidance and a specific graphical tool (module of

the Information Sharing System) allowing to assist the reporting of the scenarios in a correct and effective manner, preventing reporting errors.

- **On the Group of Analysts** the main questions were relating to the compositions of this group, its governance, if it would integrate the current Joint Network Secretariat and the clarification on the rules for accessing operators' data by this group.

The discussions with the WP members as well as the assessment of the possible legal status led to the following solution:

- o The Group of Analysts governance and organisation of its activities is drastically simplified if this group is operated as a permanent working party of the Agency.
 - o The reasons are that, as a Working Party, it can strongly and efficiently contribute to the future development and adaptation to the technical and scientific progress of the railways in safety matters, including proposing the amendments of the CSM itself, as a working party the composition of this group can be govern by already existing Agency Regulation, allowing a convenient composition, using a call for experts.
 - o The status of a working party is also compatible with the work performed by the current JNS and it allows its integration, providing a legal status to this pre-existing group, as requested by several working party members.
 - o The status of this group is completed by the description of the rules of sharing rules applicable to any entities implementing the CSM. If necessary the CSM foresees the possibility to establish an agreement for disclosing additional data and information to the Group of Analysts in addition to the data and information made available by default. This mode of functioning is also adapted to the integration of the JNS where no disclosure agreement apply when specific discussions on a particular accident take place.
 - o As a working party the working arrangements of the Group of Analysts will be approved by the Management Board.
- **On the Information Sharing System (ISS)** the main questions were relating to the rules governing the data and information exchanged with this systems by each user of this system, the applicable workflows, the common digital interface and the possibility to connect pre-existing reporting systems (from operators or from the authorities, or other parties) the detailed description of the system functioning, service level, traceability, recovery...

To those questions, the final draft CSM brought the following solutions developed with the collaboration of the WP members:

- o The rules for sharing data and information are covering each category of entities and each category of data type, with full consistence on applicable EU legislation. This is described in the CSM proposal including also a generic process for managing the information received or sent to each category of entity. It is compatible with national legislation.
- o The CSM provides the necessary elements in terms of roles and responsibility for the usage of the future ISS.
- o However, the CSM cannot provide a detailed description of the functioning of the ISS (but only high level requirements) because this system does not exist yet. It has to be developed similarly to what was already established by other Agencies, like the Maritime or Aviation EU agencies.

- This situation does not prevent to start the implementation of the CSM on a very limited scope, using existing ICT tools of the Railways Agency (for example the Extranet) however the Agency will be strongly impacted by the need for manual resources this would imply. It is strongly recommended to develop the ISS as soon as possible, within the limits of the allocated budget.
 - In terms of CSM implementation, it means that the second phase of the CSM can only start when an ISS can be used by each entities.
 - The full CSM is not applicable without ISS as in Europe, only a part of the countries (authorities) and only a part of the 'big' players are equipped with systems, partly covering the CSM requirements.
- **On a transition period / phasing of the CSM implementation** and as indicated previously, no ICT system able to fully implement the propose CSM exist today, in any of the entities having contributed to the CSM development. Therefore the CSM, and the ISS in particular, shall be seen as serving the bigger purpose of the Digitalisation of the sector in the field of safety. A transition period is thus needed and is well-justified.
- To solve this issue, the Article 11 of the proposed CSM is anticipating a phased implementation of the CSM taking into account the need to ensure the digital applicability of the CSM for all actors, from small to big operator and for each authority having currently (or not having) well-developed system.
 - The CSM is also clearly integrated in a process that allows to trigger necessary amendments during the transition period in order to ensure the full practicability of the CSM before requiring the implementation of a specific implementation phase.
 - The above is also to be seen in the context that the scope of reporting requirements, especially in the first phase, is practically matching with the already existing scope of the CSM on Monitoring and the CSM on SMS, as well as with the reporting on occurrences needed to establish the CSIs. Thus, during this phase, the effort required by the CSM is mainly a digitalisation effort, with the aim to enable collective learning based on harmonised rules for sharing data and information.
 - However, the extend of this effort is not neglected and this is why the first and second phase of application is proposed to be rather limited and the assessment of operators has requested by the Directive (EU) 2016/798 will only be achieved during the third implementation phase.

4. Consultations of the National Safety Authorities

4.1. Continuous information and feedback of the National Safety Authorities

In addition to the consultation of the NSAs representatives to the work of the Working Party reported as part of the section 4, the Network of the National Safety Authorities were continuously informed of the CSM ASLP development progress and had the opportunity to express its collective view.

While the development of the CSM text was developed in the working party a certain number of exchange between the National Safety Authorities and the European Commission took place. It principally resulted in the possibility to establish a phased implementation of the future CSM, with the identification of what would be expected as form the first phase.

The final draft for consultation already took into account the above phasing in its Article 11.

4.2. Results of the formal consultation of National Safety Authorities

The formal consultation started on 17 December 2020 and was closed on 17 March 2021. The consultation was also forwarded by the OTIF secretariat to the Technical Committee of Experts.

The results of the formal consultation of the National Safety Authorities was presented and discussed with the Network of the National Safety Authorities on the 27 April 2021 during a meeting specifically organized for this purpose.

Those results as well as the outcomes of the discussions are presented hereinafter.

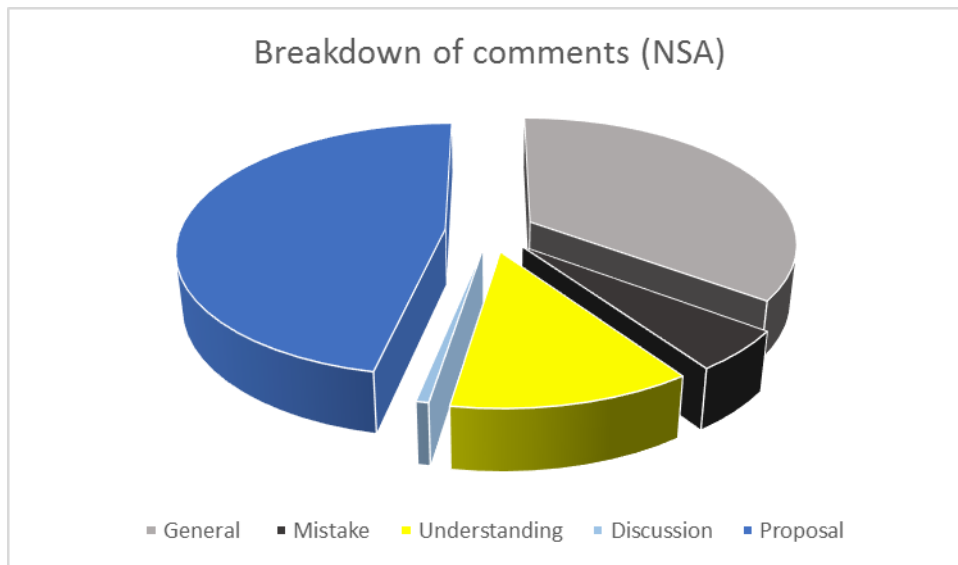
4.2.1. The comments received

The Agency received the following sets of comments. Representing the number of lines filled-in in the applicable comment template.

40	NSA AT
8	NSA PT
13	NSA FI
36	NSA ES
24	NSA IT
8	NSA NL
11	NSA DK (in the form of a letter)
20	NSA SE
4	NSA LT
10	NSA BE
5	NSA NO
29	NSA DE
7	NSA CH
27	NSA FR
242	Total number of lines of the applicable comment template
310	Actual number of comments contained in the response and answered by the Agency

In practice, the number of comments made in each line of the applicable templates can be higher than only one per line. This is why the Agency actually responded to a total of 310 comments.

The comments received followed this breakdown:



General	109
Mistakes	16
Understanding	38
Discussion needed	2
Proposals	145

It should be noted that sometimes the actual nature of the comments could belong to another category but this has no real influence on the practical usage of the comments received.

The Agency has carefully analyzed and responded each comment that will be made available on the Agency recommendation webpage.

In accordance with the applicable template the answers are allocated into the following categories:

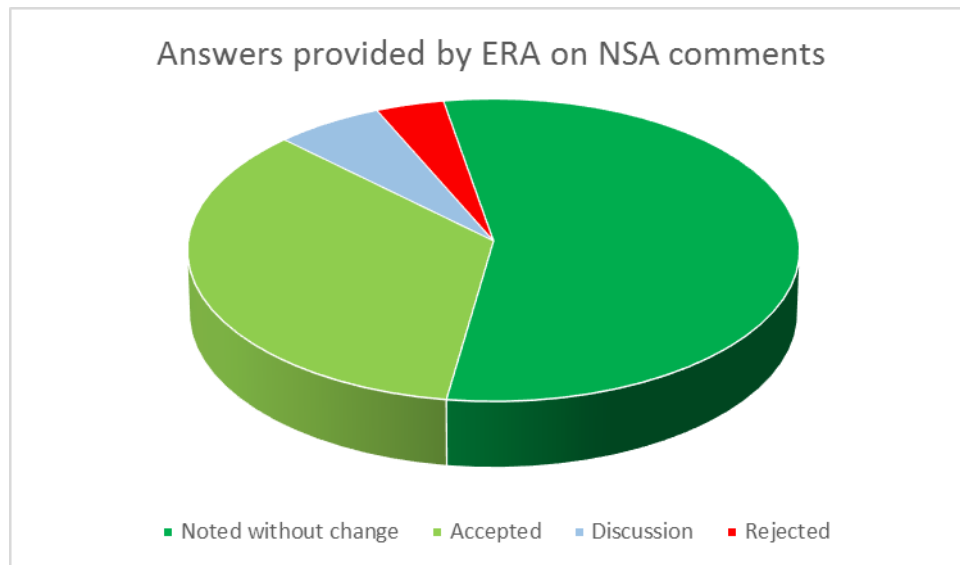
Noted without change: This category is applicable when the comment suggest an improvement of the CSM that is already covered by the proposal, meaning that a clarification may be needed ; or the comment is of general nature not calling for an actual change of the CSM text,

Accepted: This category is applicable when a comment can be taken into account to actually improve the CSM text,

Discussion: This category is applicable when the Agency consider that the CSM may be improved but several alternatives are possible and should be discussed with the WP before deciding on an amendment, or the CSM does not need to be amended but the Group of Analysts should take into account this comment for its future work,

Rejected: This category is applicable when the proposal for amending the CSM is not applicable because either, it is inconsistent with the applicable EU legislation, or it is seen as in contradiction with the Mandate requirements or objectives.

In accordance with the above the Agency has answered the NSA comments as following:



Noted without change	172
Accepted	108
Discussion	19
Rejected	10

The topics covered by the *Noted without change* do not need to be summarized here as they are covered by the solutions developed by the working party as indicated in section 4.

Below only the remaining comments are qualitatively analysed.

4.2.2. Qualitative analysis

4.2.2.1. Accepted comments

The *Accepted* comments are resulting in a strong improvement of the CSM, also comforted by the results of the social partners and user's consultation, as following:

- Strong simplification of the CSM structure with the integration of 6 Annexes into the 4 pre-existing Appendices
- Re-drafted Articles 2 and 4 to simplify and clarify the requirements to be applied by the operators directly visible from the core CSM Articles,
- Re-drafted Article 11 in order to:
 - o Express in a clearer way the phasing of the CSM implementation conditioned by the fulfillment of criteria to start the next phase
 - o Express a clearer application scope for each phase
 - o For indicating that a start of the next phase is conditioned by a recommendation of the Agency to the European Commission
- Improved Articles 6, 9 and 10 to clearly indicate that the lessons learned with the Group of Analysts shall be taken into account by the Agency when delivering an Opinion or a Recommendation concerning the CSM ASLP,
- Introduction of a few clarifications concerning the Information Sharing System (traceability of data, free access to data...)

The *Discussion* comments were reviewed with the working party during its 9th meeting (14-15 April 2021) and with the NSA Network (27 April 2021). It led to the following further accepted amendments:

- The introduction of the data items concerning a first estimation of the fatalities/injuries and damages into the 'Simple reporting' requirement, as it will be used by some NSAs to check the correctness of the reports by operators and it could also be used for supporting the implementation of the CSI regime,
- Additions in the description of the location of an occurrence (*Country Location name Station name or line number*) can be accepted for the first phase however, the Agency Management Board has adopted a decision on 'once only' reporting strategy. In principle the Geographical coordinates should give access to all the other information retrieved in other systems (for example from RINF). In the medium / long term, we propose that only the Geographical coordinates remains mandatory, other attributes should be optional as they will be retrieved automatically.

4.2.2.2. *Comments not requiring a modification of the CSM, but forwarded to the Group of Analysts*

The points concerning, further improvement of the taxonomy, the self-performance assessment, the guidance on risk control measure reporting, the Group of Analyst composition and detail functioning were already covered by the general process of the CSM continuous improvement and by the adoption of the Group of Analysts working arrangements to be adopted by the Agency Management Board.

Those comments do not need an amendment of the CSM because it is part of the normal improvement process integrated in the CSM.

Other comments have been considered by the Agency as not leading to an immediate need to propose CSM amendments but that it would be preferable to re-discuss potential future improvements with Group of Analysts, taking into account the lessons learned from the CSM implementation. Those comments are the following:

- (AT – comment 9) *“There should also be a comparison over time, especially to provide an incentive to set the targets ever tighter and higher to enable an improvement in safety”.*

The Agency considers that in accordance with the possibility offered by the Mandate to recommend further improvement of the EU legislation, including on a possible revision of CSI and CSTs, the Group of Analysts may add the potential improvement of safety level targets in their work plan for a future discussion when experience has been gained with the first phases implementation of the proposed CSM, potentially leading to a future integration of the CSI / CST workflows in the CSM ASLP.

- (ES – comment 5) *“It is proposed to specify the definition of type C event. Category C event means a variation in the performance of a railway function or the action of external events with the potential to directly or indirectly cause a category B event.”*

The Agency considers that further amendment of the Category C definition may take place after a discussion with the Group of Analysts, as the usage of the taxonomy in the first implementation phases may require a coordination of several needs for improvement. The Agency has integrated your proposal as a note in the taxonomy appendix, but did not change the definition which is broader. In this way it will let more flexibility for potential future change proposed by the Group of Analysts in case it would be needed to formulate a new Cat C event type in another way than a 'variation'.

- (ES – comment 22) *“In the data sets of Annex I, in the field of validation date & time, there is no reference to article 4.2 as indicated in Annex II (page 36). In addition, a possible inconsistency in the use of the terms is identified: article 4.2 makes express mention of the NSA, TDGA and EUAR but, nevertheless, in the data set on page 36 (already mentioned) in section 4.1 (page 55) and in the data set on page 56 there is reference to national supervisory authority and supervision authority.”*

This comment is not anymore applicable after the re-drafting of the Article 4 and the removal the sharing requests from the annexes. As discuss at the 9th working party the review by the authorities is possible at any time in accordance with new Article 4(6) independently form the dataset type reported as soon as the concerned data and information falls within the competence of the requesting authority. Those detailed sharing request may be reintegrated when the Group of Analysts will described the functioning of the ISS, potentially supplementing Appendix D (new structure) or in guides.

- (ES – comment 25) *“In relation to the reporting of volume of operation, it is requested that the number of freight ton-km to be reported only by the IM. It is proposed to be provided by the RU.”*

The 9th working party discussion concluded that IMs shall report the volume of operation performed on their infrastructure and that RU shall report the volume of operation they perform in each country they operate in accordance with their certificate. This is corresponding to the proposed CSM. As this point is only potentially influencing the third implementation phase of the CSM, earlier checks maybe discussed with the Group of Analysts.

- (ES – comment 26) *“In relation to the reporting of volume of operation, with the current wording it is requested that the following data be reported only by the IM: - Number of operated terminals. - Number of rail vehicles processed in terminals - Number of operating hours in terminals Given that there are terminals in whose exploitation the IM does not participate, it is proposed that the RU is responsible for providing this information in relation to the exploitation carried out under its responsibility.”*

The 9th working party discussion concluded that IMs shall report the volume of operation performed on their infrastructure and that RU shall report the volume of operation they perform in each country they operate in accordance with their certificate. The Agency understanding is that there is always an IM which shall fulfil the roles defined by the RSD, even if the terminal is fully operated by RU(s). The CSM is in line with this approach. As this point is only potentially influencing the third implementation phase of the CSM, earlier checks maybe discussed with the Group of Analysts.

- (ES – comment 27) *“Reviewing the fields of the table are consistent with those of the rest of the tables included in the Annex. In the request table the notification field states an end of reporting period +2 months”, when it seems that it should refer to a closing time..”*

This comment is covered by the re-drafting of the Article 4 directly containing the reporting deadline set to one month, as presented at the meeting with the National Authorities. In addition, a general validation period is set in the Article 5(1) to 1 month for any data received, which correspond to 2 months in total, in line with the former sharing request drafting. As this point is only potentially influencing the third implementation phase of the CSM, earlier checks maybe discussed with the Group of Analysts, if needed.

- (IT – comment 5) *“To guarantee an effective and efficient coordination about data collection avoiding duplication or inconsistencies, it is advisable to carry out more clarification on the consistency between the SL data collection and the national rules in force about timing and reporting of accidents and incidents.”* and,
(NO – comment 1) *“NSA Norway strongly request that CSM ASLP text clarify whether it will be possible for the NSAs to impose on the various parties that they use a pre-existing notified system.”*, similar comment also reported by other parties.

The discussions at the 9th Working Party meeting and in particular at the meeting with NSA Network led to the following conclusions on this topic. For those parties who already have well-developed systems but non-harmonised, a transition period towards a full harmonisation with the 'Information Sharing System' is to be organized to ensure further data sharing simplification and further efficiency gains. During this transition period, the full harmonization of the data and information on safety should remain a clear objective and everywhere possible the harmonisation of national rules setting requirements on monitoring or on supervision, on the top of the this CSM proposal should be further implemented. The management of this transition period will be facilitated by the establishment of Group of Analysts which can further clarify the interactions with national rules when developing the ISS business requirements and related guidelines.

- (IT – comment 11) *“In the context of the Common Safety Method a distinction is made between the ‘risk control measures’ functions and performance and the “management of the risk control measures” established to set-up, operate and maintain the designed functions and the expected performance limits. The relevant definitions must be inserted in the text.”*

In the context of the simplification of the CSM text as requested by the NSAs, this explanatory part has been removed because these explanations are more relevant for a guidance but do not specify the method, role or responsibilities. It is thus not needed anymore to introduce definitions for the management of RCM in the CSM ASLP. Further guidance can be provided outside of the CSM ASLP, taking also SMS requirements into account. It was also agreed that the Group of Analyst and the Agency will collaborate to develop those guides.

- (IT – comment 12) *“It is necessary to use the definitions of the Directive 2016/798 in order to avoid mistakes during the collection of data for CSI due to the similarities with CSM ASLP data; it may be appropriate to extend the application to the “significant accidents” as defined in the Safety Directive.”*

The Categories of events defined by the CSM are actually using consistently the 'Accident' and the 'Incident' definitions of the Directive 2016/798. Serious and Significant accidents pursuant to this Directive are smaller groups included in the bigger group of Category A events.

The collection of CSIs is not affected by the CSM ASLP.

The 9th Working Party and the discussions with NSAs led to agree that the definitions of the Directive 2016/798 are complicated and that a future evolutions of the Directive are possible to simplify the EU legislation concerning the monitoring and supervision of railway accident and incidents when the CSM ASLP will be implemented with a stable and effective regime. A review of the CSIs annex could then be proposed by the Group of Analyst when sufficient experience is gained with the implementation of the CSM and if it is demonstrated that it would be more efficient to extract the CSIs from the CSM ALSP reporting.

4.2.2.3. Comments which are not supported by the Agency

During the 9th meeting of the working party (14-15 April 2021) and with the NSA Network (27 April 2021) the Agency also reviewed the comments which cannot be supported by the Agency. These are the following:

- (FI) *“Since only some parts of the CSM are applicable in the first phase (before ISS) the text of the CSM could be simplified by removing all parts that are not applicable in the first phase.”*, and
- (BE – comment 1) *“The text of the CSM should be simplified by removing all parts that are not applicable in the 1st phase and that are susceptible (and likely) to be changed before application.”*, and

- (DE – comments 1, 23 and 27) *“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.”*, and
- (FR – comments 1, 21, 24, 25, 27) *“... leaving only technical details regarding what is necessary for the implementation of the first phase”* and, *“Annex IV – From §4 to §8 : transferred to Appendix C and marked as reserved inside the Appendix C for the first version of the CSM”* (SL assessment), *“From §4 to 8 : transferred to Appendix C and marked as reserved inside the Appendix C for the first version of the CSM”* (SP assessment); *“Appendix B : reserved”* (self-estimation questionnaire)

The Agency considers that all appendices are needed from the first implementation phase, either for immediate mandatory implementation of occurrence and scenarios reporting, or as a baseline to support the implementation of Article 6 by the Group of Analysts. It is a basic principle of the proposed CSM that the Group of Analysts can make proposal when it is proven that the CSM should be improved, by learning on its implementation. Therefore the Agency does not support the proposal consisting in removing the baseline for implementing Article 6 to be used as a clear starting point by the Group of Analysts.

- (ES – comment 29) *“Anx IV §5.1.3 establishes that, for the purposes of the assessment of the SL, the occurrences will be allocated to the different operators according to their responsibility in the occurrence. In the SR data set defined in Anx I-General §3.1.2 (p.13), it is possible to include information on responsibility in the free text field. It is proposed that responsibility be specifically indicated by an additional field in the SR data set defined in Anx I-General §3.1.2.”*

The method for counting occurrence is actually NOT allocating responsibility, it is using the reporting of causation to apply a fair SL estimation (counting method). As the SR template already asks for reporting the deemed causes it is not necessary to amend it as requested (inclusion of responsibility reporting).

In addition, the RSD and the CSM SMS ask for investigating the causes as well as the contributing and/or systemic factors, not to allocate responsibilities to parties involved in an occurrence. It would be in contradiction with the RSD, thus the proposed amendment is not supported by the Agency. As a consequence, and to avoid confusion, the text concerning the SL estimation has been amended in order to remove the word ‘responsibilities’ from the corresponding paragraph.

- (ES – comment 36) *“Agreeing with the approach that a safe work environment is linked to railway safety, it is not considered necessary to make explicit mention that one of the main results expected from self-estimation in RCM planning is to keep and provide a safe working environment adjusted to Directive 89/391/ EEC. Therefore, it is proposed to delete the reference to Directive 89/391/EEC.”*

The proposed amendment is not supported by the Agency as we aim to keep consistency with Regulation 2018/762 on SMS requirements Article 3.1.1.2.

- (SE – from comment 1) *“We recommend removing appendices, annexes and obligations relating to ROS/RRCM, SP, SOR/DOR, as these are untested. We suggest the initial phase of CSM ASLP only contains parts relating to SR/DR/VR-reporting, as well as SL-evaluation, together with ISS and GoA.”* and,
(SE – from comment 9) *“We propose annex 5 .../ on safety performance / ... is removed from the initial version of CSM ASLP until correct methods are tested by GoA”*. and,
(FR – comments 23, 26) *“Annex III reserved”* (reporting of scenarios), *“Category B events : reserved ; Category C events : reserved ; Contributing factors : reserved ; SMS factors : reserved”* (taxonomy of events)

The phased implementation approach allows to introduce progressively the implementation of methods that have been developed with the working party.

The ROS/RRCM methods correspond to already applied methods that have been tested in many industries and that are consistent with existing standards, with the CSM on risk assessment and with Regulation (EU) 2020/573. The Agency has also tested the method of scenarios reporting (ROS/RRCM) on many accident investigation reports and has acquired the full assurance that the method is applicable and sufficiently mature to serve as a baseline. The Agency considers that ROS and RRCM is a starting point for the learning curve, in collaboration with the Group of Analysts, on the understanding of accident scenarios.

SOR is marked 'reserved' and has no impact on the CSM implementation.

DOR is actually used to limit the resource to be used for the CSM implementation for frequent accidents of two given types. Therefore the DOR shall be kept to limit the impacts of the CSM, however the DOR application text has been simplified.

SP method is derived from a combination of existing requirements in EU legislation with process capability standards and is compatible with the already applied MMM model, already applied in some countries. It is a mature baseline for the following work of the Group of Analysts which can be tested – **on voluntary basis** - in a harmonized way by the operators and the authorities, as indicated in the letter '*In response to the Commission note to the members of the NSA Network on Development of common safety methods for assessing the safety level and the safety performance of railway operators (CSM ASLP)*' of the National Safety Authorities to the European Commission (dated 6/10/2020).

We would like to emphasize that several checks and balances are in place in the CSM (e.g. provision of evidence, guidelines, and requests for review by a national supervisory authority) to mitigate the risk of inaccurate SP self-estimations. As such, while risks are acknowledged, we think that the self-estimation shall not lead to biased results. As such, SP data shall at the very least be meaningful. On the point that self-estimate results are not stochastic and therefore not appropriate data for conducting statistical inferences, we want to contend this point and further explore the limitations and possibilities of statistical analyses on SP data within the framework of Group of Analysts/Subgroup C. The discussions would concern both the nature of the SP assessment data and potential self-estimation errors. The proposed SP annex V (included in Appendix C of the final CSM proposal) does not preclude any of these discussions and therefore can remain in place.

The initial phase cannot include SL assessment for practical reasons: 1) the ISS is needed considering the number of assessments to be managed 2) the Group of Analyst is tasked to finalise the Appendix C with the detailed formulas applicable for the calculation of SL estimators. This is why SL assessment is proposed for implementation only in the third phase.

In summary, the Agency considers that all the appendices are needed, either for immediate mandatory implementation in the 1st phase, or as a baseline to initiate collective learning, including the support the elaboration of the future proposals of the Group of Analysts, in accordance with Article 6 of the proposed CSM.

- (SE – comment 14) *“We suggest the scope of this draft be reworked so that it only contains RU / IM reporting, removing all references to other entities for reporting.”*and,
- (DE – comment 15) *“Replace “any party” with “any railway operator”*and,
- (FR – comment 3) *“This regulation and its requirements related to sharing of data apply only to entities defined as railway operators (actually defined as RUs and IMs). In the current wording of article 2 and structure of the regulation, it is not clear whether natural persons are deemed to report in parallel, neither whether it is a possibility that should be offered by the future ISS. In any case, this is outside of the scope of the CSM and therefore the reference to natural persons should be deleted”*

The Mandate reads *“The methods to be defined shall also **build upon the regular exchange of information on the implementation of the existing assessment methods** and may be carried out through coordination groups at the Union level with the involvement of the relevant stakeholders”* and also reads *“**the coordination of railway undertakings, infrastructure managers, entities in charge of the maintenance, national reporting entities, national safety authorities, and the Agency in the sharing of safety occurrences related information.** This coordination shall be performed in accordance with the **appropriate governance and confidentiality rules** that will have to be defined in the recommendation in conformity with Union law, and in particular Regulation (EU) 2016/679 of the European Parliament and of the Council.”*

Therefore, even if the RUs and the IMs are the reporters of their data for their assessment, other stakeholders shall also be allowed to share information in order to align with the requirement for coordination provided by the Mandate. Therefore the scope of the CSM ASLP cannot be reduced only to RUs and IMs and the CSM shall establish clear rules for sharing information with any possible stakeholders.

The CSM Article 2 has been redrafted to put the emphasis that RUs and IMs are obliged to report information that is used for their assessment and also that other actors may share relevant information pursuant to the implementation of the CSM. The Agency believes that this is in line with the responsibilities for safe operation laying on RUs and IMs and also in line with the need to exchange information with stakeholders, other actors and third parties in order to exercise the cooperation with RUs and IMs required by Article 4(3) and Article 4(4) of the Directive (EU) 2016/798. The Appendix D of the final CSM recommendation (former annex VI) establishes clear information sharing rules, respecting Regulation (EU) 2016/679, with all those potential entities (stakeholders / actors / third parties).

- (FR – comment 6) *“The use of self-estimation only for the assessment of safety performance of railway operators still poses a lot of questions as it both implies a new and heavy burden for the operators to perform such self-estimation and is not sufficient to assess the safety performance of the railway operators as additional data and information should be considered for this (result of NSA supervision, residual concerns at the stage of certification and their treatments, etc.). Among the railway operators consulted at national level, their experience shows that such approach based on self-estimation depends on the maturity of the company (a more mature company would tend to challenge more its processes than a less mature one).*

We propose to leave room for more discussion and proposal inside the GoA in order to define later the methods to be used for the assessment of safety performance.

Proposal: 4(1)(b) ~~the self-estimation of data and information to be used for the assessment of its safety performance in accordance with the applicable method and request defined in Annex II;~~”

The principle to use self-estimation has been generally agreed by the working party.

The self-estimation is not a standalone tool. The aim is to provide assistance to the railway undertakings and infrastructure managers for self-estimating their performance and defining ways to improve their safety management system. We do not recognize the extra burden as the required elements are partly covered by the activities that are necessary to perform for an operator to comply with the CSM on SMS.

The proposed self-estimation is a good baseline for the assessment of operators, in addition the Article 4.6 allows NSAs to request a review in case of need. Therefore, it does not prevent NSAs to full carry out their supervision activities, but it can act as a supporting tool for harmonised input information.

In combination with the need to keep a baseline for the work of the Group of Analysts, the Agency does not support this proposal to remove self-estimation of operators.

4.2.3. Summary of the NSA consultation outcomes

From the above analysis the Agency has implemented all the proposed modifications and a **vast majority of the comments received could be accepted.**

As a result a drastic simplification of the CSM text will be achieved thanks to the consultation outcomes, in agreement with the NSAs comments.

However some proposals are still not supported by the Agency, as following:

- Removing the texts not mandatory in the first phase is not supported by the Agency as all the CSM text including its annexes and appendices is used at least by the Group of Analyst, including in the first phase, as a baseline;
- Removing the possibility (not the obligation) for 'any party' and 'natural persons' to report information is not supported by the Agency, as it seems not to be in contradiction with the applicable EU legislation, and it is considered as supporting positive safety culture and potentially the improvement of the quality of reported data (for example, less under reporting);
- Removing the reporting of occurrence scenarios is not supported by the Agency as it is considered as one of the most promising collective (but also individual) learning method, based on the weaknesses the Agency observes in this field, and as investigation of occurrences is already required by CSM on SMS;
- Removing from the application scope the RCM in relation with safe work environment is not supported by the Agency as it is in contradiction with the scope of the CSM on SMS, which is including it;
- Using the reporting of causes to directly allocate accident responsibility on a given operator is not supported by the Agency as the allocation of responsibility seems not to be the objective established by the Directive (EU) 2016/798 for the reporting of occurrence and investigation of accidents;

It emerged also that a potential for the Group of Analyst discussion, not requiring the amendment of the proposed CSM, should be noted on the following topics (inclusion into the Group of Analysts work plan by order of priority, starting from top priority):

- The elaboration of guides, in particular for supporting the reporting of occurrence scenarios, as from the first phase.
- Integration of lessons learned by the Group of Analysts on the use of the taxonomy(ies) and the further harmonization of it based on existing national rules on reporting.
- Learning in the voluntary application of the self-estimation before the mandatory implementation of SP;
- The management of a transition period for existing national rules on occurrence reporting;
- The implementation of the 'only once' reporting strategy, (collecting information directly from other operators reporting sources, where possible);
- Future amendment of the CSI and CST annexes, when enough experience is gained from the CSM implementation and feasibility is proven,

4.2.4. Outcome from the RID Experts consultation

No TDG competent authorities responded to the consultation forwarded by the DG Move (C2) to RID Experts.

4.2.5. Outcome from the OTIF secretariat consultation

From this consultation only UK, as COTIF contracting party, provided 10 general comments.

Those are reflecting questions and concerns that are already covered by the comments of the other consulted parties and thus are already covered by the previous sections of this report.

5. Consultation of social partners and users under Articles 6 and 7 of Regulation (EU) 2016/796

5.1. Continuous information and feedback of the Network of Representative Bodies

In addition to the contributions of EIM/CER/UNIFE and UIP representatives to the work of the Working Party reported as part of the section 4, the NRBs were continuously informed of the CSM ASLP development progress and had the opportunity to express their views.

5.2. Results of the formal consultation of social partners and users

The results of the formal consultation of social partners and users was presented and discussed at the 9th meeting of the Working Party. Those results as well as the outcomes of the discussions are presented hereinafter.

5.2.1. Representative Bodies' comments

The Agency received the following sets of comments. It is broadly corresponding to the number of lines filled-in in the applicable comment template, unless several comments are inserted in a given line of the template.

Comments received from CER, EIM and UNIFE

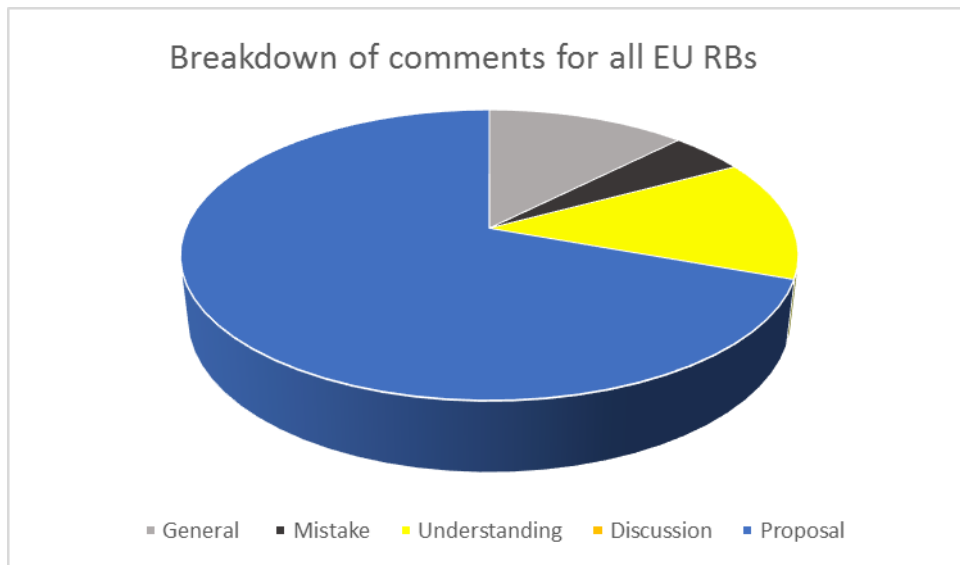
61	CER
110	EIM
21	UNIFE
192	(Total)

We noted that CER comments are containing a high number of matching comments with VDV (a National RB) (around 40 comments) and that EIM comments are containing a high number of matching comments with the operator ProRail (around 100 comments).

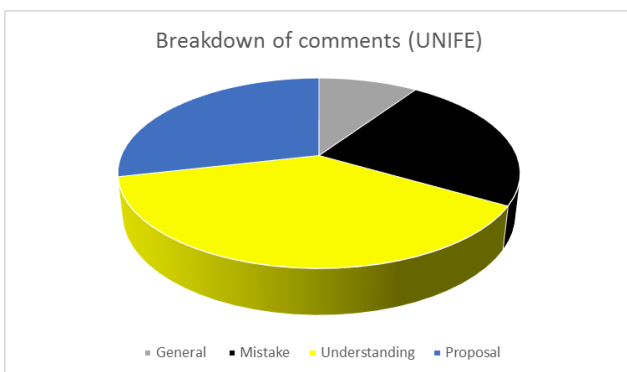
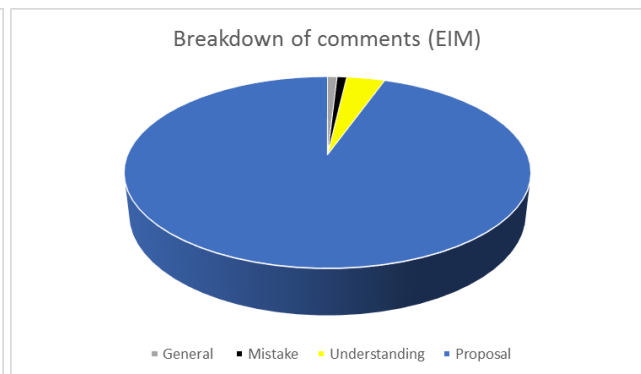
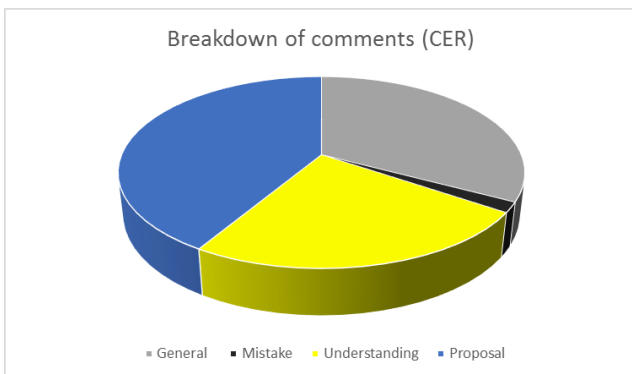
5.2.1.1. Graphical overview of EU RBs comments

In total, the Agency answered all the 192 comments from the Representative Bodies EIM, CER and UNIFE (EU RBs).

The comments received followed this breakdown:



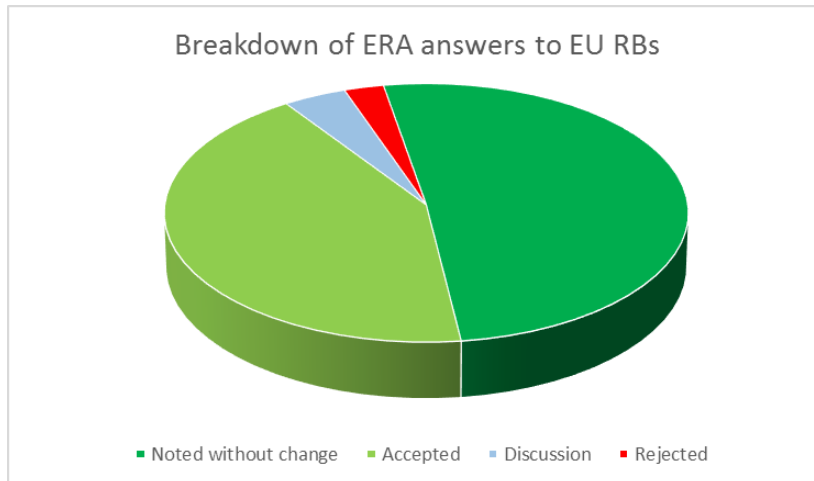
General	24
Mistakes	9
Understanding	26
Discussion needed	0
Proposals	134



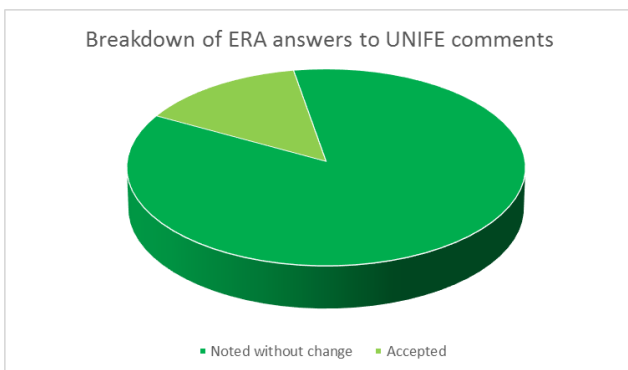
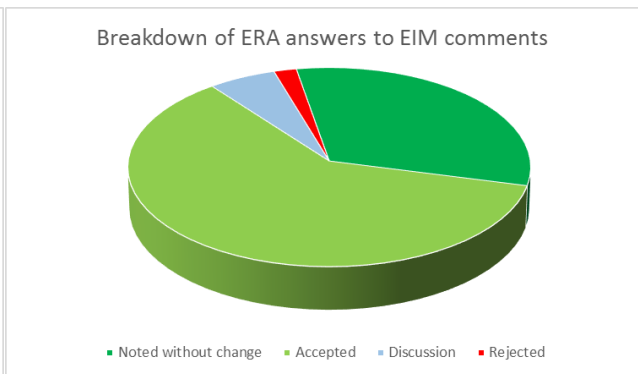
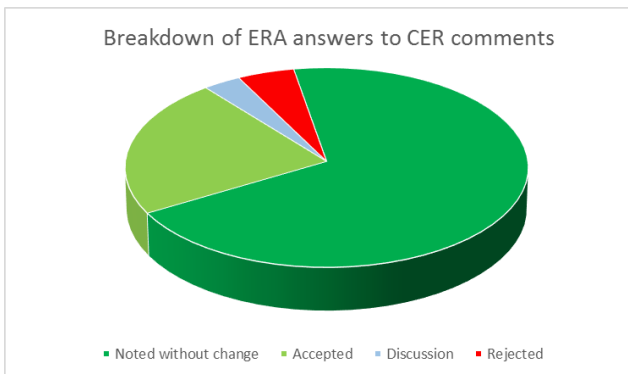
It should be noted that sometimes the actual nature of the comments may belong (for example, the type mistake in the CSM text, sometimes unduly used while the comment correspond actually to a position statement) to another category than the one selected by the respondent, however this has no real influence

on the practical usage of the comments received as all comments are analysed and provided with an answer by the Agency. The individual answers will be published beside the final recommendation on the Agency recommendation webpage.

5.2.1.2. Graphical overview of answers provided by ERA to EU RBs comments



Noted without change	98
Accepted	82
Discussion	8
Rejected	5



The topics covered by the ‘Noted without change’ comments do not need to be summarized here as they are covered by the solutions developed by the working party, as reported in section 4. Most of the comments are also corresponding to similar points as the ones reported by the National Safety Authorities.

5.2.2. Qualitative analysis

Hereinafter we address the comments that have been ‘Accepted’, or left for the work plan of the Group of Analysts and which do not require an immediate change of the proposed text in accordance with the continuous improvement approach established by Article 6 of the consulted CSM, or ‘Rejected’ with justification.

This analysis is a summary and the individual answers to each comments will be published on the Consultation website.

5.2.2.1. Accepted comments

- (CER – Comments 10, 15, 17, 33, 35, 44, 45 and 56)

Those comments led to an improvement or clarification of the existing text or the correction of mistakes, as following:

- Event taxonomy clearly indicating the events that are exactly corresponding to CSIs type events
- Re-drafted Article 4 clearly and directly indicating the obligations of the railway operators’ reporting
- Improvement of Article 4 to clearly indicate in which condition an authority can request a review of data and information reported by an operator
- Re-drafting of Article 11 to correct a mistaken reference and to introduce the phased implementation of the CSM triggered with clear criteria and taking lessons learnt by the Group of Analysts into account
- Clarification and improvement of referencing of (former) Annex II inserted in (new) Appendix B
- Further alignment of the Taxonomy of event with Directive (EU) 2016/798, setting ‘Gauge spread’, ‘Track twist’ and ‘Improper rail fastening and joints’ as subtype of ‘Track buckle and other track misalignment indicator’

- (EIM – Comments 4, 8, 14, 15, 18, 19, 20, 21, 24, 27, 29, 32, 33, 38, 39, 40, 41, 42, 43, 44, 45, 46, 48, 49, 50, 51, 52, 53, 54, 56, 57, 58, 59, 62, 63, 64, 65, 66, 68, 69, 71, 75, 76, 77, 78, 79, 80, 81, 82, 83, 86, 87, 88, 89, 90, 91, 92, 94, 95, 96, 97, 98, 99, 100, 102, 105, 107)

Those comments led to an improvement or clarification of the existing text or the correction of mistakes, as following:

- Re-drafting of Article 11 to correct a mistaken reference and to introduce the phased implementation of the CSM triggered with clear criteria and taking lessons learnt by the Group of Analysts into account,
- Correction of typos, and clarification of wording,
- Re-drafting of Article 11 to correct a mistaken reference and to introduce the phased implementation of the CSM triggered with clear criteria and taking lessons learnt by the Group of Analysts into account,
- Re-drafted Article 4 clearly and directly indicating the obligations of the railway operators’ reporting
- Article 4 improved to clarify the possibility for the operator provide further reporting updates and complements in accordance with Article 7.11, in case of absence of information at the time of the first reporting deadline.
- Clarification of requirement on the reporting of track damages,

- Adding headers to tables,
- Clarifying the section concerning DOR (re-drafted), in combination with the overall simplification of the CSM text, including the restructuration of the Appendices,
- Clarifying the aim of the self-estimation, and of the status of the Appendix B (description of expected situation)
- Definitions of contributing and systemic factors added with reference to Regulation (EU) 2020/573
- Objective to apply the sharing rules also with the temporary ICT solution,
- Clarification concerning the maintenance of the Group of Analyst risk classification scheme,
- Assessment of safety opportunities by the Group of Analysts
- Suicides not considered for default cause allocation
- Clarifications in the taxonomy of events
- Usage of the wording ‘reference element of proof’ with the possibility to propose justified equivalent elements.

- (UNIFE – Comments 5, 14, 17)

All the UNIFE comments have been categorized into ‘Noted without change’ except 3 comments which have been categorized in ‘Accepted’ category. There are no rejected comments.

Those accepted comments cover topic that were also reported by other stakeholders and NSAs, and correspond to an improvement or clarification of the existing text or the correction of mistakes, as following:

- Re-drafted Article 4 clearly and directly indicating the obligations of the railway operators’ in terms of reporting. As a consequence the sharing requests covering the same information have been withdrawn to simplify the CSM text. Potentially detailed sharing requests could be reintroduced in the form of guidance or as part of the future detailed description of the ‘Information Sharing System’.
- The entire CSM text is restructured to simplify the text (Annexes merged into 4 Appendices) and Articles 2, 4, 11 have been redrafted to better understand the requirements in each implementation phase of the CSM. The parts of the text corresponding to guidance, and not to requirements, roles or responsibilities have been removed for the CSM text. Those part can be used for the future drafting of guidance documents.
- The place of the CSM within the existing EU legislation was clarified in the CSM whereas, in particular indicating that the CSM ALSP has no impact on the other applicable legislation and is applicable in complement. It means that the roles of the NSAs are unchanged by the CSM ASLP in regards other legislation applicable by the NSAs. The Article 4 of the CSM has been clarified further indicating that the authorities (inc. NSAs) can ask a review of their reporting ‘*provided that the requested operator and the concerned data and information falls within the competence of the requesting entity*’. For the NSAs it means that it is possible, for example if it falls under their supervision role.

5.2.2.2. *Comments not requiring a modification of the CSM, but accepted and forwarded to the Group of Analysts*

- (CER – Comments 14, 46, 47, 60, 61)

Those comments concern the elaboration of guidance which is generally accepted by the Agency and should be developed in collaboration with the Group of Analysts.

- (EIM – Comments 9, 26, 72, 73)

Those comments should be considered for inclusion in the future work by the Group of Analysts, as following:

- Improvement of the taxonomy and of reporting quality is covered by the continuous improvement of the CSM established with the contribution of the Group of Analysts
- The detailed definition of the ‘degree of reducibility of the related risk’ is covered, in general, by the future work of the Group of Analyst on the complement related to the detailed definition of the Safety Level assessments, and thus the CSM does not need to be amended.
- The potential improvement of the normalizers based on ‘Volumes of operation’ is linked to previous detailed work to be done by the Group of Analyst. The results of this work will show if the current list of normalizers should be amended, as part of the generic CSM improvement process. Therefore it is not needed to remove the list of possible normalizers from the current CSM proposal, those normalizers are also part of the baseline for the Group of Analysts discussions.

5.2.2.3. Comments which are not supported by the Agency

- (CER – Comments 4, 6, 9, 11 and 52)

Those comments concern the following points:

- The restriction of the scope to potential reporter of safety relevant information only to railway operator ‘staff’ is not supported by the Agency.

The Mandate reads *“The methods to be defined shall also **build upon the regular exchange of information on the implementation of the existing assessment methods** and may be carried out through coordination groups at the Union level with the involvement of the relevant stakeholders”* and also reads *“**the coordination of railway undertakings, infrastructure managers, entities in charge of the maintenance, national reporting entities, national safety authorities, and the Agency in the sharing of safety occurrences related information.** This coordination shall be performed in accordance with the **appropriate governance and confidentiality rules** that will have to be defined in the recommendation in conformity with Union law, and in particular Regulation (EU) 2016/679 of the European Parliament and of the Council.”*

Therefore, even if the RUs and the IMs are the reporters of their data for their assessment, other stakeholders shall also be allowed to share information in order to align with the requirement for coordination provided by the Mandate. Therefore the scope of the CSM ASLP cannot only be reduced only to RUs and IMs and the CSM shall establish clear rules for sharing information with any possible stakeholders.

- The removing of ‘Natural persons’ from the Article 2 scope is not supported by the Agency as it seems not to be in contradiction with the applicable EU legislation, and it is considered as supporting positive safety culture and potentially the improvement of the quality of reported data (for example, less under reporting). Also, the data processing is controlled and protected even when it would be sourced by ‘natural person’.

The CSM Article 2 has been redrafted to put the emphasis that RUs and IMs are obliged to report information that is used for their assessment and also that other actors may share relevant information pursuant to the implementation of the CSM. The Agency believes that this is in line with the responsibilities for safe operation

laying on RUs and IMs and also in line with the need to exchange information with stakeholders, other actors and third parties in order to exercise the cooperation with RUs and IMs required by Article 4(3) and Article 4(4) of the Directive (EU) 2016/798. The Appendix D of the final CSM recommendation (former annex VI) establishes clear information sharing rules, respecting Regulation (EU) 2016/679, with all those potential entities (stakeholders / actors / third parties).

- The removing of damage reporting is not supported by the Agency as it is also considered as accident impacts by the Directive (EU) 2016/798. Removing it would be inconsistent with CSIs. This is in contradiction with the Mandate request.
- The complete removing of Category C events is not supported by the Agency as it is in contradiction with the CSM on SMS requirement to investigate occurrence and the source of prevention of reoccurrence is often laying at the level of Category C events or even in the area of contributing factors and systemic factors. It is also in contradiction with the Mandate request to learn on the occurrences causes.
 However, we agree that the Group of Analyst should work on a guidance allowing a proper usage of Category C events.

- (EIM – Comments 6, 7)

Those comments concern the following points:

- Changing the threshold of damage reporting is not supported by the Agency as it would be inconsistent with CSIs. The mandate requires consistency with CSIs.
- Changing the condition of reporting for the IMs only if the IM has a role in the risk control measure that could have prevented the occurrence and/or being impacted by the occurrence. it would basically mean that an investigation has to be done before a simple reporting is judged applicable. This is not supported as it seems un-practicable with the aim of ‘Simple reporting’.

- (UNIFE – Comments)

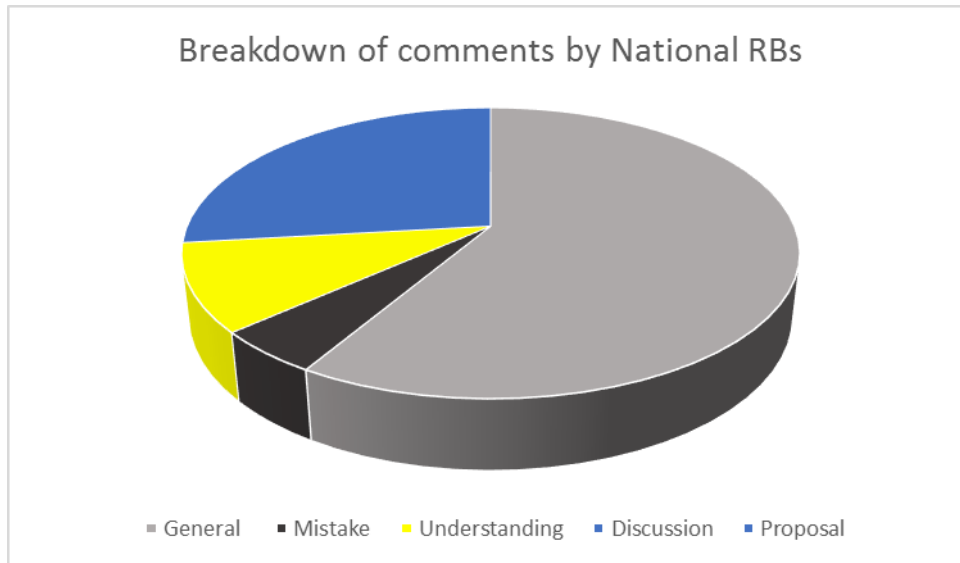
None of the UNIFE comments had to be rejected by the Agency. Some comments for improvement of the CSM are categorized ‘Noted without Change’ and will actually be covered in the generic workflow to be performed by the Group of Analysts.

5.2.3. Social Partners (National railway unions)

In total, the Agency answered all the 37 new comments from the National railway bodies (National RBs).

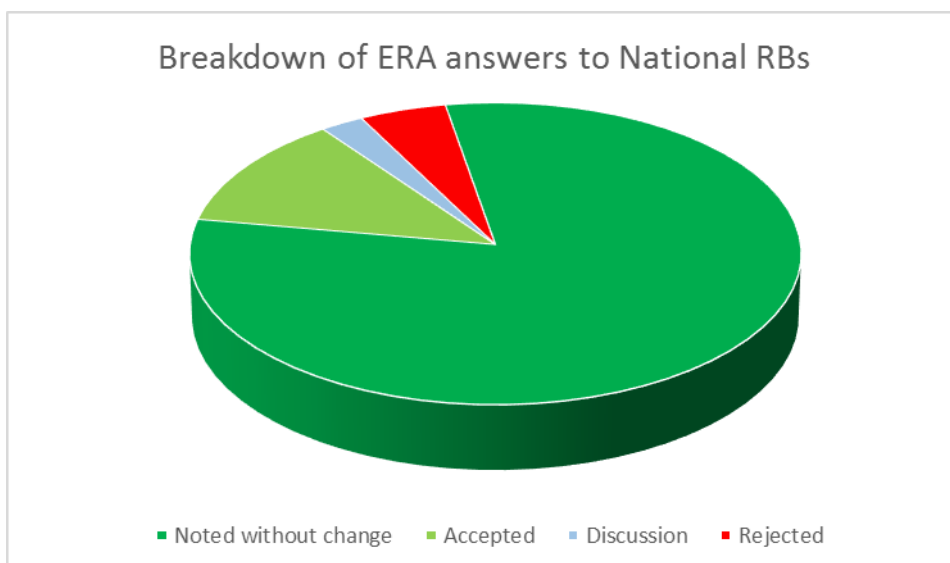
20	VDV (DE) (69 comments minus 49 comments that are already treated in CER matching comments)
8	ASTOC (Trafic safety group - SE)
9	UTP (FR)
37	(Total)

The comments from VDV are actually containing around 40 matching with CER comments, leading to the same Agency answers (not duplicated hereinafter).



	Total	VDV	ASTOC	UTP
General	24	14	4	6
Mistakes	2	2	0	0
Understanding	4	3	1	0
Discussion needed	0	0	0	0
Proposals	11	3	5	3

The analysis of the comments showed that the categories of comments are not always used in the appropriate manner as general comments actually contains proposal. This has no impact on the Agencies answers, as all the comments are analysed and answered.



	Total	VDV	ASTOC	UTP
Noted without change	33	17	7	9
Accepted	5	2	2	1
Discussion	1	1	0	0
Rejected	2	2	0	0

Several of those comments indicate that there are some misunderstanding of the legal framework or lack of awareness of the Mandate requirements. This led the Agency to mark 'Noted without change' those comments in order to keep alignment with railway legislation or with the mandate requirements.

5.2.4. Qualitative analysis

Hereinafter we address the comments that have been 'Accepted', or left for the work plan of the Group of Analysts and which do not require an immediate change of the proposed text in accordance with the continuous improvement approach established by Article 6 of the consulted CSM, or 'Rejected' with justification.

5.2.4.1. Accepted comments

- (VDV – Comments 13, 16, 17, 19, 38, 52, 53 and 64)

The accepted comments are covering the same topic as the ones accepted for CER comments. Therefore the analysis of VD comments is already covered by section 6.2.3.1.

- (ASTOC – Comments 1, 5)

Those comments are covering the same topic as the ones already covered in the other sections, and resulted in the following CSM amendments:

A phased implementation of the CSM is fully integrated in the Article 11, as also requested by other parties. It will facilitate the progressive implementation of the proposed CSM allowing time to operators to adapt. The smooth introduction will also be accompanied with lessons learned by the Group of Analysts, and guidance.

- o No double reporting is required by the CSM. The CSM is only requiring the RUs to report once, using EITHER the 'Direct' OR the 'Indirect' channel. It can be done through the NSAs (Indirect channel) or directly (Direct channel) to the Information Sharing System (ISS) which will forward the operators' information to the NSA, in accordance with the sharing rules established by the CSM. If imposed by a national rule, you may have to use the so-called 'Indirect channel' and the NSA will forward directly and immediately your information to the ISS in accordance with the CSM. However you also need to consider that one result of the consultation is that the Agency will accept national rules on occurrence reporting imposed by the NSAs to complement this CSM, as a transition period before further harmonisation of those national rules, with the aim simplifying the future operators reporting with further harmonisation between EU Member States.
- (UTP – Comment 3)

This comment, which actually composed of many proposals, is fully accepted by the Agency and already covered by the analysis of other Representative Bodies. The outcome for the CSM is mainly

resulting in the introduction of the phased approach, taking into account lessons learnt by the Group of Analysts, and allowing sufficient time to the operators to adapt to the new CSM.

5.2.4.2. Comments not requiring a modification of the CSM, but accepted and forwarded to the Group of Analysts

- (VDV – Comments 45, 63, 64, 65)

Those comments are covering the same topic as the ones from for CER comments for the topics to be discussed by the Group of Analysts. Therefore the analysis of those VDV comments is already covered by section 6.2.3.2.

- (ASTOC – Comments 4)

The Agency agrees with your comment leading to carefully consider a balanced geographical representation of the Group of Analysts members. This should be introduced as a rule in the Group of Analysts working arrangements.

- (UTP – Comments 1. 2)

Those comments do not require an amendment of the CSM. The concerns expressed by UTP are mainly resulting from misunderstanding of the Group of Analyst role or can be covered by future activities thereof.

5.2.4.3. Comments which are not supported by the Agency

- (VDV – Comment 9, 60)

This rejected comment is concerning the removing of the Category C event from the CSM taxonomy appendix and the restriction of the application scope of the CSM to railway staff only. Those comments are not supported by the Agency as justified in the section 6.2.3.3 relating to (same) CER comments (4 and 52).

- (ASTOC)
No comment from ASTOC had to be rejected by the Agency.
- (UTP)
No comment from UTP had to be rejected by the Agency.

5.2.5. Other Social Partners (German unions for chemical and petroleum industry)

In total, the Agency provided answers to those unions’ comments

6	VCI (German chemical industries’ union)
27	MWV (German petroleum industries’ union)

33	(Total)
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	Total	VCI	MWV
General	10	3	7
Mistakes	1	0	1
Understanding	10	0	10
Discussion needed	0	0	0
Proposals	12	3	9

The analysis of the comments showed that the categories of comments are not always used in the appropriate manner as general comments actually contains proposal. This has no impact on the Agencies answers, as all the comments are analysed and answered.

	Total	VCI	MWV
Noted without change	21	3	18
Accepted	12	3	9
Discussion	0	0	0
Rejected	1	0	1

The 'Noted without change' comments concern the applicability to the CSM of the definition of the Union railway system defined by Article 2(1) of Directive (EU) 2016/797, including its Annex I, as well as the applicability of the CSM to the scope of 'privately owned infrastructure' as defined by the Article 3(2) Directive (EU) 2016/798.

5.2.6. Qualitative analysis

Hereinafter we address the comments that have been 'Accepted', or left for the work plan of the Group of Analysts and which do not require an immediate change of the proposed text in accordance with the continuous improvement approach established by Article 6 of the consulted CSM, or 'Rejected' with justification.

5.2.6.1. Accepted comments

- (VCI – Comments 1, 2 and 5)

The accepted comments are related to the clarification of Articles 2 and 4, which is accepted by the Agency.

The other accepted comment is linked to the questions of the application scope of the CSM to the railway infrastructure of industrial sites, and thus to the reporting of occurrences relating to Dangerous Goods loading/unloading or filling/un-filling operations. Taking into account the application scope of reporting in both railway legislation and TDG legislation the scope of reporting

for loading/unloading or filling/un-filling operations is noted as optional in the context of the CSM, but it is also noted that such reporting may be required by other legislation.

However this scope is not removed from the CSM because the discussions with TDG competent authorities indicated that some MS may use the future ISS for the TDG occurrence reporting.

- (MWV – Comments 1, 3, 4, 12, 14, 15, 21, and 22)

The accepted comments are relating to the points also reported by VCI above, not requiring additional explanation in this section.

In addition the following points are also accepted:

- The CSM to be available in German, is normally applicable as the CSMs are translated in every EU applicable languages,
- Correction of a typo in Article 11, included in the complete re-drafting of Article 11,
- Improvement of the data items used for reporting the location of an occurrence,
- Clarification of the reference taxonomy to be used for SP self-estimation reporting (area 'P', area 'D'...)

5.2.6.2. *Comments not requiring a modification of the CSM, but accepted and forwarded to the Group of Analysts*

- (VCI)
No comment from VCI is concerning future discussions at the Group of Analysts.
- (MWV – comments 24)

MWV would like that that the CSM ASLP scope is mandatorily extended to Entities in Charge of Maintenance. As this possibility is foreseen by the Mandate, but not for the initial application scope, it may be relevant that the Group of Analysts consider such extension of the scope in their work plan and their future proposals.

5.2.6.3. *Comments which are not supported by the Agency*

- (VCI)
No comment from VCI had to be rejected by the Agency.
- (MWV – comment 9) *“Clarification that the national system used by the NSA is still the leading system in case of hearings or requests for information”*

The Agency considered this approach not in line with the setting of harmonized rules.

The harmonised data reporting are shared with the ISS.

Article 7(11) of the CSM states that any modifications of data and information retained in the Information Sharing System are notified to the connected systems (including NSA systems when applicable) which should be then updated accordingly to ensure full consistency with the Information Sharing System.

Therefore the notion of leading system is not really relevant as soon as a good consistency of data is achieved.

To ensure EU wide harmonised implementation of the CSM Article 7(8) and 7(9) clearly indicate that despite the datasets harmonised by the CSM should be the same in both the connected systems and in the ISS, in case of doubt the ISS will prevail as it is the harmonised reference system.

This approach is in fact confirmed by the discussions recently held at the dedicated NSA meeting organized on the 27/04/2021, which confirmed that existing systems and related national rules should progressively be aligned further with the CSM during a transition period.

The above does not prevent the NSAs to use their existing systems, including additional information they may contained for implementing their supervision role.

5.2.7. Individual Infrastructure Managers' comments

In total, the Agency provided 103 answers to comments from the responding Infrastructure Managers.

9	Trafikverket - SE
6	SNCF réseau - FR
11	BAN NOR - NO
18	ProRail (118 comments minus 100 comments matching the ones reported by EIM)
24	OBB - CH
24	ADIF - ES
92	(Total)

The comments from ProRail are actually containing around 100 lines of comments fully matching with EIM comments, which analysis is not duplicated by the Agency hereinafter.

	Total	Trafikverket	SNCF réseau	Ban NOR	ProRail	OBB	ADIF
General	27	2	6	4	1	7	7
Mistakes	13	0	0	0	11	1	1
Understanding	20	0	0	1	4	5	10
Discussion needed	0	0	0	0	0	0	0
Proposals	32	7	0	6	2	11	6

The analysis of the comments showed that the categories of comments are not always used in the appropriate manner as some general comments actually contains proposal. Some lines of comments are also containing several actual comments that are answered leading to a number of answered comments higher than the number of lines of comments received in the applicable template. This has no impact on the Agencies answers, as all the comments were analysed and answered.

	Total	Trafikverket	SNCF réseau	Ban NOR	ProRail	OBB	ADIF
Noted without change	49	10	5	8	3	10	16
Accepted	40	4	1	4	12	10	9
Discussion	5	0	0	0	1	3	1
Rejected	9	0	0	3	2	1	3

All the comments are responded in detail in the individual comment sheets that were sent to the Agency and will be published in the Consultation webpage.

On the basis of the comments already analysed from NSAs and Representative Bodies in the previous sections, we identified no new point needed to be highlighted in this section, as already covered by the previous sections.

5.2.8. Individual Railway Undertakings' comments

In total, the Agency answered to 94 lines of comments from the responding Railway Undertakings.

10	RENFE (ES)
6	CP (PT)
11	DSB (DK)
21	PKP (PL)
5	Hectorail (SE)
7	SNCF Voyageur (FR)
26	SBB (CH)
1	MOB (CH)
7	ILSA
94	(Total)

The comments from SBB are actually containing a lot of lines of comments matching with CER comments, which analysis is not duplicated by the Agency hereinafter.

	Total	Renfe	CP	DSB	PKP	Hectorail	SNCF Voy.	SBB	MOB	ILSA
General	37	5	6	6	1	5	7	6	1	0
Mistakes	1	0	0	0	1	0	0	0	0	0
Understanding	29	0	0	5	17	0	0	7	0	0
Discussion	0	0	0	0	0	0	0	0	0	0
Proposals	27	5	0	0	2	0	0	13	0	7

The analysis of the comments showed that the categories of comments are not always used in the appropriate manner as some general comments actually contains proposal. Some lines of comments are also containing several actual comments that are answered leading to a number of answered comments higher than the number of lines of comments received in the applicable template. This has no impact on the Agencies answers, as all the comments were analysed and answered.

	Total	Renfe	CP	DSB	PKP	Hectorail	SNCF Voy.	SBB	MOB	ILSA
NWC	70	8	6	8	13	5	7	19	1	3
Accepted	20	0	0	2	9	0	0	5	0	4
Discussion	2	0	0	0	0	0	0	2	0	0
Rejected	5	2	0	1	0	0	0	2	0	0

All the comments are responded in detail in the individual comment sheets that were sent to the Agency and will be published in the Consultation webpage.

On the basis of the comments already analysed from NSAs and Representative Bodies in the previous sections, we identified no new point needed to be highlighted in this section, each relevant element of information is already used in the previous sections.

5.2.9. Individual Logistic / Keeper /ECM companies

In total, the Agency answered to 16 comments from the logistic company Operail (EE).

16	OPERAIL (EE)
	(Total)

Operail		Operail	
General	1	NWC	15
Mistakes	0	Accepted	1
Understanding	15	Discussion	0
Discussion	0	Rejected	0
Proposals	5		

All the comments are responded in the comment sheet that was sent to the Agency and will be published in the Consultation webpage.

The comments does not require further modification of the CSM and are mainly linked to simple clarifications that can be covered by guidance already foreseen to be developed.

5.2.10. National Investigation Bodies' comments

Having in mind that NIBs only took a position observer in the Working Party and did not contribute to the development of the CSM proposal, the Agency received only one set of comments from NIB Finland.

This set is containing questions and suggestion for improving the Taxonomy that should be discussed with the Group of Analysts.

The comments do not call into question the CSM proposal, but suggest that the process of improvement integrated in the CSM will readily be used and will help improving the Taxonomy for clearer description of occurrences, as it was aimed at. It shows as well that the CSIs definition are not all very clear and the CSM Taxonomy can be used to bring more clarity for occurrence reporting.

5.2.11. International union

UIC addressed a letter to the Agency containing several comments.

The Agency replied to this letter on xxx, taking into account the results of the consultation and of the final CSM recommendation.

This letter did not contain elements that would require to amend the proposed CSM. This is mainly due to the following points:

- the CSM does not forbid operators to continue exchanging information with UIC on voluntary basis, independently,
- in some cases this exchange of information could even be improved with the existence of the Information sharing system, especially if the taxonomy used by the UIC would be further aligned with the future CSM regulatory taxonomy,
- If aligned to the CSM taxonomy, the UIC may act as third party reporting entity in the ISS on behalf an operator (indirect channel allowed),
- the UIC 'safety' groups' members may act as Group of Analyst experts within the rules established by the CSM and by the Group of Analysts working arrangements as soon as it is corresponding to the needs of the Group Analysts working plan.

Based on the above, the Agency considers that many possibilities and opportunities exist for UIC in relation with its members and the future CSM implementation.

6. Overview of the final Impact Assessment results

6.1. Steps taken for the impact assessment:

A comprehensive impact assessment has been undertaken for the CSM ASLP recommendation providing an overview of the expected consequences as well as the extent to which the recommendation is addressing the underpinning objectives expressed in the mandate. This IA work is provided for in the CSM ASLP Mandate as well as the Agency Regulation, Article 8(1). The impact assessment has been developed in line with the Agency's Impact Assessment procedure adopted by the Agency's Management Board and aligned with the European Commission's guidelines for Impact Assessment linked to the Better Regulation initiative. In particular, these guidelines stress that impact assessment should have the following structure in order to set out clearly the intervention logic and facilitate better law-making:

- Definition of the problem(s) to be addressed and quantification

- Specification of objectives
- Identification of options
- Analysis of impacts of options
- Comparison of options and preferred option
- Outline of monitoring and evaluation arrangements

For the CSM ASLP recommendation the chosen approach for the analysis was a Full Impact Assessment in order to provide proportionate depth and quantify / monetise as far as possible all key impacts associated with the recommendation for the different stakeholders concerned. Several draft versions of the impact assessment has been provided starting with IA perspectives in the Big Picture document setting the scene followed by an intermediate IA report in May 2020 and a final draft IA report in December 2020 for the public consultation. Each successive version was developed taking into account comments and contributions received from WP participants as well as ensuring alignment with the text for the CSM ASLP recommendation.

Key methodological steps to highlight for this impact assessment include:

- In-depth elaboration of the problem statement drawing on available research and studies within railways, transport and other safety-critical industries
- Identification of the core elements of the Recommendation which could be have significant impacts on stakeholders which should be reflected in the specification of options to be considered
- Comprehensive literature review undertaken during the course of the impact assessment to inform the different elements with particular emphasis on occurrence reporting, value of self-estimation as an tool for supporting continuous improvement and the potential importance of collective learning within safety management
- Structuring the impact assessment to facilitate both high-level analysis and disaggregated examination of specific elements of the CSM ASLP Recommendation

In addition, regular exchange of information with WP members and the following meetings have supported the development of this Impact Assessment:

- NSA FI (13 March 2020 and 28 September 2020)
- RENFE (14 April 2020)
- NSA SE (7 April 2020 and 7 September 2020)
- NSA DE (17 April 2020)
- EIM (7 May 2020 and 29 September 2020)
- CER + EIM (3 November 2020)

6.2. Options considered in impact assessment

The impact assessment is formed around an in-depth examination of the following elements of the CSM ASLP recommendation:

- Simple reporting of events
- Detailed reporting of events

- Railway operators' self-assessment
- Reporting on occurrence scenarios and RCMs
- Safety level assessment (SL)
- Safety performance assessment (SP)
- Group of Analysts (GoA)
- Information Sharing System (ISS)

This approach is well suited for the assessment of the CSM ASLP given the differing elements included in the Recommendation each of which would require a detailed analysis. An aggregated analysis alone would not permit to develop the detailed analysis sufficiently.

These elements have been selected in order to capture key elements of the CSM ASLP which influence variations in costs and benefits. The disaggregated analysis allows for consideration to all the elements included in the CSM ASLP with particular emphasis on highlighting where there are potential significant choices re. the specification. For each of these detailed elements a number of options are identified as outlined below. It should be noted that for some elements only 2 options are considered (do-nothing vs. 1 do-something = CSM ASLP proposal).

An aggregated assessment of monetised costs and benefits is also included in the IA report complementing the disaggregated analysis.

Simple reporting of events

- Option 0: As of today – no change
- Option 1: Reporting restricted to significant consequence events
- Option 2: Reporting Category A and Category B events
- Option 3: Reporting for significant consequence events + selected additional events
- Option 3*: Reporting for significant consequence events, all accidents with consequence above 5000 euros, all Category B events

Detailed reporting of events

- Option 0: As of today – no change
- Option 1: Reporting restricted to significant consequence events
- Option 2: Reporting for Category A events
- Option 3: Reporting for significant consequence events + selected additional events
- Option 3*: Reporting for significant consequence events only

Railway operators' self-assessment

- Option 0: As of today – no change
- Option 1: Self-assessment is voluntary
- Option 2: Self-assessment is mandatory

Reporting on occurrence scenarios and RCMs

- Option 0: As of today – no change
- Option 1: Reporting restricted to significant consequence events with part of the RCM information voluntary

- Option 2: Reporting restricted to significant consequence events with all RCM information mandatory

Safety level assessment (SL)

- Option 0: As of today – no change
- Option 1: As per CSM ASLP recommendation

Safety performance assessment (SP)

- Option 0: As of today – no change
- Option 1: As per CSM ASLP recommendation

Group of Analysts (GoA)

- Option 0: As of today – no change
- Option 1: As per CSM ASLP recommendation

Information Sharing System (ISS)

- Option 0: As of today – no change
- Option 1: Simple IT solution to reflect restrictive scope of reporting
- Option 2: Scalable IT solution to start from restrictive scope of reporting and then upgrade

6.3. Findings in the impact assessment

The impact assessment of the CSM ASLP recommendation has demonstrated that challenges exist regarding sub-optimal management of railway safety in SERA at operator, national and EU levels having implications on the overall level of railway safety in Europe as well as operational performance. On the basis of analysis undertaken it is considered likely that these challenges would persist if no action is taken. In particular, if no action is taken there could be a missed opportunity to facilitate improved sharing and learning regarding the management of safety risks and the occurrences of accidents and incidents for better informed decision making within SERA at all levels.

Our qualitative and quantitative analyses have highlighted that there are potentially significant benefits to be obtained through promoting increased sharing and learning linked to railway accidents / incidents and management of safety. However, increased level of reporting also brings costs. Key drivers for increased costs are linked to the reporting volume and the time required per reporting item. Therefore, the optimal solution depends on reconciling these elements with the possible benefits taking into account the trade-offs.

Below, the main overall benefits and costs are briefly summarised before providing an overview of the conclusions of the impact assessment covering the different elements of the CSM ASLP Recommendation.

Benefits

The following benefits have been modelled in the quantitative analysis:

- Efficiency gains: Operator savings on resources regarding the monitoring and auditing of their SMS which would benefit from access to an improved information basis that could allow for better targeted monitoring and enhanced learning from accidents and incidents.
- Effectiveness gains: Potential savings in costs associated with accidents and incidents obtained through improved management of risks. These gains for society would also involve benefits on operator side (e.g. lower damage costs for infrastructure and rolling stock).

These benefits provided by the CSM ASLP Recommendation have been estimated using conservative assumptions drawing on available evidence from the railway and transport sectors as well as other safety-critical industries.

Quantification of benefits for national safety authorities have not been quantified, although it is likely that there would be at least potential efficiency gains linked to improved targeting and prioritizing of supervision activities.

Costs

The following cost elements have been considered in the quantitative modelling:

- Cost impact for the Agency:
 - one-off costs for the Information Sharing System (ISS) as well as the setting up of GoA
 - recurring costs per annum for developing and maintaining the ISS as well as coordinating and facilitating GoA + SP / SL assessments. In addition, there would be resources linked to legal matters as well as data quality control (although operators are responsible for the quality of the data and information reported)
- Cost impact for the National Safety Authorities:
 - one-off costs for setting up the IT interfaces between any national systems and the ISS
 - recurring costs from maintaining and upgrading interfaces + participation to the GoA activities
- Cost impact for railway operators
 - one-off costs for setting up any IT interfaces to national systems
 - recurring costs for the reporting obligations in the CSM ASLP (simple & detailed reporting as well as reporting of RCMs / occurrence scenarios and operators' self-assessment)
 - recurring costs for participation in GoA
 - recurring costs linked to regular participation in training on the CSM ASLP reporting obligations

Overall

The findings from the quantitative analysis are summarised below (cost and benefit figures are expressed in mln EUR). These results demonstrate that it is likely that the benefits will outweigh the costs for the package of elements contained in the CSM ASLP Recommendation. In particular, for the aggregated Options 3*, 3 and 1 benefits are higher than costs with the highest Net Present Value obtained for Option 3*. It should be noted that the aggregated options defined here as Options 1, 2, 3 and 3* could be established in different ways based on the earlier listed disaggregated options.

Costs	O1	O2	O3	O3*
SR	0.04	2.66	0.58	0.877
DR	0.11	1.38	0.63	0.11
Self-assessment	0.81	0.81	0.81	0.81
RCM + occ scenarios	0.11	0.29	0.11	0.11
SL	0.03	0.03	0.03	0.03
SP	0.03	0.03	0.03	0.03
GOA (one-off)	0.10	0.10	0.10	0.10
GOA (ongoing)	0.99	0.99	0.99	0.99
ISS (one-off)	2.40	3.50	3.50	3.50
ISS ongoing	0.60	1.14	1.14	1.14
Other (Training, Legal, Data); ongoing	0.37	0.37	0.37	0.37
Total Costs (one-off)	2.50	3.60	3.60	3.60
Total Costs (ongoing)	3.07	7.68	4.68	4.45
Benefits				
Benefits: Efficiency	2.17	2.96	3.29	3.29
Benefits: Effectiveness	2.52	3.43	3.81	3.81
Total benefits	4.69	6.39	7.10	7.10
NPV	€ 19.42	€ (21.17)	€ 29.32	€ 32.41
B/C-ratio	1.4	0.8	1.4	1.5

On the basis of the impact assessment at aggregated and disaggregated levels we conclude that it is likely that the CSM ASLP will result in positive net-benefits and will contribute to:

- Optimising risk control measures / application of SMS
- Optimising supervision activities
- Optimising European level interventions for SERA improvement / simplification

This conclusion draws importance to:

- the scope of reporting is in principle focused on significant consequence events (except for simple reporting); and
- Additional future reporting is tightly controlled and would have to be justified in terms of demonstrating further net-benefits.

7. Final recommendation from the Agency

The Agency would like to thank all the respondents who allowed a final significant improvement of the Agency recommendation.

Considering the analysis of the comments received, the (few) remaining rejected comments are mainly related to the preservation of the legal consistency of the CSM with pre-existing legislation, as required by the Mandate. Thus, the rejection of those comments by the Agency seems to be justified.

Another comment rejected by the Agency is to remove, for the first phase of implementation, the methods developed by the Working Party. The Agency disagrees with this approach, because the methods elaborated with the working party are robust enough to constitute a baseline for the Group of Analysts work established by the CSM. Those methods capitalise on past EU projects and are consistent with standards and existing legislation. No other better baseline is foreseen to be developable in a short term, considering the intensity of effort and of the debates during the working party meetings on the related technical topics.

Therefore, knowing that one aim of the CSM is also to establish a learning curve, the Agency sees no risk to start this learning curve with the proposed methods, including the CSM review process, and taking into account the lessons learnt from the CSM implementation and the future improvement proposals of the Group of Analysts.

It is also to be noted that there is a clear support, without exception, for the constitution of this group which will also provide a legal basis for the current Joint Network Secretariat, giving a new impetus to this valuable and well-experienced safety improvement workflow.

However, the successful and smooth implementation of the CSM will be strongly influenced by the availability of an 'Information Sharing System', for which adequate resourcing is needed, supporting in general the 'safety digitalisation' of the railway sector.

The Agency has gained assurance, with a parallel investigation of the possible design option of the Information Sharing System and with starting discussion with the working party members, that this system is feasible and can be developed to cover the proposed CSM functions without major difficulties.

Such system was also developed successfully by the European Union safety Agencies for the Maritime and Aviation modes.

8. Annex 1: Definitions and abbreviations

8.1. Abbreviations

Table 1: Table of abbreviations

<i>Abbreviation</i>	<i>Description</i>
ASLP	Assessment of Safety Level and Safety Performance
CER	Community of European Railway and Infrastructure Companies
CSM	Common Safety Method
EIM	European Rail Infrastructure Managers
GoA	Group of Analysts, established by the future CSM ASLP to elaborate safety improvement and development within SERA
IM	Infrastructure Manager
ISS	Information Sharing System, established by the future CSM ASLP to exchange safety data and safety information between stakeholders
NIB	National Investigation Body
NSA	National Safety Authority
TDG	Transport of Dangerous Goods
TDG CA	TDG Competent Authority, in accordance with Annex II (RID) to the Inland TDG Directive 2008/68/EC
RID	Regulations concerning the International carriage of Dangerous goods by rail (Appendix C to COTIF)
RU	Railway Undertaking
TSI	Technical Specification for Interoperability
UIC	Union Internationale des Chemins de Fer
UNIFE	Association of European Railway Industries
WP	Working Party

9. Annex 2: Reference documents

Table 1 : Table of reference documents

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[1]	Big Picture report concerning the development of the Common Safety Method on the Assessment of the Safety Level and Safety Performance of Operators at National and Union level	Big Picture-CSM ASLP ERA1219	Final report 02.12.2019

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[2]	CSM ALSP extranet workspace	N/A	N/A
[3]	System Proposal for Common Occurrence Reporting Safety Management Data	ERA-PRG-004-TD-008	V 2.0
[4]	COR Final Report	ERA-PRG-004-TD-010	V 1.2
[5]	Inland TDG Risk Management Framework (RMF) / Framework guide (overview)	ISBN 978-92-9205-517-2	<i>Version</i> 1.0/2018
[6]	Inland TDG Risk Management Framework (RMF) / Guide for decision-making	ISBN 978-92-9205-536-3	<i>Version</i> 1.0/2018
[7]	Inland TDG Risk Management Framework (RMF) / Guide for risk estimation	ISBN 978-92-9205-515-8	<i>Version</i> 1.0/2018
[8]	Inland TDG Risk Management Framework (RMF) / Framework Glossary	ISBN 978-92-9205-522-6	<i>Version</i> 1.0/2018
[9]	DG MOVE webpages on the Transport of Dangerous Goods and the Inland TDG Risk Management Framework	link	
[10]	ERA webpages on the Inland TDG Risk Management Framework	link	
[11]	ARAMIS: Accidental risk assessment methodology for industries	https://cordis.europa.eu/project/id/EVG1-CT-2001-00036	
[12]	Root Cause Analysis (RCA)	Cenelec IEC 62740:2015	
[13]	ECCAIRS 2.0 PHASE 2 ARCHITECTURE DEFINITION DOCUMENT	CRI for EASA	<i>Version</i> 2/10/2018
[14]	ECCAIRS 2.0 Functional & Non-Functional Specifications	EASA	<i>Version</i> 24/04/2018

10. Annex 3: Reference legislation

Table 2 : Table of reference legislation

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[15]	Mandate for the development of a CSM on the Assessment of Safety Levels and Safety Performance of operators at national and Union Level (CSM ASLP)	ERAEXT-965606021-1 ERAEXT-965606021-2	07.01.2019
[16]	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	OJ L 138, 26.5.2016, p. 1.	N.A.

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[17]	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system (Recast)	OJ L 138, 26.5.2016, p. 44.	N.A.
[18]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (Recast)	OJ L 138, 26.5.2016, p.102.	N.A.
[19]	CSM on SMS	CDR (EU) 2018/762	
[20]	Practical Arrangement for issuing SSC	CIR (EU) 2018/763	
[21]	Common Safety Indicators (CSIs)	Art. 5 of Directive (EU) 2016/798	
[22]	ECM Regulation	CIR (EU) 2019/779	16 May 2019
[23]	Common Safety Targets (CSTs)	CD 2010/409/EU	
[24]	CSM on Assessment of CSTs achievement	CD 2009/460/EC	
[25]	Inland Transport of Dangerous Goods Directive	2008/68/EC	As amended
[26]	Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment	Regulation (EU) No 402/2013	
[27]	Commission Regulation (EU) No 1078/2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance	Regulation (EU) No 1078/2012	
[28]	Commission Implementing Regulation (EU) 2019/779 on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798	Regulation (EU) 2019/779	