

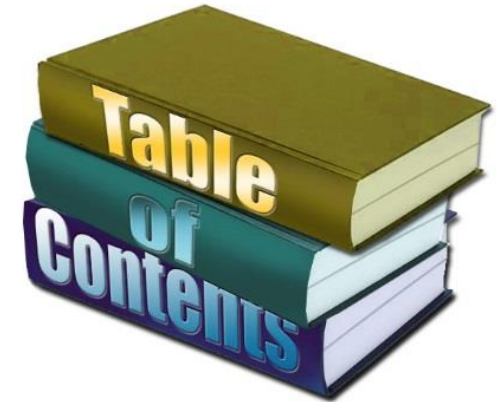


# Safety along the road towards an open single European railway market

**Seminar on Safety Management - Oslo, 7<sup>th</sup> October 2015**

**Dragan JOVICIC, European Railway Agency**

- ❑ Overview of European Transport Policy
- ❑ EU railway market opening and restructuring
  - ⇒ *Introduction of concepts of “risks” & “risk based approach”*
  - ⇒ *Change of Roles & Responsibilities for safety management and safety supervision of railways*
- ❑ Cornerstone of the Safety Management & Safety Supervision in a risk based approach
  - ⇒ *(Safety) Management System*
  - ⇒ *CSM for risk assessment*
- ❑ Overview of harmonised methods for safety management and safety supervision → *How many CSMs are there?*
- ❑ 4<sup>th</sup> Railway Package
- ❑ Discussions – Questions & Answers



# Overview of European Transport Policy



- ❑ EU railway market opening fits within overall EU Transport Policy [*a long process, older than 30 years*]
- ❑ EC conscious that Communication & Transport form basis for functioning of a modern society and economy  
→ **EC gave priority for their development**



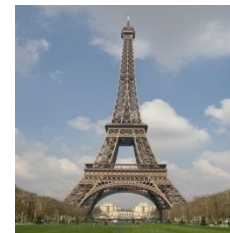
↘ an ever growing demand for transport, cannot be addressed simply by construction of new infrastructures



↘ EU enlargement and its sustainable development require optimisation of whole Transport Sector



- ❑ A modern transport system must be sustainable from Economic, Social & Environmental points of view
- ❑ Transport is a major polluter playing a central role in current climate changes
- ❑ Transport's cornerstone of EU Political Project:
  - vital for economic competitiveness within EU & world
  - foster trade & economic exchanges
  - enable cultural exchanges by bringing EU citizens closer





Signs of blocking of this tool, penalizing both users & economy, multiply:



**Traffic congestion**

**Environmental nuisances**



**Increase of rate of accidents  
or of severity of accidents**

## Turnover in EU Common Transport Policy (*White Paper*):

- ❑ balance sustainably sharing between different modes of transport



- ❑ develop inter-modality



- ❑ reduce traffic congestion

- ❑ place Safety & Quality of services at heart of action, while maintaining citizen's right to mobility



- ❑ **promote use of less polluting transport modes or least congested networks**



# European Transport Policy

## Air & Road Transport Market Opening Experience

### 1<sup>st</sup> step: 1990' **Air & Road** transport market opening

- ❑ removal of customs barriers in EU
- ❑ free movement of products & services



### Consequences:

- ❑ end of (state) monopolies → new competitors
- ❑ lower prices for customers and consumers
- ❑ **BUT** saturation of EU sky, motorways & roads (around big cities & industrial centres)



2<sup>nd</sup> step: [*White Paper 2001*] solve sky & road saturation problems by promoting use & development of alternative modes of transport more respectfull of environment → **maritime, inland water & railway market opening**



- ❑ Late 19<sup>th</sup> & early 20<sup>th</sup> centuries railways mainly small private companies
- ❑ Due to strategic importance for State economy & security, between 1935-1960:

Many railways nationalised → **State monopolies** that progressively become overstaffed, inefficient, reliant on state financing & incurring large debts



**NATIONALISATION**

- ❑ 1980' for competing with increasingly competitive road sector, many railways:

- ↪ facing financial problems due to big investments in new assets
- ↪ continue relying on state funding due to lack of return on investment

while at same time Air & Road transport market opening successful



## Directive 91/440 - Pavement for EU Railway Policy Development

- ❑ For EC & MS railways at heart of a sustainable and environmentally friendly transport system
- ❑ **A greater competition shall help creating a more efficient and customer-responsive railway industry**



- ❑ To boost railway market opening and establish a competitive sector EC & MS decide to **separate financially** Rail Operation from Infrastructure Management → **1<sup>st</sup> major railway law Directive 91/440**

- ❑ → start of a “Step by Step approach” instead of a “Big Bang approach” for development of EU railways



- ❑ Continuous decline in rail traffic between 1970-2004
  - Railway freight transport drop from 30% to 13.2%
  - Freight transport by road multiplied by 3
  - Passenger transport  $\pm$  constant 6.8% - 6.4% between 1995 & 2003
- ❑ Technical differences hindering removal of national borders and setting up international railway transport:
  - 5 types of energy systems
  - more than 21 Automatic Train Protection systems
  - 5 different track gauge & 6 line gauges
  - 5 different Maximum Permitted Axle Loads
  - different national operating rules
- ❑ In 2004 actual railway transport needs expected for 2010
  - Passengers +24%
  - Freight +38%



EU Strategy for  
Railway Development  
and removal of  
differences between  
EU Member States



Creation of European  
Railway Agency

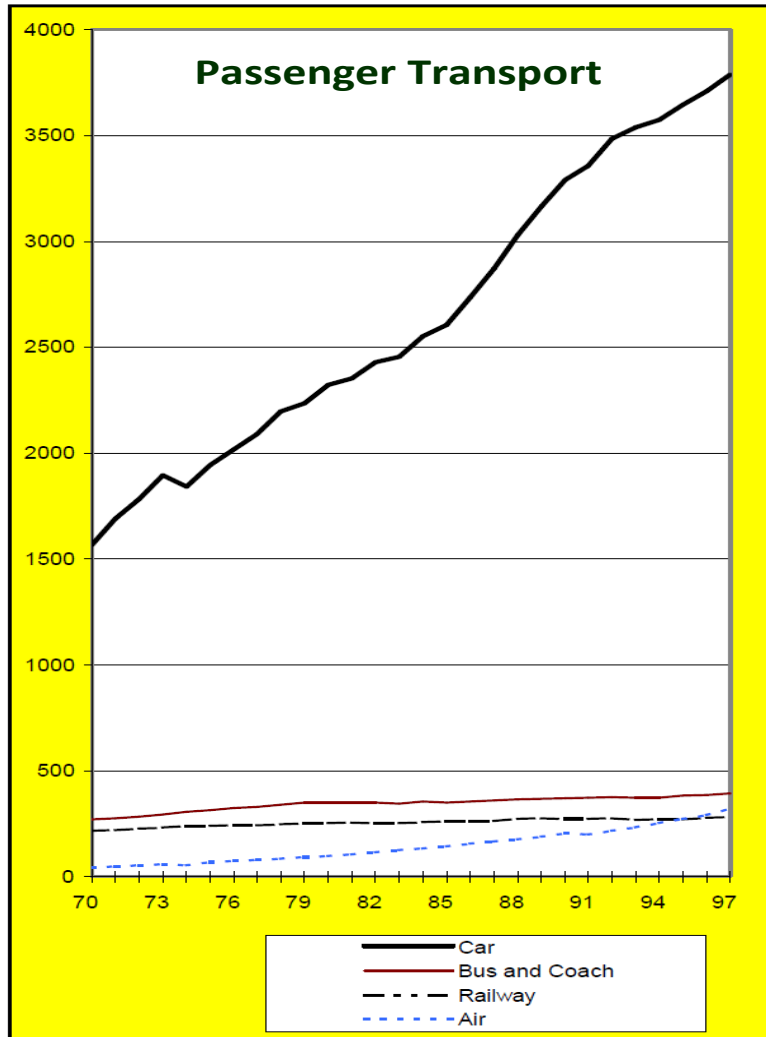
# European Transport Policy

## Transport growth between 1970-1997

eurostat 

Evolution 1970-97

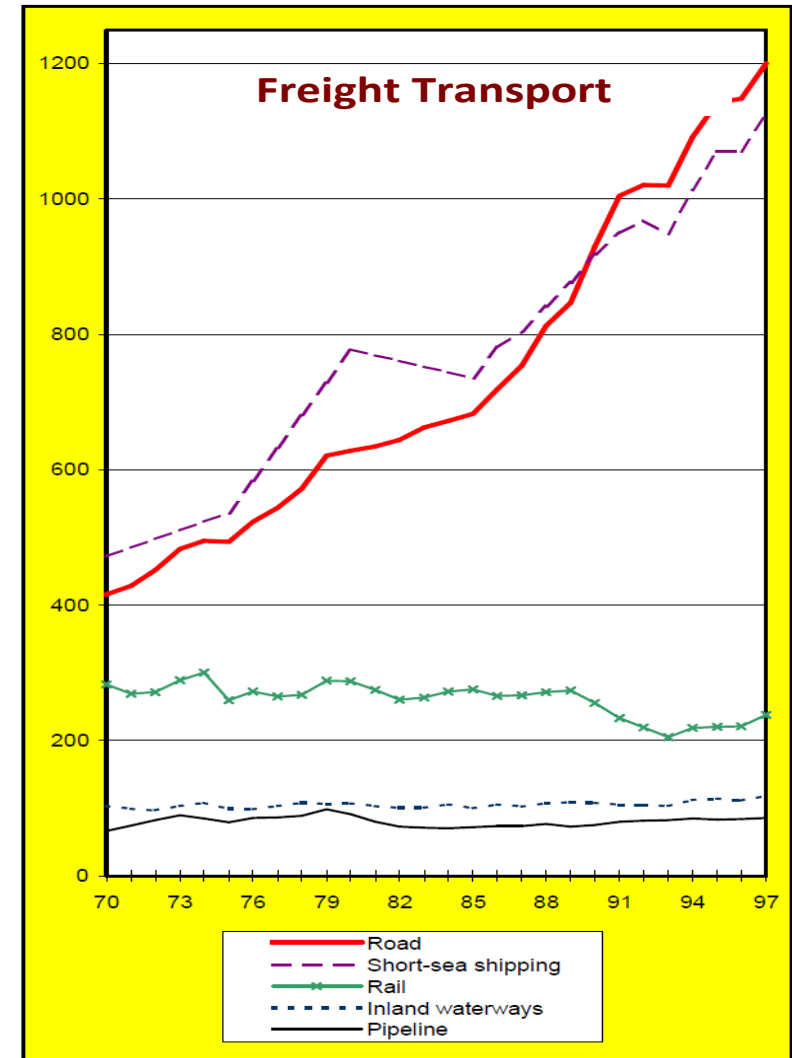
billion pkm



Evolution 1970-97

billion tkm

eurostat 



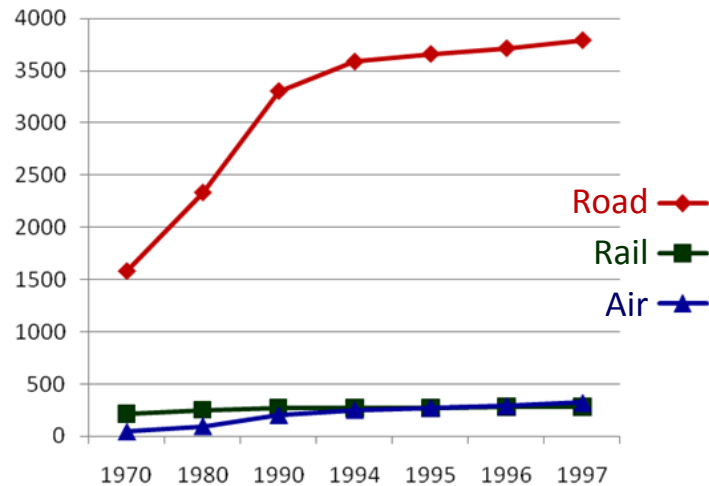


# European Transport Policy

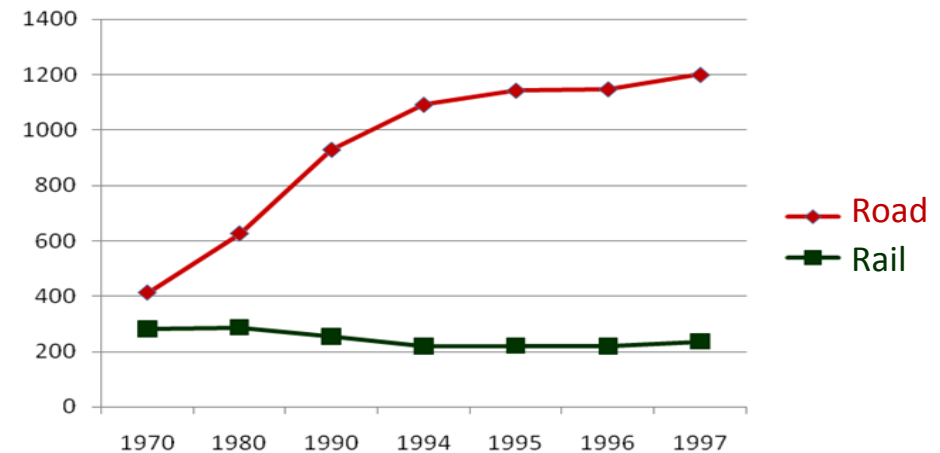
## Transport growth & modal share between 1970-1997

### Passenger transport

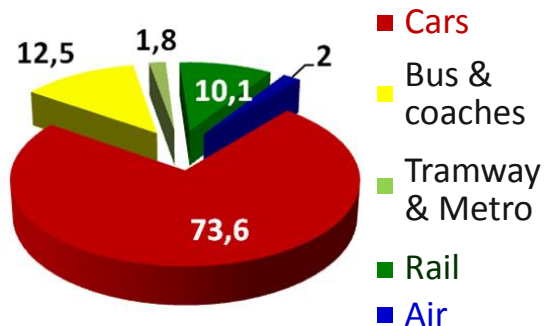
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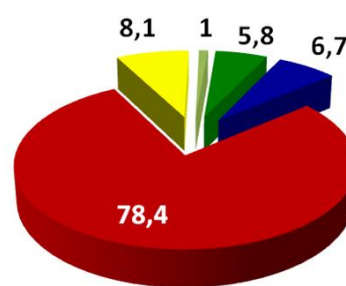
### Freight transport



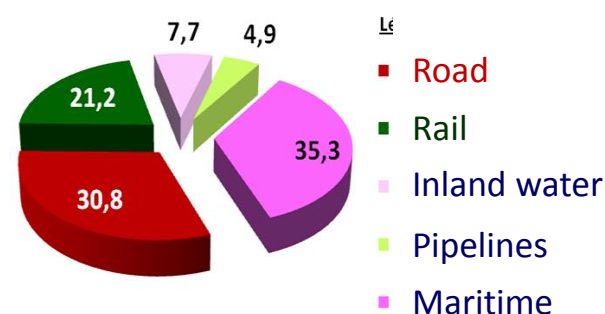
### Modal share in 1970



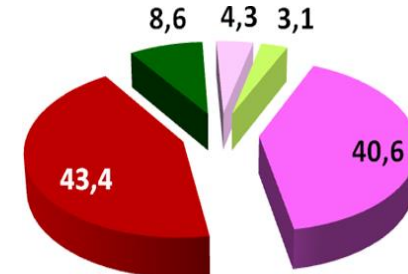
### Modal share in 1997



### Modal share in 1970



### Modal share in 1997



## Step by Step → Gradual Railway Market Opening to competition

<b>1991</b> <b>Step 0</b>	<b>1<sup>st</sup> major railway law:</b> Directive 91/440 on financial & organisational separation between Railway Operation and Infrastructure Management
<b>2001</b> <b>Step 1</b>	<b>1<sup>st</sup> railway package:</b> make existing legislation more effective, facilitate network access, improve rail freight, reduce delays at borders
<b>2004</b> <b>Step 2</b>	<b>2<sup>nd</sup> railway package:</b> revitalise railways & accelerate construction of an integrated EU railway area, improving safety, interoperability & <b>opening up of rail freight market [1 January 2007]</b> + Creation of ERA
<b>2007</b> <b>Step 3</b>	<b>3<sup>rd</sup> railway package:</b> <b>opening up of international passenger transport market [1 January 2010]</b> - Regulation of passenger rights and certification of train crews/drivers [EU driver license]
<b>2016??</b> <b>Step 4</b>	<b>4<sup>th</sup> railway package:</b> set up structural and technical reforms to eliminate last obstacles to creation of a Single EU railway market. To promote competition and innovation on national markets of railway transport

**1<sup>st</sup> major law: Directive 91/440:** financial & organisational separation of

- ❑ Railway Operation: passenger or goods transport services  
[licensing of RUs came later with Directive 95/18]
- ❑ Infrastructure Management:
  - allocation of rail capacity (“train paths” needed to operate trains)
  - infrastructure charging and licensing of infrastructure management
  - fair access to new rail operators on market
- ❑ Public funds for infrastructure and compensation for transport services under Public Service Obligations may not be used to finance transport operations [avoid distortions of competition and unfair use of public money]
- ❑ EU Member States must have Regulatory Bodies in place to monitor railway markets and to act as an Appeal Body for rail companies if they believe they have been unfairly treated

**1<sup>st</sup> railway package [RWP] - (2001):** 3 new directives [2001/12, 2001/13 & 2001/14] known as "rail infrastructure package" – **Objectives:**

- ❑ Make existing legislation more effective
- ❑ Enable Rail Operators access to trans-European network on a non-discriminatory basis
- ❑ Improve Europe's rail freight by an improved distribution of train paths
- ❑ Establish a tariff structure which reflects relevant costs
- ❑ Reduce delays at borders
- ❑ 2006 EC assessment of implementation: although implementation was still ongoing, effects were encouraging:
  - railway position vs. other transport modes stabilised
  - high level of rail transport safety safeguarded and often improved



## **2<sup>nd</sup> railway package (2004): 3 new directives & creation of ERA**

Revitalise railways & accelerate construction of an integrated European railway area, improving safety, interoperability and opening up of rail freight market  
[fully open from 1 January 2007]

- ❑ **Safety Directive 2004/49** amending Directive 95/18 on licensing of RUs and Directive 2001/14 on allocation of infrastructure capacity and levying of charges for use of railway infrastructure and safety certification
- ❑ **Directive 2004/50** amending Directive 96/48 on **interoperability** of trans-European high-speed rail system and Directive 2001/16/EC on interoperability of trans-European conventional rail system
- ❑ **Directive 2004/51** amending Directive 91/440 on **EU railway development**
- ❑ **Regulation (EC) No 881/2004 establishing a European Railway Agency** for providing technical support for safety and interoperability work

### **3<sup>rd</sup> railway package (2007):** 2 new directives and a few regulations

Opening up of international passenger transport market **[1 January 2010]** -  
Regulation of passenger rights and certification of train crews

- ❑ **Directive 2007/58** amending Directive 91/440/EEC on development of EU railways and Directive 2001/14 on allocation of railway infrastructure capacity and levying of charges for use of infrastructure
- ❑ **Directive 2007/59** on certification of train drivers
  - Basic requirements for educational level, age, physical and mental health, specific knowledge and practical training of driving skills [EU driver license].
  - Non-discrimination of persons with reduced mobility
- ❑ Regulation 1370/2007 on public passenger transport services by rail & road
- ❑ Regulation 1371/2007 on rail **passengers' rights and obligations**

- ❑ **Expectations** that directive 91/440 & 3 railway packages would create competitive railway sector independent of national governments, with a transparent governance framework & non-discriminatory rules

*By 2008 several MS not yet transposed 1<sup>st</sup> RWP → incumbent railways continuing to be dominant [sometimes backed by national governments]  
→ difficulties for new entrant trying to access markets*

- ❑ **Reasons:**

- 1) some parts of EU legislation needed simplification & modernisation
- 2) incorrect or incomplete transposition of EU legislation by MS, or lack of, low or incorrect implementation of legislation  
→ responsibility of DG Transport through its infringement power
- 3) abusive behaviour of state monopolies, hindering thus competition  
→ responsibility of DG Competition for regulating competition within the Single EU Market

## Major problems in achieving an open railway market

- (1) Low level of competition** due to market access conditions not sufficiently precise and therefore still biased in favour of incumbents railways
- ❑ access to rail related services (access to terminals, maintenance and servicing of trains, etc.), discriminatory practices with different players
  - ❑ km-based infrastructure charging or kWh-based charging for electricity giving disproportionate discounts to largest operator (incumbent)
  - ❑ Insufficient information in "network statements" on requirements for newcomers' access (characteristics of infrastructure & conditions for use)
  - ❑ denied access to central stations for international passenger trains competing with incumbent railways - No information nor ticketing facilities in stations for these same trains
  - ❑ etc.



## Major problems in achieving an open railway market

(2) **Inadequate regulatory oversight** by national authorities, often with insufficient independence, competences and **powers**.

With a small number of exceptions, in most MS regulators:

- ❑ understaffed and have limited investigating powers
- ❑ cannot enforce their decisions with financial penalties
- ❑ when appeals against decisions by Regulator have suspensive effect, these decisions can be challenged through Judicial System so that it can take years before a decision putting an end to an anti-competitive practice is enforced
- ❑ newcomers' access to services may not be brought to Regulator.

In several MS, Rail Regulator belongs to Ministry of Transport, which also owns or controls incumbent railway undertaking → **conflict of interest**

### (3) Low levels of public and private investment

As quality of infrastructure is declining in many MS because of insufficient funding and investment in railway, transport services by rail become less attractive both for incumbent and new operators.

- ❑ Underinvestment at national level partly due to absence of clear investment plans, long term strategies, transparent and state-aid compatible relations between
  - ↳ State [*nearly always infrastructure owner & often owner also of incumbent railway company*], and
  - ↳ infrastructure managers and railway undertakings

# EU railway market opening and restructuring

*Change of Roles & Responsibilities for  
management and supervision  
of railway safety*



## Barriers to creation of a Single EU Railway Market

- ❑ Historically, every country used **different** technical solutions, operational rules, standards, safety cultures and approaches in terms of safety acceptance and safety management
- ❑ **One state railway company** where all functions integrated:
  - Vehicle owner/keeper
  - Management of infrastructure
  - Operation of railway transport (passengers and freight)
  - Planning, management and performance of maintenance activities
  - etc.
- ❑ Railway company **self-regulated**, i.e. responsible for Regulation, Management and Supervision of a “safe operation” of railway transport
- ❑ International traffic: no legal obligations - Made possible thanks to (voluntary) **international or multilateral agreements**

**Incumbent  
Railway  
Company**



**Open railway market** to competition for rail transport services and railway supply industry



**Remove historical barriers**  
to free circulation of trains and  
make railways **business oriented**  
**and competitive**



**Prevent sector from using**  
**safety as a barrier** to market  
access or an excuse to resist  
change



➔ **Technical Harmonisation (TSIs) & Common approaches for safety management**

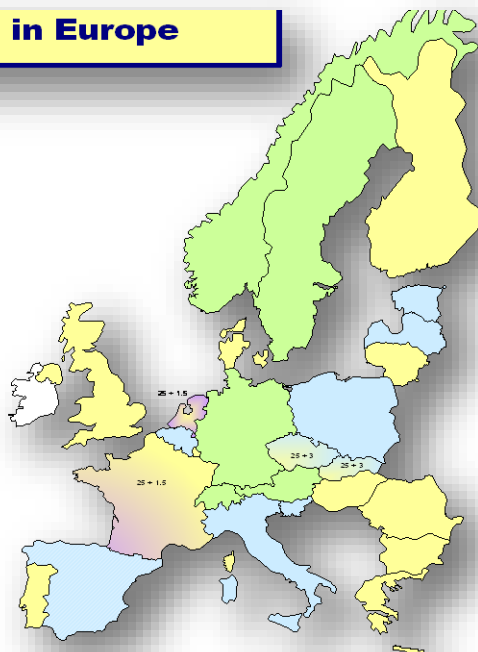
## European Railway Market Opening Railway Interoperability and Safety Directives

- ❑ 1<sup>st</sup> EU provisions (91/440<sup>2001/12</sup>, 95/18/<sup>2001/13</sup> and 2001/14) laid foundation stone towards regulation of EU railway transport market by opening market for international rail freight
- ❑ Although laying down basis, provisions on **interoperability** of whole network and on **safety** insufficient (differences in safety requirements):
  - Interoperability Directives (96/48 and 2001/16) → 2008/57 sets **conditions to achieve interoperability in EU rail system** vs. provisions SD
  - Safety Directive 2004/49<sup>2008/110</sup> complements technical legislation (ID) and **establishes common regulatory framework for railway safety**
  - Directive 2007/59 on **certification of train drivers** operating locomotives and trains on EU railway system

# European Railway Market Opening

## Interoperability Directive towards a harmonised railway system

### Voltages in Europe



#### Main voltages

25kV 50Hz

15 kV 16 2/3Hz

3kV DC

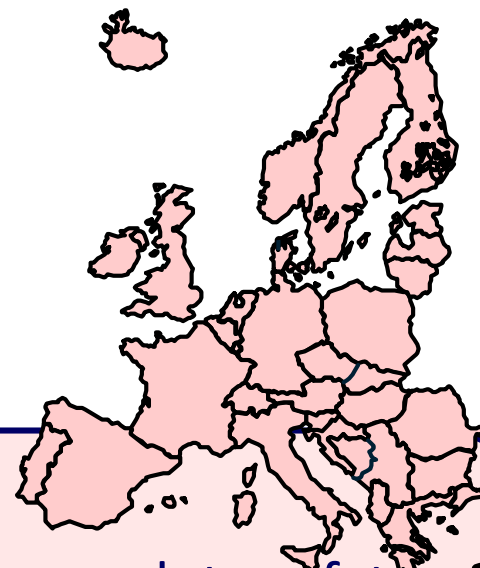
1.5kV DC

### Technical differences

- 5 types of electrification
- 21 signaling systems
- 5 track gauges
- 5 classes of axles load
- 6 line gauges
- national operational rules

### Main axis

- ❑ Define a common approach to safety
- ❑ Enhance Interoperability
- ❑ Promote cross-acceptance of assessment methods
- ❑ Create a common market
- ❑ Establish a single register format all over EU

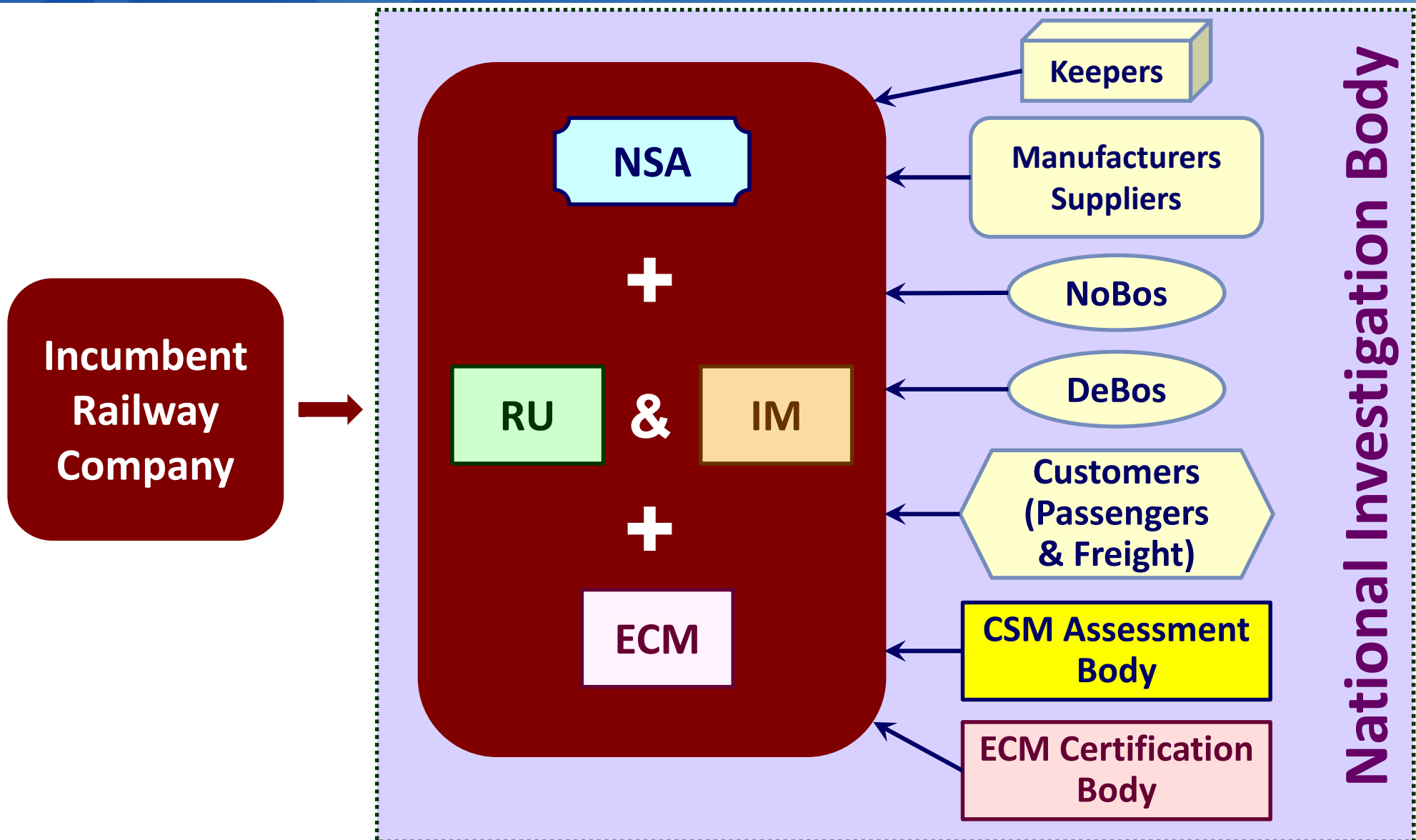


# European Railway Market Opening

## Cornerstones in EU legislation

- ❑ Technical harmonisation ..... **TSIs – NOBOs – DEBOs**  
(interoperability)
- ❑ Separation of former vertically ..... **RUs – IMs – ECMs**  
integrated railway companies
- ❑ Change from self-regulated railways to ..... **Regulatory Body + NSA**  
regulation by public authorities **(safety regulator) + NIB**
- ❑ Introduction of a framework for entry into ..... **Licensing & Safety**  
market for railway undertakings **Certification**
- ❑ Maintain at least, *and increase when* ..... **Development of common**  
*reasonably practicable, existing safety level* **approaches to safety [SMS**  
and create a basis for mutual trust **& CSMs]**
- ❑ **Transparency** of safety data ..... **CSI, CST & CSMs**  
*(monitoring that safety performance does not degrade during market opening)*

## Main stakeholders resulting from railway market opening





# European Railway Market Opening

## Main stakeholders resulting from market opening

- ❑ **Railway Undertakings (RUs) and Infrastructure Managers (IMs)** vs. former vertically integrated railway companies
- ❑ **National Safety Authority (NSA) or Safety Regulator** ensuring compliance by RUs and IMs with applicable EU and national legislation
- ❑ **National Investigation Body (NIB)**
- ❑ **Manufacturers/Suppliers**
- ❑ **Notified Body (NOBO)**
- ❑ **Designated Body (DEBO)**
- ❑ **Keepers**
- ❑ **Entity in charge of maintenance (ECM)**
- ❑ **ECM Certification Body** defined in Regulation 445/2011
- ❑ **CSM Assessment Body** defined in Regulation 352/2009

# European Railway Market Opening

## Common safety instruments for market opening

As many new railway players and interfaces are created, it is necessary to:

- 1) maintain at least the existing level of safety in the EU railways, *and increase it when reasonably practicable*
- 2) create a basis for **mutual trust**

EU railway legislation sets up a common approach for:

- ☐ safety regulation
- ☐ safety management
- ☐ safety supervision



In line with the "**New Approach**" for creation of a single European railway market

*The creation of a single market by 31 December 1992 could not have been achieved without a new regulatory technique that:*

- ☐ *set down only the **general essential requirements** to be fulfilled*
- ☐ ***reduced the control of public authorities** prior to a product being placed on the market*
- ☐ *integrated quality assurance, and*
- ☐ *modern conformity assessment techniques*

*Moreover, the decision-making procedure needed to be adapted in order to facilitate the adoption of technical harmonization directives by a qualified majority in the Council.*

*(see: **Guide** to the implementation of **directives** based on the New Approach and the Global Approach, ISBN 92-828-7500-8, © European Communities, 2000)*

# European Railway Market Opening

## EU railway legislation – Consequences of New Approach

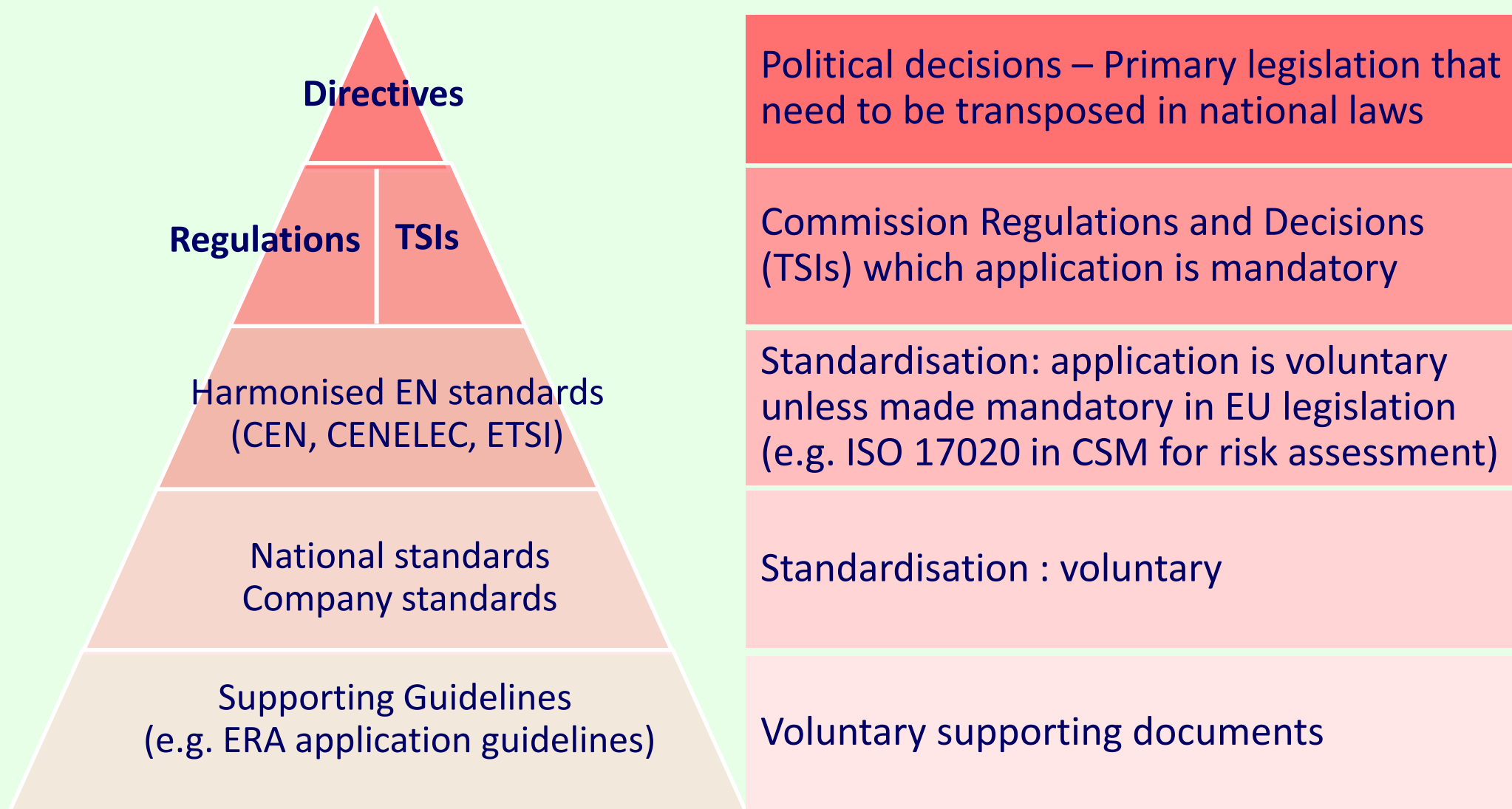
*A new regulatory technique and strategy was laid down by the **Council Resolution of 1985** on the New Approach to technical harmonisation and standardisation, which established the following principles.*

- ☐ *Legislative harmonisation is limited to **essential requirements** that products placed on the Community market must meet, if they **are to benefit from free movement within the Community***
- ☐ *The technical specifications of products meeting the **essential requirements** set out in the directives are laid down in **harmonised standards***
- ☐ ***Compliance with harmonised or other standards** remains **voluntary**, and the manufacturer may apply other technical specifications to meet the requirements*
- ☐ ***Conformity assessment bodies** may be used to check **compliance with standards***
- ☐ *Products manufactured in compliance with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements (3)*

(see: **Guide** to the implementation of **directives** based on the New Approach and the Global Approach, ISBN 92-828-7500-8, © European Communities, 2000)

# European Railway Market Opening

## EU railway legislation – Legal pyramid





# European Railway Market Opening

## Common approach to safety within an open railway market

### EU railway legislation

#### Safety Regulation

### EU legislation defines “Roles & Responsibilities”

[RUs, IMs, Vehicle Keepers, ECMs, NSAs, Notified Bodies, Designated Bodies, Manufacturers and others]

#### WHO shall do WHAT?

Responsibility for safety of railway system put on those who OPERATE and MAINTAIN railways:

#### Safety Management

- ❑ RUs, IMs must manage and monitor safely their activities **through a Safety Management System**
- ❑ ECMs must manage and monitor maintenance activities **through a “System of Maintenance”**

#### Safety Supervision

NSAs & other bodies (e.g. ECM Certification Body, NoBo, DeBo, etc.) guarantee RUs, IMs and ECMs comply with their obligations

# Harmonised thinking in terms of «risk» & «risk based approach»

## Transition from different national practice towards an SMS approach

- ❑ Existing national railway systems usually based on use of rules and retrospective review of «bad experiences» from past
- ❑ Directive 2004/49 requires to set up an SMS which shall «predict» what can happen and «prevent» it to happen instead of **«reacting and fixing»** to unwanted events
- ❑ SMS introduces concept of **RISK MANAGEMENT** which requires to LOOK both FORWARD and RETROSPECTIVE
- ❑ → only new element in SMS from existing national railway systems: develop a **«predict and prevent»** way of thinking



In a “risk based approach” the key question is thus:

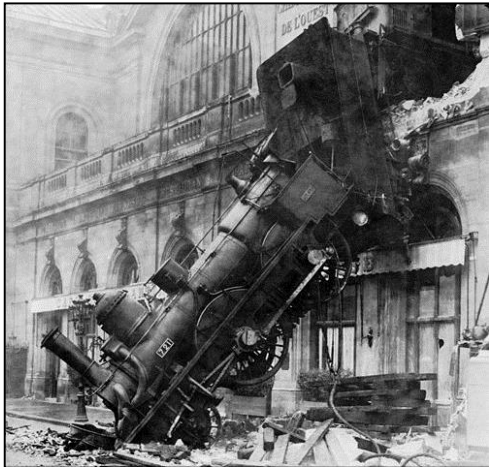
«What are the **likely risks** and the **risk control measures** I should put in place to **manage safely my activities (my business)**?»

# Reactive approach for risk management

In many domains a gradual improvement of safety resulted from costly experiences and lessons learnt from accidents

Prevention of similar events was regulated reactively (after the occurrence of such events) with the establishment of new national “laws, codes of practice, rules or standards”

## Event



## Reaction

Changes in the legislation, rules, standards or codes of practice to avoid the repetition of a new occurrence of the same type of accident.

This way of doing does not protect the system from other hazards than those that caused the accident

**Accidents are used to prevent same accidents**

# Modern and proactive approach for risk management

A proactive safety management based on risks ensures, before the event actually occurs, that:

- Hazards are identified & Causes and Consequences (risks) are analysed
- Acceptable Risk Control Measures are defined and implemented to prevent the hazard and/or to protect from consequences

## Analysis



## Safety measures



## Event



**Competence and analysis are used to prevent accidents**

# Comparison of Proactive vs. Reactive approaches

## Proactive approach (Predict & Prevent)

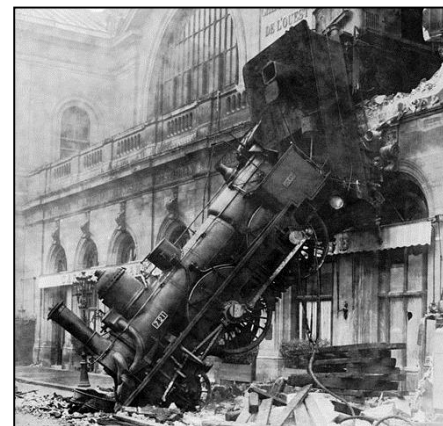


*Granville–Paris Express,  
on 22 October 1895  
Gare de Montparnasse*

**Competence and knowledge  
are used to control risks and  
then to prevent accidents**

- No impact on the system and society
- Can effectively prevent the occurrence of events

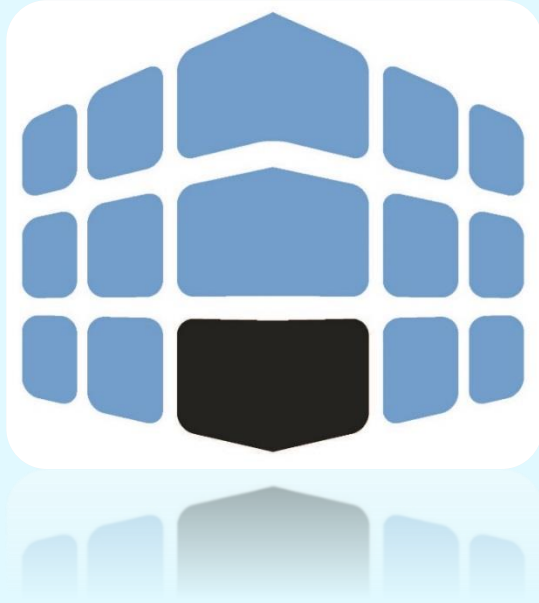
## Reactive approach (React & Fix)



**Accidents are used to  
prevent same accidents**

- Costly with high impact on the system and society
- Unable to control unknown risks





**Cornerstone of  
Safety Management &  
Safety Supervision  
in a risk based approach**

***CSM for risk assessment***

# Risk Management: links between CSM and SMS

**Risk Management is a key process of the safety management system (SMS):**

*“The **SMS** ... shall ensure the **control of all risks** associated with the activity of the IM or RU, including the supply of maintenance and material and the use of contractors...”*

***Directive 2004/49, Article 9(2)***

**The SMS organises the assessment and the management of risks**

*“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;”*

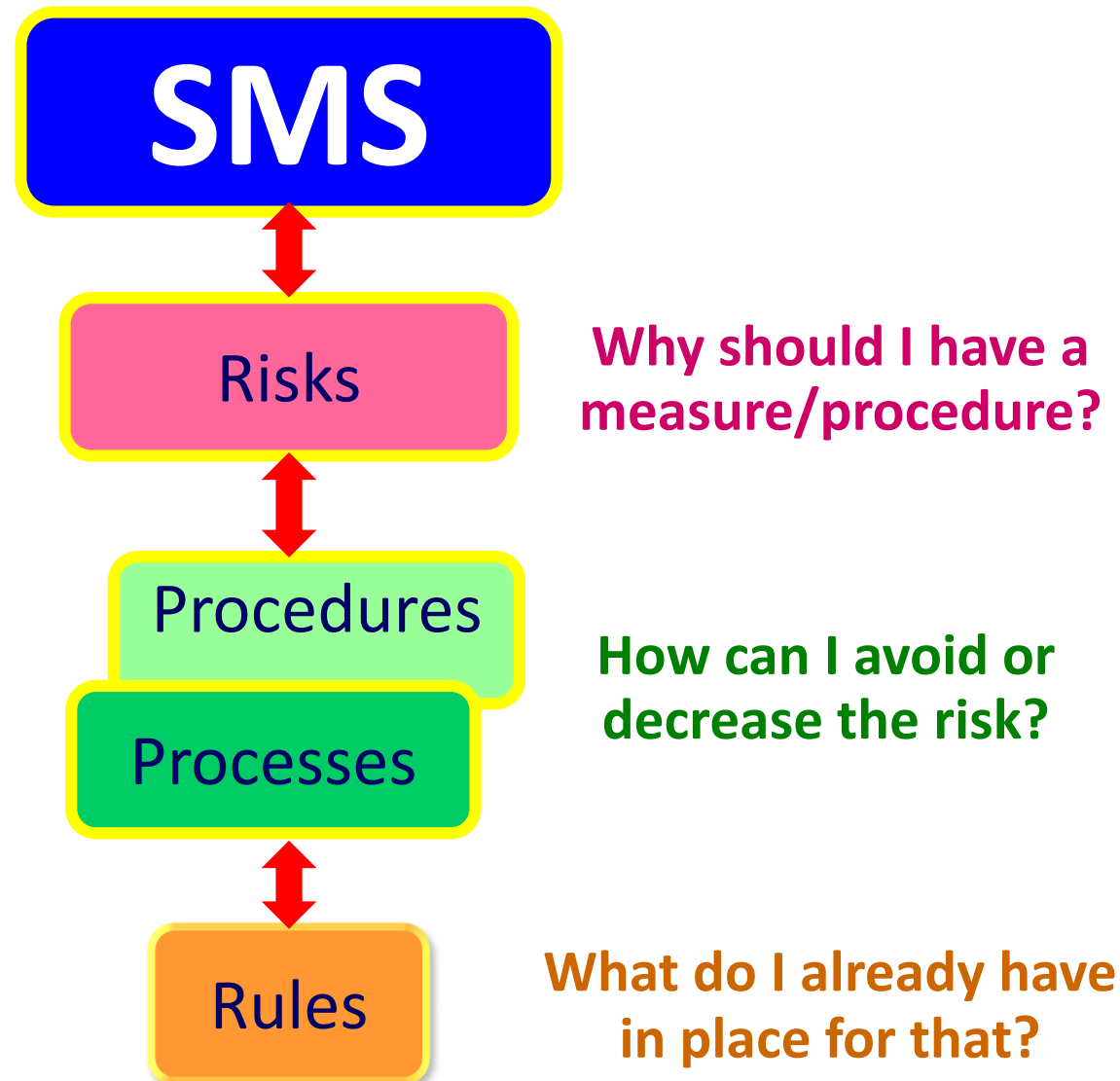
***Directive 2004/49, Annex III – art.2 Basic elements (d)***

**The implementation of a Safety Management System requires the application of the CSM for Risk Assessment**

# Building an SMS is a systematic review of "likely risks" linked to my operations and identification of "risk control measures"

## Role of rules in SMS:

- ❑ EU regulatory framework is not a conflict between a Risk & Rule based approaches but a combination of both
- ❑ It is necessary to identify & understand how rules fit into the whole management system?
- ❑ RU/IM SMS must consider not only National Rules but all rules necessary to deliver safely the operation

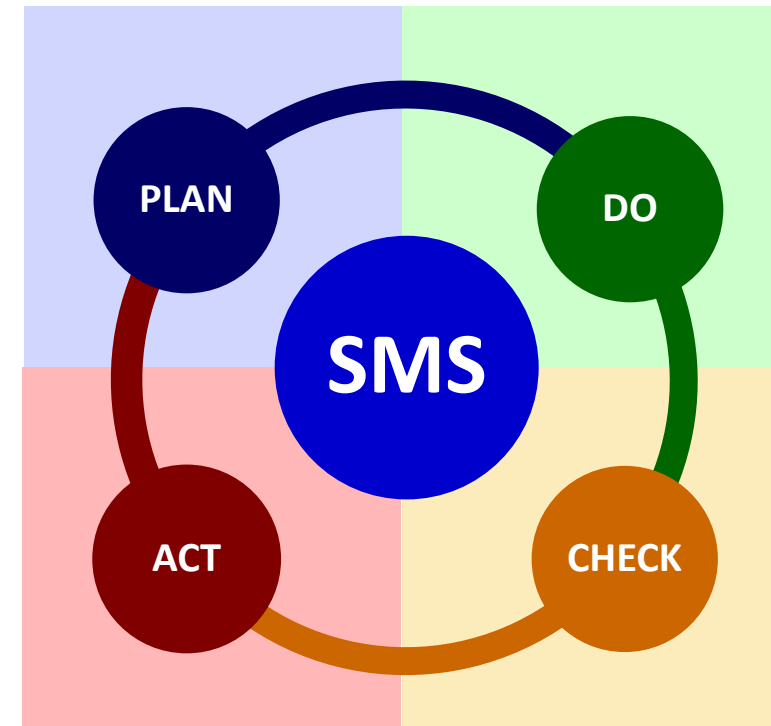


# Objective of SMS: keep "set rules" up to date

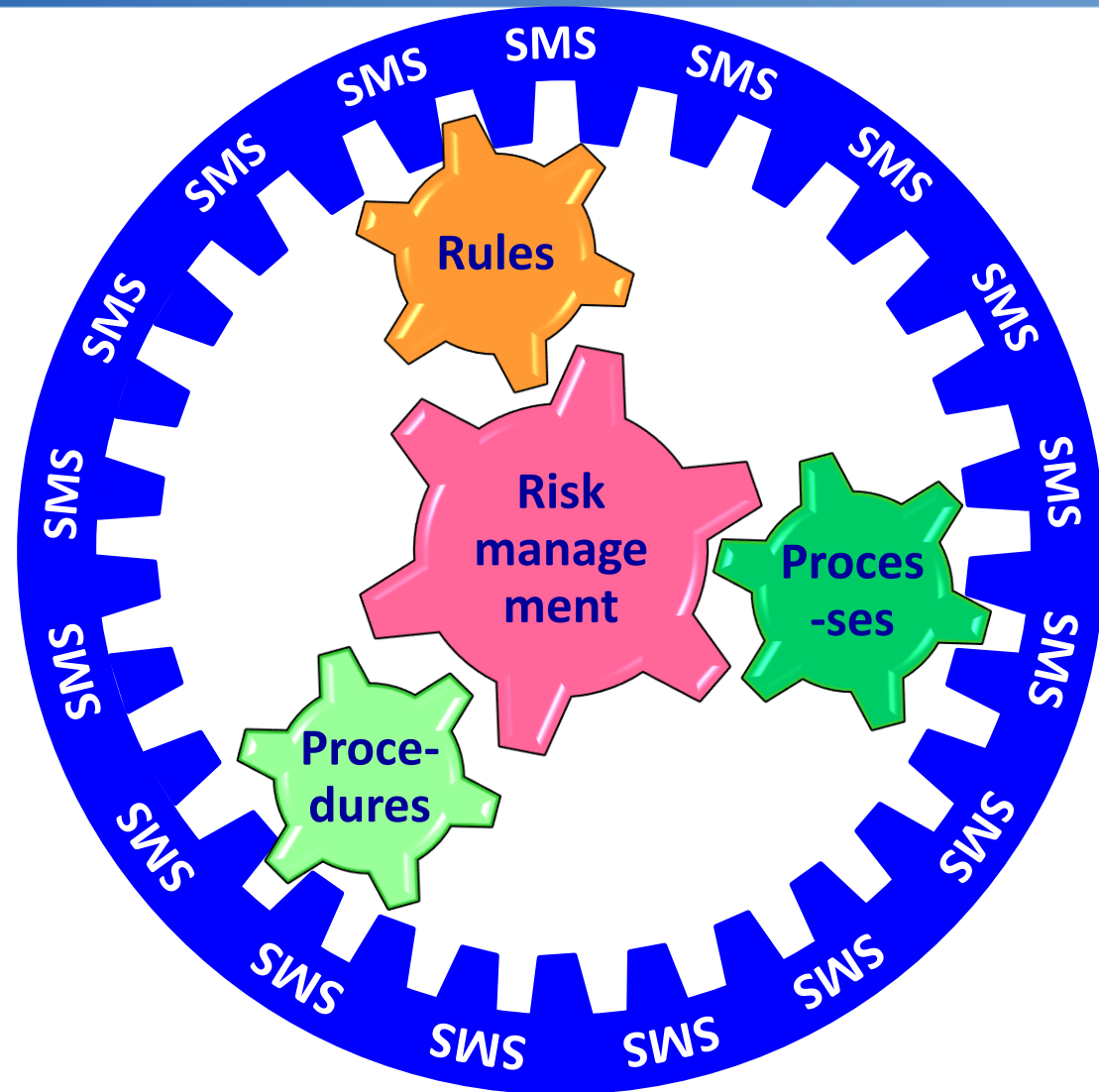
SMS is **not an alternative** to the existing set of safety related **technical and operational rules**. It is a structured way to apply them **taking into account** the risks related to the specific activities of the RU or IM

**SMS provides a structured framework to ensure that:**

- 1) **PLAN**: the company is designed (i.e. organised) to deliver safely the operation
- 2) **DO**: the company actually deploys the operational and support processes
- 3) **CHECK**: the company measures the effectiveness of the processes
- 4) **ACT/ADJUST**: the company takes preventive or corrective measures on detection of non-compliances



- ❑ A **documented and structured** framework for safe management of all company activities
- ❑ Ensures appropriate **processes, procedures** and **rules** exist for controlling all company risks
- ❑ Enables identification of hazards and **continuous management** of risks related to the company activities, with the **aim of preventing accidents**
- ❑ Uses scientific "**risk management**" tools to support company managers in taking consciously decisions for their business



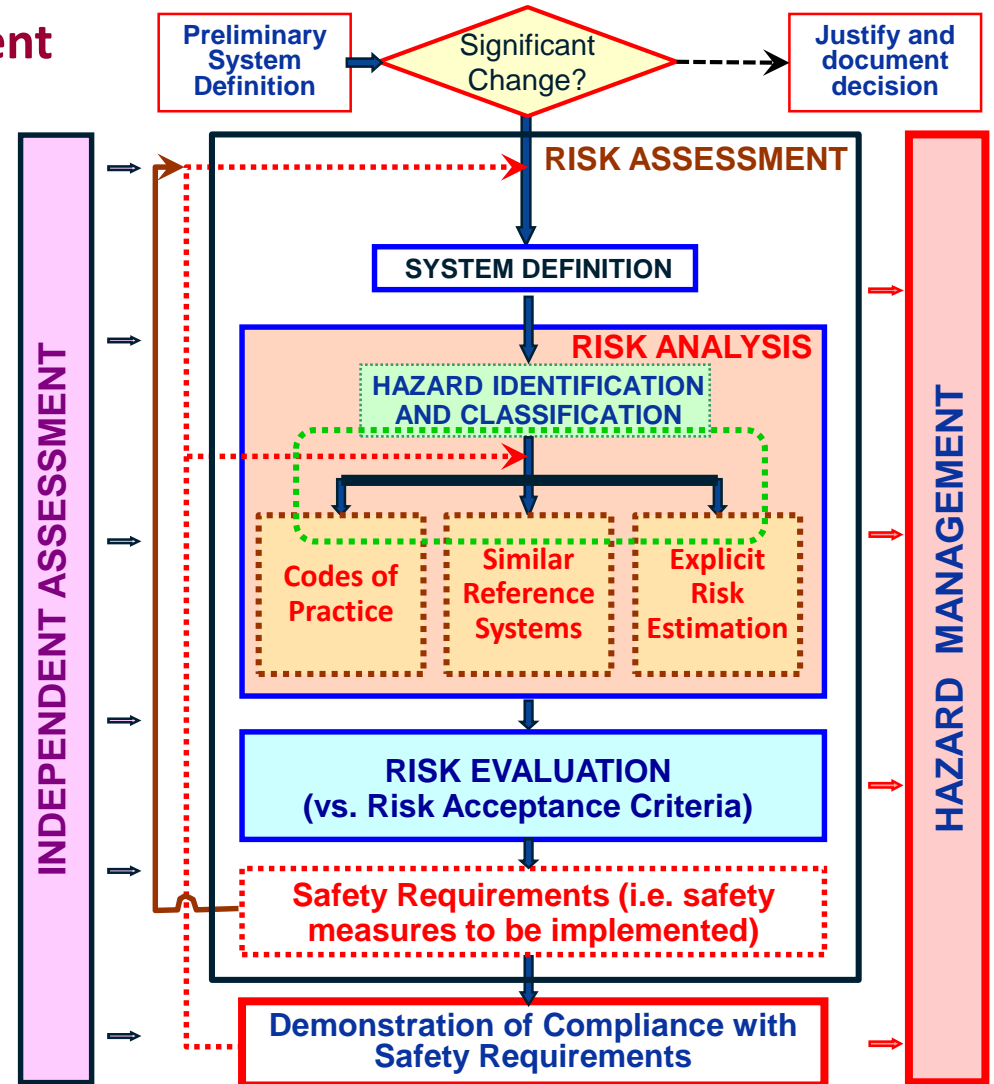
Defines a common process for risk assessment

- (a) **System definition**
- (b) **Hazard identification & classification**
- (c) Identification of **safety measures**
- (d) **Risk analysis** based on use of exiting Risk Acceptance Principles (RAP):

- 1) **Codes of practice**
- 2) **Reference Systems**
- 3) **Explicit risk estimation**

**There is no mandatory order of priority in use of these three RAP**

- (d) **Risk evaluation** for checking acceptance of risk(s)
- (e) Definition of **safety requirements** from identified safety measures



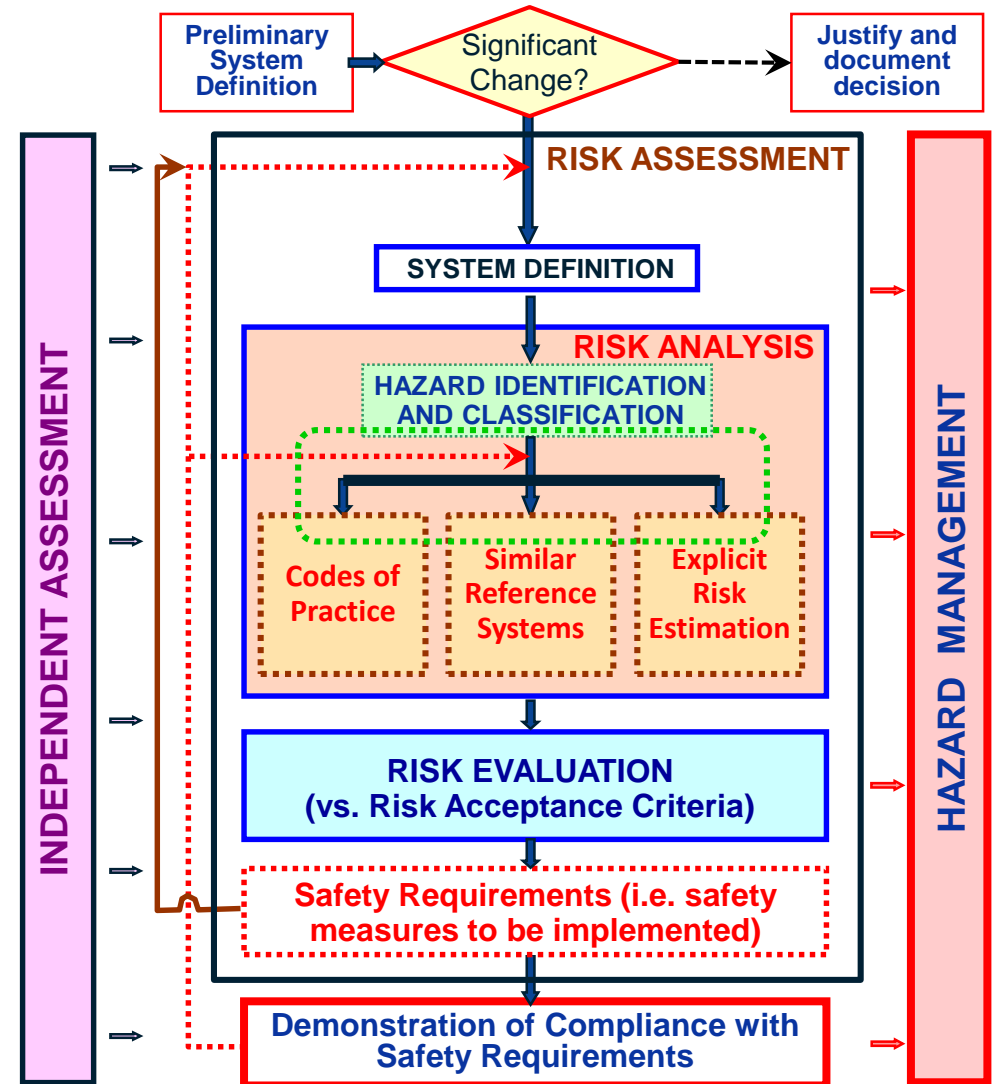


# Overview of the CSM for risk assessment

## Process in Annex I

### CSM for risk assessment also requires:

- Update system definition with identified safety requirements;
- Demonstrate compliance with system definition, and thus with safety requirements from risk assessment;
- To support mutual recognition:
  - (a) Risk assessment and risk management must be **documented in hazard record**;
  - (b) **Independent assessment by a CSM Assessment Body** of correct application of the CSM Process and of appropriateness of results





# Overview of harmonised methods for safety management and safety supervision

*How many CSMs?*

Railway Safety Directive 2004/49/EC

CSM for Risk Assessment  
Regulation 402/2013

CSM for Monitoring  
Regulation 1078/2012

*Freight wagons*

ECM Regulation  
445/2011

*Freight wagons*

ECM Regulation  
445/2011

CSM for Conformity  
Assessment - Regulations  
1158/2010 & 1169/2010

CSM for Supervision  
Regulation 1077/2012

Assessment

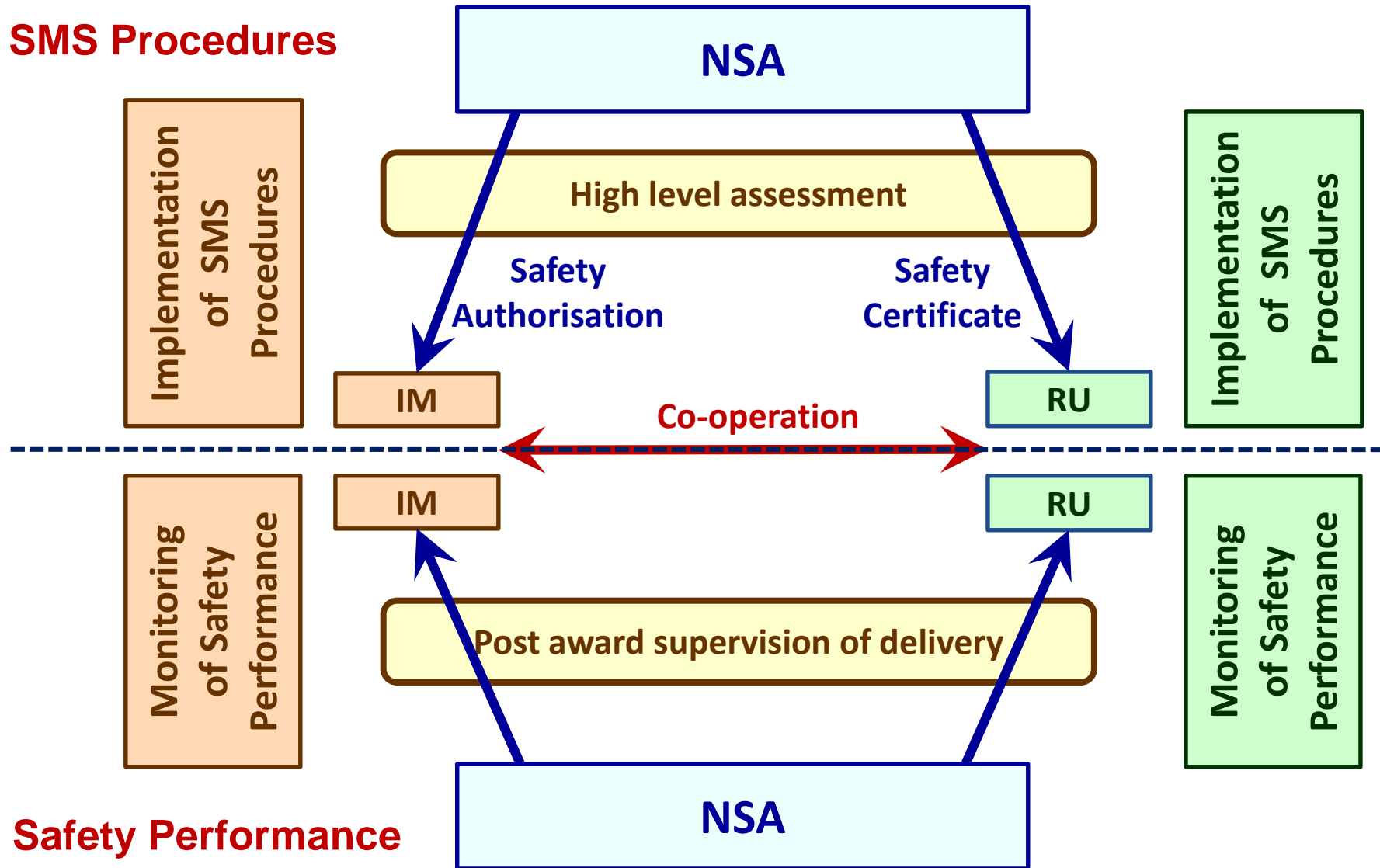
Monitoring/Supervision/Surveillance

Safe Operation & Safe Maintenance

# Roles of Public Authorities (NSAs)

## Safety Certification/Authorisation of RU/IM SMS

### SMS Procedures



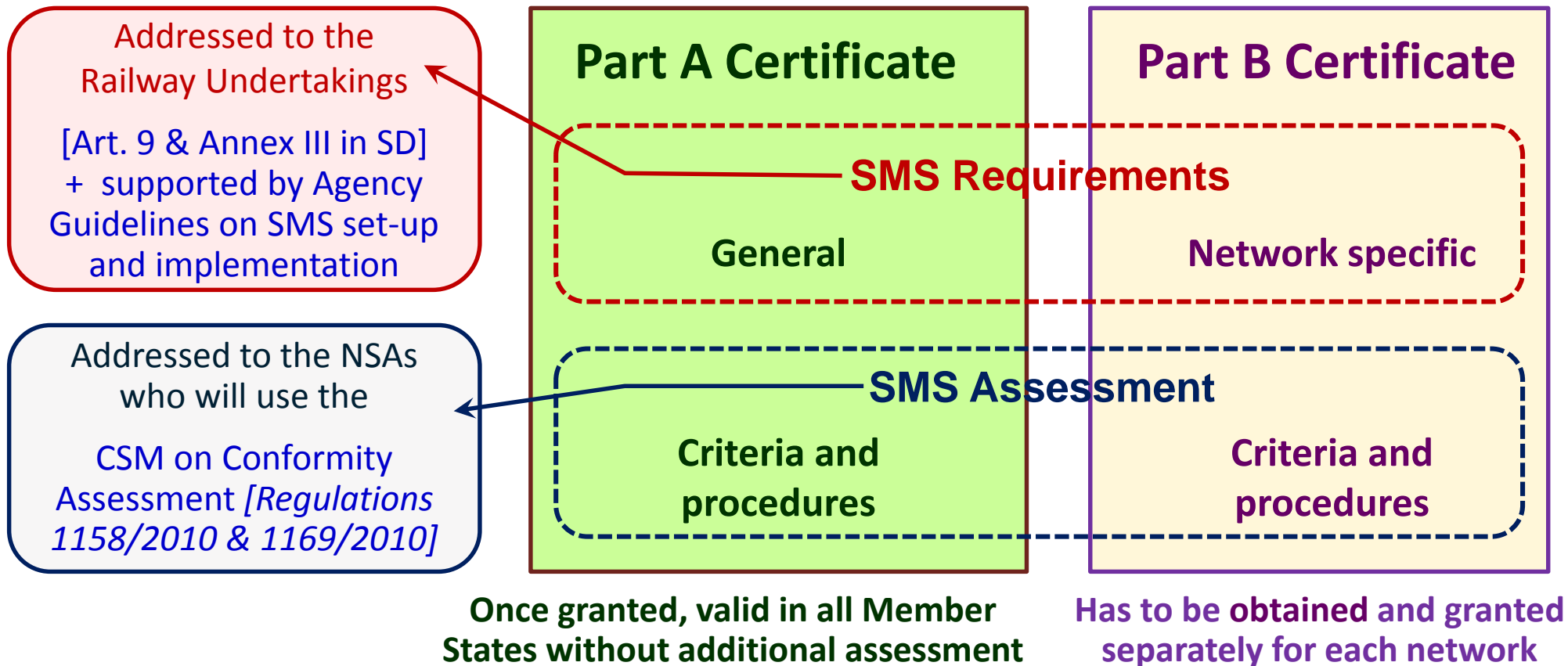
# Safety Certification for Railway Undertakings in two parts (i.e. at least two Safety Certificates)

**According to Article 10  
of Directive 2004/49**

## Safety Certification

*(in two parts, i.e. at least two Safety Certificates)*

confirming acceptance by NSA of RUs' provisions for  
management of a safe operation



# Safety Authorisation for Infrastructure Managers in one step (one single Safety Authorisation)

## According to Article 11 of Directive 2004/49

Addressed to the  
Infrastructure Managers

[Art. 9 & Annex III in SD]  
+ supported by Agency  
Guidelines on SMS set-up  
and implementation

Addressed to the NSAs  
who will use the

CSM on Conformity  
Assessment [Regulations  
1158/2010 & 1169/2010]

### Safety Authorisation

*(in one step - one single Safety Authorisation)*

confirming acceptance by NSA of IMs' provisions for  
management of a safe operation

#### SMS Requirements

General

Network specific

#### SMS Assessment

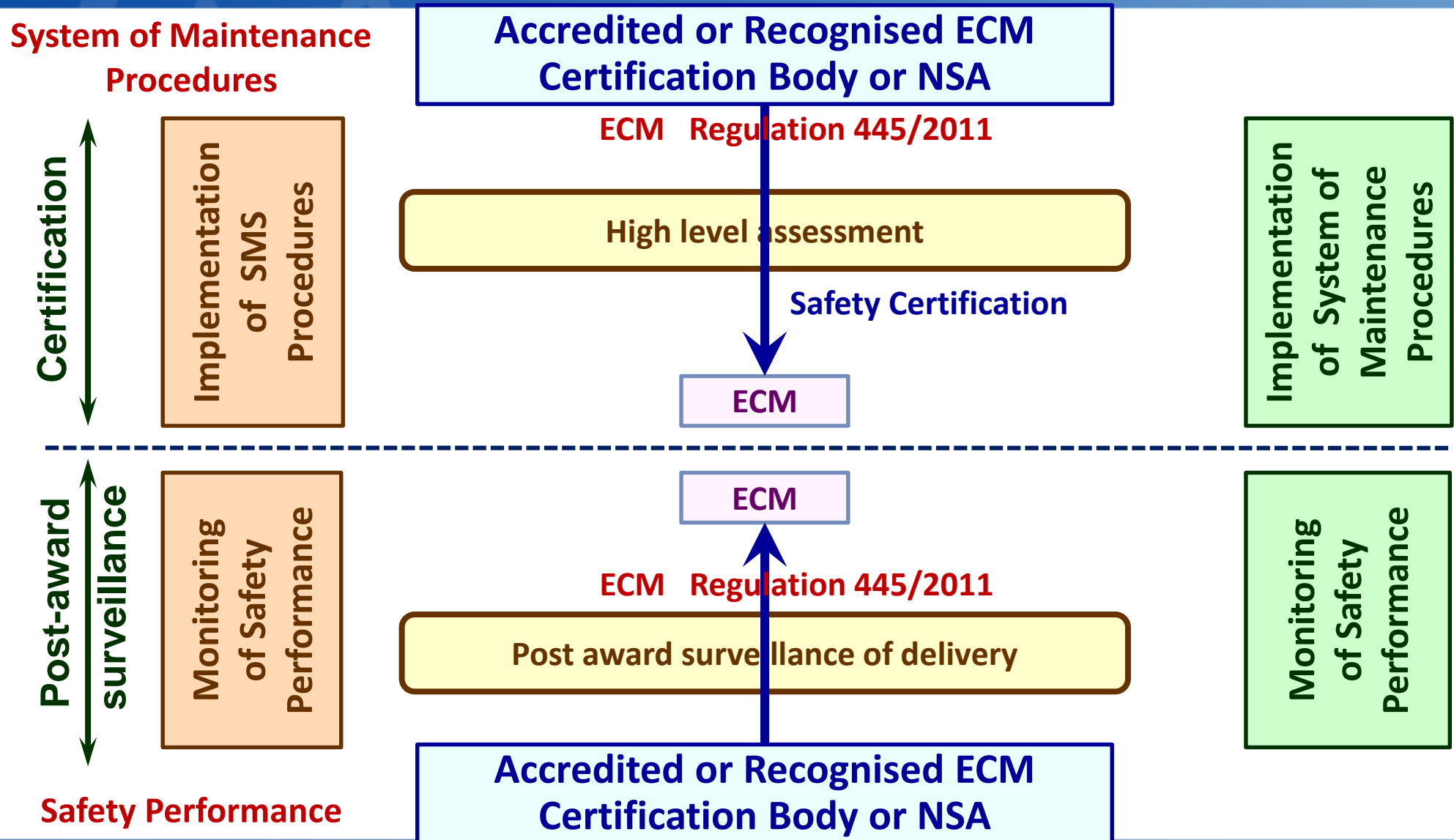
Criteria and  
procedures

Criteria and  
procedures



# Roles of Certification Bodies

## Certification of Maintenance System of ECMs



# Roles and responsibilities for placing in service

## Authorisation of Vehicles - Safe Integrations

### STEP 1

#### Responsibilities of Applicant

Design, construct, install, test  
& demonstrate  
Safe Integration within the vehicle

Technical File containing all  
Operational & Maintenance  
Requirements linked to the design

Technical compatibility and safe  
integration within the vehicle  
(Use of CSM for RA)

Conformity with TSI	Conformity with NNR	RA according to CSM
Check by NOBO	Check by DEBO	Check by CSM Assessment Body

**NSA Authorisation  
for placing in service**

### STEP 2

#### Responsibilities of Railway Undertaking

Check technical compatibility and demonstrate  
safe integration within the Route

Technical compatibility and safe  
integration within the Route  
(Use of CSM for RA)

Conformity with infrastructure register (RINF)	Conformity with NNR	SMS update accor- ding to CSM for RA
Check by RU	Check by RU	Check by CSM Assessment Body

**RU decision of  
placing in service**

### STEP 3

#### Responsibilities of RU & ECM

Operation & Maintenance  
according to Technical File

**Return of experience**

Operation  
according to  
RU SMS

Supervision  
by NSA

Supervision by NSA [Art 16(2)(f)]

Maintenance  
according to  
ECM System of  
Maintenance

Surveillance by  
ECM Cert Body

Update  
of SMS

## Assurance of compliance with EU legislation - Mutual trust/recognition

- ❑ To avoid new assessments and new safety demonstrations for a same system, EU legislation introduces concepts of:
  - Certification
  - (Independent) Conformity Assessment
  - Mutual Recognition or Acceptance (XA)
- ❑ System or safety demonstration accepted in one MS or by one CAB must be cross accepted in another MS or by another CAB if used under the **same functional, operational and environmental conditions**
- ❑ ➔ **duplication of conformity assessments** between different Conformity Assessment Bodies involved in a project **shall be avoided**
- ❑ Conformity assessment bodies: NSAs, NoBos, DeBos, ECM Certification Bodies, CSM Assessment Bodies, National Accreditation Bodies & Recognition Bodies

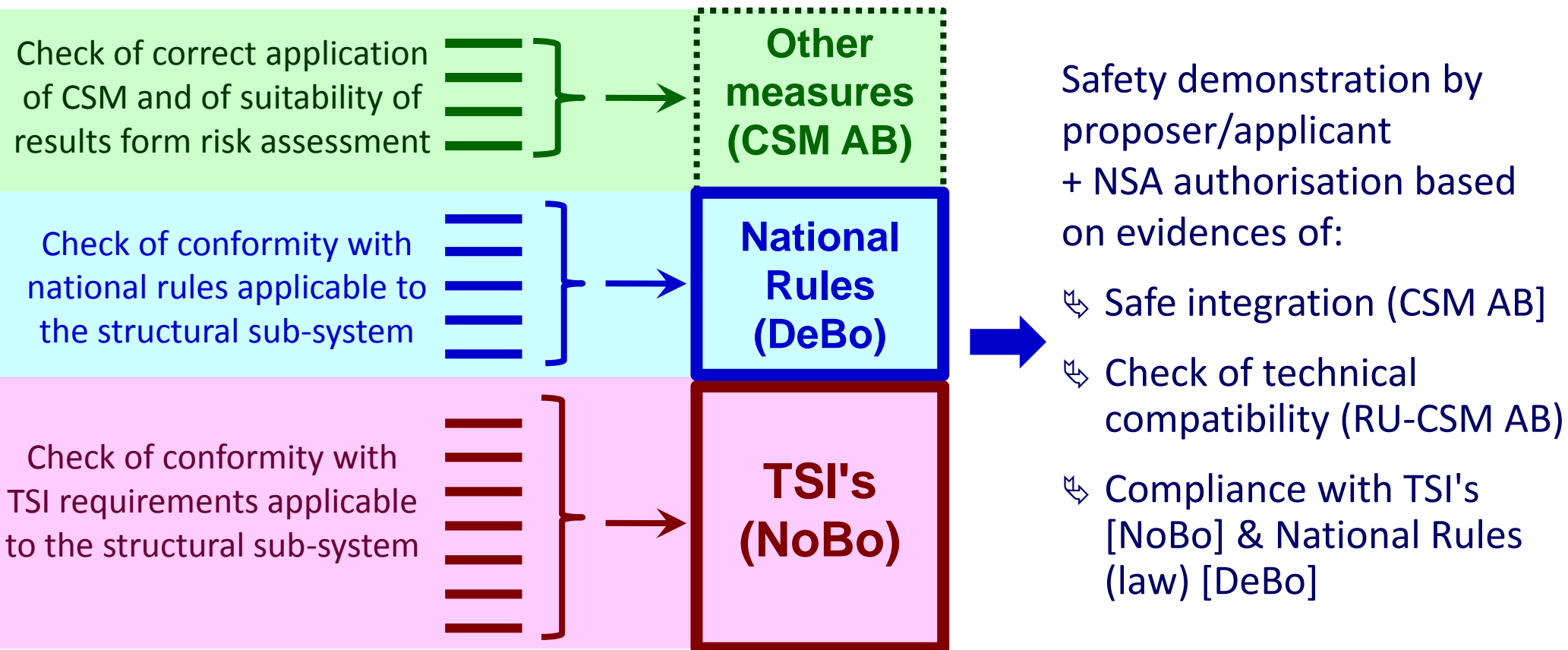


Monitoring of experience is expected to build trust between MS & between CABs

## Mutual trust/recognition – Roles of Conformity Assessment Bodies (CABs)

**Duplication of conformity assessments between different Conformity Assessment Bodies involved in a project shall be avoided**

**All risks identified with CSM for risk assessment (corner stone in risk management)**



# European Railway Market Opening

## Mutual trust/recognition – Current situation

Although all tools and principles are in place, there is a lack of mutual recognition between MS because of:

- ❑ historical differences & approaches to safety management
- ❑ differences in safety cultures & relation of railways with Public Authorities

✚ **blame culture** → encourages to keep closed & not fully transparent with NSA or within railway companies



✚ **just culture** (aviation) → encourages transparency in communication, learning through mistakes & continuously improving safety management

- ❑ existence of many National Rules requiring additional safety demonstrations and conformity assessments (DeBo, NSA) prior to system use in another MS

# European Railway Market Opening

## Mutual trust/recognition – Current situation

Although all tools and principles are in place, there is a lack of mutual recognition between MS because of:

- ❑ differences in NSA approaches to APIS – Some NSAs keep behavior of “Approving Authority” [former homologation]



- ❑ although NSA Networks put in place by ERA for exchanging on their ways of doing, NSAs fail to work & take decisions in a same way across EU



Achievement of a safe management of railway activities & operations by RUs/IMs, and therefore of a trustworthy effective and safe control of railway safety by RUs/IMs, including safe management of changes, is dependent on:

- (a) RU/IM maturity with risk based approach [risk assessment & monitoring] and an effective implementation and use of a well-designed SMS;
- (b) NSA maturity with risk based approach in assessing and supervising safety management system of RUs/IMs, and therefore;
- (c) NSA ability to prioritise their supervision activities to areas that give rise to greatest risks and, if not controlled effectively by RU/IM, could lead to adverse consequences for safety.

**NSA assessment & supervision should be proportionate to evaluated risk level**

The higher RU/IM & NSA maturity in risk assessment and risk management is, and the more developed NSA supervision is, the less unnecessary additional safety demonstrations update of safety certificate/authorisation there will be

# 4<sup>th</sup> Railway Package

*Expected to arrive in 2016*



- ❑ Recast of Safety & Interoperability Directives, of “European Railway Agency Regulation” (ERA) **+ new tasks for ERA**
- ❑ Single Safety Certificate instead of currently Part A and (several) Parts B
- ❑ New Roles & Responsibilities concerning certification & supervision of Safety Management Systems of railway undertakings:
  - ↳ **international transport services in more than one Member State**

Issuing of APIS structural sub-systems & SMS Certification by ERA



**or**

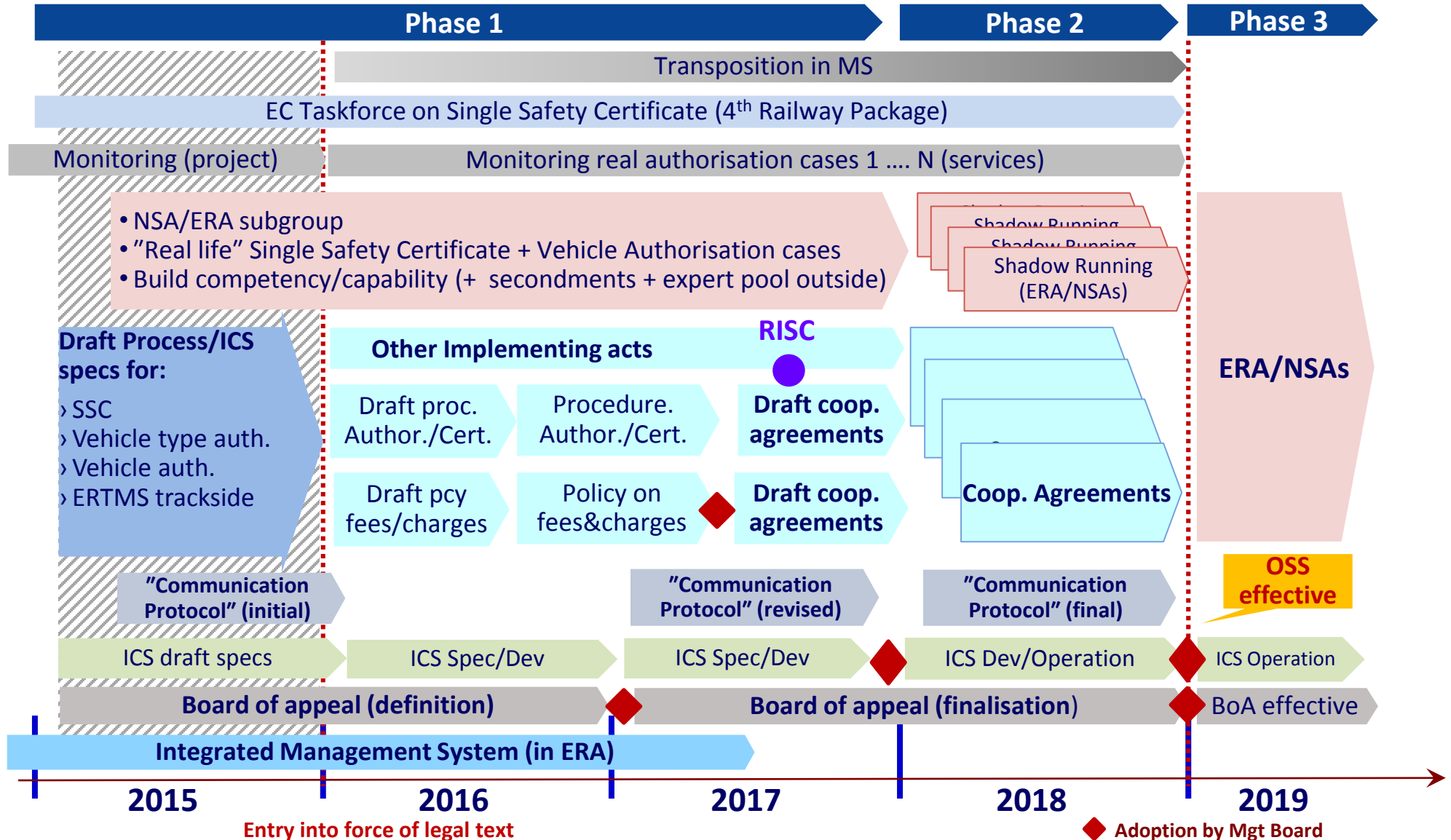


↳ **national transport services only in one MS**

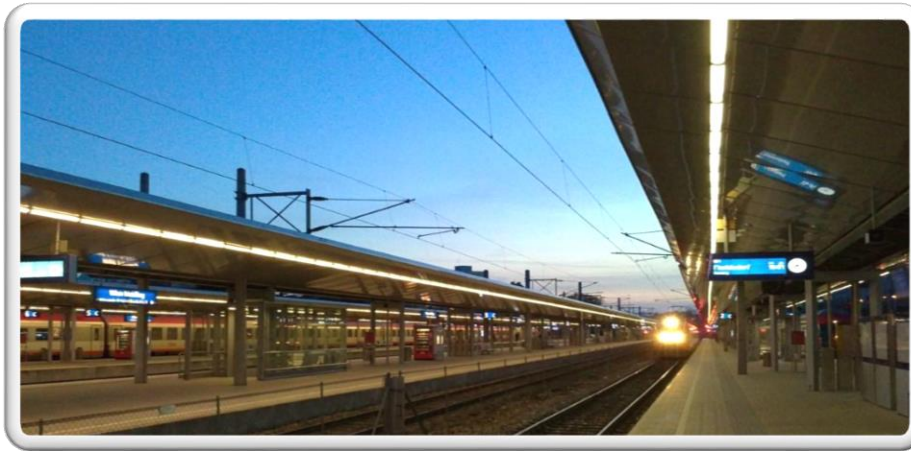
Applicant's choice for APIS & SMS certification either by NSA or by ERA

# European Railway Market Opening - 4<sup>th</sup> Railway Package

## Agency & EC 4RWP preparation







**Many thanks for your attention!**

Making the railway system work better for society.

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