

# EU legal framework for VA

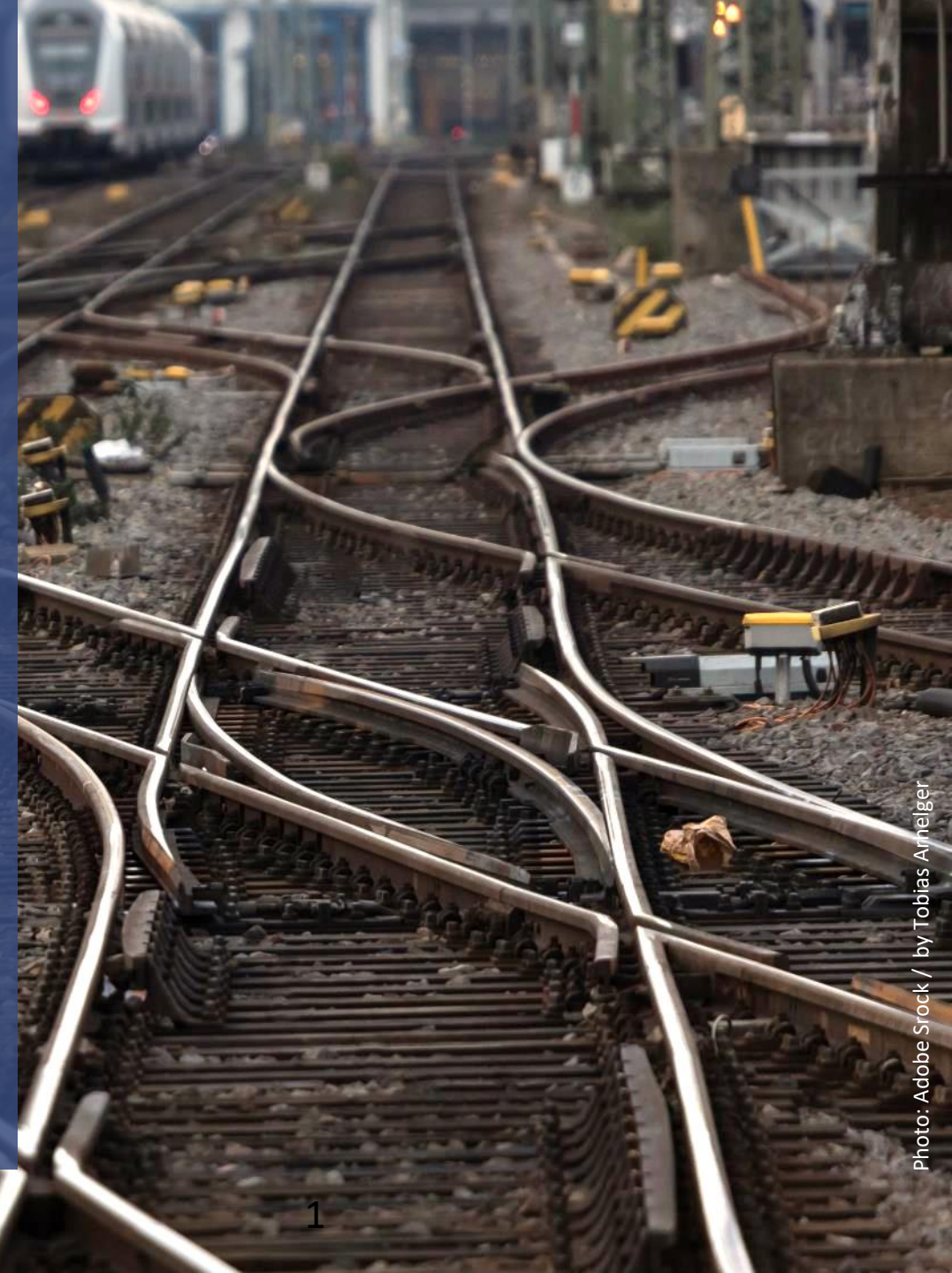
Cross Acceptance of Energy Metering Systems in  
EU

19 September 2024 | Eress forum (MS Teams)

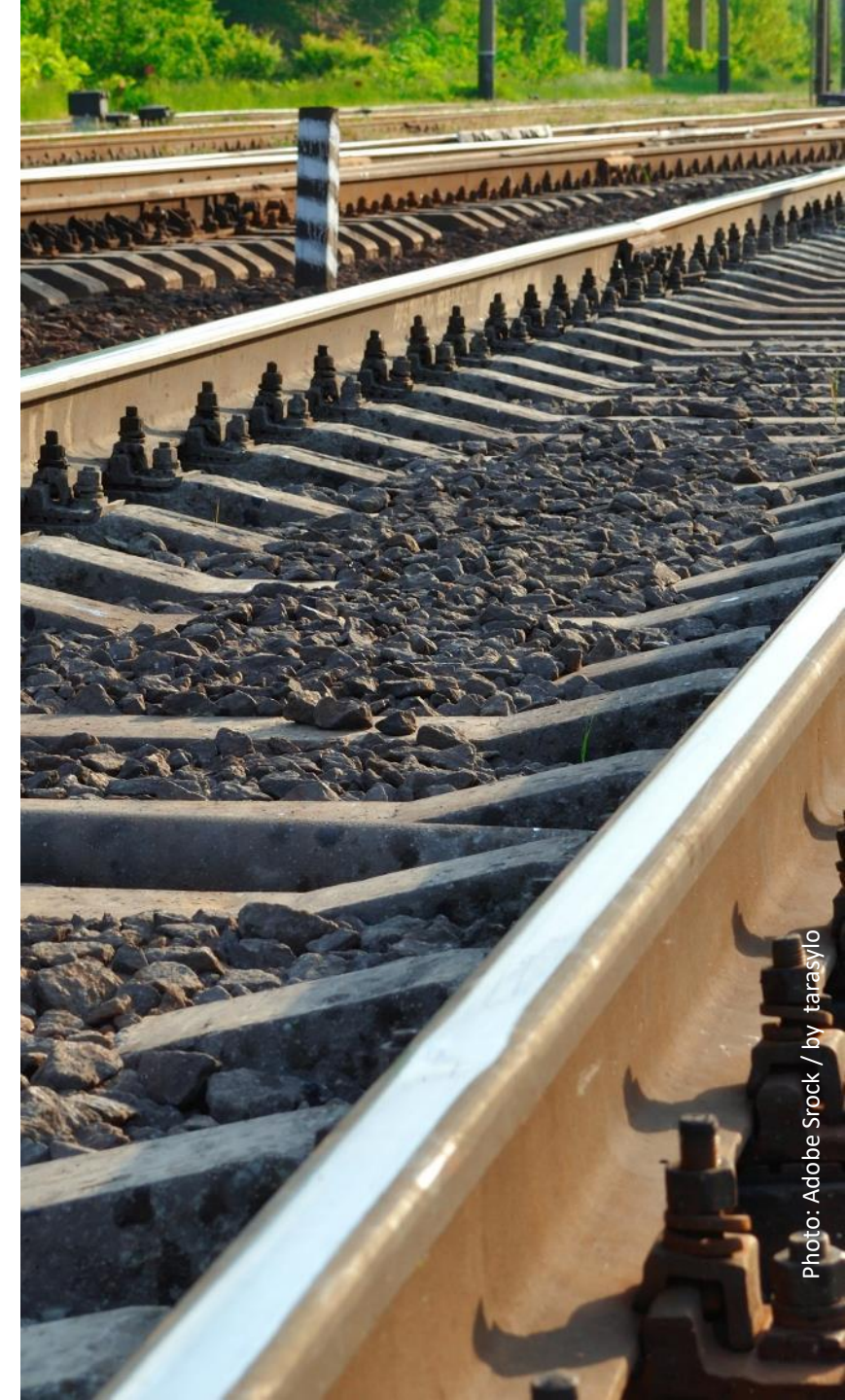
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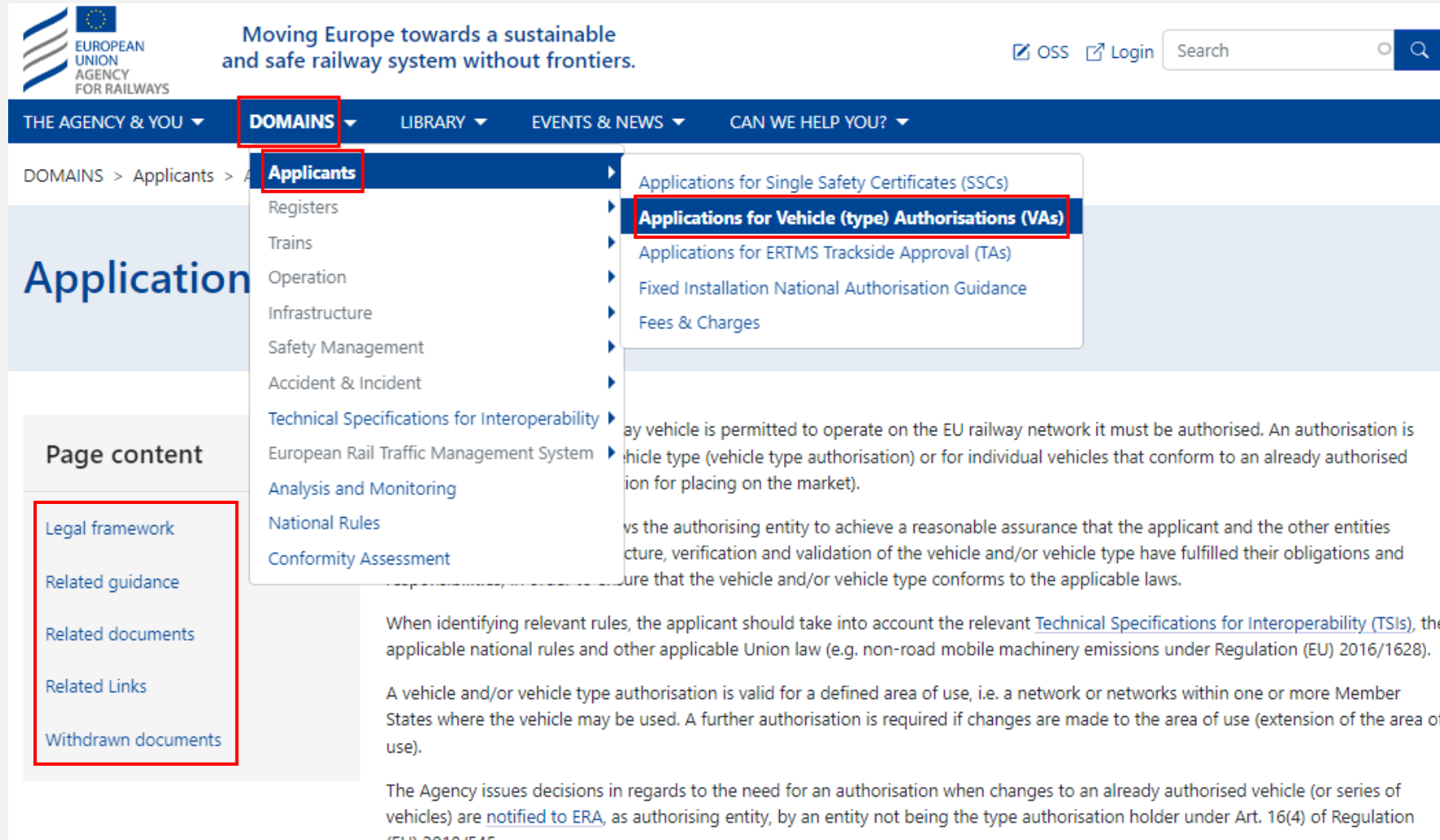
EUROPEAN  
UNION  
AGENCY  
FOR RAILWAYS



# Where to find documentation in ERA website



# Where to find the documents



The screenshot shows the ERA website interface. The top navigation bar includes 'THE AGENCY & YOU', 'DOMAINS', 'LIBRARY', 'EVENTS & NEWS', and 'CAN WE HELP YOU?'. The 'DOMAINS' menu is expanded, showing 'Applicants' as the selected item. Under 'Applicants', the sub-menu 'Applications for Vehicle (type) Authorisations (VAs)' is highlighted. The main content area displays the title 'Application' and a 'Page content' sidebar with links for 'Legal framework', 'Related guidance', 'Related documents', 'Related Links', and 'Withdrawn documents'. The main text explains that any vehicle permitted on the EU railway network must be authorised, either as a vehicle type (VA) or for individual vehicles. It also mentions that the applicant should consider relevant Technical Specifications for Interoperability (TSIs) and applicable national rules and Union law.

Moving Europe towards a sustainable and safe railway system without frontiers. [OSS](#) [Login](#) Search

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DOMAINS > Applicants > **Applicants**

- Registers
- Trains
- Operation
- Infrastructure
- Safety Management
- Accident & Incident
- Technical Specifications for Interoperability
- European Rail Traffic Management System
- Analysis and Monitoring
- National Rules
- Conformity Assessment

**Applications for Vehicle (type) Authorisations (VAs)**

- Applications for Single Safety Certificates (SSCs)
- Applications for ERTMS Trackside Approval (TAs)
- Fixed Installation National Authorisation Guidance
- Fees & Charges

## Application

### Page content

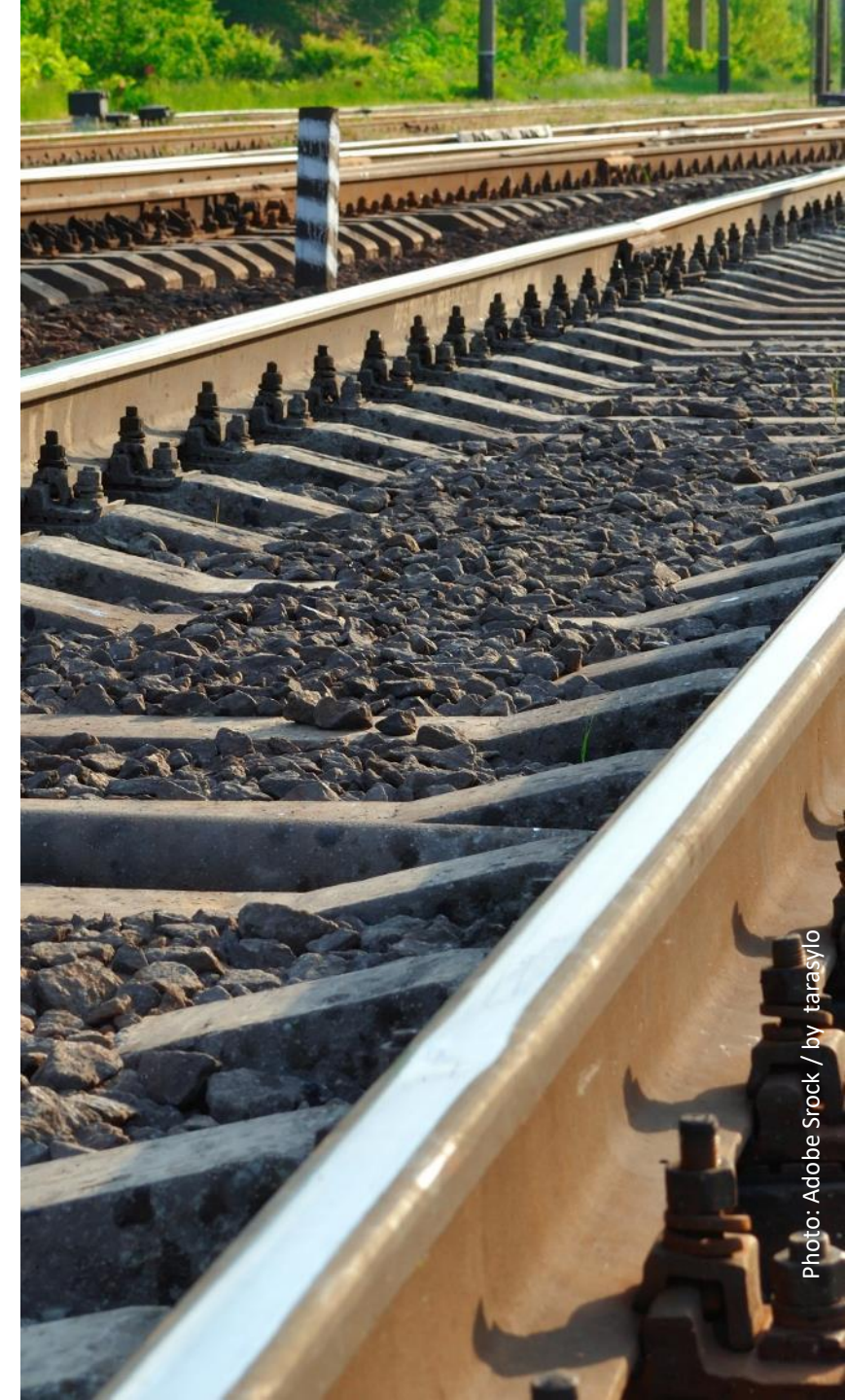
- Legal framework
- Related guidance
- Related documents
- Related Links
- Withdrawn documents

When identifying relevant rules, the applicant should take into account the relevant [Technical Specifications for Interoperability \(TSIs\)](#), the applicable national rules and other applicable Union law (e.g. non-road mobile machinery emissions under Regulation (EU) 2016/1628).

A vehicle and/or vehicle type authorisation is valid for a defined area of use, i.e. a network or networks within one or more Member States where the vehicle may be used. A further authorisation is required if changes are made to the area of use (extension of the area of use).

The Agency issues decisions in regards to the need for an authorisation when changes to an already authorised vehicle (or series of vehicles) are [notified to ERA](#), as authorising entity, by an entity not being the type authorisation holder under Art. 16(4) of Regulation (EU) 2018/545.

# The technical pillar of the 4<sup>th</sup> Railway Package



# The technical pillar of the 4<sup>th</sup> Railway Package

2004

- **2<sup>nd</sup> railway package**: Interoperability Directive amended (covering TEN network), Safety Directive 2004/49/CE and Regulation 881/2004 (European Railway Agency created)

2007

- **3<sup>rd</sup> railway package**: passenger rights better guaranteed, opening of the market for international railway services (from January 2010), European license for train drivers

2008

- Interoperability Directive 2008/57/EC covering all the railway network
- Directive 2008/110/EC amending the Safety Directive (ECMs introduced)

2016

- **4<sup>th</sup> railway package (technical pillar)**: major revision of ERA regulation, Interoperability and Safety directives: new roles and responsibilities for ERA, single safety certificate and improved vehicle authorisation process

# The technical pillar of the 4<sup>th</sup> Railway Package

## Directives & Regulations

- Regulation (EU) 2016/796 The Agency regulation
- Directive (EU) 2016/797 Interoperability <sup>(1)</sup>
- Directive (EU) 2016/798 Safety <sup>(2)</sup>

## Commission Implementing Regulations

- Regulation (EU) 2018/545 Practical arrangements for VA <sup>(3)</sup>
- Regulation (EU) 2019/250 EC declaration of verification <sup>(4)</sup>
- Classification of national rules (draft)
- Regulation (EU) 2020/424 non-application of TSIs
- Regulation (EU) 2018/764 Fees & Charges
- Regulation (EU) 2018/867 Board of Appeal

## Guidance

- ERA1209/222 Guidelines for the practical arrangements for the VA process v2.1
- Clarification notes (Agency position as Authorising Entity)

## Agreements

- Cooperation agreements between Agency and NSAs
- Multilateral agreements

(1) As amended by Directive (EU) 2020/700  
 (2) As amended by Directives (EU) 2020/700, 2020/153  
 (3) As amended by Regulation (EU) 2020/781  
 (4) As amended by Regulation (EU) 2020/779

# The technical pillar of the 4<sup>th</sup> Railway Package

## TSIs (1)

- **Regulations (EU) 2014/1302 (LOC&PAS) & 2013/321 (WAG)**, as amended by Regulations (EU) 2019/776, 2020/387 & 2023/1694
- **Regulation (EU) 2016/919 (repealed CCS TSI)** as amended by Regulations (EU) 2019/776, 2020/387 & 2020/420 (still applicable for some cases)
- **Regulation (EU) 2023/1695 (recast CCS TS)**
- **Regulation (EU) 2019/773 (OPE), repealing 2012/757/EU**, as amended by Regulations (EU) 2021/2238 & 2023/1693
- **Regulation (EU) 1304/2014 (NOI)**, as amended by Regulations (EU) 2019/774 & 2023/1694
- **Regulation (EU) 1300/2014 (PRM)**, as amended by Regulations (EU) 2019/772, 2022/721, 2023/62 & 2023/1694

## Other legal texts

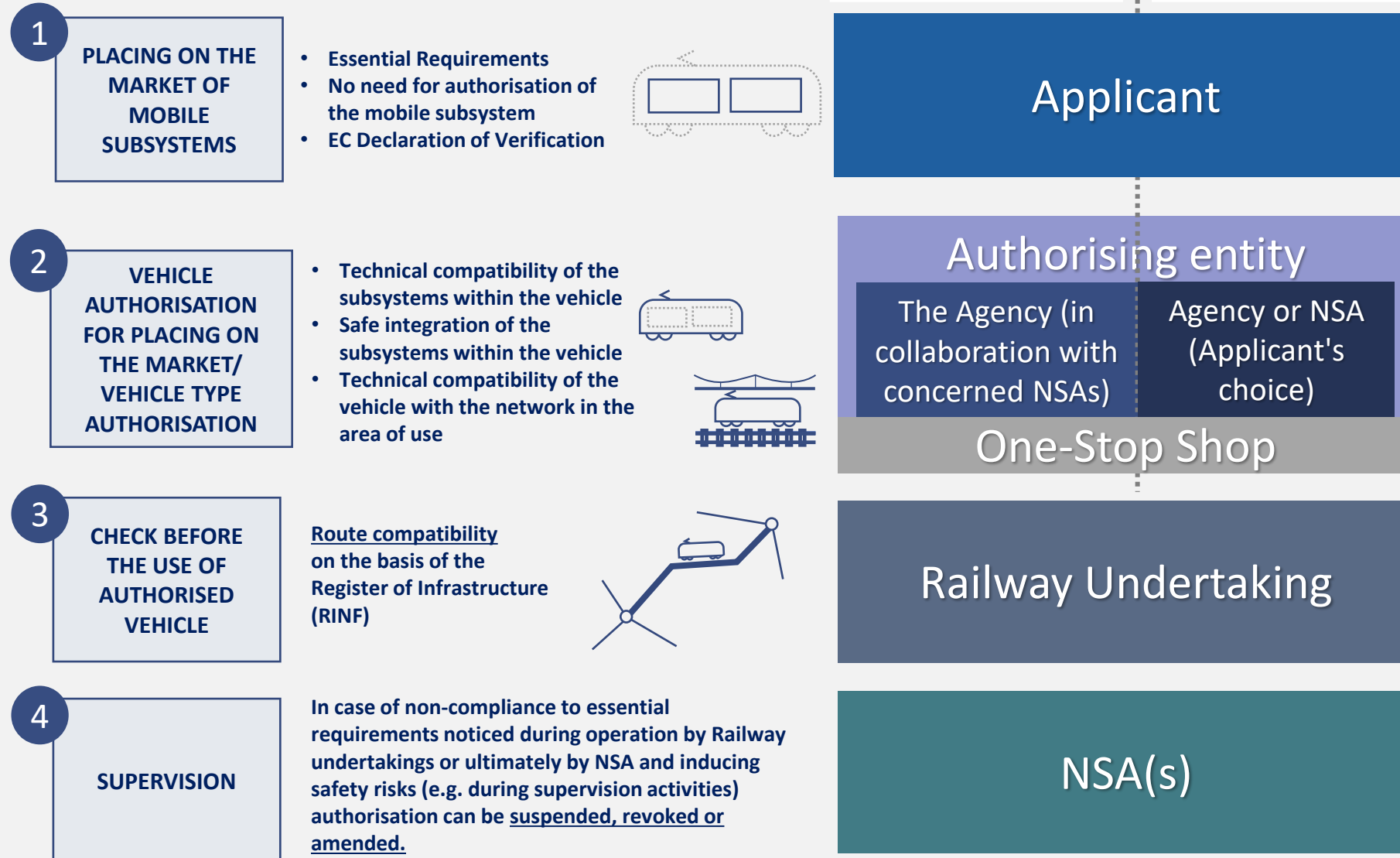
- **Regulation (EU) 402/2013 CSM RA**
- **Decision 2010/713/EU conformity assessment modules**

## Registers

- **Decision (EU) 2018/1614 (EVR)**, amending & repealing decision 2007/756/EC NVR
- **Decision 2014/880/EU (RINF)**, as amended by Regulations (EU) 2019/777 & 2023/1694
- **Decision 2011/665/EU (ERATV)**, as amended by Regulations (EU) 2019/776, 2021/701 & 2023/1696
- **RDD: decision 2011/155/EU on the reference document**
- **RDD: ERA/GUI/XA v3.0 Part 1 reference document**
- **Guidance to TSIs and Registers**

(1) Only the amendments under 4RP are mentioned, there may be previous amendments

# The technical pillar of the 4<sup>th</sup> Railway Package





# The technical pillar of the 4<sup>th</sup> Railway Package

3rd RWP

4th RWP

FIRST  
AUTHORISATION  
MS1

ADDITIONAL  
AUTHORISATION  
MS2

ADDITIONAL  
AUTHORISATION  
MS3

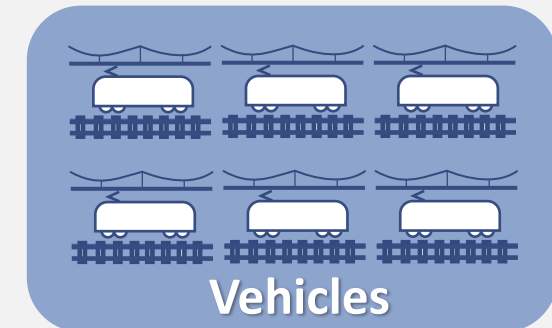
ONE SINGLE  
AUTHORISATION



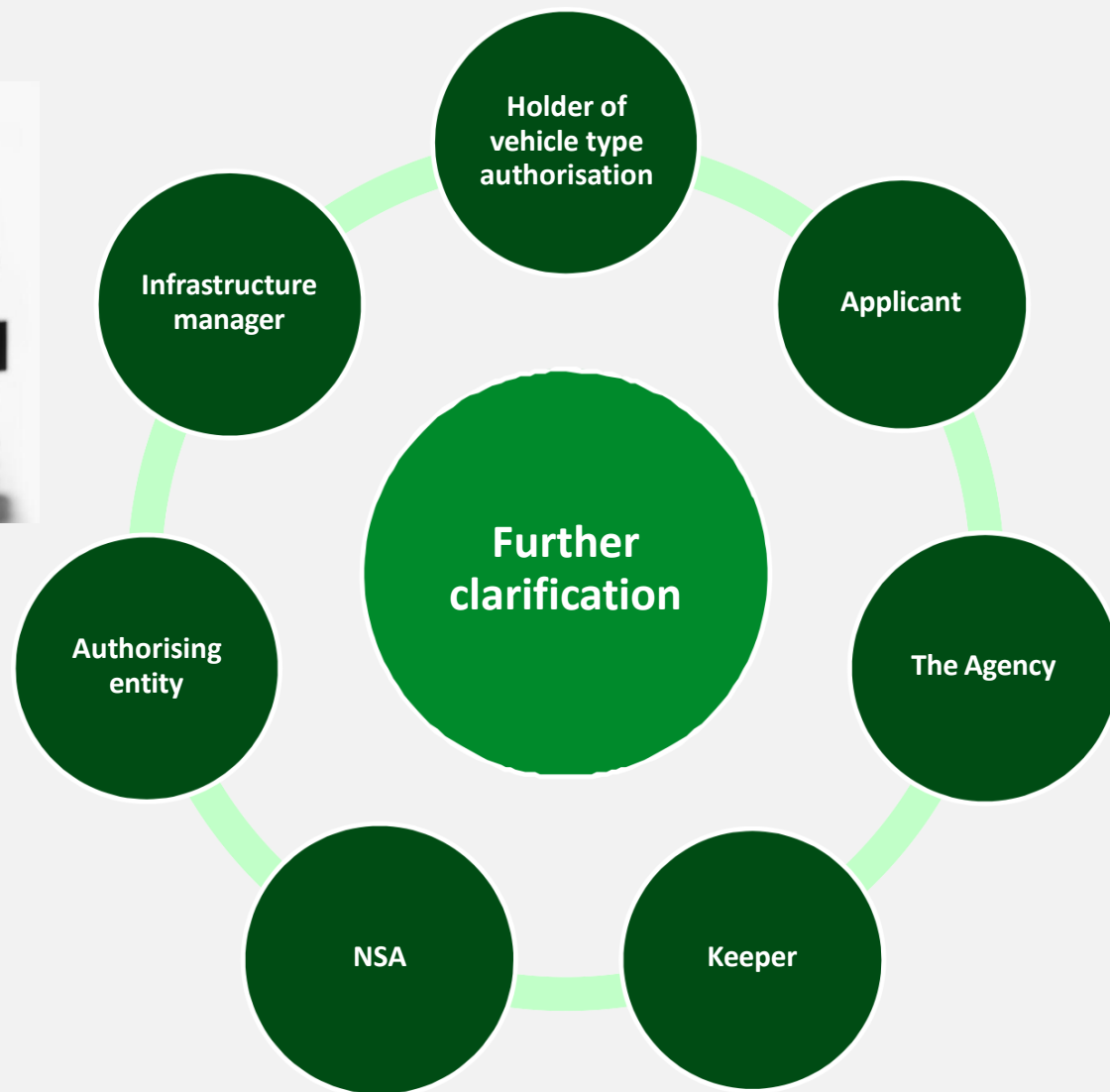
Authorisation for placing in  
service

Authorisation for placing on  
the market

Vehicle type  
+Variant & Version

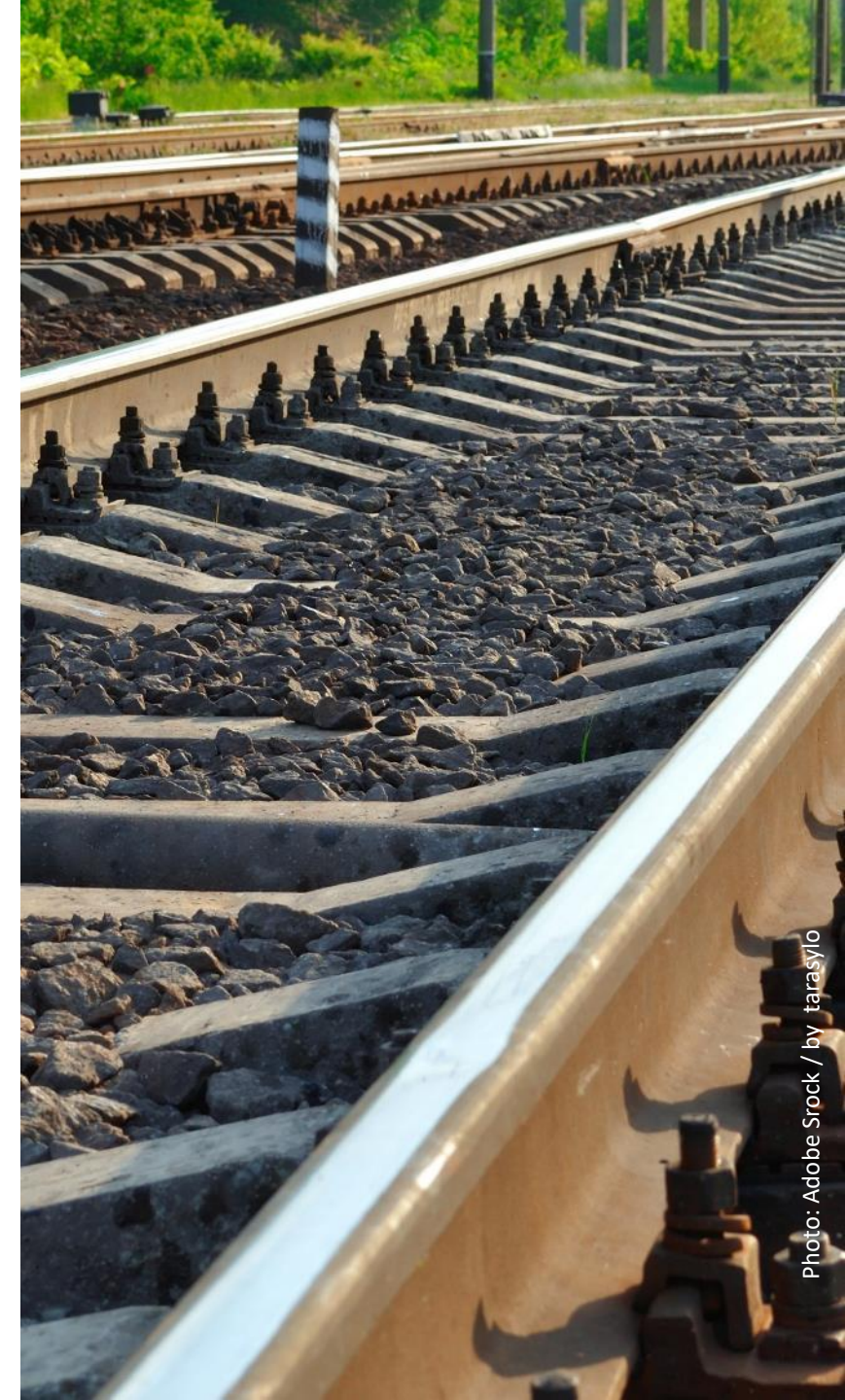


# New/amended roles



# Regulation (EU) 2018/545

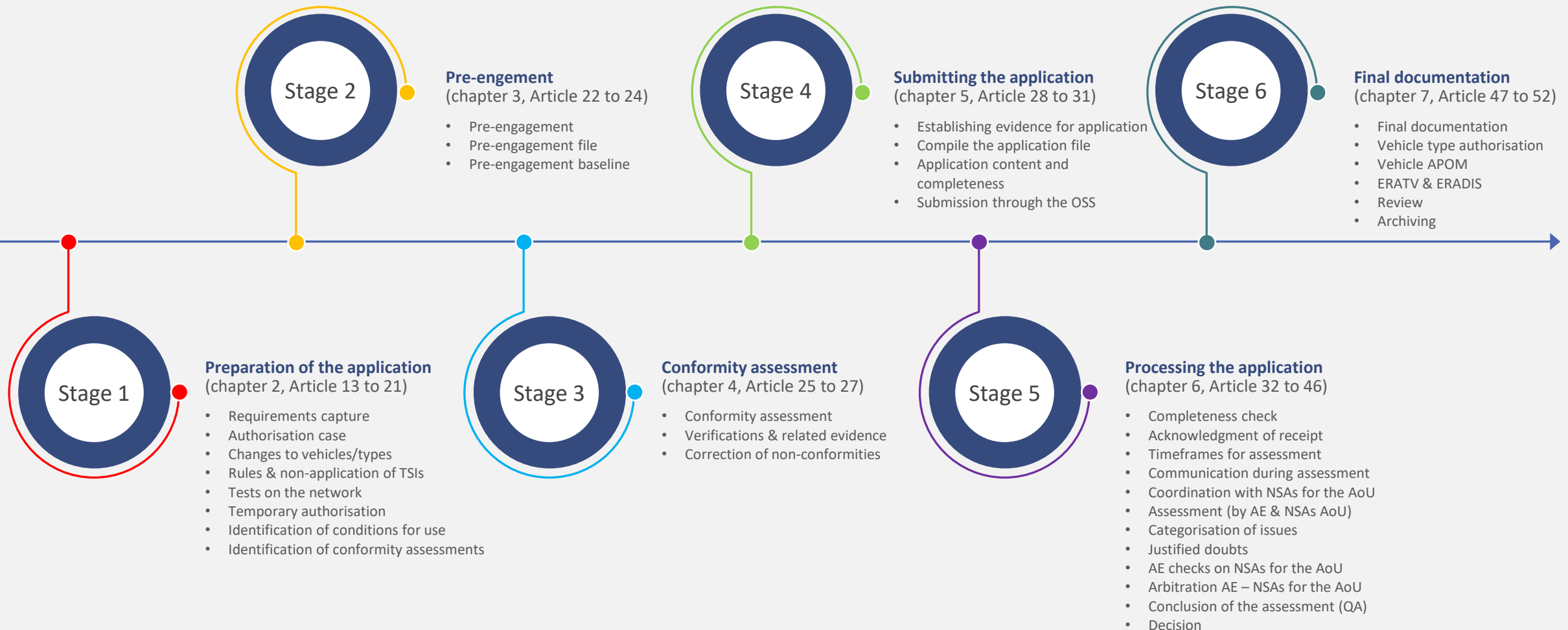
EU harmonised process



# Regulation (EU) 2018/545

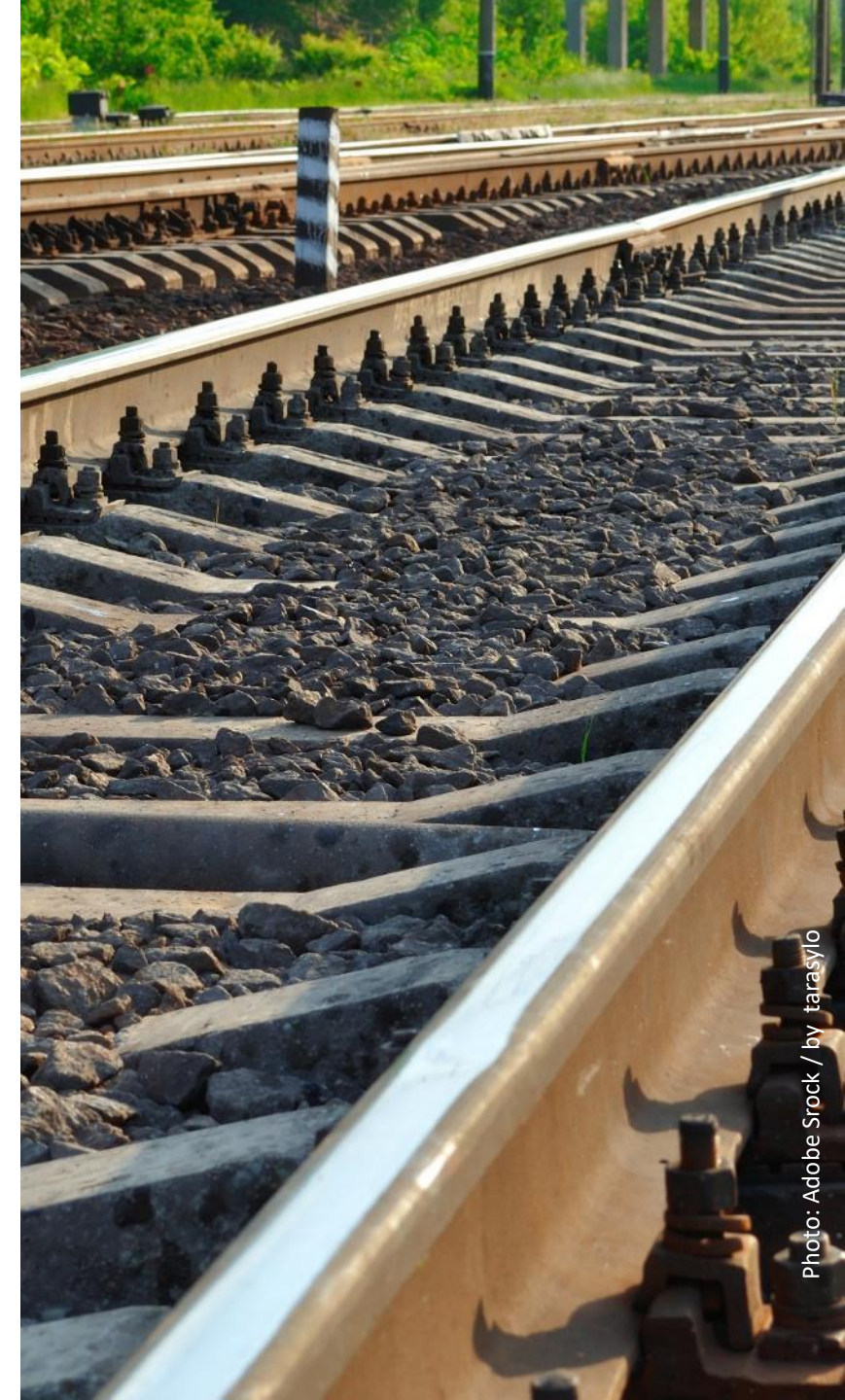
## Overview of an EU harmonised VA process

The **Commission Implementing Act (EU) 2018/545** describes a harmonised process directly applicable in all EU Member States, together with a clear allocation of roles and responsibilities to the main actors in the Railway system.



# EC verification procedure

Placing on the market of mobile subsystems



# Directive (EU) 2016/797

## EC verification procedure



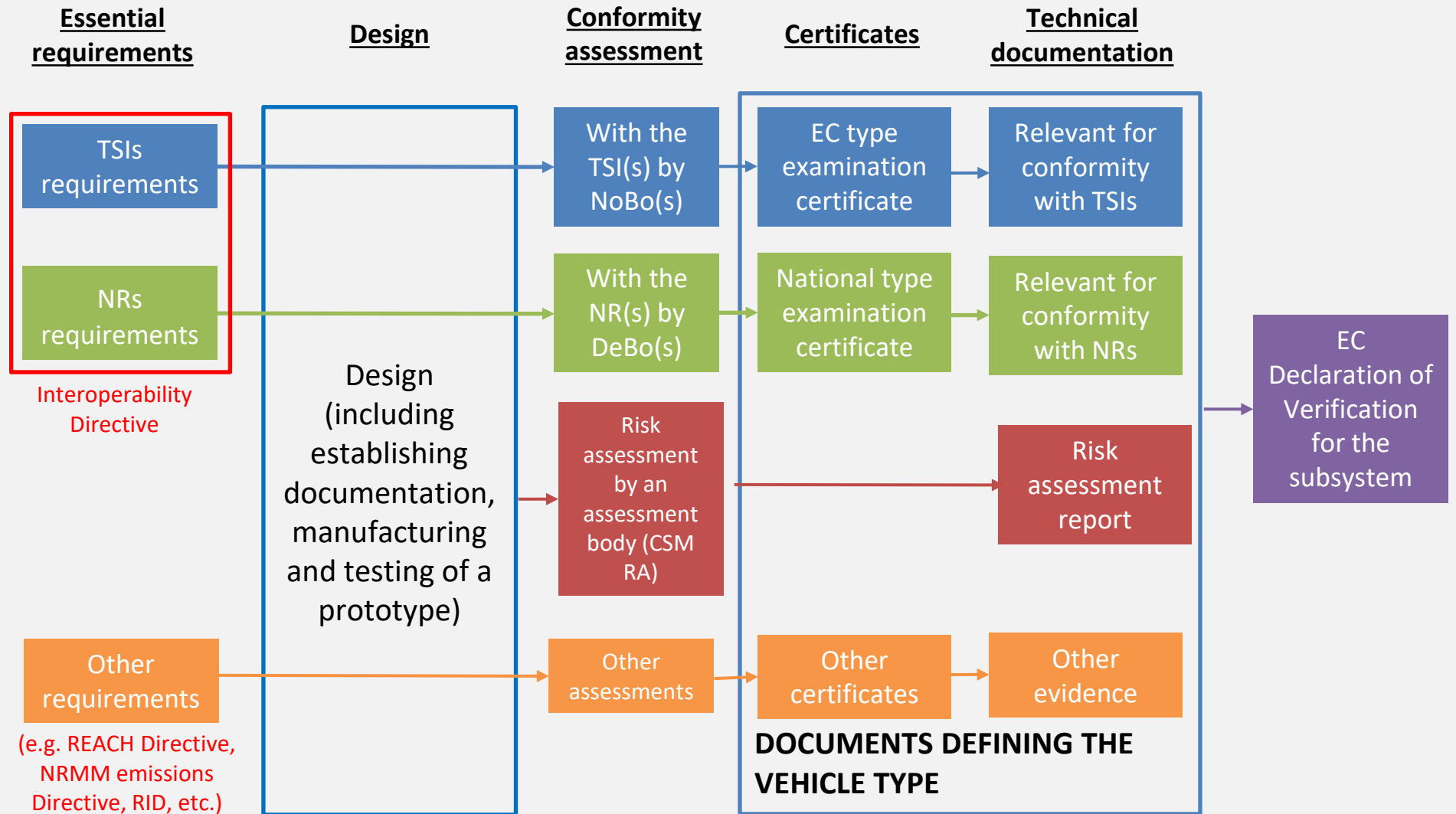
### Placing on the market of mobile subsystems

- Under (EU) 2016/797, mobile subsystems (**rolling stock, control-command and signaling**) are placed on the market, but they do not require an authorisation (as it was the case under 2008/57/EC)
- Before placing a subsystem on the market, the applicant shall perform the **EC verification procedure**, which covers compliance with TSIs, national rules and other applicable EU legislation
- The final outcome of the EC verification procedure is the **EC declaration of verification** established by the applicant (minimum content laid down in **Regulation (EU) 2019/250**), which shall describe:
  - Applicable rules (Directives, TSIs, national rules)
  - Conformity assessment bodies (NoBo, DeBo, AsBo)
  - **EC certificate of verification issued by the NoBo**
  - **Certificate of verification issued by the DeBo**
  - Risk assessment report (when required by the TSI) issued by the AsBo
  - Outcomes (certificates, reports, declarations etc.) required by other applicable EU law
  - Conditions for use and other restrictions
  - Reference to the technical file accompanying the EC declaration of verification
- The EC declaration of verification shall cover as well **national rules**:
  - No need for a different declaration of verification for national rules
  - Shall be established by the applicant even if only national rules apply (e.g. on-track machine)
- The EC declaration of verification shall have an **accompanying technical file**, with all technical details of the subsystem. The accompanying files shall be part of the application file in the OSS

# Directive (EU) 2016/797

## EC verification procedure

Placing on the market of mobile subsystems



# Directive (EU) 2016/797

## EC verification procedure

### TEMPLATE FOR CERTIFICATE

['EC'] <sup>(1)</sup> Certificate of [conformity/suitability for use/verification]

Number [unique certificate identification number] <sup>(2)</sup>

Object of Assessment <sup>(3)</sup>:

[Unique Identification of the Interoperability Constituent or of the Subsystem]

Applicant, where applicable also Manufacturer and manufacturing locations:

[Name(s), Address(es)]

Assessment Requirements:

[Reference to: the Directive(s), the TSI(s), the relevant National Rules, European specifications, other Acceptable Means of Compliance]

Module(s) applied:

[The module(s) as chosen by the applicant for the assessment of the Interoperability Constituent or of the Subsystem]

Assessment/Audit result:

[Including reference to the assessment/audit report]

The following conditions and limits of use apply <sup>(4)</sup>:

[List or reference to the list of conditions and limits of use]

Annex <sup>(5)</sup> (where applicable):

[Yes/No]

Documentation accompanying this ['EC'] <sup>(1)</sup> Certificate:

[reference to accompanying documents; list or file of documents used for the assessment]

Validity:

[Time and conditions of validity of certificate]

Done on:

[date DD/MM/YYYY]

#### Notified Body

Signature

First Name, Surname

Business name

Registration number

Complete postal address

#### Designated Body

Signature

First Name, Surname

Business name

Identification number

Complete postal address

[OR]

### TEMPLATE FOR 'EC' DECLARATION OF VERIFICATION OF SUBSYSTEM

#### 'EC' declaration of verification of subsystem

'EC' declaration identification number [ERADIS ID] <sup>(1)</sup>

We, Applicant:

[Business name]

[Complete postal address]

Declare under our sole responsibility that the following subsystem <sup>(2)</sup>:

[Name/short description of the subsystem, unique identification of the subsystem]

to which this declaration refers has been subject to the relevant verification procedures and complies with the relevant Union law and any relevant national rules:

[Reference to: the Directive(s); TSI(s); Relevant national rules;]

has been assessed by the following conformity assessment bodies:

Notified Body:	Designated Body:	Assessment body [Risk assessment]:
Business name	Business name	Business name
Registration number	Identification number	Identification number
Full address	Full address	Full address

In accordance with the following certificate(s) and or report(s):

[Certificate(s) number(s), report(s) number(s), date(s) of issue]

The following conditions of use and other restrictions apply <sup>(3)</sup>:

[List or reference to the list of conditions of use and other restrictions]

The following procedures have been followed in order to declare conformity:

[The modules chosen by applicant for the verification of the subsystem]

Identification of the technical file accompanying this declaration

[Reference to the technical file accompanying the 'EC' declaration of verification of subsystem in accordance with Article 15(4) of Directive (EU) 2016/797]

Reference to former 'EC' declaration of verification (where applicable)

[Yes/No]

Done on:

[date DD/MM/YYYY]

Signature of Applicant

First Name, Surname

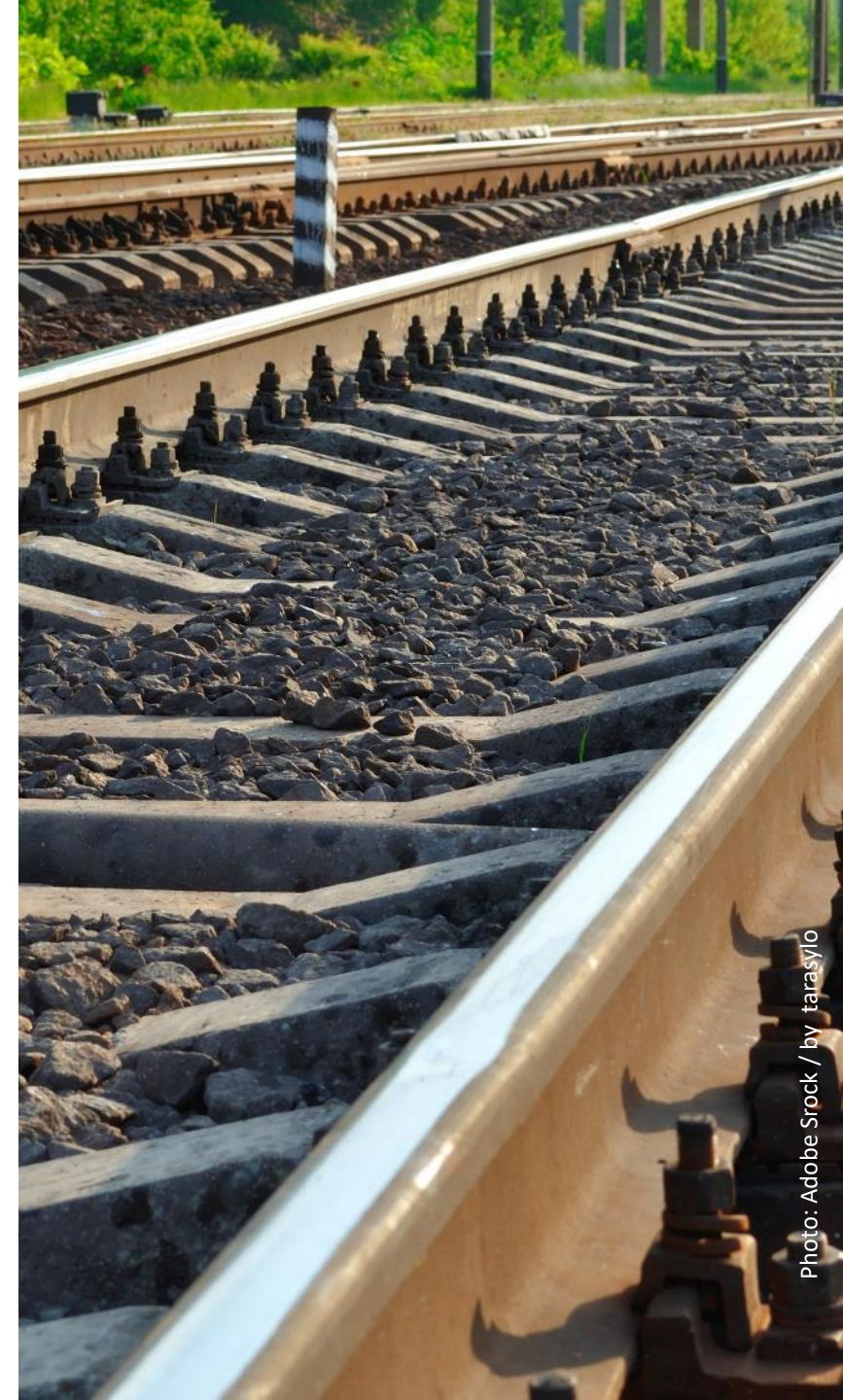
## Placing on the market of mobile subsystems

Regulation (EU) 2019/250 covers document issued by:

- NoBo
  - Certificate of conformity/suitability for use of ICs
  - Intermediate Statement of Verification for Subsystem
  - Certificate of verification of Subsystem
- DeBos :
  - Intermediate Statement of Verification for Subsystem
  - Certificate of verification of Subsystem
- Manufacturers (of interoperability constituents):
  - EC Declaration of conformity or suitability for use
- Applicants:
  - EC Declaration of verification of Subsystem
  - Declaration of conformity to an authorised vehicle type

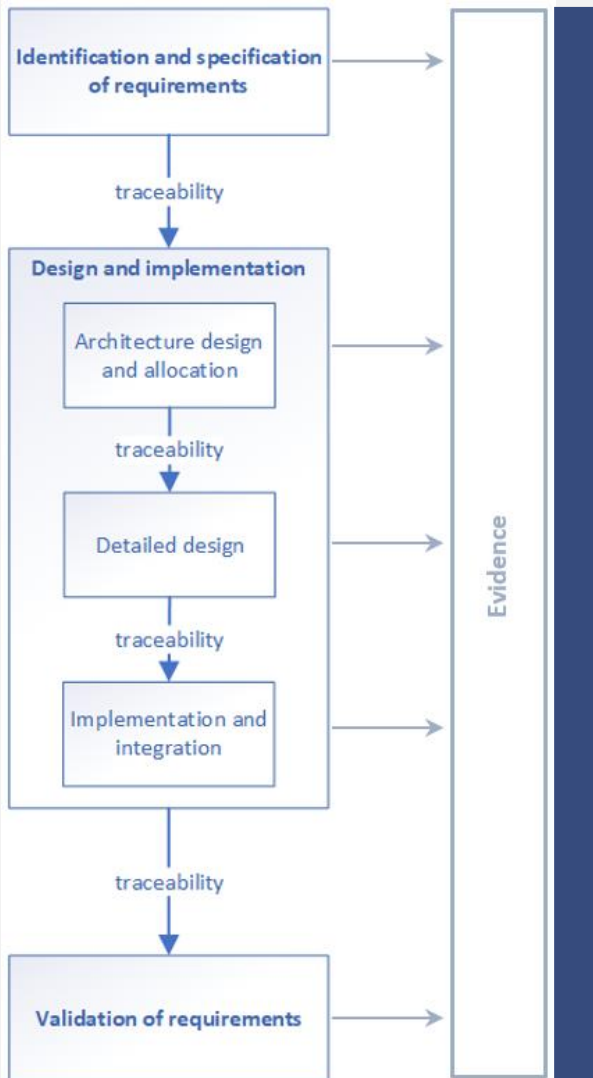


# Requirements capture



# Regulation (EU) 2018/545

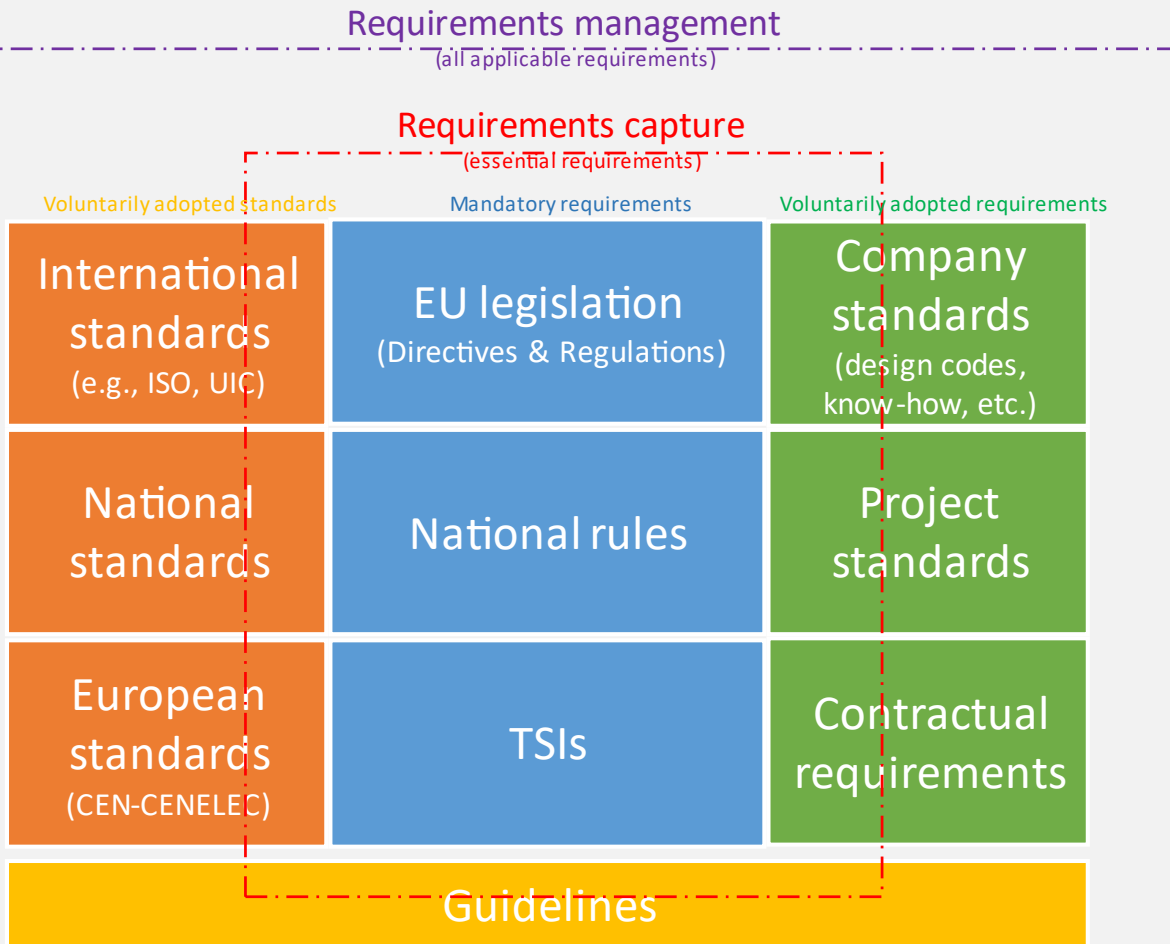
## Requirements capture



- Requirements capture is the process by which requirements applicable to a vehicle are systematically:
  - **identified**;
  - **implemented**, and
  - **validated**
 alongside with **documenting all steps** of the process and providing the necessary traceability, with the objective of meeting the essential requirements and managing and mitigating risk to an acceptable level.
- The requirements capture should start at an **early stage of the process of design and development** of the vehicle.
- For vehicle authorisation purposes, the requirements to be considered are those that need to be fulfilled in order to meet the **essential requirements**, no matter if they derive from mandatory rules or not. Essential requirements are defined in Annex III of Directive (EU) 2016/797
  - Safety
  - Reliability/availability
  - Health
  - Environmental protection
  - Technical compatibility.

# Regulation (EU) 2018/545

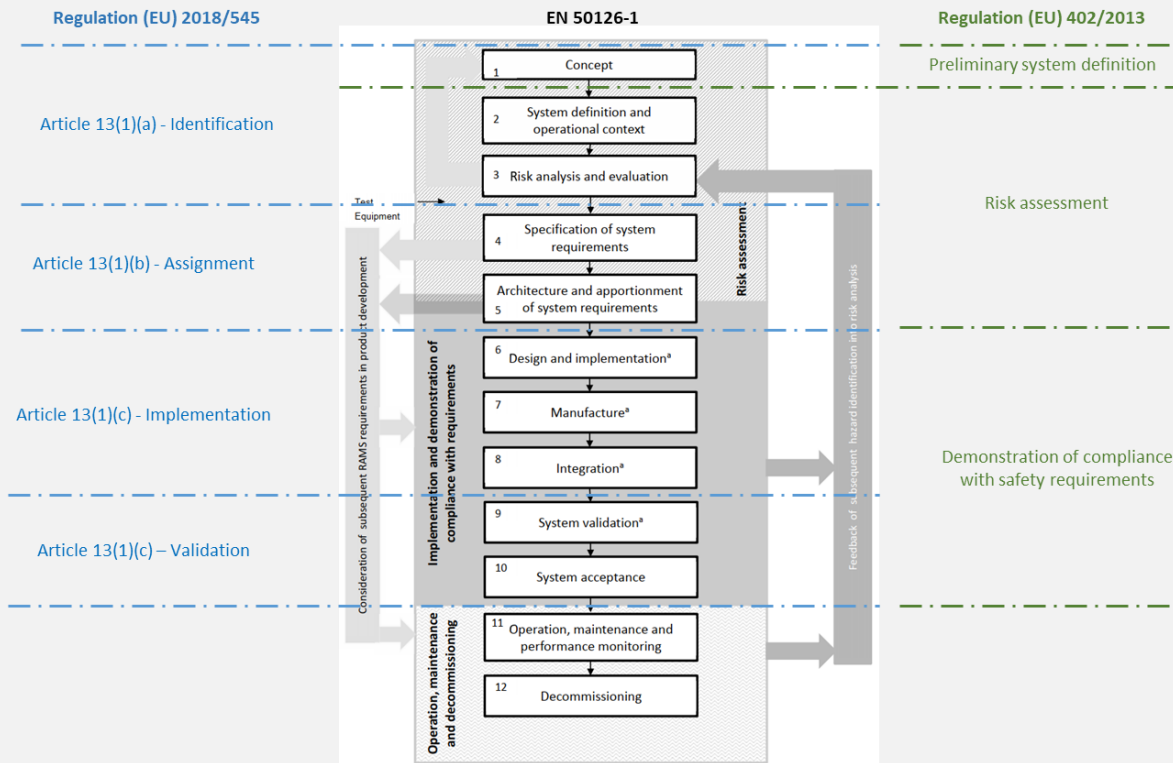
## Requirements capture



- A requirements management process should cover **all requirements that a vehicle type needs to fulfill**, no matter where the requirements come from:
  - requirements that can be found in mandatory laws (TSIs, national rules, other EU legislation);
  - contractual requirements;
  - requirements needed to control hazards and associated risks;
  - requirements adopted on a voluntary basis;
- Some requirements are not relevant for the authorisation process, even if they need to be complied with for other reasons (e.g., contractual requirements).  
Some other, while not mandatory, may trigger the need to fulfil other requirements which are mandatory.  
Some non-mandatory requirements may have an impact on mandatory requirements already applicable to railway vehicles.

# Regulation (EU) 2018/545

## Requirements capture



The **evidence** related to the requirements capture process that shall be included in a file accompanying the application through the OSS:

- For essential requirement **safety and safe integration** between subsystems:
  - Description of the methodology, confirming that it follows principles of CSM RA
  - Safety assessment report by an AsBo
  - Written declaration established by the applicant

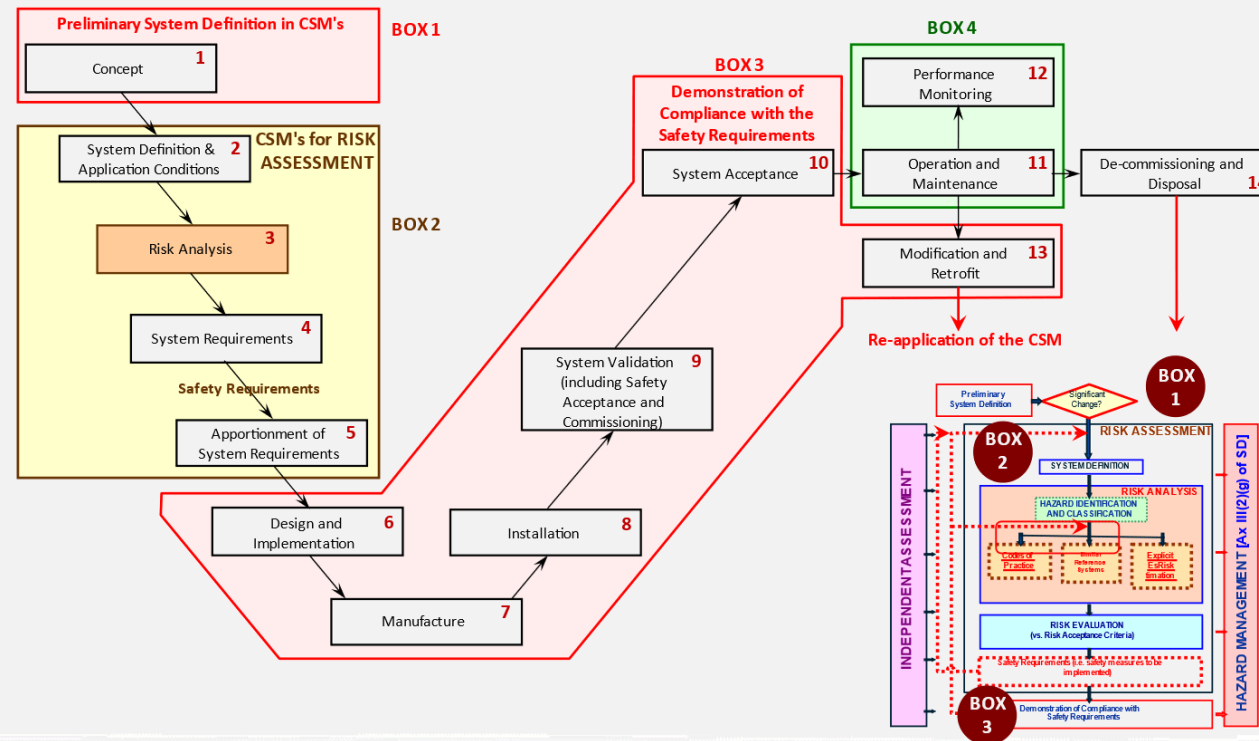
This also applies to all other essential requirements if the applicant decides to apply the methodology of Annex I of CSM RA too.

- For essential requirements **other than safety** when the applicant decides to use another methodology: evidence to demonstrate that it provides the same level of assurance
  - Description of the methodology (procedure, work instructions, checklists, etc.)
  - Evidence resulting of the application of the methodology (reports, logs, etc.)
  - Independent assessment report (not mandatory, but quite unlikely to provide similar level of assurance if there is none -> authorising entity forced to do the job of the AsBo)

In the end, applicant should include all evidence that would be provided to an independent assessor, for the authorising entity to do a similar job.

# Regulation (EU) 2018/545

## Requirements capture



### The applicant / entity managing the change:

- Performs the requirements capture process;
- Documents the requirements capture process (description of the process), its implementation in the concerned project;
- Hires an **AsBo** for an independent assessment of the requirements capture process (for aspects related to safety and safe integration between subsystems) and its application;
- Ensures that when another methodology than the Annex I of CSM RA is used for essential requirements other than safety, it provides the **same level of assurance**;
- Establishes a **declaration** that all risks and requirements have been properly managed, and
- Includes the **evidence** above in the file accompanying the application for authorisation when required by the legal texts.

# Regulation (EU) 2018/545

## Requirements capture



### The AsBo:

- Independently assesses the requirements capture process to:
  - Give assurance that the requirements capture process **meets the requirements laid down in Annex I of the CSM RA** or provides a **similar level of assurance** when another methodology is used (essential requirements other than safety);
  - Give assurance that the requirements capture process is **systematic** and allows a proper **identification and management of the requirements (implementation, verification and validation)** throughout the entire development process;
  - Form an expert judgement on the **correct application of the requirements capture process** for the concerned project and on the suitability of the results:
  - Form an expert judgment on the suitability of the vehicle and/or vehicle type to **meet the essential requirements**, and
  - Deliver an **assessment report** that contains the results of the independent assessment concerning the points mentioned above
- The independent assessment by an AsBo of the requirements capture process is more about **checking the process** followed to manage all requirements (and risks).
- The CSM RA and the Regulation (EU) 2018/545 do not require that the AsBo performs a complete and thorough assessment.

# Regulation (EU) 2018/545

## Requirements capture



### The authorising entity:

- Assesses the requirements capture process and/or the evidence related to requirements capture in the framework of issuing vehicle and/or vehicle type authorisations
- **NSAs for the area of use** assess the evidence of the process for requirements capture related to the applicable **national rules** in the framework of the issuing of a vehicle and/or vehicle type authorisation when the Agency is the authorising entity
- When an **NSA is the authorising entity**, it shall cover both aspects
- When methodology in Annex I of CSM RA is used, the authorising entity checks completeness, relevance and consistency of evidence: risk declaration established by the applicant & safety assessment report issued by the AsBo
- May challenge the assessment report if it demonstrates existence of serious safety risk (burden of proof allocated to authorities)
- When another methodology than Annex I of CSM RA is used for essential requirements other than safety, performs further checks:
  - Details of the methodology
  - Details of the evidences of the application of the methodology

# Regulation (EU) 2018/545

## Other EU legislation

### Other EU legislation

- Vehicles placed on the market shall comply with all applicable EU legislation such as REACH regulation, RID, pressure vessel directive, EMC directive etc,
- Applicants shall:
  - Apply requirements capture process and identifies the applicable EU legislation (which may be not railway specific),
  - Mention in its EC declaration of verification all applicable EU legislation to which the subsystem comply,
  - Provide evidence of compliance in the file accompanying the application
- Authorising entity shall check that :
  - Other applicable Union law has been considered by the applicant (evidence in the application file). This is not an exhaustive check (but obvious missing elements can be spotted)
  - The EU law considered is consistent with the information in the file accompanying the application, in particular with the EC declaration(s) of verification

Authorising entities are not responsible for the **completeness / accuracy** of the list; this is the sole responsibility of the applicant

- Informative list of other EU law produced by the Agency ([link](#))

EU Legislation title	Essential requirement(s)	Consolidated version (EURlex)	Related harmonised standards	Related CEN/LEC railway standards (indicative information)	Transitory provisions	Further information available in EC website (guidance, list of harmonised standard)	Useful links publicly accessible (indicative information)
Regulation (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery	Environment Protection Health	Consolidated	No information	No specific railway standards	Member States may, for a period that ends no later than <b>17 September 2026</b> authorise the placing on the market of engines of category RLL with a maximum net power greater than 2 000 kW that do not comply with the emission limits set out in Annex II to be installed in locomotives which only run on a technically isolated 1 520 mm railway network. During that period, the engines placed on the market shall, as a minimum, comply with the emission limits that engines had to meet to be placed on the market on <b>31 December 2015</b> . The approval authorities of the Member States shall grant EU type-approval and shall authorise the placing on	Non-Road mobile machinery emissions	Rail engines
Directive 2006/42/EC on machinery	Health	Consolidated	Harmonised standards	EN 13977-2011 Railway applications - Track - Safety requirements for portable machines and trolleys for construction and maintenance EN 14039-3:2013 Railway applications - Track - Railbound construction and maintenance machines - Part 3: General safety requirements EN 14039-4:2019 Railway applications - Track - Railbound construction and maintenance machines - Part 4: Technical requirements for running, travelling and working on urban rail EN 15746-2:2020 Railway applications - Track - Road-rail machines and associated	Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge-operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.	Machinery	Machinery Directive, application guide

Directive 2014/30/EU on electromagnetic compatibility	Vehicle category	How it applies to railway vehicles	Examples of impacted railway components	Evidence to be produced according to the EU legislation	Evidence validity time	Evidence for vehicle authorisation
Directive 2013/35/EU on the health and safety requirement regarding the exposure of workers to the risks arising from physical (electromagnetic fields)	Locomotives Trainsets Passengers coaches Special vehicles such as OTMs	Vehicles equipped with diesel engines	Diesel engines The engine categories applicable to the rail sector are: • Category RLL • Category RLR • Category NRE • Category NRS	EU Type approval certificate for the engine(s), and a statement of conformity and relevant documentation or marking on the engine, which includes the production date for a specific engine.	See article 30: Type approvals are of unlimited duration, unless bounded by specific restrictions or conditions.	EU Type approval for the engine(s), and a statement of conformity for each manufactured
	Locomotives Trainsets Passengers coaches Wagons Special vehicles such as OTMs	The exclusion of means of transport on rail networks concerns machinery intended for the transport of persons and/or goods on international, national, regional, suburban or urban rail networks or on rail systems connected to such networks. Machinery intended for use on rail networks that is not intended for the transport of persons and/or goods such as, for example, railbound machinery for the construction, maintenance and inspection of the rail track and structures, is also in the scope of the Machinery Directive. The same goes for machinery mounted on railbound vehicles, such as, for example, loader cranes and mobile elevating work platforms.	Typically applies to machines on special vehicles such as OTMs, but may also apply to locomotives and passenger vehicles where there is separately operated machinery.	Technical File, Depending on the machine: EC type examination & full quality assurance or assessment of conformity with internal checks on manufacturer (self declaration) EU Declaration of Conformity CE marking	Machinery type certificates are valid for five years, after which the manufacturer must cease to place the machinery on the market.	EU Declaration of Conformity
Directive 2014/30/EU on electromagnetic compatibility	Locomotives Trainsets Passengers coaches Wagons Special vehicles such as OTMs	This Directive regulates the electromagnetic compatibility of equipments. It aims to ensure the functioning of the internal market by requiring equipments to comply with an adequate level of electromagnetic compatibility. Applies to all rail vehicles and equipments on it.	Applies to all electrical and electronic equipment that can generate or be affected by electromagnetic disturbances. Apparatus (products and systems) that can be placed on the market, for which a declaration of conformity from the manufacturer is required, and this is typically required for self-propelling railway vehicles also, as well as individual items of electrical equipment (typically with motors) that may be installed on vehicles. May not apply to wagons or carriages without any form of motorised propulsion or with only low voltage equipment.	Apparatus: EU Declaration of Conformity Type Examination Certificate Technical File CE markings on apparatus  Railway vehicle Technical File: EMC management plan, EMC evidences (tests reports against EN standards) EU Declaration of Conformity for railway vehicles.	Certificates (e.g type examination certificate) may have validity date	EU Declaration of Conformity for railway vehicles.
	Locomotives Trainsets Passengers coaches Wagons Special vehicles such as OTMs	The Directive lays down minimum requirements for the protection of workers from risks to their health and safety arising, or likely to arise, from exposure to electromagnetic fields during their work.	Conducted emission and immunity levels to on-board apparatus, magnetic field for human exposure inside rolling stock (e.g. human exposure limits). Railway vehicles are sources of EMFs, particularly from their electrical systems, including traction motors, generators, and transformers.	This does not apply at the point of vehicle authorisation but is an obligation on railway undertakings when operating vehicles, however there may be information that is needed to be supplied by the manufacturer to support the railway undertaking.  The Directive requires that employers take measures to assess the levels of exposure of workers to EMFs and take action to ensure that the	Not applicable	Risk assessment of risk to workers being exposed to vibration, including mitigation measures.



# Questions?

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EUROPEAN  
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# THANK YOU

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