



Common Safety Methods (CSM) on Risk Evaluation and Assessment

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Agenda:

1. EC Decision Process;
2. Presentation of the Commission Regulation on CSM on Risk Assessment (*legal text*);
3. Presentation of the guides for the application of the CSM Regulation (*informative and non legally binding document*);
4. Discussion/Questions;

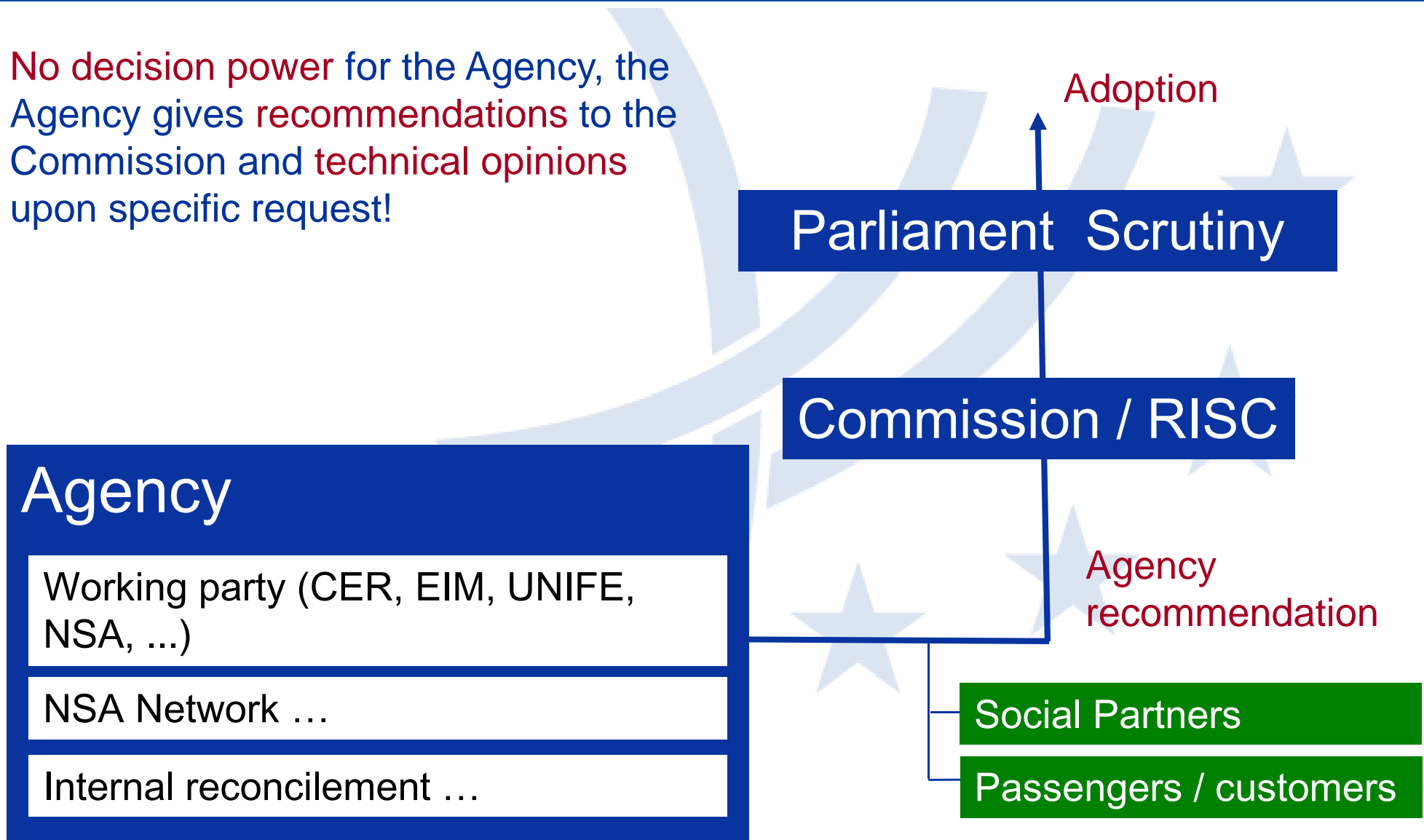


Decision Process



Decision Process

No decision power for the Agency, the Agency gives **recommendations** to the Commission and **technical opinions** upon specific request!





Commission Regulation on CSM on Risk Assessment



Commission Regulation on CSM on Risk Assessment Link of CSM to Article 9 in Safety Directive 2004/49/EC

Article 9 requires that *"IM and RU shall establish their SMS..."*

Basic elements of SMS in Annex III of Safety Directive 2004/49/EC

One of the SMS processes in Annex III

Annex III(2)(d): *"Procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations"*

RU and IM SMS will thus achieve the compliance with the procedures and methods required by the associated "conformity assessment criteria" [developed by ERA Safe Certification Sector] by referring to the CSM on Risk Assessment



Commission Regulation on CSM on Risk Assessment

Link of CSM to Article 15 in Interoperability Directive 2008/57/EC

Article 15 requires among others that before authorising *"the placing into service of those structural subsystems constituting the rail system which are located or operated in its territory"*, *"in particular"* the Member State *"shall check"*:

- *"the technical compatibility of these subsystems with the system into which they are being integrated"*,
- *"the safe integration of these subsystems in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC"*.

Article 4(3) of Directive 2004/49/EC:

"Member States shall ensure that the responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings,..."

"Without prejudice to civil liability in accordance with the legal requirements of the Member States, each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation,"

Article 6(3)(a) of SD referred to also in Articles 23(5) and 25(4) of ID

Article 6(3)(a) of Directive 2004/49/EC: *"The CSMs shall describe how the safety level, and the achievement of safety targets and compliance with other safety requirements, are assessed by elaborating and defining risk evaluation and assessment methods"*



Commission Regulation on CSM on Risk Assessment

Strategy for developing 1st Set of CSM based on existing EU methods

Two main considerations taken into account for developing 1st Set of CSM

- **Harmonise a common approach** for safety assessments based on existing safety assessment methods in EU. Therefore:
 - As Railway Sector already has a strong safety culture, freedom is left to each organisation to use its already approved Risk Assessment Methods/**Tools/Techniques**
 - CSM provide **Common Principles** but do not fix the Tools (e.g. FTA, FMECA)
 - CSM privilege the use of standards and reference systems
 - Advice of Risk Assessment “tools” done in a guideline developed alongside the CSM
 - Railway being organised into RU & IM, all activities at the **interfaces** between the different actors must be managed carefully
 - Clear identification of the different actors’ responsibilities
- **Facilitate mutual recognition** of results from risk assessments. This requires harmonisation of:
 - risk management process;
 - exchange of safety related information between actors for managing the safety across the different interfaces;
 - evidence resulting from application of risk management process



Commission Regulation on CSM on Risk Assessment

WHO shall apply the CSMs? → Proposer

- The risk management process described in the CSM shall be applied by the person in charge of implementing the change under assessment. This person is referred to in CSM Regulation as the "proposer".
- The proposer can be one of the following actors:
 - (a) the Railway Undertakings and Infrastructure Managers in the framework of the risk control measures they have to implement in accordance with Article 4 of the Safety Directive 2004/49/EC;
 - (b) the contracting entities or the manufacturers when they invite a notified body to apply the "EC" verification procedure in accordance with Article 18(1) of the Interoperability Directive 2008/57/EC or the applicant of an authorisation for placing in service of vehicles;
- Where necessary, the proposer shall ensure, through contractual arrangements, that suppliers and service providers, including their subcontractors, participate in the risk management process described in the CSM.



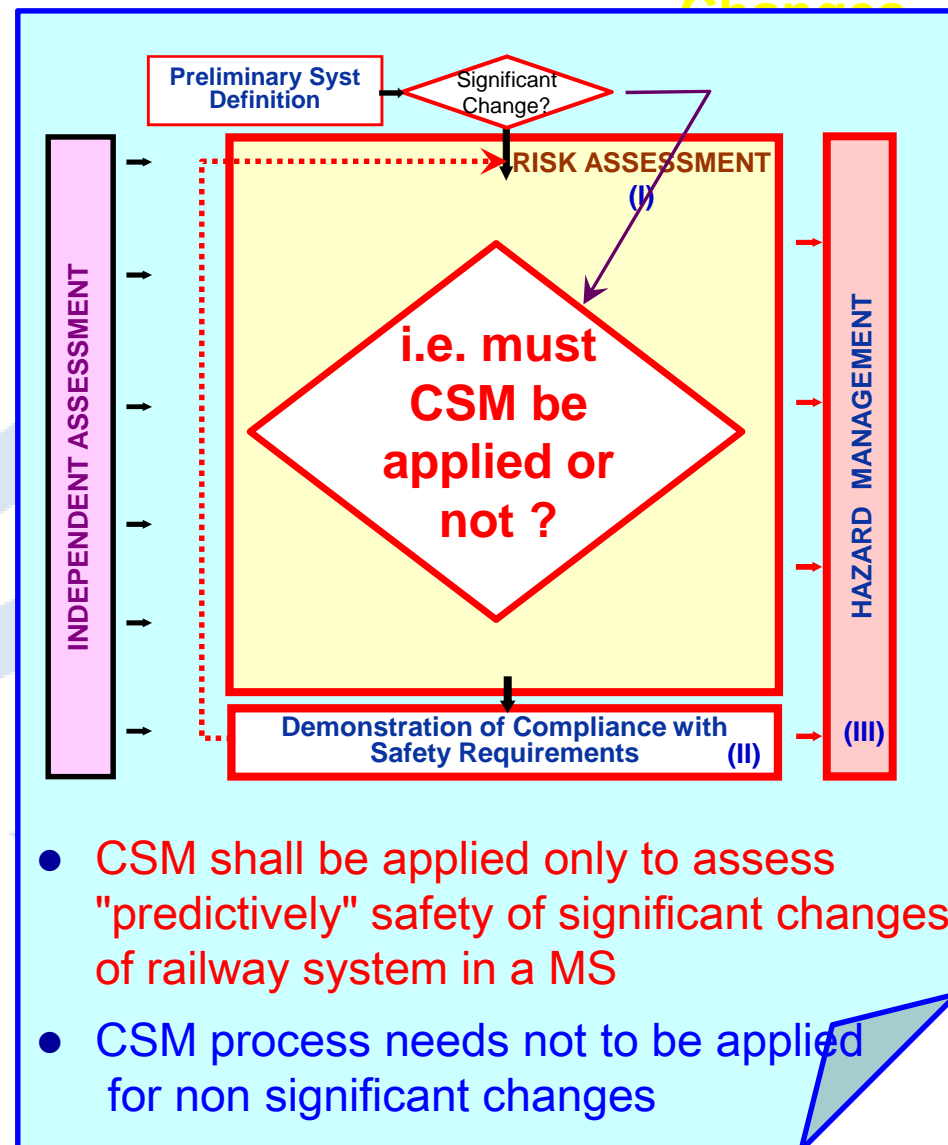
Commission Regulation on CSM on Risk Assessment

WHEN shall the CSMs be applied [Article 2]? → to Significant Changes

- CSM shall apply to any change of the railway system in a Member State, as referred to in point (2)(d) of Annex III to Safety Directive 2004/49/EC, which is **CONSIDERED TO BE SIGNIFICANT** under the terms of paragraph 2 in Article 4 of CSM Regulation.

Annex III(2)(d): requires that RU/IM SMS has *"procedures and methods for carrying out risk evaluation ... whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations"*

- Such changes may be of technical, operational or organisational nature.



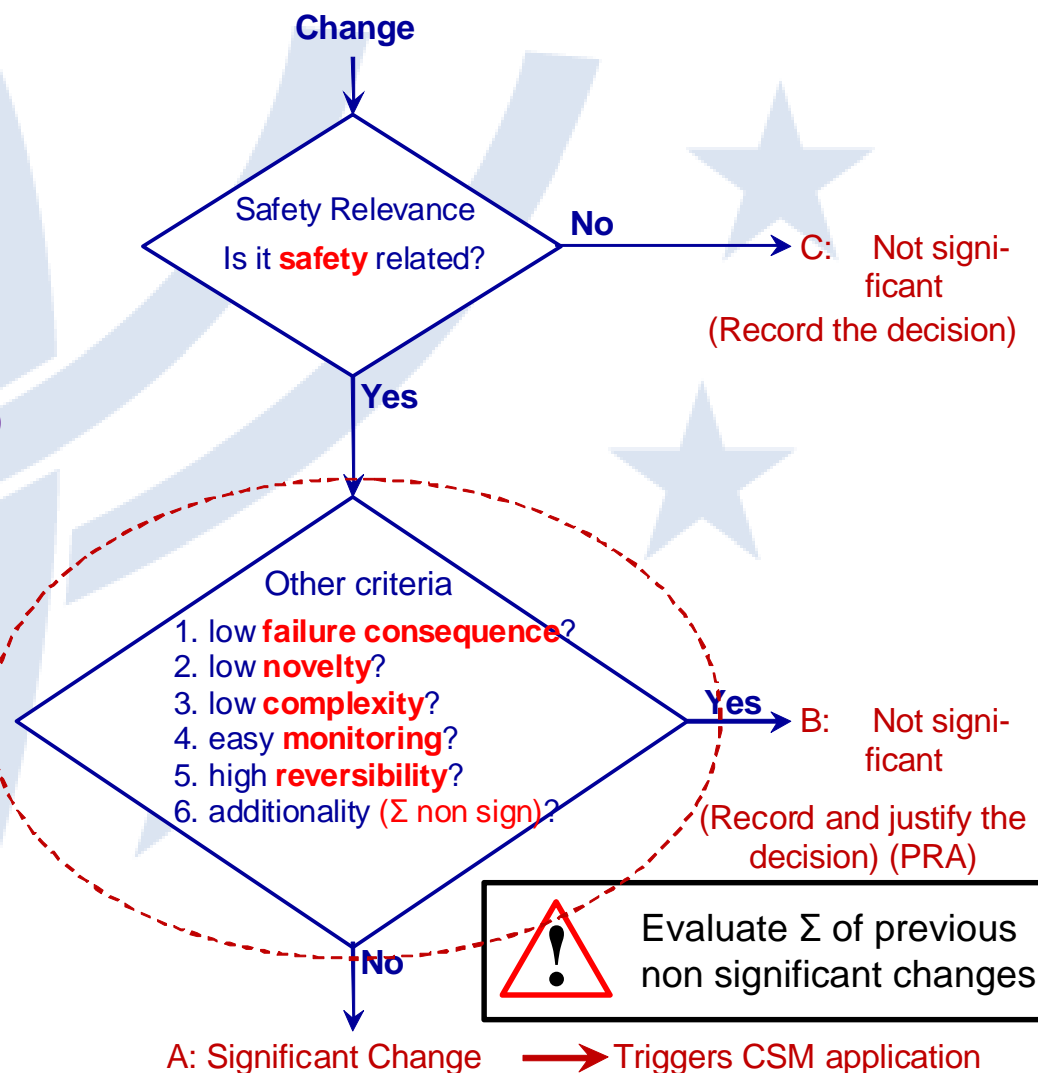


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WHAT is a significant change? → NR (if any) or expert judgement based on criteria

- When notified national rules do not define what is significant change, proposer shall evaluate significance of change based on expert's judgement and criteria in CSM
- 1st check whether change safety related?
 - 1) NOT safety-related → not significant → no CSM, but record decision ;
 - 2) YES safety-related → use other criteria to evaluate whether change significant
- Then, evaluation of other criteria may allow judgement that safety-related change could be managed safely without CSM
- Proposer should analyse all criteria but could take decision based on only one or some of them
- Proposer responsible to determine which importance to give to each criterion for change under assessment

When no notified national rules, expert's judgement based on criteria





Commission Regulation on CSM on Risk Assessment Cases where CSMs shall be applied Article 5(1) of CSM Regulation

- The risk management process described in the CSM shall apply [Art 5(1)]:
 - (a) *for a significant change as specified in Article 4 [i.e. if there are no national notified rules defining what is significant, change shall be assessed by expert judgement based on criteria (see previous two slides)], including the placing in service of structural sub-systems as referred to in Article 2(2)(b) of the CSM Regulation;*

Article 2(2)(b) requires the use of CSM "to ensure safe integration of the structural subsystems to which the TSIs apply into an existing system, by virtue of Article 15(1) of Directive 2008/57/EC"

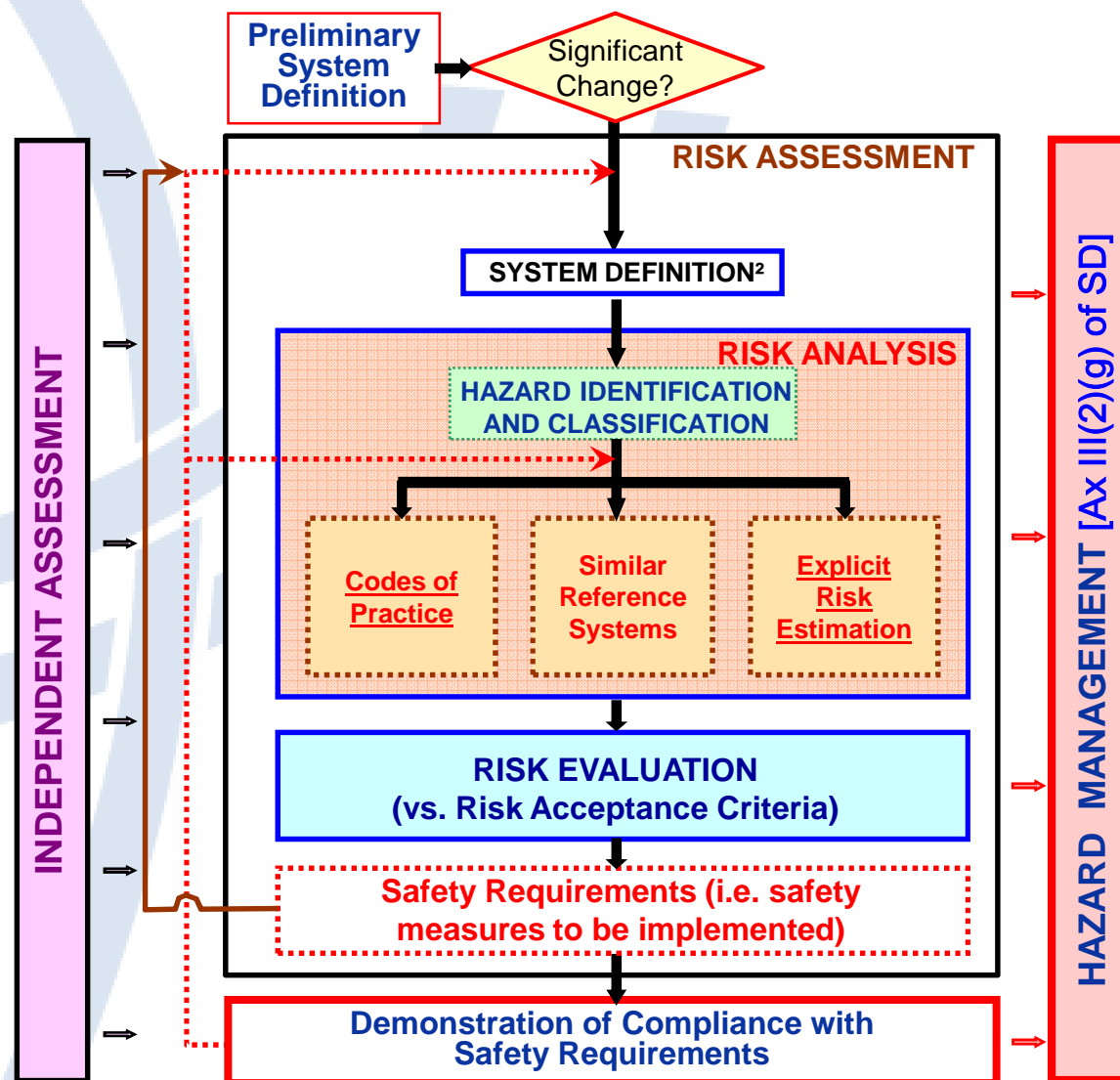
- (b) *where a TSI as referred to in Article 2(2)(a) refers to the CSM Regulation in order to prescribe the CSM risk management process*



Commission Regulation on CSM on Risk Assessment

Status and overall principles of the CSM Regulation

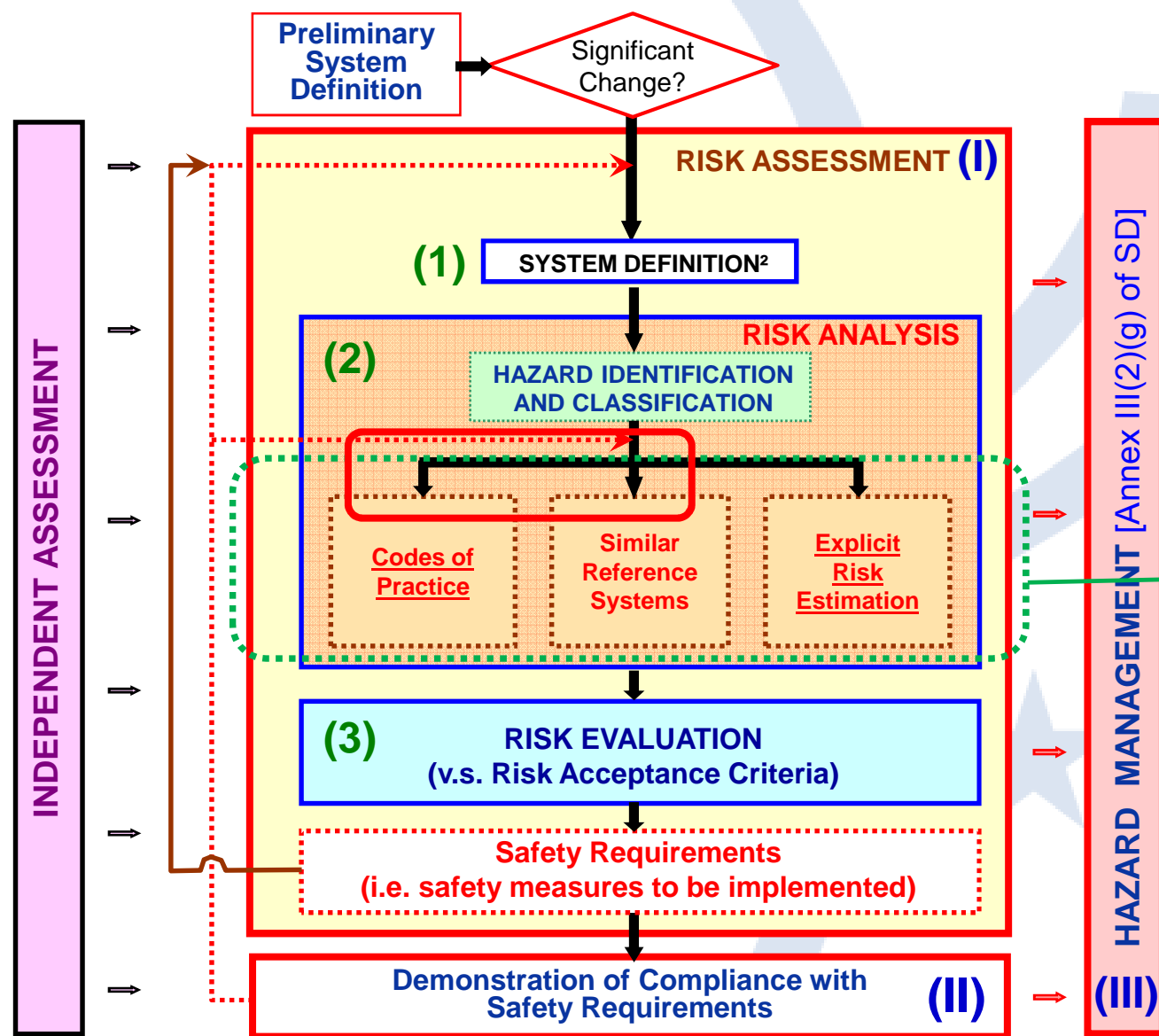
- CSM Regulation adopted by RISC in November 2008
- Basically CSM made of 3 steps:
 - (a) Hazard identification
 - (b) Risk analysis and risk evaluation based on exiting risk acceptance principles
 - (c) Demonstration of the system compliance with the identified safety requirements
- Additional requirements:
 - (a) Hazard Management
 - (b) Independent Assessment (Assessment Body)





Commission Regulation on CSM on Risk Assessment

(I) Risk Assessment Process



Risk Assessment is the overall iterative process that comprises:

(1) System Definition;

(2) Risk Analysis that includes:

- ↪ Hazard Identification and Classification;
- ↪ three Risk Acceptance Principles (*existing safety assessment methods*)
 - ↪ Codes of Practice;
 - ↪ Similar Reference Systems;
 - ↪ Explicit Risk Estimation;

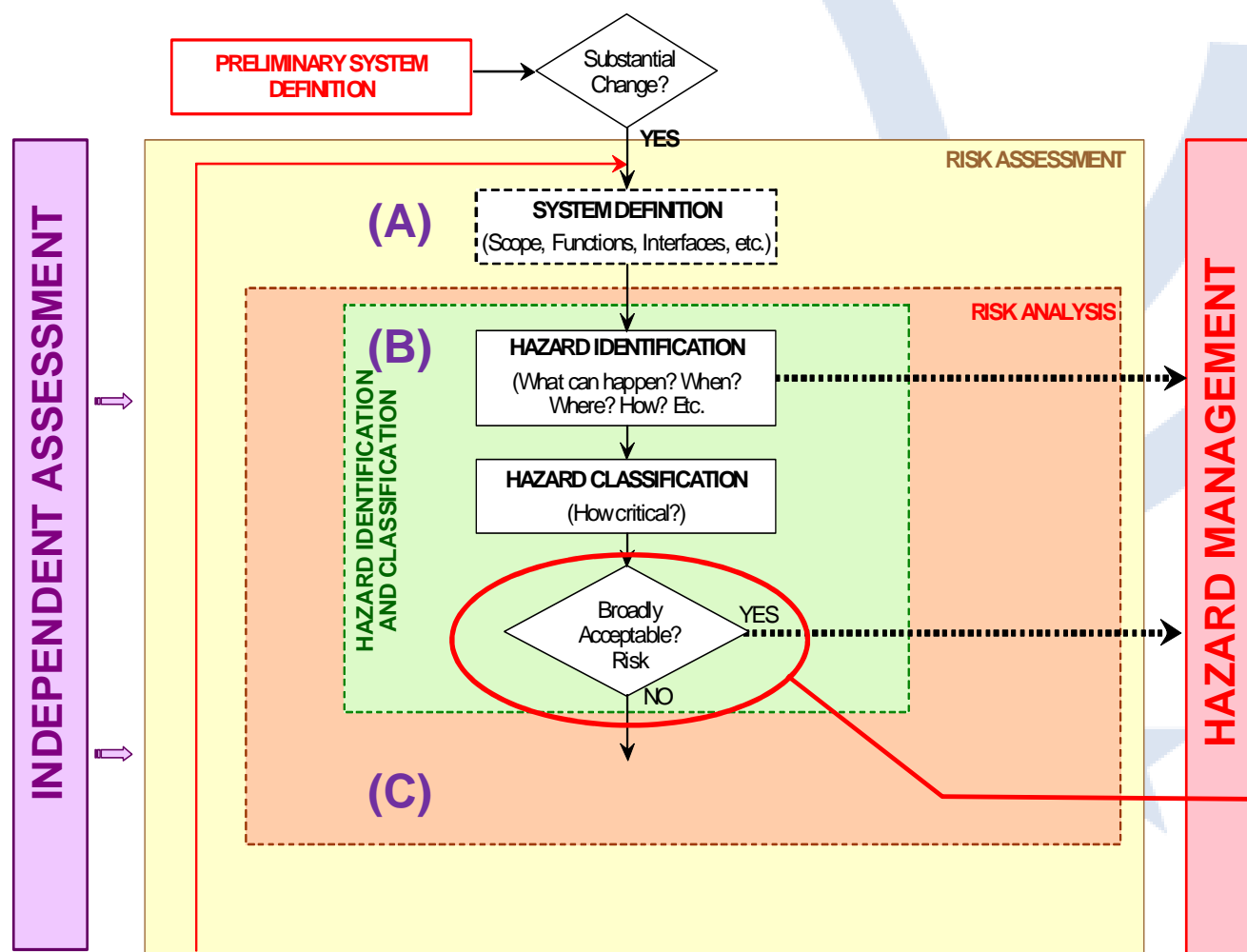
CSM do not impose any order of priority between the three Risk Acceptance Principles

(3) Risk Evaluation;



Commission Regulation on CSM on Risk Assessment

Hazard Identification and Hazard Classification



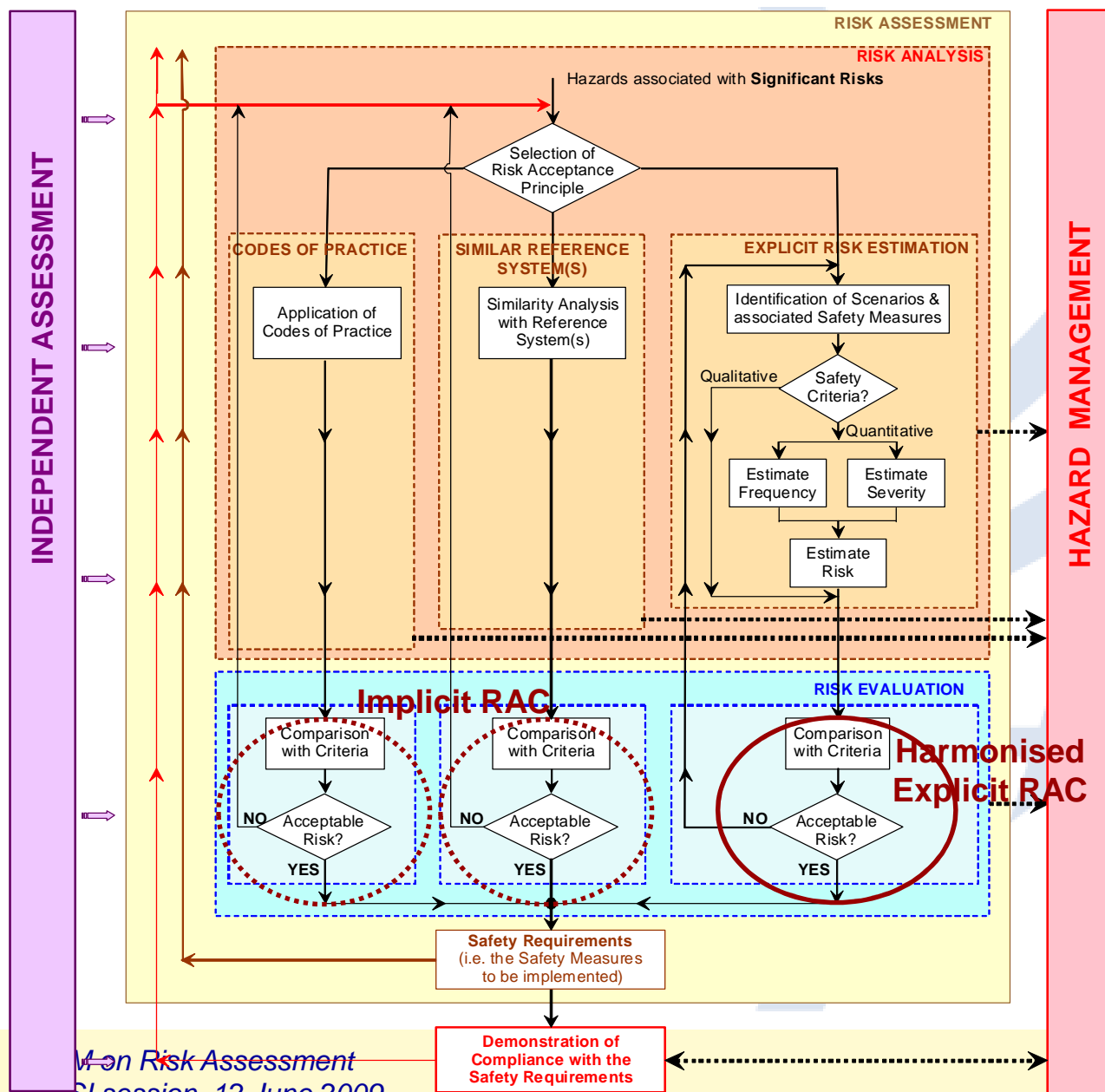
Hazard Identification

- A. Starts from the System Definition;
- B. Systematic Approaches for whole system, its functions where appropriate, and its interfaces taking into account:
 - ↗ human factors;
 - ↗ environmental conditions;
 - ↗ all operational modes;
- C. Focus Risk Assessment on most important risks based on expert's judgment
 - ➔ Hazard Classification into: hazards associated with
 - ↗ broadly acceptable risks;
 - ↗ non broadly acceptable risks;



Commission Regulation on CSM on Risk Assessment

Risk Acceptance Principles



Risk Acceptance Principles (RAP)

- (I) Codes of Practice;
e.g. TSI, EN standards, Notified National Rules, etc.
→ CSM compatible with in-use rule based approaches
- (I) Similar Reference Systems (GAME)
- (II) Explicit Risk Estimation (could be quantitative or qualitative)



3 – Commission Regulation on CSM on Risk Assessment **CENELEC safety standards in the Railway**

EN 50126 -1
Railway Applications
Process for specification and demonstration of RAMS

EN 50129
Signalling Applications
Safety Management

EN 50155
Rolling Stock Applications
Electronic Equipment

EN 50128
Signalling Applications
Software development



Safety Case structure

Part 1 : Definition of the system

Part 2 : Quality Management report

Part 3 : Safety Management report

Part 4 : Technical Safety report

Introduction

Assurance of correct operation

Effects of faults

Operation with external influences

Safety related application conditions

Safety qualification tests

Part 5 : Related safety cases

Part 6 : Conclusion

3 different types of SC

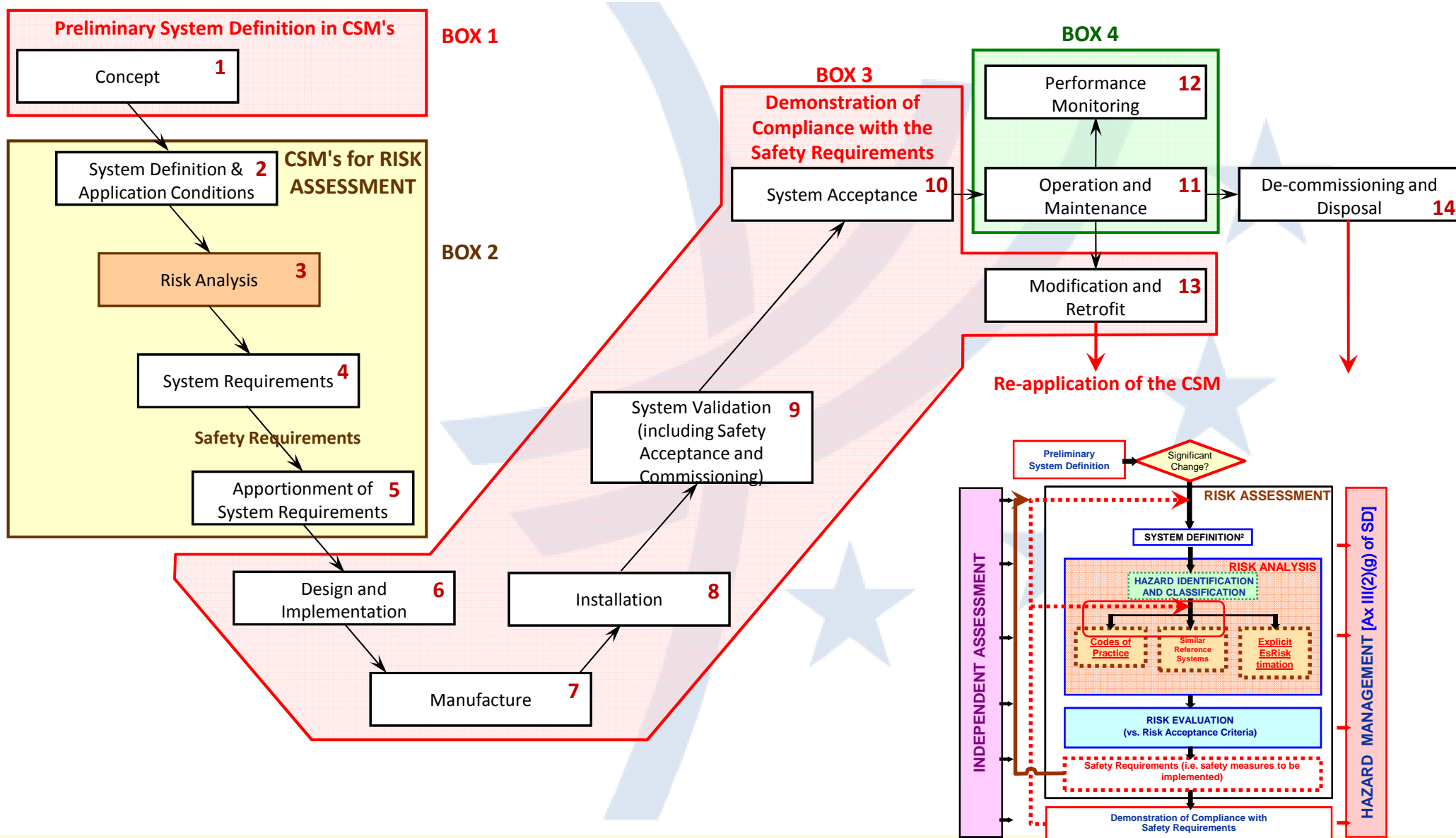
Generic product

Generic application

Specific application



3 – Commission Regulation on CSM on Risk Assessment Correspondence between CSM and CENELEC





Commission Regulation on CSM on Risk Assessment CSM Taskforces – Further harmonisation

- The following aspects are being developed further and harmonised with the support of dedicated taskforces:
 - Risk Acceptance Criteria
 - Role and Responsibilities of Assessment Bodies (NSA, ISA, NOBO)



Significant change of a technical system

- Risk matrix based on the RAC-TS (direct catastrophic consequence) decided.
- Criteria for other consequences than catastrophic.
- Possibility to derive THR for technical system when the consequence is not direct through the use of barrier analysis (additional technical barriers, human barriers, reduction factors)
 - The TF is developing a tool for this.

Frequency of hazardous event	Risk matrix			
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Acceptable	Unacceptable	Unacceptable	Unacceptable
Rare	Acceptable	Acceptable	Unacceptable	Unacceptable
Improbable	Acceptable	Acceptable	Acceptable	Unacceptable
Incredible (10 ⁻⁹ per hour)	Acceptable	Acceptable	Acceptable	Acceptable
	Insignificant	Marginal	Critical	(RAC-TS) Catastrophic Collective impact capable of resulting in deaths and several severe injuries.

- The “slope” and definition of scale for frequency and consequence is under discussion.
- This general approach has been agreed on with SSMG.



Significant change of an operational issue

- ❑ Matrix applicable but :
 - No evidence 10^{-9} h^{-1} can be used as starting point
 - Wish to avoid the development of a complex methodology for human factor quantification.
- **Work focussed on qualitative approach**
- ❑ Closed collaboration with operators
 - Operators position - Focus on the relevant redundancies and working conditions:
 - It is mainly the relevant redundancies linked to certain failure modes that should be developed for now
 - Working conditions covered by SMS



Commission Regulation on CSM on Risk Assessment Status of CSM Taskforce on R&R of Assessment Bodies

Determine:

- WHY: increase trust for mutual recognition of RA results
- WHEN: since the start of the project
- WHAT/ WHO (in relation with legal requirements of the ID and SD):
 - ⇒ check of CSM process (WHAT) + Interface SMS and TSI (WHO – legal requirements on NOBO and NSAs)
 - ⇒ criteria for Assessment Body:
 - Independence (e.g. depends on SIL level)
 - competence
 - appointed by whom? Proposers or other actors?(specific attention to avoid duplication of work)
- HOW: (to fulfil tasks above)
 - ⇒ use of modules for AB work (similar to those for TSI)?
 - ⇒ accreditation scheme for ISA? (e.g. done by NSA)
- WHERE: Regulation, Modification of Directives,...?



Commission Regulation on CSM on Risk Assessment

Entry into force

- CSM Regulation published on the 29th of April 2009 in the OJ of the European Union;
- CSM Regulation shall apply in two steps:
 - (a) from 19 July 2010
 - (1) *to all significant changes affecting vehicles, as defined in Article 2(c) of Directive 2008/57/EC;*
 - (2) *to all significant changes concerning structural sub-systems, where required by Article 15(1) of Directive 2008/57/EC or by a TSI;*
 - (b) from 1 July 2012 *to the whole scope as referred to in Article 5(1) of CSM Regulation, i.e. to other technical systems, operational and organisational changes considered to be significant by application of paragraph 2 in Article 4 of CSM Regulation;*
- In order to gain experience and enable the Agency to get a feed back for reviewing the CSM at latest at the end of 2011, the actors of the railway sector should apply the CSM Regulation on a voluntary basis to other changes (technical, operational and organisational) from 1 July 2010);



Guides for the application of the CSM Regulation



Guides for the application of the CSM Regulation

How was it elaborated?

- During the elaboration of the CSM Recommendation, ERA worked in parallel on a "Guidance for Use" for supporting the CSM Recommendation;
- Inputs for the "CSM Guidance for Use" [purely informative and not legally binding] were collected during CSM WG and CSM TF meetings, where members asked to describe further in the "Guidance for Use" requirements that could not be detailed a lot of in a legal text;
- According to those requests, as well as to questions raised within internal ERA meetings, ERA elaborated initial "Guidance for Use" and updated it vs. different versions of the Agency CSM recommendation and Commission Regulation;
- ERA regularly reported the progress on guidance for use to CSM WG during the plenary meetings;
- Based on content of "Guidance for Use", CSM WG and ERA agreed then to split the "Guidance of Use" into two new separate documents:
 - 1st document: *"Guide for the Application of the Commission Regulation on CSM on Risk Assessment"*
 - 2nd document: *"Collection of Examples of Risk Assessments and some possible Tools supporting the CSM"*



Guides for the application of the CSM Regulation

Complementarities between Guide and Collection of RA examples

[GUIDE]

- Provides general comments and explanations that could not be put in the legal text. ERA has taken care not to introduce any new requirement via the document that is not already identified in the CSM Regulation;
- [Guide] is more static and would not be modified unless the CSM process needs to be updated;

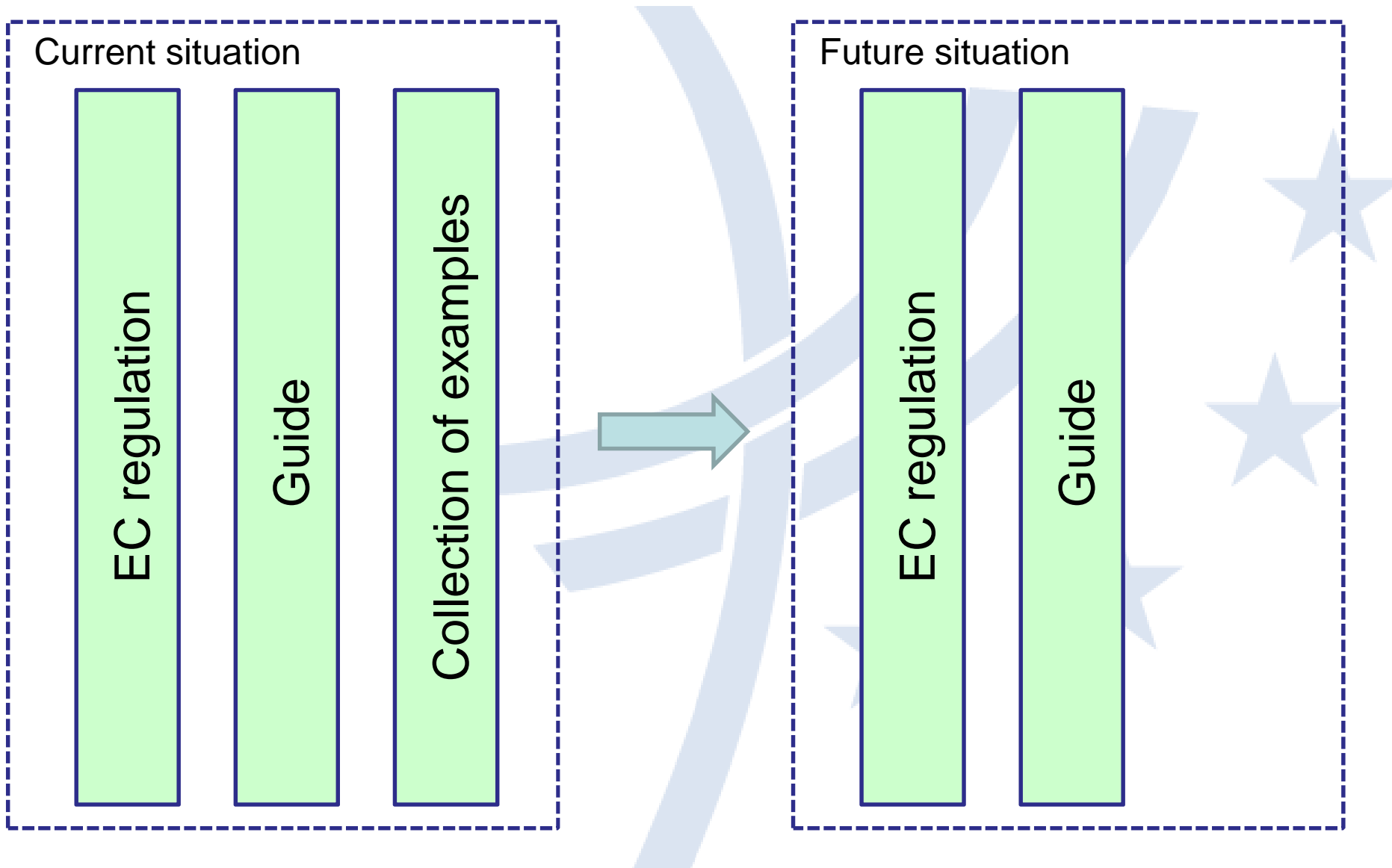
[COLLECTION OF EXAMPLES]

- Provides additional information (e.g. reference to standards or possible ways to address the requirements of the CSM) and examples of risk assessments performed in the railway sector before the existence of the CSM;
- Document offers the possibility to be updated with first implementations of CSM process and any useful tools and techniques, or examples of RA, that could help other actors to apply the CSM;

Structure of both document mapped on the regulation;



Guides for the application of the CSM Regulation Complementarities between Guide and Standards





Discussion/Questions



Many thanks you for your attention!

